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## JUSTICE BREYER: NO FRIEND TO IP LAW

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#### JUSTICE BREYER: NO FRIEND TO IP LAW\*

### KEVIN E. NOONAN\*\*

Justice Breyer's recent decision to step down from the bench has produced encomiums expected for a Justice of his tenure and standing. By all accounts, Justice Breyer is a gracious, intelligent, and kind man with a playful nature seen in his hypotheticals from the bench for which he has been well known.<sup>1</sup> The eye Justice Breyer cast on intellectual property law, on the other hand, was extremely skeptical at best, and viewed through an antitrust lens that was against "monopolies." Justice Breyer's recent decisions have had a more negative and sweeping effect that the Justice may have intended, but the consequences remain and the rationale behind them are of long standing in the Justice's approach to patent law.

The Justice's judicial prejudices in this regard are evident in his opinions (speaking for the Court or on his own, in concurrences or dissent) and colloquies from the bench. Justice Breyer's colloquies have been known to be creative and occasionally whimsical. For example, at oral argument in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,<sup>2</sup> the Justice asked:

Suppose I discover that if I take aspirin, someone takes aspirin, I discover they have to take aspirin for a headache, and, you know, I see an amazing thing: If you look at a person's little finger, and you notice the color, it shows the aspirin, you need a little more; unless it's a different color, you need a little less. Now, I've discovered a law of nature . . . and I may have spent millions on that. And I can't patent that law of nature, but I say I didn't; I said apply it. I said look at his little finger . . . Okay? Is that a good patent or isn't it?<sup>3</sup>

Even making the unremarkable point that plants existing in nature are not patenteligible the Justice framed the statement in a similar fashion during the oral argument in Association for Molecular Pathology v. Myriad Genetics, Inc.<sup>4</sup> the Justice said:

It's important to keep products of nature free of the restrictions that patents there are, so when Captain Ferno goes to the Amazon and discovers 50 new types of plants, saps and medicines, discovers them,

<sup>\*</sup> Justice Breyer's opinions, discussed herein, have invoked a fair degree of unnecessary rhetoric, to which I have no desire to join or encourage. Accordingly, much of what follows are the Justice's own words, in oral argument and his opinions, for the majority and in dissent.

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<sup>&</sup>lt;sup>1</sup> Although not always as intended, perhaps; See Kevin E. Noonan, The Fantastical World of Justice Stephen Breyer, PATENT DOCS (April 28, 2016), <u>https://www.patentdocs.org/2016/04/the-fantastical-world-of-justice-stephen-brever.html.</u>

<sup>&</sup>lt;sup>2</sup> Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66 (2012).

<sup>&</sup>lt;sup>3</sup> Transcript of Oral Argument at 13, Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66 (2012) (No. 10-1150).

<sup>&</sup>lt;sup>4</sup> 569 U.S. 576 (2013).

although that expedition was expensive, although nobody had found it before, he can't get a patent on the thing itself.  $^5$ 

But more often the Justice's questions and hypotheticals evinced his underlying antipathy for intellectual property protections. Justice Breyer succinctly enunciated his philosophy regarding patenting (and his philosophical objections to it) in oral argument in *Bilski v. Kappos*<sup>6</sup> where he said:

There are actually four things in the patent law which everyone accepts. There are two that are plus and two that are minus. And the two that are plus is by giving people a monopoly, you get them to produce more. As you said, you get them to disclose. The two minuses are they charge a higher price, so people use the product less; and moreover, the act of getting permissions and having to get permission can really slow things down and destroy advance. So there's a balance.<sup>7</sup>

And this philosophy has led the Justice to develop a fine sense of when the "two minuses" of patenting are predominant; for example, in *Cuozzo Speed Technologies,*  $LLC v. Lee^{8}$  the Justice asserted:

[Y]ou could look at this new law as you [Cuozzo] were looking at it, as trying to build a little court proceeding. If I thought it was just doing that, I would say you were right. But there is another way to look at it. And the other way to look at it . . . is that there are these things, for better words, let's call them patent trolls, and that the -- the Patent Office has been issuing billions of patents that shouldn't have been issued -- I overstate -- but only some.<sup>9</sup>

And sometimes the prejudice is more pointed; in the *Halo Electronics, Inc. v. Pulse Electronics, Inc.*<sup>10</sup> argument the Justice asserted, "[T]oday's patent world is not a steam-engine world. We have decided to patent tens of thousands of software products and similar things where *hardly anyone knows what the patent's really about.*"<sup>11</sup>

<sup>&</sup>lt;sup>5</sup> Transcript of Oral Argument at 49, Assoc. Molec. Pathol. v. Myriad Genetics, Inc., 569 U.S. 576 (2013) (No. 12-398). But to be fair, during the same argument Justice Kagan characterized the U.S. PTO as being "patent happy" with reference to there being no unsettling of settled expectations at the prospect of invalidating thousands of U.S. patents granted, and upheld in the courts, in the decades before the Myriad case. *Id.* at 53.

<sup>&</sup>lt;sup>6</sup> 561 U.S. 593 (2010).

<sup>&</sup>lt;sup>7</sup> Transcript of Oral Argument at 19–20, Bilski v. Kappos, 561 U.S. 593 (2010) (No. 08-964).

<sup>&</sup>lt;sup>8</sup> 579 U.S. 261 (2016).

<sup>&</sup>lt;sup>9</sup> Transcript of Oral Argument at 14, Cuozzo Speed Techs., LLC v. Lee, 579 U.S. 261 (2016) (No. 15-446). (The day after this oral argument, the U.S. Patent and Trademark Office issued U.S. Patent No. 9,326,435. While it is unlikely the Justice was unaware of this difference of three orders of magnitude between the actual number of granted patents and his assertion, to the extent it was intentional the Justice's statement illustrates his thinking and prejudices).

<sup>&</sup>lt;sup>10</sup> 579 U.S. 93 (2016).

<sup>&</sup>lt;sup>11</sup> Transcript of Oral Argument at 10, Halo Elecs., Inc. v. Pulse Elecs., Inc., 579 U.S. 93 (2016) (No. 14-1513) (emphasis added).

#### And in *Cuozzo*:

I apply for a patent because I have this thing that instead of putting red cellophane on the speedometer, I put purple cellophane on the speedometer. It signals the presence of a hot dog stand. All right? [Laughter] I -- I then try to patent it. And they look at this patent and, no, absolutely not.<sup>12</sup>

The Justice's motivations, with regard to his apparent animus against intellectual property "monopolies," seemed to focus on the economic costs to competitors and the public, particularly for small businesses and also (as is seen in his more noteworthy opinions, *vide infra*) in healthcare-related technologies. For example, again in *Halo* Justice Breyer asserted:

A company that's a start-up, a small company, once it gets a letter [notifying the recipient of an infringement allegation], cannot afford to pay 10,000 to \$100,000 for a letter from Counsel, and may be willing to run its chances . . . And we are afraid that if we do not use this objective standard, what we will see is a major effect discouraging invention because of fear that if we try to invent, we'll get one of these letters and we can't afford \$100,000 for an opinion.<sup>13</sup>

And in SCA Hygiene Prod. Aktiebolag v. First Quality Baby Prod., LLC:14

[A] patentee, after learning of a possible infringement in year 1, might wait until year 10 or year 15 or year 20 to bring a lawsuit. And if he wins, he can collect damages for the preceding six years of infringement. This . . . gap [could permit an infringer (including an unknowing infringer) to] invest[] heavily in the development of the infringing product (of which the patentee's invention could be only a small component), while evidence that the infringer might use to, say, show the patent is invalid disappears with time.<sup>15</sup>

Then, and this would be particularly pernicious in circumstances where the infringer is, "locked in," when "business-related circumstances make it difficult or impossible for the infringer to abandon its use of the patented invention."<sup>16</sup>

Similarly, at oral argument in *Octane Fitness, LLC v. ICON Health & Fitness*,<sup>17</sup> the Justice posed this hypothetical:

 $<sup>^{12}</sup>$  Transcript of Oral Argument at 45, Cuozzo Speed Techs., LLC v. Lee, 579 U.S. 261 (2016) (No. 15-446).

<sup>&</sup>lt;sup>13</sup> Transcript of Oral Argument at 10, 22–23, Halo Elecs., Inc. v. Pulse Elecs., Inc., 579 U.S. 93 (2016) (No. 14-1513).

<sup>&</sup>lt;sup>14</sup> 137 S. Ct. 954 (2017).

<sup>&</sup>lt;sup>15</sup> *Id.* at 968 (Breyer, J., dissenting).

 $<sup>^{16}</sup>$  Id.

<sup>&</sup>lt;sup>17</sup> 572 U.S. 545 (2014).

I patent the following: [f]or a computer, enter somebody's name; ask [for a] phone number, and they'll give you the phone number of you put in the right city. That puts some lists in the computer. They can patent that? Well, you add a couple of things, and then, apparently, you can have an argument that they can patent it. Okay? Because it'll be very abstract language *It will be able to patent almost anything* . . . *Patent attorneys are very brilliant at figuring out just how to do this*.<sup>18</sup>

And with regard to deciding where to draw the line about when a lawsuit is objectively baseless:

This vague line, no one knows what it is. In addition, all they did was say, We don't want to go to court and cost you \$2 million. Please send us a check for 1.000, we'll license it for you. They do that to 40.000people, and when somebody challenges it and goes to court, it costs them about [\$]2 million because every discovery in sight . . . No, no, but I'm -- of course, it may be a small slice of litigation, but it is a slice that costs a lot of people a lot of money . . . [and] I cannot in honesty say it's frivolous given the standards for patenting that seem to be administered ... It's highly abstract language. I gather you, like I, have read some of these claims. They are very hard to understand and when you get to the bottom of it, the abstract nature of the language, plus the fact that it has something to do with computer input, plus the fact that, you know, you suspect very strongly it's baseless, but you really don't like to say something that isn't true and you can say, well, I could see how somebody might think there was something to this claim, just in that tone of voice, which you can't write down that tone of voice.19

And while the Justice's opinion that patenting can be inimical to the practice of medicine have been somewhat thoroughly set forth in his opinions, in this regard he discussed an issue he considered "absolutely fundamental" in the oral argument in *Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc.*<sup>20</sup>

You have millions of doctors and scientists and computer people who are working extremely hard to think of useful ideas and if you don't give them an incentive, they may think of less . . . And they're all useful. At the same time, if you patent all of their ideas, including very useful mini-micro principle ideas, you will establish monopolies throughout this country beyond belief and it will be difficult for people, without paying vast amounts of money, to use their useful ideas. So

<sup>&</sup>lt;sup>18</sup> Transcript of Oral Argument at 33, Octane Fitness, LLC v. ICON Health & Fitness, 572 U.S. 545 (2014) (No. 12-1184) (emphasis added).

<sup>&</sup>lt;sup>19</sup> Id. at 33–36.

<sup>&</sup>lt;sup>20</sup> Lab'y Corp. of Am. Holdings v. Metabolite Lab'ys, Inc., 548 U.S. 124 (2006).

what principle do we use to separate the scientific idea which can't be patented from the process which can be $2^{21}$ 

Across several years and different cases having in common only patents as their subject matter, the Justice's questioning illustrated his underlying conviction that patentees overreach in what they are claiming, extending into subject matter that should not be patented as a policy matter, and were aided and abetted by patent lawyers who are "brilliant" at writing and obtaining patents reciting claims that should not have been granted. The Justice's motivation is expressed either as sympathy for small business owners unable to successfully litigate, or are not able to afford to, or for patents involved in or affecting healthcare, either its provision or its costs, although these concerns are more evident in the decisions the Justice has written as set forth below.

While these snippets of the Justice's colloquies from the bench are illustrative, it has been the Justice's opinions that of course have had the most lasting effects on the patent system and American innovation. But there is at least some evidence that those effects have not always been what the Justice may have intended. For example, during the oral argument in *Alice Corporation*. V. CLS Bank International,<sup>22</sup> in response to counsel's attribution for his argument on limiting subject matter eligibility for the invention at bar, Justice Breyer said "you realize I couldn't figure out much in Prometheus to go beyond what I thought was an obvious case, leaving it up to you and your colleagues to figure out how to go further."<sup>23</sup> And later, characterizing his opinion in  $Mayo^{24}$  and, in his concurring opinion in Bilski v. Kappos,<sup>25</sup> the Justice said that those opinions "sketch[ed] an outer shell of the content, hoping that the experts, you and the other lawyers and the ... circuit court, could fill in a little better than we had done the content of that shell."<sup>26</sup>

While his decision in Mayo Collaborative Services v. Prometheus Laboratories, Inc.<sup>27</sup> is best known (vide infra), other cases also illustrate the point. For example, in Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc.,<sup>28</sup> regarding ownership of inventions made under the provisions of the Bayh-Dole Act, the Justice writing in dissent posited the dichotomy that, on the one hand, patents, "help to elicit useful inventions and research and . . . ensure public disclosure of technological advances."<sup>29</sup> On the other hand, patents, "sometimes mean unnecessarily high prices or restricted dissemination . . . [that] sometimes discourage further innovation and competition by requiring costly searches for earlier, related

<sup>&</sup>lt;sup>21</sup> Transcript of Oral Argument at 38, Lab'y Corp. of Am. Holdings v. Metabolite Lab'ys, Inc., 548 U.S. 124 (2006) (No. 04-607).

<sup>&</sup>lt;sup>22</sup> 573 U.S. 208 (2014).

 $<sup>^{23}</sup>$  Transcript of Oral Argument at 11, Alice Corp. Pty. v. CLS Bank Int'l, 573 U.S. 208 (2014) (No. 13-298).

<sup>&</sup>lt;sup>24</sup> Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66 (2012).

<sup>&</sup>lt;sup>25</sup> Bilski v. Kappos, 561 U.S. 593 (2010).

 $<sup>^{26}</sup>$  Transcript of Oral Argument at 29, Alice Corp. Pty. v. CLS Bank Int'l, 573 U.S. 208 (2014) (No. 13-298).

<sup>&</sup>lt;sup>27</sup> 566 U.S. 66 (2011).

<sup>&</sup>lt;sup>28</sup> 563 U.S. 776 (2011).

<sup>&</sup>lt;sup>29</sup> Id. at 795 (Breyer, J., dissenting).

patents or by tying up ideas, which, were they free, would more effectively spur research and development."  $^{\prime\prime30}$ 

To be fair, these concerns were raised in the context of the Justice being reticent regarding permitting an inventor to assign an invention made using federal funds to a third party, "thereby taking that invention out from under the Bayh-Dole Act's restrictions, conditions, and allocation rules."<sup>31</sup> To do so would be "inconsistent with the Act's basic purposes" and could "significantly undercut the Act's ability to achieve its objectives... encourage[ing Federally funded institutions such as universities] to commercialize inventions that otherwise might not realize their potentially beneficial public use."<sup>32</sup> And these sentiments are consistent with the scheme Congress enacted to support technology transfer of government-financed research at universities. But this regime was directed towards changing the government's policy of *not* permitting (or at least not encouraging) patenting of university research, something that should (in the Justices view) lead to the deleterious consequences discussed above.

In the direct intellectual predecessor of the *Mayo* decision, *Laboratory Corporation of America v. Metabolite Laboratories, Inc.*,<sup>33</sup> the Justice's concerns about healthcare-related patents and their effect on medical care was evident in his dissent (joined by Justices Souter and Stevens) of the Court's decision to dismiss the *certiorari* writ as having been improvidently granted. In Justice Breyer's view, the patent claim at issue provided patentee with "control over doctors' efforts to use that correlation to diagnose vitamin deficiencies in a patient. Does the law permit such protection or does claim 13, in the circumstances, amount to an invalid effort to patent a 'phenomenon of nature'?"<sup>34</sup> As a consequence, Justice Breyer believed that "aside from the unpatented test, they embody only the correlation between homocysteine and vitamin deficiency that the researchers uncovered. In my view, that correlation is an unpatentable 'natural phenomenon,' and I can find nothing in claim 13 that adds anything more of significance."<sup>35</sup> Justice Breyer's views in this dissent set forth the same concerns that would be voiced by the Justice five years later in *Mayo*.

These competing aspects of intellectual property protections in the law provide a through-point to his thinking, which arose again in his *Mayo* decision:

Patent protection is, after all, a two-edged sword. On the one hand, the promise of exclusive rights provides monetary incentives that lead to creation, invention, and discovery. On the other hand, that very exclusivity 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, requiring potential users to conduct costly and time-consuming searches of existing patents and pending patent

<sup>35</sup> Id. at 137–38.

 $<sup>^{30}</sup>$  Id.

<sup>&</sup>lt;sup>31</sup> Id. at 797–98.

 $<sup>^{32}</sup>$  Id.

<sup>&</sup>lt;sup>33</sup> 548 U.S. 124 (2006).

 $<sup>^{34}</sup>$  *Id.* at 134 (Breyer, J., dissenting). Claim 13 of U.S. Patent No. 4,940,658 recites: "A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of: '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." *Id.* 

applications, and requiring the negotiation of complex licensing arrangements.  $^{\rm 36}$ 

Thus turning, as we must, to Mayo Collaborative Services v. Prometheus Laboratories, Inc, these concerns converged, the Court considering a claim to a diagnostic method that was easily if perhaps facilely characterized as claiming a medical practitioner's thoughts in making a medical diagnosis. The recognized predicate to these concerns for Justice Breyer was in his dissent from the Court's decision dismiss its certiorari writ in Laboratory Corporation of America v. Metabolite Laboratories as discussed above. There again the Justice showed an appreciation of the necessary contours of any opinion limiting patent rights, saying: "monopolization of [the basic tools of scientific and technological work] through the grant of a patent might tend to impede innovation more than it would tend to promote it."<sup>37</sup> But "too broad an interpretation of this exclusionary principle could eviscerate patent law [because] all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas."<sup>38</sup>

Nevertheless, under the circumstances in the claims in *Mayo*, which Justice Breyer writing for a unanimous Court characterized as merely reciting "three steps [that] simply tell doctors to gather data from which they may draw an inference in light of the correlations," the Court saw a "danger that the grant of patents that tie up [the use of a law of nature] will inhibit future innovation premised upon them, a danger that becomes acute when a patented process amounts to no more than an instruction to 'apply the natural law,' or otherwise forecloses more future invention than the underlying discovery could reasonably justify."<sup>39</sup> Under these circumstances, the Court's calculus as stated in the opinion was that "[i]f a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself."<sup>40</sup>

These principles are reasonable as far as they go and when limited to claims like the Prometheus claims in *Mayo*, which, except for conventional methods for administering a known drug and performing known tests to assess the amount of the drug in a patient's body over time, actually *do* recite nothing other than an appreciation of the naturally occurring correlation. But in drawing the lines, or providing the rubrics under which such lines should be drawn, the opinion claimed a preeminence for Section 101 that served, as understood by most patent practitioners, to undermine their doctrinal understanding of the statute. For example, in response to the Solicitor General's argument that the other Sections of the 1952 Patent Act were a more appropriate measure of whether the claims at issue were patentable, as opposed to patent-eligible, Justice Breyer's opinion states that such an approach would make

<sup>&</sup>lt;sup>36</sup> Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 92 (2012); *See also* Kevin E. Noonan, *A Modest Proposal (or Two)*, PATENT DOCS (April 22, 2015), <u>https://www.patentdocs.org/2015/04/a-modest-proposal-or-two.html</u>. This concept is also known as the "Goldilocks" standard.

<sup>&</sup>lt;sup>37</sup> Mayo, 566 U.S. at 71.

<sup>&</sup>lt;sup>38</sup> Id.

<sup>&</sup>lt;sup>39</sup> Id. at 79-80, 86.

<sup>&</sup>lt;sup>40</sup> *Id.* at 77.

Section 101 a "dead letter."<sup>41</sup> The Court's holding did the most violence to the proper application of Section 103, because by importing considerations of whether the "additional steps" were "well-understood, routine, conventional activity," these considerations, hitherto the province of the obviousness analysis under Section 103 fell into the ambit of Section 101.<sup>42</sup> This was not unintentional, the opinion stating that, "a process that focuses upon the use of a natural law also contain other elements or a combination of elements, sometimes referred to as an 'inventive concept,' sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself."<sup>43</sup>

The resulting subjectivity introduced into U.S. patent law seemingly undid sixty years of jurisprudence Congress explicitly sanctioned by enacting the nonobviousness requirement into the statute. This is particularly ironic because Giles Rich and P.J. Federico devised the concept of obviousness to counteract the subjectivity from Supreme Court opinions that led Justice Jackson to remark that the only valid U.S. patents were ones the Court had not had the opportunity to rule upon. And the culprits for patents falling outside the Justice's understanding of what should be patented were, in his view, patent practitioners, the Justice stating in this opinion and citing *Parker v. Flook*<sup>44</sup>, that the Court must beware of "interpreting patent statutes in ways that make patent eligibility 'depend simply on the draftsman's art' without reference to the 'principles underlying the prohibition against patents for [natural laws]."<sup>45</sup> Thus, reciting in this opinion the mantra warning against patent attorneys as the modern-day "artful dodgers" of patent law.

These sentiments, and their effects, must also be considered in light of an apparent change in how the Court views its role, or at least the primacy of how policy imperatives impact patent law and how they should be implemented. An example of this change is a comparison between how Chief Justice Burger addressed the question of whether "living things" are patent-eligible in *Diamond v. Chakrabarty*,<sup>46</sup> where he said in a 5-4 opinion:

Our task, rather, is the narrow one of determining what Congress meant by the words it used in the statute; once that is done our powers are exhausted. Congress is free to amend § 101 so as to exclude from patent protection organisms produced by genetic engineering. Compare 42 U.S.C. § 2181, exempting from patent protection inventions "useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon." Or it may choose to craft a statute specifically designed for such living things. But, until Congress takes such action, this Court must construe the language of § 101 as it is.<sup>47</sup>

 $<sup>^{\</sup>rm 41}$  Id. at 89.

<sup>&</sup>lt;sup>42</sup> Id. at 79–80.

<sup>&</sup>lt;sup>43</sup> *Id.* at 72.

<sup>44 437</sup> U.S. 584 (1978).

<sup>&</sup>lt;sup>45</sup> Mayo, 566 U.S. at 72.

<sup>&</sup>lt;sup>46</sup> 447 U.S. 303 (1980).

<sup>47</sup> Id. at 318.

Justice Breyer writing for a unanimous Court, apparently addresses the issue now:

[W]e must recognize the role of Congress in crafting more finely tailored rules where necessary. *Cf.* 35 U.S.C. §§ 161–164 (special rules for plant patents). We need not determine here whether, from a policy perspective, increased protection for discoveries of diagnostic laws of nature is desirable.<sup>48</sup>

Sadly, seemingly unrecognized by the Court is that Congress has addressed the issue of patents impeding the practice of medicine, in enacting 35 U.S.C. § 287(c), which states:

(c)(1) With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of sections 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.<sup>49</sup>

There is some irony in Justice Breyer's ascribing putative concerns about small business as the origin of his decisions limiting patent eligibility, the *Ariosa Diagnostics, Inc. v. Sequenom, Inc.* case providing a cogent case-in-point.<sup>50</sup> The claims at issue recited methods for detecting fetal abnormalities from maternal blood and were invalidated by the District Court on patent eligibility grounds and this determination was upheld by the Federal Circuit, which contained a "concurring" opinion by Judge Linn agreeing with the outcome based on what he considered the Supreme Court's mandate in *Mayo* and *Association for Molecular Pathology v. Myriad Genetics, Inc.*<sup>51</sup> Several members of the Federal Circuit have voiced the opinion that

<sup>&</sup>lt;sup>48</sup> *Mayo*, 566 U.S. at 92.

<sup>&</sup>lt;sup>49</sup> 35 U.S.C. § 287(c) (2022). The Court is eminently capable of appreciating its role in other circumstances, *see e.g.*, in *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519 (2012), the Chief Justice, writing in a 5-4 decision, stated:

Our permissive reading of these powers is explained in part by a general reticence to invalidate the acts of the Nation's elected leaders. "Proper respect for a coordinate branch of the government" requires that we strike down an Act of Congress only if "the lack of constitutional authority to pass [the] act in question is clearly demonstrated." Members of this Court are vested with the authority to interpret the law; we possess neither the expertise nor the prerogative to make policy judgments. Those decisions are entrusted to our Nation's elected leaders, who can be thrown out of office if the people disagree with them. It is not our job to protect the people from the consequences of their political choices.

*Id.* at 537–38 (quoting United States v. Harris, 106 U.S. 629, 635 (1883)). <sup>50</sup> 788 F.3d 1371 (Fed. Cir. 2015).

<sup>&</sup>lt;sup>51</sup> Id. at 1373–74 (Linn, J., concurring) ("[O]nly because [he is] bound by the sweeping language of the test set out in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*"); See Assoc. Molec. Pathol. v. Myriad Genetics, Inc., 569 U.S. 576 (2013); Kevin E. Noonan, *Ariosa Diagnostics, Inc. v.* Sequenom, Inc. (Fed. Cir. 2015), PATENT DOCS (June 22, 2015), https://www.patentdocs.org/2015/06/ariosa-diagnostics-inc-v-sequenom-inc-fed-cir-2015.html.

"their hands are tied" by the Court's recent pronouncements on patent eligibility.<sup>52</sup> The consequences of these decisions invalidating a patent, owned by just the type of small business that Justice Breyer purports to be his concern, were that Sequenom was acquired by Labcorp, a "global sciences leader in diagnostics" having 2020 revenues of almost \$14 billion.

And the fragmented nature of the Federal Circuit's jurisprudence in interpreting the Court's *Mayo*, *Myriad*, and *Alice* decisions has only worsened. In *Athena Diagnostics v. Mayo Collaborative Services LLC*,<sup>53</sup> another case where the Federal Circuit affirmed a district court's invalidation of claims on patent eligibility grounds, the Court's *per curiam* denial of rehearing *en banc* was accompanied by opinions, concurring and dissenting, voicing sentiments that the Supreme Court's precedents mandated (at least to some extent) their decisions. For example, Judge Lourie wrote:

If I could write on a clean slate, I would write as an exception to patent eligibility, as respects natural laws, only claims directed to the natural law itself, *e.g.*,  $E=mc^2$ , F=ma, Boyle's Law, Maxwell's Equations, etc. I would not exclude uses or detection of natural laws. The laws of anticipation, obviousness, indefiniteness, and written description provide other filters to determine what is patentable . . . But we do not write here on a clean slate; we are bound by Supreme Court precedent.<sup>54</sup>

Judge Newman, in dissent, enumerated the six decisions, at that time, where the Federal Circuit affirmed district court decisions of patent-ineligibility based on this view of the crabbed extent of the Federal Circuit's ability to disagree with how the Supreme Court's eligibility jurisprudence was being applied. Judges Moore, now Chief Judge of the Federal Circuit, in dissent and Judge Chen in concurrence agreed that the Federal Circuit had applied the Supreme Court's precedents too broadly, saying:

In the wake of *Mayo*, we have painted with a broad brush, suggesting that improved diagnostic techniques are not patent eligible. *Mayo* did not go so far, and given the import of diagnostic techniques, we should reconsider this case and clarify our precedent. Because my colleagues have declined to do so, there are no more options at this court for diagnostic patents. My colleagues' refusal deflates the Amici's hopeful suggestion that our precedent leaves the eligibility of a diagnostic claim in front of the Federal Circuit "uncertain." It is no longer uncertain. Since *Mayo*, every diagnostic claim to come before this court has been held ineligible. While we believe that such claims should be eligible for patent protection, the majority of this court has definitively

 $<sup>^{52}</sup>$  Athena Diagnostics, Inc. v. Mayo Collaborative Servs., 927 F.3d 1333, 1352 (Fed. Cir. 2019) (Moore, J., dissenting).

<sup>&</sup>lt;sup>53</sup> 927 F.3d 1333 (Fed. Cir. 2019).

<sup>&</sup>lt;sup>54</sup> Id. at 1335 (Lourie, J., concurring).

concluded that the Supreme Court prevents us from so holding. No need to waste resources with additional en banc requests.  $^{55}$ 

Nevertheless, but the Court's steadfast refusal to grant certiorari has precluded any correction. Judge O'Malley voiced a particularly strongly worded countervailing view, saying in dissent:

I agree with all my dissenting colleagues that our precedent applies the Supreme Court's holding in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012) too broadly. I write separately, however, because I believe that confusion and disagreements over patent eligibility have been engendered by the fact that the Supreme Court has ignored Congress's direction to the courts to apply 35 U.S.C. sections 101, *et seq* ("Patent Act") as written. Specifically, the Supreme Court has instructed federal courts to read into Section 101 an "inventive concept" requirement—a baffling standard that Congress to amend the Patent Act in 1952. I encourage Congress to amend the Patent Act once more to clarify that it meant what it said in 1952.<sup>56</sup>

To be fair, Justice Breyer's antipathy for intellectual property law is not the sole reason for the parlous state of IP protection in some industries, notably medical diagnostics, and the threat the current state of the law raises against innovation in these industries, as illustrated by Sequenom's fate. Both the avidity with which district courts have adopted patent eligibility challenges to invalidate patents and the Federal Circuit's reticence in distinguishing those cases from Supreme Court precedent have played a role, and the Patent Office has promulgated sometimes conflicting guidance, or they have been inconsistently applied in practice. But the Justice's jurisprudence certainly hasn't helped, nor has the Court's refusal to reconsider the effects of its decisions in over 60 certiorari petitions, including in *Sequenom*, dismissed in the past ten years. Justice Breyer's opinions and attitudes have done much to create the environment under which the current circumstances have arisen, and any honest evaluation of his tenure and legacy on the Court must recognize this incontrovertible fact.

Justice Breyer's influence on the Court's jurisprudence involving copyright law, the other constitutionally enshrined intellectual property right, was less impactful, likely due to the presence of Justice Ginsburg on the Court through most of Justice Breyer's tenure. He wrote in dissent in *Eldred v. Ashcroft*,<sup>57</sup> regarding whether Congress could increase the term of copyright protection, and again in *Petrella v. Metro-Goldwyn-Mayer*, *Inc*,<sup>58</sup> regarding whether laches could be used to defeat a copyright claim, in both cases arguing for limiting copyright exclusivities. And last year he wrote the Court's decision in *Google LLC v. Oracle America*, *Inc.*,<sup>59</sup> expanding

<sup>&</sup>lt;sup>55</sup> Id. at 1363 (Moore, J., dissenting).

<sup>&</sup>lt;sup>56</sup> Id. at 1371 (O'Malley, J., dissenting).

<sup>&</sup>lt;sup>57</sup> 537 U.S. 186 (2003).

<sup>&</sup>lt;sup>58</sup> 572 U.S. 663 (2014).

<sup>&</sup>lt;sup>59</sup> 141 S. Ct. 1183 (2021).

the scope of the "fair use" defense to infringement in computer programming languages. These dissents and his *Google* decision were consistent with his general attitudes regarding intellectual property.<sup>60</sup>

But one case in particular resonates with the Justice's patent jurisprudence,<sup>61</sup> and has a possibility of being equally disruptive: *Kirtsaeng v. John Wiley & Sons, Inc.*<sup>62</sup> In this case, Wiley sued Kirtsaeng, a student from Thailand studying in the U.S., for importing copies of textbooks legally purchased abroad, but at a much lower price than these books cost in the U.S.<sup>63</sup> Although Wiley prevailed at the district court and before the Second Circuit the Supreme Court reversed, in a 6-3 opinion by Justice Breyer. The basis for the opinion was the Court's interpretation of the language of the statute regarding whether the "first sale" doctrine imposed any geographical limitations on where the sale arose, which if it did not rendered Kirtsaeng's importation lawful and not an infringement.<sup>64</sup> But its effect was to expand the scope of the first sale principle, and copyright exhaustion, extraterritorially to activities outside the U.S.

While the decision is likely to affect copyright holders and their activities abroad, including narrowing the scope of discount pricing in some markets, the decision by analogy has the potential for a more pernicious effect in the patent realm regarding reimportation of branded drugs. These drugs are often sold outside the U.S. for less than the same drugs costs at home; at least some of these cost differences are the result of foreign governments regulating the cost of branded drugs. This is not a phenomenon limited to developing countries; European countries having a nationalized health care system (*i.e.*, all of them) also have varying levels of cost controls for branded drugs, along with regimes for generic versions of these drugs after expiration of some term of exclusivity for the branded versions. And many countries such as Brazil, China, India, Russia, and Thailand have relied upon international treaty provisions, such as the Doha Declaration under the auspices of the World Trade Organization, to provide government-subsidized generic versions of branded drugs at prices much lower than the prevailing price in Western countries. These differences in costs have not affected U.S. prices because, unlike textbooks, branded drugs cannot be reimported into the U.S. under FDA regulations and U.S. law.

But should that change, and changing the law has been a part of many propose programs for reducing drug prices, the effects could be at best counter-productive.

<sup>&</sup>lt;sup>60</sup> See Stephen Breyer, The Uneasy Case for Copyright: A Study of Copyright in Books, Photocopies, and Computer Programs, 84 HARV. L. REV. 281 (1970).

<sup>&</sup>lt;sup>61</sup> See Transcript of Oral Argument at 35–36, Impression Prods., Inc. v. Lexmark Int'l, Inc., 137 S. Ct. 1523 (2017) (No. 15-1189). Justice Breyer raised similar concerns regarding the effects of patent law on traditional rules on alienation of chattels during oral argument:

But to go back to your basic point underlying this, of course, any monopolist, including a patent monopolist, would love to be able to go to each buyer separately and extract from each buyer and user the maximum amount he would pay for that particular item. Dentists would pay more for gold perhaps than someone who wants to use gold for some other thing. Okay? They'd like that. But by and large, that's forbidden under many laws, even though it does mean slightly restricted output, and it also means a lower profit for the monopolist.

Id.

<sup>&</sup>lt;sup>62</sup> 568 U.S. 519 (2013). <sup>63</sup> *Id.* at 525–26.

 $<sup>^{\</sup>rm 64}$  Id. at 525.

Paradoxically these efforts have been spurred on in the past by increase in generic drug prices.<sup>65</sup> If successful, these efforts could create a situation akin to the consequences of the *Kirtsaeng* case in the copyright arena. Here, however, innovator drug companies will not have the option, exercised by Wiley, of increasing prices abroad to make reimportation less economically attractive. The prevalence of ANDA litigation in the U.S. over the past thirty years is one indication of the importance of exclusivity, and the attendant profits that result from exclusivity to pharmaceutical innovation. Should those profits decrease significantly, the return on investment for innovator drugs will fall, and the calculus of investment that supports new drug development will be affected unpredictably, but not positively; the unpredictability resides in how much the ROI will change and how that will affect investment decisions. A common criticism aimed at branded drug makers is the frequency with which they develop "me too" and next generation versions of already marketed drugs rather than create innovative new treatments and therapies. The same uncertainties in drug development that make such behavior sound economically also impact the decision to develop new drugs, and policies that reduce ROI for such new drugs, which bear the greatest economic risk, are unlikely to promote innovation.

Justice Breyer's approach to intellectual property has been grounded in a type of skepticism and mistrust that led Justice Jackson to assert that "the only patent that is valid is one which this Court has not been able to get its hands on."<sup>66</sup> But Justice Jackson also famously remarked that "[w]e [the Court] are not final because we are infallible, but we are infallible only because we are final."<sup>67</sup> Unfortunately that finality, particularly with regard to opinions relying on Justice Breyer's conception of the proper scope of intellectual property protection, has resulted in IP protections that are frequently not up to the task of promoting innovation. In an honest effort to balance protection of IP with protection from IP, the Justice has, at least recently, promoted policies that turned out to be contrary to the constitutional mandate to "Promote Progress." Which is at best an unhappy legacy.

<sup>&</sup>lt;sup>65</sup> See Kevin E. Noonan, *How the Kirtsaeng Decision Could Ruin the U.S. Branded Drug Industry*, PATENT DOCS (November 25, 2014), <u>https://www.patentdocs.org/2014/11/how-the-kirtsaeng-decision-could-ruin-the-us-branded-drug-industry.html</u>.

<sup>66</sup> Jungersen v. Ostby & Barton Co., 335 U.S. 560, 572 (1949) (Jackson, J., dissenting).

<sup>67</sup> Brown v. Allen, 344 U.S. 443, 427 (1953) (Jackson, J., concurring).