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And How: *Mayo v. Prometheus* and the Method of Invention

The Mayo *Court's novel test for patent eligibility—whether or not an invention involves "well-understood, routine, conventional activity, previously engaged in by researchers in the field"—focuses on* how *an invention is accomplished rather than* what *an invention is. That concern with the method of invention poses several normative, statutory, and administrative difficulties. Taken seriously, the "how" requirement will likely have broad effects across all levels of patent practice.*

INTRODUCTION

In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,[1] the Supreme Court invalidated the asserted patents' process claims as unpatentable subject matter under § 101 of the patent statute.[2] The Court gave three principal justifications for its rejection. First, the process claims were directed to "laws of nature, natural phenomena, and abstract ideas."[3] Second, in any event, the patent did not contain enough of an "inventive concept" to ensure that it "amounts to significantly more than a patent upon the natural law itself."[4] And third, the invention involved "well-understood, routine, conventional activity, previously engaged in by researchers in the field."[5]

1. No. 10-1150 (U.S. Mar. 20, 2012), http://www.supremecourt.gov/opinions/11pdf/10-1150.pdf (to be reported at 132 S. Ct. 1289).

2. 35 U.S.C. § 101 (2006). Citations of the patent statute throughout this Essay, unless otherwise noted, refer to its provisions effective March 16, 2013. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified in scattered sections of 35 U.S.C.).

3. *Mayo*, slip op. at 2.

4. *Id.* at 3.

5. *Id.* at 4.

Much has been written—and will continue to be written—about those first two justifications. But commentators thus far have paid less attention to the third. Interestingly, the third justification is quite different from the first two. Rather than focusing on *what* the invention is, it focuses on *how* the invention is accomplished. That is, the Court's first two justifications concern the characterization of the invention itself: the thing or process purported to be invented, the language of the claims, and the significance of the invention to the field. The third justification, however, concerns the method by which the invention is implemented, whether a "conventional activity" or a unique method.

Given the novelty of that justification[6] (and how recently *Mayo* was decided), the consequences of the additional inquiry remain unclear. Nonetheless, the *Mayo* Court's new focus on how an invention is conceived—a condition on which patent eligibility depends—appears to pose several doctrinal and practical difficulties. First, it fails to distinguish true "inventions" from unpatentable abstractions in contravention of § 101's historical purpose. Second, it confusingly overlaps with another requirement in the patent statute: nonobviousness. Third, it violates the principle that patent eligibility should not be tied to "the manner in which the invention is made." And last, it requires the patent office to engage in "on the ground" factfinding, even though there are scant administrative procedures for that task.

I. FAILING TO DISTINGUISH ABSTRACTIONS

A requirement to consider *how* an invention operates does not fulfill the historical purpose of § 101: to distinguish patent-eligible "inventions" from unpatentable abstractions.[7] The Supreme Court's prior interpretations of § 101 embody this concern.[8] Although § 101's text does not define the concept of

6. The *Mayo* Court's rule denying eligibility to inventions involving "well-understood, routine, conventional activity, previously engaged in by researchers in the field" was completely novel at the time, neither adopted nor even suggested by any previous court.

7. *See* O'Reilly v. Morse, 56 U.S. (15 How.) 62, 119 (1853) (concluding that the patent statute embodies the English rule against patenting mere "principles"); Le Roy v. Tatham, 55 U.S. (14 How.) 156, 175 (1852) (denying patent eligibility to a "principle," because it was not "practically applied in the construction of a useful article of commerce or manufacture").

8. *See, e.g.*, Diamond v. Diehr, 450 U.S. 175, 185 (1982) ("This Court has undoubtedly recognized limits to § 101 and every discovery is not embraced within the statutory terms. Excluded from such patent protection are laws of nature, natural phenomena, and abstract ideas."); Parker v. Flook, 437 U.S. 584, 589 (1978) ("The line between a patentable 'process' and an unpatentable 'principle' is not always clear."); Gottschalk v. Benson, 409 U.S. 63, 67 (1972) ("Phenomena of nature, though just discovered, mental processes, and abstract

"invention," it permits a patent application for "any new and useful process, machine, manufacture, or composition of matter."[9] The statute's broad language has long been thought to encompass "anything under the sun made by man"[10] and to serve as little more than a threshold inquiry.[11] Nonetheless, this threshold inquiry made ineligible patent applications involving abstract ideas, mathematical equations, or mental processes.[12] Yet it also left other applications to the remaining rigors of the patent statute.[13] Even then, § 101 was not thought to prohibit patents monopolizing discrete applications of such abstractions, such as manufacturing equipment that relied on certain mathematical formulae.[14]

The Court's novel patent-eligibility test—rendering ineligible inventions involving "well-understood, routine, conventional activity, previously engaged in by researchers in the field"[15]—does little to accomplish the goal of distinguishing "inventions" from "abstractions." Because inventions, both physical and abstract, operate in a variety of ways, an examination of how they operate fails to separate the concrete from the conceptual. Both physical and abstract inventions, for example, can call upon "well-understood, routine, conventional activity." Many inventions in the life sciences, for example, use well-understood, routine, and conventional mechanisms, even though they concretely apply to real world phenomena.[16] At the same time, new and useful,

intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.").

9. 35 U.S.C. § 101 (2006).

10. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (quoting S. REP. NO. 82-1979, at 5 (1952)).

11. *See* Bilski v. Kappos, 130 S. Ct. 3218, 3225 (2010) ("The § 101 patent-eligibility inquiry is only a threshold test."); *Diehr*, 450 U.S. at 188 ("Arrhenius' equation is not patentable in isolation, but when a process for curing rubber is devised which incorporates in it a more efficient solution of the equation, that process is at the very least not barred at the threshold by § 101.").

12. *See* Parker, 437 U.S. at 588-89 (describing the history of § 101).

13. *See Bilski*, 130 S. Ct. at 3225.

14. *Parker*, 437 U.S. at 594 ("Even though a phenomenon of nature or mathematical formula may be well known, an inventive application of the principle may be patented."); *see also Diehr*, 450 U.S. at 188 (allowing a patent for an automated rubber molding press that used the Arrhenius equation).

15. Mayo Collaborative Servs. v. Prometheus Labs., Inc., No. 10-1150, slip op. at 4 (U.S. Mar. 20, 2012), http://www.supremecourt.gov/opinions/11pdf/10-1150.pdf (to be reported at 132 S. Ct. 1289).

16. This is the rule "with respect to chemical products, as to which simple, routine reactions can often produce dramatic changes in the products' structure and properties." Eli Lilly & Co. v. Am. Cyanamid Co., 82 F.3d 1568, 1572 (Fed. Cir. 1996). Isolated genes, for example, are

but abstract, mathematical proofs may rely on poorly understood, infrequently used, unorthodox mechanisms to obtain their results.[17] The Court's inquiry into how an invention or an idea solves a particular problem does no work to distinguish between inventions and ideas themselves.

II. OVERLAPPING WITH OBVIOUSNESS

The *Mayo* Court's concern with how an invention is accomplished, relative to the state of the art in its field, overlaps with the patent statute's proscription against "obviousness," thus rendering much of it superfluous. Section 103 of the patent statute denies a patent to an invention "if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art."[18] That standard necessarily requires some inquiry into how the invention solved a problem in its field, specifically, whether the invention uses old or new methods.[19]

Section 103's standard significantly overlaps with the *Mayo* Court's view of patent eligibility as turning on "well-understood, routine, conventional activity, previously engaged in by researchers in the field."[20] The two inquiries share multiple, similar concerns that are difficult to distinguish: (1) routine vs. ordinary activity; (2) a researcher in the field vs. a person having ordinary skill in the art; and (3) previous engagement vs. activity before the effective filing date of the invention. What is the significant difference, for example, between a "researcher in the field" and a "person having ordinary skill in the art"? The

often created through little more than "routine skill in the art," even though they also encompass concrete, chemical compositions. *See In re* Kubin, 561 F.3d 1351, 1356-57 (Fed. Cir. 2009).

17. For example, the Four Color Theorem, a mathematical problem important to geometry and cartography that, although first proposed in 1852, was not proved until 1976—by supercomputer, a method mathematicians found controversial at the time. *See* RUDOLF FRITSCH & GERDA FRITSCH, THE FOUR COLOR THEOREM, at vii (1998) (describing the "controversy over the modern methods used in the proof").

18. Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 3(c), 125 Stat. 284, 287 (2011) (to be codified at 35 U.S.C. § 103).

19. *See* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 416 (2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."); *see also* Michael Abramowicz & John F. Duffy, *The Inducement Standard of Patentability*, 120 YALE L.J. 1590, 1673 (2011) ("Section 103 does not state that evidence of the manner of invention cannot be considered; its passive wording indicates that the manner of invention may be relevant but cannot alone be sufficient to determine patentability.").

20. *Mayo*, slip op. at 4.

Mayo Court's conception of patent eligibility almost swallows obviousness as a condition for patentability. Indeed, it is difficult to conceive of the invention that does not involve "well-understood, routine, conventional activity, previously engaged in by researchers in the field,"[21] but is "obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art."[22] The "how" of the *Mayo* Court's patent eligibility inquiry appears to diminish the "how" of the obviousness requirement.[23]

III. DISCRIMINATING AGAINST THE "MANNER OF INVENTION"

Similarly, the Court's concern with how an invention is created may violate § 103's bar against "negat[ing]," i.e., denying, patentability according to "the manner in which the invention was made."[24] This protection seeks to treat equally inventions made by "long toil and experimentation" and those created in a "flash of genius."[25] Yet denying patent eligibility to inventions that operate through "well-understood, routine, conventional activity" may discriminate against inventions made by "long toil and experimentation." The reason is that inventions *employing* "well-understood, routine, conventional activity" are often *created* through "long toil and experimentation." Inventions in chemistry or molecular biology, for example, frequently operate using "well-understood, routine, conventional" mechanisms, such as drugs developed by traditional chemical-screening methods.[26] In the fields of chemistry and biology, advances in those mechanisms are typically introduced through "trial and error" rather than sudden "flashes of genius."[27] In contrast, inventions that work in an unconventional manner are often the result of creative syntheses across multiple technologies that stem from "flashes of genius."[28]

21. *Id.*

22. Leahy-Smith America Invents Act § 3(c), 125 Stat. at 287 (to be codified at 35 U.S.C. § 103) ("Patentability shall not be negated by the manner in which the invention was made.").

23. While the *Mayo* Court acknowledged some overlap between its test for § 101 and other parts of the patent statute, it is unclear whether it also recognized this for § 103. *See Mayo*, slip op. at 21 ("We recognize that, in evaluating the significance of additional steps, the § 101 patent-eligibility inquiry and, say, the § 102 novelty inquiry might sometimes overlap.").

24. Leahy-Smith America Invents Act § 3(c), 125 Stat. at 287 (to be codified at 35 U.S.C. § 103).

25. 35 U.S.C. § 103 (2006) (1952 Historical and Revision Notes).

26. *See* Jacob S. Sherkow, *Negativing Invention*, 2011 BYU L. REV. 1091, 1121–22.

27. *Id.* at 1120 (discussing how chemistry and molecular biology "typically create inventions by more laborious and empirical processes, while other disciplines' inventions germinate primarily from the mind alone").

28. *Id.* at 1116–17.

The patent in *Mayo* illuminates this point. That patent claimed a method of optimizing a patient's drug dosage by measuring a particular metabolite in the patient's blood—a "well understood, routine, and conventional" method for altering drug dosage.[29] It is unsurprising, therefore, that the key to the invention—the ability to determine the particular level of the metabolite—was ascertained through rigorous clinical studies,[30] exemplars of "long toil and experimentation" rather than "flashes of genius." In that sense, denying patent eligibility according to how an invention works essentially negates patentability according to its method of invention.[31]

IV. REQUIRING ADMINISTRATIVE FACTFINDING

The addition of "how" to the patent eligibility inquiry poses administrative difficulties as well. Asking whether an activity involves "well-understood, routine, conventional activity, previously engaged in by researchers in the field"[32] would require the U.S. Patent and Trademark Office (PTO) to actually determine whether researchers in the field considered an activity routine or conventional, and whether those researchers had truly engaged in that activity. The PTO is poorly equipped to handle that inquiry. Much of the PTO's current work involves assessing prior art: reading technical documents to ascertain whether a patent application is "new" or "nonobvious" in the field.[33] Although the Court's "well-understood, routine, conventional activity" test greatly overlaps with "nonobviousness,"[34] prior art seems ill-equipped to prove "routine" or "convention." Rather, questions concerning an activity's routineness or conventionality, and questions whether researchers have performed that activity, appear much more rooted in an on-the-ground factual

29. Mayo Collaborative Servs. v. Prometheus Labs., Inc., No. 10-1150, slip op. at 4 (U.S. Mar. 20, 2012), http://www.supremecourt.gov/opinions/11pdf/10-1150.pdf (to be reported at 132 S. Ct. 1289).

30. *See id.* at 4-5 (discussing the clinical studies).

31. Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 3(c), 125 Stat. 284, 287 (2011) (to be codified at 35 U.S.C. § 103).

32. *Mayo*, slip op. at 10.

33. *See To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, FED. TRADE COMMISSION 9-10 (2003), http://www.ftc.gov/os/2003/10/innovationrpt.pdf ("With yearly applications approximating 300,000, they arrive at the rate of about 1,000 each working day. A corps of some 3,000 examiners must deal with the flood of filings. Hearings participants estimated that patent examiners have from 8 to 25 hours to read and understand each application, search for prior art, evaluate patentability, communicate with the applicant, work out necessary revisions, and reach and write up conclusions.").

34. *See supra* Part II.

assessment. "Routine" and "convention" are issues of practice, not necessarily publication, and there may be a significant delay between when researchers begin to engage in such activities and when they publicly declare they are doing so.[35] In other areas, such as the *Daubert* standard for the admissibility of scientific evidence,[36] surveying the landscape of complex technical practice is often better left to witnesses rather than documentary testimony.[37] Currently, however, the PTO has few administrative procedures to hear such testimony.[38] Nor does there seem to be any movement to expand them.[39] Despite the Court's interest in tying patent eligibility to practical activity, it is unclear how the PTO will obtain the tools it needs to make such assessments. The PTO's expertise, rather, lies in determining *what* inventions are, not *how* those inventions were made.

CONCLUSION

The future will tell whether this philosophical shift in patent eligibility, from *what* to *how*, will have the legal effects discussed in this Essay. If it does, its practical effects will likely be felt across all levels of the patent complex: research, invention, prosecution, enforcement, litigation, and licensing. Research institutions concerned with obtaining intellectual property for their investments will likely steer funds away from "conventional" research. The PTO will need to equip itself with the proper administrative tools to assess on-the-ground research behavior. Inventors will likely paint their claims with

35. *See* Jorge L. Contreras, *Confronting the Crisis in Scientific Publishing: Latency, Licensing and Access* 44 (Program on Info. Justice & Intellectual Prop. Research Paper No. 2012-11, 2012), http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1035&context=research (discussing the delay between scientific research and publication).

36. *See* Daubert v. Merrell Dow Pharm., 509 U.S. 579, 594 (1993) (allowing judges to assess, among other factors, whether scientific evidence is employed by "'a relevant scientific community,'" and to make "'an express determination of a particular degree of acceptance within that community'" (quoting United States v. Downing, 753 F.2d 1224, 1238 (3d Cir. 1985))).

37. Mark Spottswood, *Live Hearings and Paper Trials*, 38 FLA. ST. U. L. REV. 827, 858 n.127 (2011) ("[T]he clarity-enhancing virtues of live testimony might still counsel in favor of a live *Daubert* hearing, at least if the testimony in question is fairly complex.").

38. Jeffrey P. Kushan, *The Fruits of the Convoluted Road to Patent Reform: The New Invalidity Proceedings of the Patent and Trademark Office*, 30 YALE L. & POL'Y REV. 385, 412 (2012) ("[I]n the typical case, the PTO will not hear live testimony from witnesses, nor will it use a lay jury to assess disputed scientific facts—the [appellate] fact finder will be a panel of judges with relevant technical training who will evaluate written pleadings and documentary evidence.").

39. *See id.* at 413-14.

more detail to give the impression that their methods are not routine in the field. And litigators will be even more encouraged to canvass scientific experts to testify that a scientific method is, or is not, "well-understood."

All of that work will be devoted to analyzing whether an invention is even *eligible* to be patented, let alone valid or invalid under the remaining portions of the statute. As previous assessments of patent eligibility were rooted in more facial inquiries, such as whether an invention was "abstract," the Court's recent focus on the method of invention is a difference not just in degree, but in kind. Patent practitioners will need to prepare for these changes—and how.

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