

11-2016

## Photocopies, Patents, and Knowledge Transfer: "The Uneasy Case" of Justice Breyer's Patentable Subject Matter Jurisprudence

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### Recommended Citation

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# Photocopies, Patents, and Knowledge Transfer: “The Uneasy Case” of Justice Breyer’s Patentable Subject Matter Jurisprudence

*Dmitry Karshedt\**

*One aspect of Justice Stephen Breyer’s discomfort with patents, as expressed in his opinion for the Supreme Court in Mayo v. Prometheus and his dissent from the order dismissing certiorari in LabCorp v. Metabolite, is strikingly similar to one of his critiques of copyright law in The Uneasy Case for Copyright, a well-known article he wrote as Professor Breyer more than forty-five years ago. In The Uneasy Case, Breyer argued that the burdens on duplication of technical articles imposed by copyright law restrict the flow of information and prevent scientists from enjoying spillover benefits of published research. His patent opinions on the Supreme Court, too, talk of diminished access to information resulting from intellectual property protection. In this Article, I contend that the parallel that Justice Breyer implicitly draws between the harms of copyright and patent is a questionable one. In particular, Justice Breyer’s opinions on patentable subject matter do not address the notion that inducement of disclosure and dissemination of information is one of the very purposes of patent law, nor the idea that there are many noninfringing uses of information contained in patents. I argue that these omissions may provide an insight into Justice Breyer’s patent law jurisprudence—particularly, the recent reinvigoration of limits on patentable subject matter in his opinion for the Court in Mayo.*

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\* Associate Professor, George Washington University Law School. I thank Clark Asay, Stephanie Bair, Robert Brauneis, Tun-Jen Chiang, Kevin Collins, Rochelle Dreyfuss, Alan Durham, John Golden, Paul Goldstein, Patrick Goold, Brad Greenberg, Scott Kamholz, Robert Merges, Lisa Ouellette, Laura Pedraza-Fariña, Nicholson Price, Joshua Sarnoff, Sean Seymore, Jacob Sherkow, Michal Shur-Ofry, Ted Sichelman, Brenda Simon, David Taylor, and Kip Werking for helpful comments on earlier drafts. I also thank the participants in the *Vanderbilt Law Review* Symposium on the Disclosure Function of the Patent System, PatCon 6 at Boston College Law School, the 4th Annual Mid-Atlantic Patent Works-in-Progress, and the Inaugural Texas A&M Intellectual Property Scholars Roundtable for their feedback on the presentations of this Article. A special thank you to David Taylor for providing public commentary on this Article at PatCon and offering detailed and insightful feedback on an earlier draft. All errors are my own.

*To be sure, Justice Breyer's position can be defended. For even though patent law does not generally place barriers on access to information, claims like those at issue in Mayo and LabCorp may create narrow, subtle information-flow problems through recitation of mental steps at the point of the invention's novelty. I argue, however, that these problems can be solved by applying correspondingly narrow rules of novelty or claim construction to invalidate such patents or to limit their scope, making resort to the overbroad rule announced in Mayo unnecessary.*

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## INTRODUCTION

Justice Stephen Breyer has long been concerned with barriers to knowledge transfer that intellectual property rights threaten to impose. One of the claims in *The Uneasy Case for Copyright: A Study of Copyright in Books, Photocopies, and Computer Programs*—a well-known article he wrote when he was Professor Breyer—was that copyright in technical materials restricts the flow of information and

thus thwarts the goal of promoting innovation.<sup>1</sup> Specifically, Breyer contended that photocopying of “texts and other scientific, professional, or technical books and articles” has “various spillover benefits similar to those provided by the original distribution of the works copied.”<sup>2</sup> He explained that these benefits include “intellectual stimulation, greater productivity, and increased research,”<sup>3</sup> and maintained that “to discourage [such materials] from being copied is therefore particularly undesirable.”<sup>4</sup> The worry that copyright law would inhibit dissemination of information also turns up in Justice Breyer’s copyright opinions on the Supreme Court—in particular, in his dissents in *Eldred v. Ashcroft*<sup>5</sup> and *Golan v. Holder*.<sup>6</sup> Discussing his *Eldred* dissent, Justice Breyer made clear his belief that the extension of the copyright term would “unnecessarily block dissemination” of older works and thereby “fatally impede” efforts to learn from them.<sup>7</sup>

In a similar vein, and using language mirroring that found in his copyright writings, Justice Breyer has voiced concerns about the effect of patents on the disclosure and dissemination of information in his patent law opinions. For example, in his dissent from the dismissal of certiorari in *LabCorp v. Metabolite*, Justice Breyer justified limits on patentable subject matter in part by positing that “[s]ometimes [the] presence [of patents] can discourage research by impeding the free exchange of information, for example by forcing researchers to avoid the use of potentially patented ideas.”<sup>8</sup> Comparable language appears in Justice Breyer’s opinion for the unanimous Supreme Court in *Mayo v. Prometheus*,<sup>9</sup> which invalidated the patent claims asserted in that case as directed to an unpatentable law of nature (or, alternatively, a natural phenomenon).<sup>10</sup> His dissent in *Stanford University v. Roche*, a case that did not even deal with patent eligibility, likewise mentions “restricted dissemination.”<sup>11</sup> And as if to preview and summarize all these views,

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1. Stephen Breyer, *The Uneasy Case for Copyright: A Study of Copyright in Books, Photocopies, and Computer Programs*, 84 HARV. L. REV. 281, 316–18 (1970).

2. *Id.* at 318.

3. *Id.* at 315–16.

4. *Id.* at 318.

5. 537 U.S. 186, 266 (2003) (Breyer, J., dissenting).

6. 132 S. Ct. 873, 900 (2012) (Breyer, J., dissenting).

7. STEPHEN BREYER, ECONOMIC REASONING AND JUDICIAL REVIEW 14 (2004).

8. *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 127 (2006) (Breyer, J., dissenting from the order dismissing certiorari).

9. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1305 (2012) (stating that patents “can impede the flow of information”).

10. *Id.* at 1296–97.

11. *Bd. of Trs. of the Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 563 U.S. 776, 795 (2011) (Breyer, J., dissenting).

Breyer noted in a monograph published shortly after he became a judge on the United States Court of Appeals for the First Circuit that “the production, use, and dissemination of much information is protected by copyright and patent laws.”<sup>12</sup> These statements reveal a concern that patent law, like copyright law, can erect barriers in the way of information flow.

In this Article, I examine this claim. I argue that any suggestion that patents can “impede the flow of information”<sup>13</sup> cannot be validly made without considering the disclosure-forcing function of patents. This function appears to be significantly less legally salient in copyright law, which does not even require disclosure for protection.<sup>14</sup> As the Supreme Court observed in *Eldred v. Ashcroft*, disclosure is something that is “exacted from” the patentee by law,<sup>15</sup> while disclosure in the copyright context is something the rights owner frequently opts for voluntarily when he or she wishes to make a profit from selling copies of a work, performing the work publicly for a fee, and so on.<sup>16</sup> In contrast to creators of copyrightable works, inventors can often profit

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12. STEPHEN BREYER, REGULATION AND ITS REFORM 27 (1982).

13. *Mayo*, 132 S. Ct. at 1305.

14. For a leading case, see *Chi. Bd. of Educ. v. Substance, Inc.*, 354 F.3d 624, 627 (7th Cir. 2003) (arguing that it is not paradoxical to allow copyright to be obtained in secret documents); see also *Salinger v. Random House, Inc.*, 811 F.2d 90, 100 (2d Cir. 1987) (concluding that “Salinger has a right to protect the expressive content of his unpublished writings for the term of his copyright”); Patrick R. Goold, *Unbundling the “Tort” of Copyright Infringement*, 102 VA. L. REV. (forthcoming 2016) (manuscript at 17, 30–32), <http://ssrn.com/abstract=2809957> [<https://perma.cc/DGD7-57XH>] (discussing the role of copyright law in protecting privacy interests). See generally Diane Leenheer Zimmerman, *Trade Secrets and the “Philosophy” of Copyright: A Case of Culture Crash*, in THE LAW AND THEORY OF TRADE SECRECY 299 (Rochelle C. Dreyfuss & Katherine J. Strandburg eds., 2011) (discussing the interplay between copyright protection and trade secrecy).

15. 537 U.S. 186, 216 (2003) (emphasis omitted). One could argue that copyright law induces disclosure by way of incentivizing creation, which is often followed by disclosure. See Norman Siebrasse, *A Property Rights Theory of the Limits of Copyright*, 51 U. TORONTO L.J. 1, 10 (2001) (“We cannot assume that goods unprotected by copyright will be freely disseminated, since creators will seek alternative forms of protection, such as trade secret or contract.”). But while Justice Breyer’s copyright jurisprudence may be open to similar criticisms as his patent law jurisprudence, it seems clear—and the *Eldred* Court’s reference to “exaction” suggests—that the disclosure-forcing function of the patent system is a more powerful and independent rationale for patent as opposed to copyright protection. See 35 U.S.C. § 112 (2012) (mandating disclosure requirements in patent law); cf. *infra* note 21 (indicating that there are no registration requirements for copyright protection). Interestingly, there is also a strong First Amendment undercurrent behind dissemination of information once it has been created, see *infra* notes 83–100 and accompanying text, but seemingly less of a First Amendment concern behind having reduced creation and circulation of ideas due to reduced copyright protection.

16. *Eldred*, 537 U.S. at 216–17 (“For the author seeking copyright protection, in contrast [to the inventor seeking patent protection], disclosure is the desired objective, not something exacted from the author in exchange for the copyright. Indeed, since the 1976 Act, copyright has run from creation, not publication.”). An exception might be copyrighted software code. Breyer, *supra* note 1, at 349 n.269.

handsomely even if they opt out of the patent system and keep their innovative ideas completely in the dark as trade secrets.<sup>17</sup>

Indeed, the complaint that patents restrict information flow is generally something of a non sequitur because patent law, on the whole, is supposed to do the opposite: inducement of *disclosure of information*, which an inventor might well have refrained from revealing, is one of patent law's widely acknowledged purposes.<sup>18</sup> It is true that patent disclosures are often far from perfect.<sup>19</sup> And it is also true that inventors

17. Trade secret protection is effectively unavailable for “self-revealing” inventions, *see infra* note 130 and accompanying text, and can be extinguished by reverse engineering even for inventions that are not, sometimes resulting in wide disclosure. But some trade secrets can last a long time. *See, e.g.,* *Wyeth v. Nat. Biologics, Inc.*, 395 F.3d 897, 899–900 (8th Cir. 2005) (holding that a trade secret right was successfully maintained in a product “on the market since 1942”). On the choice between patent and trade secret protection, *see* Andrew Beckerman-Rodau, *The Choice Between Patent Protection and Trade Secret Protection: A Legal and Business Decision*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 371, 380 (2002) (arguing that firms might opt for trade secret protection even where patent protection is available). *But cf.* *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 489–91 (1974) (expressing doubt that firms will opt for trade secret as opposed to patent protection for “clearly patentable” inventions). Concurrent patent and trade secret protection is often possible. *See* Brian J. Love & Christopher B. Seaman, *Best Mode Trade Secrets*, 15 YALE J.L. & TECH. 1, 3–4 (2012) (arguing that the effective elimination of the best mode requirement by the Leahy-Smith America Invents Act may allow for concurrent patent and trade secret protection for overlapping subject matter). But patent law's requirement of disclosure, *see* 35 U.S.C. § 112 (2012), limits this strategy. *Cf.* Dmitry Karshedt, *Did Learned Hand Get It Wrong?: The Questionable Patent Forfeiture Rule of Metallizing Engineering*, 57 VILL. L. REV. 261, 299–331 (2012) (discussing the possibility of trade secret protection followed by patent protection).

18. *See, e.g.,* *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150–52 (1989) (explaining that the patent system mandates disclosure of an invention in exchange for the exclusive rights to practice the invention); Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, in *THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS* 609, 615 (1962) (arguing that “[w]ith suitable legal measures, information may become an appropriate commodity”); Nancy T. Gallini, *The Economics of Patents: Lessons from Recent U.S. Patent Reform*, 16 J. ECON. PERSP. 131, 132 (2002) (arguing that inventors are more likely to reveal inventions with patent protection); Jason Rantanen, *Peripheral Disclosure*, 74 U. PITT. L. REV. 1, 16–21, 27 (2012) (arguing that inventors provide certain information because patents exist); Paul M. Romer, *Endogenous Technological Change*, 98 J. POL. ECON. S71, S84 (1990) (arguing that patents increase human knowledge and productivity); *see also* Note, *The Disclosure Function of the Patent System (or Lack Thereof)*, 118 HARV. L. REV. 2007, 2011 (2005) (explaining that some court decisions have “embrace[d] the disclosure rationale as a centerpiece of patent policy”).

19. Timothy R. Holbrook, *Possession in Patent Law*, 59 SMU L. REV. 123, 139–46 (2006) (“The patent system has a number of structural flaws that inhibit the ability of a patent to perform its teaching function.”); Mark A. Lemley, *Ignoring Patents*, 2008 MICH. ST. L. REV. 19, 19–20; Note, *supra* note 18, at 2021–23; *see also* Jeanne C. Fromer, *Patent Disclosure*, 94 IOWA L. REV. 539, 539–40 (2009) (maintaining that “[p]atent disclosure is essential” but contending that “the disclosure function is underperforming”); Paul Goldstein, *Kewanee Oil Co. v. Bicron Corp.: Notes on a Closing Circle*, 1974 SUP. CT. REV. 81, 91 (“Artfully drafted specifications may defeat the disclosure objective. In any event the extent to which the scientific and engineering communities rely on these documents for instruction is speculative at best.”). *See generally* Sean B. Seymore, *The Teaching Function of Patents*, 85 NOTRE DAME L. REV. 621 (2010) (arguing for the centrality of patent law's disclosure function and proposing mechanisms for improving it).

might sometimes disclose information without patent protection, whether via scientific articles, products that could be reverse-engineered, or other means.<sup>20</sup> Nonetheless, the disclosure role of patents is substantial and cannot be ignored.<sup>21</sup> As noted by one commentator, “Disclosure requirements in patent law advance dissemination of knowledge and trigger new research initiatives and scientific discoveries.”<sup>22</sup> These benefits can be achieved via disclosures in patents themselves, as well as via “peripheral disclosures” of the claimed invention in presentations, scientific articles, negotiations with potential business partners, and the like.<sup>23</sup> It follows that the effect of diminished patent protection might be a net reduction in the volume of disseminated ideas, which is a result that Justice Breyer wishes to avoid.

There are ways in which one can defend the proposition that patents might impede the flow or exchange of information. One consequence of “avoid[ing] the use of potentially patented ideas”<sup>24</sup> might be reduced *knowledge creation or acquisition*. Information that is never generated because of patents on certain research tools and methods cannot, a fortiori, “flow”<sup>25</sup> or be “exchange[d].”<sup>26</sup> Furthermore, Justice Breyer could mean that patents reduce the flow of information-embodying goods, such as machines, chemical compositions, and other technological products, by making them more expensive.<sup>27</sup> Finally, the availability of certain types of patents might discourage the sharing of early-stage research in contravention of academic norms.<sup>28</sup> All of these arguments might justify the bottom-line conclusion that it is possible for patents to generate disclosure-related detriments. But, as I show in

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20. See *supra* note 17 and accompanying text.

21. See, e.g., Lisa Larrimore Ouellette, *Do Patents Disclose Useful Information?*, 25 HARV. J.L. & TECH. 545, 546–47 (2012) (arguing that researchers use patents as a source of technical information). Moreover, patents are issued only after an examination and are indexed and searchable, while copyright protection does not even require registration. See 17 U.S.C. § 408(a) (2012).

22. LIOR ZEMER, *THE IDEA OF AUTHORSHIP IN COPYRIGHT* 10 (2007).

23. Arrow, *supra* note 18; Rantanen, *supra* note 18. But see J. Jonas Anderson, *Secret Inventions*, 25 BERKELEY TECH. L.J. 917 (2011) (arguing that trade secrecy can be socially preferable to patenting); Michael J. Burstein, *Exchanging Information Without Intellectual Property*, 91 TEX. L. REV. 227, 274–82 (2012) (arguing that intellectual property rights are not always necessary for facilitating information exchange). This debate, however, is simply not addressed in *LabCorp* or *Mayo*.

24. *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 127 (2006) (Breyer, J., dissenting from the order dismissing certiorari).

25. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1305 (2012).

26. *LabCorp*, 548 U.S. at 127; see *infra* notes 126–127 and accompanying text.

27. See *infra* notes 129–131 and accompanying text.

28. See *infra* notes 132–138 and accompanying text.

this Article, these harms eventuate only in very limited circumstances, which are not implicated by the patents invalidated in *Mayo*.

Moreover, even granting that at least some patents might have serious negative effects on access to ideas or information, it must be made clear that patent rights impact disclosure in ways that are quite different from copyrights. An important part of Professor Breyer's argument in favor of reduced copyright protection for technical literature is that, by making it more difficult to reproduce (and own a copy of) a scientific article or a textbook, copyright impedes dissemination of the article's or textbook's informational content.<sup>29</sup> The would-be reader, to be sure, can take a license, but in Professor Breyer's view, this hurdle would impose a serious burden on access to ideas.<sup>30</sup> I take no position on whether this conclusion is correct. Instead, assuming that *The Uneasy Case* accurately characterizes the information-access harms from copyright, I explain that these specific concerns, to the extent that Justice Breyer appears to have relied on them in his patent opinions,<sup>31</sup> do not cleanly translate to patent law.<sup>32</sup>

For one thing, there is a multitude of ways to use the information in a patent without infringing the claims.<sup>33</sup> For example, follow-on researchers are free to rely on patent disclosures to develop new theories and design products outside the scope of the patent's claims,<sup>34</sup> prepare to make products within the scope of the claims after the expiration of the patent,<sup>35</sup> and otherwise make use of the information

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29. Breyer, *supra* note 1, at 333, 333 n.212; *see also id.* at 315–36, 315 n.135.

30. *Id.* at 317–18.

31. *See* discussion *infra* Section II.A for textual arguments along these lines.

32. It is also worth noting that the copyright cases in which Justice Breyer dissented involved the specific problem of term extension or restoration—another contrast from patents, for which the term is a lot shorter and has not been recently extended.

33. *See, e.g.*, Kevin Emerson Collins, *The Knowledge/Embodiment Dichotomy*, 47 U.C. DAVIS L. REV. 1279, 1315–21 (2014); Brett M. Frischmann & Mark A. Lemley, *Spillovers*, 107 COLUM. L. REV. 257, 261, 290–92 (2007); Fromer, *supra* note 19, at 547–54; R. Polk Wagner, *Information Wants to Be Free: Intellectual Property and the Mythologies of Control*, 103 COLUM. L. REV. 995, 1003–10 (2003).

34. *See, e.g.*, *Burr v. Duryee*, 68 U.S. (1 Wall.) 531, 574 (1863) (“Every man has a right to make an improvement in a machine, and evade a previous patent, provided he does not invade the rights of the patentee.”); *Slimfold Mfg. Co. v. Kinkead Indus., Inc.*, 932 F.2d 1453, 1457 (Fed. Cir. 1991) (“Designing around patents is . . . one of the ways in which the patent system works to the advantage of the public in promoting progress in the useful arts, its constitutional purpose.”).

35. *Laitram Corp. v. Cambridge Wire Cloth Co.*, 919 F.2d 1579, 1583 (Fed. Cir. 1990) (“[N]either intent nor preparation constitutes infringement under 35 U.S.C. § 271.”), *superseded on other grounds by statute*, 35 U.S.C. § 271 (1994) (amended 2010), *as recognized in* *Rotec Indus., Inc. v. Mitsubishi Corp.*, 215 F.3d 1246, 1251 (Fed. Cir. 2000), *and* *Lang v. Pac. Marine & Supply Co.*, 895 F.2d 761, 765 (Fed. Cir. 1990).



in a patent's specification without practicing the claimed invention.<sup>36</sup> More importantly, patents can serve to educate others of the developments in the field and signal to competitors what not to do.<sup>37</sup> Patents generally control a very small fraction of the uses of ideas that are disclosed in them,<sup>38</sup> and that is certainly true of many of the patents invalidated in *Mayo's* wake.<sup>39</sup> All of these observations compel a critical reexamination of Justice Breyer's analysis in *Mayo* and *LabCorp*.<sup>40</sup>

The Supreme Court in *Mayo* concluded that the claims at issue were patent-ineligible within the meaning of 35 U.S.C. § 101 after characterizing them as directed to a law of nature unadorned by an "inventive application."<sup>41</sup> The rule that Justice Breyer first suggested in *LabCorp* and wrote into law in *Mayo* is broad: the case's "sweeping language"<sup>42</sup> brought down numerous patents, leading a former Patent Trial and Appeal Board judge (who presumably had to apply the rule) to note that the rule originating from *Mayo* has resulted in the "dismemberment of the patent system" and a shift to "trade secret as

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36. See, e.g., *Classen Immunotherapies, Inc. v. Elan Pharm., Inc.*, 786 F.3d 892, 898 (Fed. Cir. 2015) ("[T]he patent statute does not identify the mere dissemination of data as a potentially infringing activity . . ."); *id.* at 898 ("Filing a patent application is generally not an infringement of a patent."). Indeed, as long as downstream inventors are not engaged in the activities of making, using, or selling within the scope of the claims, they are free to develop improvements to the patented devices or processes and patent those improvements without the permission of the owner of the upstream patent. In this respect, patent law poses less of a barrier to follow-on innovation than current U.S. copyright law, since the latter denies protection for creative modifications to a protected underlying work if permission of the owner of that underlying work has not been obtained. See 17 U.S.C. § 103(a) (2012); *Anderson v. Stallone*, 11 U.S.P.Q.2d (BNA) 1161, 1163–64 (C.D. Cal. 1989). I thank Bob Brauneis for suggesting that I make this point.

37. See *infra* Section I.C.; cf. Clark D. Asay, *The Informational Value of Patents*, 31 BERKELEY TECH. L.J. 259, 267 (2016) (arguing that "patent holders increasingly use their patents in patent pledging scenarios, inter alia, in order to credibly and efficiently signal information to product, labor, and capital markets about their research and development activities and preferences"); Clarisa Long, *Patent Signals*, 69 U. CHI. L. REV. 625, 625 (2002) (arguing that patents can be a means to publicize information in a credible way).

38. See *supra* note 33.

39. See *infra* notes 165–177 and accompanying text.

40. Of course, while copyrights forbid only copying of protected subject matter, patent protection is not limited to copying. See Christopher A. Cotropia & Mark A. Lemley, *Copying in Patent Law*, 87 N.C. L. REV. 1421, 1424–37 (2009). In addition, once someone has accessed a copyrighted work, that person can make use of the ideas in the work as long as he or she does not copy the expression, while patent law renders actionable activities, such as making or selling, that fall within the scope of the claimed invention. See 35 U.S.C. § 271(a) (2012); see also *infra* notes 65–66 and accompanying text. Nonetheless, unlike copyright law according to Professor Breyer in *The Uneasy Case*, patent law generally lacks mechanisms to prevent access to information "at the front end," thereby foreclosing any use of the ideas in the disclosure. See Breyer, *supra* note 1.

41. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1296–98, 1304–06 (2012).

42. See *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1380, 1381 (Fed. Cir. 2015) (Linn, J., concurring), *cert. denied*, 136 S. Ct. 2511 (2016).

[the] sole form of intellectual property” for some industries.<sup>43</sup> I argue that *Mayo*’s breadth may be a result of a miscalibration stemming from an exaggerated concern for patents’ disclosure-related harms and insufficient consideration of their disclosure-related benefits. Indeed, while the Court does mention some benefits of patents, addressing their role in providing incentives to innovate,<sup>44</sup> a discussion of the value of disclosure is nowhere to be found in *Mayo* (or, for that matter, *LabCorp*).<sup>45</sup> An important argument in favor of patentability—one that could well have affected the sweep of the patentable subject matter test that Justice Breyer ultimately fashioned—may have simply been left off the scale. And although the result that the specific claims asserted in those cases should be unpatentable is correct<sup>46</sup> and may even be justifiable on very narrow, and subtle, disclosure-related grounds, these particular concerns can be addressed with a proportional, minimal approach that would not threaten numerous meritorious patents.

To be clear, Justice Breyer’s concern with impeded information flow is not the only rationale for vigorous limits on patentable subject matter. Much has also been said, including in *Mayo* itself,<sup>47</sup> about the role of preemption of downstream uses in justifying restrictions on patent eligibility.<sup>48</sup> One might even contend that it is preemption that played the decisive role in *Mayo* and that disclosure is irrelevant. But I

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43. *Where Do We Stand One Year After Alice?*, LAW360 (June 17, 2015), <http://www.law360.com/articles/668773/where-do-we-stand-one-year-after-alice> [<https://perma.cc/GA22-Y25T>] (comments of Dr. Scott Kamholz).

44. *Mayo*, 132 S. Ct. at 1305.

45. A reference to patent disclosure does appear in Justice Breyer’s opinion dealing with patent claim construction, see *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 848 (2015), and his dissent on the issue whether the Bayh-Dole Act automatically vests patent title in federal contractors, see *Bd. of Trs. of the Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 563 U.S. 776, 795 (2011) (Breyer, J., dissenting). In addition, Justice Breyer discussed patent disclosure in his two patent opinions during the past term. See *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2135, 2145 (2016) (holding that the so-called “broadest reasonable construction standard . . . helps ensure precision while avoiding overly broad claims, and thereby helps prevent a patent from tying up too much knowledge, while helping members of the public draw useful information from the disclosed invention and better understand the lawful limits of the claim”) (emphasis added); *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S. Ct. 1923, 1937 (2016) (Breyer, J., concurring) (“Through a complex system of incentive-based laws, patent law helps to encourage the development of, disseminate knowledge about, and permit others to benefit from useful inventions.”) (emphasis added). But *Mayo* and *LabCorp*, Justice Breyer’s patentable subject matter opinions, do not have any references to patent disclosure.

46. See *infra* Part III.

47. *Mayo*, 132 S. Ct. at 1301–03.

48. See, e.g., 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 (2011); Mark A. Lemley et al., *Life After Bilski*, 63 STAN. L. REV. 1315, 1330–31 (2011) (cited in *Mayo*, 132 S. Ct. at 1301–02); see also *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 127–28 (2006) (Breyer, J., dissenting from the order dismissing certiorari).

believe that my focus on disclosure is justified for three reasons. First, as other commentators have noted<sup>49</sup> and as the Court itself suggested,<sup>50</sup> concerns beyond preemption seemed to be at play in *Mayo*. Second, Justice Breyer's disclosure point cannot just be throwaway or errant language. Given his long-standing concern with the relationship between intellectual property and dissemination of knowledge, Justice Breyer would not have made statements related to information access in his opinions if he did not think that this rationale was important to his bottom-line conclusion. The third reason to address disclosure is that this aspect of Justice Breyer's opinions has not attracted much focus. While there is a great deal of literature critical of *Mayo*,<sup>51</sup> very little work has been done to understand Justice Breyer's thinking in these cases by taking as the starting point his views on copyright law.<sup>52</sup> This approach may thus cast Justice Breyer's patentable subject matter jurisprudence in a new light.

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49. Tun-Jen Chiang, *Competing Visions of Patentable Subject Matter*, 82 GEO. WASH. L. REV. 1858, 1869–73 (2014) (arguing that preemption concerns cannot logically justify the result in *Mayo*); Joshua D. Sarnoff, *The Current State of Patent Eligibility of Medical and Biotechnological Inventions in the United States*, in INTELLECTUAL PROPERTY AND EMERGING BIOTECHNOLOGIES: THE NEW BIOLOGY 84, 99 (Matthew Rimmer & Allison McLennan eds., 2012) (discussing “deontological moral arguments for invalidating patents” such as those at issue in *Mayo*); Ted Sichelman, Funk *Forward*, in INTELLECTUAL PROPERTY AT THE EDGE: THE CONTESTED CONTOURS OF IP 361, 370 (Rochelle Cooper Dreyfuss & Jane C. Ginsburg eds., 2014); Katherine J. Strandburg, *Much Ado About Preemption*, 50 HOUS. L. REV. 563, 566–67 (2012).

50. *Mayo*, 132 S. Ct. at 1305 (invoking the concern that patents like those asserted in *Mayo* might interfere with “sound medical care” (quoting Brief of Amici Curiae American College of Medical Genetics et al. at 7, *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012) (No. 10-1150), 2011 WL 4071917, at \*7)).

51. See, e.g., Bernard Chao, *Moderating Mayo*, 107 NW. U. L. REV. 423, 426–27, 433–36 (2012); Chiang, *supra* note 49, at 1869–73; Rebecca S. Eisenberg, *Diagnostics Need Not Apply*, 21 B.U. J. SCI. & TECH. L. 256, 262–84 (2015) [hereinafter Eisenberg, *Need Not Apply*]; Rebecca S. Eisenberg, *Prometheus Rebound: Diagnostics, Nature, and Mathematical Algorithms*, 122 YALE L.J. ONLINE 341, 341–49 (2013); John M. Golden, *Flook Says One Thing, Diehr Says Another: A Need for Housecleaning in the Law of Patentable Subject Matter*, 82 GEO. WASH. L. REV. 1765, 1795 (2014) (“So far, the substance of the Court’s opinions [on § 101] has lacked much of the sharpness and self-awareness that the Justices have displayed at oral argument. In its written work product, the Court can do better.”); Christopher M. Holman, *Mayo, Myriad, and the Future of Innovation in Molecular Diagnostics and Personalized Medicine*, 15 N.C. J.L. & TECH. 639, 667–72 (2014); Jeffrey A. Lefstin, *Inventive Application: A History*, 67 FLA. L. REV. 565 (2016); Jacob S. Sherkow, *And How: Mayo v. Prometheus and the Method of Invention*, 122 YALE L.J. ONLINE 351, 351–58 (2013); Sichelman, *supra* note 49, at 370; David O. Taylor, *Confusing Patent Eligibility*, 84 TENN. L. REV. (forthcoming 2017), <http://ssrn.com/abstract=2754323> [<https://perma.cc/Z9P9-PL3T>]. But see I. Glenn Cohen, *Make It Work!: Justice Breyer on Patents in the Life Sciences*, 128 HARV. L. REV. 418, 419–28 (2014) (praising the approach in *LabCorp* and *Mayo*); see also KALI MURRAY, A POLITICS OF PATENT LAW: CRAFTING THE PARTICIPATORY PATENT BARGAIN 104–12 (2013). For a highly qualified defense of *Mayo* and a proposal for cabining the rule in that case, see Kevin Emerson Collins, *Patent-Ineligibility as Counteraction*, 94 WASH. U. L. REV. (forthcoming 2017), <http://ssrn.com/abstract=2748288> [<https://perma.cc/N6N5-RLMV>].

52. For a rare example, see MURRAY, *supra* note 51, at 104–12.

The rest of the Article proceeds in three Parts. Part I describes Professor Breyer's ideas in *The Uneasy Case* and a follow-up essay, and then discusses his copyright jurisprudence on the Supreme Court. This Part also explains the value of access to copyrighted articles directed to technical subject matter in the words of those who supported a fair use defense to claims of copyright infringement for their copying. Part II examines *Mayo* and *LabCorp* and evaluates the claim that patents impede access to information. This Part shows that, while certain sorts of patents directed to basic research might generate significant information-flow concerns, the patents targeted by these Justice Breyer opinions do not fall into that category. This Part accordingly questions the rule of *Mayo*, and then considers objections to my critiques of Justice Breyer's approach in that case. Part III discusses a less obvious, more limited rationale under which the specific patents at issue in *Mayo* (and *LabCorp*) might cause information-flow problems, but concludes that those problems are adequately addressed under some different, narrower rule than that announced in *Mayo*.

## I. FROM *THE UNEASY CASE* TO THE SUPREME COURT

### A. The Uneasy Case

*The Uneasy Case for Copyright*, true to its title, is mainly about copyright law. The article questions whether copyright protection is necessary to incentivize the creation and publication of books, particularly works of nonfiction, and examines whether significant societal gains might be achieved by copyright's elimination.<sup>53</sup> Much of the article focuses specifically on copyright protection for technical subject matter—for example, Professor Breyer's discussion of copyrights in books focuses on tradebooks and textbooks.<sup>54</sup> As suggested in the Introduction, he strongly favored unfettered copying of these materials. Professor Breyer explained that “much current xeroxing is of texts and other scientific, professional, or technical books and articles,”<sup>55</sup> and that their reproduction should be minimally impeded because “widespread dissemination of these kinds of works has various spillover benefits similar to those provided by the original distribution of the works copied.”<sup>56</sup> The article also includes a lengthy discussion of copyright in software; Professor Breyer expressed “substantial doubt on

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53. Breyer, *supra* note 1, at 313–23.

54. *Id.* at 300–08.

55. *Id.* at 318.

56. *Id.*

the present need for computer program copyright protection"<sup>57</sup> and also noted that "the case for future need is quite speculative."<sup>58</sup>

In an essay responding to a critique of *The Uneasy Case*,<sup>59</sup> Professor Breyer condemned the outcome of a trial in a well-known case, *Williams & Wilkins Co. v. United States*,<sup>60</sup> that made his fears a reality: a publisher had prevailed (in a judgment later overturned on appeal on fair use grounds) against the libraries of the National Institutes of Health and the National Institute of Medicine for infringing its copyrights by making photocopies of scientific articles for their patrons. Professor Breyer contended that this decision, "forbidding libraries to xerox single copies of articles for research purposes, threatens to impose a heavy 'transactions costs' burden upon research and makes more urgent the need for a properly constructed exemption."<sup>61</sup> He thus saw free photocopying of technical literature as an important means of effectuating downstream benefits of scientific research, including dissemination of knowledge and stimulation of further scientific inquiry.

Professor Breyer's interest in copyright in scientific publications, one imagines, naturally led him to engage with patent law in his seminal article. In some passages of *The Uneasy Case*, he appeared to express the uncontroversial proposition that patents may diminish social welfare by restricting access to the embodiments of patented technologies.<sup>62</sup> For example, in a footnote in a section considering the abolition of copyright, Breyer noted that "a patent provides its owner with a monopoly of an 'idea'—a fact that limits the marketing of competing products that might hold down the patented product's price."<sup>63</sup> In other passages of *The Uneasy Case*, however, Professor Breyer seemed to exhibit a more distinctive, less common concern about harmful effects of patents. He asserted that "patent protection, by imposing a charge upon using an idea, *inhibits the flow*

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57. *Id.* at 346.

58. *Id.* at 347.

59. Stephen Breyer, *Copyright: A Rejoinder*, 20 UCLA L. REV. 75, 75–83 (1972) (responding to Barry W. Tyerman, *The Economic Rationale for Copyright Protection for Published Books: A Reply to Professor Breyer*, 18 UCLA L. REV. 1100 (1970)).

60. No. 73-68, 1972 WL 17712, at \*1–19 (Ct. Cl. Feb. 16, 1972), *pet. dismissed*, 487 F.2d 1345 (Ct. Cl. 1973), *aff'd by an equally divided court*, 420 U.S. 376 (1975).

61. Breyer, *supra* note 59, at 80.

62. See also *infra* notes 157–164 and accompanying text; *cf.* Collins, *supra* note 33 (setting forth the distinction between patenting embodiments and patenting knowledge).

63. Breyer, *supra* note 1, at 318 n.149; see also *id.* at 348 n.268 (arguing that "the need to 'invent around' patented ideas may waste development resources," but not acknowledging the fact that this could be a socially productive use of patents); *cf.* *supra* note 34 and accompanying text.

of already-created ideas throughout the industry.”<sup>64</sup> The notion that patents can inhibit the flow of ideas—the dissemination of information—is more particular, and identifies a potential source of intellectual property harm that more closely aligns with some of the specific concerns that Breyer had expressed about copyright. The “flow-inhibition” argument suggests that patents might interfere not only with the use of some patented embodiments, but also with the flow and development of knowledge about the underlying invention—just as copyright-driven restrictions on the distribution of scientific literature might. As the following sections demonstrate, this argument is pervasive in Justice Breyer’s intellectual property opinions.

Overall, *The Uneasy Case* demonstrates Professor Breyer’s grave concerns with the effect of intellectual property rights on the dissemination of information. In addition, although this work was focused on copyright, it is clear that he saw patents as even more pernicious because they protect “ideas,” as opposed to merely expression.<sup>65</sup> Missing from Professor Breyer’s short critique of patents in *The Uneasy Case*, however, is an explanation of how exactly patents protect ideas, as well as consideration of the fact that patents also *reveal* ideas.<sup>66</sup> As a scholar, Breyer did not have much more to say about intellectual property, as he began focusing on administrative law. It was not until his service on the Supreme Court that we again saw his views on intellectual property.<sup>67</sup>

### B. The Copyright Cases

Justice Breyer’s concern with barriers to knowledge transfer and diffusion, long ago expressed in *The Uneasy Case*, is unmistakable in his opinions on the Court. On the copyright side, Justice Breyer dissented in *Eldred v. Ashcroft*<sup>68</sup> and *Golan v. Holder*.<sup>69</sup> In these cases, Justice Breyer concluded that Congress unconstitutionally exceeded its power under the Intellectual Property Clause in enacting, respectively, the Sonny Bono Copyright Term Extension Act and § 514 of the Uruguay Round Agreements Act (the latter granting copyright

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64. Breyer, *supra* note 1, at 348 n.268 (emphasis added).

65. *Cf. supra* note 40 (discussing idea-expression dynamics in patent and copyright).

66. Breyer does flag the trade secret option in the context of intellectual property protection for software in *The Uneasy Case*, and even alludes to patent law’s disclosure function. *See* Breyer, *supra* note 1, at 349 n.269. The value of that function, however, is never considered.

67. My research has not uncovered whether Judge Breyer authored any intellectual property opinions while serving on the First Circuit.

68. 537 U.S. 186, 242 (2003) (Breyer, J., dissenting).

69. 132 S. Ct. 873, 899 (2012) (Breyer, J., dissenting).

protection to various foreign works that had previously entered the public domain in the United States).<sup>70</sup> In *Eldred*, he wrote that copyright term extension would likely lead to “high prices [that] will unnecessarily restrict distribution of classic works”<sup>71</sup> and create additional costs of seeking permission from the copyright owner for “historians, scholars, teachers, writers, artists, database operators, and researchers of all kinds—those who want to make the past accessible for their own use or for that of others.”<sup>72</sup> The upshot of this dissent was that such restrictions clash with the values of a “Nation constitutionally dedicated to the free dissemination of speech, information, learning, and culture.”<sup>73</sup> And in *Golan*, Justice Breyer, writing for himself and Justice Alito, would have invalidated a “statute [that] inhibits an important preexisting flow of information.”<sup>74</sup> He lamented that the majority allowed “Congress seriously to exacerbate” the “dissemination-restricting harms of copyright”<sup>75</sup> and overlooked its “speech-related harms.”<sup>76</sup> The echoes of *The Uneasy Case* are loud and clear in these opinions.

The views that Breyer first expressed in *The Uneasy Case* are not limited to dissents. In *Kirtsaeng v. John Wiley & Sons*, the Court dealt with the question of whether the first-sale doctrine, which holds that an authorized sale of a copyrighted work extinguishes the copyright owner’s right in the copy that was sold and thus allows the buyer “to dispose of [that copy] as he or she wishes,”<sup>77</sup> applies to works sold abroad and imported into the United States. Writing for the Court,

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70. For an argument that intellectual property laws are not subject to strong constitutional limits under a proper interpretation of the Intellectual Property Clause, see Paul M. Schwartz & William Michael Treanor, *Eldred and Lochner: Copyright Term Extension and Intellectual Property as Constitutional Property*, 112 YALE L.J. 2331, 2363–414 (2003). *But cf.* Raymond Shih Ray Ku, *Copyright Lochnerism*, 33 N. KY. L. REV. 401 (2006) (criticizing the Schwartz-Treanor thesis).

71. *Eldred*, 537 U.S. at 249 (Breyer, J., dissenting).

72. *Id.* at 250.

73. *Id.* at 244.

74. *Golan*, 132 S. Ct. at 912 (Breyer, J., dissenting).

75. *Id.* at 906.

76. *Id.* at 907. See *infra* notes 83–86 and accompanying text for more on the First Amendment dimension of the harm at issue. In the patent context, however, First Amendment arguments against intellectual property protection have rarely been explicitly made in briefs to the Supreme Court, and would seem to be difficult to make. For one approach, see Peter Lee, “All Life is an Experiment”: *Research Tool Patents, Epistemological Monopolies, and the First Amendment* (UC Davis Legal Studies, Research Paper No. 348, Aug. 23, 2013), <http://ssrn.com/abstract=2315256> [<https://perma.cc/YB4A-RYAP>]. But the First Amendment does appear to be doing work behind the scenes in *Mayo*. See *infra* notes 96 & 109 and accompanying text. For an explicit judicial First Amendment argument against certain patents, see *Intellectual Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307, 1322–29 (Fed. Cir. 2016) (Mayer, J., concurring).

77. 133 S. Ct. 1351, 1355 (2013) (interpreting 17 U.S.C. § 109 (2012)).

Justice Breyer explained that limiting the doctrine to sales made in the United States would create “practical copyright-related harms” that “would threaten ordinary scholarly, artistic, commercial, and consumer activities.”<sup>78</sup> One of the rhetorical questions in the opinion, “Are the libraries to stop circulating or distributing or displaying the millions of books in their collections that were printed abroad?”<sup>79</sup> suggests quite strongly that the harms include diminished information access and calls to mind *The Uneasy Case*, as well as Justice Breyer’s dissents in *Eldred* and *Golan*. Justice Breyer’s copyright skepticism, then, hinges in large part on the worry about this sort of harm.<sup>80</sup> What is particularly interesting, however, is that the ideas Justice Breyer developed in *The Uneasy Case* arguably had an even more significant impact on his patent law jurisprudence. But before considering Justice Breyer’s views on patents, I take a closer look at the precise nature in which copyright law might interfere with the flow of information and then continue exploring the point that patents can do just the opposite.

### C. *The Harms of Copyrights—and the Benefits of Patents?*

As *Williams & Wilkins Co. v. United States*<sup>81</sup> and similar cases show, many educators, librarians, and researchers have cared deeply about unimpeded access to copyrighted articles.<sup>82</sup> The merits-stage amicus brief of the National Education Association to the Supreme Court, for example, argued for fair use based on “the public’s right to receive information and ideas and the public’s right to read,” as animated by the First Amendment.<sup>83</sup> Likewise, the amicus brief for the

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78. *Id.* at 1358.

79. *Id.* at 1364.

80. Justice Breyer recently authored an opinion in favor of copyright holders in *American Broadcasting Cos. v. Aereo, Inc.*, 134 S. Ct. 2498, 2502–12 (2014). But that case concerned primarily entertainment, not learning or scientific research. *Cf.* *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 949, 954 (2005) (Breyer, J., concurring) (discussing “legitimate noninfringing uses” such as “research information,” “public domain films,” “historical recordings and digital educational materials,” and “news broadcasts past and present,” among others, in a copyright infringement lawsuit involving a defendant that operated a peer-to-peer network).

81. 487 F.2d 1345 (Ct. Cl. 1973), *aff’d by an equally divided court*, 420 U.S. 376 (1975); *see supra* notes 60–61 and accompanying text; *see also* *Princeton Univ. Press v. Mich. Document Servs., Inc.*, 99 F.3d 1381, 1383 (6th Cir. 1996) (en banc); *Am. Geophysical Union v. Texaco Inc.*, 60 F.3d 913, 914 (2d Cir. 1994).

82. Starting from *Williams & Wilkins* itself, all of these cases were hard-fought and attracted significant amicus involvement. Many lower-court and certiorari-stage briefs in *Williams & Wilkins* are helpfully collected in 1 *THE WILLIAMS & WILKINS CASE (THE WILLIAMS & WILKINS COMPANY V. THE UNITED STATES)* (Marilyn G. McCormick compiler, 1974).

83. Brief of the National Education Ass’n, Amicus Curiae, in Support of Respondent at 23, *Williams & Wilkins Co. v. United States*, 420 U.S. 376 (1975) (No. 73-1279), 1974 WL 187546, at \*23 (citations, quotation marks, and emphasis omitted). There is something special about access



Association of Research Libraries and other library organizations emphasized the importance of “dissemination of knowledge” in furtherance of “scholarship and research.”<sup>84</sup> And an amicus brief to the Court of Claims in this case—joined, interestingly enough, by the Mayo Foundation—emphasized that “open communication of knowledge and ideas is an essential characteristic of a free society.”<sup>85</sup> The United States in its merits brief to the Supreme Court was in accord, contending that “[a] liberal application of the fair use doctrine is essential with respect to scientific works precisely because unless these works are disseminated, absorbed, and commented upon, their purpose will not be served.”<sup>86</sup>

The Court of Claims agreed with these sentiments in a closely divided opinion left undisturbed by the Supreme Court’s 4-4 affirmance. As summarized by a contemporary commentator, the Court of Claims was significantly motivated by a “concern over the detriment to medical and scientific research if the photocopying were held unlawful.”<sup>87</sup> In the court’s own words, one of the reasons it found fair use was that “[t]here has been no attempt to misappropriate the work of earlier scientific writers for forbidden ends, but rather an effort to gain easier access to the material for study and research.”<sup>88</sup> The court explained that “the law gives copying for scientific purposes a wide scope” and that the record “demonstrate[d] injury to medical and scientific research if photocopying of this kind is held unlawful.”<sup>89</sup> Although the Court of Claims did not cite Professor Breyer, it certainly showed sympathy for his views.

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to information: the Charter of Fundamental Rights of the European Union includes an Article titled “Freedom of expression and information,” which states that “the right to freedom of expression” includes “freedom to hold opinions and to receive and impart information and ideas without interference by public authority.” Tellingly, this Article appears between Articles titled “Freedom of thought, conscience and religion” and “Freedom of assembly and of association.” Charter of Fundamental Rights of the European Union (2000/C 364/01), art. 10, 11 & 12. The doctrine of copyright fair use in the United States is said to reflect some of these values. See Eldred v. Ashcroft, 537 U.S. 186, 219–21 (2003).

84. Brief of Amici Curiae—Ass’n of Research Libraries et al. at 74, *Williams & Wilkins Co. v. United States*, 420 U.S. 376 (1975) (No. 73-1279), 1974 WL 186244, at \*74.

85. Brief of Amici Curiae—Ass’n of Research Libraries et al. at 27, *Williams & Wilkins Co. v. United States*, 487 F.2d 1345 (Ct. Cl. 1973) (No. 73-68), reprinted in *THE WILLIAMS & WILKINS CASE*, *supra* note 82, at 104.

86. Brief of Respondent at 24, *Williams & Wilkins Co. v. United States*, 420 U.S. 376 (1975) (No. 73-1279).

87. Marc R. K. Bunker, Case Note, *Copyright—Photocopying as Fair Use—Williams & Wilkins Co. v. United States*, 16 B.C. L. REV. 141, 148 (1974).

88. *Williams & Wilkins Co. v. United States*, 487 F.2d 1345, 1354 (Ct. Cl. 1973).

89. *Id.* at 1362.

These concerns persisted through time, manifesting themselves again with an interesting twist when a corporate defendant claimed fair use in *American Geophysical Union v. Texaco Inc.* In this case, “plaintiffs American Geophysical Union and 82 other publishers of scientific and technical journals . . . brought a class action claiming that Texaco’s unauthorized photocopying of articles from their journals constituted copyright infringement.”<sup>90</sup> The Court of Appeals for the Second Circuit concluded that the photocopying was not fair use, but not without controversy—Judge Dennis Jacobs agreed with Texaco’s position and wrote a strong dissent. In a discussion reminiscent of some arguments in *The Uneasy Case*, Judge Jacobs argued that “the photocopying of journal articles, and the use of them, is customary and integral to the creative process of science.”<sup>91</sup> He explained that having a file of articles was important “to steer clear of repetition and dead ends, to evaluate theories and hypotheses for possible theoretical development or commercial application, to give credit to others,”<sup>92</sup> and so on.

Judge Jacobs’s arguments are well taken. In the practice of science, existing published work often constitutes a guide to what *not* to do, or at least a signpost of where there are gaps in research that could be filled by follow-on investigators. Here’s how Texaco, the defendant, explained the value of having access to files of scientific articles: “Without awareness of new developments, our people could continue to pursue work already conducted and reported by others. In reinventing the wheel, we would waste time, manpower and money . . . .”<sup>93</sup> The purpose of the article file was to “us[e] the reported work as a springboard to novel developments that would be the property of Texaco.”<sup>94</sup> In short, the value of access to scientific articles can often be to learn what area of research has already been occupied, to provide attribution where it is due, and to point the downstream researcher to a different area of focus.

Patents, of course, can also play the role of disseminating information to the benefit of society, including making others aware of new developments and suggesting new areas of research.<sup>95</sup> This would

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90. 60 F.3d 913, 914 (2d Cir. 1994).

91. *Id.* at 935 (Jacobs, J., dissenting).

92. *Id.* at 933.

93. Brief of Appellees at 12, *Am. Geophysical Union v. Texaco Inc.*, 60 F.3d 913 (2d Cir. 1994) (No. 92-9341), 1993 WL 13030326, at \*12.

94. *Id.*

95. See *supra* notes 13–23 & 33–39 and accompanying text. Justice Breyer’s reasoning may presuppose that equivalent information might be generated and revealed without the patent incentive. On that point, see *infra* notes 131–132 and accompanying text.

seem to make it difficult to argue, as has been done for copyright, that patents could interfere with “the public’s right to receive information and ideas and the public’s right to read.”<sup>96</sup> The traditional role of patent disclosure, to be sure, is to teach skilled artisans how to make and use the claimed subject matter so as to satisfy the quid pro quo of the patent system,<sup>97</sup> and the effectiveness of this role of the patent document is a matter of a great debate.<sup>98</sup> But even this imperfect function of disclosure surely has some value that must be weighed against any harm that patents might do with respect to knowledge dissemination and creation. Moreover, given the “what not to do” value and other peripheral benefits of patent disclosures, it becomes clear that the informational contribution of patents extends significantly beyond their foundational teaching function.<sup>99</sup> In the next Part, I further build on the observation that, while Justice Breyer placed the potentially negative effects of patents on the flow of information squarely at issue in *Mayo* and *LabCorp*, he did not mention the disclosure benefits of patents.<sup>100</sup> Specifically, I examine in detail the claim that patents such as those litigated in these cases might significantly impede information flow.

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96. Brief of the National Education Ass’n, *supra* note 83, at 23 (citations, quotation marks, and emphasis omitted). *But cf.* Brief for Petitioners at 20, 47, *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012) (No. 10-1150), 2011 WL 3919717, at \*20, \*47 (repeatedly referring to “research and speech” as though chilling both generates the same sorts of concerns); MURRAY, *supra* note 51, at 110 (arguing that Justice Breyer’s patent opinions protect “the communicative basis of the doctor-patient relationship”); *supra* note 76 and accompanying text; *infra* note 109 and accompanying text. But patents like those at issue in *Mayo* are not all about communication—the doctor generally has to order a test for there to be actionable infringement. For an argument that the patents litigated in *Mayo* are nonetheless problematic, *see infra* Part III.

97. *See supra* notes 13–23 and accompanying text.

98. *See supra* note 18–23 and accompanying text. In addition, there are problems with patents’ effectiveness at putting others on notice of the extent of the patentee’s rights. *See, e.g.*, Dan L. Burk & Mark A. Lemley, *Fence Posts or Sign Posts? Rethinking Patent Claim Construction*, 157 U. PA. L. REV. 1743, 1746–47 (2009) (questioning how well patent claims delineate property rights); Tun-Jen Chiang, *Fixing Patent Boundaries*, 108 MICH. L. REV. 523, 525 (2010) (discussing problems with the notice function of claims).

99. *See also supra* notes 33–39 and accompanying text. To this end, Professor Sean Seymore argued that there would be value in issuing patents that report negative results. *See* Sean B. Seymore, *The Null Patent*, 53 WM. & MARY L. REV. 2041, 2048 (2012).

100. *Cf. supra* note 66.

## II. JUSTICE BREYER ON PATENT LAW: THE LINKS TO COPYRIGHT AND “INFORMATION FLOW” CONCERNS

### A. Justice Breyer on Patentable Subject Matter

Justice Breyer interpreted the subject matter exclusions implied in § 101 of the Patent Act in his opinion for the unanimous Court in *Mayo v. Prometheus*<sup>101</sup> and in his dissent from the dismissal of certiorari in *LabCorp v. Metabolite*.<sup>102</sup> In these opinions, Justice Breyer endorsed a vigorous role for the patentable subject matter doctrine as a limit on what can be patented using justifications that unmistakably draw their intellectual lineage from his copyright writings. In particular, Justice Breyer focused not only on potential general social welfare losses from reduced distribution of the embodiments of the patented technology,<sup>103</sup> but also on restrictions on the flow of information and the development of knowledge—an important concern of his dating back to *The Uneasy Case*.<sup>104</sup>

Specific worries about the flow of information aside, Justice Breyer’s patentable subject matter opinions reflect wide-ranging concerns about the effects of patents on innovation that are expressed in terms not unlike those he used with respect to copyrights. In *Mayo*, Justice Breyer wrote that patenting of laws of nature and the like would “inhibit further discovery”<sup>105</sup> and “tend to impede innovation more than it would tend to promote it.”<sup>106</sup> In the *LabCorp* dissent, Justice Breyer tied these concerns to a constitutional limit on the reach of intellectual property in general, noting that “the reason for the exclusion is that sometimes *too much* patent protection can impede rather than ‘promote the Progress of Science and useful Arts,’ the constitutional objective of patent and copyright protection.”<sup>107</sup> He also made an explicit parallel to copyright law when he cited *Nichols v. Universal Pictures Corp.*, a case that stands for the proposition that copyright protection cannot extend so broadly as to cover ideas as opposed to merely expression.<sup>108</sup> These points, in turn, seem to build on the explicit constitutional argument in the *Eldred* dissent, where Justice Breyer contended that the “practical

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101. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012).

102. *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 127 (2006) (Breyer, J., dissenting from the order dismissing certiorari).

103. *Cf. supra* notes 62–64 and accompanying text.

104. *See supra* Section I.A.

105. *Mayo*, 132 S. Ct. at 1301.

106. *Id.* at 1293.

107. *LabCorp*, 548 U.S. at 126–27 (quoting U.S. CONST. art. I, § 8, cl. 8).

108. *Id.* at 127 (citing *Nichols v. Universal Pictures Corp.*, 45 F.2d 119, 122 (2d Cir. 1930)).

effect [of copyright extension] is not to promote, but to inhibit, the progress of 'Science'—by which word the Framers meant learning or knowledge."<sup>109</sup> Although *Mayo* does not explicitly mention copyright or the Constitution, the similarity of language across the three opinions is too strong to ignore.

The parallels between Justice Breyer's concerns with effects of copyright and patent on information transfer are also quite apparent. Indeed, his view that intellectual property rights threaten the flow of information clearly comes through in his patent opinions. In *LabCorp*, Justice Breyer wrote that patent rights might "*imped[e] the free exchange of information . . . by forcing researchers to avoid the use of potentially patented ideas, by leading them to conduct costly and time-consuming searches of existing or pending patents, by requiring complex licensing arrangements,*" and, perhaps most importantly, by "raising the costs of using the patented information, sometimes prohibitively so."<sup>110</sup> The parallel passage from *Mayo* is very similar: he explained that patents "can impede the flow of information that might permit, indeed spur, invention, by, for example, raising the price of using the patented ideas once created."<sup>111</sup>

In a puzzling way—because use and transfer are very different activities—the use and transfer of information seem to be equated in these passages. But the puzzle could be better understood once one recalls that hindrance of transfer of information is a problem with copyright that Justice Breyer identified in *The Uneasy Case*. The problem is that no use of information can occur without its initial transfer, which copyright law might prevent. And the quoted passages from *Mayo* and *LabCorp* convey his apparent view that patent law, like

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109. *Eldred v. Ashcroft*, 537 U.S. 186, 243 (2003) (Breyer, J., dissenting) (citing EDWARD C. WALTERSCHEID, *THE NATURE OF THE INTELLECTUAL PROPERTY CLAUSE: A STUDY IN HISTORICAL PERSPECTIVE* 125–26 (2002)). This dissent also indirectly addressed a related First Amendment argument. See *id.* at 244 ("The Copyright Clause and the First Amendment seek related objectives—the creation and dissemination of information."); see also *Golan v. Holder*, 132 S. Ct. 873, 891–92 (2012) (Breyer, J., dissenting) (similar); *supra* notes 76 & 96 and accompanying text; cf. Judith O'Neill, *Recent Developments, Copyright—Extensive Photoduplication of Copyrighted Scientific Journals by Libraries Does Not Constitute Copyright Infringement*, *Williams & Wilkins Co. v. United States*, 487 F.2d 1345 (1973), 3 U. BALT. L. REV. 306, 310–11 (1974):

The constitutional argument is that the first amendment right of the American people to freedom of speech coupled with their ninth amendment right to free dissemination of information reduce the copyright holder's protection to a privilege granted in the interest of furthering the constitutional right of the people. . . . In no case . . . is the encouragement of the author to frustrate the very purpose for which it exists, to afford the people free and unobstructed access to information.

110. *LabCorp*, 548 U.S. at 127 (emphasis added). Note that this language does not account for the fact that one can use ideas disclosed in patents without infringing. See *supra* notes 33–39 and accompanying text.

111. *Mayo*, 132 S. Ct. at 1305.

copyright law, has an information-transfer problem that might, in turn, interfere with “use.”<sup>112</sup> But this contention does not take account of the fact that patents might freely transfer the information in the first place, nor of the notion that noninfringing uses of patents are ubiquitous.

Additional copyright-patent parallels abound in Justice Breyer’s writings. By way of a further example, *Mayo*’s language may be compared to that in his dissent in *Golan*, which issued two months earlier. In that dissent, he argued for invalidation of a law that “inhibits an important preexisting flow of information”<sup>113</sup> and imposes “administrative costs, and restrictions on dissemination.”<sup>114</sup> Again, the similarity in the approaches is sufficiently striking that one can make a plausible inference that Justice Breyer sees patents and copyrights as imposing analogous sorts of harms.<sup>115</sup> This general concern with intellectual property is succinctly captured in a footnote in *The Uneasy Case*, in which Professor Breyer stated that “[i]ncreased circulation of information would seem to be a critical factor in the creation of new ideas.”<sup>116</sup>

Justice Breyer’s couching of information-access harms of patents in similar terms to copyrights is perplexing because it characterizes the patent system as doing essentially the reverse of its core function of encouraging information disclosure and dissemination.<sup>117</sup> As noted earlier, the proposition is certainly not indefensible, but it would at a minimum appear controversial and require significant unpacking.<sup>118</sup> How could patents “imped[e] the flow of information” in spite of their disclosure-forcing function? And is there something about the claims litigated in *Mayo* and *LabCorp*, in particular, that presents information-access problems? I first address the larger question of how patents might impede the flow of information, and then discuss the patents at issue in *Mayo* and the rule that came out of that case.

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112. *But cf.* Robert P. Merges, *A Few Kind Words for Absolute Infringement Liability in Patent Law*, 31 BERKELEY TECH. L.J. 1 (2016) (arguing that the rules of patent infringement liability are consistent with the goal of encouraging technical communications).

113. *Golan v. Holder*, 132 S. Ct. 873, 912 (2012) (Breyer, J., dissenting).

114. *Id.* at 903.

115. *See also supra* notes 71–75 & 109 and accompanying text.

116. Breyer, *supra* note 1, at 315 n.135. This footnote includes a “*cf.*” cite to a seminal paper by Professor Kenneth Arrow, which somewhat cuts against Breyer’s thesis when it states that “no amount of legal protection can make a thoroughly appropriable commodity of something so intangible as information.” Arrow, *supra* note 18, at 615.

117. *See supra* notes 13–23 and accompanying text.

118. *See supra* notes 24–28 and accompanying text.

*B. Patents as Threats to Information Flow*

One way that patent law could impede the flow of information is by allowing proprietization of inventions that help scientists generate or acquire useful knowledge. Patents on research tools like microscopes, foundational techniques like gene splicing, and other patents that might cover downstream research efforts may fall into this category.<sup>119</sup> Concerns about upstream patents are surely not trivial and have been raised by numerous commentators,<sup>120</sup> including me.<sup>121</sup> Discomfort with such patents is partly reflected in the applications of the utility and written description requirements of the Patent Act to prohibit the patenting of the objects of research, like chemical compounds without any known non-research uses<sup>122</sup> and functions of as-yet unknown drugs,<sup>123</sup> respectively, in certain well-defined circumstances. Furthermore, in a recent article, Professors Brenda Simon and Ted Sichelman highlighted the anti-competitive effects of patents on research-tool-type technologies that can help their owners to generate a large amount of data that could be protected as trade secrets.<sup>124</sup>

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119. See, e.g., Lemley et al., *supra* note 48, at 1339 (expressing concern over “ownership of generative building blocks”); Janice M. Mueller, *No “Dilettante Affair”: Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 10–17 (2001) (describing the dangers of upstream patenting to biotechnology research); Joshua D. Sarnoff & Christopher M. Holman, *Recent Developments Affecting the Enforcement, Procurement, and Licensing of Research Tool Patents*, 23 BERKELEY TECH. L.J. 1299, 1302–03 (2008) (expressing concern that research tool patents may have preemptive effects on research); see also Dmitry Karshtedt, *The Completeness Requirement of Patent Law*, 56 B.C. L. REV. 949, 976–81 (2015) (explaining that concern about the patenting of upstream inventions is pervasive in U.S. patent doctrine and legal scholarship).

120. See Rebecca S. Eisenberg & Robert P. Merges, *Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AIPLA Q.J. 1, 18 (1995); Peter Yun-hyoung Lee, *Inverting the Logic of Scientific Discovery: Applying Common Law Patentable Subject Matter Doctrine To Constrain Patents on Biotechnology Research Tools*, 19 HARV. J.L. & TECH. 79, 82, 106–08 (2005) (arguing that patent law must distinguish “between upstream, enabling resources . . . and downstream, end-product applications”); Arti K. Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 124 (1999) (warning that upstream patents are “likely to inhibit creativity and thus progress”); see also Mueller, *supra* note 119. See generally Michael S. Mireles, *An Examination of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation*, 38 U. MICH. J.L. REFORM 141 (2004).

121. Karshtedt, *supra* note 119.

122. *Brenner v. Manson*, 383 U.S. 519, 534–35 (1966); see also *In re Fisher*, 421 F.3d 1365, 1370–71 (Fed. Cir. 2005) (requiring that, to comply with the utility requirement, the claimed composition must have a “substantial utility” and a “particular benefit”).

123. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1358 (Fed. Cir. 2010) (en banc); *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 929 (Fed. Cir. 2004).

124. Brenda M. Simon & Ted M. Sichelman, *Data-Generating Patents*, 111 NW. U. L. REV. (forthcoming 2017), <http://ssrn.com/abstract=2753547> [<https://perma.cc/JQT8-5ZEJ>]; see Dan L. Burk, *Patents as Data Aggregators in Personalized Medicine*, 21 B.U. J. SCI. & TECH. L. 233 (2015)

Nonetheless, while the prohibition of patenting of *objects* of research is at least relatively well-established,<sup>125</sup> it seems inconceivable that a patent system would completely fail to protect research tools like microscopes, mass spectrometers, and the like,<sup>126</sup> just because the underlying technology has a role to play in the development of new knowledge.<sup>127</sup> In addition, as we will see, the patents asserted in *Mayo* decidedly were not these kinds of patents.<sup>128</sup>

Patents could also slow the dissemination of information by restricting access to information goods. Following along with the language from *Mayo*, if patents “rais[e] the price of using the patented ideas”<sup>129</sup> by covering products embodying the ideas, then the products would be less readily available due to higher prices and the flow of information embodied in the products would be thus impeded. While this is correct as a matter of economics, the argument seems to assume away two related points. First, because a product embodying technical information might not always reveal the underlying invention,<sup>130</sup> dissemination of the product does not always equal dissemination of the technical information. Second, products need not be disseminated for the technical information to be transferred. Indeed, technical information may be more effectively transferred via articles, technical disclosures, technology-transfer agreements, and, perhaps, even

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(suggesting that patents on personalized medicine inventions function primarily to aggregate “ancillary information”).

125. See John F. Duffy, *Embryonic Inventions and Embryonic Patents: Prospects, Prophecies, and Pedis Possessio*, in PERSPECTIVES ON COMMERCIALIZING INNOVATION 234, 247 (F. Scott Kieff & Troy A. Paredes eds., 2012); see also Eisenberg & Merges, *supra* note 120.

126. See Scott A. Chambers, *Comments on the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AIPLA Q.J. 53, 53 (1995); Rebecca S. Eisenberg & Robert P. Merges, *Reply to Comments on the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AIPLA Q.J. 61, 63 (1995) (agreeing with Chambers on this point); cf. Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 225 (1987) (“To allow [users] to avoid infringement liability on the ground that the machine was used in research would eviscerate patent protection for technologies used primarily in research laboratories.”).

127. In a recent paper, I argued that patents on objects of research and research tools present similar problems, and that both types of inventions might best be subject to limited patent protection. Karshtedt, *supra* note 119, at 983–85, 1021–28. In addition, expanded application of the experimental use exception as a personal defense to infringement in well-defined circumstances might modulate concerns regarding upstream patents. See *infra* notes 153 & 249 and accompanying text.

128. See *infra* Section II.C; see also Karshtedt, *supra* note 119, at 1106–07.

129. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1305 (2012).

130. See Alan Devlin, *The Misunderstood Function of Disclosure in Patent Law*, 23 HARV. J.L. & TECH. 401, 426–32 (2010) (discussing self-revealing and non-self-revealing inventions); Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 107–18 (explaining the difference in the effects of patenting on self-revealing as opposed to non-self-revealing inventions).



patents.<sup>131</sup> For this version of the argument that information would be more readily disseminated without patents to be convincing, the invention at issue would need to be developed and commercialized without the incentive of a patent, and would also need to be self-revealing (or to be accompanied by disclosures explaining how it works). While that is surely possible under some circumstances, neither *Mayo* nor *LabCorp* explains when such disclosures would eventuate. Given the series of assumptions needed for the “embodiment-flow” argument to work, and the lack of explanation from the Court, this argument is therefore also suspect.

There is still another cluster of arguments that could be made in support of the proposition that at least some patents slow rather than promote disclosure. As Professor Rebecca Eisenberg cogently argued, availability of patent rights for early-stage research might discourage sharing of information between academic scientists.<sup>132</sup> Instead of participating in the communitarian culture of exchanging ideas as quickly as they are generated, the argument continues, these researchers will conceal the ideas then and aim instead to obtain proprietary rights.<sup>133</sup> By the time the information is finally revealed in a patent application, the argument proceeds, the disclosure will be delayed and will appear in the less digestible form of the unsavory language of “patentese.” Indeed, Professors Dan Burk and Mark Lemley explained that “there is evidence that scientific papers from which discoveries are patented are significantly less likely to be cited by subsequent scientific papers, suggesting that patents may be restricting the flow of scientific knowledge.”<sup>134</sup> Relatedly, a number of

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131. See *supra* note 23 and accompanying text.

132. See Eisenberg, *supra* note 126, at 180–85; Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1017 (1989). For a challenge to this view, see F. Scott Kieff, *Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science—A Response to Rai and Eisenberg*, 95 NW. U. L. REV. 691, 692 (2001). Cf. Rebecca S. Eisenberg, *Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research*, 45 HOUS. L. REV. 1059 (2008) (discussing the phenomenon of non-enforcement of patent rights against academic institutions); Lisa Larrimore Ouellette, *Access to Bio-Knowledge: From Gene Patents to Biomedical Materials*, 2010 STAN. TECH. L. REV. N1, at ¶¶32–41 (reviewing empirical literature showing that academic scientists tend to ignore patents). For a recent perspective, see Jacob S. Sherkow, Comment, *CRISPR: Pursuit of Profit Poisons Collaboration*, 532 NATURE 172 (2016).

133. See Eisenberg, *supra* note 126, at 180–85; Eisenberg, *supra* note 132, at 1017. The *Mayo* Court alluded to early-stage research when it referenced “laws and principles [that] are ‘the basic tools of scientific and technological work.’” *Mayo*, 132 S. Ct. at 1301 (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)); see also *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 127 (2006) (Breyer, J., dissenting from the order dismissing certiorari). Thus, this argument perhaps has the most support of the three in the language of Justice Breyer’s opinions.

134. DAN L. BURK & MARK A. LEMLEY, *THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT* 88 (2009) (citing Fiona Murray & Scott Stern, *Do Formal Intellectual Property Rights Hinder*

commentators maintained that the subject matter of early-stage research is usually the provenance of academic study, and it would thus be disclosed without the need for patent-based incentives.<sup>135</sup>

These arguments are well-theorized and compelling. And in some ways, they resemble the arguments against restrictions on the copying of technical publications. First, in both circumstances, the intellectual property right at issue puts up barriers in the way of sharing information.<sup>136</sup> Second, the right threatens to interfere with the learning process.<sup>137</sup> Third, the presence of exclusivity may cut against what the creator of the information might naturally want, which is to disseminate it as widely as possible.<sup>138</sup> Nonetheless, the contentions made by Professor Eisenberg and others concern a very specific class of patents—those directed to basic or early-stage research. Outside of this unique context, to suggest that patents routinely impede the dissemination of information is counterintuitive. Moreover, as the next Section explains, the patents actually invalidated in *Mayo* were hardly drawn to the kind of invention that these scholars were concerned with. In Part III, I make one more attempt to rehabilitate the information-flow rationale for holding these patents invalid, and in fact conclude that they should be—under a narrowly tailored rule reflecting the subtle nature of the problem. In the next Section, however, I evaluate Prometheus's patents under Professor Eisenberg's specific rationale that patents could interfere with disclosure.

### C. The Patents at Issue in *Mayo*

I focus here on *Mayo* because, as opposed to *LabCorp*, the Court in *Mayo* actually invalidated the patents at issue and set forth a rule of law. The claim representative of those asserted was directed to determining whether a patient who is receiving drug treatment for a gastrointestinal disorder requires a larger or a smaller amount of the drug based on the concentration of 6-thioguanine, a so-called

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*the Free Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis*, 63 J. ECON. BEHAVIOR & ORG. 648 (2007)). *But see* Bhaven N. Sampat & Heidi L. Williams, *How Do Patents Affect Follow-On Innovation? Evidence from the Human Genome 4* (NBER, Working Paper No. 21666, 2015), <http://www.nber.org/papers/w21666> [<https://perma.cc/4MZ3-5MKW>] (concluding that “any effects of [gene] patents on follow-on innovation appear to be quantitatively small”).

135. *See, e.g.*, Rai, *supra* note 120, at 119. *But see* Alan Devlin, *Patent Law's Parsimony Principle*, 25 BERKELEY TECH. L.J. 1693, 1718 (2010) (“Given that vast rates of intellectual and pecuniary capital may be required to successfully discover rules of nature that bear great potential value for society, the utilitarian case for patent protection would appear to be strong.”).

136. *Cf. supra* notes 81–94 and accompanying text.

137. *Cf. supra* notes 71–74 and accompanying text.

138. *Cf.* Brief of Respondent, *supra* note 86, at 24–25, 36.

“metabolite” molecule, in the patient’s blood. Specifically, it recited the following:

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

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per  $8 \times 10^8$  red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per  $8 \times 10^8$  red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.<sup>139</sup>

In simple terms, the claim was directed to a method of determining whether a patient having a particular health condition is getting the right dose of a particular drug. This method involved measuring the concentration of the 6-thioguanine metabolite, which is a substance that the patient’s body produces from the drug that the patient actually ingests. Furthermore, the claim specified particular metabolite concentration thresholds indicating whether the patient is getting too much or too little of the drug. In this way, the patent purportedly improved upon the prior art, which had disclosed the general relationship between the amount of the metabolite and the effectiveness of the drug, but without specifying the concentration thresholds.<sup>140</sup>

This claim does not appear to generate the sorts of disclosure-related concerns that were noted by Professor Eisenberg and others because it is directed to applied, rather than early-stage, research. Particularly telling is Professor Eisenberg’s own critique of *Mayo*—she faulted the Court for invalidating the claim under the law of nature exception because, in her view, it “recites a very specific diagnostic application.”<sup>141</sup> Moreover, it seems safe to assume that the claim does not embody the sort of a critical invention that, if not promptly shared and disseminated among scientists, would significantly slow down

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139. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1295 (2012) (quoting U.S. Patent No. 6,355,623 col. 20 ll. 10–25 (filed Apr. 8, 1999)).

140. C. Cuffari et al., *6-Mercaptopurine Metabolism in Crohn’s Disease: Correlation with Efficacy and Toxicity*, 39 *GUT* 401, 401 (1996).

141. Eisenberg, *Need Not Apply*, *supra* note 51, at 270; *see also id.* at 268; *cf.* Chiang, *supra* note 49, at 1868 (contending that *Mayo* “never gives any theory for what constitutes a ‘law of nature’ or explains why biological correlations fall within the category,” but instead “simply asserts the conclusion”).

academic progress. And while the invention might aid in the practice of medicine, it is unlikely to be properly characterized as an object of research—or even a research tool—whose patenting might create a bottleneck for researchers looking to use it to open up new fields.<sup>142</sup>

The nature of the lawsuits in *Mayo* (and *LabCorp*) underscores these points. In both cases, the accused infringers were not exactly independent inventors, nor even downstream researchers attempting to develop new areas of research based on what the patentees have discovered. Instead, both defendants initially practiced the claimed methods with the patent owner's permission and then, essentially, decided to stop paying royalties.<sup>143</sup> To be sure, in *Mayo*, the Mayo Clinic made an attempt to fine-tune the 6-thioguanine concentration thresholds,<sup>144</sup> but the parameters it ultimately settled on still ended up within the scope of the narrow claims that Prometheus asserted.

What is more telling is that in *Mayo* in particular, it was undisputed that the information in the Prometheus patents pointed to areas of development that were not covered by the claims. As found by the trial court, these applications included “use [of the correlations] in research,” “building upon the correlations,” and “publishing articles in scientific journals concerning the correlations.”<sup>145</sup> These are the very sorts of activities that, as Breyer worried in *The Uneasy Case*, might be impeded when copyright law effectively blocks access to ideas in a scientific article, forcing the downstream researchers to miss out on new ideas that the information contained in the articles might elicit.<sup>146</sup>

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142. See Lemley et al., *supra* note 48, at 1344 (“Here, the claim was to very specific measurements of a particular drug. Like [*LabCorp*, *Mayo*] involves an application of the natural principles discovered by the patentee. It is not generative, nor will it unduly bar future inventors.”); Sichelman, *supra* note 49, at 376–78; see also Collins, *supra* note 51 (manuscript at 36 n.164) (contending that “diagnostic inferences as a class are costly to invent and validate . . . and they are not likely to be basic tools”); Sampat & Williams, *supra* note 134. *But cf.* SECY’S ADVISORY COMM. ON GENETICS, HEALTH & SOC’Y, U.S. DEP’T OF HEALTH & HUMAN SERVS., GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS 46 (2010) (contending otherwise in the context of diagnostics specifically involving genes).

143. *Mayo*, 132 S. Ct. at 1295–96 (noting the fact that the defendant first bought the patentee’s test and then developed its own test “using somewhat higher metabolite levels to determine toxicity,” which infringed the patentee’s claims); *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 129 (2006) (Breyer, J., dissenting from the order dismissing certiorari) (similar).

144. *Mayo*, 132 S. Ct. at 1295–96. Inhibited here, it appears, were “more refined treatment recommendations.” *Id.* at 1302.

145. *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, No. 04cv1200 JAH (RBB), 2008 WL 878910, at \*12 (S.D. Cal. Mar. 28, 2008).

146. *But cf.* Note, *Diagnostic Method Patents and Harms to Follow-on Innovation*, 126 HARV. L. REV. 1370, 1384–87 (2013) (contending that the patents at issue in *Mayo* and *LabCorp* created “fairly broad preemption problems,” including “prevent[ing] Dr. Rokea el-Azhary, a researcher at

The trial court in *Mayo* held the claims invalid in spite of the downstream applications left open by the patents based on its belief that they lacked “*practical* uses other than treatment for autoimmune or gastrointestinal disorders.”<sup>147</sup> This conclusion evidences a certain failure of scientific imagination and relies on a very narrow conception of what is practical. It bears repeating that the accused infringers were not barred from using the patent disclosures to develop new ideas and theories; instead, they were performing more or less the very same test that the asserted patents claimed. It is difficult to see how assertion of infringement based on a repeatedly performed, commercialized variant of the claimed invention threatens access to information or, for that matter, the progress of science.<sup>148</sup>

If anything, the concern in some § 101 cases seems to be that patents might impede the practice of medicine<sup>149</sup>—but, as Professor Eisenberg explained, this concern is wholly separate from any worry about effects on novel downstream research and development.<sup>150</sup> Medicine tends to be a conservative field, and the technician running a diagnostic test is to follow the protocol exactly as written, without deviation. The aim of commercial diagnostic tests within the scope of Prometheus’s claims was not novel, follow-on research, but more or less exact—one might say mechanical<sup>151</sup>—replication to ensure that accurate data was being collected for the purpose of effective patient treatment. Access to scientific knowledge is not the same as access to a product, even when the product happens to be a diagnostic test.<sup>152</sup>

The accused infringers in *Mayo* did, to be sure, refine the relevant metabolite concentration thresholds. But it would seem that those engaged in cutting-edge scientific research would, almost by definition, not want to make a living optimizing the same relatively narrow finding that was made by another.<sup>153</sup> Prior work is a jumping-

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*Mayo*, from disseminating her work on thiopurine metabolites in the dermatology context”). This problem is addressed in detail in Part III.

147. *Prometheus*, 2008 WL 878910, at \*12 (emphasis added).

148. *Cf. Karshtedt*, *supra* note 119, at 976–81 (explaining that § 101 could serve the role of eliminating patents on upstream inventions that might threaten the progress of science).

149. *Mayo*, 132 S. Ct. at 1304–05 (relying on amicus briefs submitted by medical practitioners).

150. *See Eisenberg*, *Need Not Apply*, *supra* note 51, at 263 (“Justice Breyer candidly reveals a concern that patent claims might impinge on the practice of medicine, as distinguished from future research.”).

151. Mechanical in a good way—because patient welfare is implicated.

152. The diagnostic test does allow the doctor to obtain information about a patient. But so do stethoscopes and other tools. *Cf. supra* notes 119–128 (discussing patents on “research-tool” technologies).

153. *See supra* notes 89–94 and accompanying text. To be sure, some patents may be directed to fundamental, or “bottleneck,” inventions that must be practiced for a research project to move

off point, an inspiration for new endeavors, rather than an experiment to optimize, repeat, and commercialize.<sup>154</sup> More generally, scientific development often proceeds in decidedly nonlinear fashion, with prior work providing inspiration for follow-on researchers trying to solve a tangentially related (or even unrelated) problem, rather than serving as a “building block” that must be in place before another block goes on top of the first.<sup>155</sup> For those sorts of researchers, the information in a patent or a scientific article is there to be mentally absorbed and then utilized in creative ways. Thus, once repetition is taken out of the picture, patent disclosures can, at least in theory, stimulate new inventions and lead to “important improvements in radically different directions.”<sup>156</sup> Justice Breyer, however, never explicitly considered benefits of this sort that patent disclosures might provide. His embrace of the building-block view of science in his patent law opinions, to the exclusion of other views, is reason enough to reexamine his patentable subject matter jurisprudence.

Furthermore, unlike copyright law, which might slow dissemination of technical materials by rendering their reproduction infringing,<sup>157</sup> patent law generally lacks mechanisms that might affirmatively hinder access to the information in patent specifications.<sup>158</sup> This feature of patent law was highlighted nicely in

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forward. See Karshedt, *supra* note 119, at 960–69. It has been argued that a more vigorous experimental use exception is needed to free up researchers’ ability to practice such inventions, if they are patented. Rochelle C. Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 ARIZ. L. REV. 457 (2004); Eisenberg, *supra* note 132; Henrik Holzapfel & Joshua D. Sarnoff, *A Cross-Atlantic Dialog on Experimental Use and Research Tools*, 48 IDEA: INTELL. PROP. L. REV. 123 (2008); Mueller, *supra* note 119; Strandburg, *supra* note 130, at 123. But the patents litigated in *Mayo* probably do not fall into this category. See *supra* notes 141–142 and accompanying text.

154. See *supra* notes 90–94 and accompanying text.

155. Cf. LARRY LAUDAN, *PROGRESS AND ITS PROBLEMS* 48–69 (1977) (proposing a non-evolutionary theory of scientific progress); Henry Rosemont, Jr., *Against Relativism*, in *INTERPRETING ACROSS BOUNDARIES: NEW ESSAYS IN COMPARATIVE PHILOSOPHY* 36, 37 (Gerald James Larson & Eliot Deutsch eds., 1988) (“Western science, as it turns out, has not been the building-block, linearly progressive affair we have always thought it to be . . .”). But cf. Imre Lakatos, *Criticism and the Methodology of Scientific Research Programmes*, 69 PROC. ARISTOTELIAN SOC. 149 (1968) (proposing a more linear, or evolutionary, view of scientific progress). See generally Michal Shur-Ofry, *Nonlinear Innovation*, 62 MCGILL L.J. 563 (2016).

156. See *Revision of Statutes Relating to Patents: Hearings on S. 3325 and S. 3410 Before the S. Comm. on Patents*, 67th Cong. 172 (1922); see also *id.* (“Inventors not only may improve on the specific idea embodied in the patent already issued and published, but also are inspired to work out their ideas for accomplishing the same result which the publication of the patent suggests to them.”); Fromer, *supra* note 19, at 547–54; Wagner, *supra* note 33, at 1003–13.

157. See 17 U.S.C. § 106(1) (2012).

158. Cf. Wagner, *supra* note 33, at 1003–10 (challenging the notion that the “control” conferred by intellectual property rights prevents information and ideas from entering the public domain).

*The Knowledge/Embodiment Dichotomy in Patent Law*, a recent article by Professor Kevin Collins.<sup>159</sup> Professor Collins observed that some courts and commentators have failed to distinguish between patenting knowledge, ideas, or information, which is generally difficult to do, from patenting *embodiments*, which is the normal province of patent law.<sup>160</sup> He explained:

By making the disclosed knowledge immediately free for all to use qua knowledge, [patent disclosure] generates “knowledge spillovers” of the patentee’s exclusive rights.

...

[A]lthough the public is prohibited from using the disclosed knowledge in a particular manner during the patent’s term (that is, to make, sell, offer to sell, or import the claimed embodiments), patent law does not prevent the public from using the disclosed knowledge in any other way that it pleases, even if those uses are detrimental to the patentee’s interests.<sup>161</sup>

The notion of knowledge spillovers is foundational to patent law and theory.<sup>162</sup> The availability of patenting induces the disclosure of information, some of which simply cannot be propertized—even during the term of the patent. As Professor Kenneth Arrow noted, “the inventor will . . . have considerable difficulty in appropriating the information produced. Patent laws would have to be unimaginably complex and subtle to permit such appropriation on a large scale.”<sup>163</sup> Thus, any suggestion that a patent might impede the flow or free exchange of information must be qualified by these considerations. But Professor (and Justice) Breyer’s statements about patents in *The Uneasy Case* and his *LabCorp* and *Mayo* opinions paint a very different picture: copyright law is bad enough because it hinders the transfer of expression, and patent law is even worse because it also hinders the

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159. Collins, *supra* note 33.

160. *Id.* at 1288–94. Justice Breyer, however, repeatedly appears to characterize patents as capturing knowledge as opposed to embodiments. See *supra* notes 63–67 and accompanying text; see also *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1305 (2012) (referring to “patented ideas”); *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 127, 134 (2006) (Breyer, J., dissenting from the order dismissing certiorari) (citing *Nichols v. Universal Pictures Corp.*, 45 F.2d 119, 122 (2d Cir. 1930), a Judge Learned Hand opinion that stands for the proposition that copyright protection extends to expressions, but not to ideas).

161. Collins, *supra* note 33, at 1316–17.

162. See *supra* note 33 and accompanying text. Copyright law, too, produces spillovers when the copyrighted matter is disclosed, but the argument in *The Uneasy Case* is that they cannot be realized at all if the intellectual property right hinders access to information “at the front end.” See *supra* note 40 and accompanying text.

163. Arrow, *supra* note 18, at 617. Of course, the goal of appropriately rewarding the inventor might be achieved with nonpatent incentives, like government grants. Cf. Lisa Larrimore Ouellette, *Patentable Subject Matter and Nonpatent Innovation Incentives*, 5 U.C. IRVINE L. REV. 1115 (2015) (arguing for greater consideration of nonpatent incentives when discussing patentable subject matter doctrine). But Justice Breyer does not seem to be arguing for, or showing the existence of, alternative incentive mechanisms of this sort.

transfer of ideas. But as the foregoing discussion shows, this account is at best not complete. And at worst, the rule of *Mayo* is counterproductive: it could inhibit information flow by discouraging the filing and publication of patent applications.<sup>164</sup>

#### D. Objections

Several objections can be raised at this stage. The first is that the approach in *Mayo* is basically correct, but was mistakenly applied to the specific facts of that case. In other words, one might argue that Justice Breyer properly formulated the general concern that patents on early-stage research might interfere with the flow of information and should, in part for that reason, be disallowed based on patentable subject matter exclusions implied in § 101—and in particular, the law of nature (or natural phenomenon) exclusion. Even if the *Prometheus* patent might have been incorrectly invalidated, the rationale and the resulting rule are both sound and will, on the whole, benefit the patent system.

This objection can be answered with several rejoinders. One is that the facts of a seminal Supreme Court case like *Mayo* naturally set the tone for future development of the law. Unsurprisingly, many patents invalidated in the wake of *Mayo* were not drawn to discoveries of fundamental principles of the  $E = mc^2$  variety but, instead, to methods of using some specific genetic markers or other narrowly drafted diagnostic or even treatment claims.<sup>165</sup> Indeed, facts matter because the courts' modus operandi in applying the opaque guidelines of *Mayo* and other § 101 cases is to ask whether the patents at issue are factually similar to the patents that had been invalidated by the Supreme Court.<sup>166</sup> Another, closely related rejoinder is that, given the character of the patents that were invalidated, lower courts cannot help but come away with an extremely expansive conception of what a law

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164. See *infra* notes 206–207 and accompanying text.

165. See, e.g., *Cleveland Clinic Found. v. True Health Diagnostics, LLC*, No. 1:15CV2331, 2016 WL 705244 (N.D. Ohio Feb. 23, 2016), *appeal docketed*, No. 16-1766 (Fed. Cir. Mar. 25, 2016) (biomarker for assessing risk of having heart disease); *Esoterix Genetic Labs. LLC v. Qiagen Inc.*, 133 F. Supp. 3d 349 (D. Mass. 2015) (genetic marker for predicting pharmacological effectiveness); *Endo Pharm. Inc. v. Actavis Inc.*, No. 14-1381-RGA, 2015 WL 5580488 (D. Del. Sept. 23, 2015), *adopted by* 2015 WL 7253674 (D. Del. Nov. 17, 2015) (method of treatment); *Genetic Techs. Ltd. v. Lab. Corp. of Am. Holdings*, No. 12-1736-LPS-CJB, 2014 WL 4379587 (D. Del. Sept. 3, 2014) (genetic marker for predicting athletic performance).

166. For an example at the Supreme Court itself, see *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2356–57 (2014) (invalidating the claims at issue because they were similar to the claims held not patentable in *Bilski v. Kappos*, 561 U.S. 593 (2010)). Cf. *Amdocs (Israel) Ltd. v. Openet Telecom, Inc.*, No. 2015-1180, 2016 WL 6440387, at \*4 (Fed. Cir. Nov. 1, 2016) (following this approach in applying the abstract idea exception to patent eligibility under § 101).



of nature is.<sup>167</sup> Finally, the *Mayo* Court's dubious reference to information may have impacted the Court's own later decision in *Association of Molecular Pathology v. Myriad*,<sup>168</sup> which puzzled many a commentator.<sup>169</sup> This case, which invalidated claims to genomic DNA molecules under the product-of-nature exception to patentability, cites the "flow of information" language in *Mayo* and is rife with references to information.<sup>170</sup>

Second, one might argue that the alleged invention implicated in *Mayo* is too trivial to be patentable, which means that the Court reached the correct bottom-line result.<sup>171</sup> In that vein, one might further contend that diagnostic inventions of the sort patented by Prometheus might not only be invented without the incentive of a patent but also freely disclosed, perhaps in an effort to demonstrate the test's clinical validity to the regulatory authorities and the relevant public.

Maybe so. But in responding to this objection, too, it is worth looking beyond *Mayo* itself to see the effects of the *Mayo* rule. Applying *Mayo*, the United States Court of Appeals for the Federal Circuit in *Ariosa Diagnostics v. Sequenom* invalidated claims directed to a method of detecting fetal DNA in maternal plasma and serum.<sup>172</sup> The court reasoned that, similar to the diagnostic inferences in *Mayo*, the existence of fetal DNA in maternal plasma and serum was a natural phenomenon to which the claims did not add an inventive application.<sup>173</sup> But in contrast to the invention patented by Prometheus, Sequenom's invention was decidedly not trivial for at least two reasons. One, before this invention, it was thought that maternal plasma and serum did not contain useful genetic information, and these materials were thus typically discarded as medical waste.<sup>174</sup> Two, the invention provided a significantly more practical and safer method of prenatal testing for genetic abnormalities than the previously available

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167. Eisenberg, *Need Not Apply*, *supra* note 51, at 265 ("The Court took a very expansive approach to the identification of natural phenomena in the first step of the analysis in *Mayo*."). *But see* Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042 (Fed. Cir. 2016) (finding a cognizable limit to the *Mayo* rule in a biotechnology case).

168. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

169. *See, e.g.*, Dan L. Burk, *The Curious Incident of the Supreme Court in Myriad Genetics*, 90 NOTRE DAME L. REV. 505 (2014); Peter Lee, *The Supreme Court's Myriad Effects on Scientific Research: Definitional Fluidity and the Legal Construction of Nature*, 5 U.C. IRVINE L. REV. 1077 (2015).

170. *Myriad*, 133 S. Ct. at 2111–12, 2115–16, 2118, 2120.

171. Indeed, I too ultimately conclude in this Article that the Prometheus invention should not be patentable. *See infra* Part III.

172. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), *cert. denied*, 136 S. Ct. 2511 (2016).

173. *Id.* at 1376–78.

174. *Id.* at 1373.

method.<sup>175</sup> Indeed, it is not at all clear that the Sequenom invention would have been invented and disclosed without the patent incentive. Several Federal Circuit judges recognized the merits of the invention, but explained that their hands were tied by *Mayo*'s broad language.<sup>176</sup> One is forced to conclude based on this example that, even if *Mayo* invalidated an unmeritorious patent, the case's overall approach is nonetheless problematic.

The objector might at this point reply by arguing that the groundbreaking invention at issue in *Ariosa* must be ineligible for patent protection on the disclosure rationale proposed by Professor Eisenberg,<sup>177</sup> or because the patent on the invention was claimed in the rare form that captures knowledge in the sense suggested by Professor Collins.<sup>178</sup> Putting to one side the incongruity of having the same legal rule that targets patents on inventions that have diametrically opposed characteristics—trivial and foundational—one would contend in response that there is no evidence that either concern applies here. To the contrary, the discovery captured by the Sequenom patent was promptly reported in academic literature<sup>179</sup> and has been cited widely<sup>180</sup>—evidence which militates against an information flow problem.<sup>181</sup> Moreover, there is some evidence that follow-on researchers were undeterred by the patent; the patentee proffered at least three academic articles building on the invention, but indisputably performing research involving activities outside the scope of the claims.<sup>182</sup> As in *Mayo*, the entities actually accused of infringement were not building on the invention to generate new knowledge, but offering a commercial test within the scope of the patentee's claims. And as for

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175. *Id.* at 1381 (Linn, J., concurring).

176. *See id.* at 1380; *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1285–86 (Fed. Cir. 2015) (Lourie, J., joined by Moore, J., concurring in the denial of the petition for rehearing en banc). *See generally* Philip Merksamer, Note, *Ariosa Diagnostics v. Sequenom: Metastasis of Mayo and Myriad and Evisceration of Patent Eligibility for Molecular Diagnostics*, 31 BERKELEY TECH. L.J. 495 (2016).

177. *See supra* notes 132–135 and accompanying text.

178. *See supra* notes 159–161 and accompanying text; *infra* Part III.

179. Y.M. Dennis Lo et al., *Presence of Fetal DNA in Maternal Plasma and Serum*, 350 LANCET 586 (1997).

180. A Web of Science citation search shows 959 citations. A Google citation search shows 2092 citations.

181. *Cf. supra* note 134 and accompanying text (suggesting that patents might be restricting the flow of scientific knowledge).

182. *See* Farideh Z. Bischoff et al., *Detecting Fetal DNA from Dried Maternal Blood Spots: Another Step Towards Broad Scale Non-Invasive Prenatal Genetic Screening and Feasible Testing*, 6 REPROD. BIOMED. ONLINE 349 (2003); Leo L. Poon et al., *Differential DNA Methylation Between Fetus and Mother as a Strategy for Detecting Fetal DNA in Maternal Plasma*, 48 CLINICAL CHEMISTRY 9 (2002); Jessica M.E. van den Oever et al., *Single Molecule Sequencing of Free DNA from Maternal Plasma for Noninvasive Trisomy 21 Detection*, 58 CLINICAL CHEMISTRY 699 (2012).

the capture of knowledge, Professor Collins made clear that his theory does not apply to the Sequenom patent.<sup>183</sup>

The Sequenom patent might be the sweet-spot patent—neither trivial nor so foundational as to hinder downstream research and information exchange between scientists. Again, that is not to say that there are no problems with the patent: scholars have expressed concerns with “commercialization-related barriers to clinical adoption and patient access”<sup>184</sup> caused by patents on prenatal diagnostic tests, as well as “lower test availability and quality.”<sup>185</sup> Concerns about the effect of patents on the cost and delivery of health are of course quite weighty and deserve serious consideration from lawmakers, who have sometimes stepped in when intervention was needed. After, for example, a doctor found himself defending an infringement suit for performing a patented surgical procedure,<sup>186</sup> Congress passed a statute that eliminated a remedy for such actions.<sup>187</sup> And perhaps government intervention may be needed when, for example, “the sole provider [of a diagnostic test] does not have agreements with specific third-party payers or health plans.”<sup>188</sup> But all this is very different from the effect of patents on the flow of information or on early-stage research.

The first two objections amount to the argument that *Mayo* is basically harmless. Given the sorts of patents that are being invalidated in the wake of *Mayo*, it is not. The third objection is different, and it goes to the fundamental premise of this Article. The core of this objection is that there is, after all, an information flow problem with the patents at issue in *Mayo* and *LabCorp*, but just not in the senses discussed so far. I examine it in detail in the Part that follows.

### III. THE NARROW INFORMATION-FLOW PROBLEM WITH *MAYO* AND *LABCORP* PATENTS

#### A. *The Problem of Claims that Contain Mental Steps*

There may be yet another way to rehabilitate Justice Breyer’s information-access rationale for invalidating the claims litigated in *Mayo* and *LabCorp*. The critique that follows is based in part on the

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183. Collins, *supra* note 51 (manuscript at 39 n.178).

184. Ashwin Agarwal et al., *Commercial Landscape of Noninvasive Prenatal Testing in the United States*, 33 *PRENATAL DIAGNOSIS* 521, 528 (2013).

185. *Id.* at 527.

186. See *Pallin v. Singer*, 36 U.S.P.Q.2d (BNA) 1050 (D. Vt. 1995), *further proceedings*, Civ. A. No. 2:93-CV-202, 1996 WL 274407 (D. Vt. 1996).

187. See 35 U.S.C. § 287(c) (2012).

188. Agarwal et al., *supra* note 184, at 527.

work of Professors Kevin Collins,<sup>189</sup> Alan Durham,<sup>190</sup> and Andrew Torrance.<sup>191</sup> To illustrate the problem, consider the following example involving a hypothetical patent on the flame test, a classic analytical technique. Suppose that a researcher discovers and claims a “method of detecting sodium in a sample by exposing it to a flame, wherein the intense yellow color of the flame indicates that sodium is present in the sample.” Inspired by this discovery, another scientist decides to investigate whether other metals could be detected using the flame test. Based on the theory of emission spectroscopy, she predicts that tungsten will give off a green color when exposed to the flame and then decides to test an unknown metal sample for the presence of tungsten. But it turns out that the sample contains sodium. The researcher sees the yellow flame—and now, the claim has been infringed. This is because the “wherein” element of the claim calls out recognition that yellow means sodium, and the second researcher cannot help but make this connection when she sees yellow.

Under these circumstances, the second researcher would potentially have been better off not having read the patent. For if she did not know (from the patent) that sodium gave off a yellow flame, the researcher may not have made the inference covered by the claim’s “wherein” element, and thus there may not have been an infringement. To be sure, if not for the patent, she might not have known about the flame test at all. Still, there is something extremely troubling about the possibility that a patent might effectively cover an activity as basic as exposing a metal to a flame, and that reading the patent might make a difference between liability and no liability.

Of course, patent infringement is a strict liability offense.<sup>192</sup> But if a claim is drafted in such a way as to include an element that is “performed” when the user merely makes a mental inference, we have

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189. Kevin Emerson Collins, *Claims to Information qua Information and a Structural Theory of Section 101*, 4 I/S: J.L. & POLY FOR INFO. SOC'Y 11, 12 (2008); Kevin Emerson Collins, *Constructive Nonvolition in Patent Law and the Problem of Insufficient Thought Control*, 2007 WIS. L. REV. 759 [hereinafter Collins, *Constructive Nonvolition*]; Kevin Emerson Collins, *Propertizing Thought*, 60 SMU L. REV. 317, 357–60 (2007). Professor Collins initially leveled his critique against the patents at issue in *LabCorp*, and then extended it to *Mayo*. See Collins, *supra* note 33; Collins, *supra* note 51; see also Kevin Emerson Collins, *The Structural Implications of Inventors' Disclosure Obligations*, 69 VAND. L. REV. 1785 (2016); Kevin Emerson Collins, *Prometheus Laboratories, Mental Steps, and Printed Matter*, 50 HOUS. L. REV. 391 (2012) [hereinafter, Collins, *Mental Steps*].

190. Alan L. Durham, *Natural Laws and Inevitable Infringement*, 93 MINN. L. REV. 933 (2009).

191. Andrew W. Torrance, *Neurobiology and Patenting Thought*, 50 IDEA: INTEL. PROP. L. REV. 27 (2009).

192. See *Hilton Davis Co. v. Warner-Jenkinson, Co.*, 62 F.3d 1512, 1523 (Fed. Cir. 1995) (en banc), *rev'd on other grounds*, 520 U.S. 17 (1997).

a situation where infringement could be contingent on the user's knowledge. It now appears that we have an information-flow problem after all. In this scenario, patents might deter the dissemination of ideas and slow the progress of science by rendering noninfringing activities infringing via mere transfer of information in the patent. More generally, such patents may inhibit research that properly attempts to make use of the ideas disclosed in patents in a noninfringing manner.<sup>193</sup>

This result seems wrong, and the problem is not merely hypothetical. In fact, Professor Collins cogently argued<sup>194</sup> that the patent at issue in *LabCorp* exhibits this very problem: the claims were directed to "assaying a body fluid for an elevated level of total homocysteine; and correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate,"<sup>195</sup> or vitamin B-12. Thus, a physician ordering a homocysteine assay for a purpose other than testing for vitamin B-12 deficiency might infringe the patent because the claimed "correlating" would occur in the physician's mind upon inspection of the homocysteine data.<sup>196</sup> The patent then, in effect, covered all homocysteine assays, including those that were previously known.<sup>197</sup>

The patents that were litigated in *Mayo* had a similar problem. As Mayo Clinic argued to the Supreme Court, one of the defendants was a doctor who was investigating concentration thresholds of the 6-thioguanine metabolite to establish a therapeutic range for the unclaimed dermatological disorders, rather than the claimed gastrointestinal ones.<sup>198</sup> The theory of infringement appeared to be that the doctor could not avoid thinking about the implications of the 6-

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193. See *supra* notes 157–163 and accompanying text.

194. See Collins, *Constructive Nonvolition*, *supra* note 189.

195. *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 129 (2006) (Breyer, J., dissenting from the order dismissing certiorari) (quoting U.S. Patent No. 4,940,658, claim 13 (filed Nov. 20, 1986)).

196. Collins, *Constructive Nonvolition*, *supra* note 189, at 814–20.

197. See *id.*

198. Brief for Petitioners, *supra* note 96, at 11; see also Defendants' Redacted Memorandum of Points and Authorities in Support of Their Motion for Summary Judgment of Patent Invalidity Under 35 U.S.C. § 101, at 17, *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, No. 04-CV-1200, 2007 WL 623848, at \*17 (S.D. Cal. Jan. 29, 2007):

The physician would . . . be in the position of infringing a patent simply by thinking about information that the physician in theory should have every right to think about, i.e., whether or not a particular metabolite level might be a reason for raising or lowering a dose of drug. . . . [T]he claims to the correlation have the effect of giving Prometheus a monopoly on the testing of the metabolites in autoimmune patients, something which has long been in the prior art, because physicians will know of the correlation regardless of the reason for which they might be testing metabolites.

thioguanine concentrations for treatment of gastrointestinal conditions even though this was not the aim of her research.<sup>199</sup>

Does all this mean that Justice Breyer was correct after all? While he was certainly correct in the result, he erred in seemingly suggesting that the patents asserted in *Mayo* and *LabCorp* were major threats to information access based, perhaps, on their questionable potential to appropriate early-stage research. The brief reference to “impede[d] flow of information” does not capture the subtle disclosure-related problem with claims that include steps directed to mental inferences,<sup>200</sup> implying instead that, like copyrights, patents such as those asserted by Prometheus impede the dissemination of knowledge writ large. A related point was captured in Durham’s insightful article written in the wake of *LabCorp*:

The danger of the LabCorp patent has little to do with research . . . The greater threat posed by the LabCorp patent and others of its kind hinges on the role that knowledge plays in infringement. Even well-intentioned competitors of the patent owner may find infringement unavoidable, except by cultivating ignorance or abandoning legitimate activity. This could supply the patent owner with unintended and undesirable market power.<sup>201</sup>

Thus, the patents in at issue in *LabCorp* and *Mayo* are surely problematic. But, as noted earlier,<sup>202</sup> the rule that *Mayo* created to deal with them is grossly overbroad. In applying it, courts have invalidated patents that include affirmative steps directed to manipulation of genetic materials<sup>203</sup> or even steps directed to patient treatment,<sup>204</sup> as opposed to mental steps, and therefore do not give rise the very limited disclosure problem raised in *LabCorp* and *Mayo*. As noted by others, the rule is causing serious problems.<sup>205</sup> One of them seems to be to push biotechnology companies toward trade secrecy.<sup>206</sup> If this is indeed the

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199. Brief for Petitioners, *supra* note 96, at 11–12.

200. Professor Collins called these types of claims “determine-and-infer” claims. Collins, *Mental Steps*, *supra* note 189, at 394.

201. Durham, *supra* note 190, at 997; *see also* Collins, *Constructive Nonvolition*, *supra* note 189, at 806–12.

202. *See supra* notes 172–188 and accompanying text.

203. *See, e.g.*, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), *cert. denied*, 136 S. Ct. 2511 (2016).

204. *See, e.g.*, *Endo Pharm. Inc. v. Actavis Inc.*, No. 14-1381-RGA, 2015 WL 5580488 (D. Del. Sept. 23, 2015), *adopted by* 2015 WL 7253674 (D. Del. Nov. 17, 2015).

205. Eisenberg, *Need Not Apply*, *supra* note 51; Holman, *supra* note 51; Taylor, *supra* note 51.

206. Erin Coe, *Weakened Patent Rights Make Trade Secrets More Attractive*, LAW360 (Apr. 1, 2014), <http://www.law360.com/articles/523575/weakened-patent-rights-make-trade-secrets-more-attractive> [<https://perma.cc/5MQU-67XF>] (summarizing attorney views that *Mayo* could be among reasons to push certain firms toward trade secrecy); *supra* note 43 and accompanying text; *see* David S. Almeling, *Seven Reasons Why Trade Secrets Are Increasingly Important*, 27 BERKELEY TECH. L.J. 1091, 1114 (2012) (arguing that *Mayo* “could cause life science and other companies to reconsider whether to pursue patent or trade secret protection”); Michael R. McGurk & Jia W. Lu,

trend, the result would be reduced disclosure, which is contrary to the aims Justice Breyer sought to further in his writings. Moreover, “trade secrecy limits cumulative innovation, where different innovators build on the inventions and innovations of other firms.”<sup>207</sup> These potential consequences of the *Mayo* rule are at least worth considering.<sup>208</sup>

### *B. Possible Solutions to the Mental Steps Problem*

As discussed in the previous Section, any information-flow problem with the patents at issue in *Mayo* and *LabCorp* relates to the capture of subject matter that is in the public domain, or otherwise unclaimed, via claims whose inventiveness lies in the mental recognition of new significance of a known activity. Where does this leave us? Perhaps § 101 may still have a role to play in dealing with such patents, though not through the law of nature exclusion. Professor Collins took this approach in a recent article, in which he proposed to cabin *Mayo* based on the intuition that “it is the mental nature of the diagnostic inference that employs the correlation as a premise that is the crux of the patentability problem.”<sup>209</sup> Professor Collins explained that § 101-based arguments against diagnostic-type patents still have their place based on what he terms the “counteraction theory” of patent eligibility. He maintained that this approach is necessary in part because other requirements of patentability cannot effectively deal with claims that reach an impermissibly broad scope through inclusion of mental steps at the point of novelty.<sup>210</sup> Accordingly, the role of § 101 is

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*The Intersection of Patents and Trade Secrets*, 27 HASTINGS SCI. & TECH. L.J. 189, 202 (2015) (“Clearly, trade secret protection is more desirable for inventions that are potentially patent ineligible.”); W. Nicholson Price, *Big Data, Patents, and The Future of Medicine*, 37 CARDOZO L. REV. 1402, 1407 (2016) (“[F]irms may increasingly turn away from the patent system and rely instead on trade secrecy law and practices to protect proprietary data and algorithms.”); see also *id.* at 1425. *But cf.* Tony Dutra, *New Trade Secret Law: More to Consider in Patent Trade-Off*, BLOOMBERG BNA (June 3, 2016), <http://www.bna.com/new-trade-secret-n57982073569> [<https://perma.cc/Z9ZU-AYR9>] (quoting email messages to the author from Bruce J. Rose and Jonathan M. Gordon) (noting that for certain inventions like drugs, “[t]rade secret protection ‘would be quite limited given the strict disclosure and testing requirements of government agencies such as the FDA’”).

207. Price, *supra* note 206, at 1419.

208. I argued in earlier work that trade secrecy might be socially favored over patenting over some circumstances. See Dmitry Karshedt, *supra* note 17, at 312–18. So did others. See, e.g., Anderson, *supra* note 23; see also Mark A. Lemley, *The Surprising Virtues of Treating Trade Secrets as IP Rights*, 61 STAN. L. REV. 311 (2008); Strandburg, *supra* note 130, at 104–07 (discussing comparative benefits of patent and trade secret protection). However, once the flow of information is made a priority, it would seem that trade secrecy would be incompatible with that goal.

209. Collins, *supra* note 51 (manuscript at 37).

210. *Id.* (manuscript at 38).

to “counteract”<sup>211</sup> the failure of the other requirements for obtaining patents.<sup>212</sup>

I think that Professor Collins’s approach has much to recommend it—for one thing, the Sequenom patent would remain valid under his interpretation of *Mayo*.<sup>213</sup> I part ways with Professor Collins, however, in that I maintain that established approaches to patentability can in fact handle claims such as those litigated in *Mayo* and *LabCorp*, obviating the need for “counteraction” via development of new § 101 doctrine. I now explore additional solutions relying on § 102, the Patent Act’s novelty provision, and on the requirement of proof of intent, to deal with the mental-steps problem.<sup>214</sup> I begin with § 102.

### 1. Novelty and Patentable Weight

Let us return to the flame test example. One might intuitively argue that people have exposed metal samples to a flame from time immemorial, and a claim cannot render this activity infringing even when it incorporates the novel discovery that sodium turns a flame yellow. This problem can be addressed by the principle that “merely discovering and claiming a new benefit of an old process cannot render the process again patentable.”<sup>215</sup> This principle has sometimes been

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211. While conceding that this interpretation “cut[s] against the grain of the opinion’s ‘laws of nature’ rhetoric,” Professor Collins nonetheless maintained that *Mayo* should be “interpreted in a mind-centered, not nature-centered, manner.” *Id.* (manuscript at 37–38); see also Collins, *supra* note 33, at 1315–21.

212. There is some debate as to whether § 101 is actually a “condition for patentability” in the same way that §§ 102, 103, 112, and 116 are—for example, for the purposes of invalidating issued patents in litigation under 35 U.S.C. § 282(b)(2). See, e.g., Dennis Crouch, *Hricik: Why Section 101 is Neither a “Condition of Patentability” nor an Invalidity Defense*, PATENTLY-O (Sept. 16, 2013), <http://patentlyo.com/patent/2013/09/hricik-why-section-101-is-neither-a-condition-of-patentability-nor-an-invalidity-defense.html> [https://perma.cc/TZ2G-CABT] (collecting arguments). Courts, however, have so far treated § 101 as any other patentability requirement. See, e.g., *Dealertrack, Inc. v. Huber*, 674 F.3d 1315, 1330 n.3 (Fed. Cir. 2012) (internal quotation marks omitted) (citing *Aristocrat Techs. Austral. Pty Ltd. v. Int’l Game Tech.*, 543 F.3d 657, 661 (Fed. Cir. 2008)); see also *Versata Dev. Grp., Inc. v. SAP Am., Inc.*, 793 F.3d 1306, 1329–30 (Fed. Cir. 2015).

213. Collins, *supra* note 51 (manuscript at 39 n.178).

214. I am not the first to suggest that Prometheus’s claims could have been invalidated under provisions other than § 101. See, e.g., Brief for the United States as Amicus Curiae Supporting Neither Party at 28–30, *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012) (No. 10-1150), 2011 WL 4040414, at \*28–30. The discussion that follows, however, specifically addresses the role of other patentability requirements, particularly § 102, in dealing with the threat of patents to information transfer.

215. *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990) (emphasis omitted); see also *Atlas Powder Co. v. IRECO Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999) (“[T]he discovery of a previously unappreciated property of a prior art composition . . . does not render the old composition patentably new to the discoverer.”); Andrew Chin, *The Ontological Function of the Patent*



understood as a restatement of the doctrine of inherent anticipation, which is a gloss on § 102.<sup>216</sup> This doctrine holds that a prior art reference that does not expressly disclose a particular limitation may nonetheless anticipate (i.e., render non-novel) a patent claim if that limitation is necessarily present in the reference given the other disclosures.<sup>217</sup> With respect to Prometheus's claims, Professor Collins explained that this formulation makes inherency an uneasy fit because the information captured in a "wherein"-type limitation is a "novel mental representation" rather than a necessary property of the prior art test.<sup>218</sup> Therefore, Professor Collins concluded, claims asserted in *Mayo* cannot be invalidated under inherent anticipation.<sup>219</sup> His concern was in fact borne out in the closely similar *LabCorp* case, where the Federal Circuit rejected an inherent anticipation challenge—holding that the mental "correlating" step was not inherently present in prior art disclosure.<sup>220</sup>

To this, I have two responses. One is that the Federal Circuit's view of inherent anticipation is overly cramped.<sup>221</sup> Although, as Professor Collins argued, one role of inherency is to prevent density or undue proliferation of patents,<sup>222</sup> the major justification for the doctrine is to eliminate what Professors Robert Merges and John Duffy called "backsliding"—in other words, the capture of subject matter that is already available to the public to practice without the encumbrance of a patent.<sup>223</sup> If so, it is not unreasonable to extend the doctrine to cover claims like those at issue in *LabCorp* and *Mayo*. One way to do so is to

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*Document*, 74 U. PITT. L. REV. 263, 291 (2012) ("[T]he claimed method of using the old object must also recite a *new manipulative step*." (citations omitted) (emphasis added)).

216. See generally Dan L. Burk & Mark A. Lemley, *Inherency*, 47 WM. & MARY L. REV. 371 (2005).

217. *Schering Corp. v. Geneva Pharm., Inc.*, 339 F.3d 1373, 1377–81 (Fed. Cir. 2003) (applying the doctrine of inherent anticipation); *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349–52 (Fed. Cir. 2002) (same). For a further exploration of the connection between §§ 101 and 102, see Dan L. Burk, *Anticipating Patentable Subject Matter*, 65 STAN. L. REV. ONLINE 109, 111 (2013), [http://www.stanfordlawreview.org/wp-content/uploads/sites/3/2013/02/Burk\\_65\\_SLRO\\_109.pdf](http://www.stanfordlawreview.org/wp-content/uploads/sites/3/2013/02/Burk_65_SLRO_109.pdf) [<https://perma.cc/26Q9-S269>].

218. Collins, *supra* note 51 (manuscript at 25–26).

219. See *id.* (discussing the role of inherent anticipation).

220. *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367–68 (Fed. Cir. 2004).

221. Cf. *King Pharm., Inc. v. Eon Labs., Inc.*, 616 F.3d 1267, 1278–79 (Fed. Cir. 2010) (applying the "printed matter" doctrine in a manner that resembles the doctrine of inherent anticipation). Another, related approach is to argue that certain method claims do not qualify as "a new use of a known process" under 35 U.S.C. § 100(b). *In re Ducci*, 225 F.2d 683, 687–88 (C.C.P.A. 1955). I thank Josh Sarnoff for pointing me to this case. See also *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376–77 (Fed. Cir. 2001) (applying this rule).

222. Collins, *supra* note 51 (manuscript at 39).

223. See ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, *PATENT LAW AND POLICY: CASES AND MATERIALS* 354–77 (6th ed. 2013).

hold that any mental inference drawn from prior art activities, like the assaying in *LabCorp* or administering and determining in *Mayo*, is per se inherently disclosed.<sup>224</sup> This rule would be sensible because it would ensure that the novelty requirement serves its essential purpose of safeguarding the public domain.<sup>225</sup> Although the mental representation recited in a claim may well be novel, the fact that downstream users cannot help forming it, even when they seek merely to perform steps in the public domain, suggests that the inherent anticipation doctrine is properly deployed to rule the claim invalid. As one Federal Circuit opinion explained, “If granting patent protection on the disputed claim would allow the patentee to exclude the public from practicing the prior art, then that claim is anticipated.”<sup>226</sup>

Second, another line of Federal Circuit precedent arguably already supports this result. The relevant doctrine holds that the recognition of a new benefit or result of a known process cannot be accorded patentable weight during construction of the patent claims.<sup>227</sup> Although the invalidity and claim construction instantiations of the “new benefit of old process” principle call for different burdens of proof on the accused infringer, they lead to essentially the same outcome in the end.<sup>228</sup> The accused infringer in *LabCorp*, to be sure, failed to make this argument, essentially conceding that “correlating” was a “positive

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224. In some contexts, the Federal Circuit appears to have accepted this reasoning. See *supra* note 215 and accompanying text; see also *Bristol-Myers Squibb*, 246 F.3d at 1376; cf. *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1378 (Fed. Cir. 2005) (characterizing *Bristol-Myers Squibb* as standing for the proposition that “newly discovered results of known processes are not patentable because those results are inherent in the known processes”). See generally *EMI Grp. N. Am., Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342 (Fed. Cir. 2001).

225. This issue resembles the problem of withdrawing material from the public domain in *Golan v. Holder*, 132 S. Ct. 873, 906–07, 912 (2012) (Breyer, J., dissenting), though not in the other copyright opinions that Justice Breyer wrote.

226. *Atlas Powder Co. v. IRECO Inc.*, 190 F.3d 1342, 1346 (Fed. Cir. 1999).

227. Cf. *Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329 (Fed. Cir. 2005) (“[A] whereby clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited.” (quoting *Minton v. Nat’l Ass’n of Sec. Dealers*, 336 F.3d 1373, 1381 (Fed. Cir. 2003))). A similar rule governs “wherein” clauses, such as those at issue in *Mayo*. See U.S. PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2111.04 (9th ed. 2014) [hereinafter MPEP]; Brief for the United States as Amicus Curiae Supporting Neither Party, *supra* note 214, at 28–29 (arguing that the language following “wherein” in Prometheus’s claims has no “patentable weight”). But cf. *In re Jasinski*, 508 F. App’x 950 (Fed. Cir. 2013) (non-precedential).

228. In addition, this approach does not require the application of the highly rigid inherent anticipation test, though it has its own problems—like the “meaning and purpose” test. See MPEP, *supra* note 227, § 2111.04 (quoting *Griffin v. Bertina*, 285 F.3d 1029, 1034 (Fed. Cir. 2002)). Again, the doctrine can be straightened out by keeping a key policy goal of the patent system—protection from patent coverage of the subject matter in the public domain and of unclaimed subject matter generally—firmly in mind.

limitation.”<sup>229</sup> Had the argument been successfully made, however, perhaps the claim could have failed on novelty grounds after all. The claims litigated in *Mayo*, too, could have been invalidated under the “new benefit of an old process” approach<sup>230</sup>—and, indeed, it has been suggested that those claims would not and should not have survived a challenge based on the prior art.<sup>231</sup>

These results would have avoided the potential appropriation of subject matter in the public domain, but using the chisel of § 102 rather than the hammer of § 101 that Justice Breyer tested out in *LabCorp* and swung in *Mayo*. Instead, the narrow information-access problem generated by claims with a mental step at the point of novelty has led, perhaps needlessly,<sup>232</sup> to an uncontrolled expansion of the law of nature doctrine.<sup>233</sup> In an area of law as complex as patents, judicial minimalism is probably a virtue.<sup>234</sup> Rather than rely on the “gatekeeper” function of § 101,<sup>235</sup> it might have been more advisable to use a problem-specific rule to deal with the issue of capture of unclaimed material. The § 102-based approaches rooted in inherency or claim construction could have

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229. *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1362 (Fed. Cir. 2004).

230. See *supra* notes 215–227 and accompanying text.

231. See, e.g., Brief for the United States as Amicus Curiae Supporting Neither Party, *supra* note 214, at 26–33; see also Taylor, *supra* note 51 (manuscript at 56).

232. Although arguments have been made that the Prometheus and LabCorp patents should have been invalidated on other grounds, it should be noted that only § 101 was raised in the Questions Presented in both cases. Petition for a Writ of Certiorari at i, *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012) (No. 10-1150), 2011 WL 992001, at \*i (raising only the § 101 issue); Petition for a Writ of Certiorari at i, *Lab. Corp. of Am. Holdings v. Metabolite Labs, Inc.*, 548 U.S. 124 (2006) (No. 04-607), 2004 WL 2505526, at \*i (not raising the § 102 issue, although it was squarely decided below).

233. But see *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1050–51 (Fed. Cir. 2016) (distinguishing *Mayo* in a biotechnology case and finding the claims at issue patent-eligible).

234. See CASS R. SUNSTEIN, *LEGAL REASONING AND POLITICAL CONFLICT* 192 (1996). For a deeper exploration of this thesis, see, for example, CASS R. SUNSTEIN, *ONE CASE AT A TIME* 259 (1999):

[M]inimalism has distinctive virtues, especially in a heterogeneous society in which reasonable people often disagree. When judges lack, and know they lack, relevant information, minimalism is an appropriate response. Sometimes judicial minimalism is a reasonable or even inevitable response to the sheer practical problem of obtaining consensus amid pluralism. Within the Supreme Court, . . . this problem produces incompletely specified abstractions and incompletely theorized, narrow rulings.

While Professor Sunstein focuses his approach mainly on constitutional adjudication, it is applicable to non-statutory patentable subject matter exclusions—which might have a constitutional dimension. See, e.g., Peter S. Menell, *Forty Years of Wondering in the Wilderness and No Closer to the Promised Land: Bilski’s Superficial Textualism and the Missed Opportunity to Return Patent Law to Its Technology Mooring*, 63 STAN. L. REV. 1289, 1307–13 (2011); *supra* notes 107–109 and accompanying text.

235. See Sichelman, *supra* note 49, at 372 (arguing that “gatekeeping rules often take on a life of their own, continually removing themselves with each additional judicial opinion or agency interpretation from their fundamental purposes”).

provided the minimalist path by targeting the limited mental steps problem in a narrowly tailored way.

## 2. Construing Claims to Include an Intent Element

More difficult questions can arise when a claimed method does not recite a known test like the homocysteine assay in *LabCorp*, but includes process limitations that are specifically targeted to the new information to be obtained. This kind of a claim is best illustrated by an example. In *Griffin v. Bertina*, the representative claim was directed to

[a] method for diagnosing an increased risk for thrombosis or a genetic defect causing thrombosis comprising the steps of:

(A) obtaining . . . test nucleic acid comprising codon 506 within EXON 10 of the human Factor V gene; and

(B) assaying for the presence of a point mutation in the nucleotides of codon 506 within EXON 10 of the human Factor V gene, wherein said point mutation correlates to a decrease in the degree of inactivation of human Factor V . . . by activated protein C, wherein the presence of said point mutation *in said test nucleic acid indicates an increased risk for thrombosis or a genetic effect causing thrombosis.*<sup>236</sup>

This claim, whose structure is similar to the claim at issue in *LabCorp*, would almost certainly be invalid under § 101 today because of its “determine-and-infer” character.<sup>237</sup> But it is worth examining whether this sort of a claim might realistically impede the flow of information in the same way that the flame test claim or the *LabCorp* (and *Mayo*) claims likely could. While testing genes for point mutations (i.e., mutations in which the “mutant” gene deviates from the normal or “wild-type” gene by a single nucleotide) is well-known, the claim does not have the potential to capture this fundamental technique because it is directed specifically to the testing of codon 506. More importantly, the testing of this specific codon for a point mutation was not an activity in the prior art.<sup>238</sup> Indeed, “nucleic acid comprising codon 506 within EXON 10 of the human Factor V gene” had no scientific value until it was discovered that point mutations in this gene were predictive of thrombosis.<sup>239</sup> Accordingly, the principle that “merely discovering and

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236. 285 F.3d 1029, 1031 (Fed. Cir. 2002) (emphasis added).

237. See *supra* note 200 and accompanying text; see also *supra* note 165 and accompanying text.

238. *Griffin*, 285 F.3d at 1034.

239. *Id.* at 1031–34. Technically, this issue arose in the context of an interference proceeding—a priority contest between multiple inventors seeking a patent on “the same or substantially the same subject matter.” 35 U.S.C. § 135(b)(1) (2006). Bertina, who first recognized and claimed this utility of testing codon 506 for a point mutation, was awarded the patent. *Griffin*, 285 F.3d at 1035.

claiming a new benefit of an old process cannot render the process again patentable” does not have an application here.<sup>240</sup>

Nevertheless, some discomfort remains. For a researcher who is genuinely looking for a new application of assaying the nucleotides of codon 506 for a point mutation, there is a problem similar to that with the hypothetical scenario of the flame test patent. Since the claims are limited to the diagnosis of thrombosis, it would seem that the follow-on researcher should be able to search for new uses of the codon 506 test without the danger of infringing the patent through a reflexive act of thought. In other words, upon reading the patent and learning that a point mutation on that codon is predictive of thrombosis, the researcher cannot unthink this application of the correlation, even if that researcher is looking for something new. How do we allow this person to study the codon without the reflexive infringement?<sup>241</sup>

One solution, suggested in Professor Collins’s early work, is an intent requirement to prove infringement in cases like this.<sup>242</sup> Although it is true that direct infringement does not require a showing of intent to infringe,<sup>243</sup> the claims at issue here could be construed to include their own element of intent because they recite what the newly invented

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240. *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990) (emphasis omitted). And indeed, the MPEP uses this case as an example where a “wherein” clause in fact has patentable weight. See MPEP, *supra* note 227, § 2111.04.

241. *Cf.* Collins, *Constructive Nonvolition*, *supra* note 189, at 814–24.

242. *Id.* In his more recent work, Professor Collins has been less optimistic that the requirement of intent can play a meaningful role in this area because of the difficulty of enforcement by the patentee. Collins, *supra* note 51 (manuscript at 27–28). I am sympathetic to the idea that proof of intent is difficult. See generally Dmitry Karshedt, *Causal Responsibility and Patent Infringement*, 70 VAND. L. REV. (forthcoming 2017), <http://ssrn.com/abstract=2744427> [<https://perma.cc/S5DN-X94D>]. But the patentee would rather have a patent that is difficult to enforce than no patent at all due to § 101. Moreover, in spite of the rigorous intent requirements to prove indirect infringement, which include knowledge of the patent and the lack of a good-faith belief in noninfringement, see *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1926–28 (2015), it must be conceded the patentee has met them in significant cases. See, e.g., *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1320 (Fed. Cir. 2009). Here, it would seem, communications between doctors and testing laboratories in cases involving claims like those in *Griffin*, as well as the doctors’ own notes or testimony from patients, might readily allow fact-finders to draw an inference of intent to infringe. *Cf.* *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1365 (Fed. Cir. 2004) (establishing intent sufficient for indirect infringement). Moreover, claims reciting an intent limitation actually reflect what the patentee invented—for example, a test for a point mutation in the nucleotides of codon 506 for the purpose of diagnosing thrombosis, not for any other purpose.

243. See *supra* notes 192–194 and accompanying text; see also Chin, *supra* note 215, at 291–92 (“[I]nfringement doctrine does not treat a preambular purpose as an essential property of a patent claim, because intent is not an element of infringement.” (citations and internal quotation marks omitted)). *But cf.* *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329 (Fed. Cir. 2003).

processes of assaying codon 506 for a point mutation is for.<sup>244</sup> If so, then perhaps the patentee must prove that the accused infringer looked for a point mutation in the codon's nucleotides with the claimed purpose of diagnosing an increased risk of thrombosis—and if his or her intent were different, the infringement claim would fail. Patent law has handled intent in other contexts,<sup>245</sup> and there is no reason why it cannot do so here. Given the fact that the step of assaying codon 506 for a point mutation for any purpose was not in the public domain, follow-on researchers would perhaps not be unduly burdened from looking for new uses of the test if the requirement of proof of intent is in place.<sup>246</sup> Again, this would be a narrow solution targeted to the specific problem with many of the claims that are now addressed under the patentable subject matter requirement.

### CONCLUSION

In the end, Justice Breyer was correct to conclude that patents in *LabCorp*, and likely in *Mayo*, should be held invalid. Moreover, he was also accurate in his general diagnosis that the patents at issue presented information-access concerns of some sort. The particular problem these patents created was effective blockage of access to unpatented processes by including steps directed to mental inferences. In an indirect way, then, a noninfringer could turn into an infringer merely after consuming information in a patent and performing an otherwise unpatented method.<sup>247</sup>

But unlike copyright in scientific articles, these patents—and many others invalidated in the wake of *Mayo*—have not presented some generalized threat to the dissemination of knowledge.<sup>248</sup> The problem of information access is simply less salient for patents than it is for copyrights. Moreover, patents, in contrast to copyrights, are more specifically designed to do just the opposite—to force disclosure of information. To the extent that the information-access problem exists

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244. *But see* David A. Kelly, *What Constitutes a "New Use" of a Known Composition and Should a Patentee's Purported Objective Make Any Difference?*, 21 SANTA CLARA COMPUTER & HIGH TECH. L.J. 319 (2005).

245. *See supra* note 242 and accompanying text.

246. While there are administrative costs to defending allegations of intent, state of mind does need to be pled with particularity. *Addiction & Detoxification Inst. L.L.C. v. Carpenter*, 620 F. App'x 934, 938 (Fed. Cir. 2015) (non-precedential); *In re Bill of Lading Transmission & Processing Sys. Patent Litig.*, 681 F.3d 1323, 1337 (Fed. Cir. 2012); *see also* Caroline N. Mitchell & David L. Wallach, *Pleading State of Mind After Ashcroft v. Iqbal*, 2009 FIN. FRAUD L. REP. 201.

247. *See supra* notes 191–197 and accompanying text.

248. *See supra* Part II (explaining the role of patents in the process of dissemination of knowledge).

in patent law in the form of claims that encroach upon the public domain, the novelty requirement has long been in place to address this very problem. And to the extent that follow-on researchers might be deterred from reading certain patents because of the possibility of becoming infringers through reflexive thought, the problem could also be addressed by imposing the requirement to prove intent to infringe in certain contexts.<sup>249</sup>

Reliance on similarities between copyrights and patents has its place, but it must not be taken too far. Unlike copyrights in technical articles, patents are generally unlikely to halt the spread of ideas—if for no other reason than that they are intended to do the opposite. Because Justice Breyer’s patent law jurisprudence might rest on a questionable parallel between patent and copyright, it ought to be reexamined.

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249. Because of space constraints, I do not extensively consider another set of potential solutions—involving an experimental use exception or some form of copyright-style fair use defense to patent infringement—for dealing with problems that some patents might cause for cumulative innovation. See *supra* note 153 and accompanying text; see also 35 U.S.C. § 271(e)(1) (2012) (providing downstream researchers with a shield from infringement liability in specific circumstances); Timothy R. Holbrook, *The Return of the Supreme Court to Patent Law*, 1 AKRON INTELL. PROP. J. 1, 5 (2007) (“Expansion of the statutory safe harbor defense may be appropriate in promoting the creation and dissemination of information, particularly in light of the Federal Circuit’s evisceration of the common law ‘experimental use’ defense.” (citing *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002))); Maureen A. O’Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177, 1180 (2000) (proposing a fair use defense to patent infringement); Katherine J. Strandburg, *Patent Fair Use 2.0*, 1 U.C. IRVINE L. REV. 265, 292–304 (2011) (similar); Taylor, *supra* note 51 (manuscript at 45–46) (arguing that § 101 is doing some of the work that the experimental use exception should be doing); cf. Ouellette, *supra* note 132 (discussing and critiquing calls for the experimental use exception for academic scientists). If experimental use shields are applied, it is essential for the rules to make clear ex ante how the liability would be limited. See Alan Devlin, *Restricting Experimental Use*, 32 HARV. J.L. & PUB. POL’Y 599, 635 (2009) (“Indeterminate ex post interference in proprietary rights by courts tends to inject further uncertainty into an already flawed system, to undermine efficient contractual exchange, and to endanger ex ante technological research.”).