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MODERATING *MAYO*[†]

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ABSTRACT—The Supreme Court's latest pronouncements on patentable subject matter in *Mayo v. Prometheus* have already created a firestorm of controversy. The Court found that various limitations did not add enough to the law of nature that lies at the heart of Prometheus' medical diagnostic patents to render the claims patent eligible. Because the Supreme Court never explained what "enough" is, critics have been quick to deride *Mayo* and warn that it would radically limit patent eligibility in a wide-ranging number of industries. Although I agree with the ultimate result reached by the Supreme Court, I am also concerned that its reasoning unnecessarily jeopardizes too many deserving patents. But the decision does not have to create the havoc that so many fear. There is room for a more restrained understanding of *Mayo*.

This Essay offers a moderate interpretation of *Mayo* by building on recent efforts to revive the out-of-favor "point-of- novelty" analysis. For years, patent law has refused to consider an invention's point of novelty in its decisionmaking. In other words, the law does not attribute any special significance to a subset of claim limitations regardless of how important those limitations are to the invention; patent law treats all the limitations as equally important. However, it makes no sense for patent law to take such a formalistic approach and ignore the fundamental idea underlying a patent's invention. Fortunately, the *Mayo* decision implicitly adopts some point-of-novelty thinking. This Essay builds on these ideas to develop a fuller point-of-novelty framework that explains when a claim has added enough to an unpatentable concept to make it patent eligible. By applying this approach to both Prometheus' claims and a hypothetical claim that Prometheus could have drafted, this Essay explains how *Mayo* can be interpreted as only a modest rejection of a particular type of abstract claim.

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INTRODUCTION

Patent law has long held that laws of nature, natural phenomena, and abstract ideas are not patentable. At the same time, many patents cover applications that grow out of these fundamental concepts. Courts have recognized that such applications are patentable. Observers had hoped that the Supreme Court's decision in *Mayo v. Prometheus* would illuminate the line between unpatentable concepts and patentable applications of those concepts. Unfortunately, the recent decision issued by the Supreme Court raises more questions than it answers.[1] Although the Court gave a variety of reasons to explain why Prometheus Laboratories' (Prometheus) patents were not patent eligible, the Court's primary rationale involved dissecting Prometheus' claim. The Court found that the limitations did not add "enough" to the law of nature that lies at the heart of Prometheus' invention.

Because the Court never explained what "enough" is, critics have been quick to deride *Mayo*.[2] One commentator went so far as to say that the decision "creates a framework for patent eligibility in which almost any

[1] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012).

[2] Michael Risch, *Patentable Subject Matter, the Supreme Court, and Me*, MADISONIAN.NET (Mar. 20, 2012), http://madisonian.net/2012/03/20/patentable-subject-matter-the-supreme-court-and-me/ (complaining about how difficult it will be to determine what detail needs to be added); *see also* Ryan Chirnomas, *Supreme Court Strikes Down Diagnostic Method Claims as Non-Patent-Eligible Subject Matter*, CAFC BLOG (Mar. 20, 2012), http://whda.com/cafc/2012/03/20/supreme-court-strikes-down-diagnostic-method-claims-as-non-patent-eligible-subject-matter/ ("[T]his decision is deeply disturbing to many patent practitioners as well as those in the diagnostics industry."); Gene Quinn, *Killing Industry: The Supreme Court Blows* Mayo v. Prometheus, IPWATCHDOG (Mar. 20, 2012, 1:44 PM), http://www.ipwatchdog.com/2012/03/20/supreme-court-mayo-v-prometheus/id=22920/ ("The sky is falling! . . . Those in the biotech, medical diagnostics and pharmaceutical industries have just been taken out behind the woodshed and summarily executed . . . .").

method claim can be invalidated."[3] Although I agree with the Supreme Court's ultimate decision, I am also concerned that its reasoning unnecessarily jeopardizes many deserving patents that have not previously been thought to have any vulnerability under 35 U.S.C. § 101—the federal patent statute that defines what types of subject matter may be patented.[4] By failing to provide a framework for determining when additional limitations can change an unpatentable concept into a patentable application, the Supreme Court has cast doubt on a host of less controversial patents. But the decision does not have to wreak the havoc that many fear it will. There is room for a more restrained understanding of *Mayo*.

This Essay rehabilitates the decision in *Mayo* by building on recent efforts to revive the out-of-favor "point-of-novelty" analysis. A patent's point of novelty is the claim limitation or limitations that correspond to the heart or gist of the invention.[5] For years, patent law has refused to consider an invention's point of novelty in its decisionmaking. In other words, the law does not attribute any special significance to a subset of claim limitations regardless of how important those limitations are to the invention; patent law treats all limitations as equally important. Recently, Professor Mark Lemley and I have separately criticized the failure to consider the point of novelty in a wide-ranging number of doctrines.[6] Lemley succinctly summarized the problem in the *Northwestern University Law Review* when he asserted that "[i]t makes little sense for a law focused on invention to pay no attention to what is inventive about the patentee's technology."[7]

Interestingly, the *Mayo* decision implicitly uses point-of-novelty thinking, but its ideas are underdeveloped. This Essay relies on the Court's ideas to create a fuller point-of-novelty framework for patentable subject matter. This framework creates a clearer boundary that separates claims that cover unpatentable concepts—like Prometheus' claim—from claims directed at patentable applications of those concepts. Under such a

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[3] Robert R. Sachs, *Punishing Prometheus: The Supreme Court's Blunders in* Mayo v. Prometheus, PATENTLY-O (Mar. 26, 2012, 9:10 AM), http://www.patentlyo.com/patent/2012/03/punishing-prometheus-the-supreme-courts-blunders-in-mayo-v-prometheus.html. *But see* Chris Holman, Mayo v. Prometheus*: Analysis and Implications of an Important Supreme Court Decision*, HOLMAN'S BIOTECH IP BLOG (Mar. 21, 2012, 5:20 PM), http://holmansbiotechipblog.blogspot.co.uk/2012/03/prometheus-v-mayo-analysis-and.html ("[I]mplemented literally, [the *Mayo* decision] would seem to deny patent protection to much of biotechnology . . . . However, I think in practice the lower courts will attempt to limit the impact of the decision, and find ways to maintain patent eligibility for drug methods of treatment . . . .").

[4] 35 U.S.C. § 101 (2006).

[5] A patent's claims define the scope of the patentee's property rights. Each claim is made up of a number of separate limitations. To fall within a claim, each of those limitations must be present.

[6] *See* Bernard Chao, *Breaking* Aro*'s Commandment: Recognizing that Inventions Have Heart*, 20 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1183 (2010); Mark A. Lemley, *Point of Novelty*, 105 NW. U. L. REV. 1253 (2011).

[7] Lemley, *supra* note 6, at 1274–75.

framework, courts would first examine the limitation that embodies the point of novelty to determine whether it describes an unpatentable concept. If it does, the law should then determine whether the other limitations can bring the principle into the realm of patentable subject matter. That occurs when the other limitations are both concrete and strongly connected to the point of novelty. However, if the other limitations do not satisfy these requirements, the claim is not patent eligible.

Finally, this Essay applies the proposed framework to Prometheus' claims and confirms that they are not patent eligible. It then applies the same approach to a claim that Prometheus could have drafted. Under the point-of-novelty analysis, this hypothetical claim turns out to be patentable. This result demonstrates how *Mayo* can be interpreted and applied in the future as only a modest rejection of a particular type of abstract claim.

I. THE TENSION IN PATENTABLE SUBJECT MATTER

Section 101 of the Patent Act broadly defines patentable subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[8] Although the legislative history of the Patent Act suggested that "anything under the sun that is made by man" is patent eligible, the courts have created exceptions.[9] Laws of nature, physical phenomena, and abstract ideas are not eligible to be patented.[10] But an invention is not unpatentable simply because it contains one of these unpatentable concepts.[11] "[A]n application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection."[12] Courts have had difficulty determining when a patent is drawn to one of these unpatentable concepts as opposed to a patentable application. That is because the Supreme Court has never provided a framework for determining when additional limitations change an unpatentable idea into a patentable application.

The Supreme Court unsuccessfully attempted to provide guidance on this issue less than two years ago in *Bilski v. Kappos*.[13] In that case, the Federal Circuit had ruled that the machine-or-transformation test was the sole test for determining the patentability of a "process" under § 101.[14] In other words, a process was only patentable if it was tied to a particular machine or transformed an article to another state. The Supreme Court

[8] § 101.

[9] Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (citation and internal quotation mark omitted).

[10] *Id.*; *see also* Gottschalk v. Benson, 409 U.S. 63, 67 (1972) (saying that a mathematical expression is simply a "scientific truth" and unpatentable (quoting Mackay Radio & Tel. Co. v. Radio Corp., 306 U.S. 86, 94 (1939))).

[11] *See* Diamond v. Diehr, 450 U.S. 175, 187 (1981).

[12] *Id.* (emphasis omitted).

[13] 130 S. Ct. 3218 (2010).

[14] *In re* Bilski, 545 F.3d 943, 954 (Fed. Cir. 2008) (en banc), *aff'd*, 130 S. Ct. 3218 (2010).

decision modified that holding, finding that the "test may be a useful and important clue or investigative tool," but "it is not the sole test for deciding whether an invention is a patent-eligible 'process' under § 101."[15] Unfortunately, the Court did not identify other tests that should be used, and the lower courts continue to rely on the machine-or-transformation test while rotely noting that it is not the only test.[16]

II. *MAYO V. PROMETHEUS*

The Supreme Court took up the issue of subject matter patentability again in *Mayo v. Prometheus*. The patents at issue related to medical diagnostic methods. Synthetic thiopurine compounds have been used to treat various immune-mediated gastrointestinal disorders. Because everyone metabolizes thiopurines differently, calculating the correct dose had proven to be difficult. The inventors of Prometheus' patents discovered a specific correlation between the levels of metabolized drug in the body and the optimal drug dosage. They received two U.S. patents, Nos. 6,355,623 (the '623 patent) and 6,680,302 (the '302 patent). The patents differ in some respects, but all the claims describe multistep processes that use metabolite measurements to help calculate optimal drug doses. Claim 1 of the '623 patent is representative. It recites:

> A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
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> (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
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> (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,
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> 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
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> 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.[17]

At first blush, Prometheus' claims appear quite unusual. The inventors discovered a correlation between the level of 6-thioguanine metabolite in the blood and the optimal drug dose, yet their claims do not contain the step

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[15] *Bilski*, 130 S. Ct. at 3221.

[16] Mark A. Lemley, Michael Risch, Ted M. Sichelman & R. Polk Wagner, *Life After* Bilski, 63 STAN. L. REV. 1315, 1316 (2011) ("[T]he U.S. Patent and Trademark Office (PTO), patent litigants, and district courts have all continued to rely on the machine-or-transformation test in the wake of *Bilski*: no longer as the sole rule, but as a presumptive starting point that threatens to become effectively mandatory.").

[17] U.S. Patent No. 6,355,623 (filed Apr. 8, 1999) (emphasis added). Some claims from Prometheus' patents do not include the first administering step.

of adjusting the drug dosage. Instead, claim 1 contains two "wherein" clauses that say that a particular metabolite level "indicates a need" to increase or decrease the dose. As written, claim 1 therefore appears to seek a patent for an unpatentable law of nature, natural phenomenon, or abstract idea rather than a patentable application. The district court, however, construed claim 1's "indicates a need" language to cover instances in which a doctor is warned that an adjustment in dosage may be required.[18] So long as the warning takes place, there can be infringement even when a doctor does not adjust the dose or adjusts the dose by relying on different parameters. Thus, by including the "wherein" limitations instead of the expected "adjusting step" limitations, Prometheus was able to significantly expand the scope of its patents.

When Mayo Medical Laboratories (Mayo Labs)—a laboratory operated by the Mayo Clinic—announced that it would offer a thiopurine metabolite test to compete with Prometheus' test, Prometheus immediately sued for patent infringement. Mayo Labs moved for summary judgment, asserting that the claims from Prometheus' patents were not patent eligible under 35 U.S.C. § 101. The district court granted the motion, finding that the claims recite correlations between thiopurine drug metabolite levels and therapeutic efficacy or toxicity that are natural phenomena.[19] Applying the machine-or-transformation test, the Federal Circuit reversed that decision.[20] The Federal Circuit found that the administering and determining steps result in transformations of the human body.[21] Moreover, the claimed "steps involve a particular application of the natural correlations: the treatment of a specific disease by administering specific drugs and measuring specific metabolites."[22] Consequently, the Federal Circuit concluded that Prometheus' claims were properly drawn to patentable subject matter.

On March 20, 2012, the Supreme Court reversed the Federal Circuit and found that Prometheus' patents were not patent eligible. The Supreme Court explicitly discussed the distinction between an unpatentable law of nature and a patent-eligible application of such a law. The Court first noted that "Prometheus' patents set forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the

[18] Prometheus Labs., Inc. v. Mayo Collaborative Servs., No. 04cv1200 JAH (RBB), slip op. at 17–18 (S.D. Cal. Nov. 22, 2005).

[19] Prometheus Labs., Inc. v. Mayo Collaborative Servs., No. 04cv1200 JAH (RBB), 2008 WL 878910, at *6, *14 (S.D. Cal. Mar. 28, 2008).

[20] Prometheus Labs., Inc. v. Mayo Collaborative Servs., 628 F.3d 1347 (Fed. Cir. 2010). The Federal Circuit initially ruled on this case earlier. Prometheus Labs., Inc. v. Mayo Collaborative Servs., 581 F.3d 1336 (Fed. Cir. 2009). When Mayo appealed the decision to the Supreme Court, the Court remanded the case to the Federal Circuit in view of the recently decided *Bilski*, 130 S. Ct. 3218. The decision did not change the Federal Circuit's view of the claims. See *supra* text accompanying notes 13–14 for an explanation of the machine-or-transformation test.

[21] *Prometheus*, 628 F.3d at 1355.

[22] *Id.*

likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm."[23] Accordingly, the Supreme Court framed the question by asking: "[D]o the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws?"[24]

Relying on an examination of each of the claimed limitations, the Supreme Court answered its own question in the negative. The Court concluded that none of the limitations individually or in combination were "sufficient to transform the nature of the claim."[25] The decision first examined the "administering" step. According to the Court, this step simply limited the use of the correlation to the relevant audience: doctors. Since limiting the use of an abstract idea to a particular technological environment cannot circumvent the prohibition against patenting abstract ideas, that step did not render the claims patentable.[26] Second, the Court examined the "wherein" limitations. The Court characterized these limitations as "simply tell[ing] a doctor about the relevant natural laws, at most adding a suggestion that he should take those laws into account when treating his patient."[27] Apparently, it was so clear that these limitations could not change an unpatentable concept into a patentable application that the decision said nothing more. The decision then turned to the "determining" step. This step was well known in the prior art. Since conventional or obvious presolution activity is not normally sufficient to transform an unpatentable law of nature into a patent-eligible application, the Court disregarded this step as well.[28]

The Court's analysis culminated with the conclusion "that the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities."[29] Thus, the Supreme Court held that three types of limitations do not make an unpatentable idea patent eligible: (1) limiting an unpatentable concept to a particular audience, (2) telling someone about the concept, or (3) adding a conventional or obvious presolution activity.

The *Mayo* decision then pursued three additional lines of analysis that ostensibly corroborated its conclusion. First, the Court compared the Prometheus patent to the patents in *Parker v. Flook*[30] and *Diamond v.*

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[23] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1296 (2012).

[24] *Id.* at 1297. The correlation is the relationship between 230 pmol to 400 pmol per 8×10^8 red blood cells level of 6-thioguanine in the blood and the indicated drug dose adjustment.

[25] *Id.*

[26] *Id.* (citing Bilski v. Kappos, 130 S. Ct. 3218, 3230 (2010)).

[27] *Id.*

[28] *Id.* at 1297–98.

[29] *Id.* at 1298.

[30] 437 U.S. 584 (1978).

Diehr.[31] In *Flook*, the claims involved a new formula for calculating an alarm limit for a catalytic chemical conversion of hydrocarbons. The claimed process contained three steps: "an initial step which merely measures the present value of the process variable (*e.g.*, the temperature); an intermediate step which uses an algorithm to calculate an updated alarm-limit value; and a final step in which the actual alarm limit is adjusted to the updated value."[32] The Supreme Court found that Flook's invention was not patent eligible "because once [the] algorithm is assumed to be within the prior art, the application, considered as a whole, contains no patentable invention."[33] Thus, under *Flook*, the claim's point of novelty cannot be based on an unpatentable concept like a mathematical equation.

Three years later, the Supreme Court decided *Diehr*. Like *Flook*, the *Diehr* patent also involved a mathematical equation. This time the equation was used in a process for molding and curing raw rubber into products. The claims added the steps of "installing rubber in a press, closing the mold, constantly determining the temperature of the mold, constantly recalculating the appropriate cure time through the use of the formula and a digital computer, and automatically opening the press at the proper time."[34] Notably, the Court appeared to reject *Flook*'s approach by saying that "[i]t is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis."[35] However, the *Diehr* Court never explicitly overruled *Flook*. In the end, the Supreme Court held that Diehr's invention was patent eligible because the Court did "not view [the] claims as an attempt to patent a mathematical formula, but rather to be drawn to an industrial process for the molding of rubber products."[36]

Even the *Mayo* Court had difficulty understanding why the additional steps in *Diehr* rendered its claims patent eligible, noting that "[t]hese other steps apparently added to the formula *something* that in terms of patent law's objectives had *significance*."[37] Unfortunately, the Supreme Court never identified the "something" nor what "significance" that something had. Perhaps this confusion lies in the Court's failure to acknowledge that *Flook* and *Diehr* are simply irreconcilable.[38] However, the Supreme Court

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[31] 450 U.S. 175 (1981).

[32] *Flook*, 437 U.S. at 585 (footnote omitted).

[33] *Id.* at 594.

[34] *Diehr*, 450 U.S. at 187.

[35] *Id.* at 188; *see also* Lemley, *supra* note 6, at 1278 (stating that the *Diehr* decision repudiated the point-of-novelty approach applied in *Flook*).

[36] *Diehr*, 450 U.S. at 192–93.

[37] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1299 (2012) (emphasis added).

[38] *See* Kevin Emerson Collins, *Propertizing Thought*, 60 SMU L. REV. 317, 349 (2007) ("*Flook* and *Diehr* are difficult to reconcile."); Horacio E. Gutiérrez, *Peering Through the Cloud: The Future of Intellectual Property and Computing*, 20 FED. CIR. B.J. 589, 590 (2011) (noting that *Diehr* and *Flook*

still seems to believe that these two decisions provide understandable guideposts; it concluded that Prometheus' claims "present[ed] a case for patentability that is weaker than the (patent-eligible) claim in *Diehr* and no stronger than the (unpatentable) claim in *Flook*."[39] But that discussion is unhelpful given the confusion about *Flook* and *Diehr*. Until the Court provides a framework for explaining why certain types of limitations can transform an otherwise unpatentable concept into a patent-eligible claim, determinations of patentable subject matter will continue to be unpredictable.

The Supreme Court next engaged in a second line of corroborating analysis. The Court noted that precedent has firmly established that "simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable."[40] Indeed, several decisions say that adding insignificant postsolution limitations does not make an abstract idea patentable.[41] But these decisions do not explain how to distinguish a limitation directed at postsolution activity from one directed at the solution itself. *Mayo* compared the addition of very general limitations to a claim that simply says "apply the algorithm." This might suggest that adding specific limitations would have rendered Prometheus' claims patentable. However, those claims already had a great deal of specificity. A change in dose was indicated if the level of 6-thioguanine strays from a range of 230 pmol to 400 pmol per 8×10^8 red blood cells. Thus, this line of analysis could be interpreted as either disingenuous or the application of a standard akin to obscenity: The Court knows it when it sees it.

Finally, the Supreme Court expressed concern "that patent law not inhibit further discovery by improperly tying up the future use of laws of nature."[42] The concern with overbroad claims is firmly rooted in subject-matter patentability jurisprudence,[43] and several commentators have suggested that it should be the sole basis for assessing subject matter patentability decisions.[44] As interpreted by the district court, Prometheus' claims served to "tie up the doctor's subsequent treatment decision whether

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had "very similar facts" with opposite results); Lemley, *supra* note 6, at 1278 (characterizing the claims in *Diehr* and *Flook* as "exactly parallel").

[39] *Mayo*, 132 S. Ct. at 1299.

[40] *Id.* at 1300.

[41] Bilski v. Kappos, 130 S. Ct. 3218, 3231 (2010); *Diehr*, 450 U.S. at 191–92; Parker v. Flook, 437 U.S. 584, 590 (1978).

[42] *Mayo*, 132 S. Ct. at 1301.

[43] Gottschalk v. Benson, 409 U.S. 63, 68 (1972) (Douglas, J.) (noting that the claims before it were "so abstract and sweeping as to cover both known and unknown uses of the [mathematical formula]"); *see also Bilski*, 130 S. Ct. at 3231 ("Allowing petitioners to patent risk hedging would pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea.").

[44] Lemley et al., *supra* note 16, at 1341 (proposing five factors for a scope-based § 101 determination).

that treatment does, or does not, change in light of the inference he has drawn using the correlations."[45] Thus, the Court said that the fact that Prometheus' 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."[46]

Unfortunately, the Supreme Court has created panic in the patent world. By failing to provide a framework for determining when additional limitations can change an unpatentable concept into a patentable application, *Mayo* has created a kind of pessimistic uncertainty.[47] Moreover, by discussing so many ways to reject a patent under § 101, the decision provides defendants an opportunity to latch onto one of these arguments to raise a patentable subject matter defense against a host of different kinds of patents.[48] Almost all patents involve unpatentable concepts. Biological and pharmaceutical inventions inevitably involve natural phenomena.[49] Many current patents involve the application of equations to a new problem using a computer, just as they did in *Flook* and *Diehr*.[50] Moreover, almost any claim can be characterized as too broad depending on how the concept is defined.[51] The fear is that *Mayo* has opened a Pandora's Box of patentable subject matter defenses.

I believe these fears are unwarranted. After all, the Court recognized that "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas."[52] Moreover, the decision clearly suggested that some types of limitations could add

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[45] *Mayo*, 132 S. Ct. at 1302.

[46] *Id.*

[47] *See supra* notes 2–3.

[48] *See* Michel Barclay, *Medical Diagnostic Processes Not Patentable*, IPDUCK (Mar. 20, 2012, 5:03 PM), http://ipduck.blogspot.com/2012/03/medical-diagnostic-processes-not.html ("Other cases dealing with §101 involve adding conventional things such as a computer to abstract concepts such as advertising, and those patents will be highly suspect in the future as well."); Tony Dutra, *Computer, Medical Diagnostics, Gene Patents at Risk in Light of* Mayo*, Panelists Contend*, PAT. TRADEMARK & COPYRIGHT L. DAILY (Apr. 4, 2012), http://www.bna.com/computer-medical-diagnostics-n1288490881 2/ ("[Intel's Tina] Chappell predicted that the court would view the algorithms that are typically cited in software patents in the same way that it analyzed the law of nature in medical diagnostics in Mayo.").

[49] *See, e.g.*, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011) (holding that patents to "isolated" human genes associated with a predisposition to breast cancer and ovarian cancer were patent eligible under § 101), *vacated sub nom.* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012). The Supreme Court immediately vacated this decision after *Mayo* and remanded it to the Federal Circuit for further consideration.

[50] *See, e.g.*, Ultramercial, LLC v. Hulu, LLC, 657 F.3d 1323 (Fed. Cir. 2011), *vacated sub nom.* WildTangent, Inc. v. Ultramercial, LLC, 132 S. Ct. 2431 (2012). The Federal Circuit held that a method for distributing Internet content was patent eligible under § 101. On May 21, 2012, the Supreme Court vacated this decision and remanded it to the Federal Circuit for further consideration in light of *Mayo*. *WildTangent, Inc.*, 132 S. Ct. 2431.

[51] *See* Tun-Jen Chiang, *The Rules and Standards of Patentable Subject Matter*, 2010 WIS. L. REV. 1353, 1369–71 (explaining how claims can be viewed at different levels of abstraction).

[52] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1293 (2012).

"enough" to an unpatentable concept to make it patent eligible. Thus, the problem with *Mayo* was not that it radically constricted patentable subject matter. Rather, the problem was that *Mayo* failed to explain how to separate unpatentable concepts from patentable applications of those concepts.

Reviving the out-of-favor point-of-novelty analysis would bring order to this doctrinal chaos and provide a more coherent framework for making patentable subject matter determinations. Interestingly, the *Mayo* decision is already unconsciously littered with point-of-novelty concepts. Thus, the advantage of the framework proposed below is that it builds on current jurisprudence. In fact, this framework also uses the existing (but heavily criticized) machine-or-transformation test.[53] In sum, the recommendations offer a realistic and practical adjustment to the law, not an idealized view of what the law should be. In so doing, they show that *Mayo* can be understood, under the proposed point-of-novelty framework, as a modest rejection of a particular type of abstract claim rather than a fundamental change to patentable subject matter doctrine.

III. THE POINT OF NOVELTY IN PATENTABLE SUBJECT MATTER

For decades, courts have refused to consider the point of novelty in making decisions in patent law. Under this view, the law should not attribute any special significance to a subset of claim limitations regardless of how important those limitations are to the invention; the law treats all the limitations as equally important. This principle can trace its roots to at least as far back as *Aro Manufacturing Co. v. Convertible Top Replacement Co.*,[54] when the Supreme Court refused to consider the point of novelty in determining whether an item was permissibly repaired or improperly reconstructed. This principle has become one of the basic "commandments" of patent law and has affected many of its doctrines, including patentable subject matter.[55]

In separate works, Mark Lemley and I have recently called this view into question.[56] As Lemley puts it, "a patent regime that pays attention to what the patentee actually invented, not what the patent lawyer wrote down,

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[53] Lemley et al., *supra* note 16, at 1338 (discussing the failures of the machine-or-transformation test).

[54] 365 U.S. 336 (1961).

[55] Chao, *supra* note 6, at 1192–94 (explaining how patent law refuses to consider the heart of the invention—or, as Lemley calls it, the point of novelty—in the context of infringement, anticipation, obviousness, and the written description requirement).

[56] *Id.* at 1240 ("[I]t is time to . . . explicitly recognize that the heart of the invention has its place in patent law."); Lemley, *supra* note 6, at 1255 ("[P]atent law would be better off focusing on the point of novelty in evaluating inventions."); *see also* Kevin Emerson Collins, *Getting Into the "Spirit" of Innovative Things: Looking to Complementary and Substitute Properties to Shape Patent Protection for Improvements*, 26 BERKELEY TECH. L.J. 1217, 1237 (2011) (arguing that the failure to consider the point of novelty is "highly problematic in the context of patent protection for improvements").

is more likely to achieve the goal of promoting innovation."[57] Although Lemley and I both criticize patent law's failure to consider the point of novelty in a wide-ranging number of doctrines, Lemley has been critical of applying point-of-novelty analysis in subject matter patentability determinations.

Lemley is concerned that applying a point-of-novelty analysis in this context will return us "to the bad old days of restrictive patentable subject matter eligibility."[58] By that, Lemley is referring to *Parker v. Flook*. In *Flook*, the Supreme Court noted that the patent's point of novelty was a mathematical algorithm. Since mathematical algorithms are not patentable, the Supreme Court concluded that the patent was invalid under § 101. Under this reasoning, any patent that was based on an unpatentable concept was not patent eligible. It did not matter what additional limitations were added. Of course that would mean that applications of unpatentable concepts are also not patentable. Michael Risch, Ted Sichelman, and R. Polk Wagner have all joined with Lemley in criticizing *Flook*'s point-of-novelty methodology.[59] To some extent, I agree with these critics. *Flook* improperly focused on the point of novelty to the exclusion of all of the other claim limitations. That methodology makes no sense because many inventions involve the application of an unpatentable abstract idea or natural phenomenon. Indeed, the *Mayo* decision recognized that, to assess whether a claim is properly directed at an *application* (as opposed to just the unpatentable concept), courts must consider those other claim limitations.[60] In other words, under the approach the Supreme Court has already adopted in *Mayo*, a court must examine limitations that are not at the invention's point of novelty.

But the particular point-of-novelty analysis approach outlined by *Flook* was short lived.[61] Under *Diehr*, the "claims must be considered as a whole," it being "inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis."[62] So when Mayo Labs focused on the limitations that covered the correlation between metabolite levels and drug doses, Prometheus responded that Mayo Labs was improperly considering the point of novelty.[63] Prometheus argued that

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[57] Lemley, *supra* note 6, at 1255.

[58] *Id.* at 1278.

[59] Lemley et al., *supra* note 16, at 1335 (arguing that the problem with *Flook* was "its apparent reliance on 'point of novelty' analysis").

[60] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1293 (2012).

[61] Brief for the Respondent at 1, 18, 29, *Mayo*, 132 S. Ct. 1289 (No. 10-1150); Lemley et al., *supra* note 16, at 1335–36 (saying *Diehr* "essentially overruled" *Flook*'s holding on the point of novelty).

[62] Diamond v. Diehr, 450 U.S. 175, 188 (1981).

[63] Brief for the Respondent, *supra* note 61.

it did not matter what the point of novelty was because the administering and determining steps made its claims patent eligible.[64]

Although *Diehr* certainly took a step back from *Flook*, it was not a wholesale rejection of point-of-novelty analysis. Quite the contrary, *Diehr* also noted that "insignificant postsolution activity will not transform an unpatentable principle into a patentable process."[65] Analyzing what is or is not "insignificant postsolution activity" requires identifying the claim's point of novelty. Indeed, the *Mayo* decision has broadly interpreted this concept to encompass limitations that are not central to the point of novelty regardless of when they take place.[66] Thus, without explicitly holding that point-of-novelty analysis should be considered when analyzing patentable subject matter, the Supreme Court has called for precisely this kind of analysis in both *Diehr* and *Mayo*.[67]

Unfortunately, these decisions do not explain how to consider a claim "as a whole" while simultaneously discounting limitations that are not strongly related to the point of novelty. Yet it is possible that these two seemingly contradictory requirements can be satisfied. In particular, applying a point-of-novelty approach to subject matter patentability can be divided into two parts. First, the limitation—or limitations[68]—that embody the point of novelty must be identified to determine whether it only describes an unpatentable concept. Those concepts could be laws of nature (e.g., *Mayo*), physical phenomena, or abstract ideas. As *Mayo* recognizes, this approach requires that courts view evidence of prior art as part of the patentable subject matter analysis.[69] This may not be an easy task.[70] But the current doctrine of patentable subject matter is already considered one of the most costly and complex.[71] At least when a point-of-novelty approach is

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[64] *Id.* at 32–34.

[65] *Diehr*, 450 U.S. at 191–92. The Supreme Court recently reiterated this view in *Bilski v. Kappos*. 130 S. Ct. 3218, 3231 (2010) ("*Flook* established that limiting an abstract idea to one field of use or adding token postsolution components did not make the concept patentable."); *see also Mayo*, 132 S. Ct. at 1293–94.

[66] *Mayo*, 132 S. Ct. at 1298 (discussing conventional or obvious presolution activity); *see also In re* Bilski, 545 F.3d 943, 957 n.14 (Fed. Cir. 2008) (en banc) (noting that the Court's reasoning on "postsolution" activity "is equally applicable to any insignificant extra-solution activity regardless of where and when it appears in the claimed process"), *aff'd*, 130 S. Ct. 3218 (2010).

[67] *See* Chao, *supra* note 6, at 1192 (explaining how courts often use a point-of-novelty analysis using different language).

[68] The point of novelty may be embodied in more than one limitation. For the purposes of simplicity, this Essay uses the singular.

[69] *Mayo*, 132 S. Ct. at 1297–98 (referring to the "determining" step as "conventional activity previously engaged in by scientists who work in the field").

[70] Collins, *supra* note 56, at 1237 ("Identifying the 'spirit' of an invention is an information-intensive and error-prone exercise. It takes work to identify the one or more ways in which a patented invention differs from the prior art.").

[71] *See* Dennis Crouch & Robert P. Merges, *Operating Efficiently Post*-Bilski *by Ordering Patent Doctrine Decision-Making*, 25 BERKELEY TECH. L.J. 1673 (2010).

explicitly applied to Prometheus' claims below, the analysis proves far simpler.

This Essay proposes a new point-of-novelty analysis for determining whether a patent is eligible under § 101. The proposal first determines whether any limitation covers an unpatentable concept. This can be accomplished using existing analytical tools. For example, the court could determine if the limitation satisfies the machine-or-transformation test.[72] If the limitation embodying the point of novelty does not describe an unpatentable concept, the claim qualifies as patentable subject matter. If the limitation embodying the point of novelty merely describes one of these unpatentable concepts, the court should proceed to the second part of the analysis—examining the other limitations.

If the other limitations are not directed at an unpatentable concept *and* have a strong nexus with the point of novelty, the claim is patentable. The nexus requirement excludes "insignificant postsolution activity" and other limitations that are not central to the point of novelty. Moreover, it requires courts to judge how important these other limitations are to the point of novelty. If they are not, these additional limitations cannot render an unpatentable concept patent eligible. Notably, this approach does not require that the other limitations be novel themselves.

This approach follows the requirements set forth in *Diehr* and *Mayo*. It does not examine the limitation representing the point of novelty in total isolation as the Court did in *Flook*. Rather, it considers the point of novelty in the context of the claim as a whole. By accounting for the possibility that "other" limitations will demonstrate that the claim is directed toward a patentable application of an unpatentable concept, this approach closely follows the *Mayo* decision. Moreover, it should address Lemley's concerns about the prior point-of-novelty analysis.

To illustrate how this approach works, Part IV analyzes two variations of Prometheus' claims. Specifically, it looks both at the claims Prometheus drafted and at the hypothetical claims it could have drafted. Applying the point-of-novelty analysis described above, I conclude that Prometheus could have received claims that are patentable. But I also find that the claims that it actually received do not qualify as patentable subject matter.

IV. EXAMINING PROMETHEUS' POINT OF NOVELTY

A. The Claims that Could Have Been

As mentioned earlier, neither claim 1 of the '623 patent nor any of Prometheus' other claims contain the expected third step of adjusting the

[72] The machine-or-transformation test is an important clue to determine whether a process qualifies as patentable subject matter. *See* Bilski v. Kappos, 130 S. Ct. 3218, 3221 (2010).

drug dose according to the indicated parameters. Prometheus could have easily replaced the two "wherein" clauses with the following language:

> when the level of 6-thioguanine is determined to be less than about 230 pmol per $8x10^8$ red blood cells, *increasing the amount of said drug* subsequently administered to said subject and
> when the level of 6-thioguanine is determined to be greater than about 400 pmol per $8x10^8$ red blood cells, *decreasing the amount of said drug* subsequently administered to said subject

Analyzing this hypothetical claim serves two purposes. First, if the claim is both patentable and enforceable,[73] then the *Mayo* decision will not upset patent law in the way so many foresee. In other words, deciding that the claims *as drafted* are not drawn to patentable subject matter does not undercut the entire medical diagnostic industry. Such a result merely requires its attorneys to draft more concrete claims. Although those claims may be somewhat narrower, they should still allow the industry to cover the way treatments change in response to particular tests. Second, the hypothetical claim illustrates how the point-of-novelty approach would handle a claim that appears patentable.

Under the point-of-novelty approach outlined above, such a claim would be patentable. According to the Supreme Court, the inventors discovered a law of nature—namely, the specific correlation between the levels of metabolized drug in the body and the optimal drug dosage. The point of novelty is found in the new "increasing" and "decreasing" limitations outlined above. However, these limitations do not only describe an unpatentable concept. Rather, they are also directed to a concrete application—changing drug doses. This characterization can be confirmed by applying the machine-or-transformation test to the limitations. Since the two steps either increase or decrease drug doses, they satisfy the test by transforming the human body.

Of course, the point-of-novelty approach only confirms what everyone thought they knew before *Mayo*—a hypothetical claim that contained a final dose-adjusting step would be patentable.[74] Naturally, this raises questions concerning the reasons why Prometheus failed to draft its claims with this kind of limitation. When Justice Kagan asked this question, Prometheus' counsel said that such a limitation "doesn't correspond with how doctors

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[73] The issue of enforcement relates to a question of divided infringement discussed *infra* notes 77–80.

[74] Transcript of Oral Argument at 22, 47, *Mayo*, 132 S. Ct. 1289 (No. 10-1150). During oral argument, both parties were asked about such a hypothetical claim, and they both answered that it would be patentable. In an unscientific experiment, I provided the same hypothetical claim to my patent class and asked them to apply the *Mayo* decision and assess whether the claim was patent eligible. There were six groups of three. Each group was given twenty-four hours to provide their answer. Four out of the six groups found that the new claim remained unpatentable.

practice medicine."[75] Based on the patient's condition, a doctor may decide to tolerate higher or lower levels of the metabolite before adjusting the dose.[76] Apparently, Prometheus believed that adding an adjusting step would not allow it to capture the conduct of doctors when they varied from the parameters specified in the claim. But this concern was already addressed by the "about" limitation included in the drafted claims. Even if that safeguard was not adequate, Prometheus could have included a broader range in its claims.

In its amicus brief, the Solicitor General suggested that Prometheus may have omitted the final adjusting step to avoid a different issue—the problem of divided infringement.[77] There is no direct infringement of a method claim unless "one party exercises 'control or direction' over the entire process such that every step is attributable to the controlling party."[78] If Prometheus had included the final adjusting step in its claims, Mayo Labs could have pointed out that, while they performed some of the steps, other steps were performed by doctors. Unless the doctors controlled or directed Mayo Labs—or Mayo Labs controlled or directed the doctors—there could be no infringement.

However, this explanation does not justify the omission of a final adjusting step. Although the hypothetical claim could certainly face a problem of divided infringement, the same is true for the actual claims found in the Prometheus patents. Presumably, doctors are responsible for the first step of administering the drug and the final step of being warned about the correlation between the metabolite levels and any indicated adjustment. However, diagnostic laboratories are likely to perform the second step of determining the metabolite levels. Again, unless one party is controlling or directing the other, there can be no direct infringement.[79] Of course, adding a concrete final adjusting step may exacerbate the divided infringement issue because different doctors may perform the original administering step and the final adjusting step. But that seems to be a problem that the jurisprudence on divided infringement needs to address.[80] The outcome of a determination on patentable subject matter should not turn on whether adding a limitation aggravates a divided infringement issue.

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[75] *Id.* at 48.

[76] *Id.* at 48–49.

[77] Brief for the United States as Amicus Curiae Supporting Neither Party at 31, *Mayo*, 132 S. Ct. 1289 (No. 10-1150).

[78] Muniauction, Inc. v. Thomson Corp., 532 F.3d 1318, 1329 (Fed. Cir. 2008).

[79] Moreover, without a predicate act of direct infringement, there can be no contributory infringement or inducement.

[80] In fact, since the original version of this Essay was published, an en banc panel of the Federal Circuit reviewed the issue of divided infringement in *Akamai Technologies, Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301 (Fed. Cir. 2012) (en banc).

B. The Claims as Drafted

Consider next the application of the point-of-novelty analysis to the claims Prometheus actually obtained. Initially, this approach looks quite similar to the approach the Supreme Court first took in *Mayo*. Again, the first part of the analysis requires a court to identify the limitation or limitations that correspond to the point of novelty. There are two important facts that inform the analysis of Prometheus' claims. First, the administering and determining steps are found in the prior art. Thus, those two steps do not lie at the point of novelty. Second, the inventors are credited with discovering the specific correlation between the levels of metabolized drug in the body and the optimal drug dosage. The two "wherein" clauses correspond to that discovery. Therefore, these two limitations embody the point of novelty.

Next a court must determine whether these limitations describe an unpatentable concept. Again, the *Mayo* decision informs us that the limitations involve an unpatentable law of nature—the specific correlation between the levels of metabolized drug in the body and the optimal drug dosage. Applying the proposed test, there is nothing within the limitations that would suggest that they cover an application. The two limitations simply require that a doctor recognize the correlation between a particular metabolite level and how to adjust the dose. Certainly, recognizing the correlation does not satisfy the machine-or-transformation test. By itself, the doctor's recognition is not tied to a machine, nor does it transform anything. Consequently, the "wherein" limitations are directed to unpatentable concepts, and the point-of-novelty analysis should proceed.

The second part of the point-of-novelty analysis requires an examination of the other limitations. If they are not directed at an unpatentable concept *and* have a strong nexus with the point of novelty, the claim is patentable. Here, those limitations are the steps of administering a drug containing 6-thioguanine and determining the levels of 6-thioguanine found in the patient's blood. Those steps clearly are not directed at an unpatentable concept. Indeed, the underlying Federal Circuit decision relied on these steps to show that they satisfy the machine-or-transformation test.[81]

However, to render the claim patentable, these limitations must also have a sufficiently strong nexus with the point of novelty. But understanding the specific correlation between the levels of metabolized drug in the body and the optimal drug dosage does not affect the administering and determining steps. Unlike the patents in *Flook* and *Diehr*, there is nothing about the point of novelty that changes how those other steps are performed. Therefore, the administering and determining steps are not sufficiently related to the point of novelty to make Prometheus' claims

[81] Prometheus Labs., Inc. v. Mayo Collaborative Servs., 628 F.3d 1347, 1355–56 (Fed. Cir. 2010).

patent eligible under § 101.[82] Thus, the point-of-novelty analysis outlined above arrives at the same conclusion that the Supreme Court actually reached in *Mayo*—that Prometheus' claims are not patent eligible.

The point-of-novelty framework offered here builds on some important concepts that are already found in *Mayo*. In *Mayo*, the Supreme Court understood that adding some limitations to laws of nature, physical phenomena, or abstract ideas could render a claim patentable. The Court also understood that certain kinds of limitations would not suffice. Limiting an unpatentable concept to a particular audience, telling someone about the concept, or adding a conventional or obvious pre- or postsolution activity would not change the nature of an unpatentable concept. What was missing from *Mayo* (and Supreme Court jurisprudence in general) was a framework that tied these different strands together.

The revised point-of-novelty approach serves this purpose. Assuming that the point of novelty is an unpatentable concept, this approach explains what types of additional limitations will render the concept patentable. Under this approach, concrete limitations that have a strong nexus with the unpatentable concept can make the concept patent eligible. In other words, if the additional limitations are not sufficiently concrete (e.g., understanding the concept or telling someone about the concept), or if the limitations are not strongly linked to the concept (e.g., limiting a patent to a particular audience), they cannot make a law of nature, physical phenomenon, or abstract idea patent eligible.

At the same time, the point-of-novelty framework rejects much of *Mayo*'s dicta.[83] This framework does not care how broadly the claim sweeps (as some advocate).[84] Nor does it try to reconcile *Flook* and *Diehr*. Indeed, under the point-of-novelty analysis outlined here, *Flook* was probably decided incorrectly because the additional limitations describing a catalytic chemical conversion of hydrocarbons were both concrete and strongly linked to *Flook*'s formula.

Finally, and perhaps most importantly, the proposed point-of-novelty framework does not jeopardize a broad swath of medical, pharmaceutical, and technology patents. By explaining precisely what types of limitations must be added to an unpatentable concept, the point-of-novelty framework removes much of the uncertainty that surrounds *Mayo*. Moreover, the

[82] In contrast, the Federal Circuit said that "[t]he administering step . . . is not merely data-gathering but a significant transformative element." *Id.* at 1356–57. This confuses two unrelated concepts. A step that transforms something to a new state may still have no connection to a claim's point of novelty.

[83] The analyses comparing Prometheus' claims to those in *Flook* and *Diehr* and discussing the scope of preemption were both said to "reinforce" the Court's conclusion. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1298, 1302 (2012). Therefore, they are both technically dicta.

[84] *See* Lemley et al., *supra* note 16, at 1341. Since the Supreme Court appears reluctant to make a fundamental change to the law of patentable subject matter, this Essay does not address the merits of this or any other more far-reaching proposal. *See Mayo*, 132 S. Ct. at 1305. Rather, this Essay seeks to apply current jurisprudence and prevent *Mayo* from being interpreted as a radical attack on patents.

Prometheus hypothetical and *Flook* example show that most patents should be found to be patent eligible under this framework. The only reason Prometheus' patents failed this test was because they claimed a law of nature without adding any concrete steps that had a strong nexus with the discovery they made—a mistake that could have easily been avoided.

CONCLUSION

In *Mayo*, the Supreme Court held that the limitations found in Prometheus' claims did not add "enough" to the law of nature Prometheus discovered to render that discovery patent eligible. Unfortunately, the Court's failure to explain what might be "enough" casts doubt on many patents that have properly been considered patent eligible. Many commentators fear that *Mayo* marks a fundamental shift in subject matter patentability jurisprudence that may radically limit patents. This Essay offers a more restrained view of *Mayo* by reviving the out-of-favor point-of-novelty analysis. Importantly, *Mayo* already contains the seeds of this revival. Thus, the current proposal does not reject *Mayo*, but builds on it. When a patent's point of novelty is based on a law of nature, natural phenomenon, or abstract idea, this proposal defines what types of limitations can transform the unpatentable concept into a patentable application of the concept. That occurs when the additional limitations are concrete and have a strong nexus to the unpatentable concept.

This proposal achieves two goals. First, it maintains patent eligibility for many medical, pharmaceutical, and technology patents that might be jeopardized by a less nuanced reading of *Mayo*. Second, the point-of-novelty framework creates clearer boundaries between claims covering unpatentable concepts—like Prometheus' claims—and claims directed at patentable applications of those concepts. In sum, if and when *Mayo* is understood as the initial step toward a point-of-novelty framework for patentable subject matter, it will not create the havoc that so many fear.