

## Wisdom of the Ages or Dead-Hand Control?

### Patentable Subject Matter for Diagnostic Methods After *In re Bilski*

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In 1980, the Supreme Court gave a reassuring signal to the then-nascent biotechnology industry about the availability of patent protection for the fruits of its research when it upheld the patentability of a genetically modified living organism in *Diamond v. Chakrabarty*.<sup>1</sup> Twenty-five

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<sup>1</sup> 447 U.S. 303 (1980). See Rebecca S. Eisenberg, *The Story of Diamond v. Chakrabarty*, in INTELLECTUAL PROPERTY STORIES 327 (Jane C. Ginsburg & Rochelle Cooper Dreyfuss, eds., 2006).

years later, the Court seemed poised to reexamine the limits of patentable subject matter<sup>2</sup> for advances in the life sciences when it granted *certiorari* in *Laboratory Corporation v. Metabolite*.<sup>3</sup> But the Federal Circuit had not addressed the patentable subject matter issue in *Laboratory Corporation*, and the Court ultimately dismissed the *certiorari* petition as improvidently granted.<sup>4</sup> Five years later, two pending cases in which the issue of patentable

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2 “Patentable subject matter” refers to the categories of inventions that might be patented, assuming the inventions meet the statutory standards for patent protection, as distinguished from those that are categorically excluded from the patent system because of the kinds of things they are. 35 U.S.C. § 101 (2010); *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010). If the invention is within patentable subject matter, the application still needs to be examined to be sure it meets the tests for novelty, 35 U.S.C. § 102 (2010); utility, 35 U.S.C. §§ 101 (2010); nonobviousness, 35 U.S.C. § 103 (2010); and adequate disclosure, 35 U.S.C. § 112 (2010). *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010). But if the subject matter of the invention is categorically outside the patent system, the invention may not be patented even if it meets these other tests. *But cf.* Michael Risch, *Everything Is Patentable*, 75 TENN. L. REV. 591 (2008) (arguing that judicial decisions that purport to rest on categorical exclusions from patentable subject matter may be better explained as involving patents that fail other standards for patent protection).

3 *Metabolite Labs. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354 (Fed. Cir. 2004), *cert. granted sub nom.* *Lab. Corp. of Am. Holdings v. Metabolite Labs.*, 546 U.S. 999 (2004).

4 *Lab. Corp. of Am. Holdings v. Metabolite Labs.*, 546 U.S. 999 (2005), *cert. dismissed as improvidently granted*, 548 U.S. 124 (2006). In both the initial grant of *certiorari* and the dissenting opinion of three Justices from the subsequent decision to dismiss *certiorari*, the Justices focused on the question of whether the diagnostic method patent at issue improperly claimed “a basic scientific relationship” that was categorically excluded from the patent system. 548 U.S. at 129 (Breyer, J., dissenting) (“We granted *certiorari* in this case to determine whether the patent

subject matter has been fully litigated in the lower courts<sup>5</sup> provide opportunities for the Court to resolve some of the uncertainties exposed in *Laboratory Corporation*.

For the quarter century preceding *Laboratory Corporation*, the United States Patent and Trademark Office (“PTO”), the courts, and the patent bar, had—for the most part—taken it for granted that new advances in biotechnology were patentable subject matter,<sup>6</sup> and moved on to the details of applying patent law standards such as novelty,<sup>7</sup> nonobviousness,<sup>8</sup> utility,<sup>9</sup> written

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claim is invalid on the ground that it improperly seeks to ‘claim a monopoly over a basic scientific relationship, ... namely, the relationship between homocysteine and vitamin deficiency.’”).

5 *Prometheus Labs. v. Mayo Collab. Servs.*, 628 F.3d 1347 (Fed. Cir. 2010), *cert. granted sub nom. Mayo Collab. Servs. v. Prometheus Labs*, 131 S.Ct. 3027 (2011); *Ass’n for Molecular Pathology v. USPTO*, 653 F.3d 1329 (Fed. Cir. 2011).

6 There were a few more issues to be worked out after *Chakrabarty*, such as the availability of utility patents for plants and animals. *See Ex parte Allen*, No. 86-1790, 2 U.S.P.Q.2d (BNA) 1425, 1987 WL 123816 (B.P.A.I, Apr. 3, 1987) (plants); *J.E.M. Ag Supply v. Pioneer Hi-Bred*, 534 U.S. 124 (2001) (plants); *In re Hibberd*, 227 U.S.P.Q. (BNA) 443, 1987 WL 71986 (B.P.A.I. Sept. 24, 1985) (animals).

7 *See Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1380 (Fed. Cir. 2003) (holding that the patent claims at issue were invalid because there were inherently anticipated by prior art).

8 *See In re Deuel*, 51 F.3d 1552, 1554 (Fed. Cir. 1995) (holding the patent to be invalid because “Deuel’s claims 5 and 7 [which were] directed to specific cDNA molecules[,] would have been obvious in light of the applied references.”); *In re Kubin*, 561 F.3d 1351, 1352 (Fed. Cir. 2009) (affirming “that appellants’ claims [were] unpatentably obvious”).

description,<sup>10</sup> and enablement<sup>11</sup> to biotechnology inventions. Older precedents that might have called patentable subject matter into question,<sup>12</sup> although never clearly overruled, had seemed destined to be lost in antiquity, as more recent decisions from the Court of Appeals for the Federal Circuit consistently overruled prior judicial exclusions from patentable subject matter.<sup>13</sup>

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9 See *In re Fisher*, 421 F.3d 1365, 1367 (Fed. Cir. 2005) (holding patent claims to be invalid because the claimed invention lacked specific and substantial utility).

10 See *Ariad Pharms. v. Eli Lilly*, 598 F.3d 1336, 1340 (Fed. Cir. 2010) (en banc) (holding that the asserted claims were “invalid for failure to meet the statutory written description requirement.”).

11 See *Enzo Biochem v. Calgene*, 188 F.3d 1362, 1365 (Fed. Cir. 1999) (holding that the claims at issue were “invalid as nonenabled”); *In re Wands*, 858 F.2d 731, 733 (Fed. Cir. 1988) (holding that the appellant’s claims did not fail 35 U.S.C. § 112 because a person skilled in the art could make and practice the claimed invention without undue experimentation).

12 See, e.g., *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 132 (1948) (holding patent claims on mixed culture of naturally occurring bacteria to be invalid). For a review and analysis of these precedents, see Eileen M. Kane, *Patent Ineligibility: Maintaining a Scientific Public Domain*, 80 ST. JOHN’S L. REV. 519 (2006) (discussing the limits of patentability) and Linda J. Demain & Aaron Xavier Fellmeth, *Reinventing the Public Domain: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STANFORD L. REV. 303 (2002) (discussing the scope and purpose of patent law in biotechnology).

13 E.g., *State St. Bank & Trust v. Signature Fin. Grp.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998) (finding that a computer-implemented accounting system for pooling assets from different mutual funds was patentable subject matter, rejecting arguments that this was a computer-implemented algorithm and a business method, and holding that patentable subject matter extended to anything that produces a “useful, concrete, and tangible result”); *AT&T Corp. v. Excel Commc’ns, Inc.*, 172 F.3d 1352, 1356 (Fed. Cir. 1999) (“Because § 101 includes processes as a

The Supreme Court's renewed interest in patentable subject matter threatened to revive these aging precedents, disturbing the expectations of a patent-sensitive industry.

In 2010, the Supreme Court finally reached the merits of a patentable subject matter dispute in *Bilski v. Kappos*,<sup>14</sup> a case involving a business method<sup>15</sup> rather than a diagnostic method. Although the Justices were unanimous in concluding that the claims were not drawn to patentable subject matter, they differed in their reasoning. Four Justices would have embraced a categorical exclusion for “business methods”<sup>16</sup> but five Justices rejected such an exclusion as

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category of patentable subject matter, the judicially-defined proscription against patenting of a ‘mathematical algorithm,’ to the extent such a proscription still exists, is narrowly limited to mathematical algorithms in the abstract.”).

14 130 S. Ct. 3218 (2010).

15 *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008), *aff'd sub. nom.* *Bilski v. Kappos*, 130 S. Ct. 3218 (2010). Specifically, Claim 1 of Bilski's patent application claimed: “A method for managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price comprising the steps of: (a) initiating a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase said commodity at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumer; (b) identifying market participants for said commodity having a counter-risk position to said consumers; and (c) initiating a series of transactions between said commodity provider and said market participants at a second fixed rate such that said series of market participant transactions balances the risk position of said series of consumer transactions.” *In re Bilski*, 545 F.3d at 949 (citation omitted).

16 *Bilski*, 130 S. Ct. at 3231 (Stevens, J. joined by Ginsburg, Breyer & Sotomayor, J.J., concurring)

inconsistent with the statutory text.<sup>17</sup> All the Justices apparently agreed, however, that *Bilski*'s claim fell within the Court's traditional exclusion of "abstract ideas" from patentable subject matter.<sup>18</sup> The Justices also agreed that the Federal Circuit had repeatedly erred in its interpretation of the Supreme Court's precedents on patentable subject matter: first, by setting the bar too low under the "useful, concrete and tangible" test from its 1998 decision in *State Street Bank & Trust Co. v. Signature Financial Group*<sup>19</sup>; and second, by setting too rigid a rule

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<sup>17</sup> *Bilski*, 130 S. Ct. at 3228-29. Five Justices (Kennedy, Roberts, Alito, Thomas, and Scalia) rejected a "business methods" exclusion as inconsistent with 1999 statutory amendments to provide an infringement defense, codified at 35 U.S.C. § 273(b)(1), for prior users of patented business methods, *id.* at 3228-29, while four of these Justices (not including Scalia) would also reject such an exclusion as outmoded in the "Information Age," *id.* at 3229.

<sup>18</sup> *Bilski*, 130 S. Ct. at 3229-30 ("[T]he Court resolves this case narrowly on the basis of this Court's decisions in *Benson*, *Flook*, and *Diehr*, which show that petitioners' claims are not patentable processes because they are attempts to patent abstract ideas. Indeed, all members of the Court agree that the patent application at issue here falls outside of § 101 because it claims an abstract idea."); *id.* at 3235 (Kennedy, J., concurring) ("Although I happen to agree that petitioners seek to patent an abstract idea, the Court does not show how this conclusion follows 'clear[ly],' [] from our case law.") (citation omitted).

<sup>19</sup> *Compare* *State St. Bank & Trust v. Signature Fin. Grp.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998) (holding that the transformation of data constitutes "a practical application of a mathematical algorithm, formula, or calculation, because it produces a 'useful, concrete, and tangible result.'"), *with Bilski*, 130 S.Ct. at 3231 ("[N]othing in today's opinion should be read as endorsing interpretations of § 101 that the Court of Appeals for the Federal Circuit has used in the past. See, e.g., *State Street*, []; *AT&T Corp.*, []") (citations omitted), *and id.* at 3232 n.1 (Stevens, J.,

in the “machine-or-transformation test” as set forth in its 2008 *en banc* decision in *In re Bilski*.<sup>20</sup> Meanwhile, the Supreme Court left it to the Federal Circuit to figure out the implications of *Bilski v. Kappos* for pending cases involving method claims from the biopharmaceutical industry.<sup>21</sup>

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concurring) (“[I]t would be a grave mistake to assume that anything with a ‘useful, concrete and tangible result,’ *State Street Bank & Trust v. Signature Financial Group, Inc.* [], may be patented.”).

<sup>20</sup> Compare *In re Bilski*, 545 F.3d 943, 956 (Fed. Cir. 2008) (*en banc*) (reaffirming “that the machine-or-transformation test, properly applied, is the governing test for determining patent eligibility of a process under § 101.”), with *Bilski*, 130 S. Ct. at 3227 (Kennedy, J., joined by Roberts, C.J., Thomas, & Alito, JJ., and, in pertinent part, by Scalia, J.) (“This Court’s precedents establish that the machine-or-transformation test is a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101. The machine-or-transformation test is not the sole test for deciding whether an invention is a patent-eligible ‘process.’”); *id.* at 3232 (Stevens, J., joined by Ginsberg, Breyer, & Sotomayor, J.J., concurring) (“The Court correctly holds that the machine-or-transformation test is not the sole test for what constitutes a patentable process; rather, it is a critical clue.”).

<sup>21</sup> On the same day that it handed down its decision in *Bilski v. Kappos*, the Supreme Court granted *certiorari*, vacated and remanded two such cases that the Federal Circuit had previously decided under its “machine-or-transformation” test. *Prometheus Labs. v. Mayo Collab. Servs.*, 581 F.3d 1336 (Fed. Cir. 2009) (claims patentable subject matter under machine-or-transformation test), *cert. granted, judgment vacated, and case remanded*, 130 S. Ct. 3543 (2010), *on remand*, 628 F.3d 1347 (Fed. Cir. 2010) (same); *Classen Immunotherapies v. Biogen IDEC*, 304 Fed. Appx. 866 (Fed. Cir. 2008) (claims not patentable subject matter under machine-or-transformation test), *rehearing denied*, 2009 U.S. App. LEXIS 24202 (Fed. Cir. 2009), *cert. granted, judgment vacated, and case remanded*, 130 S. Ct. 3541 (2010).

One case that was then pending before the Federal Circuit, *Association for Molecular Pathology v. U.S. Patent & Trademark Office*,<sup>22</sup> involved challenges to product and process claims related to DNA sequences used in diagnosing breast cancer susceptibility. Before the Supreme Court's decision in *Bilski v. Kappos*, the district court in *Association for Molecular Pathology* granted summary judgment of invalidity in favor of the challengers, invalidating claims to isolated DNA sequences encoding the breast cancer susceptibility genes BRCA1 and BRCA2, as well as claims to diagnostic methods involving the analysis of DNA samples for mutations in those genes.<sup>23</sup> Many biotechnology firms hold patents with similar claims, creating enormous interest in the outcome of this case on appeal.<sup>24</sup> Indeed, the biotechnology industry filed *amicus* briefs in *Bilski v. Kappos* alerting the Court to the implications the decision might have for existing biotechnology patents.<sup>25</sup>

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22 No. 09 Civ. 4515 (RWS), 2010 U.S. Dist. LEXIS 35418 (S.D.N.Y. Apr. 5, 2010) (amending Ass'n for Molecular Pathology v. USPTO, 702 F. Supp. 2d 181 (S.D.N.Y. 2010)).

23 *Id.*

24 See, e.g., Donald Zuhn, *AMP v. USPTO – Briefing Update III*, PATENT DOCS (Feb. 8, 2011), <http://www.patentdocs.org/2011/02/amp-v-uspto-briefing-update.html> (containing links to most of the thirty *amicus* briefs that were filed in this case).

25 See *Preview of United States Supreme Court Cases, Briefs: November 2009 – 2010 Term*, AMERICAN BAR ASSOCIATION, [http://www.americanbar.org/publications/preview\\_home/publiced\\_preview\\_briefs\\_nov09.html#bilski](http://www.americanbar.org/publications/preview_home/publiced_preview_briefs_nov09.html#bilski) (last visited Oct. 24, 2011) (containing links to sixty-eight *amicus* briefs that were filed in the Supreme Court in *Bilski v. Kappos*).



Perhaps the Supreme Court concluded that the safest course was to decide *Bilski* in a way that sheds as little light as possible on pending biotechnology cases. The *Bilski* tea leaves have something to offer both challengers and defenders of biotechnology patents. Challengers may find support in the Court’s renewed endorsement of historical nonstatutory exclusions of “laws of nature, physical phenomena, and abstract ideas” from patentable subject matter and in the overarching directive to the Federal Circuit to look to Supreme Court precedents in elaborating patentable subject matter doctrine.<sup>26</sup> Defenders of biotechnology patents may find support in the Court’s disapproval of the Federal Circuit’s rigid application of the “machine-or-transformation” test as the sole test of patent-eligibility for processes,<sup>27</sup> in its emphasis on the expansive statutory

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<sup>26</sup> *Bilski*, 130 S. Ct. at 3225 (noting that these exceptions are not required by statute, but “they are consistent with the notion that a patentable process must be ‘new and useful.’”).

<sup>27</sup> The Court in *Bilski* did not reject the machine-or-transformation test entirely, but instead approved it as a “useful and important clue” that is not the sole test for determining patentable subject matter for processes. *Id.* at 3226-27. Both the USPTO and the Federal Circuit subsequently seized upon this “clue” in reaffirming the centrality of the machine-or-transformation test in defining patentable subject matter. *See* *Prometheus Labs.*, 628 F.3d 1347, 1355 (Fed. Cir. 2010) (“The Supreme Court’s decision in *Bilski* ... rejected the machine-or-transformation test only as a definitive test ... Thus, the Court did not disavow the machine-or-transformation test. And, as applied to the present claims, the ‘useful and important clue, an investigative tool,’ leads to a clear and compelling conclusion, *viz.*, that the present claims pass muster under § 101.”); U.S. Patent & Trademark Office Memorandum from Robert W. Bahr, Acting Associate Commissioner for Patent Examination Policy, to Patent Examining Corp, Regarding Supreme Court Decision in *Bilski v. Kappos* (June 28, 2010), available at [http://www.uspto.gov/patents/law/exam/bilski\\_guidance\\_28jun2010.pdf](http://www.uspto.gov/patents/law/exam/bilski_guidance_28jun2010.pdf) (“Examiners should continue to examine

text as the primary determinant of patentable subject matter,<sup>28</sup> and in an explicit expression of concern from four Justices in *Bilski* about the impact of the machine-or-transformation test on the patentability of “advanced diagnostic medicine techniques.”<sup>29</sup>

The majority’s dual focus on the expansive language of the statutory text and on the *stare decisis* effects of its own more restrictive prior decisions sends mixed signals about the Court’s own interpretive inclinations. It provides limited guidance for future decisions because it does not rest on any general principles that might inform analysis of future claims. Indeed, continuing in the tradition of the precedents it reaffirms, the Court offers no account of what function subject matter limitations serve in the patent system beyond reciting that patentable subject matter is “only a threshold test.”<sup>30</sup> In the absence of an account of the function of this threshold test, one can only wonder why the Supreme Court has reached out to revive previously moribund limitations on patentable subject matter, and what work those limitations should be doing that distinguishes the threshold test from the further sorting that goes on in the course of examining

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patent applications with §101 using the existing guidance concerning the machine-or-transformation test as a tool for determining whether the claimed invention is a process under §101.”).

28 *Bilski*, 130 S. Ct. at 3226 (The Supreme Court has “more than once cautioned that courts ‘should not read into the patent laws limitations and conditions which the legislature has not expressed.’”).

29 *Id.* at 3227 (“As numerous *amicus* briefs argue, the machine-or-transformation test would create uncertainty as to the patentability of software [and] advanced diagnostic medicine techniques.”) (Justice Scalia did not join this portion of the opinion).

30 *Id.* at 3225 (“The § 101 patent-eligibility inquiry is only a threshold test.”).

claims that get beyond the threshold for patentability. Some commentators have suggested that most if not all of the Court's patentable subject matter precedents could be better understood in terms of other requirements for patent protection such as novelty, nonobviousness, or limitations on claim scope.<sup>31</sup> In *Bilski v. Kappos*, the Court not only failed to offer clear guidance as to the boundaries of patentable subject matter, but also missed an opportunity to explain what patentable subject matter is about.

In this article, I consider alternative accounts of the work that patentable subject matter doctrine might do for the patent system in the hope of clarifying the application of that doctrine to diagnostic method claims. I begin with a review of recent doctrinal developments to show that current patentable subject matter doctrine suffers from a lack of clarity not only as to what the applicable rules are, but also as to what those rules are supposed to accomplish. I then consider what it might mean for patentable subject matter to function, as it is sometimes described, as a “threshold test” of patentability that precedes a more in-depth examination for compliance with other statutory standards. Although such a threshold test might offer administrative benefits,

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<sup>31</sup> *E.g.*, John F. Duffy, *Rules and Standards on the Forefront of Patentability*, 51 WM. & MARY L. REV. 609, 622-23 (2009) (highlighting the Court's ability to restrict the patent system by using the obviousness doctrine); Kristen Osenga, *Ants, Elephant Guns, and Statutory Subject Matter*, 39 ARIZ. ST. L.J. 1087, 1115-18 (2007) (arguing that the courts and the Patent Office “may be using § 101 rejections as proxies for other difficult questions of patentability and policy.”); Risch, *supra* note 2.

current patentable subject matter doctrine cannot and does not function as a threshold test. I next consider what functions patentable subject matter doctrine might perform beyond the threshold that are distinct from the functions performed by other doctrinal standards for patent protection such as novelty, nonobviousness, and adequate disclosure. I conclude that patentable subject matter doctrine performs functions that are neither entirely distinct from these other doctrines nor redundant to them. Patentable subject matter doctrine leaves some aspects of new discoveries in the public domain and limits the scope of allowable claims in ways that might depart from limitations imposed by prior art and disclosure requirements. Although perhaps suggestive of prior moorings in public policy, existing doctrine provides minimal guidance as to how to use patentable subject matter doctrine to further the goals of the patent system.

#### I. Revival of Subject Matter Exclusions

Although §101 of the Patent Act<sup>32</sup> defines patentable subject matter in broad terms to include “any new and useful process, machine, manufacture, or composition of matter,” a long line of judicial decisions recites additional exclusions from patent protection.<sup>33</sup> In *Bilski v.*

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<sup>32</sup> 35 U.S.C. § 101 (2010).

<sup>33</sup> The Supreme Court’s recent interest in patentable subject matter has inspired a rich literature reviewing these exclusions. *See, e.g.*, Tun-Jen Chiang, *The Rules and Standards of Patentable Subject-Matter*, 2010 WIS. L. REV. 1353 (2010); Kevin Emerson Collins, *Bilski and the Ambiguity of “An Unpatentable Abstract Idea,”* 15 LEWIS & CLARK L. REV. 37 (2011); John F. Duffy, *supra* note 31; Allen K. Yu, *Within Subject Matter Eligibility – A Disease and a Cure*, 84 So. CAL. L. REV. 387 (2011).

*Kappos*, the Supreme Court characterized these non-statutory exclusions narrowly as “three specific exceptions to § 101's broad patent-eligibility principles: ‘laws of nature, physical phenomena, and abstract ideas.’”<sup>34</sup> Prior Supreme Court cases have sometimes recited the exclusions in different and more expansive terms, free of the narrowing qualifier “specific.” For example, the Court has stated that “a scientific truth, or the mathematical expression of it, is not patentable invention,”<sup>35</sup> that “patents cannot issue for the discovery of the phenomena of nature,”<sup>36</sup> that “[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work,”<sup>37</sup> and that “an algorithm, or mathematical formula, is like a law of nature.”<sup>38</sup> In addition to these broadly articulated exclusions, past judicial decisions and administrative practice seemed to recognize specific field exclusions from patentable subject matter for plants and animals,<sup>39</sup> medical and surgical techniques,<sup>40</sup> business methods,<sup>41</sup> and printed matter.<sup>42</sup>

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34 *Bilski*, 130 S. Ct. at 3225 (citing *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980)).

35 *Mackay Radio & Tel. v. Radio Corp. of Am.*, 306 U.S. 86, 94 (1939).

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

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

38 *Parker v. Flook*, 437 U.S. 584, 589 (1978).

39 *See Duffy, supra* note 31 at 625-32 (exploring the “[u]npatentability of plants and animals.”).

40 *Morton v. N.Y. Eye Infirmary*, 17 F. Cas. 879, 882-83 (C.C.S.D.N.Y. 1862) (use of ether for anesthesia cannot be patented); *Ex parte Brinkerhoff*, No. 182, 24 Dec. Comm'r Pat. (1883) (Case No. 182), *reprinted in* 27 J. PAT. OFF. SOC'Y 797, 798 (1945) (methods of treatment of diseases not patentable).

None of these limitations is apparent from the statutory language, and some that once looked like settled, black-letter law have subsequently been questioned if not entirely disavowed by the courts in more recent decisions.<sup>43</sup> Most of the action has been in the Court of Appeals for the Federal Circuit, although the U.S. Supreme Court has affirmed the patentability of living subject matter in decisions that broadly assert that patentable subject matter extends to “anything under the sun that is made by man.”<sup>44</sup> The Federal Circuit has repeatedly invoked this language in decisions expanding patentable subject matter to include computer-implemented inventions<sup>45</sup>

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41 *Lowe’s Drive-In Theatres v. Park-In Theaters*, 174 F.2d 547, 551-52 (1st Cir. 1949) (invalidating a patent for a terraced drive-in movie theater); *Hotel Sec. Checking v. Lorraine, Co.*, 160 F. 467, 469 (2d Cir. 1908) (invalidating a patent for a bookkeeping register to prevent fraud in hotels and restaurants).

42 *In re Sterling*, 70 F.2d 910, 912 (C.C.P.A. 1934) (bank check and stub system); *In re Reeves*, 62 F.2d 199, 200 (C.C.P.A. 1932) (chart to aid in appraising buildings); *In re Russell*, 48 F. 2d 668 (C.C.P.A. 1931) (system for indexing names in a directory) .

43 *See State St. Bank & Trust v. Signature Fin. Grp.*, 149 F.3d 1368, 1375-78 (Fed. Cir. 1998) (disavowing business methods exclusion); *In re Lowry*, 32 F.3d 1579, 1583 (Fed. Cir. 1994) (questioning “legal and logical footing” of printed matter exclusion); *Ex parte Scherer* 103 U.S.P.Q. 107, 110 (B.P.A.I. 1954) (expressly overruling *Brinkerhoff*, *supra* note 40).

44 *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (citing Congressional committee reports accompanying 1952 Patent Act); *J.E.M. Ag Supply v. Pioneer Hi-Bred*, 534 U.S. 124, 145 (2001) (holding that plants are patentable subject matter).

45 *In re Alappat*, 33 F.3d 1526, 1582 (Fed. Cir. 1994); *Arrhythmia Research Tech. v. Corazonix*, 958 F.2d 1053, 1056 (Fed. Cir. 1992).

and business methods.<sup>46</sup> This expansive approach reached a peak in *State Street Bank & Trust v. Signature Financial Group* and *AT&T v. Excel Communications*. In these cases the Federal Circuit rejected the strictures of earlier decisions that had limited patentable subject matter to inventions that were “tangible” in the sense of physical or material<sup>47</sup> in favor of a broader standard that embraced anything that produces a “useful, concrete, and tangible result.”<sup>48</sup>

The Supreme Court has never disavowed its own exclusions from patentable subject matter for laws of nature, products of nature, abstract ideas, and mental processes. But after upholding the patentability of a living organism in *Diamond v. Chakrabarty*, and of a computer-implemented method for calculating the cure time for molded rubber articles the next year in *Diamond v. Diehr*,<sup>49</sup> the Court seemed to retire from policing the subject matter boundaries of

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46 *AT&T v. Excel Communications*, 172 F.3d 1352, 1360 (Fed. Cir. 1999); *State St. Bank & Trust v. Signature Fin. Grp.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998).

47 *Compare Arrhythmia*, 958 F.2d at 1059-60 (“These claimed steps of ‘converting’, ‘applying’, ‘determining’, and ‘comparing’ are physical process steps that transform one physical, electrical signal into another.”), *with AT&T*, 172 F.3d at 1358 (“physical transformation” is not “an invariable requirement, but merely one example of how a mathematical algorithm may bring about a useful application.”).

48 *State St. Bank*, 149 F.3d at 1373; *AT&T*, 172 F.3d at 1357.

49 *Diamond v. Diehr*, 450 U.S. 175 (1981).

the patent system following the creation of the Court of Appeals for the Federal Circuit in 1982.<sup>50</sup>

After a long period of acquiescence<sup>51</sup> in the expansive approach of the Federal Circuit, the Supreme Court surprisingly reached out to address the topic of patentable subject in *Laboratory Corporation v. Metabolite*. The patent at issue in that case claimed a method of diagnosing vitamin deficiency by observing homocysteine levels and noticing whether they are elevated.<sup>52</sup> The lower courts did not address whether the patent covered patentable subject matter,<sup>53</sup> but the Supreme Court granted *certiorari* solely on the question of whether the claims covered patentable subject matter or whether they impermissibly claimed a basic scientific relationship.<sup>54</sup> This set off alarm bells in the biotechnology patent community because the claim

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50 Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25.

51 The one Supreme Court case to address patentable subject matter during this period approved the eligibility of plants for utility patent protection. *J.E.M. Ag Supply v. Pioneer Hi-Bred*, 534 U.S. 124 (2001).

52 The sole claim at issue recited: “A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of: assaying a body fluid for an elevated level of total homocysteine; and correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.” *Metabolite Labs. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1358-59 (Fed. Cir. 2004), *cert. granted*, 546 U.S. 999 (2004), *cert. dismissed as improvidently granted*, 548 U.S. 124 (2006).

53 *Id.*

54 More specifically, the Court granted *certiorari* “limited to question three as presented in the petition.” 546 U.S. 999. Question three asked “[w]hether a method patent setting forth an indefinite, undescribed, and nonenabling



at issue resembled many other patent claims on diagnostic methods that involve observing and analyzing a biological marker to make a diagnosis or to determine an appropriate course of treatment.<sup>55</sup> A majority of the Court, perhaps figuring it was not appropriate for the Supreme Court to address such an important question of patent law without the benefit of the Federal Circuit's analysis, dismissed *certiorari* as improvidently granted.<sup>56</sup> However, three Justices thought the issue presented was "not unusually difficult" and were therefore ready to invalidate the patent claims on subject matter grounds without waiting for the issue to percolate in the lower courts.<sup>57</sup>

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step directing a party simply to 'correlat[e]' test results can validly claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result." <http://www.supremecourt.gov/qp/04-00607qp.pdf> (last visited Oct. 25, 2011).

55 Kevin Collins calls such claims "determine-and-infer claims." See Kevin Emerson Collins, *An Initial Comment on Prometheus: The Irrelevance of Intangibility*, PATENTLY-O (Sept. 17, 2009), <http://www.patentlyo.com/collins.intangibility.pdf>; Kevin Emerson Collins, *Propertizing Thought*, 60 S.M.U. L. Rev. 317, 323-42 (2007); Kevin Emerson Collins, *The Irrelevance of Intangibility in Medical Diagnostic Patents* U. ILL. L. REV. (forthcoming 2011); Kevin Emerson Collins, *Rethinking Patent Eligibility: The Knowledge/Embodiment Dichotomy* (working paper on file with the author).

56 *Lab. Corp. of Am. Holdings v. Metabolite Labs.*, 548 U.S. 124, 125 (2006).

57 *Id.* at 126 (Breyer, J. dissenting). Although Justice Breyer is still on the Court, the two Justices who joined his dissenting opinion (Souter & Stevens, JJ.) have since retired.

The claim, according to the dissent, improperly sought to patent a basic scientific relationship between homocysteine levels and vitamin deficiencies, and was therefore unpatentable for the same reasons that preclude patenting  $e=mc^2$ , the law of gravity, or the heat of the sun.<sup>58</sup> Clearly distinguishing patentable subject matter from other requirements for patent protection, the dissent justified the exclusion as a way to preserve free access to the “basic tools” of scientific research:

The justification for the principle does not lie in any claim that “laws of nature” are obvious, or that their discovery is easy, or that they are not useful. To the contrary, research into such matters may be costly and time-consuming; monetary incentives may matter; and the fruits of those incentives and that research may prove of great benefit to the human race. Rather, the reason for the exclusion is that sometimes too much patent protection can impede rather than “promote the Progress of Science and useful Arts,” the constitutional objective of patent and copyright protection.<sup>59</sup>

The dissenting Justices feared that patents on fundamental scientific principles could

discourage research by impeding the free exchange of information, for example by forcing researchers to avoid the use of potentially patented ideas, by leading them to conduct costly and time-consuming searches of existing or pending patents, by requiring complex licensing arrangements, and by raising the costs of using the patented information, sometimes prohibitively so.<sup>60</sup>

The dissent recognized the difficulty of defining categories like phenomena of nature, mental processes and abstract intellectual concepts, but nonetheless concluded that the claim before them was not close to the boundary. They saw the correlation between homocysteine

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<sup>58</sup> *Id.*

<sup>59</sup> *Id.* at 126-27.

<sup>60</sup> *Id.* at 127.

levels and vitamin deficiency as a “natural phenomenon,”<sup>61</sup> and it did not save the claim from invalidity that it was necessary to process a tissue sample in order to measure homocysteine levels.<sup>62</sup>

Notably, it was a diagnostic method patent, rather than a business method patent, that brought the attention of the Supreme Court back to the issue of patent eligibility in *Laboratory Corporation*. Although some diagnostic method patents have provoked controversy,<sup>63</sup> business method patents have been far more controversial among legal scholars and economists.<sup>64</sup> But

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<sup>61</sup> *Id.* at 134-35.

<sup>62</sup> See *infra* note 123 and accompanying text.

<sup>63</sup> See, e.g., Mildred C. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3 (2003); Jon F. Merz et al., *Diagnostic Testing Fails the Test: The Pitfalls of Patents Are Illustrated by the Case of Hemochromatosis*, 415 NATURE 577 (2002); Sirpa Soini et al., *Patenting and Licensing in Genetic Testing: Ethical, Legal, and Social Issues*, 16 EUR. J. HUMAN GENETICS 10 (2008).

<sup>64</sup> See, e.g., Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1577-1589 (2003); Rochelle Cooper Dreyfuss, *Are Business Method Patents Bad for Business?* 16 COMPUTER & HIGH TECH. L.J. 263 (2000); 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 (1999); David S. Olson, *Taking the Utilitarian Basis for Patent Law Seriously: The Case for Restricting Patentable Subject Matter*, 82 TEMPLE L. REV. 181, 227-36 (2009); Leo J. Raskind, *The State Street Bank Decision: The Bad Business of Unlimited Patent Protection for Methods of Doing Business*, 10 FORDHAM INTELL. PROP., MEDIA & ENT. L.J. 61, 92 (1999); Bronwyn H. Hall, *Business Method Patents, Innovation and Policy*, University of California, Berkeley Competition Policy

business methods are not basic tools of scientific research, and patents on business methods do not make a good poster child for the rhetorical moves and policy argument advanced by Justice Breyer for excluding patents on building blocks to leave room for further innovation.

Although *Laboratory Corporation* created no binding authority,<sup>65</sup> it sounded a warning to the Federal Circuit that its expansive approach to patentable subject matter might be vulnerable to reversal in an appropriate case. After a series of unanimous reversals of Federal Circuit decisions by the Supreme Court,<sup>66</sup> the Federal Circuit seemed eager for an opportunity to address the issue of patentable subject matter ahead of the Supreme Court; it went so far as to ask for supplemental briefing on patentable subject matter in an appeal from a rejection on entirely

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Center Working Paper No. CPC03-39 (2003), *available at*

[http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=463160](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=463160) (last visited Oct. 25, 2011).

<sup>65</sup> See *Prometheus Labs. v. Mayo Collab. Servs.*, 628 F.3d 1347, 1356 n.2 (Fed. Cir. 2010) (“Mayo, as did the district court, points to the opinion of three Justices dissenting from the dismissal of the grant of certiorari in *Lab. Corp.*.... Again, with respect, we decline to discuss a dissent; it is not controlling law, and it involved different claims from the ones at issue here.”).

<sup>66</sup> See, e.g., *Quanta Computer, Inc. v. LG Elecs., Inc.*, 128 S. Ct. 2109 (2008); *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 427–28 (2007); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 394 (2006); *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 208 (2005); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 741–42 (2002); *Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 834 (2002); *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 41 (1997).

different grounds.<sup>67</sup> Meanwhile, the PTO and the lower courts resumed rejecting and invalidating claims for lack of patentable subject matter,<sup>68</sup> renewing the flow of appeals and setting the stage for Federal Circuit and Supreme Court review.<sup>69</sup>

The first of these cases to command both *en banc* attention of the Federal Circuit and Supreme Court review on the merits was *Bilski v. Kappos*. Bilski's patent application claimed a method of hedging against risks of price fluctuations in commodities trading.<sup>70</sup> The PTO Board of Patent Appeals and Interferences affirmed the examiner's rejection for lack of patentable

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<sup>67</sup> *In re Comiskey*, 499 F.3d 1365, 1371 (Fed. Cir. 2007) ("We do not reach the ground relied on by the Board below--that the claims were unpatentable as obvious ... --because we conclude that many of the claims are 'barred at the threshold by § 101.'") (quoting *Diamond v. Diehr*, 450 U.S. 175, 188 (1981)).

<sup>68</sup> See *Prometheus Labs. v. Mayo Collab. Servs.*, 2008 U.S. Dist. LEXIS 25062; 86 U.S.P.Q.2D (BNA) 1705 (S.D. Cal. Mar. 28, 2008), *rev'd*, 581 F.3d 1336 (Fed. Cir. 2010), *cert. granted, vacated and remanded*, 130 S. Ct. 3543 (2010), *on remand*, 628 F.3d 1347 (Fed. Cir. 2010); *Ex parte Bilski*, No. 2002-2257, Patent Application Publ'n No. 2004/0122764, 2006 Pat. App. LEXIS 51, 2006 WL 5738364 (B.P.A.I. Sept. 26, 2006), *available at* <http://www.uspto.gov/ip/boards/bpai/decisions/inform/fd022257.pdf> (last visited Nov. 22, 2011)

<sup>69</sup> See, e.g., *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc), *aff'd*, 130 S. Ct. 3218 (2010); *Prometheus Labs. v. Mayo Collab. Servs.*, 581 F.3d 1336 (Fed. Cir. 2009), *cert. granted, vacated and remanded*, 130 S.Ct. 3543 (2010), *on remand*, 628 F.3d 1347 (Fed. Cir. 2010); *Classen Immunotherapies v. Biogen IDEC*, 304 F. App'x. 866 (Fed. Cir. 2008), *cert. granted, vacated and remanded*, 130 S.Ct. 3541 (2010), *on remand*, 2011 U.S. App. LEXIS 18126 (Fed. Cir. Aug. 31, 2011); *Research Corp. Technologies v. Microsoft*, 627 F.3d 859 (Fed. Cir. 2010); *In re Nuijten*, 500 F.3d 1346 (Fed. Cir. 2007); .

<sup>70</sup> See *Bilski*, *supra* note 15.

subject matter.<sup>71</sup> The Federal Circuit had by this time affirmed rejections for lack of patentable subject matter in two other cases, using inconsistent analytical approaches.<sup>72</sup> To clarify the law, the court ordered *en banc* review in *In re Bilski*.<sup>73</sup>

Congress created the Federal Circuit in order to bring greater uniformity and predictability to the application of patent law.<sup>74</sup> Mindful of that mandate, the Federal Circuit often prefers bright-line rules that point towards clear outcomes in future cases<sup>75</sup> over broad, open-ended standards that require the exercise of judgment and on which reasonable minds can differ. But Supreme Court precedents on patent law, including its decisions about patentable

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<sup>71</sup> *Ex parte Bilski*, No. 2002-2257, Patent Application Publ'n No. 2004/0122764, 2006 Pat. App. LEXIS 51, 2006 WL 5738364 (B.P.A.I. Sept. 26, 2006).

<sup>72</sup> Compare *In re Comiskey*, 499 F.3d 1365, 1378-79 (Fed. Cir. 2007) (method and system for mandatory arbitration involving legal documents not patentable because neither the Framers nor Congress intended patentable subject matter to include “business systems . . . that depend entirely on the use of mental processes”), with *In re Nuijten*, 500 F.3d 1346, 1357 (Fed. Cir. 2007) (transitory watermarked “signal” in digital audio file not patentable under textual analysis of categories set forth language of § 101). The Federal Circuit subsequently vacated and withdrew its opinion in *In re Comiskey* and revised its decision. 554 F.3d 967 (Fed. Cir. 2009).

<sup>73</sup> *In re Bilski*, 545 F.3d 943, 949 (Fed. Cir. 2008).

<sup>74</sup> See generally Richard H. Seamon, *The Provenance of the Federal Courts Improvement Act of 1982*, 71 GEO. WASH. L. REV. 543 (2003).

<sup>75</sup> See John R. Thomas, *Formalism at the Federal Circuit*, 52 AM. U. L. REV. 771 (2003); Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1103-15 (2003).

subject matter, more typically state broad, open-ended principles.<sup>76</sup> The Supreme Court had repeatedly faulted and reversed the Federal Circuit for applying unduly rigid rules that departed from the flexibility of its own precedents.<sup>77</sup> This dynamic is apparent in *Bilski*.

The Federal Circuit *en banc* majority attempted to unify the Supreme Court’s previously announced subject matter exclusions and “to clarify the standards applicable in determining whether a claimed method constitutes a statutory ‘process’ under § 101.”<sup>78</sup> They began by

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<sup>76</sup> See *supra* notes 35-38 and accompanying text.

<sup>77</sup> See, e.g., *KSR Int’l v. Teleflex*, 550 U.S. 398, 415 (2007) (“We begin by rejecting the rigid approach of the Court of Appeals. Throughout this Court’s engagement with the question of obviousness, our cases have set forth an expansive and flexible approach inconsistent with the way the Court of Appeals applied its TSM test here.”); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 732 (2002) (“It is true that the doctrine of equivalents renders the scope of patents less certain. It may be difficult to determine what is, or is not, an equivalent to a particular element of an invention. . . . These concerns with the doctrine of equivalents, however, are not new. Each time the Court has considered the doctrine, it has acknowledged this uncertainty as the price of ensuring the appropriate incentives for innovation, and it has affirmed the doctrine over dissents that urged a more certain rule.”). A notable counterexample is *Pfaff v. Wells Electronics*, 525 U.S. 55, 67 n.11 (1998), in which the Supreme Court replaced the Federal Circuit’s open-ended standard for determining whether an invention is “substantially complete” based upon a “totality of the circumstances,” as announced in *Micro Chemical, Inc. v. Great Plains Chemical Co.*, 103 F.3d 1538, 1544 (Fed. Cir. 1997) with a (perhaps) clearer standard of “ready for patenting.” *Pfaff*, 525 U.S. at 567.

<sup>78</sup> The majority opinion commanded the votes of nine of the twelve members of the Court of Appeals for the Federal Circuit. *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008). One judge wrote a separate concurrence, and three filed

blending the Supreme Court’s categorical exclusions into one, characterizing the issue as “whether Applicants are seeking to claim a fundamental principle (such as an abstract idea) or a mental process.”<sup>79</sup> After a lengthy review of the Supreme Court cases, they concluded that:

The Supreme Court... has enunciated a definitive test to determine whether a process claim is tailored narrowly enough to encompass only a particular application of a fundamental principle rather than to pre-empt the principle itself. A claimed process is surely patent-eligible under § 101 if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.<sup>80</sup>

Because *Bilski*’s risk hedging method did not “involve the transformation of any physical object or substance, or an electronic signal representative of any physical object or substance,” and because *Bilski* admitted failure to meet the alternative machine-implementation prong of the test, the court concluded that his claims did not qualify as patentable subject matter under the machine-or-transformation test and affirmed the rejection.<sup>81</sup>

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dissents. 545 F.3d at 966 (Dyk, J., concurring); 545 F.3d at 976 (Newman, J., dissenting); 545 F.3d at 998 (Mayer, J., dissenting); 545 F.3d at 1011 (Rader, J., dissenting).

<sup>79</sup> *In re Bilski*, 545 F.3d at 952. This conflation is quite explicit. The majority posits: “As used in this opinion, ‘fundamental principles’ means ‘laws of nature, natural phenomena, and abstract ideas.’ *Id.* at 952 n.5.

<sup>80</sup> *Id.* at 954 (citing *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)).

<sup>81</sup> *Id.* at 963-64.



The machine-or-transformation test thus supplied a single bright-line rule for excluding all “fundamental principles,” uniting the treatment of a claimed method of hedging risks in commodities trading with the treatment of  $e=mc^2$ , the law of gravity, and the heat of the sun. This comprehensive rule threatened to exclude not only patents on risk-hedging methods, but also patents on methods of analyzing diagnostic markers.<sup>82</sup> Indeed, shortly after the Federal Circuit *en banc* embraced the machine-or-transformation test in *Bilski*, a Federal Circuit panel relied on *Bilski* in summarily affirming a trial court decision invalidating a patent claiming “a method of determining whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder in a treatment group of mammals, relative to a control group of mammals.”<sup>83</sup> The trial court had held the patent invalid on the ground that it claimed a natural phenomenon. In a very brief opinion, the Federal Circuit affirmed, but on the different ground that “Dr. Classen’s claims are neither ‘tied to a particular machine or apparatus’ nor do they ‘transform[] a particular article into a different state or thing.’”<sup>84</sup>

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82 See Kevin Emerson Collins, *The (Ir)relevance of Intangibility in Medical Diagnostic Patents*, U. ILL. L. REV. (forthcoming 2011) (on file with the author).

83 *Classen Immunotherapies v. Biogen IDEC*, No. WDQ-04-2607, 2006 U.S. Dist. LEXIS 98106, at \*13 (D. Md. Aug. 16, 2006), *aff’d*, 304 F. App’x. 866 (Fed. Cir. 2008), *cert. granted, vacated in part, and remanded*, 130 S. Ct. 3541 (2010), *on remand*, 2011 U.S. App. LEXIS 18126 (Fed. Cir. Aug 31, 2011). See *infra* notes 181-205 and accompanying text.

84 *Classen Immunotherapies*, 304 Fed. Appx. at 866. The Federal Circuit did not consider claim language in its brief unpublished opinion, but at least some of the claims included as a step in the method “immunizing mammals in

In *Prometheus v. Mayo Collaborative Services*, the Federal Circuit came out the other way, reversing a district court decision invalidating a patent on a “a method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder.”<sup>85</sup> Although the District Court had held the claims excluded from patentable subject matter because they recited “mental steps” and “natural phenomena,”<sup>86</sup> the Federal Circuit did not separately address these exclusions but instead used the machine-or-transformation test.<sup>87</sup> Rather than reciting a purely diagnostic method, the *Prometheus* claims embedded a diagnostic step within a claimed method of optimizing treatment.<sup>88</sup> Most of the claims included the steps of (1) administering a

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the treatment group of mammals with one or more doses of one or more immunogens,” *Classen Immunotherapies*, 2011 U.S. App. LEXIS 18126, at \*8, a step that triggers an (arguably transformative) immune response in the immunized mammals.

85 *Prometheus Labs. v. Mayo Collab. Servs.*, 581 F.3d 1336, 1340 (Fed. Cir. 2009) (reversing 2008 U.S. Dist. LEXIS 25062 (S.D. Cal. Mar. 28, 2008)). The Federal Circuit again reached the same decision through very similar reasoning on remand for reconsideration in light of *Bilski v. Kappos*. *Prometheus Labs., Inc. v. Mayo Collab. Servs.*, 628 F.3d 1347 (Fed. Cir. 2010), *cert. granted sub nom. Mayo Collab. Servs. v. Prometheus Labs.*, 2011 U.S. LEXIS 4764 (2011). See *infra* notes 109-125 and accompanying text.

86 *Prometheus Labs.*, 581 F.3d at 1341.

87 *Id.* at 1346 (holding that “transformation . . . of the human body following administration of a drug” satisfied the machine-or-transformation test for a diagnostic method that involved administering a drug and measuring drug metabolites in a tissue sample).

88 *For example*, U.S. Patent No. 6,355,623 claim 1, which the Federal Circuit took to be representative of the independent claims at issue, reads: “A method of optimizing therapeutic efficacy for treatment of an immune-

drug to a patient and then (2) determining the level of metabolites in the patient's blood to determine whether the dose was too high or too low, but some claims did not recite the "administering" step.<sup>89</sup> The Federal Circuit concluded that each of these two steps satisfied the machine-or-transformation test because (1) giving a drug to a patient causes transformation in the patient's body and (2) determining metabolite levels involves chemical assays that bring about physical and chemical changes in the patient's tissue samples.<sup>90</sup> According to the Federal Circuit, these transformative steps were not merely incidental data-gathering, but were integral to the treatment regime.<sup>91</sup>

In both *Classen* and *Prometheus*, the Federal Circuit took its machine-or-transformation test to be entirely dispositive of the issue of patentable subject matter for the claimed methods, and did not consider whether claims to the analysis of biological markers might call for a

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mediated gastrointestinal disorder, comprising: (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder, wherein the level of 6-thioguanine less than about 230 pmol per  $8 \times 10^8$  red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and wherein the level of 6-thioguanine greater than about 400 pmol per  $8 \times 10^8$  red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject." *Prometheus Labs.*, 581 F.3d at 1340.

<sup>89</sup> *Id.* at 1347.

<sup>90</sup> *Id.* at 1346-47.

<sup>91</sup> *Id.* at 1348.

different analysis than claims to business methods. The machine-or-transformation rule did not find favor with the biopharmaceutical industry, and numerous *amicus* briefs filed with the Supreme Court in *Bilski v. Kappos* alerted the Court to the risks that rule posed for patents on diagnostic methods.<sup>92</sup>

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<sup>92</sup> See, e.g., Brief for Novartis Corp. as Amicus Curiae Supporting Petitioners, *Bilski v. Kappos*, 130 S. Ct. 3218 (2010) (No. 08-964) *available at* [http://www.americanbar.org/content/dam/aba/publishing/preview/publiced\\_preview\\_briefs\\_pdfs\\_07\\_08\\_08\\_964\\_PetitionerAmCuNovartisCorp.authcheckdam.pdf](http://www.americanbar.org/content/dam/aba/publishing/preview/publiced_preview_briefs_pdfs_07_08_08_964_PetitionerAmCuNovartisCorp.authcheckdam.pdf); Brief for Caris Diagnostics as Amicus Curiae Supporting Petitioners, 130 S. Ct. 3218 (2010) (No. 08-964), *available at* [http://www.americanbar.org/content/dam/aba/publishing/preview/publiced\\_preview\\_briefs\\_pdfs\\_07\\_08\\_08\\_964\\_PetitionerAmCuCarisDiagnostics.authcheckdam.pdf](http://www.americanbar.org/content/dam/aba/publishing/preview/publiced_preview_briefs_pdfs_07_08_08_964_PetitionerAmCuCarisDiagnostics.authcheckdam.pdf); Brief for The Univ. of S. Florida as Amicus Curiae Supporting of Petitioners, 30 S. Ct. 3218 (2010) (No. 08-964), *available at* [http://www.americanbar.org/content/dam/aba/publishing/preview/publiced\\_preview\\_briefs\\_pdfs\\_07\\_08\\_08\\_964\\_PetitionerAmCuUnivofSFlorida.authcheckdam.pdf](http://www.americanbar.org/content/dam/aba/publishing/preview/publiced_preview_briefs_pdfs_07_08_08_964_PetitionerAmCuUnivofSFlorida.authcheckdam.pdf); Brief of Adamas Pharm. and Tethys Bioscience as Amicus Curiae Supporting Respondent, 130 S. Ct. 3218 (2010) (No. 08-964), *available at* [http://www.americanbar.org/content/dam/aba/publishing/preview/publiced\\_preview\\_briefs\\_pdfs\\_09\\_10\\_08\\_964\\_RespondentAmCu2PharmCos.authcheckdam.pdf](http://www.americanbar.org/content/dam/aba/publishing/preview/publiced_preview_briefs_pdfs_09_10_08_964_RespondentAmCu2PharmCos.authcheckdam.pdf); Brief for Biotechnology Indus. Org. et. al as Amici Curiae Supporting Neither Party, 130 S. Ct. 3218 (2010) (No. 08-964), *available at* [http://www.americanbar.org/content/dam/aba/publishing/preview/publiced\\_preview\\_briefs\\_pdfs\\_07\\_08\\_08\\_964\\_NeutralAmCu4MedTechOrgs.authcheckdam.pdf](http://www.americanbar.org/content/dam/aba/publishing/preview/publiced_preview_briefs_pdfs_07_08_08_964_NeutralAmCu4MedTechOrgs.authcheckdam.pdf); Brief for Pharm. Research and Mfrs. of Am. as Amicus Curiae Supporting Neither Party, 130 S. Ct. 3218 (2010) (No. 08-964), *available at* [http://www.americanbar.org/content/dam/aba/publishing/preview/publiced\\_preview\\_briefs\\_pdfs\\_07\\_08\\_08\\_964\\_NeutralAmCuPhRMA.authcheckdam.pdf](http://www.americanbar.org/content/dam/aba/publishing/preview/publiced_preview_briefs_pdfs_07_08_08_964_NeutralAmCuPhRMA.authcheckdam.pdf).

## II. The Limited Guidance of *Bilski v. Kappos*

The Supreme Court had no occasion to speak directly to the proper treatment of diagnostic method claims in its opinion in *Bilski v. Kappos*.<sup>93</sup> There was little in the majority opinion that would provide even indirect guidance as to the patentability of any claims other than those at issue. The Justices all agreed that *Bilski*'s claims were not patentable subject matter because they "are attempts to patent abstract ideas,"<sup>94</sup> but they did not explain what that means. Although the Court insisted that the Federal Circuit's machine-or-transformation test is not the exclusive test for patentability of processes, they affirmed that test as "a useful and important clue" without indicating when that clue might prove inadequate or misleading.<sup>95</sup> Nor, for that matter, did they explain whether the machine-or-transformation test is "a useful and important clue" in evaluating the patentability of inventions that are not processes,<sup>96</sup> or of inventions that

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<sup>93</sup> See *supra* notes 14-21 and accompanying text.

<sup>94</sup> See *supra* note 18.

<sup>95</sup> As noted *supra* at n.29 and accompanying text, four Justices expressed concern that "the machine-or-transformation test would create uncertainty as to the patentability of software, advanced diagnostic medicine techniques, and inventions based on linear programming, data compression, and the manipulation of digital signals." *Bilski*, 130 S. Ct. at 3227. The opinion went on to "emphasize that the Court today is not commenting on the patentability of any particular invention, let alone holding that any of the above-mentioned technologies from the Information Age should or should not receive patent protection." *Id.* at 3228.

<sup>96</sup> The machine-or-transformation test, which the Federal Circuit in *Bilski* attributed to the Supreme Court, has its origins in cases involving the patentability of processes. See *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972)

are not “abstract ideas” but that might fall within a different exclusion, such as products of nature, phenomena of nature, or mental processes.

Nonetheless, the decision in *Bilski v. Kappos* alleviated some of the anxiety triggered in the biopharmaceutical patent community by the dissenting opinion in *Laboratory Corporation v. Metabolite*<sup>97</sup> and by the *en banc* decision of the Federal Circuit in *In re Bilski*.<sup>98</sup> Significantly, the Justices were unanimous in concluding that the machine-or-transformation test was not the sole test of patent-eligibility for processes, leaving room to argue that process patents involving the analysis of biomarkers might be patentable even if they do not pass the machine-or-transformation test.<sup>99</sup> To the extent that the Justices limited the use of that test, they seemed

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(“Transformation and reduction of an article ‘to a different state or thing’ is the clue to the patentability of a process claim that does not include particular machines.”); *Cochrane v. Deener*, 94 U.S. 780, 788 (1877) (a “process” is “an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing”);.

<sup>97</sup> See *supra* notes 52-62 and accompanying text.

<sup>98</sup> See *supra* notes 70-82 and accompanying text.

<sup>99</sup> See William J. Simmons, *Bilski v. Kappos: The U.S. Supreme Court Broadens Patent Subject Matter Eligibility*, 28 NATURE BIOTECHNOLOGY 801, 805 (2010) (“the Court narrowly avoided a catastrophe for the biotech and pharmaceutical industry”); Roy Zwahlen, *BIO Commends Supreme Court for Expansive View of Patentability in Bilski Decision*, BIOTECHNOLOGY INDUS. ORG. (June 28, 2010) <http://patentlybiotech.wordpress.com/2010/06/28/bio-commends-supreme-court-for-expansive-view-of-patentability-in-bilski-decision/> (“This ruling specifically states that the ‘machine-or-transformation test is not the

worried that it would exclude too much rather than too little.<sup>100</sup> The rhetorical tone of the majority opinion in *Bilski v. Kappos* was more cautious than that of the dissenters in *Laboratory Corp. v. Metabolite*, emphasizing fidelity to statutory language and *stare decisis* and explicitly declining to adopt “categorical rules that might have wide-ranging and unforeseen impacts.”<sup>101</sup> For an industry seeking to preserve the patent-eligibility of its advances, a narrow opinion limited to the facts of *Bilski v. Kappos* was grounds for cautious optimism.

The post-*Bilski* decisions of the Federal Circuit reveal a divergence of views within that court as to the impact of *Bilski* on the revival of patentable subject matter exclusions set off by

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sole test for patent eligibility’ and recognized that the lower court’s ruling could have created uncertainty in fields such as advanced diagnostic medicine techniques.”).

100 This concern is most clearly articulated in portions of Justice Kennedy’s opinion that Justice Scalia did not join and that therefore failed to command a majority of the Court. *See, e.g., Bilski*, 130 S.Ct. at 3227 (“The machine-or-transformation test may well provide a sufficient basis for evaluating processes similar to those in the Industrial Age — for example, inventions grounded in a physical or other tangible form. But there are reasons to doubt whether the test should be the sole criterion for determining the patentability of inventions in the Information Age. As numerous *amicus* briefs argue, the machine-or-transformation test would create uncertainty as to the patentability of software, advanced diagnostic medicine techniques, and inventions based on linear programming, data compression, and the manipulation of digital signals.”).

101 *Bilski*, 130 S. Ct. at 3229.

*Laboratory Corporation v. Metabolite*. Two opinions authored by Judge Lourie<sup>102</sup> make the most of the Supreme Court’s qualified endorsement in *Bilski* of the machine-or-transformation test as an “important clue” for distinguishing patent-eligible processes from abstract ideas. These opinions apply that test to diagnostic method claims, notwithstanding concerns expressed by a plurality of four Justices about its appropriateness for “advanced diagnostic medical techniques.” Under this approach the key to patent eligibility for diagnostic methods is a chemically transformative step recited in the claim language. Judge Lourie also looks to chemistry to define the scope of the exclusion from patentable subject matter for products of nature, holding that a claim to isolated DNA is patentable subject matter if isolation of the claimed material from its natural environment requires the breaking of “covalent bonds.”<sup>103</sup> By reverting to the bright-line approach of the Federal Circuit’s own *en banc* decision in *Bilski*, these opinions arguably curtail patentable subject matter further than the Supreme Court required when it rejected the machine-or-transformation test as the “sole test” of patent eligibility.<sup>104</sup>

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102 *Prometheus Labs. v. Mayo Collab. Servs.*, 628 F.3d 1347 (Fed. Cir. 2010), *cert. granted sub nom. Mayo Collab. Servs. v. Prometheus Labs.*, 2011 U.S. LEXIS 4764 (2011); *Ass’n for Molecular Pathology v. USPTO*, 653 F.3d 1329 (Fed. Cir. 2011).

103 *Ass’n for Molecular Pathology*, 653 F.3d at 1352.

104 Cf. *CyberSource v. Retail Decisions*, 654 F.3d 1366 (Fed. Cir. 2011) (claimed method for verifying the validity of an internet transaction invalid both under machine-or-transformation test and because process could be performed by human mentally or using pen and paper).



Chief Judge Rader takes a different approach, reading the Supreme Court in *Bilski* as disapproving of non-statutory limitations on patentable subject matter, such as the machine-or-transformation test, while directing the Federal Circuit to develop criteria for identifying unpatentable “abstract ideas” that are not inconsistent with the statutory text.<sup>105</sup> Eschewing bright-line rules, Judge Rader emphasizes that patentable subject matter is only a “threshold test” that need not exclude every invention that is unworthy of a patent.<sup>106</sup> Instead, before excluding a claim from patentable subject matter for abstractness, “this disqualifying characteristic should exhibit itself so manifestly as to override the broad statutory categories of eligible subject matter and the statutory context that directs primary attention on the patentability criteria of the rest of the Patent Act.”<sup>107</sup> Under this minimalist approach to patentable subject matter exclusions, “inventions with specific applications or improvements to technologies in the marketplace are not likely to be so abstract that they override the statutory language and framework of the Patent Act.”<sup>108</sup> This approach, while responsive to the Supreme Court’s admonition to honor the

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105 *Research Corp. Techs. v. Microsoft*, 627 F.3d 859 (Fed. Cir. 2010); *Classen Immunotherapies v. Biogen IDEC*, Nos. 2006-1636, 2006-1649, slip op. at 13 (Fed. Cir. Aug. 31, 2011) (additional views of Rader, C.J., joined by Newman, J.).

106 *Research Corp. Techs.*, 627 F.3d at 868.

107 *Id.* at 868.

108 *Id.* at 869. *See also* *Ultramercial v. Hulu*, 657 F.3d 1323 (Fed. Cir. 2011) (method of distributing content over the internet in exchange for viewing advertisements was patentable subject matter as a practical application of idea that advertising can serve as currency).

expansive statutory language of § 101, seems to ignore the Court’s explicit rejection of the Federal Circuit’s own previous “useful, concrete and tangible” test for patentable subject matter from its 1998 decision in *State Street Bank & Trust v. Signature Financial Group*.<sup>109</sup>

#### A. The Enduring Machine-or-Transformation Test

The first opportunity to apply the teachings of *Bilski v. Kappos* to biopharmaceutical methods fell to Judge Lourie. On reconsideration of *Prometheus Labs.* on remand from the Supreme Court, the Federal Circuit affirmed the continuing centrality of the machine-or-transformation test as the primary determinant of patentability.<sup>110</sup> Judge Lourie began the opinion for a unanimous panel<sup>111</sup> by characterizing the patentable subject matter issue as whether the claims<sup>112</sup> would “entirely preempt” the use of a natural phenomenon, which would make them invalid under *Gottschalk v. Benson* and *Parker v. Flook*, or whether they were drawn “only to a particular application of that phenomenon,” as permitted by *Diamond v. Diehr*.<sup>113</sup> He noted that the Federal Circuit’s first decision in the same case had concluded “that Prometheus’ claims are drawn not to a law of nature, but to a particular application of naturally occurring

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<sup>109</sup> See *supra* note 19 and accompanying text.

<sup>110</sup> *Prometheus Labs. v. Mayo Collab. Servs.*, 628 F.3d 1347 (Fed. Cir. 2010), *cert. granted sub nom. Mayo Collab. Servs. v. Prometheus Labs.*, 2011 U.S. LEXIS 4764 (2011).

<sup>111</sup> *Id.* at 1349. The other panel members were Chief Judge Rader and Judge Bryson.

<sup>112</sup> See *supra* note 88.

<sup>113</sup> *Prometheus Labs.*, 628 F.3d at 1354.

correlations, and accordingly do not preempt all uses of the recited correlations between metabolite levels and drug efficacy or toxicity.”<sup>114</sup> Noting that the Supreme Court opinion did not “disavow” the machine-or-transformation test, but rather characterized it as “a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101,” Judge Lourie concluded that “as applied to the present claims, the ‘useful and important clue, an investigative tool,’ leads to a clear and compelling conclusion, *viz.*, that the present claims pass muster under § 101. They do not encompass laws of nature or preempt natural correlations.”<sup>115</sup> In other words, the panel found the same “useful and important clue” that helped determine that the claims in *Bilski* covered “abstract ideas” also useful in

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114 *Id.* at 1355. Although the Federal Circuit does not pinpoint where in its prior decision it analyzes the preemption issue, the prior decision pervasively conflates the question of preemption of a natural phenomenon with the machine-or-transformation test. *See, e.g., Prometheus Labs.*, 581 F.3d at 1349 (“The claims cover a particular application of natural processes to treat various diseases, but transformative steps utilizing natural processes are not unpatentable subject matter. Moreover, the claims do not preempt natural processes; they utilize them in a series of specific steps. ... Regardless, because the claims meet the machine-or-transformation test, they do not preempt a fundamental principle. *See Bilski*, 545 F.3d at 954 (characterizing the machine-or-transformation test as ‘a definitive test to determine whether a process is tailored narrowly enough to encompass only a particular application of a fundamental principle rather than to pre-empt the principle itself’). The inventive nature of the claimed methods stems not from preemption of all use of these natural processes, but from the application of a natural phenomenon in a series of transformative steps comprising particular methods of treatment.”)

115 *Prometheus Labs.*, 628 F.3d at 1353-55.

discerning whether a claim is impermissibly drawn to laws of nature or preempts natural correlations; otherwise, the panel's conclusion would be a non sequitur.

But the equivalence of “abstract ideas” and “phenomena of nature” is by no means self-evident. “Abstract idea” is an ambiguous term that the Supreme Court has regrettably left undefined.<sup>116</sup> One understanding of the term “abstract” is the opposite of “concrete” or “tangible.”<sup>117</sup> The machine-or-transformation test may be a good proxy for this particular meaning of “abstract,” but phenomena of nature are not necessarily abstract in this sense. Although abstract ideas and mental processes may be recognized by their intangible character, many natural phenomena (including the judicial litany of  $e=mc^2$ , gravity, and the heat of the sun) bring about the transformation of matter from one state to another. Perhaps, then, we need another clue to separate out patentable applications of natural phenomena from the unpatentable phenomena themselves.

The excluded category that seems most relevant to the *Prometheus* claims is “mental processes.”<sup>118</sup> The *Prometheus* claims are an example of what Professor Kevin Collins calls

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116 See Kevin Emerson Collins, *Bilski and the Ambiguity of “An Unpatentable Abstract Idea”*, 15 LEWIS & CLARK L. REV. 37, 53-60 (2011) (analyzing the possible meaning of “abstract idea”).

117 *Id.* at 54.

118 *Cf. id.* at 46 (arguing that Federal Circuit has improperly conflated the excluded categories of “abstract idea” and “mental process”).

“determine and infer” claims.<sup>119</sup> These claims involve determining a measurable medical fact or biomarker for an individual<sup>120</sup> and then making an inference from the value of that biomarker about the individual’s health or diagnosis. The inference step may be what makes the invention useful, and perhaps what distinguishes it from the prior art.

Consider the following claim at issue in *Prometheus*:

A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per 8x10<sup>8</sup> red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per 8x10<sup>8</sup> red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.<sup>121</sup>

The *Prometheus* opinion recognizes that the exclusion for mental processes might be a problem for those elements of the claim that recite diagnostic inferences, but concludes that the claim as a whole nonetheless recites patentable subject matter because it satisfies the machine-or transformation test:

We agree with the district court that the final “wherein” clauses are mental steps and thus not patent-eligible per se. However, although they alone are not

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<sup>119</sup> See *supra* note 55.

<sup>120</sup> E.g., *Prometheus Labs.*, *supra* note 88.

<sup>121</sup> *Prometheus Labs.*, 581 F.3d at 1340 (quoting U.S. Patent No. 6,355,623 claim 1 (filed Apr. 8, 1999)).

patent-eligible, the claims are not simply to the mental steps. A subsequent mental step does not, by itself, negate the transformative nature of prior steps. Thus, when viewed in the proper context, the final step of providing a warning based on the results of the prior steps does not detract from the patentability of Prometheus's claimed methods as a whole. ... No claim in the Prometheus patents claims only mental steps.<sup>122</sup>

This analysis stands in marked contrast to that of the dissenting justices in *Laboratory Corporation of America Holdings v. Metabolite Laboratories*.<sup>123</sup> The *Laboratory Corporation* claim also included transformative process steps to detect homocysteine levels, and the patent holder pointed to those steps in arguing that the claim was drawn to an “application of a law of nature” rather than to the natural correlation itself, but the dissenting Justices were unpersuaded:

Claim 13's process instructs the user to (1) obtain test results and (2) think about them. Why should it matter if the test results themselves were obtained through an unpatented procedure that involved the transformation of blood? Claim 13 is indifferent to that fact, for it tells the user to use any test at all. ... [A]side from the unpatented test, they embody only the correlation between homocysteine and vitamin deficiency that the researchers uncovered. In my view, that correlation is an unpatentable ‘natural phenomenon,’ and I can find nothing in claim 13 that adds anything more of significance.<sup>124</sup>

Judge Lourie dismissed this analysis in a footnote to the *Prometheus* opinion, stating that “with respect, we decline to discuss a dissent; it is not controlling law, and it involved different claims from the ones at issue here.”<sup>125</sup> The panel might instead have distinguished *Laboratory*

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<sup>122</sup> *Prometheus Labs.*, 628 F.3d at 1358.

<sup>123</sup> *Lab. Corp. of Am. Holdings v. Metabolite Labs.*, 548 U.S. 124, 125 (2006) (*per curiam*) (Breyer, J., dissenting).

<sup>124</sup> *Id.* at 136-38 (Breyer, J. dissenting).

<sup>125</sup> *Prometheus Labs.*, 628 F.3d at 1356 n.2.

*Corporation* in ways that would have been more illuminating in future cases.<sup>126</sup> That they did not even make the effort suggests, perhaps, that they no longer think the views of the dissenters could command a majority of the Supreme Court today.

The Supreme Court granted *certiorari* in *Mayo Collaborative Services v. Prometheus Laboratories*<sup>127</sup> on the following question, as framed by Mayo in its petition:

Whether 35 U.S.C. § 101 is satisfied by a patent claim that covers observed correlations between blood test results and patient health, so that the claim effectively preempts all uses of the naturally occurring correlations, simply because well-known methods used to administer prescription drugs and test blood may involve “transformations” of body chemistry.<sup>128</sup>

This framing packs into a single sentence at least three distinct issues, including (1) the relevance (and meaning) of whether observed correlations are “naturally occurring,” (2) the relevance (and meaning) of whether the claim “effectively preempts all uses” of the correlations, and (3) the relevance of whether the steps in the process relied upon to satisfy the machine-or-transformation test—administering a drug and taking a blood test—are “well-known.” A fourth

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126 They might, for example, have considered whether it mattered that the diagnostic analysis set forth in the *Prometheus* claims was embedded in a treatment intervention, while the diagnostic analysis set forth in the *Laboratory Corporation* claim would cover observation and analysis of data from a patient who was not receiving any treatment.

127 *Mayo Collaborative Servs.*, 2011 U.S. LEXIS 4764 (June 20, 2011).

128 Petition for Writ of Certiorari, *Mayo Collaborative Servs. v. Prometheus Labs.*, (No. 10-1150), available at <http://www.supremecourt.gov/qp/10-01150qp.pdf>.

issue is the relevance of the machine-or-transformation test to the patent eligibility of the claims at issue.

The first of these issues goes to the meaning of the exclusion for “phenomena of nature” in the context of medical interventions. The petitioner’s assertion that the correlation between observed levels of a drug metabolite and the need to adjust drug dosage is “naturally occurring,” perhaps intended to revive the concerns of the *Laboratory Corporation* dissenters, points to the clearest ground for distinguishing the two cases. Even accepting that the correlation between homocysteine levels and vitamin deficiency was a “natural phenomenon” that removed the *Laboratory Corporation* claim from patentable subject matter,<sup>129</sup> the correlation recited in the *Prometheus* claim between drug metabolite levels and the need to adjust a patient’s drug dosage poses a more difficult question. Vitamin deficiencies arguably arise in nature, but the *Prometheus* correlation is embedded in a therapeutic regimen that requires human intervention. If observations of the biological consequences of therapeutic interventions, and related inferences about the need to adjust those interventions, were to be excluded from patent protection, it would seem that the reason must lie outside the exclusion for “phenomena of nature.”

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129 This assertion might not withstand close analysis. Quite apart from the (entirely conventional) human interventions necessary to measure cobalamin levels, a diagnosis of “vitamin deficiency” is itself a human construct, requiring human judgment as to what is normal and what is pathological.



The second issue recalls prior Supreme Court cases invalidating claims that “wholly preempt” use of an unpatentable claim element, such as a mathematical algorithm or a natural phenomenon, and that are thus deemed to claim the unpatentable element itself.<sup>130</sup> Again, this issue might look different in the context of a purely diagnostic claim (such as that at issue in *Laboratory Corporation*) than it does in claims that embed a diagnostic step in a specific regimen for adjusting ongoing treatment (such as those at issue in *Prometheus*). A claim that is tied to a particular treatment regimen might not “wholly preempt” a natural correlation between biomarker and inferred medical condition if the claim would not be infringed by substituting different biomarker values as indicators of a need to adjust the drug dosage, or by prescribing a different treatment for the same condition. Every claim “wholly preempts” the subject matter that it covers; the issue is how broadly one may claim a diagnostic inference. One might further question whether it is fair to characterize a correlation between an observed biomarker and the inference of a need to adjust treatment as a natural phenomenon, or whether that correlation is more accurately understood as an artifact of human medical intervention.

The third issue concerns the fact that the novel contribution of the inventor—the mental step of inferring a need to adjust the drug dosage from observed values for a biomarker—is not patentable subject matter taken alone, as the Federal Circuit conceded.<sup>131</sup> Some prior Supreme Court decisions have invalidated claims in which the value-added of the inventor beyond

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130 See *infra* note 208 and accompanying text.

131 See *supra* note 121 and accompanying text.

unpatentable elements (such as a mathematical algorithm or a product of nature) is unworthy of patent protection in its own right; however, it has not always been clear whether the problem with these claims is lack of patentable subject matter or something else, such as obviousness or lack of novelty.<sup>132</sup> The *Laboratory Corporation* dissenters dismissed as irrelevant to patent eligibility the fact that the diagnostic method claim before them included an assay step that required chemical transformation of a tissue sample through an unspecified (and unclaimed) process.<sup>133</sup> Intuitively it may seem odd to rest the determination of patentable subject matter on the transformative character of incidental claim elements that do not otherwise contribute to the patentability of the invention. But arguably the Supreme Court did just that in *Diamond v. Diehr*,<sup>134</sup> when it affirmed the patent eligibility of a computer-implemented “method of operating a rubber-molding press with the aid of a digital computer,”<sup>135</sup> over a vigorous dissent pointing out that the only patentable difference between the invention and the prior art was the use of an unpatentable “algorithm” to calculate the rubber cure time.<sup>136</sup> In *Bilski v. Kappos* the Supreme Court noted that patentable subject matter is only a “threshold test,” and that inventions that pass that test must still meet other statutory requirements for protection, including novelty, utility,

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132 See *infra* notes 245-252 and accompanying text.

133 See *supra* note 124 and accompanying text.

134 450 U.S. 175 (1981).

135 *Id.* at 179 n. 5, 192-93.

136 *Id.* at 193, 207-208 (Stevens, J., dissenting).

nonobviousness, and adequate description.<sup>137</sup> Perhaps, then, the Court will affirm the Federal Circuit’s approach of relying on physically transformative steps that are not themselves new or patentable to establish the patent eligibility of a method that relies upon non-transformative mental steps to meet the other requirements for patentability, thus leaving it to other doctrinal tools to reject or invalidate the claims for lack of novelty or for obviousness if appropriate.<sup>138</sup> But if the machine-or-transformation test has more than talismanic significance as a clue to patent eligibility, perhaps it should not be so easily evaded by reciting in the claims conventional steps that do nothing to distinguish the invention from the prior art.<sup>139</sup>

Rather than elaborating upon the machine-or-transformation test, the Court might instead seize the opportunity to clarify what it meant in *Bilski v. Kappos* when it disapproved of the Federal Circuit’s reliance on the machine-or-transformation test as the “sole test” of patent eligibility.<sup>140</sup> Although explicitly acknowledging this directive from the Supreme Court, in practice some Federal Circuit panels and the PTO have used the machine-or-transformation test to the exclusion of other analytical approaches to identify patentable subject matter.<sup>141</sup> If this is

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<sup>137</sup> *Bilski*, 130 S. Ct. at 3225.

<sup>138</sup> 35 U.S.C. §§ 102, 103 (2010).

<sup>139</sup> Of course, new combinations of old elements may be patentable if the combination itself is not suggested in the prior art.

<sup>140</sup> See *supra* notes 20 and 27.

<sup>141</sup> The PTO directed examiners to continue using the machine-or-transformation test the day after the Supreme Court decision in *Bilski v. Kappos*. See U.S. Patent & Trademark Office Memorandum from Robert W.

not what the Supreme Court intended, it may need to be clearer about when use of the machine-or-transformation test is inappropriate.

Readers of Justice Kennedy's opinion in *Bilski v. Kappos* might suspect that what he (and the three Justices joining Part II.B.2 of his opinion)<sup>142</sup> meant in stating that the machine-or-transformation test is not the sole test for patentability is that while inventions that *pass* that test are patent-eligible subject matter, inventions that *fail* that test might get to take a different test:

The machine-or-transformation test may well provide a sufficient basis for evaluating processes similar to those in the Industrial Age -- for example, inventions grounded in a physical or other tangible form. But there are reasons to doubt whether the test should be the sole criterion for determining the patentability of inventions in the Information Age. As numerous *amicus* briefs argue, the machine-or-transformation test would create uncertainty as to the patentability of software, advanced diagnostic medicine techniques, and

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Bahr, Acting Associate Commissioner for Patent Examination Policy, to Patent Examining Corp, Regarding Supreme Court Decision in *Bilski v. Kappos* (June 28, 2010), available at [http://www.uspto.gov/patents/law/exam/bilski\\_guidance\\_28jun2010.pdf](http://www.uspto.gov/patents/law/exam/bilski_guidance_28jun2010.pdf) ("Examiners should continue to examine patent applications for compliance with section 101 using the existing guidance concerning the machine-or-transformation test as a tool for determining whether the claimed invention is a process under §101. If a claimed process meets the machine-or-transformation test, the method is likely patent-eligible under §101 unless there is a clear indication that the method is directed to an abstract idea. If a claimed method does not meet the machine-or-transformation test, the examiner should reject the claim under §101 unless there is a clear indication that the method is not directed to an abstract idea.").

<sup>142</sup> *Bilski*, 130 S.Ct. at 3223 (The excerpt from Justice Kennedy's opinion set forth in text was joined by Justices Roberts, Thomas, and Alito, but not by Justice Scalia, who joined other portions of the opinion.).

inventions based on linear programming, data compression, and the manipulation of digital signals. ...

In the course of applying the machine-or-transformation test to emerging technologies, courts may pose questions of such intricacy and refinement that they risk obscuring the larger object of securing patents for valuable inventions without transgressing the public domain. ... As a result, in deciding whether previously unforeseen inventions qualify as patentable “process[es],” it may not make sense to require courts to confine themselves to asking the questions posed by the machine-or-transformation test. §101's terms suggest that new technologies may call for new inquiries.<sup>143</sup>

The Federal Circuit has sometimes persisted in applying the machine-or-transformation test to “advanced diagnostic medicine techniques” even when it excludes such techniques from patent eligibility. Writing for a different Federal Circuit panel, Judge Lourie used the machine-or-transformation test to invalidate diagnostic method claims in *Association for Molecular Pathology v. U.S. Patent & Trademark Office*.<sup>144</sup> In that case, the Federal Circuit reviewed a district court ruling<sup>145</sup> issued after the Federal Circuit’s embrace of the machine-or-transformation test in *In re Bilski* and its first opinion in *Prometheus v. Mayo*, but before the Supreme Court decision in *Bilski v. Kappos*. The district court held invalid multiple product and process claims related to the BRCA1 and BRCA2 breast cancer susceptibility genes. A sharply

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143 *Id.* at 3227-28 (citations omitted).

144 *Ass’n for Molecular Pathology v. USPTO*, 653 F.3d 1329 (Fed. Cir. 2011) (The panel included Judge Lourie, Judge Moore, and Judge Bryson.).

145 *Ass’n for Molecular Pathology v. USPTO*, 2010 U.S. Dist. LEXIS 35418 (S.D.N.Y. Apr. 2, 2010).

divided Federal Circuit panel<sup>146</sup> reversed the district court in part to uphold the validity of “composition of matter” claims to “isolated DNA” molecules.<sup>147</sup> However, the panel was unanimous in its analysis of the process claims. Each member of the panel joined Judge Lourie’s opinion affirming the invalidity of claims to methods of comparing or analyzing human DNA samples to detect alterations or mutations indicating increased susceptibility to breast cancer<sup>148</sup> and reversing the district court to uphold the patent eligibility of a claim to a method of screening potential cancer therapeutics.<sup>149</sup>

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146 *Ass’n for Molecular Pathology*, 653 F.3d 1329. Each member of the 3-judge panel wrote separately, with two judges concluding that the claims to isolated DNA were patentable subject matter, *id.* at 1333-34 (opinion of Lourie, J.); *id.* at 1358 (opinion of Moore, J., concurring in part); *id.* at 1373 (Bryson, J., concurring in part and dissenting in part) (concluding that claims to BRCA genes and gene fragments were not directed to patentable subject matter).

147 *Id.* at 1334 (quoting U.S. Patent No. 5,747,282 claim 1 (filed June 7, 1995)) (“An isolated DNA coding for a BRCA1 polypeptide, said polypeptide having the amino acid sequence set forth in SEQ ID NO: 2.”).

148 *E.g., id.* at 1334 (quoting U.S. Patent No. 5,709,999 claim 1 (filed June 7, 1995)) (“A method for detecting a germline alteration in a BRCA1 gene, said alteration selected from a group consisting of the alterations set forth in Tables 12A, 14, 18, or 19 in a human which comprises analyzing a sequence of a BRCA1 gene or BRCA1 RNA from a human sample or analyzing a sequence of BRCA1 cDNA made from mRNA from said human sample with the proviso that said germline alteration is not a deletion of 4 nucleotides corresponding to base numbers 4184-4187 of SEQ ID N0:1.”).

149 *See id.* at 1335 (quoting U.S. Patent No. 5,747,282 claim 20 (filed June 7, 1995)) (“A method for screening potential cancer therapeutics which comprises: growing a transformed eukaryotic host cell containing an altered

Judge Lourie’s analysis of the method claims is a straightforward application of the machine-or-transformation test, which the district court had relied upon in holding these claims invalid.<sup>150</sup> The panel held that the method claims to “comparing” or “analyzing” gene sequences “fall outside the scope of § 101 because they claim only abstract mental processes.”<sup>151</sup> The opinion rejected the argument that the method is patent eligible because it can only be performed after the prior steps of extracting DNA from a human sample and sequencing the BRCA DNA molecules in the sample, noting that the claim language does not include these prior steps.<sup>152</sup> This allowed the court to distinguish the *Prometheus* claims, which included the “transformative” steps of “administering” a drug to a patient and “determining” the levels of a drug metabolite in a patient.<sup>153</sup> The opinion concluded that claims to methods of “comparing” and “analyzing” DNA sequences “fail to satisfy the machine-or-transformation test, and are instead directed to the

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BRCA1 gene causing cancer in the presence of a compound suspected of being a cancer therapeutic, growing said transformed eukaryotic host cell in the absence of said compound, determining the rate of growth of said host cell in the presence of said compound and the rate of growth of said host cell in the absence of said compound and comparing the growth rate of said host cells, wherein a slower rate of growth of said host cell in the presence of said compound is indicative of a cancer therapeutic.”).

150 *Ass'n for Molecular Pathology v. USPTO*, No. 09 Civ. 4515 (RWS), 2010 U.S. Dist. LEXIS 35418 at \*147-61. Indeed, the district court had the Federal Circuit’s first opinion in *Prometheus* before it and took pains to distinguish the two cases. *Id.* at \*149-60.

151 *Ass'n for Molecular Pathology*, 653 F.3d at 1355.

152 *Id.* at 1356.

153 *Id.* at 1357. *See also supra* notes 85-91.

abstract mental process of comparing two nucleotide sequences. The claims thus fail to claim a patent-eligible process under § 101.”<sup>154</sup>

The panel also relied on the machine-or-transformation test as an “important clue” to reverse the district court’s holding of invalidity for a claim to a method for screening potential cancer therapeutics.<sup>155</sup> The court noted that the claim recites the “inherently transformative” steps of (1) “growing” host cells transformed with an altered BRCA1 gene in the presence or absence of a potential cancer therapeutic, and (2) “determining” the growth rate of the host cells with or without the potential therapeutic:

The claim thus includes more than the abstract mental step of looking at two numbers and “comparing” two host cells’ growth rates. The claim includes the steps of “growing” transformed cells in the presence or absence of a potential cancer therapeutic, an inherently transformative step involving the manipulation of the cells and their growth medium. The claim also includes the step of “determining” the cells’ growth rates, a step that also necessarily involves physical manipulation of the cells.<sup>156</sup>

After this analysis of the method claims under the machine-or-transformation test, the opinion recites a litany of phrases from the patentable subject matter caselaw in support of its conclusion, including that “the claim is not so ‘manifestly abstract’ as to claim only a scientific principle” and that “the claims do not preempt all uses of the natural correlations; they utilize them in a

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154 *Ass'n for Molecular Pathology*, 653 F.3d at 1357.

155 *Id.* at 1357-58; *see supra* note 149 for the language of the claim.

156 *Ass'n for Molecular Pathology*, 653 F.3d at 1357.



series of specific steps.”<sup>157</sup> But it is the machine-or-transformation test that appears to do the real work for the panel of distinguishing between the unpatentable claims to methods of “comparing” and “analyzing” and the patent eligible claims to methods of screening potential cancer therapeutics.

With the benefit of the Federal Circuit’s opinion it would not be difficult to redraft future diagnostic method claims to recite patentable subject matter. Using *Prometheus Laboratories v. Mayo Collaborative Services* and *American Association for Molecular Pathology v. USPTO* as guides, patent applicants could satisfy the machine-or-transformation steps by reciting as claim limitations transformative steps that necessarily precede any comparison of the value of a biomarker for a particular patient with a reference value. Consider, for example, claim 1 of U.S. Patent No. 5,709,999, held invalid under the machine-or-transformation rule:

A method for detecting a germline alteration in a BRCA1 gene, said alteration selected from a group consisting of the alterations set forth in Tables 12A, 14, 18, or 19 in a human which comprises analyzing a sequence of a BRCA1 gene or BRCA1 RNA from a human sample or analyzing a sequence of BRCA1 cDNA made from mRNA from said human sample with the proviso that said germline alteration is not a deletion of 4 nucleotides corresponding to base numbers 4184-4187 of SEQ ID N0:1.<sup>158</sup>

The downfall of this claim is that it begins with the mental step of “analyzing” a sequence without reciting the prior steps necessary to obtain and process a tissue sample in order to have a

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<sup>157</sup> *Id.* at 1358.

<sup>158</sup> U.S. Patent No. 5,709,999 claim 1 (filed June 7, 1995).

sequence to analyze. Compare claim 46 of U.S. Patent No. 6,355,623, which the Federal Circuit approved as claiming patentable subject matter in *Prometheus*:

A method of optimizing therapeutic efficacy and reducing toxicity associated with treatment of an immune-mediated gastrointestinal disorder, comprising:

....

(b) determining the level of 6-thioguanine or 6-methylmercaptapurine in a subject administered a drug selected from the group consisting of 6-mercaptopurine, azathiopurine, 6-thioguanine, and 6-methyl-mercaptoriboside, said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per  $8 \times 10^8$  red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per  $8 \times 10^8$  red blood cells or a level of 6-methylmercaptapurine greater than about 7000 pmol per  $8 \times 10^8$  red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.<sup>159</sup>

The Federal Circuit saw the analytical inferences in the “wherein” clauses of this claim as unpatentable mental steps, but the “determining” step set forth prior to those clauses was a transformative step that satisfied the machine-or-transformation test and saved the claim from invalidity. If that is all it takes, it would seem that Claim 1 of the ’623 patent could likewise be saved by inserting explicit claim steps of “obtaining a DNA sample from a patient” and

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<sup>159</sup> U.S. Patent No. 6,355,623 claim 1 (filed Apr. 8, 1999); *Prometheus Labs*, 628 F.3d at 1349 (“[W]e again hold that Prometheus’s asserted method claims are drawn to statutory subject matter, and we again reverse the district court’s grant of summary judgment of invalidity under § 101.”).

“determining the BRCA1 or BRCA2 DNA sequence in the patient’s DNA” immediately before the word “analyzing.”<sup>160</sup>

It is by no means clear that this is what the Supreme Court had in mind in approving the machine-or-transformation test as a “useful clue” but not the “sole test” of the patent eligibility of processes. Prior decisions have sometimes found similar claims-drafting maneuvers inadequate to avoid an exclusion from patentable subject matter, insisting, for example, that the transformative claim element should be disregarded when it amounts to “insignificant post-solution activity”<sup>161</sup> or mere “data-gathering steps.”<sup>162</sup> Even if the Court is generally disposed to recognize patent eligibility for “advanced diagnostic medical techniques,” it might not be satisfied with identifying a claims-drafting maneuver that works for future patent applicants, but leaves current holders of claims drafted in “determine and infer” format with disappointed expectations.

Concern for the disappointed expectations of patent holders may have played a decisive role in the divided panel’s analysis of the patentability of composition of matter claims to isolated DNA, an issue on which the Supreme Court opinion in *Bilski v. Kappos* offers little

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<sup>160</sup> *Prometheus Labs*, 628 F.3d at 1350.

<sup>161</sup> *Diamond v. Diehr*, 450 U.S. at 191-192.

<sup>162</sup> *E.g.*, *In re Grams*, 888 F.2d 835, 839-40 (Fed. Cir. 1989) (“The sole physical process step in Grams’ claim 1 is step [a], *i.e.*, performing clinical tests on individuals to obtain data. ... The presence of a physical step in the claim to derive data for the algorithm will not render the claim statutory.”).

guidance.<sup>163</sup> The United States as amicus curiae did not defend the PTO's longstanding practice of allowing patents to issue on isolated DNA molecules, but instead urged the Federal Circuit to affirm the District Court's holding that these claims were unpatentable products of nature.<sup>164</sup>

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163 The Court in *Bilski* was not concerned with the patentability of products of nature and did not include "products of nature" in its list of time-honored exclusions from patent eligibility. On the other hand, the Court cited with approval its own prior decisions in cases recognizing such an exclusion. *See, e.g.,* *Diamond v. Chakrabarty*, 447 U.S. 303, 313 (1980) ("Congress thus recognized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions."); *Funk Bros. Seed v. Kalo Inoculant*, 333 U.S. 127, 131 (1948) (Mixed culture of naturally occurring strains of bacteria selected for their non-inhibition of each other's function was not patentable subject matter because "[i]t is no more than the discovery of some of the handiwork of nature .... 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. .... 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."); *J. E.M. Ag Supply v. Pioneer Hi-Bred*, 534 U.S. 124, 134 (2001) (citing with approval the above-quoted passage from *Chakrabarty*); *Am. Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11-13 (1931) (Orange rind treated with borax to protect against decay was not sufficiently changed from its natural state to constitute a patentable "manufacture" because "[a]ddition of borax to the rind of natural fruit does not produce from the raw material an article for use which possesses a new or distinctive form, quality, or property.").

164 Brief for the United States as Amicus Curiae in Support of Neither Party in *Ass'n for Molecular Pathology v. USPTO*, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406), 2010 WL 4853320, *available at* <http://graphics8.nytimes.com/packages/pdf/business/genopatents-USamicusbrief.pdf> (last visited Oct. 30, 2011).

Nonetheless, Judge Lourie and Judge Moore both noted that such a departure from longstanding practice should come from Congress rather than from the courts.<sup>165</sup>

The main disagreement among the panel members concerned whether segments of DNA that have been isolated from chromosomes but are otherwise unaltered are unpatentable products of nature. For Judge Lourie, human intervention to cleave the covalent bonds that unite the DNA molecule to other genetic material in its natural state is enough to make the isolated DNA molecules “markedly different [with a] distinctive chemical identity and nature [] from molecules that exist in nature,” making the claims patent eligible.<sup>166</sup> Judge Moore, however, read the precedents as requiring that the isolated molecule must do more than “serve the ends nature originally provided,” and that human modifications must give the product “markedly different characteristics with the potential for significant utility” in order to avoid the exclusion for products of nature.<sup>167</sup> Judge Moore concluded that short DNA molecules isolated from chromosomes meet this standard because they could be used as primers and probes for diagnostic testing, but that longer DNA sequences that are unsuitable for these uses present a more difficult question.<sup>168</sup> Nonetheless, given the longstanding practice of the PTO to allow patents on isolated

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165 *Ass’n for Molecular Pathology*, 653 F.3d at 1354-55 (Lourie, J.); *id.* at 1367-68, 1370-73 (Moore, J., concurring in part)

166 *Id.* at 1351 (Lourie, J.).

167 *Id.* at 1359-60 (Moore, J., concurring in part) (citations omitted).

168 *Id.* at 1365-67.

DNA, Judge Moore concluded that the longer sequences were also patentable subject matter, noting concern for the impact of a contrary decision on the settled expectations of the biotechnology industry.<sup>169</sup> Judge Bryson dissented from the holding of patent eligibility for isolated DNA, reasoning that, notwithstanding the breaking of chemical bonds, the isolated genes are not “materially different” from the same genes as they occur in nature.<sup>170</sup>

The variety of claims at issue, the sharp disagreements among the panel members, and the care taken in each opinion to be faithful to precedent provide a strong foundation for Supreme Court review.

#### B. The Minimalist “Coarse Filter” Approach

Other post-*Bilski* patentable subject matter opinions from the Federal Circuit suggest a different approach, assigning a minimal role to subject matter exclusions reminiscent of the pre-*Laboratory Corporation* era in the Federal Circuit. The first of these opinions was authored by Chief Judge Rader in *Research Corporation Technologies v. Microsoft*,<sup>171</sup> shortly before the second Federal Circuit decision in *Prometheus v. Mayo*. Judge Rader, who also joined Judge Lourie’s opinion as a member of the *Prometheus* panel, set an entirely different tone in writing

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<sup>169</sup> *Id.* at 1366-70.

<sup>170</sup> *Id.* at 1373, 1375 (Bryson, J., concurring in part and dissenting in part).

<sup>171</sup> 627 F.3d 859 (Fed. Cir. 2010)

for the *Research Corporation* panel.<sup>172</sup> That case involved an invention in the longstanding patent eligibility battleground of information technology – specifically, a new method for allowing computers and printers to more efficiently render approximations of an image using digital halftoning technology.<sup>173</sup>

Judge Rader began by noting that patentable subject matter is only a “threshold test,” and that the statute directs primary attention to the other conditions and requirements for patentability.<sup>174</sup> He mentioned the “machine or transformation” test only to recognize that the Supreme Court had faulted that test as “nonstatutory.”<sup>175</sup> Turning to the question of whether the claimed processes were excluded from patentable subject as “abstract,” Judge Rader did not seek clues to the meaning of that term, but saw its ambiguity as empowering the Federal Circuit to minimize the exclusion:

The Supreme Court did not presume to provide a rigid formula or definition for abstractness. ... Instead, the Supreme Court invited this court to develop “other limiting criteria that further the purposes of the Patent Act and are not inconsistent with its text.” ... With that guidance, this court also will not presume to define “abstract” beyond the recognition that this disqualifying characteristic should exhibit itself so manifestly as to override the broad statutory categories of

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172 *Id.* at 862 (The panel consisted of Chief Judge Rader and Judges Newman and Plager.).

173 *Id.* at 862-63.

174 *Id.* at 868.

175 *Id.*

eligible subject matter and the statutory context that directs primary attention on the patentability criteria of the rest of the Patent Act.<sup>176</sup>

Explaining why “this court perceives nothing abstract in the subject matter of the processes claimed,” Judge Rader noted the “functional and palpable applications” of the process, and observed that “inventions with specific applications or improvements to technologies in the marketplace are not likely to be so abstract that they override the statutory language and framework of the Patent Act.”<sup>177</sup> The opinion notes in passing that some of the claims require a “high contrast film,” “a film printer,” “a memory,” and “printer and display devices” and that these features “also confirm this court's holding that the invention is not abstract.”<sup>178</sup> But Judge Rader does not dwell on these physical elements or use the words “machine or transformation” to explain their relevance.<sup>179</sup> The discussion of patentable subject matter concludes by noting that claims that “pass the coarse eligibility filter” might still fail the tests of claim definiteness and written description and that § 112 of the Patent Act<sup>180</sup> might be a more appropriate way to invalidate claims that are not clear and concrete rather than a subject matter exclusion.<sup>181</sup>

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<sup>176</sup> *Id.* at 868.

<sup>177</sup> *Id.* at 868-69.

<sup>178</sup> *Id.* at 869.

<sup>179</sup> *Id.* at 868-69.

<sup>180</sup> 35 U.S.C. § 112 (2010) (outlining the extent to which claims must be specified).

<sup>181</sup> *Research Corp. Techs.*, 627 F.3d at 869.



This minimalist approach to the role of § 101 appears again in the analysis of biopharmaceutical method claims in the recent decision of the Federal Circuit in *Classen Immunotherapies v. Biogen IDEC* on remand from the Supreme Court.<sup>182</sup> Prior to the Supreme Court decision in *Bilski v. Kappos*, the Federal Circuit had affirmed summary judgment of invalidity for the patent claims under the machine-or-transformation test in a brief opinion.<sup>183</sup> The Supreme Court granted *certiorari*, vacated and remanded for reconsideration in light of *Bilski*.<sup>184</sup> The three opinions from a divided panel on remand reveal sharp divisions both on the role of patentable subject matter doctrine and on its application to the claims at issue. None of the opinions embraces the machine-or-transformation test.

Judge Newman, joined by Chief Judge Rader, found the claims of two of the three patents at issue patent-eligible under § 101, although questioning whether the same claims would survive challenges to their validity based on other statutory requirements, but affirmed the judgment of invalidity as to the claims of a third patent.<sup>185</sup> Regrettably, the invalidity analysis for the third patent rests on a questionable reading of the claim language, as Judge Moore

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182 *Classen Immunotherapies v. Biogen IDEC*, Nos. 2006-1634, 2006-1649, 2011 U.S. App. LEXIS 18126 (Fed. Cir. Aug. 31, 2011). *See also supra* notes 83-84 and accompanying text (prior history).

183 *Classen Immunotherapies v. Biogen IDEC*, 304 F. App'x. 866 (Fed. Cir. 2008).

184 *Classen Immunotherapies v. Biogen IDEC*, 130 S. Ct. 3541 (2010).

185 *Classen Immunotherapies*, 2011 U.S. App. LEXIS 18126 at \*44.

explains in an emphatic dissent.<sup>186</sup> Judge Rader wrote separately in an opinion joined by Judge Newman to inveigh against “a rising number of challenges under 35 U.S.C. § 101” and to implore the court to “decline to accept invitations to restrict subject matter eligibility.”<sup>187</sup>

Although expressing profound skepticism toward “judge-made” restrictions on patent eligibility, Judge Rader attributes the problem to “litigants”<sup>188</sup> rather than to the Supreme Court and does not enter into an analysis of how the Court’s precedents apply to the claims at issue in *Classen*.

As Judge Newman explains, the patents arise from Dr. Classen’s discovery that administering the first dose of a vaccine prior to 42 days of age substantially decreases the likelihood of chronic immune-mediated disorders.<sup>189</sup> The two patents that Judge Newman deems patent-eligible (the ’139 patent and the ’739 patent) claim a method of immunizing subjects by first “screening” information about the occurrence of chronic disease in patients who have been immunized according to different immunization schedules, “comparing” the results,

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186 *Id.* at \*51, \*53-54, \*55 n.1 (Moore, J., dissenting) (“I am perplexed by the majority’s suggestion that this claim ‘is directed to the single step of reviewing the effects of known immunization schedules,’ Maj. Op. at 20, as the claim clearly requires *immunizing mammals* and then comparing the results to the known group .... The ’283 patent claim clearly and unequivocally requires the physical act of immunization and it is unfair of the majority to analyze the claim for § 101 purposes as though it did not have that step.”).

187 *Id.* at \*45 (additional views of Rader, C.J., joined by Newman, J.).

188 *Id.* at \*45 (“The language of § 101 is very broad. Nevertheless, litigants continue to urge this court to impose limitations not present in the statute.”)

189 *Id.* at \*5 (majority opinion).

“identifying” the lower risk immunization schedule, and then “immunizing” patients according to the schedule that shows a lower risk of chronic immune-mediated disorders.<sup>190</sup> The third patent (the ’283 patent), according to Judge Newman, omits the final step of immunizing patients and “claims the idea of comparing known immunization results that are, according to the patent, found in the scientific literature, but does not require using this information for immunization purposes.”<sup>191</sup> In other words, the ’139 and ’739 patents claim methods that include first comparing the results of studies to figure out the lower risk schedule and then immunizing patients according to that schedule, while the ’283 patent does not require actually immunizing patients and may be infringed merely by reading study results.

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<sup>190</sup> *Id.* at \*5-6.

<sup>191</sup> *Id.* at \*25. This interpretation is difficult to reconcile with the language of the claim, which explicitly calls for immunizing patients in a trial in order to determine the lowest risk immunization schedule: “A method of determining whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder in a treatment group of mammals, relative to a control group of mammals, which comprises immunizing mammals in the treatment group of mammals with one or more doses of one or more immunogens, according to said immunization schedule, and comparing the incidence, prevalence, frequency or severity of said chronic immune-mediated disorder or the level of a marker of such a disorder, in the treatment group, with that in the control group.” *Id.* at \*8-9. According to Judge Newman, “The ‘immunizing’ in the ’283 patent refers to the gathering of published data, while the immunizing of the ’139 and ’739 patent claims is the physical implementation of the mental step claimed in the ’283 patent.” *Id.* at \*25.

Given these claim interpretations, the results Judge Newman reaches would be easy to justify under the machine-or-transformation rule in reliance on *Prometheus v. Mayo* and *Association for Molecular Pathology*, but she instead looks primarily to Judge Rader’s opinion in *Research Corporation* for guidance. She invokes *Research Corporation* repeatedly for the principles that § 101 is a “coarse eligibility filter,” that other substantive conditions and requirements are available to weed out patents that are too vague or indefinite or conceptual, and that inventions with applications in the marketplace are unlikely to be so abstract that they are excluded from the broad reach of the statute.<sup>192</sup>

Under this approach, Judge Newman concludes that the ’139 and ’739 patents pass the threshold of patentability because they are “directed to a specific, tangible application, as in *Research Corporation*.”<sup>193</sup> That application is “lowering the risk of chronic immune-mediated disorder.”<sup>194</sup> Although she notes that the claims include “the physical step of immunization on the determined schedule,” she does not purport to apply the machine-or-transformation test. Instead she invokes “the guidance of *Bilski v. Kappos* that ‘[r]ather than adopting categorical rules that might have wide-ranging and unforeseen impacts,’ exclusions from patent-eligibility should be applied ‘narrowly,’” and notes that the claims “raise cogent questions of patentability”

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192 *Id.* at \*21-24.

193 *Id.* at \*24.

194 *Id.*

that are better resolved under the substantive requirements for patentability.<sup>195</sup> Turning to the '238 patent, Judge Newman asserts that it would be infringed merely “by reviewing information on whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder” without “the subsequent step of immunization on an optimum schedule.”<sup>196</sup> She concludes that the claims “do not include putting this knowledge to practical use, but are directed to the abstract principle that variation in immunization schedules may have consequences for certain diseases” and are therefore too abstract to get past “the coarse filter of § 101.”<sup>197</sup> She mentions the machine-or-transformation test only to explain the Supreme Court’s disapproval of it as the “sole test” of patent eligibility and to summarize Classen’s arguments for patent eligibility.<sup>198</sup>

Two difficulties with this analysis make it problematic as an explanation for the decision. First, as noted previously, the '238 patent claim language, contrary to Judge Newman’s account, appears to require immunizing research subjects:

A method of determining whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder in a treatment group of mammals, relative to a control group of mammals, *which comprises immunizing mammals in the treatment group of mammals with one or more doses of one or more immunogens*, according to said immunization schedule, and

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<sup>195</sup> *Id.* at \*24.

<sup>196</sup> *Id.* at \*25.

<sup>197</sup> *Id.* at \*25-28.

<sup>198</sup> *Id.* at \*13, \*26, \*29.

comparing the incidence, prevalence, frequency or severity of said chronic immune-mediated disorder or the level of a marker of such a disorder, in the treatment group, with that in the control group.<sup>199</sup>

That Judge Newman would attempt the difficult sleight of hand necessary to read this limitation out of the claim language suggests that the transformative step of bringing about bodily changes by administering treatment to a mammal in fact does matter to her assessment of patent eligibility, notwithstanding her avoidance of the label “machine-or-transformation” or other “categorical rules.”

Second, if we take Judge Newman at her word that what matters is not chemical transformation in the bodies of immunized mammals, but the practical application of the lower-risk immunization schedule, then it is not clear why a method of determining whether an immunization schedule affects the incidence or severity of chronic immune-mediated disorders fails that test. In biopharmaceutical fields, many patents cover inventions useful in drug development that do not recite steps of administering the as yet undiscovered drugs to patients. In fact, the one claim that was unanimously upheld by the panel in *Association for Molecular Pathology*—the claim to a method of screening potential cancer therapeutics—did not recite a step of administering the effective compounds to patients.<sup>200</sup> Presumably, Judge Newman does not mean to call into question the validity of these patents, yet it is unclear that they would pass

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199 *Id.* at \*8-9 (emphasis added) (citing U.S. Patent No. 5,723,283 claim 1 (filed May 31, 2005)).

200 *Ass’n for Molecular Pathology*, 653 F.3d at 1334.

the test of “practical use” that purportedly distinguishes the patent-eligible from patent-ineligible claims in *Classen*.

In dissent, Judge Moore argues that, properly interpreted, the claims of the ’238 patent are indistinguishable from those of the ’139 and ’739 patents for § 101 purposes,<sup>201</sup> and that all of them improperly claim fundamental scientific principles:

Having discovered a principle – that changing the timing of immunization may change the incidence of chronic immune mediated disorders –Classen now seeks to keep it for himself. In the ’283 patent, he accomplishes this goal by claiming the use of the scientific method to study the incidence of chronic immune mediated disorders. This preempts the field of study, and prevents any investigation into any immunogen, known or unknown, and to any disease, known or unknown, over any period of time. Where, as here, a patent preempts an idea, a basic building block of science, within a field of study, the patent in practical effect is a patent on the idea itself.<sup>202</sup>

Judge Moore repeatedly quotes Justice Breyer’s dissent in *Laboratory Corporation* in arguing that allowing claims of the sort at issue would interfere with the development of further knowledge.<sup>203</sup> Like Judge Newman, Judge Moore does not dwell on the machine-or-transformation test. For Judge Moore the inclusion in the claims of a claim step of immunizing patients, whether subsequent to a comparison of immunization schedules as in the ’139 and ’739 patents or prior to that comparison as in the ’238 patent, could not transform an unpatentable principle into a patentable process; in the former case the immunizing step was “nothing more

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201 *Classen Immunotherapies*, 2011 U.S. App. LEXIS 18126 at \*51, \*53-57, \*54 n.1.

202 *Id.* at \*60-61 (citing *Gottschalk v. Benson*, 409 U.S. 63, 72 (1972)).

203 *Id.* at \*61, \*63.

than post-solution activity” and in the latter case it was “nothing more than a data gathering step.”<sup>204</sup> Distinguishing *Prometheus v. Mayo*, she notes that the *Prometheus* court concluded that the claims in that case “were not merely data gathering steps or insignificant post-solution activity” and that because they were limited to the administration of specific drugs, they did not “preempt broadly the use of any natural correlation,” and faults the majority for failing to consider the preemptive sweep of Classen’s claims.<sup>205</sup> She rejects the majority’s view that it was necessary to consider the substantive conditions for patentability in order to invalidate these claims:

When, as here, the claims so clearly offend the constitutional imperative to promote the useful arts, where they preempt all application of a principle or idea, it is entirely appropriate to hold them unpatentable subject matter before reaching anticipation, obviousness, or any other statutory section that might also prove invalidity.<sup>206</sup>

In sum, the patentable subject matter cases decided by the Federal Circuit since the Supreme Court decision in *Bilski v. Kappos* reveal considerable disagreement within that court about the limitations of patentable subject matter and about the role those limitations should play in determining what may be patented. Without further clarification from the Supreme Court, some members of the Federal Circuit seem ready to return to the pre-*Bilski* machine-or-transformation rule, while others seem ready to roll the clock back even further and return to the

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204 *Id.* at \*62.

205 *Id.* at \*53.

206 *Id.* at \*66.



“useful, concrete, and tangible” rule of *State Street Bank v. Signature Financial Group*.<sup>207</sup> Yet if the Justices agreed on anything about the contours of patentable subject matter in *Bilski v. Kappos*, it was that both of these positions get it wrong.

### III. Identifying the Purpose of Subject Matter Boundaries

The Supreme Court has directed the Federal Circuit to consult the statute and Supreme Court precedent in elaborating rules of patentable subject matter, but the task of extrapolating from these sources to address unresolved issues is challenging without more clarity as to the purposes and functions of subject matter boundaries in the patent system. The majority opinion in *Bilski v. Kappos* avoids reference to any policy moorings that might either guide the interpretation of prior decisions or steer courts in future cases. But without understanding what patentable subject matter boundaries are supposed to accomplish, it is difficult to figure out where those boundaries belong.

Earlier judicial opinions have advanced policy arguments in favor of exclusions from patentable subject matter that overlap with policies served by other doctrinal limitations on what may be patented, inviting the argument that patentable subject matter is redundant to these other limitations.<sup>208</sup> For example, the Supreme Court has repeatedly justified exclusions of “fundamental principles,” “abstract ideas” and “mathematical algorithms” by invoking concerns

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<sup>207</sup> See *supra* note 13.

<sup>208</sup> See Risch, *supra* note 2; Duffy, *supra* note 33.

about allowing unduly broad patent rights.<sup>209</sup> But patent law addresses this concern elsewhere by limiting the allowable scope of patent claims to exclude prior art<sup>210</sup> and nonenabled embodiments.<sup>211</sup> Indeed, some of the older precedents date back to a time before the statute explicitly distinguished “patentable subject matter” from other doctrinal limitations on the allowance of patents, making it difficult to map the basis for those decisions onto modern doctrinal categories.<sup>212</sup>

Commentators have stepped into the void, producing a rich and varied scholarly literature. Some scholars find unarticulated normative intuitions lurking behind the boundaries laid down in prior decisions and seek to guide courts, Congress, and the PTO to use subject matter boundaries to ensure that the patent system continues to advance similar normative goals today.<sup>213</sup> Some see the boundaries as failed attempts to lay down rules that have inevitably

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209 *E.g.*, *Gottschalk v. Benson*, 409 U.S. 63, 68, 72 (1972) (“Here the ‘process’ claim is so abstract and sweeping as to cover both known and unknown uses of the BCD to pure binary conversion .... [T]he patent would wholly preempt the mathematical formula and, in practical effect, would be a patent of the algorithm itself.”); *see also* *Collins*, *supra* note 33, at 50-53 (discussing *O’Reilly v. Morse*, 56 U.S. 62 (1853)).

210 35 U.S.C. §§ 102-103 (2010).

211 35 U.S.C. § 112 (2010).

212 *E.g.*, *Funk Bros. Seed v. Kalo Inoculant*, 333 U.S. 127 (1948)

213 *E.g.*, *Olson*, *supra* note 64 (arguing that until recently courts deployed patentable subject matter to exclude categories of invention that did not require patent incentives, using an implicit but unarticulated economic analysis to determine which fields would exhibit public goods problems that would lead to underproduction of inventions in

become outmoded in the face of technological change, preferring other doctrinal tools for identifying what is and is not patentable that offer more flexible standards and have proven more stable over time.<sup>214</sup> Some attempt to disaggregate the limitations on patentable subject matter in order to sharpen and distinguish criticisms that apply to some parts of the doctrine but not others.<sup>215</sup> Some take the boundaries as given and try to identify interpretive moves that will

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the absence of patents, and that under that analysis business methods should be excluded); Yu, *supra* note 33 (arguing that patentable subject matter should ensure that patents advance Constitutional goal of promoting progress of science and useful arts by excluding basic tools of scientific and technological work, distinguishing invention from discovery, and defining subject matter boundaries consistent with industrial policy).

214 See Duffy, *supra* note 33, at 614 (arguing that over time clear “rules” restricting patentable subject matter have proven unstable in the face of technological change relative to more flexible “standards,” and that other patent law “standards,” such as nonobviousness and enablement, better address concerns about excessive patenting than rigid exclusionary rules); Richard S. Gruner, *Intangible Inventions: Patentable Subject Matter for an Information Age*, 35 LOY. L.A. L. REV. 355, 356 n.5 (2003) (“Adjustments in patentable subject matter standards frequently follow changes in technological knowledge. These adjustments are needed to maintain patent incentives as inducements for design efforts and disclosures in new technological realms.”).

215 Chiang, *supra* note 33 (distinguishing two kinds of patentable subject matter limitations that present different costs and benefits: (1) categorical exclusions, which trade off administrative cost savings against the costs of over- and under-inclusiveness; and (2) scope limitations, which are more costly to administer but less prone to error); Duffy, *supra* note 33 at 614 (distinguishing patentable subject matter “rules” from “standards”). See also Collins, *supra* note 55 (arguing that the focus on the machine-or-transformation test has led to miscoding of determine-and-infer claims as possibly within exclusion for “abstract ideas” rather than as possibly within exclusion for “mental processes”).

better advance normative goals within those constraints.<sup>216</sup> And some would largely eliminate patentable subject matter limitations, relying on other rules of patent law to separate the patentable wheat from the unpatentable chaff.<sup>217</sup>

#### A. Threshold Inquiry

The closest that prior decisions have come to distinguishing the function of patentable subject matter from the functions of other patent law doctrines is the characterization of patentable subject matter as a “threshold inquiry” or the “first door” an invention must pass through in order to get a patent. This image, which appears in decisions of the Supreme Court,<sup>218</sup> the Federal Circuit,<sup>219</sup> and the Court of Customs and Patent Appeals,<sup>220</sup> suggests a gatekeeper

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216 *E.g.*, Collins, *Bilski and the Ambiguity of “an Unpatentable Abstract Idea”*, *supra* note 33 (identifying multiple distinct meanings of “abstract idea” that raise different concerns and merit different treatment).

217 *E.g.*, Risch, *supra* note 2; Osenga, *supra* note 31.

218 *Bilski*, 130 S. Ct. at 3225 (“The § 101 patent-eligibility inquiry is only a threshold test. Even if an invention qualifies as a process, machine, manufacture, or composition of matter, in order to receive the Patent Act’s protection the claimed invention must also satisfy ‘the conditions and requirements of this title.’ § 101. Those requirements include that the invention be novel, see § 102, nonobvious, see § 103, and fully and particularly described, see § 112.”).

219 *In re Comiskey*, 554 F.3d 967, 973 (Fed. Cir. 2009) (“We do not reach the ground relied on by the Board below ... because we conclude that many of the claims are ‘barred at the threshold by § 101.’ It is well-established that ‘[t]he first door which must be opened on the difficult path to patentability is § 101.’ ... Only if the requirements of § 101 are satisfied is the inventor ‘allowed to pass through to’ the other requirements for

role for patentable subject matter at the point of entry to the patent system, providing a rough first cut that leaves some kinds of inventions outside the system while admitting others to be examined more closely within the PTO to determine their patentability. Subject matter exclusions that may be applied at the front door of the patent system (such as, for example, a rule that excludes “business methods” from patentable subject matter) could potentially reduce administrative costs of the patent system by restricting the number of patent applications that require more costly individualized examination.

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patentability, such as novelty under § 102 and, of pertinence to this case, non-obviousness under § 103.”); *In re Bilski*, 545 F.3d 943, 950-51 (Fed. Cir. 2008) (en banc) (“Whether a claim is drawn to patent-eligible subject matter under § 101 is a threshold inquiry, and any claim of an application failing the requirements of § 101 must be rejected even if it meets all of the other legal requirements of patentability.”), *but cf. id.* at 950 n.1 (“Although our decision in *Comiskey* may be misread by some as requiring in every case that the examiner conduct a § 101 analysis before assessing any other issue of patentability, we did not so hold. As with any other patentability requirement, an examiner may reject a claim solely on the basis of § 101. Or, if the examiner deems it appropriate, she may reject the claim on any other ground(s) without addressing § 101. But given that § 101 is a threshold requirement, claims that are clearly drawn to unpatentable subject matter should be identified and rejected on that basis. Thus, an examiner should generally first satisfy herself that the application's claims are drawn to patent-eligible subject matter.”).

220 *In re Bergy*, 596 F.2d 952, 960 (C.C.P.A. 1979), *vacated in part sub nom. Diamond v. Chakrabarty*, 444 U.S. 1028 (1980) (“The first door which must be opened on the difficult path to patentability is § 101 .... If the invention, as the inventor defines it in his claims ... falls into any one of the named categories, he is allowed to pass through to the second door, which is § 102; ‘novelty and loss of right to patent’ is the sign on it.”).

Such a threshold rule is especially attractive if the excluded subject matter either does not require the incentive of patent protection or would not get past the additional tests of patentability that are administered in the course of examination. On the other hand, to the extent that the rule excludes subject matter that might otherwise pass these tests and withholds patents from fields that might benefit from patent incentives, it may be criticized as “eliminating broad swaths of innovation with a machete” when a more carefully deployed “scalpel” would do a better job of promoting progress.<sup>221</sup> But as Professor Tun-Jen Chiang explains, this tradeoff between administrative costs and over- and under-inclusiveness is inherent in the choice of a bright-line rule over more discriminating standards.<sup>222</sup>

A number of problems limit the value of patentable subject matter as a threshold test. First, if the threshold test is to provide a useful screen, the exclusions should rest on at least a rough assessment of whether patent protection is socially desirable for different categories of invention, thereby excluding patents in areas where they are either unnecessary to promote innovation or impose monopoly costs that exceed corresponding benefits in the form of innovation incentives.<sup>223</sup> Yet in the absence of systematic investigations of these effects by

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221 Risch, *supra* note 2, at 658; Duffy, *supra* note 33, at 622-23.

222 Chiang, *supra* note 33, at 1357-63.

223 Olson, *supra* note 64, at 203 (“[T]he critical first inquiry for the patentability of an invention should be whether the invention is within a subject matter area that is subject to a public goods problem such that absent patent protection an underproduction of inventions in that subject matter will result. If a public goods problem exists, then

policymakers, judicial exclusions from patentable subject matter rest at best on seat-of-the-pants intuitions of jurists from earlier eras. According to Professor David Olson, courts in the past “implicitly analyzed” the economic effects of patents by subject matter area in developing rules that “distinguish, albeit not explicitly, efficient from inefficient subject matter for patentability,”<sup>224</sup> but beginning with the 1980 decision of the Supreme Court in *Diamond v. Chakrabarty* courts have “largely abandoned any gatekeeping role” in favor of a broad reading of statutory standards for patentable subject matter.<sup>225</sup> But the attribution of implicit economic analysis to courts of the past is fraught with possibilities for misunderstanding, projection and revisionist history. Moreover, if one trusts that the decisions of judges are guided by economic intuitions that they fail to articulate, it is not clear why one would have more confidence in the decisions that restricted patentable subject matter in the distant past than in the decisions that expanded patentable subject matter in the recent past. Either way, it takes a leap of faith to believe that the rules courts devise are smarter than the reasons they adduce in support of those rules. The less confidence one has that the rules of patentable subject matter correspond even

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the subject matter should be patentable and the other tests for patentability should be applied. If no public goods problem exists, either because of the nature of the subject matter, or because other factors exist that adequately incentive production of the public good, then subject matter patentability should be denied and the patentability inquiry should end.”).

<sup>224</sup> *Id.* at 205-15.

<sup>225</sup> *Id.* at 214-15.

roughly to the goals of the patent system, the less sense it makes to assign a gatekeeper function to those rules.

Second, in order to provide a means for economizing on administrative costs, patentable subject matter exclusions must provide clear rules that can be applied without the need for individualized examination. While some exclusions from patentable subject matter have provided clear rules for a period of time, such as past exclusions for business methods and living things,<sup>226</sup> often these exclusions have eventually proven to be overinclusive in the face of technological change.<sup>227</sup> Technological change makes categorical exclusions that may have made sense in an earlier era seem out of date and unworkable. Thus an exclusion for living things, taken for granted as long as that category overlapped substantially with products of nature, became anomalous with the advent of genetic engineering,<sup>228</sup> an exclusion for mathematical algorithms became problematic when the advent of computers made the execution of algorithms by machine a field of applied technology and incorporated information technology into industrial processes,<sup>229</sup> and an exclusion for business methods became problematic when information technology and the internet blurred the boundaries between business and technology.<sup>230</sup> As

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226 Chiang, *supra* note 33, at 1382-83; Duffy, *supra* note 33 at 623-38.

227 Chiang, *supra* note 33, at 1383-85; Duffy, *supra* note 33, at 616-17.

228 Duffy, *supra* note 33, at 625-32; Eisenberg, *supra* note 1.

229 Olson, *supra* note 64, at 206-18.

230 *Id.* at 218-24.



Professor John Duffy has documented, bright-line rules have difficulty keeping up with technological change, which is especially challenging for a legal regime that functions to promote technological change.<sup>231</sup> Those categorical exclusions that are clear enough to be applied by a bouncer at the front door of the PTO may thus become unstable over time.

Conversely, subject matter exclusions that operate as flexible standards, such as that for “abstract ideas,” have proven more durable over time, but their meaning is too vague and uncertain for them to serve as gatekeepers in a way that economizes on administrative costs. Critics of patentable subject matter doctrine cite its lack of clarity relative to other requirements for patent protection,<sup>232</sup> suggesting that administrative efficiency might be better served by proceeding directly to individualized examination. Indeed, the Federal Circuit has recognized the impracticality of requiring that patentable subject matter determinations precede full examination in every case and clarified that, contrary to the implication of the phrase “threshold test,” there is

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231 Duffy, *supra* note 33, at 616 (“[C]hanging conditions present well-known difficulties for rules, and the law of patentable subject matter inevitably operates on the ever-changing forefront of human knowledge and creativity.”).

232 Risch, *supra* note 2, at 606-07 (“Attention to rigorous application of the patentability standards would replace unclear and undefined subject matter rules based on supportable statutory interpretations of the Patent Act.”).

no rule that requires that patentable subject matter be considered first when it might be more expeditious to dispose of an application on another ground.<sup>233</sup>

Patentable subject matter also fails to economize on administrative costs when it operates as a limitation on allowable claim language and scope rather than as a complete exclusion from the patent system. As categorical field exclusions have disappeared, remaining limitations on patentable subject matter, such as the exclusions for abstract ideas and natural phenomena, are more likely to require careful claim-drafting than to keep an invention from crossing the threshold of the PTO. As Professor Chiang explains, the prohibitions on patenting abstract ideas and scientific principles are not about excluding certain subject matter from the patent system entirely but rather about avoiding unduly broad claims.<sup>234</sup> Inventors can often respond by narrowing their claims, and it requires the attention of an examiner to determine which of the claims in a patent application are worded so broadly that they wholly preempt the use of an abstract idea or a natural correlation and which are permissibly confined to particular applications. Such limitations may be useful as a means of avoiding the allowance of unduly broad claims, but they do not serve as threshold tests that economize on administrative costs.

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<sup>233</sup> *In re Bilski*, 545 F.3d 943, 950 n.1 (Fed Cir. 2008).

<sup>234</sup> Chiang, *supra* note 33, at 1385-92 (explaining Supreme Court decisions in *O'Reilly v. Morse*, *The Telephone Cases*, *Funk v. Kalo*, and *Gottschalk v. Benson* as concerned with unduly broad claims).

In sum, although one could imagine patentable subject matter serving a useful role as a threshold inquiry, economizing on administrative costs by excluding some kinds of subject matter from the front door of the patent system without the need for a full examination, patentable subject matter doctrine does not and cannot serve that role in its current form.

## B. Limiting heterogeneity

A different function for patentable subject matter boundaries may be to limit the technological diversity of inventions that must be accommodated in a one-size fits all patent system.<sup>235</sup> By longstanding tradition, now locked in by treaty,<sup>236</sup> the U.S. patent laws apply essentially the same rules of patent law across all fields of technology.<sup>237</sup> Yet economic research

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<sup>235</sup> Rebecca S. Eisenberg, *Analyze This: A Law & Economics Agenda for the Patent System*, 53 VAND. L. REV. 2081, 2084 (2000).

<sup>236</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 27, Apr.15, 1994, 33 I.L.M. 81 (commonly known as the TRIPS Agreement), Art. 27, § 1 (“[P]atents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. ... [P]atents shall be available and patent rights enjoyable without discrimination as to ... the field of technology ....”).

<sup>237</sup> Congress has nonetheless sometimes enacted field-specific patent law provisions, including a prior user defense against infringement of business method patents, 35 U.S.C. § 273 (2010), relief from the nonobviousness requirement for certain biotechnology process claims, 35 U.S.C. § 103(b) (2010), relief from remedies for infringement of patents by medical practitioners and related health care entities, 35 U.S.C. § 287(c) (2010), and term extensions for drug patents, 35 U.S.C. § 155 (2010). The recently passed Leahy-Smith America Invents Act, Pub.

has repeatedly demonstrated that the needs of innovators for patent protection vary significantly across fields.<sup>238</sup> Because of variation in the conditions for innovation, patent rules that provide the correct balance between patent incentives and competition in one field are likely to get the balance wrong in other fields, providing too much protection in some contexts and too little in others. Professor Michael Carroll calls the resulting inefficiencies “uniformity costs.”<sup>239</sup>

Patentable subject matter boundaries can help to minimize uniformity costs by limiting the diversity of innovations that patent law covers, thus making it easier to achieve a more optimal level of protection for a narrower range of innovations. The challenge of arriving at rules of patent law that satisfy the diverse denizens of the patent system today is visible in the

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L. No. 112-29 (Sept. 16, 2011) extends prior user rights to all fields of technology, *id.* § 5 (codified at 35 U.S.C. § 273) and eliminates special rules for evaluating the nonobviousness of biotechnological processes, *id.* § 3(c) (codified at 35 U.S.C. § 103) but has additional field-specific provisions treating tax strategies as prior art, *id.* § 14, providing a transitional period of post-grant review of business method patents, *id.* § 18, and prohibiting the issuance of patents on human organisms, *id.* § 33,

<sup>238</sup> See generally DAN L. BURK & MARK A. LEMLEY, *THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT* (2009) (discussing the economic analysis and rapid changes that have occurred since 2003 in patent reform).

<sup>239</sup> See Michael W. Carroll, *One Size Does Not Fit All: A Framework for Tailoring Intellectual Property Rights*, 70 OHIO ST. L.J. 1361 (2009); Michael W. Carroll, *One For All: The Problem of Uniformity Cost in Intellectual Property Law*, 55 AM. U. L. REV. 845, 849 (2006) (defining uniformity cost as “the distortions caused by rights that are more or less robust than necessary to have induced investments in innovation that deliver a net benefit to society.”).

divergent positions of different industries concerning patent law reform. Relative newcomers to the patent system—mostly from the information technology and service sectors—have favored reforms that old-timers such as the pharmaceutical industry have opposed.<sup>240</sup> New categories of patentable subject matter also pose administrative challenges for the PTO, which initially may lack the necessary expertise and record of prior art to evaluate patent applications properly in new fields.<sup>241</sup> Perhaps a less diverse community of innovators, maintained through the use of patentable subject matter boundaries to exclude newcomers, would more readily agree on what the rules should be.

This picture of the patent system as a gated community, with subject matter boundaries to exclude newcomers, invites a number of objections. First, although subject matter boundaries may limit uniformity costs for those fields that remain patent eligible, they do nothing to achieve the correct balance between incentives and competition for excluded fields. Unless there is reason to believe that patent protection is unnecessary for the excluded fields, the resulting uneven pattern of protection seems at least as likely to create distortions and inefficiencies as a uniform set of rules applied to diverse fields. It seems especially problematic to exclude new fields from patent protection, since the development of new technologies may have far greater

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240 Brian Kahin, *Patents and Diversity in Innovation*, 13 MICH. TELECOMM. & TECH. L. REV. 389 (2007).

241 *See* Merges, *supra* note 64, at 589-91 (1999) (describing initial difficulties for the PTO in examining applications in the areas of business methods, biotechnology, and software).

social value than incremental improvements in existing fields.<sup>242</sup> Even a requirement for explicit Congressional action to extend patent protection to new fields of technology would add another layer of costs and uncertainty to pathbreaking innovations, creating a risk that new technologies could get delayed or derailed.

From a political economy perspective, having diverse interests with a stake in the patent system may be advantageous if it provokes vigorous debate about public policy initiatives. Otherwise, like-minded firms might encounter little opposition when they lobby for legislative changes that are more likely to advance their private interests than to balance competing interests in innovation and competition. In other words, uniformity costs from a patent system that seeks to regulate diverse interests may be preferable to unchecked rent-seeking in a system that is more narrowly tailored to affect concentrated interests.<sup>243</sup>

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242 *Diamond v. Chakrabarty*, 447 U.S. 303, 315-16 (1980) (“[*Parker v. Flook* did not announce a new principle that inventions in areas not contemplated by Congress when the patent laws were enacted are unpatentable per se. To read that concept into *Flook* would frustrate the purposes of the patent law. This Court frequently has observed that a statute is not to be confined to the ‘particular application[s] ... contemplated by the legislators.’ [] 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.”)

243 WILLIAM M. LANDES, & RICHARD A. POSNER, *THE POLITICAL ECONOMY OF INTELLECTUAL PROPERTY LAW* (AEI Press 2004), available at [http://www.aei.org/docLib/20040608\\_Landes.pdf](http://www.aei.org/docLib/20040608_Landes.pdf) (last visited Oct. 31, 2011).

Finally, even if patentable subject matter boundaries might be deployed to minimize uniformity costs, current patentable subject matter doctrine is not well-suited to that task, for essentially the same reasons that it is not well-suited to serve as a gatekeeper at the threshold to the patent system. Uniformity calls for field exclusions of a sort that the courts have repeatedly rejected, rather than for vague crosscutting standards, such as the exclusion for “abstract ideas,” that do not correspond to field distinctions in any apparent way. And of course, if the goal is to exclude those fields in which less protection is optimal, it would make sense to engage in policy analysis, largely absent in the current system, to identify which fields belong inside and outside patentable subject matter boundaries.

### C. Beyond the threshold: public domain, claim scope and building blocks

Most patentable subject matter decisions that invalidate some claims spare other claims in the same patent or application, suggesting that patentable subject matter is functioning as a scalpel that determines how inventions may be claimed rather than as a barricade that excludes certain categories of invention entirely. Even if patentable subject matter doctrine lacks the necessary clarity and field specificity to function as an efficient threshold test, it might still provide a useful tool for the PTO and the courts to use in denying or invalidating particular patent claims that threaten to impose costs that exceed their benefits. Some scholars have suggested that patentable subject matter is redundant to other doctrinal limitations on patentability that would support the same outcomes, raising the question of whether it is

necessary or appropriate to use patentable subject matter limitations to do this work.<sup>244</sup> But these other doctrines may sometimes fail, leaving patentable subject matter limitations as a backstop. Doctrinal redundancy is a common feature of legal systems and may make sense if the interest at stake is important.

## 1. Prior Art

Some cases about the exclusion of natural products and phenomena of nature from patentable subject matter suggest a concern that the claimed invention is largely the handiwork of nature, and that the value-added of the inventor is relatively slight. For example, in *Funk Brothers Seed v. Kalo Inoculant*,<sup>245</sup> the Court held invalid a claim to a mixed culture of bacterial strains that were selected by the inventor for their capacity to allow plants to fix nitrogen from the environment without inhibiting each other's effectiveness. The Court's description contrasts the wonders of nature with the inventor's trivial advance in packaging:

Bond does not create a state of inhibition or of noninhibition in the bacteria. Their qualities are the work of nature. Those qualities are, of course, not patentable. For patents cannot issue for the discovery of the phenomena of nature. The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none.

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The aggregation of select strains of the several species into one product is an application of that newly discovered natural principle. But however ingenious the

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<sup>244</sup> *E.g.*, Risch, *supra* note 2, at 598.

<sup>245</sup> *Funk Brothers Seed v. Kalo Inoculant* 333 U.S. 127 (1948).



discovery of that natural principle may have been, the application of it is hardly more than an advance in the packaging of the inoculants.

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[O]nce nature's secret of the noninhibitive quality of certain strains of the species of *Rhizobium* was discovered, the state of the art made the production of a mixed inoculant a simple step. Even though it may have been the product of skill, it certainly was not the product of invention.<sup>246</sup>

This analysis does not rest entirely on the exclusion of phenomena of nature from patentable subject matter. Indeed it cannot, because the Court concedes that Bond's "aggregation of select strains ... into one product is an application of that newly discovered natural principle" rather than a claim to the natural principle itself.<sup>247</sup> It is difficult to imagine what a claim to the natural principle itself would look like or what it would mean. As Professor Collins explains,

On its face, this prohibition on claiming unapplied natural principles and the like might seem simply to mean that Einstein cannot claim  $E=mc^2$  itself and Newton cannot claim the universal law of gravitation itself. However, the doctrine of patent eligibility would not be needed to keep such direct claims to newly discovered principles, truths, or laws out of the patent regime. They are patent gibberish. Patent claims describing "the state of affairs in which  $E=mc^2$ " are malformed in that they don't describe a set of things or processes at all.<sup>248</sup>

The ground for invalidation of Bond's claim to the mixed culture seems to be as much about the obviousness of the inventor's aggregation of strains ("a simple step ... not the product of invention")<sup>249</sup> as it is about the exclusion of the phenomena of nature from patentability.

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<sup>246</sup> *Id.* at 130-32 (citations omitted).

<sup>247</sup> *Id.*

<sup>248</sup> Collins, *supra* note 33 at 56-57.

<sup>249</sup> *Funk Bros. Seed*, 333 U.S. at 132.

Essential to the Court’s conclusion that the mixed culture was “not the product of invention” is its treatment of the newly discovered properties of the bacteria as “part of the storehouse of knowledge of all men.”<sup>250</sup> In effect, the Court treats Bond’s discovery of noninhibitive strains as if that much of his contribution were prior art, and concludes that the further step of combining those strains in a mixed culture was nothing more than the exercise of “ordinary skill.” Prior<sup>251</sup> and subsequent<sup>252</sup> cases have taken a similar approach, treating excluded subject matter as if it were prior art in evaluating the patentability of the claimed invention. This approach seems to have one foot in the doctrine of patentable subject matter and the other in prior art doctrines such as novelty and nonobviousness.

Judge Giles Rich, one of the principal architects of the 1952 Patent Act, criticized this approach as fundamentally confused in an opinion for the Court of Customs and Patent Appeals

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<sup>250</sup> *Id.* at 130.

<sup>251</sup> *E.g.*, *O’Reilly v. Morse*, 56 U.S. 62, 115 (quoting with approval the following passage from the decision in *Neilson and others v. Harford and others* in the English Court of Exchequer: “[T]he plaintiff does not merely claim a principle, but a machine, embodying a principle, and a very valuable one. We think the case must be considered as if the principle being well known, the plaintiff had first invented a mode of applying it by a mechanical apparatus to furnaces ....”).

<sup>252</sup> *E.g.*, *Parker v. Flook*, 437 U.S. 584, 591-92 (1978) (“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.”) (citation omitted).

in the case of *In re Bergy* that borders on insubordination.<sup>253</sup> The Supreme Court had vacated and remanded for reconsideration in light of the Supreme Court’s decision in *Parker v. Flook*.<sup>254</sup> Judge Rich took the opportunity instead to criticize the Supreme Court’s approach, stating that “we find in *Flook* an unfortunate and apparently unconscious, though clear, commingling of distinct statutory provisions which are conceptually unrelated, namely, those pertaining to the *categories* of inventions in § 101 which *may* be patentable and to the *conditions* for patentability demanded by the statute for inventions within the statutory categories, particularly the nonobviousness condition of § 103....”<sup>255</sup> Focusing on the statement in *Flook* “that a ‘mathematical algorithm’ or formula is like a law of nature in that it is one of the ‘basic tools of scientific and technological work’ and as such must be *deemed* to be ‘a familiar part of the prior art,’ even when it was not familiar, was not prior, was discovered by the applicant for patent, was novel at the time he discovered it, and was useful,” Judge Rich warned that “[t]his gives to the term ‘prior art,’ which is a *very* important term of art in patent law, particularly in the application of § 103, an entirely new dimension with consequences of unforeseeable magnitude.”<sup>256</sup>

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253 596 F.2d 952, 959 (CCPA 1979).

254 *In re Bergy*, 563 F.2d 1031 (CCPA 1977), *vacated sub nom. Parker v. Bergy*, 438 U.S. 902 (1978).

255 *In re Bergy*, 596 F.2d 952, 959 (C.C.P.A. 1979).

256 *Id.* at 965-66 (emphasis in original). If the Court’s approach represented a departure from the scheme of the Patent Act at the time, Congress more recently appears to be following the Court’s lead by providing for the treatment of “any strategy for reducing, avoiding, or deferring tax liability, whether known or unknown at the time

Shortly thereafter, the Supreme Court appeared to retreat from the approach of treating natural products and phenomena as prior art. In *Diamond v. Diehr*, the Court even cited Judge Rich's opinion in *Bergy* with approval for the proposition that the question of whether a particular invention meets the test of novelty under § 102 is "wholly apart from whether the invention falls into a category of patentable subject matter."<sup>257</sup> Yet the Court has never explicitly overruled the approach of the prior decisions, and in *Bilski v. Kappos* the Court quoted the same passage from *Parker v. Flook* that Judge Rich had criticized in *Bergy* without expressing any disapproval.<sup>258</sup>

Some scholars have responded to the recent revival of patentable subject matter limitations by arguing that subject matter exclusions are redundant to other limitations on what may be patented, including those based on prior art. Professor Michael Risch argues that cases like *Parker v. Flook* could be resolved through rigorous application of prior art doctrines without the need for murky rules concerning patentable subject matter,<sup>259</sup> while Professor Kristen Osenga

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of the invention or application for patent," as if it were a part of the prior art in evaluating inventions for patentability. Leahy-Smith America Invents Act, Pub. L. No. 112-29 §14,(a) (Sept. 16, 2011).

<sup>257</sup> *Diamond v. Diehr*, 450 U.S. 175, 190 (1980) (citing *In re Bergy*, 596 F.2d at 961).

<sup>258</sup> *Bilski*, 130 S. Ct. at 1330 ("The Court concluded that the process at issue there was 'unpatentable under § 101, not because it contain[ed] a mathematical algorithm as one component, but because once that algorithm [wa]s assumed to be within the prior art, the application, considered as a whole, contain[ed] no patentable invention.'") (citing *Parker v. Flook*, 437 U.S. at 594).

<sup>259</sup> Risch, *supra* note 2, at 598-609.

criticizes the PTO and courts for use of subject matter exclusions as “proxies for other difficult questions of patentability and policy.”<sup>260</sup>

However, it is not at all clear that existing prior art doctrine on its own would provide an alternative basis for the holdings that the Supreme Court arrived at through its patentable subject matter jurisprudence. The Patent Act itemizes the available categories of prior art in § 102.<sup>261</sup> Each of the categories listed in the statute identifies a prior source of human knowledge with no mention of products or phenomena of nature that have not yet come to the attention of humans. Section 102 thus precludes the patenting of an invention if it was previously known or used by others,<sup>262</sup> patented or described in a printed publication,<sup>263</sup> in public use or on sale,<sup>264</sup> disclosed in a co-pending patent application,<sup>265</sup> and so forth. Products and phenomena of nature would

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<sup>260</sup> Osenga, *supra* note 31, at 1115-23.

<sup>261</sup> *In re Bergy*, 596 F.2d 952, 961 (C.C.P.A. 1979) (“[I]n 1952 Congress voiced its intent to consider the novelty of an invention under § 102 where it is first made clear what the statute means by ‘new’, notwithstanding the fact that this requirement is first *named* in § 101.”). The same list determines the sources of prior art for evaluating the nonobviousness of an invention under 35 U.S.C. § 103 (2010). *Hazeltine Research v. Brenner*, 382 U.S. 252, 255-56 (1965) (§ 102(e)); *In re Foster*, 343 F.2d 980, 984 (C.C.P.A. 1965) (§ 102(b)); *In re Bass*, 474 F.2d 1276, 1287 (C.C.P.A. 1973) (§ 102(g)); *Oddzon Products v. Just Toys*, 122 F.3d 1396, 1401 (Fed. Cir. 1997) (§102(f)).

<sup>262</sup> 35 U.S.C. § 102(a) (2010).

<sup>263</sup> 35 U.S.C. § 102 (a) - (b) (2010).

<sup>264</sup> 35 U.S.C. § 102 (b) (2010).

<sup>265</sup> 35 U.S.C. § 102 (e) (2010).

seem to count as prior art only to the extent that they fall into one of the categories listed in § 102. In other words, without assistance from the doctrine of patentable subject matter, newly discovered products and phenomena of nature do not seem to qualify as prior art under § 102 alone.<sup>266</sup>

In a challenge to the validity of patents on isolated and purified DNA sequences, Professor Oskar Liivak has argued that patent claims to products isolated from nature violate a Constitutional requirement of originality, codified at § 102(f) in a provision that precludes the issuance of a patent if the applicant “did not himself invent the subject matter sought to be patented.”<sup>267</sup> This provision is generally understood to prohibit the patenting of an invention by one who derived it from someone else.<sup>268</sup> Professor Liivak believes that the same limitation

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<sup>266</sup> *But cf.* Collins, *supra* note 33, at 57 (arguing that claims to phenomena of nature “would be inherently anticipated under section 102, as the states of affairs described by the claims long predated their discovery by humankind.”).

<sup>267</sup> 35 U.S.C. § 102(f) (2010); *see* Oskar Liivak, *The Forgotten Originality Requirement: A Constitutional Hurdle for Gene Patents*, 87 J. PAT. & TRADEMARK OFF. SOC’Y 261 (2005). This provision will be eliminated for claims with an effective filing date after March 16, 2013 under § 3 of the Leahy-Smith America Invents Act, Pub. L. No. 112-29 (Sept. 16, 2011).. *See* Joshua D. Sarnoff, *Derivation and Prior Art Problems with the New Patent Act*, available at <http://www.patentlyo.com/files/sarnoff.2011.derivation.pdf> (visited Nov. 12, 2011).

<sup>268</sup> *See* *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1576 (Fed. Cir. 1997) (“To show derivation, the party asserting invalidity must prove both prior conception of the invention by another and communication of that conception to the patentee.”).

applies (or should apply) to inventions that are derived from nature.<sup>269</sup> Moreover, consistent with the approach of the Supreme Court, he would count material derived from nature as prior art in evaluating the obviousness of inventions that have been modified through human intervention.<sup>270</sup> But there is little authority to support this interpretation of current law; indeed, none of the four judges—three on the Federal Circuit and one on the District Court for the Southern District of New York—who considered the patent eligibility of claims to isolated and purified DNA sequences in *Association for Molecular Pathology v. U.S. Patent & Trademark Office*<sup>271</sup> even mentioned derivation or § 102(f), resting instead on §101 and cases excluding products of nature from patentable subject matter.

In sum, although some patentable subject matter decisions concerning products and phenomena of nature appear to rest in part on considerations of novelty, originality, and nonobviousness that find expression elsewhere in the Patent Act, prevailing interpretations of these other statutory provisions do not make these subject matter limitations redundant. Instead, to the extent that the patentable subject matter cases remain good law, they seem to go beyond the definitions of prior art in the statute and case law to exclude newly discovered natural products and phenomena, and obvious variations of them, from patent protection.

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<sup>269</sup> Liivak, *supra* note 267, at 265.

<sup>270</sup> *Id.* at 291-92 (citing *Oddzon Products v. Just Toys*, 122 F.3d 1396 (Fed. Cir. 1997)).

<sup>271</sup> *Ass'n for Molecular Pathology v. USPTO*, No. 09 Civ. 4515 (RWS) 2010 U.S. Dist. LEXIS 35418 (2010), *aff'd in part and rev'd in part*, 653 F.3d 1329 (Fed. Cir. 2011).

## 2. Claim Scope

Many patentable subject matter cases reflect a concern that the invalidated claims are unduly broad. An early example is *O'Reilly v. Morse*,<sup>272</sup> in which the Supreme Court held invalid the eighth claim of a patent to Samuel Morse on his invention of the telegraph machine:

I do not propose to limit myself to the specific machinery or parts of machinery described in the foregoing specification and claims; the essence of my invention being the use of the motive power of the electric or galvanic current, which I call electromagnetism, however developed, for making or printing intelligible characters, signs or letters at any distances, being a new application of that power, of which I claim to be the first inventor or discoverer.<sup>273</sup>

In invalidating this claim, the Court stressed that its broad scope would give Morse control over future advances yet to be made by others.<sup>274</sup> The Court worried that Morse could dominate future advances without having to seek additional patent rights, and therefore without providing further disclosure:

[T]he patentee would be able to avail himself of new discoveries in the properties and powers of electro-magnetism which scientific men might bring to light. ...

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<sup>272</sup> *O'Reilly v. Morse*, 56 U.S. 62 (1854).

<sup>273</sup> *Id.* at 112.

<sup>274</sup> *Id.* at 113 (“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. ... But yet if it is covered by this patent, the inventor could not use it, nor the public have the benefit of it, without the permission of this patentee.”)



And if he can secure the exclusive use by his present patent, he may vary it with every new discovery and development of the science, and need place no description of the new manner, process, or machinery upon the records of the patent office.... 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. The court is of opinion that the claim is too broad, and not warranted by law.<sup>275</sup>

The Court's repeated observation that the eighth claim extends beyond the specific means disclosed by Morse in his specification<sup>276</sup> suggests to some commentators that the best way to understand the holding is that the eighth claim was not properly enabled by the disclosure.<sup>277</sup> Yet the opinion also recites that "the discovery of a principle in natural philosophy or physical science is not patentable,"<sup>278</sup> and subsequent cases have cited *O'Reilly v. Morse* as authority for the exclusion of fundamental principles and abstract ideas from patentable subject matter.<sup>279</sup>

A similar concern with claim scope appears in many subsequent cases invalidating particular claims as drawn to fundamental principles and abstract ideas. For example, the Supreme Court in *Gottschalk v. Benson* observed that the claim it held invalid for lack of patentable subject matter was "so abstract and sweeping as to cover both known and unknown

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<sup>275</sup> *Id.* at 113.

<sup>276</sup> *Id.* at 118-21.

<sup>277</sup> See Risch, *supra* note 2, at 600-01; Duffy, *supra* note 33, at 641-42 (citing late 19th century sources).

<sup>278</sup> *O'Reilly*, 56 U.S. at 116.

<sup>279</sup> *E.g.*, *The Telephone Cases*, 126 U.S. 1, 534 (1888); *Gottschalk v. Benson*, 409 U.S. 63, 67-68 (1972); *Parker v. Flook*, 437 U.S. 584, 592 (1978).

uses of the BCD to pure binary conversion” and that “the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself.”<sup>280</sup> This theme reappears in *Bilski v. Kappos*, in which the Supreme Court notes that “[a]llowing petitioners to patent risk hedging would pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea.”<sup>281</sup>

The Federal Circuit has also used patentable subject matter doctrine to invalidate broad claims. For example, in its 1989 decision in *In re Grams*,<sup>282</sup> the Federal Circuit upheld a rejection for lack of patentable subject matter of an astonishingly broad claim to “a method of diagnosing an abnormal condition in an individual” by performing clinical laboratory tests, comparing the parameter values for the individual with reference values, and determining whether there are any abnormalities.<sup>283</sup> The Federal Circuit held that the claim was improperly drawn to a

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280 *Gottschalk*, 409 U.S. at 68.

281 *Bilski*, 130 S. Ct. at 3231.

282 *In re Grams*, 888 F.2d 835 (Fed. Cir. 1989).

283 The full claim reads: “1. A method of diagnosing an abnormal condition in an individual, the individual being characterized by a plurality of correlated parameters of a set of such parameters that is representative of the individual's condition, the parameters comprising data resulting from a plurality of clinical laboratory tests which measure the levels of chemical and biological constituents of the individual [sic] and each parameter having a reference range of values, *the method comprising* [a] performing said plurality of clinical laboratory tests on the individual to measure the values of the set of parameters; [b] producing from the set of measured parameter values and the reference ranges of values a first quantity representative of the condition of the individual; [c] comparing the

mathematical algorithm, noting that although the claim refers to the performance of clinical tests, the patent disclosure “does not bulge with disclosure about those tests, and indeed the specification states that ‘the invention is applicable to any complex system, whether it be electrical, mechanical, chemical or biological, or combinations thereof.’”<sup>284</sup> The court concluded that “applicants are, in essence, claiming the mathematical algorithm, which they cannot do under *Gottschalk v. Benson*. The presence of a physical step in the claim to derive data for the algorithm will not render the claim statutory.”<sup>285</sup>

In each of these cases the courts see the breadth of the claim as indicating that it is not limited to a particular application of the principle/idea/algorithm, but reaches beyond that application to claim the principle/idea/algorithm itself. In other words, claim scope is what

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first quantity to a first predetermined value to determine whether the individual's condition is abnormal; [d] upon determining from said comparing that the individual's condition is abnormal, successively testing a plurality of different combinations of the constituents of the individual by eliminating parameters from the set to form subsets corresponding to said combinations, producing for each subset a second quantity, and comparing said second quantity with a second predetermined value to detect a non-significant deviation from a normal condition; and [e] identifying as a result of said testing a complementary subset of parameters corresponding to a combination of constituents responsible for the abnormal condition, said complementary subset comprising the parameters eliminated from the set so as to produce a subset having said non-significant deviation from a normal condition.” *Id.* at 836-37 (emphasis and alteration appear in decision).

284 *Id.* at 840.

285 *Id.*

distinguishes an unpatentable principle/idea/algorithm from its patent-eligible particular applications.<sup>286</sup>

If the problem with the claims in these cases is that they are unduly broad, arguably the statutory grounds for invalidity should be failure of enablement under § 112 of the Patent Act<sup>287</sup> rather than lack of patentable subject matter under of § 101 of the Patent Act. But enablement doctrine hardly offers any clearer or more predictable tools than patentable subject matter for discerning the allowable scope of patent claims. Although some judicial decisions say that claim scope must be commensurate with the scope of embodiments that have been enabled by the patent disclosure,<sup>288</sup> others say that the requirement of an enabling disclosure is satisfied if the specification provides an enabling disclosure of a single embodiment falling within the scope of a claim.<sup>289</sup> Patent claims must extend beyond the particular disclosed embodiments in order to

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<sup>286</sup> *Cf.* Collins, *supra* note 33, at 50 (noting that one possible meaning of “an unpatentable abstract idea” relates to abstraction or generality in the claim language itself).

<sup>287</sup> § 112 provides: “The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same ....” 35 U.S.C. § 112 (2010).

<sup>288</sup> *E.g.*, *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993); *Invitrogen Corp. v. Clontech Labs, Inc.*, 429 F.3d 1052, 1070-71 (Fed. Cir. 2005); *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1378 (Fed. Cir. 2009).

<sup>289</sup> *E.g.*, *Spectra-Physics, Inc. v. Coherent, Inc.* 827 F.2d 1524, 1533 (Fed. Cir. 1987); *Engel Industries, Inc. v. Lockformer Co.*, 946 F.2d 1528, 1533 (Fed. Cir. 1991).

have any value, and enablement doctrine offers inconsistent guidance about how far beyond those embodiments a claim may reach.<sup>290</sup>

Particularly problematic for enablement doctrine are claims that cover future embodiments using technologies that have yet to be invented as of the filing date. Some decisions say that such claims fail the test of enablement, reasoning that as of the filing date it would have required undue experimentation to make the future embodiments,<sup>291</sup> but other decisions have upheld similar claims, reasoning that the original specification disclosed at least one mode of making and using the invention, even though it did not disclose the later

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290 For thoughtful analyses of the doctrine, see Tun-Jen Chiang, *Fixing Patent Boundaries*, 108 MICH. L. REV. 523, 535-38 (2010) (discussing contradictions that arise from current enablement doctrine); Tun-Jen Chiang, *The Rules and Standards of Patentable Subject Matter*, 2010 WISCONSIN L. REV. 1353, 1368-72 (2010) (examining conflicting case law on contemporary enablement doctrine and doctrinal confusion arising from choosing the level of abstraction to define patent protection); Kevin Emerson Collins, *Enabling After-Arising Technology*, 34 J. CORP. L. 1083 (2009) (characterizing contemporary enablement doctrine as “chaotic” and proposing different rules); Jeffrey A. Lefstin, *The Formal Structure of Patent Law and the Limits of Enablement*, 23 BERKELEY TECH. L.J. 1141 (2008) (arguing that written description requirement compensates for indeterminacy of enablement standard).

291 *E.g.*, *Plant Genetic Systems v. DeKalb Genetics Corp.*, 315 F.3d 1335 (Fed. Cir. 2003) (finding that patent claims to a plant cell transformed with a DNA fragment were not fully enabled where the specification taught how to transform dicot plants but not monocot plants, and existing technology as of filing date did not provide such a method for monocots).

technology.<sup>292</sup> Some decisions insist that the disclosure must enable the “full scope” of the patent claims without undue experimentation,<sup>293</sup> yet others hold that “a broad claim may be enabled by disclosure of a single embodiment.”<sup>294</sup> Determining the validity of prior claims that dominate later-developed technologies presents a difficult choice about how best to allocate incentives between earlier and later inventors. With competing lines of authority available to justify different outcomes, enablement fails to provide useful guidance to courts or examiners in making that fundamental policy choice.

In recent years the Federal Circuit has provided an additional constraint on claim scope in the form of a fortified requirement for a “written description” of the invention that is distinct from the requirement of enablement.<sup>295</sup> This somewhat controversial development has been

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292 *See, e.g.,* Amgen Inc. v. Hoechst Marion Roussel, 314 F.3d 1313, 1334-37 (Fed. Cir. 2003) (finding that patent claim to vertebrate cells with DNA control sequences for producing erythropoietin was adequately enabled by disclosure of examples using transformed Chinese hamster ovary and monkey cells yet also covered later technology using endogenous activation of erythropoietin in human cells).

293 *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997) (“[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation.’”) (quoting *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993)).

294 *Spectra-Physics v. Coherent*, 827 F.2d 1524, 1533 (Fed. Cir. 1987).

295 *See Ariad Pharmaceuticals v. Eli Lilly*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc); *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004); *Regents of the Univ. of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997).

particularly important in limiting the scope of claims in biopharmaceutical patents,<sup>296</sup> and has arguably eclipsed enablement doctrine as a limitation on claim scope.<sup>297</sup>

Patentable subject matter provides another backstop to the indeterminate doctrine of enablement for limiting the scope of claims arising out of discoveries of fundamental principles or natural phenomena. Such claims raise special concerns for the patent system for two reasons. First, fundamental principles and natural phenomena are likely to be especially important to the work of future innovators, and promoting future innovation is a primary goal of patent law. Second, newly discovered fundamental principles and natural phenomena may face few constraints from prior art, which is ordinarily an important determinant of allowable claim scope.<sup>298</sup>

Understood as a limitation on claim scope rather than as an exclusion of entire fields from patent protection, this exclusion provides a principle for limiting the scope of claims that

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296 See Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 617 (1998); Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827, 834-35 (1999); Margaret Sampson, *The Evolution of the Enablement and Written Description Requirements Under 35 U.S.C. § 112 in the Area of Biotechnology*, 15 BERKELEY TECH. L.J. 1233, 1262 (2000).

297 See, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916 (Fed. Cir. 2004). In this case, the district court held claims to be invalid for lack of both enablement and written description. The Federal Circuit affirmed on written description alone, without reaching enablement.

298 See Chiang, *supra* note 290, at 535.

might otherwise be quite broad and impose social costs that are quite high. Like the doctrine of enablement, this exclusion balances the interests of prior innovators against those of subsequent innovators. But while enablement directs attention towards determining the range of embodiments that the patent disclosure puts within easy reach of those skilled in the art, the patentable subject matter exclusion directs attention towards determining which aspects of the discovery must remain in the public domain to encourage future innovation. Both determinations present difficult line-drawing problems and would benefit from clearer policy guidance.

### 3. Basic tools of scientific and technological work

A recurring mantra in many judicial opinions about patentable subject matter is that excluded subject matter constitutes “basic tools” of scientific or technological work.<sup>299</sup> The Supreme Court even recited this mantra in *Bilski v. Kappos*, declaring that business methods are “the basic tools of *commercial* work” and, “in many cases, the basic tools of further business innovation.”<sup>300</sup> But taken this far, the “basic tools” concept would seem to cover every step in the course of incremental innovation in any field, and thus fails to explain distinctions between patentable and excluded subject matter.

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<sup>299</sup> *Diamond v. Diehr*, 450 U.S. at 185; *Gottschalk v. Benson*, 409 U.S. at 67; *Prometheus Labs. v. Mayo Collab. Servs.*, 628 F.3d at 1353-54; *In re Bilski*, 545 F.3d at 952; *In re Comiskey*, 554 F.3d at 979; Ass’n for Molecular Pathology v. USPTO, 2010 U.S. Dist. LEXIS 35418 at \*104.

<sup>300</sup> *Bilski*, 130 S. Ct. at 3255.



Perhaps the relationship between homocysteine levels and vitamin deficiency in *Laboratory Corporation of American Holdings v. Metabolite Laboratories* makes a better poster child for the “basic tools” argument than the risk-hedging method in *Bilski v. Kappos*. Justice Breyer explains in his *Laboratory Corporation* dissent that the exclusion of “laws of nature, natural phenomena, and abstract ideas” from patentable subject matter preserves free access to “fundamental building blocks” that are likely to be of value in many future research paths, thus preventing patents from obstructing future research.<sup>301</sup> While conceding that “the category of non-patentable ‘phenomena of nature,’ like the categories of ‘mental processes,’ and ‘abstract intellectual concepts,’ is not easy to define,” Justice Breyer concluded “[t]here can be little doubt that the correlation between homocysteine and vitamin deficiency set forth in claim 13 is a ‘natural phenomenon.’”<sup>302</sup>

The line-drawing problems may be more difficult than Justice Breyer recognizes. Professor Allen Yu argues that the traditional exclusions from patentable subject matter for natural phenomena and products may no longer correspond as closely to the “basic tools of scientific and technological work” as they did in the past, given that “[m]uch of biomedical know-how today is based on discoveries about basic workings of the human body.”<sup>303</sup> He explains that “[a]lmost all medical interventions involve restoring or mimicking nature, not

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301 *Lab. Corp. of Am. Holdings*, 548 U.S. at 126-28.

302 *Id.* at 135.

303 Yu, *supra* note 33, at 395.

replacing or improving nature.”<sup>304</sup> In this environment, robust subject matter exclusions based on a distinction between what is “natural” and what is “man-made” seem to rest on “ungrounded legalistic and semantics-based arguments” rather than on sound policy considerations.<sup>305</sup>

Professor Yu proposes as one of several alternatives that the Court replace its relatively weak prohibition against the patenting of nature and abstract ideas with “a stronger, more explicit prohibition against the patenting of ‘basic tools of scientific and technological work,’” assessed from the perspective of a “person having ordinary skill in the art” or “PHOSITA.”<sup>306</sup> Professor Yu predicts that a PHOSITA would not consider a test for homocysteine to detect vitamin deficiency to be a basic tool of scientific and technological work, but would consider genes to be unpatentable under this standard.<sup>307</sup> While recognizing that this standard is no easier to apply than the distinction between what is natural and what is man-made, Professor Yu nonetheless argues that his standard is superior because it “focuses on articulating the costs of patents.”<sup>308</sup> Less salient in this approach are the benefits of patents, such as the social value of the incentives they provide for commercial product development, which ought to be weighed against these costs to achieve an efficient balance. Many inventions are simultaneously both basic tools of scientific and technological work and commercial technologies that may be put to immediate

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304 *Id.* at 400-01.

305 *Id.* at 401.

306 *Id.* at 428-29.

307 *Id.* at 429-30.

308 *Id.* at 430.

practical use in the diagnosis and treatment of disease. Withholding patents to keep basic tools in the public domain may thus simultaneously withhold incentives for new medical interventions, posing a stark conflict between avoiding the costs and securing the benefits of patents.

If the goal of withholding patents on basic tools of scientific and technological work is to provide a clear field for future researchers to make unfettered use of these tools, perhaps an exclusion from patentable subject matter is not the best doctrinal approach. An alternative that might be less destructive of incentives to develop new medical interventions would be to give researchers an infringement exemption, while leaving patent holders with patents that they could assert against providers of new medical interventions. Regrettably, U.S. law has done almost exactly the opposite: the Federal Circuit has restricted the scope of the common law research exemption from infringement liability,<sup>309</sup> while Congress has provided a statutory exemption from patent infringement remedies for medical practitioners and related health care entities.<sup>310</sup>

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309 *See* *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002) (unauthorized use of a patented invention in noncommercial academic research furthers the university's "legitimate business objectives, including educating and enlightening students and faculty participating in these projects" and therefore "does not qualify for the very narrow and strictly limited experimental use defense"). A separate statutory defense originally designed for generic drug manufacturers exempts the use of an invention "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. § 271(e) (2010). This shelters some uses of patented inventions in

A policy of promoting unfettered access to the basic tools of scientific and technological work does not provide a fully coherent account of patentable subject matter doctrine, and it is not clear that exclusions from patentable subject matter are the best way to advance that policy. But it is as coherent a story as the courts have offered on the topic of patentable subject matter. The repeated references to “basic tools of scientific and technological work” in judicial opinions about patentable subject matter suggest a policy interest that might explain past decisions and guide future decisions about the scope of those exclusions. But there is little evidence in the opinions that the courts take this interest seriously. Instead the words appear inside quotation marks in paragraphs full of string citations, as part of a formal homage to prior decisions rather than as an analytical tool for resolving current controversies at the frontiers of patentable subject matter.

### Conclusion

The Supreme Court has created a state of high uncertainty as to the rules of patentable subject matter. By directing the lower courts to seek guidance from its own prior decisions without actually explaining the policies served by patentable subject matter doctrine, it demands formal adherence to the principle of *stare decisis* without following the discipline of common law reasoning. Many cases speak of patentable subject matter as a threshold test at the front door

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biopharmaceutical research that is directed towards new drug development. *See Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005).

310 35 U.S.C. § 287(c) (2010).

of the patent system, but current doctrine lacks the necessary clarity to function as an initial screen prior to full examination. Although field exclusions from patentable subject matter might in the past have limited the heterogeneity of inventions covered by patent law, field exclusions have largely been repudiated by the courts, leaving vaguely worded exclusions that are as challenging to interpret and apply as any other standards for patentability. Some cases, particularly those asserting the unpatentability of natural phenomena and fundamental principles, have called for treating discoveries about the natural world as if they were already in the public domain, an approach that is sometimes criticized for conflating subject matter limitations with doctrines concerning prior art and disclosure. But patentable subject matter limitations are not redundant to these other doctrines. Patentable subject matter offers an additional tool for limiting the scope of patents that might otherwise unduly impede future research. Language in patentable subject matter opinions about “basic tools of scientific and technological research” hints at a policy justification for this approach that is not fully examined, although it is consistently quoted approvingly. Perhaps these cases have wisdom to offer that could guide courts today in adapting patentable subject matter doctrine to inventions at the current forefronts of technology. But in the absence of a more careful judicial account of the role of patentable subject matter to guide modern courts in channeling the wisdom of their predecessors, continued adherence to these prior decisions seems instead like a form of dead-hand control. By reasserting its precedents as binding authority without explaining them, the Supreme Court compounded this problem in *Bilski v. Kappos*. In future decisions, it might do better to begin by

distinguishing the function of patentable subject matter limitations from the functions served by other requirements for patent protection.