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The Role of Patent Eligibility in Policing Claim Scope

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The Role of Patent Eligibility in Policing Claim Scope

Christopher M. Holman*

Four Supreme Court decisions dating back to the 1970s and early 1980s (*Benson*,[1] *Flook*,[2] *Chakrabarty*,[3] and *Diehr*[4]) provide the foundation for the modern doctrine of patent eligibility. The criterion for patent eligibility established by these cases is easy to state, at least in the abstract. Under the controlling precedent, a patent claim limited to a man-made invention falling within the statutory categories established under Section 101 (processes, compositions of matter, machines, and articles of manufacture) is generally treated as patent eligible.[5] However, a patent claim is patent ineligible (and hence invalid) if it "claims" or "patents" a so-called "fundamental principle." Specific examples of fundamental principles that have been identified by the Supreme Court include natural phenomena, physical phenomena, principles of nature and abstract ideas. To my mind, the designations natural phenomena, physical phenomena, principles of nature and laws of nature are all essentially synonymous, at least as used in this context, so for simplicity throughout the rest of this article I simply refer to the two fundamental categories of abstract ideas and natural phenomena.

Most of the Supreme Court's treatment of patent eligibility has focused on the "abstract idea" category of fundamental principle, including *Benson*, *Flook*, *Diehr* and the recent *Bilski II* decision.[6] The only Supreme Court decisions to address the other category of fundamental principle are *Chakrabarty* and *J.E.M.*, both of which rejected (at least implicitly) the contention that a genetically modified organism is a patent ineligible natural phenomenon.[7] Moreover, since the enactment of the 1952 patent statute the Supreme Court has never found a patent claim patent ineligible for claiming a natural phenomenon. Some would argue that earlier decisions of the Court found claims directed towards biological materials patent ineligible, most notably *Funk Brothers*[8] and *American Fruit Growers*,[9] but in my view

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1. Gottschalk v. Benson, 409 U.S. 63 (1972).
2. Parker v. Flook, 437 U.S. 584 (1978).
3. Diamond v. Chakrabarty, 447 U.S. 303 (1980).
4. Diamond v. Diehr, 450 U.S. 175 (1981).
5. 35 U.S.C. § 101.
6. Bilski v. Kappos (*Bilski II*), 130 S. Ct. 3218 (2010).
7. J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124 (2001).
8. Am. Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1 (1931).
9. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948).

these cases are addressing issues distinct from the modern doctrine of patent eligibility, and to the extent they might have had any bearing on patent eligibility they have been effectively overruled by more recent Supreme Court precedent, most particularly *Chakrabarty*.[10]

While the Supreme Court has been consistent in maintaining that fundamental principles cannot be patented, a striking aspect of the Supreme Court precedent in this area is the lack of any meaningful, coherent guidance as to just exactly what it means for a claim to "claim a fundamental principle." This ambiguity was noted recently in a concurrence by Justice Stevens to *Bilski II*, wherein he complained:

> The Court, in sum, never provides a satisfying account of what constitutes an unpatentable abstract idea. . . . [In this case, for example, the] Court essentially asserts its conclusion that petitioners' application claims an abstract idea. This mode of analysis (or lack thereof) may have led to the correct outcome in this case, but it also means that the Court's musings on this issue stand for very little.[11]

Justice Stephen correctly recognizes the lack of Supreme Court guidance on what it means to patent an abstract idea, but I would point out that the Court has provided even less guidance with respect to natural phenomena.

The Federal Circuit has also noted the ambiguity of the Supreme Court's patent eligibility precedent, and the practical difficulty lower courts face in attempting to apply the abstract standard to actual claims, particularly claims directed to twenty–first century technology that is difficult to analogize to the claims analyzed in the Supreme Court decisions establishing the controlling precedent. I believe it was largely this ambiguity that motivated the Federal Circuit in *In re Bilski* (*Bilski I*) to create the machine or transformation test (MORT) as the sole and definitive test for patent eligibility, in an attempt to provide the lower courts and US Patent and Trademark Office (PTO) with a more objective and administrable test.[12]

I. The Effect of *Bilski II* on the Criterion for Patent Eligibility

Prior to *Bilski I*, the prevailing view of the patent community was that patent eligibility hinges upon whether or not a claim wholly preempts the practical applications of a

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10. This interpretation of *Funk Brothers* was put forward in an amicus curiae brief filed by Alnylam Pharmaceuticals in support of Myriad Genetics in its appeal to the Federal Circuit of the decision in *Ass'n for Molecular Biology v. US Patent & Trademark Office*, Federal Circuit docket number 2010-1406. I commented upon the Alynlam brief on my blog, available at http://holmansbiotechipblog.blogspot.com/2010/11/amicus-brief-filed-by-alynlam.html.
11. 130 S. Ct. at 3236 (Stevens, J., Ginsburg, J., Breyer, J., Sotomayor, J., concurring).
12. *In re* Bilski (*Bilski I*), 545 F.3d 943, 954 (Fed. Cir. 2008).

fundamental principle, which I refer to as the "preemption test."[13] Under this test, a claim is patent ineligible if it effectively preempts all substantial practical applications of the fundamental principle. However, in 2008, in an attempt to impose more objectivity and predictability on the heretofore vaguely articulated doctrine, the en banc Federal Circuit in *Bilski I* established MORT as the sole and definitive test for the patent eligibility of all process claims (leaving largely unresolved the appropriate test for patent eligibility of product claims).

But the preeminence of MORT was to prove short-lived, with the Supreme Court intervening in 2010 with its *Bilski II* decision, which explicitly held that while MORT can be highly probative of patent eligibility, it is not the sole and definitive test. *Bilski II* also makes clear, at least implicitly, that a finding of preemption is not a prerequisite for invalidating a claim for lack of patent eligibility.[14] But as pointed out by Justice Stevens, *Bilski II* provides no additional guidance with respect to what the test for patent eligibility is, other than an admonition to consult the patent statute for its definition of the term "process," and to look "to the guideposts in *Benson*, *Flook*, and *Diehr*."[15] The essence of *Bilski II* was succinctly captured by two commentators who characterized the decision as the Supreme Court pushing a reset button on the doctrine of patent eligibility.[16]

While neither the preemption test nor MORT constitutes the definitive test for patent eligibility, *Bilski II* clearly permits lower courts the discretion to use these tests in assessing patent eligibility. In the absence of any other meaningful objective criteria to guide the inquiry, I predict that the courts and PTO will continue to rely heavily (and in some cases exclusively) on these tests, and early indications are that this is the case, in the Federal Circuit, district courts, and the PTO Board of Patent Appeals and Interferences (BPAI).[17] Both of these approaches to assessing patent eligibility are specifically identified in the PTO's *Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of Bilski v. Kappos*.[18]

Significantly, both the preemption test and MORT treat claim scope as a critical consideration in assessing patent eligibility. Discretionary flexibility in the application of these tests effectively empowers the courts and PTO to invoke patent eligibility as a doctrinal policy lever for policing claim scope. In the remainder of this essay, I discuss the role of patent eligibility in regulating claim scope.

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13. *See infra* Part III.
14. *Id*.
15. Donald Chisum has made a similar observation. *See* Donald S. Chisum, *Patenting Intangible Methods: Revisiting Benson (1972) After Bilksi* 1 (Working Paper, 2010), *available at* http://ssrn.com/abstract=1698724.
16. Gerry J. Elman & Jerome R. Smith, Jr., *What Kinds of Inventive Processes Are Patentable?*, Elman Tech. Law, P.C. (June 30, 2010), http://elman.com/2010/06/bilskireport-elman-smith/.
17. *See infra* Parts III, IV. *See also* Mark A. Lemley et al., *Life after* Bilski, Stan. L. Rev. (forthcoming 2011), *available at* http://ssrn.com/abstract=1725009.
18. Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of *Bilski v. Kappos*, 75 Fed. Reg. 43,922 (July 27, 2010).

II. Patent Eligibility as a Restriction on Claim Scope

While patent eligibility can be conceptualized as a threshold screen to determine whether or not an innovation can be patented, in many cases the doctrine functions more as a tool for calibrating the scope of protection afforded an invention.[19] For example, in *Chakrabarty* the PTO rejected the claim at issue in the appeal, which broadly recites a genetically modified bacterium *per se*, but allowed other claims reciting Dr. Chakrabarty's invention in more narrow terms.[20] Some of the initially allowed claims appear on their face to be quite broad, including claims reciting the method of producing the new bacteria, and claims reciting an inoculum comprised of the new bacteria in combination with a carrier material floating on water.

Recall that the defining feature of Dr. Chakrabarty's bacteria was their ability to break down multiple components of crude oil, the primary utility of which was believed to be in the treatment of oil spills. Practically speaking, use of the bacteria for this purpose would almost certainly require the use of an inoculum capable of floating on water, so it would seem that the originally allowed claims would have provided the inventor with reasonably expansive patent coverage for his invention. It was only at the point where Dr. Chakrabarty sought a claim broadly reciting the bacteria *per se* that the patent office balked, invoking the doctrine of patent eligibility in an attempt to limit the scope of the allowed claims.

While the Supreme Court ultimately reversed the PTO's decision in *Chakrabarty*, in other cases the PTO has been more successful in invoking the doctrine of patent eligibility to rein in the scope of patent protection afforded to an otherwise patentable invention. For example, in *In re Nuijten* the inventor had come up with a method for reducing distortion in a digital signal caused by the introduction of a "watermark," which involved embedding the watermark's signal with supplemental data.[21] The PTO allowed ten claims directed toward the process itself, and another four claims directed towards articles of manufacture used to perform the process, including a claim to a "storage medium having stored thereon a signal with embedded supplemental data." These claims would appear to provide relatively broad protection for the invention, but in this case the inventor again asked for more, this time in the form of claims reciting the "signal" *per se*. The PTO rejected this broad claim to a signal as patent ineligible, unconstrained as it was to any tangible medium, and in this case the Federal Circuit affirmed, holding that the signal did not fall within any of the four statutory categories of patentable subject matter.

III. The Preemption Test Explicitly Focuses on Claim Scope

The role of preemption analysis in assessing patent eligibility dates back to *Benson*, wherein the Court opined that if the patent ineligible claims had been allowed to issue in

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19. The role of patent eligibility in policing claim scope was recently noted by Lemley et al., *supra* note 17.
20. Diamond v. Chakrabarty, 447 U.S. 303, 305-06 (1980).
21. 500 F.3d 1346 (Fed. Cir. 2007).

a patent, they would have entirely preempted every "substantial practical application" of a mathematical algorithm, such that the practical effect would have been patent on the mathematical algorithm itself.[22] Prior to *Bilski I*, a claim's preemptive effect was often treated as the primary, if not only, relevant consideration in assessing whether a claim is patent ineligible for patenting a fundamental principle.

For example, in a brief submitted to the Supreme Court in connection with *LabCorp*, the United States government as amicus curiae focused entirely on issues of preemption in considering the patent eligibility of the claim, summing up the applicable test for patent eligibility as "no one can patent process that comprises every substantial practical application of a law of nature, because such a patent in practical effect would be a patent on the law of nature itself."[23] The government opined that under the broad construction adopted in the lower courts the claim appeared to cover all substantial practical applications of a natural phenomenon, which would in its view render the claim patent ineligible. However, it went on to observe that since the claim is limited to assaying a "body fluid," researchers or physicians might be able to employ the natural phenomenon implicated by the claim (i.e., the correlation between total homocysteine and vitamin B) without infringing the patent merely by using an alternate approach that does not entail assaying a body fluid, implying that this opportunity to decide around the claim would render it patent eligible. The government's brief goes on to point out that a more narrowly drafted diagnostic claim, covering some but not all substantial practical applications of a natural phenomenon, should be considered clearly patent eligible.

Similarly, in a guidance document issued shortly after the Supreme Court granted certiorari in *LabCorp*, the PTO set forth a test for patent eligibility that focuses largely on whether the claim covers every substantial practical application of principle.[24] A test based on preemption would hold an obvious appeal for the PTO, because it has the potential to provide its corps of examiners with a relatively objective and reviewable criterion for patent eligibility. By focusing explicitly on claim scope, preemption analysis is quite analogous to other patentability analyses performed by patent examiners, such as examination for novelty, nonobviousness, and enablement.

While the preemption test is undoubtedly useful and relevant, the Supreme Court has unambiguously established that preemption is not the sole test for patent eligibility, and that a finding of preemption is not a prerequisite to claim invalidation based on patent ineligibility. In *Flook*, for example, the patent applicant argued that under *Benson* its claim should be patent eligible because it did not preempt all substantial practical applications of

22. Gottschalk v. Benson, 409 U.S. 63, 71-72 (1972).
23. Brief for the United States as Amicus Curiae at 20, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124 (2006) (No. 04-607) (internal quotes omitted), 2005 WL 3533248.
24. PTO, Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (Interim Subject Matter Eligibility Guidelines), 1300 Off. Gaz. Pat. Office 142, 146 (Nov. 22, 2005).

a mathematical algorithm, implicitly reading *Benson* as though it established preemption as the definitive test for patent eligibility.[25] The Court, however, rejected this argument.

The *Flook* Court agreed with the patent applicant that since the claim was limited to applications in the petrochemical industry, it did not "wholly preempt the mathematical formula," and left other uses of the formula in the public domain. Nonetheless, the Court went on to find the claim patent ineligible, clearly establishing the principle that preemption is not a prerequisite for patent ineligibility. The Court justified its decision by noting that the prohibition against patenting a fundamental principle cannot be circumvented by attempting to limit its use to a particular technological environment, or by adding insignificant "post-solution activity" to a claim.[26] Subsequent Supreme Court decisions have explicitly cited this aspect of *Flook* with approval.[27]

Bilski II reaffirmed this principle of *Flook* by holding that dependent claims limited to specific practical applications of the abstract idea at issue in that case (risk hedging), and thus clearly not preemptive of all practical applications of the abstract idea, were nonetheless patent ineligible. Nevertheless, *Bilski II* does seem to ascribe a significant role to the preemption test in analyzing for patent eligibility, pointing out that some of the broader claims at issue in the case "pre-empt use of [risk hedging] in all fields, and would effectively grant a monopoly over an abstract idea."[28] While preemption is clearly not a prerequisite for a finding of patent ineligibility, it would seem to be sufficient. Nothing in the Court's decisions would suggest that a claim could preempt all substantial practical applications of a fundamental principle and nonetheless retain patent eligibility.

While the preemption test does impose some order on the otherwise amorphous patent eligibility inquiry, it nonetheless provides courts ample room to exercise judicial discretion and apply the test in a manner that furthers perceived public policy objectives. For example, as sanctioned by *Flook*, courts have interpreted the preemption test in a manner such that literal preemption of all uses of a fundamental principle is not necessary in order for a claim to fail the test. Rather, the test is often stated as whether the claim preempts substantially all practical uses of the fundamental principle, with terms like "substantial" and "practical" providing the courts and PTO flexibility in applying the test to achieve the "right" outcome.

For example, in *Prometheus I*, the inventors had discovered a correlation between the level of certain drug metabolites observed in a patient's body and optimal drug dosage, and obtained patent claims directed towards methods of using the correlation to determine

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25. Parker v. Flook, 437 U.S. at 589-90 (1978).
26. *Id*.
27. Diamond v. Diehr, 450 U.S. 175, 191-92 (1981); *Bilski II*, 130 S. Ct. 3218, 3231 ("[L]imiting an abstract idea to one field of use are adding token postsolution components [does] not make the concept patentable.").
28. 130 S. Ct. at 3231.

whether to increase or decrease the amount of drug being given to the patient.[29] The district court invoked the preemption test and held the claims patent ineligible for preempting all substantial practical applications of the correlation, which the court characterized as a natural phenomenon.[30] The patent owner had argued that the claims did not preempt all practical uses of the correlation, and bolstered its argument by specifically identifying six uses of the correlation that it alleged were not covered by the claims.[31] The district court rejected this argument however, apparently concluding that none of these applications were sufficiently "substantial" and/or "practical" enough to satisfy its interpretation of the preemption test.[32]

On appeal, however, the Federal Circuit in *Prometheus II* reversed, applying a much more permissive interpretation of the preemption test to the challenged claims.[33] As articulated by the Federal Circuit, in an opinion authored by Judge Lourie, a claim fails the preemption test only if it would entirely preempt the use of a fundamental principle.[34] Conspicuously absent in the Federal Circuit's formulation of the test is any reference to "substantial" or "practical" uses of the fundamental principle.

Turning to the claims, Judge Lourie concluded that because they use the natural phenomena in a series of specific steps, they do not preempt all uses of the natural phenomena. Notably, the Court's decision offers no suggestion as to what sorts of applications of the fundamental principle fall outside the scope of the claims, and makes no reference to the six alleged examples put forth by the patent owner. I would suggest that under Judge Lourie's approach to preemption analysis, the fact that a fundamental principle is utilized in a series of specific steps to achieve a reasonably specific and practical result (in this case treatment of specific disease by specific drugs) will be enough to defeat an allegation of patent ineligibility based on preemption, regardless of claim scope.

The divergent interpretations of the preemption test by the district court and Federal Circuit in *Prometheus* illustrates the malleability of the test, providing flexibility for the courts to exercise discretion in the application of the test to police claim scope in a manner the court deems to be appropriate. A court, faced with a claim it considers to be overly expansive in scope, can essentially ignore the existence of practical applications of the fundamental principle that fall outside the scope of the claim by characterizing the unclaimed applications as "insubstantial" or "impractical," and proceed to invalidate the claim for failing to preemption test. Alternatively, a court of a different mindset could easily uphold the validity of the same claim by concluding that the claim is not entirely preemptive, without necessarily identifying any meaningful unclaimed application of the principle.

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29. Prometheus Labs., Inc. v. Mayo Collaborative Servs. (*Prometheus I*), 86 U.S.P.Q.2d 1705, 1715-16 (S.D. Cal. 2008).
30. *Id*.
31. *Id*.
32. *Id*.
33. Prometheus Labs., Inc. v. Mayo Collaborative Servs. (*Prometheus II*), 581 F.3d 1336 (Fed. Cir. 2009).
34. *Id*. at 1349-50.

One interesting aspect of the "substantial practical application" implementation of the preemption test is the effect of after-arising advances in technology. In order for claim to fail the preemption test, is it necessary that the claim encompass substantially all practical applications of the fundamental principle that might be developed in the future, or is preemption of all practical applications as of the filing date (or perhaps the date infringement) sufficient? If the former, how is a court expected to anticipate all practical applications of a fundamental principle which might become available at some future date based on subsequent advances in technology? If the latter, does this imply that a claim that is patent ineligible at one point in time might be rendered patent eligible by subsequent advances in technology that create new opportunities to apply the fundamental principle in applications falling outside the scope of the claim? Or would preemption analysis be locked into the state-of-the-art at the time the patent application was filed (or perhaps at the time the claim was first added to the patent application, or the date the patent issues?), such that even though after the patent issues there exists substantial practical uses of the fundamental principle lying outside the claim, the claim is nonetheless patent ineligible because these uses only became practical after the application was filed?

At this point is perhaps worth noting that some language from Supreme Court precedent suggests that the extent to which a patent claim encompasses applications of a fundamental principle "unknown" at the time of invention is relevant to the question of patent eligibility.[35] This approach is related to the preemption test, but focuses specifically on "unknown" applications of the fundamental principle, rather than "practical" applications. This approach to patent eligibility does not seem to have garnered much traction in the courts in recent years, although Lemley et al. suggest that a focus on "unknown" uses could establish a meaningful doctrinal role for patent eligibility, a doctrine which they suggest is otherwise largely redundant with enablement and written description.[36]

To my mind, the doctrines of enablement and written description are perfectly capable and better suited for addressing the policy concerns associated with claims encompassing embodiments of an invention unknown as of the filing date. Precedent clearly establishes that a claim reciting embodiments unknown and unattainable as of the filing date can, but does not necessarily, run afoul of the enablement and written description requirements, and the patent eligibility doctrine should not be made available as a backdoor to achieve a different result.[37] Instead, patent policy would be better served if the courts, most particularly the Federal Circuit, focused more energy on refining the enablement doctrine

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35. Gottschalk v. Benson, 409 U.S. 63, 68 (1972). This aspect of patent eligibility doctrine is discussed by Lemley et al., *supra* note 17, at 17-18.
36. Lemley et al., *supra* note 17.
37. LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1344-45 (Fed. Cir. 2005) (affirming written description-based invalidation of claims for encompassing embodiments of the invention unknown as of the filing date); *In re* Goodman, 11 F.3d 1046, 1052 (Fed. Cir. 1993) (finding a claim broadly encompassing genetically modified monocots and dicots invalid for lack of enablement because genetically modified monocots were unknown as of the filing date).

as a doctrinal tool for policing claim scope, generally applicable to embodiments of the claimed invention both known and unknown as of the filing date.[38]

IV. The Machine or Transformation Test Implicitly Addresses Claim Scope

Although *Bilski II* rejected the Federal Circuit's assertion that MORT is the sole and definitive test, it by no means disavowed the use of MORT in assessing patent eligibility. To the contrary, the Court acknowledged that MORT is in many cases a "useful and important clue, an investigative tool" for answering the ultimate question of whether a claim patents a fundamental principle. In view of the fact that *Bilski II* does not offer any alternative "clues" or "tools" to assist the lower courts in this regard, and the fact that a majority of the judges on the Federal Circuit have so recently voiced their approval of MORT, I predict that courts will continue to rely heavily on MORT in assessing patent eligibility. This prediction is borne out, for example, in the Federal Circuit's recent *Prometheus II* decision, in which the claims were found to be patent eligible based almost entirely on a MORT analysis.

On the other hand, under *Bilski II* a court can at its discretion ignore MORT in its patent eligibility analysis. This approach can be seen in *Research Corporation Technologies v. Microsoft*, another recent Federal Circuit decision case that upheld the patent eligibility of the challenged claims, but this time without any reference to MORT.[39]

MORT can function as a doctrinal tool for policing claim scope that complements the preemption test. For example, in *Prometheus II* the claimed invention was based on the discovery of a correlation between the level of specific drug metabolites in the patient's body and the optimal dosage of the drug for that patient. The Federal Circuit stated in dicta that a claim broadly directed to this correlation, which could be infringed by mere mental steps, such as a doctor warning a patient that he should reduce his drug dosage based on the result of a test showing high levels of drug metabolite, would be *per se* patent ineligible.

However, in fact none of the claims were this broad, since all included additional steps of administering a drug to patient and or determining the level of drug metabolite in a patient's body. These steps were held to be inherently transformative, thus satisfying MORT. In short, the requirement of a transformative step limits the availability of patent protection to methods of using the correlation involving actual treatment of the patient and/or analysis of a biological sample. As applied in *Prometheus II*, MORT functions to defuse concerns that parties like Prometheus might be able to obtain patent protection of such broad scope that it could be used to prevent doctors from thinking about the correlations, or from communicating with their patients.

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38. Ariad Pharm., Inc. v. Eli Lilly & Co., 560 F.3d 1366, 1381 (Linn, J., concurring) (opining that the appropriate doctrinal total for policing claim scope is enablement, not written description, and bemoaning the fact that the Court has "left unresolved" the question of to what extent the enablement requirement constrains the ability of an inventor to claim "known and unknown" embodiments of the invention).
39. Research Corp. Techs., Inc. v. Microsoft Corp., 627 F.3d 859, 868-69 (Fed. Cir. 2010).

The machine prong of MORT can also be employed to limit claim scope. For example, in *Ex parte Sesek*, the invention was a method of "notifying a carrier in a mass mailing operation of an anticipated mail load to allow the carrier to adapt to the mail load instead of merely reacting to it."[40] The Board of Patent Appeals and Interferences (BPAI) rejected the claims as patent ineligible, for failure to satisfy either prong of MORT, but did not reject corresponding claims limited to an apparatus for performing the method.[41]

Like the preemption test, MORT is sufficiently malleable to permit a court to arrive at a desired outcome based on the stringency by which the test is applied. In *Bilski I*, the Federal Circuit held that the presence of a machine or transformation is not necessarily sufficient to satisfy MORT, particularly if the involvement of a machine or transformation is found to be mere "extra-solution activity."[42] The ability to dismiss machine-implemented or transformative steps as mere extra-solution activity provides substantial discretion for a court to apply to MORT in a manner that achieves the desired result.

For example, in *Classen Immunotherapies, Inc. v. Biogen IDEC* the Federal Circuit held that a claim that specifically recited a step of immunizing patients nonetheless failed MORT.[43] Immunizing a patient against disease clearly transforms a patient; *Prometheus II*, decided after *Classen*, unambiguously states that treating a patient is inherently transformative.[44] The only rational explanation for the outcome in *Classen* would appear to be that the Federal Circuit disregarded the immunization step as mere extra-solution activity, an analytical expedient explicitly sanctioned by *Bilski I*.

Similarly, in *Prometheus II* the Federal Circuit cited with approval *In re Grams*, a 1989 Federal Circuit decision that held patent ineligible a claim directed toward a method that involves performing a clinical test on individuals and applying an algorithm to the data generated by the test.[45] In a manner reminiscent of *Classen*, the Court simply disregarded the inherently transformative clinical testing step in its patent eligibility analysis as mere data-gathering extra-solution activity.[46]

In *Every Penny Counts v. Bank of America Corp.*,[47] the district court applied a similar approach to conclude that claims directed toward a process that inherently requires the use of a machine nonetheless failed MORT based on its conclusion that the involvement of the machine represented only insignificant extra-solution activity. In this case, the district court found that the claimed process necessarily requires the use of machines or computers

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40. *Ex parte* Sesek, at 1, No. 2009-0458, 2009 WL 803089 (B.P.A.I. Mar. 25, 2009).
41. *Id*. at 4-6.
42. *Bilski I*, 545 F.3d 943, 961-62 (Fed. Cir. 2010).
43. Classen Immunotherapies, Inc., v. Biogen IDEC, 304 F. App'x 866, 867 (Fed. Cir. 2008).
44. *Prometheus II*, 628 F.3d 1347, 1356 (Fed. Cir. 2010).
45. *In re* Grams, 888 F.2d 835, 840-41 (Fed. Cir. 1989).
46. *See id*. at 839.
47. Every Penny Counts, Inc. v. Bank of Am. Corp., 2009 WL 6853402 at 2-3 (M.D. Fla. 2009).

to work, and hence does not impose any limits on the process itself. Thus, this is another example of using the expedient of declaring a step mere extra-solution activity to invalidate a claim the court clearly considers overly broad.

V. The Manner in Which the Court Defines the "Fundamental Principle" at Stake Can Impact Patent Scope

The manner in which a court or the PTO interprets the meaning of "fundamental principle" can dictate the role of patent eligibility in policing claim scope. For example, even an extremely broad claim will pass muster if the court concludes that the "principle" captured by the claim is not "fundamental." We see this in *Research Corporation Technologies*, wherein the Federal Circuit held that, because the claimed method provides a functional and palpable utility in the field of computer technology, the district court was incorrect in characterizing the idea behind the claim as "abstract." With no "abstract idea" implicated by the claim, it necessarily follows that the claims could not be patent ineligible for claiming an abstract idea, regardless of how broadly the "non-abstract idea" behind the claim is claimed. By defining abstract idea in such a restricted manner, the Court effectively negates the role of patent eligibility in policing claim scope. The district court, in contrast, had subscribed to a more expansive definition of what it means to be an "abstract idea," resulting in the divergent outcomes.

Different interpretations of what it means to be a "natural phenomenon" might also explain the conflicting rulings emanating from the district court and Federal Circuit in *Prometheus*. As discussed above, the district court seemed to adopt an unjustifiably expansive definition of natural phenomena, characterizing the correlation between the metabolic breakdown products of a defined category of non-naturally occurring drugs (i.e., certain thiopurine drugs) and the optimal dosage of the drug as a natural phenomenon. While the Federal Circuit did not explicitly address the district court's questionable definition of natural phenomenon, its decision to reverse the district court might be explained by assuming that the Federal Circuit defined the relevant natural phenomenon differently. At one point in *Prometheus II,* the Federal Circuit explains that the challenged claims are directed towards an application "of naturally occurring correlations between metabolite levels and efficacy or toxicity, and thus do not wholly preempt all uses of the recited correlations."[48] This statement suggests that perhaps the Federal Circuit defined the fundamental principle implicated by the claims more broadly, i.e., as the general phenomenon that a correlation exists between the level of drug metabolite in the body and drug efficacy and toxicity, as opposed to the more specific correlation involving thiopurine drugs identified by the district court. As such, the Federal Circuit's "natural phenomenon" encompassed all drugs generally, and thus was not preempted by claims limited to a specific category of drugs. The district court's "natural phenomenon," on the other hand, was limited to a specific category of drugs, which the court found to be effectively preempted by the claims.

48. *Prometheus II*, 628 F.3d at 1355.

Note the analogy between what occurred in *Research Corporation Technologies* and the foregoing interpretation of *Prometheus*. In both cases, the district court adopted a relatively narrow interpretation of the fundamental principle at stake, and found the claim invalid for effectively preempting the fundamental principle. On appeal, the Federal Circuit defined the fundamental principle more broadly, and based on this interpretation reversed the lower court. In *Research Corporation Technologies*, the Federal Circuit achieved this end by finding that no fundamental principle (i.e., abstract idea) was implicated by the claims. In *Prometheus*, on the other hand, the Federal Circuit acknowledged that the claims implicated a natural phenomenon, but after defining the natural phenomenon more broadly had no trouble concluding that the claims are patent eligible by virtue of being limited to certain specific applications of the phenomenon, i.e., a limited category of drugs. While the *Prometheus* claims appeared overly broad under the district court's narrow definition of the natural phenomenon, from the perspective of the Federal Circuit the claims are relatively narrow, limited as they are to an application of the natural phenomenon (as they defined it) to a specific category of drugs.

This interpretation of *Prometheus II* might also help explain the different outcomes in that case and *In re Grams*.[49] In both cases, the challenged claims recited a method that involved obtaining clinical laboratory data from a patient and applying what the court characterized as a fundamental principle to the data, resulting in clinically useful diagnostic information. In *Prometheus*, the claim is limited to a fairly specific category of drugs, leaving most applications of the fundamental principle outside the scope of the claims. In contrast, the *Grams* claim broadly recited applying the fundamental principle to "clinical laboratory tests" in general, rather than being limited to any specific clinical laboratory test or tests. The greater preemptive effect of Grams' claims, in contrast with the relatively specific application of a fundamental principle claimed by Prometheus, could provide a principled distinction that would explain the divergent outcomes in the cases.

Alternatively, the Federal Circuit could have arrived at the same outcome in *Prometheus II* by finding that the alleged natural phenomenon identified by the district court was not in fact "natural." On the initial appeal of *Prometheus* to the Federal Circuit, I filed an amicus brief explaining my position that the district court had erred in characterizing a correlation involving a synthetic, non-naturally occurring drug breakdown product as a natural phenomenon.[50] In that brief I argued that the correlation does not and cannot occur naturally, since it only arises as a result of the administration of a synthetic drug to patient. By limiting the applicability of the doctrine of patent eligibility to claims implicating truly natural phenomena, courts could modulate the effect of the doctrine on claim breadth.

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49. As I pointed out in a post to my blog, I found the Federal Circuit's attempt to distinguish the two cases provided by *Prometheus II* less than entirely convincing. Chris Holman, *On Remand, Federal Circuit (Once Again) Decides* Prometheus v. Mayo *in Favor of Patent Eligibility for Methods of Treatment and Diagnostic Tests*, Holman's Biotech IP Blog (Dec. 17, 2010, 3:22 PM), http://holmansbiotechipblog.blogspot.com/2010/12/on-remand-federal-circuit-once-again.html.

50. *See* Brief of Amici Curiae Interested Patent Law Professors in Support of Neither Party at 11, Prometheus Labs., Inc. v. Mayo Collaborative Servs., 628 F.3d 1347 (Fed. Cir. 2010) (No. 2008-1403).

For example, consider the case of a researcher who has discovered a correlation between a specific genetic variation and the suitability of a particular drug for a patient bearing that genetic variation, i.e., a personalized medicine invention. A court could reasonably conclude that since the correlation involves a non-naturally occurring drug, it is not a natural phenomenon, and thus patent eligibility is not implicated, regardless of how broadly the researcher chooses to claim a diagnostic method applying the correlation to healthcare. On the other hand, assuming that the genetic variation occurs naturally, and thus could be rightly characterized as a natural phenomenon, the doctrine of patent eligibility would be available to preclude the researcher from obtaining a claim broadly reciting the genetic variation *per se*, untethered to its correlation with a non-naturally occurring drug.

The virtue of this approach might lie in its ability to provide a principled doctrinal tool for distinguishing between claims broadly reciting diagnostic testing for naturally occurring genetic variations, which have become highly controversial and widely unpopular, and personalized medicine claims directed toward correlations between genetic variation and optimal drug treatment regimen. It is widely believed that personalized medicine has the potential to play a critical role in advancing future healthcare, and should the courts decide to use patent eligibility to invalidate unpopular "gene patents" claims, such as those at issue in *Ass'n for Molecular Pathology*,[51] it is important that they do so in a manner that does not unduly prejudice the ability of personalized medicine innovators to obtain adequate patent protection for their discoveries. This important policy objective might be achieved by limiting the applicability of the doctrine of patent eligibility to claims implicating truly "natural" phenomena.

VI. Policing Claim Scope by Limiting Claims to the Statutory Categories of Patentable Subject Matter

Under Section 101 of the patent statute, only machines, articles of manufacture, compositions of matter, and processes are patent eligible.[52] These terms have been interpreted broadly, to encompass living organisms, chemical compounds, and in at least one case an elemental particle (Element 95, i.e., Americium).[53] However, the recent decision in *Nuijten* invalidating a claim to a signal illustrates that at some point the Federal Circuit is willing to draw the line and declare a claim patent ineligible for claiming subject matter that is neither a process nor product as defined by Section 101.[54] Similarly, in *Bilski II* the Court explicitly pointed to the statutory definition of process as a limitation on patent eligibility. Moving forward, the courts could potentially adopt a more stringent interpretation of what it means to be a patent eligible product or process under section 101 as another doctrinal policy lever to regulate claim scope.

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51. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F.Supp.2d 181, 200-06 (S.D.N.Y. 2010).
52. 35 U.S.C. § 101 (2006).
53. *See In re* Seaborg, 328 F.2d 996 (C.C.P.A. 1964).
54. *See supra* Part II.

VII. What Role Will Patent Eligibility Play in Policing Claim Scope?

Clearly, under *Bilski II* the lower courts are empowered to deploy patent eligibility as a doctrinal tool for policing claim scope. Because *Bilski II* leaves the test for patent eligibility largely undefined, the lower courts and PTO, in particular the Federal Circuit, could actively invoke the doctrine as a "wildcard" to invalidate patent claims deemed unduly broad, or otherwise "unworthy" by the court. Judge Rader made a similar observation recently with respect to the Lilly written description requirement, another doctrine of patentability for which the criteria for compliance remains largely undefined.[55]

However, early indications suggest that the Federal Circuit and PTO are disinclined to invoke patent eligibility as a front-line doctrinal tool for policing claim scope. There are already more appropriate doctrinal tools for policing claim scope, most particularly the enablement requirement, but increasingly in recent years the written description requirement. In most cases, these doctrines will be the more appropriate vehicle for guarding against overly expansive claiming of inventions.

For example, in *Prometheus II* the Federal Circuit went out of its way to articulate a permissive approach to patent eligibility analysis that emphatically supports the patent eligibility of method claims reciting a step of administering a drug or otherwise treating a patient, or of obtaining and/or analyzing a biological sample from a patient. In *Research Corporation Technology*, a different panel of the Federal Circuit issued a broad holding to the effect that any invention providing a functional and palpable application addressing a technological need is patent eligible. In that decision, Judge Rader stresses that under his interpretation of *Bilski II*, patent eligibility should not become a substitute for a patentability analysis related to prior art, adequate disclosure, or other requirements of patentability. In the words of Judge Rader, "section 101 does not permit a court to reject subject matter categorically because it finds that a claim is not worthy of a patent."[56]

Similarly, the PTO has instructed its examiners to "avoid focusing on issues of patent-eligibility under § 101 to the detriment of considering an application for compliance with the requirements of §§ 102, 103, and 112, and . . . avoid treating an application solely on the basis of patent-eligibility under § 101 ***except in the most extreme cases***."[57] This suggests to me that, like the Federal Circuit, the PTO does not intend to implement *Bilski II* in a manner that substantially alters the criteria for patentability as applied by the office.

In conclusion, at this point in time it seems apparent that while under *Bilski II* patent eligibility is available to the courts and PTO as a doctrinal tool for policing claim scope,

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55. Ariad Pharm. v. Eli Lilly & Co., 598 F.3d 1336, 1366 (Fed. Cir. 2010) (Rader, J, dissenting).
56. Research Corp. Techs., Inc. v. Microsoft Corp., 627 F.3d 859, 868 (Fed. Cir. 2010).
57. Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of *Bilski v. Kappos*, 75 Fed. Reg. 43,922, 43923-24 (2010) (emphasis added).

early indications are that the doctrine will not be invoked in cases where other doctrines are available to accomplish the same end. That said, some situations might very well warrant the use of patent eligibility, particularly to police against claims drafted so broadly as to encompass mental thoughts, mere analysis or manipulation of data, or other processes too far removed from what one would generally characterize as "technology." ■