record.[89] But ineffective assistance of counsel, more than most other constitutional defenses, is "visible to laymen,"[90] and if a system requiring a threshold showing is less than ideal from the defendant's perspective, it is at least no worse than the cause-and-prejudice regime created by *Martinez*, under which the prisoner must convince a federal judge *both* that his ineffective-trial-counsel claim is "substantial" *and* that his postconviction counsel fell below the *Strickland* standard.

In sum, an intermediate constitutional holding would have allowed the *Martinez* majority to guarantee defendants a real opportunity to challenge the adequacy of trial counsel without imposing upon the states the burden of a full Sixth Amendment right to guaranteed counsel at postconviction review. Such a compromise might have proven an attractive alternative to the middle road the Court took with the cause-and-prejudice approach.

III. FEDERAL STATUTES AND REGULATIONS

A. Patent Act of 1952

Patentable Subject Matter. — The Supreme Court's line of precedent regarding patentable subject matter under § 101 of the Patent Act[1] has historically yielded some of its most enduring, yet most complex patent law jurisprudence.[2] Recently, however, § 101 has come under fire in academic circles for its various perceived inadequacies in the patentable subject matter context, with scholars arguing that other provisions of the Patent Act are better suited for the patentable subject matter analysis, if one is even needed at all.[3] Last Term, in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,[4] the Supreme Court invalidated a series of process claims involving diagnostic methods under § 101 as directed to mere laws of nature.[5] In doing so, the

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[89] *See* Jackson v. State, 732 So. 2d 187, 190 (Miss. 1999).

[90] Strazzella, *supra* note 58, at 464.

[1] Patent Act of 1952, 35 U.S.C. §§ 1–376 (2006 & Supp. V 2011). Under § 101, "[w]hoever 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." *Id.* § 101.

[2] *See generally, e.g.*, Bilski v. Kappos, 130 S. Ct. 3218 (2010); Diamond v. Chakrabarty, 447 U.S. 303 (1980). The Justices certainly recognize its complexity. *See* Transcript of Oral Argument at 14, Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012) (No. 10-1150).

[3] *See, e.g.*, Dennis Crouch & Robert P. Merges, *Operating Efficiently Post-*Bilski *by Ordering Patent Doctrine Decision-Making*, 25 BERKELEY TECH. L.J. 1673, 1674 (2010); Michael Risch, *Everything Is Patentable*, 75 TENN. L. REV. 591, 647–48 (2008). *But see* Rebecca S. Eisenberg, *Wisdom of the Ages or Dead-Hand Control? Patentable Subject Matter for Diagnostic Methods After* In re Bilski, 3 CASE W. RES. J.L. TECH. & INTERNET 1, 64 (2012) ("[P]atentable subject matter limitations are not redundant to these other doctrines.").

[4] 132 S. Ct. 1289 (2012).

[5] *Id.* at 1294.

Court also reaffirmed the continuing vitality of § 101 as the appropriate locus for the patentable subject matter inquiry.[6] Yet in failing to acknowledge that this academic debate has already spread to the Federal Circuit,[7] the Court missed an opportunity not only to engage fully with the arguments against the use of § 101, but also to provide guidance to lower courts on this issue. The Court should have clearly articulated the policy concerns motivating the relevant Patent Act sections, tying those concerns to their respective doctrinal inquiries and emphasizing that the doctrinal provision employed in a given situation must be capable of responding to the policy concerns involved.

Prometheus Laboratories is the exclusive licensee of two patents[8] that provide "a method of optimizing therapeutic efficacy and reducing toxicity associated with 6-mercaptopurine drug treatment of an immune-mediated gastrointestinal disorder such as inflammatory bowel disease."[9] Based on these patents, Prometheus developed a blood test called PRO-Predict, which was designed to measure thiopurine metabolites.[10] Laboratories seeking to use this test would send blood samples to Prometheus, which performed the test and provided the results.[11] After using PRO-Predict for a number of years, Mayo Collaborative Services (a laboratory within the Mayo Clinic) created its own test[12] to measure the same metabolites, and it intended both to use its test internally at its extensive network of clinics[13] and to market its test for sale.[14] Mayo's test differed from PRO-Predict in a number of ways, including its use of technologically superior assays to measure

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[6] *Id.* at 1303–04.

[7] *See, e.g.*, MySpace, Inc. v. GraphOn Corp., 672 F.3d 1250, 1260 (Fed. Cir. 2012).

[8] Prometheus Labs., Inc. v. Mayo Collaborative Servs., 628 F.3d 1347, 1349–50 (Fed. Cir. 2010).

[9] U.S. Patent No. 6,355,623 abstract (filed Apr. 8, 1999). A representative claim is claim 1 of the '623 patent, which claims

> [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 . . . , wherein the level of 6-thioguanine less than about 230 pmol per $8x10^8$ 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 $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

Id. col.20 ll.10–25 (emphases added).

[10] Brief for Petitioners at 7, *Prometheus*, 132 S. Ct. 1289 (2012) (No. 10-1150).

[11] *Id.*

[12] Due to the subsequent litigation, however, Mayo had not yet brought its test to market as of September 2011, over seven years after this litigation commenced. *Id.* at 11.

[13] Mayo possesses the largest gastroenterology practice in the United States. *Id.* at 8.

[14] Prometheus Labs., Inc. v. Mayo Collaborative Servs., 628 F.3d 1347, 1351 (Fed. Cir. 2010).

a patient's thiopurine metabolite levels and its use of different, more precise metabolite levels to assess drug toxicity.[15]

On June 15, 2004, Prometheus brought a patent infringement suit against Mayo in the United States District Court for the Southern District of California.[16] Mayo subsequently filed a motion for summary judgment of invalidity under § 101, and on March 28, 2008, Judge Houston granted Mayo's motion.[17] In doing so, he first held that the claims in suit recited "natural phenomena,"[18] which courts have explicitly excluded from patentable subject matter under § 101.[19] Finding that the steps of the claims "embod[ied] only the correlations themselves" between blood metabolite levels and therapeutic effectiveness or toxicity,[20] Judge Houston concluded that "the inventors of the patents-in-suit did not 'invent' the claimed correlation" but "merely observed" its existence in the natural world.[21] And second, Judge Houston held that the claims in suit were so broad as to "wholly preempt" use of the natural phenomenon addressed therein.[22]

The Federal Circuit reversed the District Court's grant of summary judgment of invalidity.[23] Writing for a unanimous panel, Judge Lourie articulated the machine-or-transformation test[24] as the "'definitive test' for determining whether a process is patent-eligible under § 101"[25] and found that Prometheus's claims not only passed the test but further were not subject to any of the typical limits on its application.[26] The Supreme Court, however, subsequently handed down *Bilski v. Kap-*

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[15] Brief for Petitioners, *supra* note 10, at 9–10. Mayo would also have priced its test twenty-five percent lower than Prometheus's. *Id.* at 10.

[16] Prometheus Labs., Inc. v. Mayo Collaborative Servs., No. 04CV1200JAH (RBB), 2008 WL 878910, at *1 (S.D. Cal. Mar. 28, 2008).

[17] *Id.* Mayo argued that "the patents impermissibly claim natural phenomena — the correlations between thiopurine drug metabolite levels on the one hand and therapeutic efficacy and toxicity on the other — and the claims 'wholly pre-empt' use of the natural phenomena." *Id.* at *2.

[18] *Id.* at *5.

[19] *See, e.g.*, Diamond v. Diehr, 450 U.S. 175, 185 (1981) ("Excluded from such patent protection are laws of nature, natural phenomena, and abstract ideas."); Gottschalk v. Benson, 409 U.S. 63, 67 (1972) ("Phenomena of nature . . . are not patentable . . . .").

[20] *Prometheus*, 2008 WL 878910, at *6.

[21] *Id.* at *7.

[22] *Id.* at *10 (internal quotation marks omitted); *see id.* at *10–12. Full preemption results in the invalidation of a claim under § 101. *Benson*, 409 U.S. at 71–72.

[23] Prometheus Labs., Inc. v. Mayo Collaborative Servs., 581 F.3d 1336, 1339 (Fed. Cir. 2009).

[24] In general terms, under this test a claimed method "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." Bilski v. Kappos, 130 S. Ct. 3218, 3224 (2010) (quoting *In re* Bilski, 545 F.3d 943, 954 (Fed. Cir. 2008) (en banc)) (internal quotation mark omitted).

[25] *Prometheus*, 581 F.3d at 1342.

[26] *Id.* at 1342–43. Where the machine or transformation fails to impose "meaningful limits" on claim scope or represents mere "insignificant extra-solution activity" or "data-gathering step[s]," even claims that pass the machine-or-transformation test may fail under § 101. *Id.*

pos,[27] in which it held that the machine-or-transformation test constituted merely a "useful and important clue" in the patentable subject matter analysis and was not the sole, definitive inquiry.[28] The Court then granted certiorari, vacated, and remanded *Prometheus* for reconsideration in light of *Bilski*.[29]

On remand, the Federal Circuit again unanimously reversed the district court,[30] with Judge Lourie's analysis closely tracking his previous opinion in the case.[31] Judge Lourie began by considering *Bilski*'s significance, noting that "the Court did not disavow the machine-or-transformation test" and even touted it as an "investigative tool" in the patentable subject matter inquiry.[32] Proceeding to apply the machine-or-transformation test yet again, Judge Lourie found that Prometheus's claims "recite[d] specific treatment steps," in opposition to the district court's finding that the claims recited mere correlations.[33] Judge Lourie also held that because the claims used any natural correlations that may be involved "in a series of specific steps," they did not wholly preempt the broader use of the correlations.[34] Further, Judge Lourie held not only that the claims in suit satisfied the "transformation" prong of the machine-or-transformation test, but also that each of the main steps in the representative claims — "administering" a drug and "determining" the levels of its metabolites — individually satisfied the "transformation" prong.[35] Finally, Judge Lourie held that Prometheus's claims constituted neither "insignificant extra-solution activity" nor "mere[] data-gathering steps"[36] and that the presence of a mental step[37] in the "wherein" clause of the representative claims did "not, by itself, negate the transformative nature of prior steps."[38]

The Supreme Court reversed.[39] Writing for a unanimous Court, Justice Breyer held that Prometheus's claims encompassed "laws of nature — namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine

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[27] 130 S. Ct. 3218 (2010).

[28] *Id.* at 3226–27.

[29] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 130 S. Ct. 3543 (2010).

[30] Prometheus Labs., Inc. v. Mayo Collaborative Servs., 628 F.3d 1347, 1355 (Fed. Cir. 2010).

[31] *See id.* ("We do not think that either the Supreme Court's *GVR Order* or the Court's *Bilski* decision dictates a wholly different analysis or a different result on remand.").

[32] *Id.* (internal quotation marks omitted).

[33] *Id.*

[34] *Id.*

[35] *Id.* at 1357.

[36] *Id.*

[37] In the decades after the Patent Act's enactment, the "mental steps" doctrine was marshaled to deny patents on processes involving mental operations, such as those "consisting primarily of mathematical formulae." Diamond v. Diehr, 450 U.S. 175, 195–96 (1981) (Stevens, J., dissenting).

[38] *Prometheus*, 628 F.3d at 1357–58.

[39] *Prometheus*, 132 S. Ct. at 1305.

drug will prove ineffective or cause harm," and that the claims failed to transform these mere relationships into patent-eligible applications of natural laws.[40] In reaching this holding, Justice Breyer first examined the language of the claims, considering their steps both in isolation and in the context of the claim as a whole, to conclude that the claims "simply [told] doctors to gather data from which they may draw an inference in light of the correlations."[41] He then compared the claims in suit to those at issue in the Court's prior patentable subject matter jurisprudence, particularly *Diamond v. Diehr*[42] and *Parker v. Flook*,[43] finding additional support for his conclusion in the outcomes of those cases.[44] Finally, in discussing the policy aspects of the decision, Justice Breyer called attention to concerns that patents might be used to stifle future innovation and study of natural phenomena,[45] noting that the patents in this case in particular "threaten[ed] to inhibit the development of more refined treatment recommendations" for patients and thereby posed broad preemption concerns.[46]

Justice Breyer went on to address the government's argument, advanced in an amicus curiae brief in support of neither party, that the claims in suit were more properly challenged under §§ 102, 103, and 112 of the Patent Act, rather than under § 101.[47] In rejecting this argument, he offered two primary lines of reasoning: First, conducting the patent-eligibility inquiry under §§ 102, 103, or 112 "would make the 'law of nature' exception to § 101 patentability a dead letter."[48]

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[40] *Id.* at 1296–97; *see also id.* at 1294 (describing the claims as containing "unpatentable natural laws").

[41] *Id.* at 1298.

[42] 450 U.S. 175, 192 (1981) (holding the use of a mathematical equation patentable where the claim, "when considered as a whole, is performing a function which the patent laws were designed to protect").

[43] 437 U.S. 584, 596 (1978) (holding the use of a mathematical equation unpatentable where the additional claim steps constituted mere post-solution activity).

[44] *Prometheus*, 132 S. Ct. at 1298.

[45] *Id.* at 1301; *see also* Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 127 (2006) (Breyer, J., dissenting from dismissal of certiorari) ("Patent law seeks to avoid the dangers of overprotection just as surely as it seeks to avoid the diminished incentive to invent that underprotection can threaten.").

[46] *Prometheus*, 132 S. Ct. at 1302.

[47] *Id.* at 1303; Brief for United States as Amicus Curiae Supporting Neither Party at 11–12, *Prometheus*, 132 S. Ct. 1289 (2012) (No. 10-1150). Broadly speaking, § 101 has served a threshold screening function. *See id.* at 12 ("Section 101 marks the 'threshold' of the patent system." (quoting Bilski v. Kappos, 130 S. Ct. 3218, 3225 (2010))). Only after passing this test would claims be subject to the hurdles posed by the substantive conditions of patentability: §§ 102, 103, and 112. To be valid, claims must meet the novelty requirements of § 102, the nonobviousness requirement of § 103, and the written description and enablement requirements of § 112. The government's proposal, by contrast, would either convert the § 101 inquiry into a rubber stamp–like test or at the very least reorder the validity inquiry to examine the substantive conditions of patentability before determining whether the claim is even patent eligible.

[48] *Prometheus*, 132 S. Ct. at 1303.

Such a holding would be inconsistent with the Court's nearly forty years of patentable subject matter jurisprudence, all of which was resolved on § 101 grounds.[49] And second, adopting the proposed paradigm would exacerbate, rather than solve, extant problems in the patentable subject matter inquiry,[50] particularly considering that such an adoption could force §§ 102, 103, and 112 to "do work that they are not equipped to do."[51]

Prometheus's largest impact on future case law may come from its primary holding invalidating Prometheus's claims under § 101.[52] But the Court's evaluation of the choice among various sections of the Patent Act may have equally significant ramifications for lower court decisionmaking. Justice Breyer was right to reaffirm the continuing vitality of § 101. However, the opinion does not confront the fact that courts were *already* looking to other sections of the Patent Act and accordingly does not address the full range of arguments for this shift. The opinion should have explicitly recognized the pervasiveness of these arguments in the lower courts, and accordingly should have provided more detailed guidance to lower courts not only about how to carry out the patentable subject matter inquiry, but also about why and when § 101 is superior to other statutory provisions in doing so.

Justice Breyer's characterization of the government's position as a mere "invitation"[53] to consider patentable subject matter issues under §§ 102, 103, and 112 understated how prevalent such arguments have become. Indeed, the opinion lacked any reference to the numerous lower court decisions that have explicitly questioned whether subject matter eligibility arguments ought to be made at all, and if so, whether

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[49] *See, e.g.*, Diamond v. Diehr, 450 U.S. 175, 177 (1981); Parker v. Flook, 437 U.S. 584, 588 (1978); Gottschalk v. Benson, 409 U.S. 63, 64 n.2 (1972).

[50] *Prometheus*, 132 S. Ct. at 1304 ("[T]o shift the patent-eligibility inquiry entirely to these later sections risks creating significantly greater legal uncertainty . . . ."). Legal uncertainty is a sizable problem facing both inventors and companies investing in innovation, as they endeavor to avoid protracted legal battles. The Federal Circuit's refusal to defer to lower courts on critical matters such as claim construction contributes to the high degree of uncertainty in patent law. *See, e.g.*, Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) ("[T]he construction given [patent] claims is reviewed *de novo* on appeal."), *aff'd*, 517 U.S. 370 (1996).

[51] *Prometheus*, 132 S. Ct. at 1304.

[52] *Cf.* WildTangent, Inc. v. Ultramercial, LLC, 132 S. Ct. 2431 (2012) (granting certiorari, vacating, and remanding *Ultramercial, LLC v. Hulu, LLC*, 657 F.3d 1323 (Fed. Cir. 2011), in light of *Prometheus*); Ass'n for Molecular Pathology v. Myriad Genetics, Inc. (*AMP*), 132 S. Ct. 1794 (2012) (granting certiorari, vacating, and remanding *Association for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011), in light of *Prometheus*). The Court's clarification of its holding in *Bilski*, in particular, *see Prometheus*, 132 S. Ct. at 1303, may mollify those who felt that *Bilski* offered unclear guidance to lower courts. *See* CLS Bank Int'l v. Alice Corp., No. 2011-1301, 2012 WL 2708400, at *14 (Fed. Cir. July 9, 2012) (Prost, J., dissenting) (noting that in *Prometheus*, the Court "made clear what had been written between the lines before").

[53] *Prometheus*, 132 S. Ct. at 1304.

they ought to be made under § 101.[54] Beginning with Chief Judge Rader's additional opinion in *Classen Immunotherapies, Inc. v. Biogen IDEC*,[55] which derisively referred to patentable subject matter as the "'substantive due process' of patent law,"[56] Federal Circuit judges have repeatedly expressed concerns about the importance of § 101 and of the patentable subject matter inquiry more broadly.[57] Just a few weeks before the Court handed down *Prometheus*, the Federal Circuit incorporated this approach into the main holding of a case, bypassing § 101 in invalidating the claims at issue under §§ 102 and 103.[58] This analysis has even trickled down to the Board of Patent Appeals and Interferences, which recently refused to resolve a § 101 question, instead invalidating the claims as indefinite under § 112.[59] The choice between Patent Act provisions in the patentable subject matter context, therefore, is a growing trend in the lower courts and is in need of guidance beyond that provided in *Prometheus*.

Justice Breyer very clearly articulated why some type of patentable subject matter inquiry is needed within patent law, adverting to the policy concerns behind the patentable subject matter inquiry. In considering the potential preemption issues posed by Prometheus's and other similar patents, Justice Breyer expressed the concern that "patent law not inhibit further discovery by improperly tying up the future use

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[54] Instead, the opinion referenced only the government's brief and a set of law review articles by leading patent scholars. *Id.* at 1303–04. The opinion also neglected to mention a number of amicus briefs arguing that § 101 is inapposite to the analysis. *See, e.g.*, Brief for Amicus Curiae Novartis Corp. Supporting Respondent at 12, *Prometheus*, 132 S. Ct. 1289 (No. 10-1150) ("[T]o the extent a claim like the ones featured in *Prometheus* or *Lab. Corp.* raises concerns that a natural phenomenon itself is being wholly preempted . . . it should not be struck down under § 101. Rather, the appropriate section under which to test the patentability of such a claim is § 112 . . . .").

[55] 659 F.3d 1057 (Fed. Cir. 2011).

[56] *Id.* at 1073–74 (Rader, C.J., providing additional views) (stating that subject matter eligibility "has become the 'substantive due process' of patent law — except that reading non-procedural requirements into the constitutional word 'process' has more historical and contextual support than reading abstractness into the statutory word 'process'").

[57] *See, e.g.*, MySpace, Inc. v. GraphOn Corp., 672 F.3d 1250, 1260 (Fed. Cir. 2012) ("[C]ourts could avoid the swamp of verbiage that is § 101 by exercising their inherent power to control the processes of litigation and insist that litigants initially address patent invalidity issues in terms of the conditions of patentability defenses as the statute provides, specifically §§ 102, 103, and 112." (citation omitted)); Dealertrack, Inc. v. Huber, 674 F.3d 1315, 1335 (Fed. Cir. 2012) (Plager, J., concurring in part and dissenting in part) ("[T]his court should exercise its inherent power to control the processes of litigation and insist that litigants, and trial courts, initially address patent invalidity issues in infringement suits in terms of the defenses provided in the statute: 'conditions of patentability,' specifically §§ 102 and 103, and in addition §§ 112 and 251, and not foray into the jurisprudential morass of § 101 unless absolutely necessary." (footnote omitted) (citation omitted) (citing Chambers v. NASCO, Inc., 501 U.S. 32, 43 (1991))).

[58] *See MySpace*, 672 F.3d at 1261–62. While the § 101 issue was not raised by the parties in the appeal or in the lower court, Judge Mayer's dissent argued that § 101 was a threshold issue in the case and deserved attention. *Id.* at 1264 (Mayer, J., dissenting).

[59] Ex parte Adelman, No. 2010-011767, 2012 WL 750983, at *2, *4 (B.P.A.I. Mar. 2, 2012).

of laws of nature."[60] Perhaps the most succinct expression of this concern appears in his dissent from a dismissal of certiorari in *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*[61] (*LabCorp*): the central problem is that "sometimes *too much* patent protection can impede rather than 'promote the Progress of Science and useful Arts.'"[62] *LabCorp*, however, went on to disentangle this policy issue from those involved in other statutory provisions, noting that "[t]he justification for the principle does not lie in any claim that 'laws of nature' are obvious, or that their discovery is easy."[63]

Yet in *Prometheus*, Justice Breyer somewhat less clearly articulated why § 101 is the most suitable location for the patentable subject matter inquiry.[64] *Prometheus* did implicitly extend *LabCorp*'s analysis in its suggestion that §§ 102, 103, and 112 are "not equipped" to perform a patentable subject matter analysis,[65] and in its statement that § 112 in particular "does not focus on the possibility that a law of nature . . . that meets [the § 112 requirements] will nonetheless create the kind of risk that underlies the law of nature exception."[66] It also rejected the government's theory that §§ 102 and 103 might usurp the functions of § 101 and briefly distinguished the policy concerns behind § 112 from those behind § 101.[67] However, the opinion's analysis of this issue stopped there. It did not go on to argue clearly that each provision of the Patent Act is based upon different policy considerations, that the doctrinal inquiries conducted under each provision are anchored in those policy considerations, or that in selecting the proper statutory provision to use in analyzing a given claim, it is critical to ensure that the choice of doctrinal questions occasioned by the selection permits the court to reach the concern at issue.

Making this argument would have explained the way in which § 101 provides a superior avenue for patent-eligibility inquiries and when § 101, rather than another statutory provision, ought to be used.

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[60] *Prometheus*, 132 S. Ct. at 1301.

[61] 548 U.S. 124 (2006) (per curiam).

[62] *Id.* at 126 (Breyer, J., dissenting from dismissal of certiorari) (quoting U.S. CONST. art. I, § 8, cl. 8).

[63] *Id.* As previously noted, § 103 is the inquiry into obviousness, and while § 102 inquires into novelty, rather than ease per se, a driving policy concern behind § 102 is that patent protection is not needed for the invention or development of ideas that are already known. Similarly, the case for granting patent protection for inventions that would be relatively easy to develop may be quite weak. *See also* Transcript of Oral Argument, *supra* note 2, at 17 (noting that "discovering natural laws is often a very expensive process").

[64] Justice Breyer did very clearly state that refusing to conduct § 101 analyses would be contrary to existing case law, *Prometheus*, 132 S. Ct. at 1303, but the policy- and doctrine-based argument presented in this comment goes beyond this stare decisis concern.

[65] *Id.* at 1304.

[66] *Id.*

[67] *Id.*

Specifically, because § 101 is driven by concerns about overprotection and harms to follow-on innovation, the doctrinal questions asked under the § 101 inquiry do or should relate to these concerns.[68] And because §§ 102, 103, and 112 are not driven by follow-on innovation concerns,[69] the doctrinal questions asked under those statutory provisions do not relate to these concerns.[70] In many cases, these doctrinal questions not only will be poorly suited for but also will be incapable of resolving these problems.[71] An inventor who discovers a novel, nonobvious law of nature, and who in the patent specification sufficiently describes and enables its use, would be able to obtain a patent on that law of nature if not for § 101.[72] Since the doctrinal analyses considered under §§ 102, 103, and 112 are powerless to remedy concerns about preemption and the scope of follow-on innovation, § 101 alone can and must be used to address these issues.

This need for further clarity in *Prometheus* has already led to confusion in two post-*Prometheus* Federal Circuit opinions. Initially, the Federal Circuit handed down a partially encouraging[73] decision, *CLS*

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[68] *See* Eisenberg, *supra* note 3, at 61 ("[W]hile 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.").

[69] As noted, the desire to avoid granting patent protection for inventions needing only minimal investment for their creation, and thus not requiring the carrot of a patent to call them forth, underlies §§ 102 and 103. While the end result of applying the § 112 enablement and written description inquiries — narrowed claim scope — might seem related to overprotection concerns, § 112 is motivated by concerns about disclosure and ensuring that the scope of patent protection is commensurate with the inventor's contribution. *See* Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1070 (Fed. Cir. 2005) (noting that the purpose of the enablement requirement is "to extract meaningful disclosure of the invention and, by this disclosure, advance the technical arts"); Reiffin v. Microsoft Corp., 214 F.3d 1342, 1345 (Fed. Cir. 2000) (noting that the purpose of the written description requirement "is to ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art").

[70] *See, e.g.*, *In re* Fisher, 421 F.3d 1365, 1378 (Fed. Cir. 2005) (noting that the test for enablement is whether one skilled in the art would be able to use the invention); Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 923 (Fed. Cir. 2004) (noting that the written description requirement must be met so as to "describe the claimed invention so that one skilled in the art can recognize what is claimed" (quoting Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 968 (Fed. Cir. 2002)) (internal quotation marks omitted)).

[71] Although the opinion did acknowledge that §§ 102, 103, and 112 are "not equipped" to perform the tasks performed by § 101, the opinion did not discuss the doctrinal questions involved in these various provisions nor did it explain *how* §§ 102, 103, and 112 are incapable of remedying the concerns behind § 101. *See Prometheus*, 132 S. Ct. at 1304.

[72] *See* Eisenberg, *supra* note 3, at 56 ("[T]he patentable subject matter cases . . . 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.").

[73] The Federal Circuit's decision in the *AMP* case on remand was less encouraging, stating that "*Mayo* does not control the question of patent-eligibility of [isolated DNA] claims." Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, No. 10-1406, 2012 WL 3518509, at *15 (Fed. Cir. Aug. 16, 2012). The fact that the Supreme Court instructed the Federal Circuit to re-

Bank International v. Alice Corp.,[74] in which it held that a patent covering a "computerized trading platform" survived the machine-or-transformation test and therefore survived § 101.[75] In doing so, Judge Linn appeared to adopt at least some lessons from *Prometheus*, recognizing that §§ 101, 102, 103, and 112 each "serves a different purpose and plays a distinctly different role," and that therefore "invalidity, patentability, and patent eligibility challenges under these sections present distinctly different questions."[76] Unfortunately, the court did not clarify these respective "purposes" and "roles," and perhaps as a consequence thereof, the court drew yet another bright-line rule[77] out of *Prometheus*'s standard-based approach.[78] A more recent decision, however — *MagSil Corp. v. Hitachi Global Storage Technologies*[79] (*MagSil*) — suggests that the Federal Circuit has not adopted the lessons of *Prometheus*. In *MagSil*, Chief Judge Rader addressed the enablement requirement of § 112, stating that "[t]he enablement doctrine's prevention of over broad claims ensures that the patent system preserves necessary incentives for follow-on or improvement inventions."[80] Yet this stance contradicts Justice Breyer's explicit statement that § 112 does not address "the risk that a patent on the law [of

consider both *AMP* and *Ultramercial*, a case involving copyrighted content and the Internet, in light of *Prometheus* might indicate that it thought otherwise.

74 No. 2011-1301, 2012 WL 2708400 (Fed. Cir. July 9, 2012).

75 *Id.* at *1.

76 *Id.* at *6.

77 The Federal Circuit is known for its adoption of "bright-line rules that are insensitive both to technological fact and to related issues of innovation policy." Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1037 (2003). One example is its pre-*Bilski* insistence on the status of the machine-or-transformation test as the definitive inquiry for patent eligibility. Prometheus Labs., Inc. v. Mayo Collaborative Servs., 581 F.3d 1336, 1342 (Fed. Cir. 2009). Yet even after *Bilski* deemed the test merely "useful," 130 S. Ct. 3218, 3226 (2010), the Federal Circuit saw little reason to apply a complex standard, albeit one more consistent with policy, where it could more easily apply a rule. *See* Prometheus Labs., Inc. v. Mayo Collaborative Servs., 628 F.3d 1347, 1355 (Fed. Cir. 2010). The Federal Circuit's objections to § 101 may even be an artifact of its own use of bright-line rules. Classen Immunotherapies, Inc. v. Biogen IDEC, 659 F.3d 1057, 1074 (Fed. Cir. 2011) (Rader, C.J., providing additional views) (noting that § 101 "excludes entire areas of human inventiveness . . . on the basis of judge-created standards"). That is, Chief Judge Rader identified "claim drafting evasion" as a primary unintended consequence of — and thus a reason to eliminate — patentable subject matter analysis under § 101. *Id.* But the Federal Circuit itself created the market for claim drafting evasion, as its penchant for bright-line rules led it to shoehorn cases into rigid frameworks and incentivize the development of new claim forms to evade its restrictions. Chief Judge Rader's *Classen* opinion even identifies two such forms. *Id.*

78 *CLS Bank*, 2012 WL 2708400, at *10. In a scathing dissent, Judge Prost responded that the majority had "resurrected the very approach to § 101 that the Solicitor General advocated — and the Supreme Court laid to rest — in *Prometheus*," *id.* at *15 (Prost, J., dissenting), and that the majority "ha[d] failed to follow the Supreme Court's instructions — not just in its holding, but more importantly in its approach," *id.* at *14.

79 No. 2011-1221, 2012 WL 3289973 (Fed. Cir. Aug. 14, 2012).

80 *Id.* at *6.

nature] would significantly impede future innovation."[81] If the Federal Circuit has yet to adopt even the explicit content of Justice Breyer's opinion, it almost certainly has not adopted the opinion's more implicit lessons. A clearer discussion in *Prometheus* of the policy roles of the various provisions might have helped the Federal Circuit break free of its continuing fascination with rigid bright-line rules.[82]

In short, the Court should have recognized the increasing frequency with which courts have begun debating the appropriateness of various statutory provisions for the patentable subject matter analysis and subsequently considered the reasons behind these arguments. Doing so would likely have resulted in an opinion that provided more guidance to the Federal Circuit as it insists on maintaining its stable of bright-line rules, even in the face of repeated reversals from the Supreme Court.[83] Without this guidance, the Federal Circuit is not likely to give Justice Breyer's opinion the appropriate level of consideration, setting the stage for an appeal of yet another § 101 case.

B. Fair Labor Standards Act of 1938

Auer *Deference.* — The allocation of interpretive authority between courts and administrative agencies is one of the central difficulties in administrative law. *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*[1] established that agencies, rather than courts, have the primary role in determining the meaning of the statutes they administer.[2] Long before *Chevron*, the Supreme Court in *Bowles v. Seminole Rock & Sand Co.*[3] also made agencies the primary interpreters of their own regulations.[4] The Supreme Court recently reaffirmed *Seminole Rock* in *Auer v. Robbins*.[5] Like *Chevron* deference, which requires courts to defer to reasonable agency interpretations of ambiguous statutes,[6] *Auer* deference, as this flavor of deference has come to be known, obliges courts to give controlling

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[81] *Prometheus*, 132 S. Ct. at 1304.

[82] Concededly, this fascination is not an unqualified evil. *See* John R. Thomas, *Formalism at the Federal Circuit*, 52 AM. U. L. REV. 771, 810 (2003) ("As we assess the court's movement into adjudicative rules formalism, we would do well to remember that the goals of certainty and predictability rank high among the list of legal aspirations.").

[83] *See, e.g.*, *Prometheus*, 132 S. Ct. at 1296; eBay, Inc. v. MercExchange, LLC, 547 U.S. 388, 391 (2006) (rejecting the Federal Circuit's de facto policy of granting injunctions upon request rather than applying the traditional four-factor test established in equity, as the test applies "with equal force to disputes arising under the Patent Act").

[1] 467 U.S. 837 (1984).

[2] *Id.* at 843.

[3] 325 U.S. 410 (1945).

[4] *Id.* at 414.

[5] 519 U.S. 452, 461 (1997).

[6] *See Chevron*, 467 U.S. at 843.