PATENT LAW — PATENTABLE SUBJECT MATTER — FEDERAL CIRCUIT INVALIDATES DIAGNOSTIC METHOD CLAIMS AS DRAWN TO "ABSTRACT MENTAL PROCESSES." — *Association for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011).

Courts and scholars have recently debated whether to offer patent protection to diagnostic methods, and if so, how much protection to give.[1] While granting patents can incentivize costly research, overprotection may discourage follow-on innovation and negatively impact patient care.[2] Recently, in *Association for Molecular Pathology v. U.S. Patent & Trademark Office*,[3] the Federal Circuit held that gene sequences are patentable subject matter under 35 U.S.C. § 101,[4] but that diagnostic method claims drawn to "abstract mental processes" are not patent eligible under § 101.[5] Yet the Federal Circuit failed to articulate a reason for characterizing the diagnostic method claims at issue under the "mental process" exception to § 101 rather than under the "abstract idea" or "natural phenomenon" exceptions. While the Federal Circuit invalidated these particular claims, the court's analysis may make it easier to patent diagnostic methods in the future, a potential consequence the court did not acknowledge.

On May 12, 2009, the Association for Molecular Pathology, physicians, researchers, genetic counselors, and patients brought suit in the Southern District of New York against the United States Patent and Trademark Office (PTO) and Myriad Genetics (Myriad).[6] The plaintiffs sought a declaratory judgment of invalidity on fifteen claims from seven of Myriad's patents, arguing that the claims in suit failed to qualify as patentable subject matter under § 101.[7] The seven challenged patents related to the BRCA genes, mutations in which "correlate with an increased risk of breast and ovarian cancer."[8] Of the fif-

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[1] *See, e.g.*, Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 126 (2006) (Breyer, J., dissenting from dismissal of certiorari); Rochelle C. Dreyfuss & James P. Evans, *From* Bilski *Back to* Benson*: Preemption, Inventing Around, and the Case of Genetic Diagnostics*, 63 STAN. L. REV. 1349, 1353–61 (2011).

[2] *See* Joshua D. Sarnoff, *Patent Eligible Medical and Biotechnology Inventions After* Bilski*,* Prometheus*, and* Myriad, 19 TEX. INTELL. PROP. L.J. 393, 417–18 (2011).

[3] 653 F.3d 1329 (Fed. Cir. 2011).

[4] The statute provides that "[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." 35 U.S.C. § 101 (2006).

[5] *Ass'n for Molecular Pathology*, 653 F.3d at 1334, 1355.

[6] Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 186–89 (S.D.N.Y. 2010).

[7] *Id.* at 184.

[8] *Id.* at 203.

teen challenged claims, nine were composition claims covering DNA sequences, and six were method claims, five covering methods of comparing or analyzing DNA sequences to detect mutations and one covering a method of screening potential cancer therapeutics.[9]

Judge Sweet held that all of Myriad's myriad claims were invalid under § 101.[10] Regarding the nine composition claims, he noted that the isolated DNA claimed therein must possess "markedly different characteristics" from DNA occurring in nature in order to be patent eligible.[11] Yet because DNA's "unique characteristics" — most saliently, that DNA is a "physical embodiment of information" — are present in both isolated and cellular DNA, he concluded that the nine composition claims were "directed to unpatentable products of nature."[12] Judge Sweet then held that the six method claims were invalid under the "machine or transformation" test.[13] He concluded that the five claims directed to methods of "comparing" or "analyzing" DNA sequences to identify BRCA mutations[14] were invalid under § 101 because they were "directed only to . . . abstract mental processes."[15] He also invalidated the single claim for identifying potential cancer therapeutics, noting that the claim "seeks to patent a basic scientific principle," and therefore is not patentable under § 101.[16]

The Federal Circuit affirmed in part and reversed in part.[17] Writ-

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[9] *See id.* at 211–14.

[10] *Id.* at 185.

[11] *Id.* at 223 (quoting Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980)).

[12] *Id.* at 228–29.

[13] *Id.* at 236–37. Since the district court issued its opinion, the Supreme Court has ruled that this test is a "useful and important clue" for determining the patentability of claimed methods, although it is not the only available test. Bilski v. Kappos, 130 S. Ct. 3218, 3227 (2010). Under the 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." *Id.* at 3224 (quoting *In re* Bilski, 545 F.3d 943, 954 (Fed. Cir. 2008) (en banc)) (internal quotation mark omitted). Patent law jurisprudence has placed additional limitations on this test — for instance, "the involvement of the machine or transformation in the claimed process must not merely be insignificant extra-solution activity," *Bilski*, 545 F.3d at 962 (citing Parker v. Flook, 437 U.S. 584, 590 (1978)). Courts commonly cite three Supreme Court cases for these various limitations: *Gottschalk v. Benson*, 409 U.S. 63 (1972), *Parker v. Flook*, 437 U.S. 584, and *Diamond v. Diehr*, 450 U.S. 175 (1981). *See, e.g.*, *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 218–19.

[14] A representative example is claim 1 of U.S. patent 5,709,999, the relevant portions of which claim "[a] method for detecting a germline alteration in a BRCA1 gene . . . which comprises analyzing a sequence of a BRCA1 gene or BRCA1 RNA from a human sample or analyzing a sequence of BRCA1 cDNA made from mRNA from said human sample." *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 213.

[15] *Id.* at 234.

[16] *Id.* at 237.

[17] *Ass'n for Molecular Pathology*, 653 F.3d at 1333–34. Before reaching the merits, Judge Lourie affirmed the district court's decision regarding standing, albeit on narrower grounds. *Id.* at 1348. The district court incorrectly held that all the plaintiffs had standing to sue, but Judge Lourie found that one plaintiff, Dr. Harry Ostrer, possessed standing under the "all-the-circumstances" declaratory judgment jurisdiction test announced by the Supreme Court in *Med-*

ing for the panel, Judge Lourie[18] affirmed the district court regarding Myriad's five method claims drawn to "comparing" or "analyzing" gene sequences, holding that they "claim only abstract mental processes" and are therefore unpatentable.[19] After noting that "[p]henomena of nature, . . . mental processes, and abstract intellectual concepts are not patentable,"[20] the Federal Circuit reasoned to its conclusion through detailed comparisons to its recent decision in *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*,[21] in which it held that a method for calibrating drug dosages was patent eligible under § 101.[22] While the method claims at issue in *Prometheus* explicitly included transformative steps such as "administering" a drug and "determining" that drug's metabolite levels in a patient, the court held that Myriad's claims included no such transformative steps and denied Myriad's attempts to read such steps into the claims.[23] Yet regarding the method claim for screening cancer therapeutics, the Federal Circuit reversed the district court. Reasoning that the steps of "growing" cells and "determining" their growth rates were both transformative and "central to the purpose of the claimed process," the court held that this claim was drawn to patent-eligible subject matter under § 101.[24]

The Federal Circuit reversed regarding the nine composition claims. Judge Lourie held that all the isolated DNA claims were patent eligible under § 101.[25] He argued that isolated DNA is "markedly

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Immune, Inc. v. Genentech, Inc., 549 U.S. 118, 127 (2007). *See Ass'n for Molecular Pathology*, 653 F.3d at 1343–48. Myriad had directed "affirmative patent enforcement actions" toward Dr. Ostrer, *id.* at 1344, and Dr. Ostrer had stated "unequivocally that he [would] immediately begin [BRCA] testing" if the court invalidated the claims in suit, *id.* at 1346.

18 Judge Lourie was joined on the standing, method claim patentability, and cDNA patentability issues by Judge Bryson and Judge Moore. Judge Moore concurred in the judgment regarding the remaining claims on DNA sequences but wrote separately to provide different reasons. Judge Bryson dissented with respect to those remaining claims.

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

20 *Id.* at 1355–56 (quoting Gottschalk v. Benson, 409 U.S. 63, 67 (1972)) (internal quotation mark omitted).

21 628 F.3d 1347 (Fed. Cir. 2010), *cert. granted*, 131 S. Ct. 3027 (June 20, 2011).

22 *See Ass'n for Molecular Pathology*, 653 F.3d at 1357; *see also Prometheus*, 628 F.3d at 1359.

23 *Ass'n for Molecular Pathology*, 653 F.3d at 1357 (quoting *Prometheus*, 628 F.3d at 1350). For instance, Myriad argued that "comparing" gene sequences required determining the sequences first. *See id.* at 1356. The Federal Circuit's rejection of this argument on narrow doctrinal grounds is unsurprising, as the court has long preferred crystalline rules to muddy standards. *See, e.g.*, Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1037 (2003) (noting that the Federal Circuit has a history of adopting "bright-line rules that are insensitive both to technological fact and to related issues of innovation policy"). Many scholars have criticized this tendency. *See, e.g.*, John F. Duffy, *Rules and Standards on the Forefront of Patentability*, 51 WM. & MARY L. REV. 609, 614 (2009) ("Eventually, rules always fail. . . . [S]tandards [are] more durable than rules when conditions are changing, and innovation presents a quintessential circumstance of change.").

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

25 *Id.* at 1350.

different . . . from molecules that exist in nature" because DNA molecules within cells are covalently bonded to other DNA molecules.[26] "Thus, when cleaved, an isolated DNA molecule is not a purified form of a natural material, but a distinct chemical entity."[27] Judge Lourie also noted that this holding "comports with the longstanding practice of the PTO," and that if "DNA inventions" are to be "excluded from the broad scope of § 101 contrary to the settled expectation of the inventing community, the decision must come . . . from Congress."[28]

Judge Moore joined Judge Lourie's opinion regarding the cDNA[29] claims and concurred in the judgment regarding the remaining composition claims, but she wrote separately to explain her reasons.[30] She first rejected the district court's holding that the cDNA claims fall within the "laws-of-nature" exception for a simple reason: "cDNA sequences do not exist in nature."[31] She then went on to discuss Myriad's claims drawn to sequences that do appear in nature, explaining that these claims cover both short and long DNA fragments.[32] Ultimately, she appealed to the PTO's history of granting patents on isolated DNA, the "settled expectations of the biotechnology industry," and the Supreme Court's deference to such expectations to conclude that long DNA fragments are also patent eligible under § 101.[33]

Judge Bryson dissented regarding the gene fragment claims.[34] First, he rejected the majority's theory about the importance of covalent bonds, finding the claimed fragments unpatentable because they are "the same, structurally and functionally, in both the native gene and the isolated . . . gene."[35] Second, he expressed concerns about the potential negative ramifications of such patents on the progress of biotechnology, noting that "[b]road claims to genetic material present a significant obstacle to the next generation of innovation in genetic medicine — multiplex tests and whole-genome sequencing."[36] Finally,

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[26] *Id.* at 1351.

[27] *Id.* at 1352.

[28] *Id.* at 1354–55.

[29] Complementary DNA, or cDNA, is a double-stranded DNA molecule containing only the coding portions of a gene, the non-coding introns having been excised during the conversion to mRNA. Therefore, cDNA sequences differ from the DNA sequences naturally found in the human body. *See id.* at 1339.

[30] *Id.* at 1358 (Moore, J., concurring in part and concurring in the judgment).

[31] *Id.* at 1364.

[32] *See id.* at 1365.

[33] *Id.* at 1368. In *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), the Supreme Court noted that "courts must be cautious before adopting changes that disrupt the settled expectations of the inventing community." *Id.* at 739.

[34] *Ass'n for Molecular Pathology*, 653 F.3d at 1373 (Bryson, J., concurring in part and dissenting in part).

[35] *Id.* at 1378.

[36] *Id.* at 1379–80.

he dismissed his fellow panel members' institutional deference arguments, noting that "the PTO lacks substantive rulemaking authority as to issues such as patentability" and thus should not receive deference.[37]

While the popular press has fixated on the gene patent claims,[38] diagnostic method claims[39] are both proliferating and becoming increasingly relevant to patient care.[40] *Association for Molecular Pathology* is one of the first cases to confront the patent eligibility of such methods, and it is also the first case to contravene the Supreme Court's opinion in *Bilski v. Kappos*,[41] which warned against categorical rules regarding patent eligibility.[42] Further, this case marks a revival of the rarely used "mental steps" doctrine.[43]

Yet in these remarkable circumstances, the Federal Circuit neglected to articulate its reasoning for holding that the diagnostic method claims in suit were drawn to "mental processes"[44] rather than "natural phenomena" or "abstract ideas," even though past § 101 jurisprudence suggests that it would have also been reasonable to label them as such.[45] Even ignoring the plaintiffs' arguments,[46] the Federal Circuit could have proceeded as it did in *Prometheus*, in which it held that the method claims at issue were "application[s] of a natural phenomenon."[47] Alternatively, the court could have looked to *Bilski*, in

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[37] *Id.* at 1380. For a scholarly discussion of this issue, see Michael J. Burstein, *Rules for Patents*, 52 WM. & MARY L. REV. 1747, 1751 (2011), which argues that the PTO ought to possess substantive rulemaking authority.

[38] *See, e.g.*, Jess Bravin, *In Reversal, Court Rules Human Gene Can Be Patented*, WALL ST. J., July 30, 2011, at B4; Andrew Pollack, *Ruling Upholds Gene Patent in Cancer Test*, N.Y. TIMES, July 30, 2011, at B1.

[39] Diagnostic method claims can be conceived of in broad terms. For instance, the methods in this case for determining the existence of BRCA mutations and the methods in *Prometheus* for calibrating optimal drug dosages both qualify as diagnostic methods.

[40] *See* Robert Cook-Deegan et al., *The Dangers of Diagnostic Monopolies*, 458 NATURE 405, 405 (2009); Aaron S. Kesselheim & Michelle M. Mello, *Medical-Process Patents — Monopolizing the Delivery of Health Care*, 355 NEW ENG. J. MED. 2036, 2036 (2006).

[41] 130 S. Ct. 3218 (2010).

[42] *See id.* at 3229 (resolving the case narrowly and warning against "adopting categorical rules that might have wide-ranging and unforeseen impacts").

[43] *See* Kevin Emerson Collins, *Semiotics 101: Taking the Printed Matter Doctrine Seriously*, 85 IND. L.J. 1379, 1387 n.38 (2010) ("[T]he courts . . . abandoned the mental steps doctrine during their struggle with the patent eligibility of computer software and programmed computers." (citing *In re* Musgrave, 431 F.2d 882, 890 (C.C.P.A. 1970))).

[44] *Ass'n for Molecular Pathology*, 653 F.3d at 1355.

[45] The Federal Circuit has never articulated a test for choosing among these exceptions.

[46] The plaintiffs argued that the claims in suit encompassed "the *abstract idea* of comparing one sequence to a reference sequence and preempt[ed] a *phenomenon of nature* — the correlation of genetic mutations with a predisposition to cancer." *Ass'n for Molecular Pathology*, 653 F.3d at 1355 (emphases added).

[47] Prometheus Labs., Inc. v. Mayo Collaborative Servs., 628 F.3d 1347, 1355 (Fed. Cir. 2010), *cert. granted*, 131 S. Ct. 3027 (June 20, 2011). While it is not binding precedent, Justice Breyer's opinion in *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, 548 U.S. 124 (2006) (per curiam), would have invalidated the claims at issue there on the grounds that they

which the Supreme Court held that the business method claim at issue was an "unpatentable abstract idea."[48] Another diagnostic method case, *Classen Immunotherapies, Inc. v. Biogen IDEC*,[49] has since been decided under the abstract idea framework, as well.[50] The court could have analyzed the claims in suit under one of these exceptions by reading into the claim the transformative step of determining the DNA sequence involved, an interpretation that was certainly open to it.[51]

When the Federal Circuit labels claims as being drawn to "abstract ideas" or "natural phenomena," it conducts a standard-based inquiry[52] that is difficult for patentees to draft around. While natural phenomena and abstract ideas themselves are not patent eligible, their applications "to a known structure or process" may be.[53] Yet as "[t]he line between a patentable 'process' and an unpatentable 'principle' is not always clear,"[54] the court must apply the tests articulated in *Gottschalk v. Benson*,[55] *Parker v. Flook*,[56] and *Diamond v. Diehr*[57] to determine whether the claim limitations are sufficient to eliminate the § 101 concern.[58] In cases like these, the claims involved "must be considered as a whole,"[59] and "the scope asserted by the patentee must be considered."[60] Because this analysis seeks to determine whether the claimed method preempts all possible uses of the recited natural phenomenon or abstract idea, it is difficult to draft around, although as a

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"amount[ed] to an invalid effort to patent a 'phenomenon of nature.'" *Id.* at 134 (Breyer, J., dissenting from dismissal of certiorari).

48 Bilski v. Kappos, 130 S. Ct. 3218, 3231 (2010).

49 Nos. 2006-1634, 2006-1649, 2011 WL 3835409 (Fed. Cir. Aug. 31, 2011).

50 *Id.* at *10 (holding that a diagnostic method claim did not "transcend[] an 'abstract idea'" and therefore failed under the "coarse filter of § 101").

51 To give one example of how the court might have proceeded, the claim at issue refers only to a "sequence," which the court interpreted as "nucleotide sequence." *See Ass'n for Molecular Pathology*, 653 F.3d at 1356. Yet because the term "nucleotide sequence" appears in the patent specification, *id.*, it might be argued under traditional doctrines of claim differentiation that Myriad intended "sequence" to mean something broader than "nucleotide sequence." *But see* Dan L. Burk & Mark A. Lemley, *Fence Posts or Sign Posts? Rethinking Patent Claim Construction*, 157 U. PA. L. REV. 1743, 1753–54 (2009).

52 Justice Breyer's dissent from a dismissal of certiorari in *Lab. Corp.* also applies a standard-based test. *See* 548 U.S. at 137–38 (Breyer, J., dissenting from dismissal of certiorari); *see also* Duffy, *supra* note 23, at 639.

53 Diamond v. Diehr, 450 U.S. 175, 187 (1981).

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

55 409 U.S. 63 (1972).

56 437 U.S. 584.

57 450 U.S. 175.

58 *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 218–19 (S.D.N.Y. 2010).

59 Prometheus Labs., Inc. v. Mayo Collaborative Servs., 628 F.3d 1347, 1354 (Fed. Cir. 2010), *cert. granted*, 131 S. Ct. 3027 (June 20, 2011).

60 Classen Immunotherapies, Inc. v. Biogen IDEC, Nos. 2006-1634, 2006-1649, 2011 WL 3835409, at *10 (Fed. Cir. Aug. 31, 2011).

downside it does entail the higher administrative costs traditionally associated with standards as opposed to rules.[61]

The patent-eligibility bar for mental processes, however, is more easily surpassed than that for natural phenomena or abstract ideas. In this case, the Federal Circuit appears to have created a relatively clear rule: claims that are drawn only to mental processes are not patent eligible, but any additional elements will render the entire claim patent eligible. In *Prometheus*, the Federal Circuit held that the portions of the claims in suit directed to mental steps were not themselves patent eligible, but the "administering" and "determining" portions of the claims were sufficiently transformative and central to the claimed process to preserve the patent eligibility of the claim as a whole.[62] Drawing an analogy to *Prometheus*, the panel in this case strongly implied that, had Myriad explicitly included the step of "determining" the BRCA sequences in its claims, they would have likely been patentable.[63] Yet in the absence of any such step, the court merely asked whether the claim contained any steps occurring in the physical world, and given that answer, whether the claim satisfied the machine-or-transformation test.[64] The court did not use either of these inquiries to ask broader questions about the scope of the patent claim or to consider the possibility that such a claim could preempt the entire field. Thus, this analysis is far narrower than that employed in cases like *Prometheus* and *Classen*.

This "mental process" patentability rule for diagnostic method claims may expand the scope of patentable subject matter in this area due to its effects on claim drafting, rendering the "mental process" ex-

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[61] *See generally* Isaac Ehrlich & Richard A. Posner, *An Economic Analysis of Legal Rulemaking*, 3 J. LEGAL STUD. 257 (1974); Louis Kaplow, *Rules Versus Standards: An Economic Analysis*, 42 DUKE L.J. 557 (1992).

[62] 628 F.3d at 1358.

[63] *See Ass'n for Molecular Pathology*, 653 F.3d at 1356 (noting that extracting and sequencing DNA would constitute "additional, transformative steps"). Inserting such a step would likely narrow the claim's scope very little, if at all, as this step was already implicit in the claim. Brian Murphy and Daniel Murphy have called this approach the "determine-and-infer template," such that claims constructed accordingly should withstand scrutiny under the machine-or-transformation test. Brian P. Murphy & Daniel P. Murphy, Bilski*'s "Machine-or-Transformation" Test: Uncertain Prognosis for Diagnostic Methods and Personalized Medicine Patents*, 20 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 755, 777 (2010).

While the court might avoid this result by reconsidering cleverly drafted claims under the abstract idea or natural phenomenon exceptions, this case did not acknowledge that these exceptions could conceivably be in play, even though the plaintiffs explicitly prompted the court to do so. *See supra* note 46. Chief Judge Rader also failed to mention this possibility in his *Classen* opinion, in which he explicitly acknowledged the potential for claim-drafting workarounds. *See* 2011 WL 3835409, at *16 (Rader, C.J., additional views). These two cases suggest that the inclusion of transformative steps in a "mental process" claim is likely to be dispositive and that the court would be unlikely to conduct additional standard-based analyses.

[64] *See Ass'n for Molecular Pathology*, 653 F.3d at 1355–57.

ception toothless. Because rule-like § 101 exceptions "exalt[] form over substance," "competent draftsm[e]n" quickly learn to draft claims that satisfy these rules and pass the § 101 barrier without narrowing claim scope.[65] The Supreme Court,[66] other Federal Circuit judges,[67] and scholars[68] have all acknowledged the potential for such a result, and the panel here should have done so as well, openly confronting the choice between the § 101 exceptions in light of innovation policy considerations.[69] This analysis, like that in Justice Breyer's *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*[70] dissent,[71] would consider questions such as whether patent protection is necessary to incentivize research in the field in question,[72] as well as what effect granting such patents could have on follow-on innovation.[73]

In this case, the Federal Circuit should have openly addressed the likely consequences of imposing a rigid rule. As a specialty appellate court, the need for the Federal Circuit to express its conclusions clearly and anticipate potential negative effects of its decisions is particularly acute, since only the Supreme Court can constrain its decisionmaking and no peer courts exist to help it reconsider its holdings. Due to the importance of diagnostic method patents for both research and patient care, the Supreme Court's review of *Prometheus* this Term[74] will hopefully bring much-needed clarity to this area of patent law.

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[65] Parker v. Flook, 437 U.S. 584, 590 (1978). This observation is perhaps counterintuitive, given that traditional rules-versus-standards analysis as applied to § 101 has tended to criticize rules creating categorical exclusions from patentability as overinclusive. *See* Tun-Jen Chiang, *The Rules and Standards of Patentable Subject Matter*, 2010 WIS. L. REV. 1353, 1382–85.

[66] *See Flook*, 437 U.S. at 590.

[67] *See, e.g.*, *Classen*, 2011 WL 3835409, at *16 (Rader, C.J., additional views) (noting that § 101 restrictions may "engender a healthy dose of claim-drafting ingenuity" and that "[w]hen careful claim drafting . . . avoid[s] eligibility restrictions, the doctrine becomes very hollow").

[68] *See, e.g.*, Chiang, *supra* note 65, at 1411 ("[T]he more rigidly a category is defined, the easier it would be to evade the rule through clever claim drafting.").

[69] *But see* Michael Risch, *Everything Is Patentable*, 75 TENN. L. REV. 591 (2008) (arguing that § 101 jurisprudence is inconsistent and that its nonstatutory exceptions should be implemented through the other statutory patentability requirements, such as novelty and nonobviousness).

[70] 548 U.S. 124 (2006) (per curiam).

[71] *See id.* at 126 (Breyer, J., dissenting from dismissal of certiorari) ("[S]ometimes *too much* patent protection can impede rather than 'promote the Progress of Science and the useful Arts.'" (quoting U.S. CONST. art. I, § 8, cl. 8)). The Federal Circuit's paucity of citations to *Lab. Corp.* is emblematic of its refusal to engage with the policy arguments on this issue. *See* Rochelle Cooper Dreyfuss, *The Federal Circuit as an Institution: What Ought We to Expect?*, 43 LOY. L.A. L. REV. 827, 840–41 (2010). The merits briefs in *Prometheus* have dealt with these policy issues as well. *See, e.g.*, Brief for Petitioners at 48–58, Mayo Collaborative Servs. v. Prometheus Labs., Inc., No. 10-1150 (U.S. Sept. 2, 2011).

[72] *See* Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 508 (2009).

[73] *See* Kesselheim & Mello, *supra* note 40, at 2039.

[74] *See* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 131 S. Ct. 3027, 3027 (2011) (granting certiorari).