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JUSTICE BREYER AND PATENT ELIGIBILITY

DAVID O. TAYLOR

ORCID: 0000-0001-6531-6100



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JUSTICE BREYER AND PATENT ELIGIBILITY

DAVID O. TAYLOR*

Justice Breyer had a significant impact on patent law during his tenure on the Supreme Court. Unfortunately, in my view, that impact was significantly negative for the doctrine of patent eligibility. Indeed, Justice Breyer authored arguably one of the worst Supreme Court decisions in the field of patent law in recent memory: *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*¹

I. BACKGROUND

Before discussing *Mayo*, some background might help set the stage. Justice Breyer joined the Supreme Court on August 3, 1994.² Prior to that, he served as an appellate judge on the U.S. Court of Appeals for the First Circuit.³ He joined that court late in 1980.⁴ Notably, however, President Reagan and Congress signed the Federal Courts Improvement Act on April 2, 1982.⁵ Thereafter, on October 1, 1982, the U.S. Court of Appeals for the Federal Circuit gained exclusive jurisdiction over almost all appeals in patent infringement and validity cases.⁶ So, while then-Judge Breyer served on an intermediate appellate federal court for about fourteen years, it was only from late 1980 to October 1, 1982—around two years—that that court held jurisdiction over appeals in patent infringement and validity cases. Notably, during those almost two years then-Judge Breyer never wrote a single opinion in a patent infringement or validity case.⁷ Nor did he sit on a panel that released any opinion in any patent infringement or validity case.⁸ During his time on the First Circuit, he did author

* © Professor of Law and Director of the Tsai Center for Law, Science and Innovation, SMU Dedman School of Law; J.D., 2003, Harvard Law School; B.S., 1999, Texas A&M University. This essay expounds upon oral remarks I gave at an online event entitled “Special Program: Justice Breyer and His Complicated Intellectual Property Legacy,” organized by the Center for Intellectual Property Law and Innovation at the Indiana University Robert H. McKinney School of Law. Thanks to Xuan-Thao Nuygen for inviting me to that event, and to Dylan Freeman for his assistance editing this essay. Special thanks to Rachel, Caroline, Emily, and Joshua Taylor. The views and any errors in this essay are my own.

¹ *Mayo Collaborative Servs. v. Prometheus Lab’s, Inc.*, 566 U.S. 66 (2012).

² Current Members, SUPREME COURT OF THE UNITED STATES, <https://www.supremecourt.gov/about/biographies.aspx> (last visited Apr. 4, 2022).

³ *Id.*

⁴ *Id.*

⁵ Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (codified as amended in scattered sections of 28 U.S.C.).

⁶ *Id.*

⁷ A search of Westlaw reveals no such cases.

⁸ Again, a search of Westlaw reveals no such cases. One opinion joined by then-Judge Breyer vacated and remanded a decision of the U.S. Patent and Trademark Office to strike a reissue application on the basis of fraud on the Patent Office. *See generally* *Digital Equip. Corp. v. Diamond*, 653 F.2d 701 (1st Cir. 1981).

opinions in antitrust cases that mentioned patents⁹ and also in a licensing case that involved patents.¹⁰ But, effectively, he joined the Supreme Court without any experience analyzing issues in patent infringement and validity cases.

He did join the Court with some experience in intellectual property more broadly. For example, when he was on the Harvard Law School faculty he wrote an article entitled “The Uneasy Case for Copyright: A Study of Copyright in Books, Photocopies, and Computer Programs.”¹¹ As explained in a brief summary attached to the beginning of his article, “[o]n the basis of existing evidence he is unable to conclude that copyright should be abolished, but he argues that its extension is unnecessary and would be harmful.”¹² This was not a ringing endorsement of Congress’s decision to create intellectual property rights.

He also served two years in the Antitrust Division of the U.S. Department of Justice, where his views of patent law may have developed.¹³ Indeed, Justice Breyer would repeatedly refer to patents as “monopolies” in his opinions,¹⁴ despite the fact that patents rarely grant their owners actual economic monopolies.¹⁵ In this respect he seems to have adopted an attitude resembling that of a prior Supreme Court Justice,

⁹ See *Grappone, Inc. v. Subaru of New England, Inc.*, 858 F.2d 792 (1st Cir. 1988); *Clamp-All Corp. v. Cast Iron Soil Pipe Inst.*, 851 F.2d 478 (1st Cir. 1988); *Kartell v. Blue Sheild of Mass., Inc.*, 749 F.2d 922 (1st Cir. 1984); *Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d 227 (1st Cir. 1983).

¹⁰ *Maruho Co. v. Miles, Inc.*, 13 F.3d 6 (1st Cir. 1993).

¹¹ Stephen Breyer, *The Uneasy Case for Copyright: A Study of Copyright in Books, Photocopies, and Computer Programs*, 84 HARV. L. REV. 281 (1970).

¹² *Id.*

¹³ Current Members, SUPREME COURT OF THE UNITED STATES, <https://www.supremecourt.gov/about/biographies.aspx> (last visited Apr. 4, 2022).

¹⁴ *Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 279 (2016) (indicating that “inter partes review helps protect the public’s ‘paramount interest in seeing that patent monopolies . . . are kept within their legitimate scope’”) (quoting *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945)); *Medtronic, Inc. v. Mirowski Fam. Ventures, LLC*, 571 U.S. 191, 851–52 (2014) (“A patentee ‘should not be . . . allowed to exact royalties for the use of an idea . . . that is beyond the scope of the patent monopoly granted.’”) (quoting *Blonder-Tongue Lab’ys, Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 349–50 (1971)); *Fed. Trade Comm’n v. Actavis, Inc.*, 570 U.S. 136, 148 (2013) (“[T]his Court has indicated that patent and antitrust policies are both relevant in determining the ‘scope of the patent monopoly’—and consequently antitrust law immunity—that is conferred by a patent.”); *Mayo Collaborative Servs. v. Prometheus Lab’ys, Inc.*, 566 U.S. 66, 71 (2012) (“And monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it.”).

¹⁵ 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, 1368 (2011) (noting that “patents are rarely true monopolies; usually alternative ways exist to achieve a result similar to the one for which the patented invention is utilized.”).

Justice Douglas, whose patent decisions also referred to patents as monopolies.¹⁶ Unfortunately, Justice Douglas's opinions have also gained significant attention for their poor quality, and Justice Douglas's noted antipathy toward patents may have similarly stemmed from a misguided understanding of economics and concern with antitrust laws.¹⁷

Regardless, whatever the cause or excuse, Justice Breyer authored one of the most infamous Supreme Court decisions in the field of patent law: *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*¹⁸ Before I discuss that particular case in detail, however, there are two cases that form the backdrop to Justice Breyer's understanding and analysis of patent law demonstrated in his *Mayo* opinion. In particular, these cases show Justice Breyer developing, if not gaining support, for his view of the doctrine of patent eligibility.

II. LABORATORY CORP. V. METABOLITE LABORATORIES, INC.

The first is *Laboratory Corp. v. Metabolite Laboratories, Inc* (“*LabCorp*”).¹⁹ In this case, the Supreme Court originally granted a writ of certiorari to the Federal Circuit, only to later dismiss the writ as improvidently granted.²⁰ Justice Breyer dissented from the decision to dismiss the writ.²¹ As explained in his dissenting opinion, the Court granted the writ “to determine whether the patent claim [at issue in the case] is invalid on the ground that it improperly seeks to claim a monopoly over a basic scientific relationship.”²² Based on this question, it is clear the Court anticipated analyzing patent law's eligibility requirement. It is also clear that Justice Breyer held the view that the patent in question, which, he explained, “claims a process for helping to diagnose deficiencies of two vitamins, folate and cobalamin,” was invalid.²³ In particular, he explained, the patented “process consists of using any test (whether patented or unpatented) to measure the level in a body fluid of an amino acid called

¹⁶ *Gottschalk v. Benson*, 409 U.S. 63, 69 (1972) (“The chemical process or the physical acts which transform the raw material are, however, sufficiently definite to confine the patent monopoly within rather definite bounds”); *Cuno Eng'g Corp. v. Automatic Devices Corp.*, 314 U.S. 84, 92 (1941) (referring to “a class of speculative schemers who make it their business to watch the advancing wave of improvement, and gather its foam in the form of patented monopolies, which enable them to lay a heavy tax upon the industry of the country, without contributing anything to the real advancement of the art.”) (quoting *Atlantic Works v. Brady*, 107 U.S. 192, 200 (1883)).

¹⁷ *Cf.* C. Paul Rogers III, *The Antitrust Legacy of Justice William O. Douglas*, 56 CLEV. ST. L. REV. 895, 998–99 (2008) (noting that Justice Douglas was “the leading antitrust hawk in our history,” yet held an “intrinsic inconsistency of his antitrust philosophy”; highlighting the “poor quality of his opinions in his later years on the Court,” where “[o]ften his fact analysis was superficial and incomplete”; and concluding that “perhaps the most telling observation of Justice Douglas' antitrust legacy is that . . . the first antitrust opinion of the longest sitting Supreme Court justice in our history (and the Justice who authored more antitrust opinions than anyone on the high Court) . . . is the only lasting antitrust precedent flowing from Douglas' pen”).

¹⁸ 566 U.S. 66 (2012).

¹⁹ *Lab'y Corp. of Am. Holdings v. Metabolite Lab'ys, Inc.*, 548 U.S. 124 (2006).

²⁰ *Id.* at 125.

²¹ *Id.* (Breyer, J., dissenting).

²² *Id.*

²³ *Id.*

homocysteine and then noticing whether its level is elevated above the norm,” which indicates “a vitamin deficiency is likely.”²⁴

He explained that “those who engage in medical research, who practice medicine, and who as patients depend upon proper health care might well benefit from this Court’s authoritative answer” to the question of whether this claim is invalid as claiming subject matter ineligible for patenting.²⁵ The problem, and no doubt the reason the Court dismissed the writ, was that the Federal Circuit never ruled on the eligibility of the claim.²⁶ That, however, made no difference to Justice Breyer: “The question presented is not unusually difficult. We have the authority to decide it. We said that we would do so. The parties and *amici* have fully briefed the question. And those who engage in medical research, who practice medicine, and who as patients depend upon proper health care might well benefit from this Court’s authoritative answer.”²⁷

He then explained in detail why, in his view, the claim is invalid. He focused on the law of eligibility, listing the three historical, common-law exclusions of “laws of nature, natural phenomena, and abstract ideas” before enlisting the Constitution for support, arguing 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.”²⁸ Without acknowledging the governing statutory provision on point (later in the opinion he would call the fact that the Federal Circuit had not referred to the governing statutory language, 35 U.S.C. § 101, a “technical procedural reason” for not analyzing eligibility), he argued that “patents do not only encourage research by providing monetary incentives for invention” but also “[s]ometimes . . . discourage research by impeding the free exchange of information, for example 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 by raising the costs of using the patented information, sometimes prohibitively so.”²⁹ In other words, in Justice Breyer’s mind it was a matter of constitutional imperative that the Supreme Court weigh the benefits and costs of particular patent doctrines to ensure that the benefits of the patent system exceed its cost. This is a particularly momentous role for the Supreme Court, especially when its Justices have no relevant qualification or even experience, let alone empirical data, to serve as a guide in this analysis.

After reciting the facts of the case, as I mentioned, he admitted that “[t]here is a technical procedural reason for not” answering the question presented, “namely, that LabCorp did not refer in the lower courts to § 101 of the Patent Act, which sets forth subject matter that is patentable, and within the bounds of which the ‘law of nature’ principle most comfortably fits.”³⁰ He also conceded that “[t]here is also a practical reason for not doing so, namely, that we might benefit from the views of the Federal

²⁴ *Id.*

²⁵ *Id.* at 126.

²⁶ See generally *Metabolite Lab’ys, Inc. v. Lab’y Corp. of Am. Holdings*, 370 F.3d 1354 (Fed. Cir. 2004).

²⁷ *Lab’y Corp.*, 548 U.S. at 126 (Breyer, J., dissenting).

²⁸ *Id.* at 126–27 (emphasis in original).

²⁹ *Id.* at 127.

³⁰ *Id.* at 132.

Circuit, which did not directly consider the question.”³¹ Those barriers to review, however, he thought were overridden by countervailing considerations. He ultimately wanted to answer the question presented to, in his view, further “the public interest—including that of clarifying the law in this area sooner rather than later” and, notably, without hearing the views of the Federal Circuit, despite the fact that “further consideration by the Federal Circuit might help [the Court] reach a better decision.”³² Even if it amounted to a short circuit to the procedure, Justice Breyer indicated that, in his view, “the extra time, cost, and uncertainty that further proceedings would engender are not worth the potential benefit.”³³ In short, the court with the relevant experience considering the policies underlying patent law (the Federal Circuit) need not help the Supreme Court in answering the momentous question he embraced.

On the merits, Justice Breyer provided one more concession. He conceded that “the category of nonpatentable phenomena of nature, like the categories of mental processes and abstract intellectual concepts, is not easy to define.”³⁴ But, he argued, “this case is not at the boundary.”³⁵ As a result, he proceeded to address the merits of the question presented in the case.

The relevant claim, he concluded, “is invalid no matter how narrowly one reasonably interprets” the natural phenomena doctrine.³⁶ “There can be little doubt that the correlation between homocysteine and vitamin deficiency,” he added, “is a natural phenomenon.”³⁷

The most significant problem with the reasoning Justice Breyer used to reach his conclusion—an error that would only appear clearly later when he finally found the opportunity in *Mayo* to author a majority opinion addressing patent eligibility law—only made a faint appearance in this case. He (seemingly, here; more clearly later) rejected the longstanding, traditional approach to patent eligibility that long provided the dividing line between ineligible natural phenomena and eligible applications of natural phenomena.³⁸ He highlighted how the respondents argued “that the correlation is nonetheless patentable because claim 13 packages it in the form of a ‘process’ for detecting vitamin deficiency, with discrete testing and correlating steps.”³⁹ After recognizing how the Supreme Court’s recent cases supported this distinction, e.g., *Diehr* (“an *application* of a law of nature . . . to a known . . . process may well be deserving of patent protection”), he nevertheless seemed to reject it.⁴⁰

He did, at first, indicate he would consider whether the claim in question described an *application* of the law of nature or natural phenomena.⁴¹ He concluded, on point, that the claims “embody only the correlation between homocysteine and vitamin deficiency that the researchers uncovered.”⁴² There was, however, an

³¹ *Id.*

³² *Id.* at 133–34.

³³ *Id.* at 133.

³⁴ *Id.* at 134 (internal quotations omitted).

³⁵ *Id.* at 135.

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.*

³⁹ *Id.* at 136.

⁴⁰ *Id.* at 135.

⁴¹ *Id.* at 126.

⁴² *Id.* at 128.

argument that the claims did not *only* embody this correlation. The claims required drawing blood and testing for the presence of the relevant biomarker.⁴³ Under the traditional analysis of patent eligibility, any practical application of the natural phenomenon would make the claim eligible for patenting.⁴⁴ And, here, there at least was a basis to argue that the practical application of the law of nature or natural phenomenon was use of these steps to diagnose disease. Under this analysis, however, the Court would need to decide whether a diagnosis qualifies as a practical application.

Justice Breyer, however, did not answer that question. Thus, the irony is that, despite his inflated view of the role of the Supreme Court and dismissal of Congressional statutory language, his discounting of the importance of Federal Circuit insights, and his decision to plow ahead despite difficulty defining the relevant legal principles, the traditional approach to patent eligibility may have justified finding the particular claim in this case invalid.⁴⁵ The claim may not have involved any *application* of the relevant law of nature or natural phenomenon.

In Justice Breyer's view, however, it did not matter whether diagnosis qualified as an application of the newly-discovered natural phenomenon.⁴⁶ In short, according to Justice Breyer, to the extent a medical diagnostic used an *old* method to detect a biomarker, that medical diagnostic should not be patentable.⁴⁷ It did not matter that no one in history had ever identified the correlation between the biomarker and the presence of disease and, moreover, no one had ever used that knowledge to diagnose disease. And this approach—Justice Breyer's approach to patent eligibility—history would later prove, completely undermined the idea of patenting medical diagnostics.

Notably, Justice Breyer gained the support of only two of his colleagues, Justices Stevens and Souter.⁴⁸

III. BILSKI V. KAPPOS

The second case that forms the backdrop to the *Mayo* opinion is the Supreme Court's consideration of *Bilski v. Kappos*.⁴⁹ In *Bilski*, the Court granted certiorari to consider whether, in Justice Breyer's words, "a general method of engaging in business transactions" is a "patentable process within the meaning of 35 U.S.C. § 101."⁵⁰ Notably, Justice Breyer joined Justice Stevens's opinion that would have held that "business methods" are not eligible for patenting.⁵¹ The Court's majority opinion,

⁴³ See *Metabolite Lab'ys, Inc. v. Lab'y Corp. of Am. Holdings*, 370 F.3d 1354, 1358–59 (Fed. Cir. 2004).

⁴⁴ Jeffrey A. Lefstin, *Inventive Application: A History*, 67 FLA. L. REV. 565, 565 (2016) ("[F]or over one hundred years, American authority consistently maintained that practical application distinguished unpatentable discovery from patentable invention.").

⁴⁵ See *e.g.*, *Diamond v. Diehr*, 450 U.S. 175, 187–88 (1981) (stating that "an *application* of a law of nature . . . to a known . . . process may well be deserving of patent protection") (emphasis in original).

⁴⁶ *Lab'y Corp.*, 548 U.S. at 135–36 (Breyer, J., dissenting).

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ *Bilski v. Kappos*, 561 U.S. 593 (2010).

⁵⁰ *Id.* at 657 (Breyer, J., concurring).

⁵¹ *Id.* "Business methods," at least in the context of this case, include computerized methods of conducting business transactions. *Id.* at 599–605.

written by Justice Kennedy, did not go so far, although it rejected the particular claim at issue in the case as ineligible for patenting because it was an unpatentable abstract idea (not because it described a “business method”).⁵²

One thing that is particularly notable about Justice Stevens’s concurring opinion, which Justice Breyer joined, is that it misunderstands the legislative history behind the Patent Act of 1952.⁵³ That legislative history states that “[a] person may have ‘invented’ a machine or a manufacture, which may include anything under the sun that is made by man, but it is not necessarily patentable under section 101 unless the conditions of [this] title are fulfilled.”⁵⁴ This language refers to the fact that § 101 does not express all the conditions of patentability. Other sections of the patent statute also define the conditions of patentability, including, for example, novelty and non-obviousness, conditions the patent statute recites in §§ 102 and 103.⁵⁵ But Justice Stevens misunderstood that language to mean that, even if someone invented “anything under the sun,” § 101 itself may still define why that invention is not patentable.⁵⁶ Justice Breyer would later rely on similarly misguided reasoning to distort the purpose of § 101 of the patent statute and, indeed, to confuse § 101 with the other conditions of patentability created by Congress and put into other statutory sections.

Justice Breyer also wrote separately in *Bilski* to make several points, many reflected in *LabCorp.*, that he would later work into his opinion for the court in *Mayo*. First, he argued that the text of § 101, while broad, “is not without limit.”⁵⁷ He then, after quoting an opinion describing patents as an “embarrassment” and as a “limited . . . monopoly,” repeated his concern for the court-created, non-statutory exceptions to patent eligibility (phenomena of nature, mental processes, and abstract intellectual concepts) and the need for the Court to interpret the Patent Act to “determine not only what is protected, but also what is free for all to use.”⁵⁸ Second, while purporting to support the usefulness of the so-called machine-or-transformation test for patent eligibility, saying it has “repeatedly helped the Court to determine what is a patentable process,” he rejected it as the “sole test” for determining patent eligibility.⁵⁹ Third, he cited to his *LabCorp* dissent as support for rejecting the Federal Circuit’s test for determining eligibility.⁶⁰ Notably, however, he did not articulate the eligibility test he would later express in *Mayo*.⁶¹

In short, in *Bilski*, Justice Breyer, while not identifying any test for determining eligibility, demonstrated, again, solicitude for arguments constraining patent eligibility, for considering patents to be embarrassing monopolies, and for

⁵² *Id.* at 612.

⁵³ *See Bilski*, 561 U.S. at 641 (Stevens, J., concurring).

⁵⁴ *See Id.* at 642 (citing S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952) and H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952)).

⁵⁵ 35 U.S.C §§ 102, 103, 112 (2022).

⁵⁶ *See Bilski*, 561 U.S. at 642 (Stevens, J. concurring) (construing “not necessarily patentable under section 101 unless the conditions of [this] title are fulfilled” from the legislative history to mean “not necessarily patentable under section 101”) (emphasis added).

⁵⁷ *Id.* at 658 (Breyer, J., concurring).

⁵⁸ *Id.*

⁵⁹ *Id.* at 659.

⁶⁰ *Id.*

⁶¹ *See Mayo Collaborative Servs. v. Prometheus Lab’sys*, 566 U.S. 66 (2012).

making the Supreme Court (and not Congress or the Federal Circuit) the arbiter of patent eligible subject matter. Justice Breyer's opinion indicated support for Justice Stevens's primary dissent, which gained the support of four Justices.⁶² But Justice Breyer's opinion, at least the relevant part for our purposes, was joined only by Justice Scalia.⁶³ Justice Breyer had not yet, apparently, persuaded the Court to join in his views. He would, though, in *Mayo*.

IV. MAYO COLLABORATIVE SERVICES V. PROMETHEUS LABORATORIES, INC.

As I have been noting, *LabCorp* and *Bilski* proved to be prelude to *Mayo*. In this later case, Justice Breyer finally gained the opportunity to author a majority opinion reflecting own views about the dangers of expansive patent eligibility. Indeed, his opinion in this case was joined by all of the other Justices; it was a unanimous opinion.⁶⁴

Justice Breyer's analysis of the law of eligibility in *Mayo* starts innocuously enough. He explains that an application of a law of nature may be eligible, and that a claim must do more than simply state the law of nature and add the words "apply it."⁶⁵ The opinion, however, goes downhill from there. Instead of explaining why the patent claim at issue—a process of determining the effectiveness of an administered drug—did not actually describe how to apply the law of nature (the law of nature was the correlation of a biomarker and effectiveness of a drug), Justice Breyer created a new test for eligibility that has no legitimate basis in the history of the Supreme Court's analysis of patent eligibility, let alone in the patent statute or even in good policy.⁶⁶

The test Justice Breyer created in this case is the requirement that a claim describe "significantly more"—whatever that means—than a law of nature, a requirement the opinion describes as the search for an "inventive concept."⁶⁷ Remarkably, this test directly contradicted over 100 years of Supreme Court case law, because what Justice Breyer sought to find—even when an inventor made a discovery of a previously-unknown law of nature and applied that discovery to some useful end—was something "significantly more" than a useful application of a law of nature.⁶⁸ But the historical standard was the idea that whoever discovers a natural phenomenon or law of nature may obtain a patent if that person discloses how to use that natural phenomenon or law of nature to achieve some real benefit.⁶⁹ Instead of allowing the patent system to reward that inventor, Justice Breyer layered on top of the traditional requirement the idea that "something more" is required.⁷⁰ What exactly that something more is, he did not explain. He only condemned a discovery when it was combined with any "well-understood, routine, conventional activity previously engaged

⁶² *Bilski*, 561 U.S. at 658–60 (Breyer, J., concurring).

⁶³ *Id.* at 657.

⁶⁴ *Mayo Collaborative Servs. v. Prometheus Lab's*, 566 U.S. 66 (2012).

⁶⁵ *Id.* at 72.

⁶⁶ *Id.* at 72–73.

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ See *Diamond v. Diehr*, 450 U.S. 175, 187 (1981) ("It is now commonplace that an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.") (emphasis in original).

⁷⁰ *Mayo*, 566 U.S. at 72–73.

in by researchers in the field”—but it was exactly that conventional activity that, for over a century, had been enough to earn a patent.⁷¹ Indeed, Peter Menell and Jeff Lefstin in subsequent cases at the Supreme Court have repeatedly explained how Justice Breyer’s misunderstood the foundational, 19th Century English and American precedent on point.⁷² While true, the opinion also contradicts more recent precedent. For example, in *Diamond v. Diehr*,⁷³ decided by the Court in 1981, the Court explained that “[t]he ‘novelty’ of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.”⁷⁴ In other words, for eligibility purposes, it does not matter whether the method applying the newly-discovered law of nature is conventional or includes something that is new.⁷⁵ It is enough that the discovery is applied to achieve some benefit.⁷⁶

Beyond the creation of a test without precedential support, in *Mayo* Justice Breyer rejected the notion (notably supported by the government in its amicus brief)⁷⁷ that the statutory patentability requirements outside of § 101 provide the necessary screening of claims.⁷⁸ These patentability requirements include the novelty, non-obviousness, enablement, written description, and definiteness requirements found in §§ 102, 103, and 112.⁷⁹ Despite the clear legislative history supporting this exact proposition, Justice Breyer rejected it out of hand in the same way Justice Stevens misunderstood it in *Bilski*, as discussed above.⁸⁰

The test Justice Breyer created in *Mayo* also has had pernicious effects. No medical diagnostic claim has survived a patent eligibility challenge at the Federal Circuit since *Mayo*. Just imagine how diagnostic inventions may have helped fight the COVID pandemic, when we repeatedly heard cries for increased and improved diagnoses of infection. One particularly disheartening example of the way Justice Breyer’s test ultimately causes incorrect results and eliminates the incentive for developing advances in medical diagnostics is *Ariosa Diagnostics, Inc. v. Sequenom*,

⁷¹ *Id.* at 73.

⁷² Brief of Professors Jeffrey A. Lefstin and Peter S. Menell as *Amici Curiae* in Support of Petition for A Writ of Certiorari, *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, No. 20-891 (S. Ct. Mar. 1, 2021); Brief of Professors Jeffrey A. Lefstin and Peter S. Menell as *Amici Curiae* in Support of Petition for A Writ of Certiorari, *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, No. 15-1182 (S. Ct. Apr. 20, 2016).

⁷³ *Diehr*, 450 U.S. 175.

⁷⁴ *Id.* at 188–89.

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ See Brief for the United States as Amicus Curiae Supporting Neither Party, *Mayo*, 566 U.S. 66 (2007) (No. 10-1150) 2011 WL 4040414 at *8, 32 (“Properly conceived, however, petitioners’ objections arise not under Section 101, but under the novelty and nonobviousness requirements of 35 U.S.C. 102 and 103 . . . The only role of Section 101 . . . is to identify the types of subject matter that may be eligible for patent protection if “the conditions and requirements” of Title 35 are satisfied.”).

⁷⁸ *Mayo*, 566 U.S. at 89 (“[I]n [the United States] view, other statutory provisions—those that insist that a claimed process be novel, 35 U.S.C. § 102, that it not be obvious in light of prior art, § 103, and that it be ‘full[ly], clear[ly], concise[ly], and exact[ly]’ described, § 112—can perform this screening function . . . This approach, however, would make the “law of nature” exception to § 101 patentability a dead letter.”).

⁷⁹ *Id.*

⁸⁰ See *id.*; *Bilski v. Kappos*, 561 U.S. 593, 642 (2010) (Stevens, J., concurring); S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952) and H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952).

*Inc.*⁸¹ In this case, the *Mayo* test was used to invalidate patent claims on an invention that allowed for the diagnosis of genetic abnormalities in unborn babies.⁸² The inventors made an award winning advance that significantly reduced the risk of miscarriages; they discovered that certain fetal DNA could be detected in a mother's bloodstream, and they combined this discovery with conventional techniques to detect this fetal DNA.⁸³ Instead of taking tissue samples from the fetus or placenta, they determined that only a simple blood test would be necessary.⁸⁴ One Federal Circuit judge lamented that the Supreme Court's historic standard for patent eligibility would have resulted in the inventors securing a valid patent, because their invention "effectuated a practical result and benefit not previously attained."⁸⁵ He saw "no reason, in policy or statute, why this breakthrough invention should be deemed patent ineligible," but was required to find it ineligible under the *Mayo* test.⁸⁶

The test unfortunately has also migrated, ultimately infecting all of patent eligibility law. While Justice Breyer's opinion in *Mayo* focused on medical technologies, later the Supreme Court would adopt his test in *Alice v. CLS Bank* and apply it in the context of computer technology.⁸⁷ The non-statutory prohibition on claiming an "abstract idea" now depends on whether the claim includes "something more," and in particular an "inventive concept." But we still do not have any indication of what an "inventive concept" is (rather than what it is not), and this test still contradicts the historical eligibility standard.⁸⁸ Moreover, most recently, Justice Breyer's test has even been used to invalidate claims to mechanical technologies. In *American Axle & Manufacturing, Inc. v. Neapco Holdings LLC*, the Federal Circuit invalidated claims to liner for an automobile driveshaft, where the liner is designed to reduce vibrations.⁸⁹ According to the Federal Circuit and in light of *Mayo*, it did not matter that the claims described a liner that was new and non-obvious.⁹⁰ The claims, said the court, merely applied Hook's law in a conventional way.⁹¹ A petition in that case, notably, is pending at the Supreme Court, and the Supreme Court has asked for the views of the Solicitor General.⁹² Regardless of how that cases ultimately is resolved, it is quite startling that Justice Breyer's test has resulted in a court finding that a mechanical invention is not the type of invention even eligible to be considered for patenting.

Finally, and perhaps most disheartening, in my own research I have shown that investors have reduced investments in the development of medical technologies as a result of Justice Breyer's *Mayo* decision.⁹³ As I explain there, "the major takeaway is clear: the Supreme Court's 'drastic and far-reaching experiment' in patent eligibility

⁸¹ *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015).

⁸² *Id.*

⁸³ *Id.* at 1373–74.

⁸⁴ *Id.*

⁸⁵ *Id.* at 1381 (Linn, J., concurring).

⁸⁶ *Id.*

⁸⁷ *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208 (2014)

⁸⁸ *Id.* at 217, 221–22.

⁸⁹ *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 967 F.3d 1285 (Fed. Cir. 2020).

⁹⁰ *Id.* at 1291–92

⁹¹ *Id.*

⁹² *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 141 S. Ct. 2594 (2021) (inviting the Solicitor General to file a brief expressing the views of the United States).

⁹³ See generally David O. Taylor, *Patent Eligibility and Investment*, 41 CARDOZO L. REV. 2019 (2020).

standards”—an experiment that began in earnest with Justice Breyer’s *Mayo* opinion—“has likely resulted in lost investment in the life sciences that has delayed or altogether prevented the development of medicines and medical procedures.”⁹⁴

V. CONCLUSION

Justice Breyer leaves the Supreme Court having left a significant mark on patent eligibility law. In *Mayo*, he eliminated the ability to obtain patents on many useful applications of new (and even breakthrough) discoveries. Unfortunately, as I have discussed, the test he created to do so both contradicts the historical approach to patent eligibility (something he appears not to have even recognized) and has had pernicious impact on the patent system and investment in development of technology, including, and in particular, medical technologies. While of course I wish him well in retirement, I hope the full Court, including his successor, will give the patent eligibility doctrine a fresh look when it reviews the government’s upcoming amicus brief in *American Axle*. Without Justice Breyer on the bench, I have more hope the Court might reconsider the “inventive concept” requirement he created in *Mayo*.

⁹⁴ *Id.* at 2094.