

Mayo v. Prometheus: The Overlap Between Patent Eligibility and Patentability

By Teige P. Sheehan

I. Introduction

In March 2012, the U.S. Supreme Court issued an important and potentially far-ranging holding on patent eligibility in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, ruling unanimously that the methods at issue—for determining the optimum dose of a particular class of drugs for individual patients—are not patent eligible.¹ *Prometheus* has attracted the attention of practitioners and members of the business community across multiple disciplines because of its ostensible breadth, its apparent break with Supreme Court precedent, and its potential to create widespread uncertainty as to patent validity.

The Court had most recently addressed patent eligibility in 2010 in *Bilski v. Kappos*,² in which it reiterated the patent ineligibility of abstract ideas. *Prometheus*, in turn, addressed the patent eligibility of inventions that invoke a purported natural law, and in doing so the Court appeared to import the patentability questions of novelty and obviousness into the patent-eligibility inquiry, despite having held in 1981 in *Diamond v. Diehr*³ that those analyses should be conducted separately. In this regard, *Prometheus* could be relevant to evaluating the validity of claims that implicate exceptions to eligibility other than laws of nature,⁴ including claims unrelated to medical treatment methods.

This article discusses *Prometheus* in the context of the ongoing, recently reinvigorated development of patent-eligibility jurisprudence.⁵ Part II summarizes the Court's holding, while Parts III and IV present analyses of its legal and policy-based justifications, respectively. Part V discusses the uncertain fate of the Federal Circuit's "machine-or-transformation" test of patent eligibility in light of *Prometheus*. Part VI addresses the potential relevance of *Prometheus* to other current patent-eligibility debates, and Part VII provides guidance for claiming patent-eligible inventions in accordance with *Prometheus*.

It is to be hoped that as lower courts and the PTO implement the teachings of *Prometheus* in a constructive and meaningful way, the anxiety induced in the patent community by the Court's holding will be assuaged.

II. Summary of *Prometheus*

The claims at issue in *Prometheus* were drawn to methods of determining an optimal thiopurine drug dose for use in treating a patient suffering from an autoimmune-related gastrointestinal disorder. At the time of invention, administering thiopurine drugs to treat such disorders was known. However, because rates of

metabolism of such drugs differ from patient to patient, it was difficult to predict in the abstract a dose that was high enough to be effective for a given patient but not so high as to cause harmful side effects. The inventors identified correlations between an individual's blood levels of thiopurine metabolites following drug administration and the effectiveness or harmfulness of the administered dose, and they claimed using these relationships to calculate what dose to administer on a patient-by-patient basis.⁶

Prometheus Laboratories, Inc., the exclusive licensee of the patents at issue, sued Mayo Collaborative Services (hereinafter "Mayo") for patent infringement, but the case was dismissed on summary judgment on the ground that the claimed inventions were not eligible for patent protection.⁷ On appeal, the Federal Circuit reversed, and Mayo petitioned for certiorari.⁸ The Supreme Court granted certiorari, vacated the Federal Circuit's holding, and remanded the case for further proceedings in light of *Bilski*, which it had handed down in the interim.⁹ On remand, the Federal Circuit again held the claimed inventions to be patent eligible, and Mayo again petitioned for certiorari, which the Court granted.¹⁰

In an opinion by Justice Breyer, the Court considered the eligibility of the following claim, which it deemed sufficiently representative of all the claims at issue:

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

- (a) administering a [thiopurine] drug...to a subject having said immune-mediated gastrointestinal disorder; and
- (b) determining the level of [a thiopurine metabolite] in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of [said metabolite below a specific level] indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of [said metabolite above a specific level] indicates a need to decrease the amount of said drug subsequently administered to said subject.¹¹

In deciding that the claimed invention was not patent eligible, the Court characterized the correlations the inventors had identified between metabolite levels and

effectiveness and harmfulness as laws of nature.¹² It thus cast the claim as falling within an exception to the broad scope of patent-eligible subject matter established under 35 U.S.C. § 101,¹³ having stated in prior opinions that there are “three specific exceptions to § 101’s broad principles: ‘laws of nature, physical phenomena, and abstract ideas.’”¹⁴ The Court described the claim as containing an “‘administering’ step [that] simply refers to the relevant audience, namely doctors who treat patients with certain diseases with thiopurine drugs... ‘wherein’ clauses [that] simply tell a doctor about the relevant natural laws, [and a] ‘determining’ step [that] tells the doctor to determine the level of the relevant metabolite in the blood.”¹⁵ The Court thus held that the effect was “simply to tell doctors to apply the law[s of nature] somehow when treating their patients.”¹⁶

III. The Law of Nature Exclusion, Patent Eligibility, and Patentability

Arguably, the correlations made use of in the claimed methods are not laws of nature to begin with, at least not in the patent-ineligibility sense, in which case the Court’s characterization of them as such would represent the “most damaging misstep” in the decision.¹⁷ Although they describe to some degree how the human body responds to exposure to thiopurine drugs, which response itself depends upon the body’s natural metabolic processes and autoimmune pathology, the correlations do not directly co-opt those underlying principles of thiopurine pharmacokinetics and pharmacodynamics per se.¹⁸ In this respect, the claimed processes are very different from those employing mathematical algorithms that were held to be patent ineligible for preempting laws of nature in prior Supreme Court decisions.¹⁹ The broad conception of what qualifies as a law of nature for purposes of the patent-eligibility inquiry adopted in *Prometheus* could well engulf a wide swath of issued claims; the Court itself recognized that “all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.”²⁰

However, even assuming the claimed methods did make use of natural laws in a way that threatened their patent eligibility, the Court acknowledged that such use is not by itself fatal to validity.²¹ Rather, the Court stated that a claim to “a process that focuses upon the use of a natural law [must] also contain other elements or a combination of elements...sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself.”²² The Court thus required that the steps in addition to the use of a natural law must be parsed and examined to determine whether they provide something more than “well-understood, routine, conventional activity previously engaged in by researchers in the field,”²³ rather than something “purely ‘conventional or obvious.’”²⁴ The Court “recognize[d] that, in evaluating the significance of additional steps, the [35 U.S.C.] § 101 patent-eligibility inquiry and, say,

the § 102 novelty inquiry might sometimes overlap.”²⁵ Because, according to the Court, the aspects of the disputed claims in *Prometheus* other than the purported manifestations of natural laws merely told doctors to “engage in well-understood, routine, conventional activity previously engaged in by scientists who work in the field,” the claims did not “add enough to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws.”²⁶

In reaching this conclusion, the Court upset its own long-standing rule, derived from both the statutory language and legislative history of the 1952 Patent Act, that the determination of patent eligibility under 35 U.S.C. § 101 is entirely separate from and unaffected by whether the conditions of patentability set forth in 35 U.S.C. §§ 102 (novelty) and 103 (nonobviousness) are met.²⁷ Although the Court recently had held in *Bilski* that dependent claims that merely add “well-known...techniques” and “token postsolution components” to an abstract concept recited in a patent-ineligible independent claim do not “make the concept patentable,” it did not in *Bilski* expressly reverse its holding from thirty years ago that patent eligibility and patentability are distinct inquiries,²⁸ as it appears to have done in *Prometheus*.

And yet, although the Court in *Prometheus* asserted that patent-eligibility and patentability analyses may overlap, it explicitly declined to perform a patentability analysis under, for example, section 102. Rather, it confined its analysis and discussion of what was routine and conventional in the art to the supposedly “better established inquiry under § 101.”²⁹ Avoiding a patent-eligibility analysis in favor of patentability analysis, the Court warned, “would make the ‘law of nature’ exception to § 101 patentability a dead letter.”³⁰

This conflation of patent-eligibility and patentability analysis threatens to create substantial uncertainty as to patent validity, for a number of reasons. First, most practitioners likely disagree with the Court and believe that patentability jurisprudence developed under sections 102, 103, and 112 is far more well developed than the patent-eligibility jurisprudence under section 101.³¹ Second, the Court appears to endorse the view that invalidity arguments that previously would have been within the purview of sections 102, 103, or 112—and therefore required claim construction as part of the analysis—can now be brought under section 101 without the court having to construe the claims.³² Third, if patent-eligibility and patentability analyses do overlap, parties may unjustifiably take advantage of the additional opportunity to challenge claims under section 101 on the basis of prior art that is more traditionally relevant under sections 102 or 103, requiring multiple responses to what is essentially the same, duplicative argument and reducing judicial efficiency.³³ Fourth, the Court’s method of concluding that the claimed inventions were patent ineligible by dissecting the claims into their constituent parts and finding

each on its own to be lacking in sufficient inventiveness contrasts sharply with the long-standing doctrine that claims are to be considered as a whole.³⁴

Finally, the Court evinced a dispiriting lack of appreciation for the function of claims in protecting economic incentives, stating that its holding was necessary to safeguard innovation from the apparently mischievous influences of the “draftsman’s art.”³⁵ Rather than bring clarity to the patent-eligibility issue, however, the decision instead has the potential to substantially destabilize long-standing, well-established doctrines.

Notably, however, in a post-*Prometheus* decision, the Federal Circuit emphasized the “distinctly different role[s]” played by sections 101, 102, 103, and 112.³⁶ Subsequent to *Bilski*, in which the Supreme Court characterized section 101 as a “threshold test” of validity,³⁷ but before *Prometheus*, the Federal Circuit had stated that sections 102, 103, and 112 are capable of weeding out patents that could otherwise pass through the “coarse eligibility filter” of section 101.³⁸ *Prometheus* undercuts this position, asserting that some claims to subject matter that is patent ineligible under section 101 still could satisfy the requirements of these other sections, perhaps signaling the pre-eminent importance of the patent-eligibility inquiry over other questions of validity.³⁹

In emphasizing the different functions served by section 101 as compared to sections 102, 103, and 112, the Federal Circuit held that “a district court properly acts within its discretion in deciding when to address the diverse statutory challenges to validity” and that section 101 issues “need not always be addressed first, particularly when other sections might be discerned by the trial judge as having the promise to resolve a dispute more expeditiously or with more clarity and predictability.”⁴⁰ Thus, whatever the relative importance of section 101 in light of *Bilski* and *Prometheus*, the Federal Circuit maintains that a patent-eligibility analysis need not always be performed if, for example, discretionary considerations of judicial economy favor dispensing with cases on the basis of other validity requirements.

IV. Safeguarding Innovation

The Supreme Court’s principal justification for its holding is the policy against allowing patentees to monopolize fundamental natural laws through the grant of a patent, thereby preempting entire domains of innovation.⁴¹ As the Court acknowledged, the quid pro quo of the U.S. patent regime allows an inventor a limited-time right to exclude others from practicing his or her invention so as to incentivize innovation and, in time, to stimulate successive technological improvements.⁴² To avoid tilting the balance too far toward monopolization, to the detriment of innovation, the Court has historically limited patent eligibility by denying patents that have the effect of excluding others from applying fundamental laws of nature.⁴³

There was, however, a notable absence of factual evidence presented in *Prometheus* to support the Court’s protectiveness of innovation. Beyond the exclusionary right that is an integral aspect of the patent regime in general,⁴⁴ was there any record evidence that the claims at issue in the case did in fact prevent others from using fundamental laws of nature relating to pharmacokinetics and pharmacodynamics outside of the application claimed by the patentees? This question is not as impertinent as it may seem, particularly with respect to the preemption concern. The Court acknowledged that the “laws of nature at issue...are narrow laws that may have limited applications.”⁴⁵ It nevertheless stated that there is a “bright-line prohibition against patenting laws of nature” irrespective of the breadth of preemption⁴⁶—a statement that seems at odds with the Court’s ostensible policy concerns.⁴⁷ That is, arguably the disincentive of a “bright-line” rule against claims to inventions that apply narrowly circumscribed natural laws is at least as likely to diminish the patent regime’s ability to stimulate innovation as is allowing patentees to preemptively claim such laws.

Also notably absent from *Prometheus* is any discussion of either the presumption of validity that issued patents enjoy or of the clear and convincing evidentiary standard required to invalidate a patent.⁴⁸ After *Prometheus*, however, the Federal Circuit has reiterated the evidentiary burden required to prevail on a claim of invalidity under section 101, stating that “when—after taking all of the claim recitations into consideration—it is not manifestly evident that a claim is directed to a patent ineligible abstract idea, that claim must not be deemed for that reason to be inadequate under § 101,” and “[u]nless the single most reasonable understanding is that a claim is directed to nothing more than fundamental truth or disembodied concept, with no limitations in the claim attaching that idea to a specific application, it is inappropriate to hold that the claim is directed to a patent ineligible ‘abstract idea.’”⁴⁹

V. Evisceration of the Machine-or-Transformation Test

The *Prometheus* Court also addressed whether satisfying the Federal Circuit’s “machine-or-transformation” test would render the claims at issue eligible for patent, apparently answering in the negative.⁵⁰ The Federal Circuit had enunciated the machine-or-transformation test as way to determine whether a claimed process was patent eligible: a process is only patent eligible if “(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.”⁵¹ On appeal in *Bilski*, the Supreme Court disagreed, stating that while “the machine-or-transformation test is a useful and important clue, [it] is not the sole test for deciding whether an invention is a patent-eligible ‘process.’”⁵²

The machine-or-transformation test having thereby been declared by the Supreme Court as a permissible,

if non-exclusive, test of patent eligibility, the Federal Circuit in *Prometheus* “reasoned that the claimed processes are therefore patent eligible, since they involve transforming the human body by administering a thiopurine drug and transforming the blood by analyzing it to determine metabolite levels.”⁵³ But the Supreme Court, in reviewing that decision, took a very different position than it had in *Bilski*, stating that the machine-or-transformation test does not “trump[] the ‘law of nature’ exclusion” from patent eligibility and “the test fails here.”⁵⁴ Thus, in addition to having been declared unnecessary as a litmus test of patent eligibility in *Bilski*, under *Prometheus* the machine-or-transformation test appears to have been deemed insufficient as a screen as well. Its status as a very “useful and important clue” of patent eligibility therefore seems doubtful.⁵⁵ Note, however, that the machine-or-transformation test, if on life support, is not quite dead yet, as the Federal Circuit applied it post-*Prometheus* in finding that claims to using a computer system to mitigate risk in financial transactions were patent eligible.⁵⁶

VI. Implications for Other Disputes

Soon after issuing *Prometheus*, the Supreme Court agreed to hear two other cases involving patent eligibility, vacated the Federal Circuit holdings that the claims at issue in those cases were patent eligible, and remanded the cases to the Federal Circuit for further proceedings in light of *Prometheus*.⁵⁷ In *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.* a divided panel of the Federal Circuit had held that claims to isolated sequences of DNA were patent eligible because the process of isolating them so altered them from their native state that they were no longer products of nature and therefore were patent eligible.⁵⁸ And in *Ulramercial, LLC v. Hulu, LLC* the Federal Circuit had held that a method for distributing copyrighted material over the Internet was patent eligible because it involved “an extensive computer interface” for practically applying “the age-old idea that advertising can serve as currency.”⁵⁹ Considering that the requirement of *Prometheus* that patent-ineligible facets of claims require additional recitation of some non-obvious or unconventional element or limitation, these bases for upholding the biotechnological and computer software claims in *Myriad* and *Ulramercial*, respectively, are likely called into question.⁶⁰

VII. Implementing *Prometheus*

After *Prometheus* was handed down, the PTO issued guidance to its corps of patent examiners for determining patent eligibility of process claims.⁶¹ The guidelines set out a series of three inquiries that should be made to determine whether a claim in a patent application is patent eligible under *Prometheus*. The first inquiry asks whether the claim is to a method. If so, the guidelines are applicable. The second inquiry asks whether the claim focuses “on use of a natural principle, i.e., a law of nature,

a natural phenomenon, or naturally-occurring relation or correlation” as “a limiting feature of the claim.” If so, then the third inquiry is made: “Is [the claim] more than a law of nature [plus] the general instruction to simply ‘apply it?’” If not, the claim is not patent eligible.⁶²

The most straightforward, if glib, response to the admonitions in *Prometheus* is to ensure that, where a natural law is relied upon in a claimed process, additional claim elements require applying it in a manner that is not merely routine or conventional.⁶³ In this regard, the holding in *Prometheus* may not be as broadly applicable as it may appear. One important aspect of the decision was the Court’s reference to the fact that the claims do not require administering a higher or lower dose of a thiopurine drug on the basis of the detected metabolite blood levels.⁶⁴ The claim clauses stating that “wherein [metabolite levels] indicate[] a need to increase [or] decrease the amount of [thiopurine] drug subsequently administered” do not actually require that any activity be taken once metabolite blood levels have been determined, such as subsequent administration of a thiopurine drug, at any dose at all, irrespective of whether metabolite blood levels were detected to be below or above the levels stated in the “wherein” clauses.⁶⁵

These clauses arguably need not have been considered by the Court in its analysis.⁶⁶ Indeed, the step of administering a thiopurine drug to a patient, by itself, would surely be patent eligible, irrespective of issues of novelty and nonobviousness.⁶⁷ It is odd, then, that adding *more* to the claims removed them from patent eligibility.⁶⁸ Perhaps the Court’s disapproval of the claims was predominantly the result of the presence of these “wherein” clauses that merely intimated the supposed laws of nature without adding actionable substance to the claims. Notwithstanding the Court’s suggestion that the addition of “less conventional” steps to these claims would be required for them to attain patent eligibility, it ultimately may not hold the claims of other patents to that seemingly heightened standard.⁶⁹

VIII. Conclusion

After several decades of relative lack of involvement by the Supreme Court in patent eligibility issues, the Court in *Prometheus*, following *Bilski*, introduced substantial analytical changes. As was the case following *Bilski*, there is a widespread sense that previously established principles and settled expectations and interests have been upset by a bold decision that lacks practical guidance. It may be a long time before the full ramifications of *Prometheus* are understood and felt by the patent community. One hopes that the worst fears expressed in the immediate wake of the decision will prove unfounded.

Endnotes

1. 132 S. Ct. 1289.
2. 130 S. Ct. 3218.

3. 450 U.S. 175.
4. See *infra* note 14 and associated text.
5. *MySpace, Inc. v. GraphOn Corp.*, 672 F.3d 1250, 1258 (Fed. Cir. 2012) (noting “what has become a plethora of opinions adding to...§ 101 jurisprudence”).
6. *Prometheus*, 132 S. Ct. at 1294-95.
7. *Id.* at 1295-96.
8. *Id.* at 1296.
9. *Id.*
10. *Id.*
11. *Id.* at 1295.
12. *Id.* at 1296-97.
13. “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” 35 U.S.C. § 101.
14. *Bilski*, 130 S. Ct. at 3221 (quoting *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)). The Court has not always been consistent in identifying which exception operates to render a given invention patent ineligible. For example, in *Gottschalk v. Benson*, 409 U.S. 63, 68 (1972), the Court rejected as patent ineligible a claim that recited a mathematical algorithm because it was too “abstract,” but the holding in *Benson* was subsequently characterized in *Parker v. Flook*, 437 U.S. 584, 589 (1978), as applying “the established rule that a law of nature cannot be the subject of a patent.” The Court in *Flook*, in turn, held a claim to a process using an algorithm to be patent ineligible because it was drawn to a law of nature (437 U.S. at 589-90), but the Court in *Bilski* characterized *Flook* as pertaining to the exemption of abstract ideas from patent eligibility (130 S. Ct. at 3230). Thus, the Court does not appear to consider the boundaries between these exemptions to be particularly restrictive and somewhat freely cross-applies analytical frameworks between them.
15. *Prometheus*, 132 S. Ct. at 1297.
16. *Id.* at 1299-1300.
17. Posting by Robert R. Sachs to Patently-O, <http://www.patentlyo.com/patent/2012/03/punishing-prometheus-the-supreme-courts-blunders-in-mayo-v-prometheus.html> (Mar 26, 2012) (hereinafter “*Sachs I*”).
18. See *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1067 (Fed. Cir. 2012) (“Pharmacokinetics is the study of what a person’s body does to a drug after administration [and pharmacodynamics] describes the effect that a drug renders on a person’s body.”).
19. *Flook*, 437 U.S. at 589-90. See also *Benson*, 409 U.S. at 68 and *supra*, note 14.
20. *Prometheus*, 132 S. Ct. at 1293; See *Sachs I*, *supra* note 17 (noting that the Court’s erroneous characterization of the dosage-efficacy-safety correlations as laws of nature rather than applications of such laws or, perhaps, of natural phenomena, puts many patents at risk); Posting by Robert R. Sachs to Patently-O, <http://www.patentlyo.com/patent/2012/03/punishing-prometheus-part-ii-what-is-a-claim.html> (Mar 27, 2012) (hereinafter “*Sachs II*”) (“Patents which only last week had been utterly ordinary, run of the mill, *Landis on Mechanics of Patent Claim Drafting*-certified claims are now suspect, merely because they do what every claim ought to do: comply with the laws of thermodynamics.”).
21. *Prometheus*, 132 S. Ct. at 1294.
22. *Id.*
23. *Id.*
24. *Id.* at 1299 (quoting *Parker v. Flook*, 437 U.S. 584, 590 (1978)).
25. *Prometheus*, 132 S. Ct. at 1304.
26. *Id.* at 1289, 1298. See *Sachs II*, *supra* note 20 (“Reducing the claim to this ‘instruction manual’ allows the Court to analogize the claim to Einstein ‘telling linear accelerator operators about his basic law’ [*Prometheus*, 132 S. Ct. at 1297]—a low point in modern legal reasoning.”).
27. *Diehr*, 450 U.S. at 1058-59. See also *Diamond v. Chakrabarty*, 447 U.S. 303, 307 n.5 (1980) (“This [patent-eligibility] case does not involve the other ‘conditions and requirements’ of the patent laws, such as novelty and nonobviousness. 35 U.S.C. §§ 102, 103.”); *In re Bergy*, 596 F.2d 952, 960-61 (C.C.P.A. 1979) (arguing that the legislative history of the 1952 Patent Act supports separating patent-eligibility inquiries under 35 U.S.C. § 101 from patentability inquiries under other sections of Title 35); Harold C. Wegner, *Patent-Eligibility from Benson to Diehr (1972-1981): Patenting Biotechnology “Nylon,”* at 32-34, (May 14, 2012), http://www.grayonclaims.com/storage/Wegner_PaentEligibility_May14.pdf (noting that the Supreme Court, in *Chakrabarty* and *Diehr*, adopted the rule that patent-eligibility and patentability inquiries should be separate inquiries in accordance with the holding in *Bergy*, which was authored by Judge Rich, a principal author of the 1952 Patent Act).
28. 130 S. Ct. at 3231.
29. *Prometheus*, 132 S. Ct. at 1304.
30. *Id.* at 1303.
31. See Lynn C. Tyler, *Section III of Mayo v. Prometheus: Better Left Unwritten?*, [2012] 83 PAT. TRADEMARK & COPYRIGHT J. (BNA) No. 2059 (Apr. 6, 2012), at 841 (hereinafter “*Tyler*”) (“It is simply hard to know what the court meant by this statement” that the § 101 inquiry is better established than other, patentability inquiries); *Sachs II*, *supra* note 20 (“What is especially Kafkaesque is the Court’s intimation that analysis under §§ 102 and 103 is somehow significantly more uncertain than under § 101.”); *CLS Bank Int’l v. Alice Corp. Pty. Ltd.*, No. 2011-1301, 2012 WL 2708400, at *7 (Fed. Cir. 2012) (“Notwithstanding...well-intentioned efforts and the great volume of pages in the Federal Reporters treating the abstract ideas exception, the dividing line between inventions that are directed to patent ineligible abstract ideas and those that are not remains elusive.”).
32. James R. Klaiber & Stephen M. Goodman, *Diagnosing Patent Ineligibility: The Supreme Court’s Mayo v. Prometheus Decision and Computer-Implemented Claims*, [2012] 83 PAT. TRADEMARK & COPYRIGHT J. (BNA) No. 2062 (Apr 27, 2012), at 969 (hereinafter “*Klaiber*”). Although the Court did refer to the claim construction that had been conducted by the district court (132 S. Ct. at 1296), it did not explicitly rely on or refer to such claim construction in much of its opinion, leaving the question of the importance of claim construction in a § 101 inquiry unsettled.
33. Christine Willgoos, *Lessons of Mayo v. Prometheus: Did the Supreme Court Clarify or Confuse the Patent Eligibility of Biotechnology Inventions?*, [2012] 84 PAT. TRADEMARK & COPYRIGHT J. (BNA) No. 2065, at 121-22 (May 18, 2012) (hereinafter “*Willgoos*”) (“Where does the Section 101 inquiry end and the Section 102/103 inquiry begin? The *Mayo* decision offers little guidance on this matter.”); *Klaiber*, *supra* note 32 at 969; Harold C. Wegner, *Mayo v. Prometheus: Implications for “Composition[s] of Matter,”* at 71-74, April 27, 2012, http://www.grayonclaims.com/storage/Wegner_Mayo_v_Prometheus_April27REV.pdf (“The model thus goes around in a meaningless circle of redundant effort.”).
34. *Diehr*, 450 U.S. at 188 (“In determining the eligibility of respondents’ claimed process for patent protection under § 101, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis. This is particularly true in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made.”); *CLS Bank Int’l v. Alice Corp. Pty. Ltd.*, 2012 WL 2708400, at *12 (“The limitations of the claims as a whole...are what place meaningful boundaries on the meaning of the claims.”); *Hockerson-Halberstadt, Inc. v. Converse Inc.*, 183

- F.3d 1369, 1374 (Fed. Cir. 1999) (“Proper claim construction... demands interpretation of the entire claim in context, not a single element in isolation.”); *Sachs II*, *supra* note 20; William K. Merkel, *Understanding Mayo v. Prometheus*, LAW360, July 10, 2012, <http://www.law360.com/ip/articles/350658/understanding-mayo-v-prometheus> (subscription required) (“What competent patent attorney, patent agent or pro se applicant would draft a claim to patentable subject matter and then further limit its scope by adding an element reciting a law of nature? It is reasonable to expect the vast majority of issued and pending treatment, and diagnostic, claims will fail to demonstrate an inventive concept in any subset of claim elements, and will instead define an incomplete process missing an essential element.”).
35. *Prometheus*, 132 S. Ct. at 1294 (quoting *Flook*, 437 U.S. at 593); *Sachs II*, *supra* note 20 (“The Court’s suggestion that patent attorneys engage in ‘drafting effort[s] designed to monopolize [a] law of nature itself is absurd. We draft claims that read on actual infringers in the real world. Intentionally drafting a claim that read[s] on an abstract idea or a law of nature itself would be foolish at best and malpractice at worst, for there would be no infringers. No one makes, sells, or uses an abstract idea.”) (emphasis in original); Posting by Robert R. Sachs to Patently-O, <http://www.patentlyo.com/patent/2012/03/punishing-prometheus-part-iv-machine-or-transformation-we-hardly-knew-thee-.html> (Mar 31, 2012) (“For some reason the Court seems to delight in denigrating the role of patent counsel in drafting claims, treating patent attorneys as either mere scribes or crafty manipulators of words and phrases, clauses and conjunctions.”); Posting by Robert R. Sachs to Patently-O, <http://www.patentlyo.com/patent/2012/04/punishing-prometheus-part-v-the-long-punt-and-the-improbable-return.html> (Apr. 4, 2012) (“[T]he Court should... understand [that] the entire purpose of the patent law is to encourage innovation through economic incentives.”) (emphasis removed) (hereinafter “*Sachs V*”).
 36. *CLS Bank Int’l v. Alice Corp. Pty. Ltd.*, No. 2011-1301, 2012 WL 2708400, at *6 (Fed. Cir. July 9, 2012).
 37. *Bilski*, 130 S. Ct. at 3225.
 38. *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1066 (Fed. Cir. 2011); *Research Corp. Technologies, Inc. v. Microsoft Corp.*, 627 F.3d 859, 869 (Fed. Cir. 2010).
 39. *Prometheus*, 132 S. Ct. at 1303-04.
 40. *CLS Bank Int’l*, 2012 WL 2708400, at *6.
 41. *Prometheus*, 132 S. Ct. at 1289 (“The presence here of the basic underlying concern that these patents tie up too much future use of laws of nature simply reinforces our conclusion that the processes described in the patents are not patent eligible.”).
 42. *Id.* at 1301.
 43. *Id.*
 44. *Sachs II*, *supra* note 20 (“By definition claims preempt, that is what they are designed to do: to preclude one from making, using, selling etc., the invention.”) (emphasis in original).
 45. *Prometheus*, 132 S. Ct. at 1302.
 46. *Id.* at 1303.
 47. See Tyler, *supra* note 31, at 840.
 48. *Microsoft Corp. v. i4i Ltd. P’ship*, 131 S. Ct. 2238, 2242 (2011).
 49. *CLS Bank Int’l*, 2012 WL 2708400, at *10. See also *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d at 1057 (claims not patent ineligible unless they “are so manifestly abstract ‘as to override the broad statutory categories of eligible subject matter’” (quoting *Research Corp. Technologies, Inc. v. Microsoft Corp.*, 627 F.3d at 868)).
 50. *Prometheus*, 132 S. Ct. at 1303.
 51. *In re Bilski*, 545 F.3d 943, 954 (Fed. Cir. 2008).
 52. *Bilski v. Kappos*, 130 S. Ct. 3218, 3227 (2010).
 53. *Prometheus*, 132 S. Ct. at 1302.
 54. *Id.* at 1303.
 55. See Tyler, *supra* note 31, at 840; Posting by Robert R. Sachs to Patently-O, <http://www.patentlyo.com/patent/2012/03/punishing-prometheus-part-iv-machine-or-transformation-we-hardly-knew-thee-.html> (Mar 31, 2012).
 56. *CLS Bank Int’l*, 2012 WL 2708400, at *8, 12-13.
 57. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 132 S. Ct. 1794 (2012); *WildTangent, Inc. v. Ultramercial, LLC*, 132 S. Ct. 2431 (2012).
 58. 653 F.3d 1329, 1350 (Fed. Cir. 2011).
 59. 657 F.3d 1323, 1328 (Fed. Cir. 2011).
 60. *High Court’s Mayo Standards Applicable to Myriad Remand Stakeholders Say*, [2012] 83 Pat. Trademark & Copyright J. (BNA) No. 2062, at 809 (Apr 6, 2012); *Willgoos*, *supra* note 33 at 122-23; *Klaiber*, *supra* note 32 at 969-71; Posting by Dennis Crouch to Patently-O, <http://www.patentlyo.com/patent/2012/05/patentable-subject-matter-supreme-court-challenges-chief-judge-raders-broad-notion-of-software-patentability.html> (May 21, 2012).
 61. 2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature. Andrew H. Hirschfeld, Deputy Commissioner for Patent Examination Policy, USPTO (July 3, 2012) (available at http://www.uspto.gov/patents/law/exam/2012_interim_guidance.pdf).
 62. *Id.* at 3.
 63. *Sachs V*, *supra* note 35; *Klaiber*, *supra* note 32, at 970.
 64. *Prometheus*, 132 S. Ct. at 1296.
 65. John Witherspoon, *The Real Tragedy in Mayo v. Prometheus* [2012], 83 PAT. TRADEMARK & COPYRIGHT J. (BNA) No. 2061 (Apr. 20, 2012), at 926-27.
 66. *Id.*
 67. Posting by Courtenay Brinckerhoff to PharmaPatents, <http://www.pharmapatentsblog.com/2012/05/24/puzzled-by-prometheus/> (Apr. 24, 2012).
 68. *Id.*
 69. Mayo, Myriad *Subject to Debate, Professors, IP Practitioners Argue*, 84 PAT. TRADEMARK & COPYRIGHT J. (BNA) No. 2063 (May 4, 2012), at 21 (“Prometheus never walked away from the expressed fear that any physician, any researcher who thought about the level of metabolites in connection with a potential therapeutic result or marker would simply by virtue of thinking about that would be infringing. And I think that’s what nine justices find unacceptable, and all the rest I believe is mischief,” quoting Seth P. Waxman, former U.S. solicitor general, who opined that the Court thinks its holding is narrower than many people fear). See *Prometheus*, 132 S. Ct. at 1302 (“[These claims] tell a treating doctor to measure metabolite levels and to consider the resulting measurements in light of the statistical relationships they describe. In doing so, they tie up the doctor’s subsequent treatment decision whether that treatment does, or does not, change in light of the inference he has drawn using the correlations.” (emphasis added)).

Teige P. Sheehan, Ph.D., is an associate attorney in the Albany office of Heslin Rothenberg Farley & Mesiti, P.C.

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