

# EXPANDING STANDING IN PATENT DECLARATORY JUDGMENT ACTIONS TO BETTER AIR PUBLIC POLICY CONSIDERATIONS

NICHOLAS D. WALRATH\*

*This Note argues that modern-day patent litigation lacks sufficient consideration of public policy concerns. In order to remedy this, I propose three potential solutions that would broaden standing in patent declaratory judgment actions, thereby allowing more plaintiffs who are likely to raise such arguments to have their day in court. First, I discuss expanding standing within the Supreme Court’s MedImmune framework, which requires courts to apply a broad all-the-circumstances test in determining patent declaratory judgment standing. Within this test, I urge courts to consider (1) the degree to which a potential infringer raises important public policy concerns and (2) the extent to which the potential infringer has a unique economic incentive to challenge the patent-at-issue. Second, I consider altering the framework for standing in patent declaratory judgment actions based on a reassessment of the fundamental justifications for standing doctrine generally. Observing that the traditional justifications for a standing requirement—and the separation of powers justification in particular—do not apply in the context of patent declaratory judgment actions, I suggest that the Supreme Court might craft a new standing framework. Third, I explore the extent to which Congress might statutorily expand standing in such cases. I conclude by noting that the post-grant opposition procedure created by the America Invents Act—the patent reform legislation signed into law in September 2011—is insufficient to assuage unease regarding the lack of public policy arguments in patent litigation. Courts might therefore look to standing in order to address this problem.*

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INTRODUCTION

Modern-day patent litigation to a large degree consists of lawsuits between two large corporations, both holding a litany of patents.<sup>1</sup> Because each party seeks to maintain the strength of its own patent portfolio, including patents unrelated to the particular case at hand, neither party is likely to raise arguments that might weaken the protection afforded by its patents generally.<sup>2</sup> This problem is especially prevalent when, as is oftentimes the case in patent litigation, both parties compete in the same industry and own patents covering similar technologies.<sup>3</sup> In such circumstances, a defendant is even less likely to argue for weaker patent protection on public policy or economic grounds for fear that such an argument, if adopted by the court, would

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<sup>1</sup> One principal exception is litigation brought by Non-Practicing Entities (NPEs), which do not utilize their patents directly by manufacturing goods or providing services, but rather exploit their patents through litigation and licensing. NPEs, however, have incentives similar to most practicing entities in terms of their desire for strong patent protection because they assert their patents against other companies but are seldom sued for infringement.

<sup>2</sup> Moreover, as Professor Shobita Parthasarathy notes, “[T]he same players—patent lawyers and representatives of major universities and companies—appear over and over again as witnesses at Congressional hearings and as authors of amicus briefs to the courts. These insiders generally agree on the importance of robust and expansive patent rights.” Shobita Parthasarathy, *Whose Knowledge? What Values? The Comparative Politics of Patenting Life Forms in the United States and Europe*, 44 POL’Y SCI. 267, 269 (2011).

<sup>3</sup> A major exception in this respect is “Hatch-Waxman” litigation in which a generic pharmaceutical company brings a declaratory judgment action against a branded pharmaceutical company, challenging the validity of a patent covering a branded product. In such litigation, the generic company clearly has an incentive to raise arguments that would weaken pharmaceutical patents as a whole because generic companies generally do not rely on the enforcement of their own pharmaceutical patents. See, e.g., MICHAEL A. CARRIER, *INNOVATION FOR THE 21ST CENTURY: HARNESSING THE POWER OF INTELLECTUAL PROPERTY AND ANTITRUST LAW* 345–82 (2009).

weaken its own patent portfolio.<sup>4</sup> As a result of this dynamic, as well as the Federal Circuit's reluctance to consider non-doctrinal arguments,<sup>5</sup> public policy concerns<sup>6</sup> are seldom raised in patent litigation, leading to stronger patent protection than may be socially optimal.<sup>7</sup>

Since Congress created the Court of Appeals for the Federal Circuit in 1982 to hear all patent appeals,<sup>8</sup> the protection afforded by patents has undoubtedly increased. Not only have patents been held valid and infringed more frequently since the creation of the Federal Circuit,<sup>9</sup> but it has also become easier for a patent holder to obtain an injunction barring an infringer from practicing a patent.<sup>10</sup> Moreover, patent damages have increased steadily since the establishment of the Federal Circuit.<sup>11</sup> This is unsurprising given that the Federal Circuit

<sup>4</sup> See Einer R. Elhauge, *Does Interest Group Theory Justify More Intrusive Judicial Review?*, 101 *YALE L.J.* 31, 77 (1991) (describing disadvantages of the litigation process and concluding that “[e]ach party may argue only for the policy or rule that is best for it; none may argue for the policy or rule that is best for society”).

<sup>5</sup> See *infra* Part I.B (discussing the Federal Circuit's lack of emphasis on policy in issuing decisions).

<sup>6</sup> I use the phrase “public policy concerns” in contrast to the technical and doctrinal arguments that pervade patent litigation today. See *infra* Part I.B. As I use the term, public policy concerns include arguments that would support a particular interpretation of the Patent Act, Pub. L. No. 593, 66 Stat. 792 (1952) (codified as amended at 35 U.S.C. §§ 1–376 (2006)), based on the net economic effect of such an interpretation, the degree to which such an interpretation might unnecessarily restrict consumer access to a particular product, the extent to which such an interpretation might hinder or promote future innovation, and so forth.

<sup>7</sup> As Professors Dan Burk and Mark Lemley note:

At least three major economic studies in the last five years have suggested that the patent system may actually do more harm than good to innovation, because the assertion and litigation of too many bad patents against companies that make innovative products ends up raising their costs and reducing their innovation more than the existence of those patents spurs new innovation.

DAN L. BURK & MARK A. LEMLEY, *THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT* 30 (2009).

<sup>8</sup> 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.).

<sup>9</sup> See *infra* notes 48–50 and accompanying text (discussing the increase in patent validity determinations).

<sup>10</sup> See *infra* notes 55–56 and accompanying text (discussing the strengthening of patent protection).

<sup>11</sup> See ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, *PATENT LAW AND POLICY: CASES AND MATERIALS* 11 (3d ed. 2002) (explaining that, since the creation of the Federal Circuit, “money damages have soared . . . both on average and in the highest-visibility cases”); see also *infra* notes 57–59 and accompanying text (describing the extent to which patent damages have increased since the creation of the Federal Circuit). This trend, however, may be reversing. See, e.g., *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 868 (Fed. Cir. 2010) (reversing damages award for “reli[ance] on speculative and unreliable evidence”); *Lucent Techs., Inc. v. Gateway Inc.*, 580 F.3d 1301, 1324 (Fed. Cir. 2009) (“[The damages] award is not supported by substantial evidence and is against the clear weight of the evidence.”).

was founded, in part, with the goal of enhancing the position of the patent system by strengthening patent rights.<sup>12</sup>

Still, as Justice Breyer noted in his dissenting opinion in *Laboratory Corp. v. Metabolite Laboratories, Inc.*, “sometimes *too much* patent protection can impede rather than ‘promote the Progress of Science and useful Arts.’”<sup>13</sup> For this reason, “[p]atent law seeks to avoid the dangers of overprotection”—including the discouragement of research and information exchange, as well as the resulting higher prices and reduced consumer choice—“just as surely as it seeks to avoid the diminished incentive to invent that underprotection can threaten.”<sup>14</sup> When the vast majority of parties litigating patent disputes have similar incentives to uphold strong patent rights, however, public policy arguments—which often challenge overprotection—may not be sufficiently aired. Thus, modern-day patent law may be viewed as a one-way ratchet, continually tending towards stronger patent protection with only brief excursions limiting patent rights.

Consider, for instance, *Association for Molecular Pathology v. U.S. Patent & Trademark Office (Myriad)*, in which a group of physicians and medical associations, represented by the American Civil Liberties Union, challenged the validity of Myriad’s patents covering two genes associated with breast cancer.<sup>15</sup> Because Myriad’s patents cover the breast cancer genes themselves, competing diagnostic test companies cannot offer an alternative test that would allow consumers to confirm the results of a test performed by Myriad. At the same time, the lack of competing diagnostic test companies means that there is no clear litigant to challenge the patentability of Myriad’s gene patents, even though the validity of these patents is highly suspect.<sup>16</sup> Moreover, even if a competing diagnostic test company did

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<sup>12</sup> MERGES & DUFFY, *supra* note 11, at 11 (“While the Federal Circuit was ostensibly formed strictly to unify patent doctrine, it was no doubt hoped by some (and expected by others) that the new court would make subtle alterations in the doctrinal fabric, with an eye toward enhancing the stature of the patent system.”).

<sup>13</sup> 548 U.S. 124, 126 (2006) (Breyer, J., dissenting) (quoting U.S. CONST. art. I, § 8, cl. 8).

<sup>14</sup> *Id.* at 127; *see also* *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1293 (2012) (“And monopolization of [the basic tools of scientific research] through the grant of a patent might tend to impede innovation more than it would tend to promote it.”); *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989) (“The Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the ‘Progress of Science and useful Arts.’” (quoting U.S. CONST. art. I, § 8, cl. 8)).

<sup>15</sup> 689 F.3d 1303, 1309 (Fed. Cir. 2012), *cert. granted sub nom.* *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 694 (2012).

<sup>16</sup> The district court in *Myriad* ruled that isolated gene patents are unpatentable. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 238 (S.D.N.Y. 2010). Even though the Federal Circuit eventually reversed this holding, *Myriad*,

exist, it would be unlikely to challenge the patentability of Myriad's gene patents on the grounds that genes as a whole are not patentable subject matter, given the detrimental effect that such arguments might have on its own patent portfolio. Instead, a nontraditional group of challengers—physicians and medical associations who wish to offer competing diagnostic test services to their patients—have challenged Myriad's patents. Unlike competing diagnostic test companies, these plaintiffs do not have an interest in maintaining patent protection for genes generally. They are therefore able to question the validity of Myriad's patents on a wider range of grounds, including a public policy claim that *all* gene patents should be outside of the scope of patentable subject matter allowed by statute.<sup>17</sup> However, as I discuss below, if these parties are denied their day in court because they are found to lack standing,<sup>18</sup> their novel policy arguments will never have the chance to inform our patent jurisprudence.

Given the degree to which patent protection has increased recently, combined with the lack of public policy considerations in modern-day patent litigation that would tend to serve as a counterbalance for overprotection, I suggest three avenues through which we might expand standing in patent declaratory judgment actions in order to increase the prevalence of such arguments.<sup>19</sup> In Part I of this Note, I describe the dearth of public policy arguments in patent litigation. In Part II, I discuss the current framework for determining whether a potential patent infringer has standing to bring a declaratory judgment action—a framework that tends to exclude the potential infringers who are most likely to raise public policy concerns. As discussed in greater detail below,<sup>20</sup> patent declaratory judgment actions are suits in

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689 F.3d at 1333, the Federal Circuit's opinion was highly fractured, with Judges Lourie and Moore finding isolated genes to be patentable on different grounds, *id.* at 1337 (Moore, J., concurring in part), and Judge Bryson dissenting, *id.* at 1348 (Bryson, J., concurring in part and dissenting in part).

<sup>17</sup> Section 101 of the Patent Act defines the scope of patentable subject matter, or what type of "stuff" qualifies for patent protection in the first instance, before considering the statutory requirements of novelty, nonobviousness, and utility. 35 U.S.C. § 101 (2006).

<sup>18</sup> For a discussion of standing in *Myriad*, see *infra* notes 136–42 and accompanying text.

<sup>19</sup> Although I discuss the need to further incorporate public policy concerns in patent jurisprudence in Part I, the exact extent to which these concerns should play a role in patent jurisprudence is a far more difficult question, which I do not seek to answer. Rather, I contend that a mechanism must be created through which these concerns may be addressed. Once a mechanism is in place, courts may adjust the exact role that such concerns play.

<sup>20</sup> See *infra* Part II.B (describing patent declaratory judgment actions).

which a potential patent infringer<sup>21</sup> sues the patent holder claiming that it is not liable for patent infringement. Although declaratory judgment actions are raised primarily as counterclaims to patent infringement suits, potential infringers may also bring a declaratory judgment action before an infringement suit has been filed. Such actions allow a potential infringer to reduce the uncertainty of operating with a possible patent infringement suit hanging over its head.

Next, in Part III.A, I consider expanding standing doctrine within the existing framework for patent declaratory judgment actions, increasing the potential for public policy concerns to be raised in patent litigation. More radically, in Part III.B, I argue that courts should reconsider the existing framework for patent declaratory judgment standing because the fundamental justifications for the standing requirement do not apply with particular force in patent cases. In Part III.C, I discuss the possibility that Congress could statutorily broaden patent declaratory judgment standing. Finally, I conclude by considering whether the America Invents Act's post-grant opposition procedures,<sup>22</sup> which allow parties to challenge the issuance of a patent after it has been granted by the Patent and Trademark Office (PTO), might assuage concerns regarding the need to broaden standing in patent cases.

## I

### THE NEED FOR GREATER CONSIDERATION OF PUBLIC POLICY IN PATENT LAW

To justify broadening patent declaratory judgment standing, I first discuss the need for greater consideration of public policy arguments in patent litigation. In Part I.A, I briefly consider the extent to which the creation of the Federal Circuit has increased patent protection. Next, in Part I.B, I discuss the degree to which Federal Circuit jurisprudence historically has considered public policy concerns. Finally, in Part I.C, I argue that Supreme Court precedent supports the proposition that courts ought to consider public policy considerations more often in the patent context.

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<sup>21</sup> As I use the phrase, "potential infringer" refers to patent declaratory judgment plaintiffs—individuals who bring patent declaratory judgment actions against patent holders seeking a judicial finding of noninfringement or patent invalidity.

<sup>22</sup> Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (2011) (to be codified in scattered sections of 35 U.S.C.).

### A. *The Strengthening of Patent Rights Since the Creation of the Federal Circuit*

The Court of Appeals for the Federal Circuit was created in 1982, in part to hear all patent appeals.<sup>23</sup> In creating a single appellate court for patent cases, Congress hoped to reduce the variability of patent decisions between circuits, increase the manageability and quality of patent rulings, and decrease the potential for forum shopping.<sup>24</sup> In many respects, the Federal Circuit has been a great success.<sup>25</sup> As Professor Robert Merges puts it, “The Federal Circuit has increased the stability and predictability of patent doctrine, to the benefit of innovative private firms.”<sup>26</sup> Moreover, appellate-level forum shopping has largely decreased.<sup>27</sup> Still, though Congress intended to strengthen the patent system,<sup>28</sup> many scholars have argued that patent protection has become too strong.<sup>29</sup>

In the three decades since the creation of the Federal Circuit, the protection afforded by patents has increased in several profound ways.<sup>30</sup> First, the scope of patentable subject matter under section 101 of the Patent Act—or what type of “stuff” qualifies for patent protection in the first place even before considering the statutory requirements of novelty, nonobviousness, and utility<sup>31</sup>—has grown

<sup>23</sup> 28 U.S.C. § 1295 (2006).

<sup>24</sup> See Rochelle Cooper Dreyfuss, *In Search of Institutional Identity: The Federal Circuit Comes of Age*, 23 BERKELEY TECH. L.J. 787, 787–88 (2008).

<sup>25</sup> Indeed, Professor Rochelle Dreyfuss notes that “[t]he Federal Circuit has, rightly, become a template for nations around the globe” and “the successes of the Federal Circuit have attracted considerable new interest in specialization.” Rochelle Cooper Dreyfuss, *The Federal Circuit: A Continuing Experiment in Specialization*, 54 CASE W. RES. L. REV. 769, 771 (2004).

<sup>26</sup> Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CALIF. L. REV. 805, 806 (1988); see also Dreyfuss, *supra* note 25, at 771 (“[T]he court has very clearly used its special position to focus considerable thought on key patent law issues, such as standards of obviousness and claim interpretation.”).

<sup>27</sup> Rochelle Cooper Dreyfuss, *The Federal Circuit as an Institution: What Ought We to Expect?*, 43 LOY. L.A. L. REV. 827, 829 (2010); Kimberly A. Moore, *Forum Shopping in Patent Cases: Does Geographic Choice Affect Innovation?*, 79 N.C. L. REV. 889, 937 (2001).

<sup>28</sup> See MERGES & DUFFY, *supra* note 11, at 11 (noting that the idea of a unified court of appeals for patent cases “was proposed as a way to return patents to a more central position in the commercial world”).

<sup>29</sup> See BURK & LEMLEY, *supra* note 7, at 3 (“The consensus in favor of strong patent protection that has existed since the 1982 creation of the Federal Circuit . . . has broken down.”).

<sup>30</sup> See, e.g., ADAM B. JAFFE & JOSH LERNER, *INNOVATION AND ITS DISCONTENTS* 104 (2004) (explaining that over the decade since the Federal Circuit’s creation, “in case after case, the court significantly broadened patent holders’ rights”).

<sup>31</sup> 35 U.S.C. § 101 (2006). The requirements of novelty, nonobviousness, and utility stem from 35 U.S.C. §§ 102, 103, and 112, respectively.

significantly.<sup>32</sup> In particular, patentable subject matter has been broadened by a series of decisions holding that man-made living organisms,<sup>33</sup> software,<sup>34</sup> “business methods,”<sup>35</sup> and isolated genes<sup>36</sup> are all potentially patentable.<sup>37</sup> At the same time, the patenting of research tools (inventions used in research that do not have an independent commercial use) and other “upstream”<sup>38</sup> technologies has skyrocketed, to the dismay of many scholars.<sup>39</sup> In particular, Professors Michael Heller and Rebecca Eisenberg have called attention to the danger of patenting upstream technologies, describing the “tragedy of the anticommons” in which multiple, overlapping patents on upstream technologies deter downstream innovation.<sup>40</sup>

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<sup>32</sup> CARRIER, *supra* note 3, at 206 (“In the 1980s and 1990s, courts dramatically expanded the range of patentable subject matter by holding that inventions related to biotechnology, computer software, and methods for doing business were all potentially patentable.”). *But see, e.g.*, *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1297 (2012) (holding that a process reciting a law of nature is not patentable “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>33</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (holding that “respondent’s micro-organism plainly qualifies as patentable subject matter”).

<sup>34</sup> *Diamond v. Diehr*, 450 U.S. 175, 187 (1981) (holding that “a claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula, computer program, or digital computer”).

<sup>35</sup> *Bilski v. Kappos*, 130 S. Ct. 3218, 3229 (2010) (“[T]he Patent Act leaves open the possibility that there are at least some processes that can be fairly described as business methods that are within patentable subject matter . . . .”); *State St. Bank & Trust Co. v. Signature Fin. Grp., Inc.*, 149 F.3d 1368, 1375 (Fed. Cir. 1998) (“Since the 1952 Patent Act, business methods have been, and should have been, subject to the same legal requirements for patentability as applied to any other process or method.”).

<sup>36</sup> *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office (Myriad)*, 689 F.3d 1303, 1309 (“On the merits, we reverse the district court’s decision that Myriad’s composition claims to ‘isolated’ DNA molecules cover patent-ineligible products of nature . . . .”), *cert. granted sub nom. Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 694 (2012).

<sup>37</sup> As Professor Kara Swanson argues, this “US-led expansion in patentable subject matter . . . has changed the configuration of world-wide agribusiness and arguably also the trajectory of medical research and health care, with negative consequences for public health and distributive justice.” Kara W. Swanson, *Patents, Politics and Abortion*, in *INTELLECTUAL PROPERTY LAW IN CONTEXT: LAW AND SOCIETY PERSPECTIVES ON IP* (William T. Gallagher & Debora J. Halbert eds., forthcoming 2013) (manuscript at 33), available at [http://www.law.nyu.edu/ecm\\_dlv4/groups/public/@nyu\\_law\\_website\\_\\_engelberg\\_center\\_on\\_innovation\\_law\\_and\\_policy/documents/documents/ecm\\_pro\\_071610.pdf](http://www.law.nyu.edu/ecm_dlv4/groups/public/@nyu_law_website__engelberg_center_on_innovation_law_and_policy/documents/documents/ecm_pro_071610.pdf).

<sup>38</sup> The concept of “upstream” versus “downstream” technologies is used widely in the literature on intellectual property law. Upstream technologies are more closely related to basic research, whereas downstream technologies are more closely related to commercially realizable products.

<sup>39</sup> See CARRIER, *supra* note 3, at 253 (noting that many scholars have lamented this development).

<sup>40</sup> Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 *Sci.* 698, 699 (1998). The *Myriad* case,

While the patenting of upstream technologies has increased over the past three decades, the Federal Circuit simultaneously has increased the protection afforded to patents by limiting the scope of the “experimental use” defense.<sup>41</sup> The experimental use defense has its roots in the 1813 case *Whittemore v. Cutter*.<sup>42</sup> Historically, the defense has been used by researchers who employed a patented invention in the course of their research. For much of the twentieth century, the defense protected accused infringers who used a patented product in a “noncommercial” way.<sup>43</sup> For example, in *Ruth v. Stearns-Roger Manufacturing Co.*, a district court ruled that using a patented invention solely for experimental purposes without a desire to make a profit was a defense against patent infringement.<sup>44</sup> Since the creation of the Federal Circuit, however, the experimental use defense has been narrowed to the extent that it no longer has much practical import in modern patent litigation.<sup>45</sup> Indeed, in 2002, the Federal Circuit ruled in *Madey v. Duke University* that:

[R]egardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer’s legitimate business and is *not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry*, the act does not qualify for the *very narrow and strictly limited* experimental use defense.<sup>46</sup>

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described in detail *infra* Parts II.B and III.A, provides a striking example of the dangers inherent in allowing patents on such upstream technologies. *Myriad*, 689 F.3d 1303. Because Myriad owns patents covering the *BRCA1* and *BRCA2* cancer genes—upstream inventions—potential competitors are foreclosed from creating competing diagnostic tools using these genes—downstream applications. As a result, patients are denied access to secondary, confirmatory tests.

<sup>41</sup> CARRIER, *supra* note 3, at 253 (“[I]n the past two decades, the Federal Circuit has scaled back the [experimental use] defense.”). For a more complete discussion of the history of the experimental use defense, see *id.* at 257–60.

<sup>42</sup> 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600) (“[I]t could never have been the intention of the legislature to punish a man who constructed such a machine merely for philosophical experiments . . .”).

<sup>43</sup> See CARRIER, *supra* note 3, at 258 (“In three cases in the mid-20th century, for example, courts found that the defense applied where the defendant engaged in noncommercial use of patented technology.”); Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 96 (describing the history of the experimental use defense for “noncommercial” uses).

<sup>44</sup> 13 F. Supp. 697, 713 (D. Colo. 1935), *rev’d on other grounds*, 87 F.2d 35 (10th Cir. 1936).

<sup>45</sup> See CARRIER, *supra* note 3, at 260 (“In short, courts have whittled down the experimental use defense to the point that it does not cover university researchers or those attempting to avoid infringement by using a patent to design around it. For all intents and purposes, researchers cannot lawfully rely on the defense.”).

<sup>46</sup> 307 F.3d 1351, 1362 (Fed. Cir. 2002) (emphases added).

As a result, the Federal Circuit has extended patent protection to cover all but the most “idle” experimental uses of a patented product, potentially curtailing research by universities and competitors who would require use of the patented invention as a research tool.<sup>47</sup>

Just as patentable subject matter has been broadened and the experimental use defense has been narrowed, patents have also been held valid and infringed more frequently since the creation of the Federal Circuit.<sup>48</sup> In one study, which analyzed three hundred final validity determinations by district courts and the Federal Circuit between 1989 and 1996, Professors John Allison and Mark Lemley found that patents were held valid fifty-four percent of the time, compared to a thirty-five percent validity rate before the Federal Circuit was created.<sup>49</sup> Similarly, Professors Adam Jaffe and Josh Lerner note that the Federal Circuit has been significantly more likely to uphold a finding that a patent is both valid and infringed than its predecessors:

Whereas the circuit courts had affirmed 62 percent of district-court findings of patent infringement in the three decades before the creation of the [Federal Circuit], the [Federal Circuit] in its first eight years affirmed 90 percent of such decisions. On the other hand, when the district court had found that a patent was invalid or not infringed—thereby denying the [patent holder] enforcement of the patent—the circuits had reversed only 12 percent of the cases. In the first eight years of the Federal Circuit, 28 percent of these cases were reversed.<sup>50</sup>

One principal factor explaining the increase in patent validity determinations may be the Federal Circuit’s heightened standard for holding a patent invalid for obviousness. Section 103 of the Patent Act

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<sup>47</sup> *But see* John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, in PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285, 285 (Wesley M. Cohen & Stephen A. Merrill eds., 2003) (“We also find little evidence that university research has been impeded by concerns about patents on research tools.”); Amy Yancey & C. Neal Stewart, Jr., *Are University Researchers at Risk for Patent Infringement?*, 25 NATURE BIOTECHNOLOGY 1225, 1225 (2007) (claiming that “[a]cademic researchers have regularly ignored patents on key technologies as a strategy to maneuver around patent thickets and freedom-to-operate issues”).

<sup>48</sup> MERGES & DUFFY, *supra* note 11, at 11; *see also* Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUD. 247, 270 (1994) (“Today the unchallenged leadership of the Federal Circuit, as the highest patent court of the land, has led not only to greater respect for patents and a higher percentage of validity judgments in favor of [patent holders] but also less of a gunslinging attitude toward patent issues.”).

<sup>49</sup> John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 205–06 (1998); *see also* JAFFE & LERNER, *supra* note 30, at 106 (“Prior to the creation of the [Federal Circuit], about 30 percent of the patents were found to be valid and infringed at the district court level. After the creation of the [Federal Circuit], the percentage of awards upheld rose to over 55 percent.”).

<sup>50</sup> JAFFE & LERNER, *supra* note 30, at 104–05.

requires an invention to be “nonobvious” in order to qualify for patent protection.<sup>51</sup> For a time, the Federal Circuit required a specific “teaching, suggestion, or motivation” to combine aspects from two pieces of “prior art”—prior disclosures such as patents and publications—when assessing an invention’s obviousness.<sup>52</sup> This heightened standard for finding a patent invalid for obviousness made it easier for patent holders to protect their patents from validity challenges, bolstering patent holders’ rights. The Supreme Court subsequently rejected the Federal Circuit’s rigid application of its “teaching, suggestion, or motivation” test, thereby easing the required showing by defendants to prove a patent invalid for obviousness.<sup>53</sup> However, the extent to which this ruling has truly eased the burden on patent infringement defendants has yet to be seen.<sup>54</sup>

Finally, patent protection has been strengthened since the creation of the Federal Circuit in the sense that patent damages have escalated and injunctive relief has become routine, increasing both the deterrent effect of patents and the incentives for patent holders to litigate.<sup>55</sup> For the first twenty-five years of the Federal Circuit’s

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<sup>51</sup> 35 U.S.C. § 103 (2006). Under the three-step *Graham* inquiry for nonobviousness, courts first determine the scope and content of “prior art”—a technical term that encompasses certain prior disclosures such as patents, publications, and public uses. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). Second, courts determine the differences between the prior art and the patent whose validity is being questioned. *Id.* Finally, courts determine whether the patent-at-issue would be obvious, given the prior art, to a person with ordinary skill in the relevant art. *Id.* In making such a nonobviousness determination, courts may combine two or more pieces of prior art, taking, for instance, one particular aspect of an invention from one piece of prior art and another aspect of the invention from another piece of prior art. *See, e.g., id.* at 30 (using two prior art patents).

<sup>52</sup> That is, if a challenger argued that a patent were obvious by taking one particular aspect of an invention from one piece of prior art and another aspect of the invention from another piece of prior art, the Federal Circuit required that there be a specific “teaching, suggestion, or motivation” in the prior art to make the combination. *See, e.g., Teleflex, Inc. v. KSR Int’l Co.*, 119 F. App’x 282, 285 (Fed. Cir. 2005) (“When obviousness is based on the teachings of multiple prior art references, the movant must also establish some ‘suggestion, teaching, or motivation’ that would have led a person of ordinary skill in the art to combine the relevant prior art teachings in the manner claimed.” (citing *Tec Air, Inc. v. Denso Mfg. Mich.*, 192 F.3d 1353, 1359–60 (Fed. Cir. 1999), and *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1572 (Fed. Cir. 1996))), *rev’d*, 550 U.S. 398 (2007).

<sup>53</sup> *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398, 415–22 (2007).

<sup>54</sup> Another possible explanation for the increase in patents being found valid since the creation of the Federal Circuit may be the Federal Circuit’s increased reliance on so-called “secondary considerations” for determining nonobviousness. For further discussion, see JAFFE & LERNER, *supra* note 30, at 120–21; Natalie A. Thomas, Note, *Secondary Considerations in Nonobviousness Analysis: The Use of Objective Indicia Following KSR v. Teleflex*, 86 N.Y.U. L. REV. 2070 (2011).

<sup>55</sup> Professors Burk and Lemley argue that:

[T]he patent remedy rules as currently designed give patent owners more than they should be entitled to as a matter of good patent policy. The combination of injunctive relief, patent damages that do not take sufficient account of the

existence, it automatically upheld the issuance of injunctions upon a finding of patent infringement.<sup>56</sup> At the same time, the Federal Circuit has made it easier for patent holders to obtain larger damage awards. The Federal Circuit has, for instance, decreased the barriers for plaintiffs to recover interest in damages awards.<sup>57</sup> Moreover, the Federal Circuit has promoted the use of “lost profits” to calculate damages, as opposed to the more modest “reasonable royalties” method.<sup>58</sup> As a result, the median damage award in patent infringement cases increased from approximately \$750,000 between 1982 and 1989 to approximately \$2,000,000 between 1990 and 1999, increasing once again to approximately \$3,750,000 between 2000 and 2006.<sup>59</sup>

Although a detailed analysis of the myriad ways in which Federal Circuit doctrine has strengthened patent protection over the previous three decades is beyond the scope of this Note, this Subpart has sought to illustrate a basic point of nearly universal agreement: Patent rights have become vastly stronger since the creation of the Federal Circuit.<sup>60</sup> Some commentators have even gone so far as to claim that

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contributions made by others, and the prospect of treble damages for willful infringement even if the defendant developed its product on its own, all lead to a litigation system that is skewed in favor of patent plaintiffs . . . .

BURK & LEMLEY, *supra* note 7, at 28–29; *see also* JAFFE & LERNER, *supra* note 30, at 110 (claiming that the Federal Circuit has increased patent holders’ incentives to litigate by increasing patent damage awards and making it easier to obtain an injunction).

<sup>56</sup> CARRIER, *supra* note 3, at 236. The Supreme Court has, however, subsequently relaxed the Federal Circuit’s automatic presumption in favor of injunctive relief, ruling in *eBay, Inc. v. MercExchange, LLC* that a court must consider “traditional equitable principles” when determining whether or not to grant an injunction in patent cases. 547 U.S. 388, 391–94 (2006). Still, the extent to which *eBay* will alter courts’ automatic presumption favoring permanent injunctions in patent infringement cases is unclear. For a discussion of post-*eBay* rulings on injunctive relief in patent cases, *see* CARRIER, *supra* note 3, at 238–44.

<sup>57</sup> JAFFE & LERNER, *supra* note 30, at 110 (citing *Laitram Corp. v. Cambridge Wire Cloth Co.*, 785 F.2d 292 (Fed. Cir. 1986)).

<sup>58</sup> *Id.* at 110–11 (citing *Del Mar Avionics, Inc. v. Quinton Instrument Co.*, 836 F.2d 1320 (Fed. Cir. 1987)). Moreover, Professors Jaffe and Lerner note that the Federal Circuit “has made it possible for [patent holders] to receive the sum of the damages calculated from a reasonable royalty and lost profits calculations.” *Id.* at 111 (citing *State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573 (Fed. Cir. 1989)).

<sup>59</sup> J. Shawn McGrath & Kathleen M. Kedrowski, *Trends in Patent Damages*, 2001 A.B.A. SEC. LITIG. 5 Exhibit 5, available at <http://docs.piausa.org/ABA/07-06-01-ABA-Report-On-Patent-Damages.pdf>. *But cf.* Michael J. Mazzeo et al., *Predicting the “Unpredictable”: An Empirical Analysis of U.S. Patent Infringement Awards* 23 (Oct. 20, 2012) (unpublished manuscript), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2164787](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2164787) (concluding that “the concerns regarding the unpredictability of patent damage awards are overstated and unfounded”).

<sup>60</sup> Scholars are in broad agreement on this point. For instance, as Professors Jaffe and Lerner state: “[L]egal commentators—whether sympathetic to the court’s rulings or not—collectively agree that the primary direction of the changes has been in the direction of strengthening patent-holders’ rights.” JAFFE & LERNER, *supra* note 30, at 125. For an example of a decision limiting patent protection, *see Festo Corp. v. Shoketsu Kinzoku*

“patent rights ha[ve] now gone beyond recalibration to reach troubling proportions”<sup>61</sup> and that “[t]he patent system is in crisis.”<sup>62</sup> At the very least, the continual ratcheting of patent law in favor of patent holders suggests the need for a counterbalance to ensure that society is not burdened by the dangers of patent overprotection. In Parts I.B and I.C, I suggest that greater consideration of public policy arguments in patent litigation would serve as such a counterbalance.

### B. *The Lack of Public Policy Considerations in Patent Litigation*

Scholars contend that the Federal Circuit has historically placed little emphasis on public policy concerns in its decisionmaking. Professor Rochelle Dreyfuss, for instance, claims that:

[W]hile Federal Circuit judges routinely recite policy justifications for the statutory requirements of patent law, they rarely provide policy reasons for their own decisions. Thus, the court has adopted a rather formalistic approach to judging. In fact, some of its members have publicly suggested that it would be wrong to explain (or even to be motivated by) policy.<sup>63</sup>

Similarly, Professor Kenneth Dam argues that the Federal Circuit issues narrow, technical opinions, which tend to mask the underlying policy issues.<sup>64</sup> This narrow view of judicial decisionmaking, according to Dam, results in a tendency to discount economic and policy arguments, potentially restricting innovation.<sup>65</sup>

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Kogyo Kabushiki Co., 172 F.3d 1361 (Fed. Cir. 1999), *rev'd en banc*, 187 F.3d 1381 (Fed. Cir. 2001), *vacated*, 535 U.S. 722 (2002), in which the Federal Circuit narrowed the reach of the doctrine of equivalents. Although the Supreme Court partially overruled the Federal Circuit in *Festo*, Jaffe and Lerner note that “[t]he general consensus today . . . is that patents are narrower than they were before this decision.” JAFFE & LERNER, *supra* note 30, at 218 n.120.

<sup>61</sup> JAFFE & LERNER, *supra* note 30, at 126.

<sup>62</sup> BURK & LEMLEY, *supra* note 7, at 3.

<sup>63</sup> Dreyfuss, *supra* note 27, at 834. Professor Dreyfuss summarizes such criticism of the Federal Circuit, stating:

At bottom, critics are concerned that the court’s work product is suboptimal—that its isolation from other areas of the law, and from the wear and tear of debating issues with sister circuits, has *stripped it of all incentive to write persuasive opinions or grapple with the broad policy issues* a knowledge-based economy generates.

*Id.* at 830 (emphasis added); see also Craig Allen Nard, *Toward a Cautious Approach to Obedience: The Role of Scholarship in Federal Circuit Patent Law Jurisprudence*, 39 HOUS. L. REV. 667, 668, 674–75 (2002) (arguing that, while “[t]he Federal Circuit’s opinions embody sophisticated reasoning and thoughtfulness, and the judges certainly understand the contextual nature of patent law,” the Federal Circuit ought to signal its awareness of pragmatic scholarship more thoroughly in its opinions).

<sup>64</sup> Dam, *supra* note 48.

<sup>65</sup> *Id.* at 271.

According to another scholar, the lack of public policy concerns in patent law extends beyond the courtroom. Professor Shobita Parthasarathy asserts that “expertise barriers”—formal and informal rules within a policymaking domain that restrict the extent to which novel arguments may be raised by outsiders—have caused many policy arguments in the patent realm to fall upon deaf ears.<sup>66</sup> Patent policy in the United States has generated “dominant narratives, institutional arrangements, and legal and regulatory frameworks” that restrict policymakers from seriously considering new types of knowledge and expertise.<sup>67</sup> These institutionally entrenched narratives in U.S. patent law—such as the need for robust patent rights—when combined with the oversight of a singular appellate court, result in inertia. It therefore becomes extremely difficult for patent law outsiders to raise novel policy concerns.<sup>68</sup> For instance, because the PTO only allows third parties to challenge the issuance of a patent on a narrow set of grounds, excluding patentable subject matter,<sup>69</sup> patent law outsiders are unable to present novel arguments concerning what type of inventions ought to be patentable unless they file a declaratory judgment action in court. By contrast, the European Patent Office, through its broader opposition procedure, allows for the consideration of unorthodox evidence such as bioethics and policy reports, as well as public opinion polls.<sup>70</sup>

### C. *The Need for Public Policy Considerations in Patent Litigation*

Given the dearth of public policy arguments in American patent litigation, why should courts be further inclined to consider such arguments? As discussed above, there is a general concern that patent law may be conferring too strong of a right upon patent holders. In addition, Supreme Court precedent supports the proposition that patent law, by its very nature, is principally concerned with the public

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<sup>66</sup> Parthasarathy, *supra* note 2, at 4. As Professor Parthasarathy explains: [T]he patent policy domain in the United States is made up of a few highly specialized institutions, bureaucrats, and stakeholders. Most of the players in this domain have both legal and either scientific or engineering training. Given this environment, discussions are usually narrow and highly technical, and opportunities for broad reflection are few. These structural and cultural dimensions have led to the development of a particularly strong expertise barrier.

*Id.*

<sup>67</sup> *Id.* at 2.

<sup>68</sup> *See id.* at 18–19 (discussing the expertise barrier concept).

<sup>69</sup> As discussed in the conclusion, the AIA will create a post-grant opposition procedure that will allow for a broader set of patent challenges at the PTO, including challenges based on patentable subject matter. Pub. L. No. 112-29, § 6, 125 Stat. 284, 299–313 (2011) (to be codified at 35 U.S.C. §§ 311–319).

<sup>70</sup> Parthasarathy, *supra* note 2, at 5.

interest—and that therefore courts ought to grant public policy arguments great weight.<sup>71</sup> A common theme running throughout these Supreme Court cases is the public benefit that results from challenging potentially invalid patents. When a potential infringer successfully challenges an invalid patent, the potential infringer not only reduces the uncertainty under which its own business operates, but also allows other competitors to practice the previously patented invention without the need to obtain a license. The public, in return, benefits in two ways. First, the public is no longer forced to pay hyper-competitive prices for products that incorporate the previously patented invention, transferring the deadweight loss from the former patent holder to consumers.<sup>72</sup> Second, the public benefits from incremental innovations that result from more competitors practicing the previously patented invention.

For instance, in *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, Justice Murphy observed that:

A patent by its very nature is affected with a public interest. As recognized by the Constitution, it is a special privilege designed to serve the public purpose of promoting the “Progress of Science and useful Arts.” At the same time, a patent is an exception to the general rule against monopolies and to the right of access to a free and open market. The far-reaching social and economic consequences of a patent, therefore, *give the public a paramount interest* in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope.<sup>73</sup>

Two decades later, in *Lear, Inc. v. Adkins*, the Supreme Court overturned the doctrine of licensee estoppel—which had held that a licensee<sup>74</sup> to a patent could not challenge the validity of the licensed patent—in light of “the strong federal policy favoring free competition in ideas which do not merit patent protection.”<sup>75</sup> Noting that

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<sup>71</sup> Professor Kenneth Dam, for instance, notes that “[i]n the twentieth century . . . the Supreme Court began to treat patent law issues as public policy issues. More specifically, the Court viewed patent law as public law in which it should fashion new rules to achieve what it considered desirable public policy goals.” Dam, *supra* note 48, at 268.

<sup>72</sup> “Deadweight loss” refers to the loss in economic utility that results from the difference between marginal benefit and marginal cost for those consumers who no longer purchase a product at the hyper-competitive price.

<sup>73</sup> 324 U.S. 806, 816 (1945) (emphasis added) (quoting U.S. CONST. art. I, § 8, cl. 8).

<sup>74</sup> A “licensee” to a patent is an individual who has been granted a license to practice the patent by the patent holder (the “licensor”). The license immunizes the licensee from infringement liability and is usually granted in exchange for money.

<sup>75</sup> 395 U.S. 653, 656 (1969). Echoing *Precision Instrument*, the *Lear* Court noted that “the Sherman Act made it clear that the grant of monopoly power to a patent owner

licensees are often the only individuals with sufficient economic incentive to challenge a patent, the Court feared that muzzling such licensees would allow patent monopolies to go unchallenged to the public's detriment.<sup>76</sup> As a result, even though the law of contracts would advise otherwise, the Court allowed licensees to challenge a patent's validity because of public policy concerns that favored litigating suspect patents.

The Supreme Court raised these same concerns two years later in *Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation*, the seminal Supreme Court case concerning collateral estoppel.<sup>77</sup> The Court held that a patent holder is estopped from claiming a patent is valid after the patent has been held invalid by another court absent a showing that the plaintiff lacked a "full and fair opportunity for judicial resolution" of the initial validity determination.<sup>78</sup> For instance, if District Court A holds a particular patent holder's patent invalid, that patent holder may not bring an infringement action in District Court B claiming that the same patent is valid. In so holding, Justice White, writing for a unanimous Court, quoted extensively from both *Precision Instrument* and *Lear*, relying on Supreme Court precedent that "encourage[d] authoritative testing of patent validity" in the public's interest.<sup>79</sup>

Most recently, Justice Breyer discussed the need to consider public policy concerns in patent cases in his dissent from a dismissal of writ of certiorari in *Laboratory Corp. v. Metabolite Laboratories, Inc.*<sup>80</sup> The case involved the patentability of a process used to diagnose certain vitamin deficiencies. In particular, the patented process in question covered any test that (1) measured the level of a patient's homocysteine concentration and (2) determined whether this level was above or below the norm. In discussing the general principle in patent law that "laws of nature" may not be patented, Justice Breyer argued that:

[T]he reason for the exclusion is that sometimes *too much* patent protection can impede rather than 'promote the Progress of Science and useful Arts'. . . . Sometimes [patents] can discourage research

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constituted a limited exception to the general federal policy favoring free competition." *Id.* at 663.

<sup>76</sup> *Id.* at 670.

<sup>77</sup> 402 U.S. 313 (1971). Collateral estoppel, or issue preclusion, prevents a litigant from re-litigating a particular issue when the litigant has already had a "full and fair opportunity for judicial resolution" of the issue in another court. *Id.* at 328.

<sup>78</sup> *Id.* at 328, 349–50.

<sup>79</sup> *Id.* at 344.

<sup>80</sup> *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 125, 128 (2006) (Breyer, J., dissenting).

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 . . . .<sup>81</sup>

For this reason, “[p]atent law seeks to avoid the dangers of overprotection just as surely as it seeks to avoid the diminished incentive to invent that underprotection can threaten.”<sup>82</sup> With this in mind, Justice Breyer concluded that public interest concerns strongly argued for the Court’s accepting the writ of certiorari.<sup>83</sup>

Scholars have echoed this theme. For instance, Professor Megan La Belle observes that the public as a whole benefits from increased competition and consumer choice, as well as lower prices, when private parties invalidate suspect patents.<sup>84</sup> La Belle goes further, claiming that, “[w]hile patent litigation certainly implicates private interests, the public is the primary intended beneficiary of our patent system.”<sup>85</sup> Moreover, because litigation is the primary means through which patent quality is tested, she argues that courts should adopt legal standards that promote cases raising important policy issues.<sup>86</sup> In a similar vein, Professor Parthasarathy calls for novel procedures in U.S. patent law that would allow for greater flexibility to accommodate policy-based arguments in light of the high expertise barriers that often stifle such reasoning.<sup>87</sup>

Given that patent litigation has traditionally lacked robust consideration of public policy arguments, we are left to consider what options are available to promote their use in patent law. Because the Federal Circuit, like all courts, depends on litigants to raise policy arguments, I argue in Part III that broadening standing in patent declaratory judgment actions to promote such arguments provides a

<sup>81</sup> *Id.* at 126–27 (quoting U.S. CONST. art. I, § 8, cl. 8).

<sup>82</sup> *Id.* at 127; *see also* *White v. Samsung Elecs. Am., Inc.*, 989 F.2d 1512, 1513 (9th Cir. 1993) (Kozinski, J., dissenting from the denial of rehearing en banc) (“Overprotecting intellectual property is as harmful as underprotecting it. . . . Overprotection stifles the very creative forces it’s supposed to nurture.”).

<sup>83</sup> *Lab. Corp.*, 548 U.S. at 134. In particular, Justice Breyer noted that refusing to hear the case might negatively affect patient care and raise the cost of health care in the United States. *Id.* at 138.

<sup>84</sup> Megan M. La Belle, *Standing to Sue in the Myriad Genetics Case*, 2 CALIF. L. REV. CIRCUIT 68, 85 (2011), [http://www.californialawreview.org/assets/pdfs/Circuit/La\\_Belle\\_20\\_FINAL.pdf](http://www.californialawreview.org/assets/pdfs/Circuit/La_Belle_20_FINAL.pdf).

<sup>85</sup> *Id.* at 85 n.116 (“[T]he promotion of the progress of science and the useful arts is the ‘main object’ [of patent law]; reward of inventors is secondary and merely a means to that end.” (quoting *United States v. Masonite*, 316 U.S. 265, 278 (1942))).

<sup>86</sup> *Id.* at 71.

<sup>87</sup> Parthasarathy, *supra* note 2, at 284–85.

potential solution. To support this argument, I first discuss the current framework under which courts analyze standing in patent declaratory judgment actions.

## II

### STANDING IN PATENT DECLARATORY JUDGMENT ACTIONS

#### A. *Basics of Standing: The Existing Framework*

Standing is one of several judge-made doctrines used to define the scope of federal judicial power.<sup>88</sup> Rooted in Article III of the Constitution, standing doctrine restricts federal courts to adjudicating “cases” and “controversies.”<sup>89</sup> This “case or controversy” requirement is based on the idea of separation of powers, “founded in concern about the proper—and properly limited—role of the courts in a democratic society.”<sup>90</sup> The basic idea is that allowing an unelected and unrepresentative judiciary to hear cases brought by too broad a set of plaintiffs would usurp the Executive’s duty to “take Care that the Laws be faithfully executed.”<sup>91</sup>

In essence, the standing inquiry asks whether a particular litigant qualifies to have a court decide the merits of her lawsuit.<sup>92</sup> In addition to discretionary “prudential” limits,<sup>93</sup> standing doctrine also contains a

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<sup>88</sup> Standing, mootness, ripeness, and the political question doctrine comprise the justiciability requirements for federal courts. RICHARD H. FALLON, JR. ET AL., *HART AND WECHSLER’S THE FEDERAL COURTS AND THE FEDERAL SYSTEM* 49 (6th ed. 2009).

<sup>89</sup> U.S. CONST. art. III, § 2, cl. 1.

<sup>90</sup> *Allen v. Wright*, 468 U.S. 737, 750 (1984) (quoting *Warth v. Seldin*, 422 U.S. 490, 498 (1975)); *see id.* at 752 (“[T]he law of Art. III standing is built on a single basic idea—the idea of separation of powers.”).

<sup>91</sup> U.S. CONST. art. II, § 3; *see Vander Jagt v. O’Neill*, 699 F.2d 1166, 1178–79 (D.C. Cir. 1984) (Bork, J., concurring) (“All of the doctrines that cluster about Article III . . . relate in part . . . to an idea . . . about the constitutional and prudential limits to the powers of an unelected, unrepresentative judiciary in our kind of government.”). For a more complete discussion of the justifications underlying a standing requirement, including the separation of powers rationale, *see infra* Part III.B.

<sup>92</sup> *Warth v. Seldin*, 422 U.S. 490, 498 (1975).

<sup>93</sup> Standing doctrine has developed both prudential and core constitutional limits to adjudication. The prudential component of standing doctrine includes judicially self-imposed limits on the exercise of federal adjudication, including “the general prohibition on a litigant’s raising another person’s legal rights, the rule barring adjudication of generalized grievances more appropriately addressed in the representative branches, and the requirement that a plaintiff’s complaint fall within the zone of interests protected by the law invoked.” *Allen*, 468 U.S. at 751. Although courts often consider such prudential standing limits, Congress may override the courts’ discretion regarding these limits and “confer standing by statute when . . . a plaintiff would have been denied standing on prudential grounds.” William A. Fletcher, *The Structure of Standing*, 98 *YALE L.J.* 221, 222–23 (1988); *see also Warth*, 422 U.S. at 501 (“Congress may grant an express right of action to persons who otherwise would be barred by prudential standing rules.”).

set of core constitutional limits.<sup>94</sup> This “irreducible constitutional minimum,” as the Supreme Court explained in *Lujan v. Defenders of Wildlife*, comprises three elements.<sup>95</sup> First, a potential plaintiff must have “suffered an ‘injury in fact’—an invasion of a legally protected interest which is (a) concrete and particularized and (b) ‘actual or imminent,’” as opposed to “conjectural” or “hypothetical.”<sup>96</sup> The injury-in-fact element requires more than merely an “injury to a cognizable interest”; rather, it requires that the plaintiff herself be injured.<sup>97</sup> Second, there must exist a “causal connection between the injury and the conduct complained of—the injury has to be ‘fairly . . . trace[able] to the challenged action of the defendant.’”<sup>98</sup> Third, the injury must be judicially redressable.<sup>99</sup> Congress may not force courts to abandon these three core constitutional standing requirements altogether—although, as discussed in Part III.C, Congress does have some ability to make it easier for plaintiffs to meet these requirements. The remainder of this Note focuses on these core constitutional limits for standing in the context of patent declaratory judgment actions.

### B. *Standing in Patent Declaratory Judgment Actions*

Patent suits generally arise in two circumstances. First, a patent holder may bring suit against an alleged infringer seeking damages or an injunction. Second, a potential infringer may bring a declaratory judgment action against a patent holder, claiming that it does not infringe a particular patent or that the patent-at-issue is invalid or otherwise unenforceable. Although declaratory judgment actions are primarily raised as counterclaims to patent infringement suits, potential infringers may also bring declaratory judgment actions *before* an infringement suit has been filed. Such actions seek a legal determination of the patent issue so that the potential infringer can resume its activities without the threat of an infringement suit looming over its head.<sup>100</sup>

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<sup>94</sup> *Allen*, 468 U.S. at 751.

<sup>95</sup> 504 U.S. 555, 560 (1992).

<sup>96</sup> *Id.* at 560 (citations omitted).

<sup>97</sup> *Id.* at 563.

<sup>98</sup> *Id.* at 560 (quoting *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 41 (1976)).

<sup>99</sup> *Id.* at 561. In particular, the dispute must “admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.” *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 241 (1937)).

<sup>100</sup> See KIMBERLY A. MOORE ET AL., *PATENT LITIGATION AND STRATEGY* 50 (3d ed. 2008) (“Declaratory judgment actions can be a sword for the alleged infringer as well as a shield.”). The offensive use of declaratory judgment actions carries the added benefit of

The procedural mechanism through which courts hear patent declaratory judgment actions is the Federal Declaratory Judgment Act of 1934, which provides that:

In a case of actual controversy within its jurisdiction, . . . any court of the United States . . . may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.<sup>101</sup>

In *Aetna Life Insurance Co. v. Haworth*, the Supreme Court held that the Declaratory Judgment Act was procedural only: The Act neither enlarged nor limited Article III's "case or controversy" requirement, but rather provided a procedural mechanism through which courts may hear declaratory judgment actions that would otherwise satisfy Article III.<sup>102</sup> As a result, declaratory judgment actions must still satisfy the standing requirements outlined in Part II.A, although the particular analysis that courts apply to make this determination differs from that used in suits that do not arise from the Declaratory Judgment Act.

Since its creation in 1982, the Federal Circuit has attempted to clarify the requirements for standing in patent declaratory judgment actions. Although the court has held that "[t]he mere existence of a potentially adverse patent" alone will not confer standing,<sup>103</sup> it has not made clear precisely which circumstances would allow a potential infringer to sue for declaratory judgment.<sup>104</sup> As a whole, the Federal Circuit's jurisprudence on patent declaratory judgment standing seeks to relieve the tension between two competing desires. On the one hand, courts do not want to force a patent holder to litigate the validity of a patent when it has no intention of bringing a patent infringement suit in the first place. To do so would force the patent holder to expend unnecessary resources with little upside for the potential infringer. On the other hand, courts do not want to allow

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allowing the potential infringer to choose the forum and time at which the suit will begin. *Id.* at 50–51.

<sup>101</sup> 28 U.S.C. § 2201(a) (2006). Courts did not always view declaratory judgment actions as constitutional. *See MedImmune*, 549 U.S. at 126 ("There was a time when this Court harbored doubts about the compatibility of declaratory-judgment actions with Article III's case-or-controversy requirement."). Three years after the Declaratory Judgment Act of 1934 was passed, however, the Supreme Court unanimously upheld the Act in *Aetna Life Insurance Co. v. Haworth*, explaining that the phrase "cases of actual controversy" in the Act referred to "cases" and "controversies" that are justiciable under Article III. 300 U.S. 227, 239–40 (1937).

<sup>102</sup> *Haworth*, 300 U.S. at 239–40.

<sup>103</sup> *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1338 (Fed. Cir. 2008).

<sup>104</sup> *See La Belle*, *supra* note 84, at 74.

patent holders to use the specter of a potentially invalid patent in an anticompetitive manner.<sup>105</sup> The discussion that follows outlines the Federal Circuit's and the Supreme Court's recent attempts to address these competing concerns.

## I. MedImmune

Prior to the Supreme Court's 2007 decision in *MedImmune, Inc. v. Genentech, Inc.*,<sup>106</sup> the Federal Circuit applied a two-step standing inquiry in patent declaratory judgment cases. First, the court asked whether the potential infringer had an objectively reasonable apprehension of facing an infringement suit.<sup>107</sup> Second, the court determined whether the potential infringer had either already infringed the patent-at-issue or had taken concrete steps in preparation to infringe the patent.<sup>108</sup> While the reasonable-apprehension-of-suit prong generally proved more difficult, potential infringers did not need to prove the existence of an express threat, such as a cease-and-desist letter, in order to satisfy this test.<sup>109</sup> Rather, the Federal Circuit considered several factors to determine whether an objectively reasonable apprehension of suit existed, including the extent to which the patent holder had previously enforced its patent rights, the relationship between the patent holder and the potential infringer at the time of suit, and the nature of any communication between the two parties prior to suit.<sup>110</sup>

In *MedImmune*, the Supreme Court considered whether a nonrepudiating licensee of a patent had standing to bring a declaratory judgment action against a patent holder to invalidate the licensed patent.<sup>111</sup> The Federal Circuit had ruled that *MedImmune* lacked standing because it had not breached its license agreement with

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<sup>105</sup> In the words of Judge Markey, the first Chief Judge of the Federal Circuit, the Declaratory Judgment Act sought, in part, to resolve situations in which "a patent owner engages in a *danse macabre*, brandishing a Damoclean threat with a sheathed sword." *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 734–35 (Fed. Cir. 1988), *overruled on other grounds by MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007).

<sup>106</sup> 549 U.S. 118 (2007).

<sup>107</sup> *E.g.*, *Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 887 n.2 (Fed. Cir. 1992). The "reasonable apprehension of suit" requirement is a constitutional limit on standing, not a prudential limit up to the discretion of the court. *See, e.g.*, *MedImmune, Inc. v. Genentech, Inc.*, 427 F.3d 958, 965 (Fed. Cir. 2005), *rev'd*, 549 U.S. 118 (2007) ("[T]here is no discretion to accept an action when there is no controversy of immediacy or reality because there is no reasonable apprehension of suit.").

<sup>108</sup> *E.g.*, *Shell Oil*, 970 F.2d at 887 n.2.

<sup>109</sup> *See* MOORE ET AL., *supra* note 100, at 53.

<sup>110</sup> *Id.*; *see, e.g.*, *W. Interactive Corp. v. First Data Res., Inc.*, 972 F.2d 1295, 1297–98 (Fed. Cir. 1992) (affirming a dismissal because there was no direct or indirect contact between the patent owner and the potential infringer, even though the patent owner had been willing to enforce its patent rights in the past).

<sup>111</sup> *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007).

Genentech and therefore had no reasonable apprehension of being sued.<sup>112</sup> Reversing, the Supreme Court held that a licensee need not “bet the farm” and repudiate its license to a patent—thereby risking infringement damages—before bringing suit.<sup>113</sup> In so doing, the Court questioned the continued relevance of the reasonable-apprehension-of-suit test, noting that it conflicted with Supreme Court precedent.<sup>114</sup> Instead, the Court determined that the basic question in patent declaratory judgment actions should be: “whether the facts alleged, *under all the circumstances*, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.”<sup>115</sup> Under this all-the-circumstances test, the Court held that MedImmune had standing to bring its declaratory judgment action.<sup>116</sup>

Underlying the Supreme Court’s decision to rely on the all-the-circumstances test instead of the Federal Circuit’s reasonable-apprehension-of-suit test was the idea that standing should not be precluded because a potential infringer has eliminated the threat of suit by altering its behavior *as long as* “the threat-eliminating behavior was effectively coerced.”<sup>117</sup> With this in mind, *MedImmune* suggests that there are at least two circumstances under which a potential infringer might satisfy the all-the-circumstances test. First, a potential infringer can show that it has a reasonable apprehension of suit. In this way, the reasonable-apprehension-of-suit test may be seen as a sufficient—but not necessary—condition to satisfy the all-the-circumstances test. Second, absent a reasonable apprehension of suit, a potential infringer can show that its threat-eliminating behavior was coerced by the actions of the patent holder. Justice Scalia relied on this “coercion principle”<sup>118</sup> in concluding that declaratory judgment standing exists “where payment of a claim is demanded as of right and where payment is made, but where *the involuntary or coercive nature*

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<sup>112</sup> See *MedImmune*, 427 F.3d at 964 (“MedImmune avoided and continues to avoid such a situation, by avoiding breach and avoiding apprehension of suit.”).

<sup>113</sup> *MedImmune*, 549 U.S. at 134 (“The rule that a plaintiff must destroy a large building, bet the farm, or (as here) risk treble damages and the loss of 80 percent of its business, before seeking a declaration of its actively contested legal rights finds no support in Article III.”).

<sup>114</sup> *Id.* at 132 n.11 (citing *Cardinal Chem. Co. v. Morton Int’l, Inc.*, 508 U.S. 83, 98 (1993), *Altwater v. Freeman*, 319 U.S. 359, 365 (1943), *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941), and *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239 (1937)).

<sup>115</sup> *Id.* at 127 (emphasis added) (quoting *Md. Cas. Co.*, 312 U.S. at 273).

<sup>116</sup> *Id.* at 137.

<sup>117</sup> *Id.* at 129.

<sup>118</sup> *Id.* at 134 n.12. Importantly, the *MedImmune* Court determined that this “coercion principle” applied both when the government and when private parties have threatened action. *Id.* at 128–32.

of the exaction preserves the right [for the potential infringer] . . . to challenge the legality of the claim.”<sup>119</sup>

## 2. Post-MedImmune Cases

Courts and commentators alike have noted that *MedImmune* established a lower bar for patent declaratory judgment standing than previously set by the Federal Circuit.<sup>120</sup> After *MedImmune*, the Federal Circuit initially abandoned the reasonable-apprehension-of-suit test and instead applied the all-the-circumstances test.<sup>121</sup> In *SanDisk Corp. v. STMicroelectronics, Inc.*, for instance, the Federal Circuit considered whether a potential infringer had declaratory judgment standing prior to acquiring a license.<sup>122</sup> The court first recognized that the Supreme Court had rejected the reasonable-apprehension-of-suit test,<sup>123</sup> but went on to distinguish *MedImmune* on the grounds that it arose in the context of a signed license agreement, whereas the suit in *SanDisk* resulted from a series of failed licensing negotiations.<sup>124</sup> Still, the court cited the all-the-circumstances test<sup>125</sup> in holding that the plaintiff had standing.<sup>126</sup> Judge Bryson expressed concern that such a rule had “no practical stopping point short of allowing declaratory judgment actions in virtually any case in which the recipient of an invitation to take a patent license elects to dispute the need for a license and then to sue the [patent holder].”<sup>127</sup> Still, Judge Bryson concurred in the result, finding dispositive

<sup>119</sup> *Id.* at 131 (emphasis added) (quoting *Altwater*, 319 U.S. at 365).

<sup>120</sup> See, e.g., *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1336 (Fed. Cir. 2008) (noting the lowered bar); Ronald A. Bleeker & Michael V. O’Shaughnessy, *One Year After MedImmune—The Impact on Patent Licensing & Negotiation*, 17 FED. CIR. B.J. 401, 435 (2008) (“The new standard . . . make[s] it easier for accused infringers to bring a declaratory judgment action.”).

<sup>121</sup> *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1339 (Fed. Cir. 2007); see also *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1381 (Fed. Cir. 2007) (stating that the boundaries of declaratory judgment standing depend upon the facts and circumstances of each case).

<sup>122</sup> *SanDisk*, 480 F.3d at 1380–81.

<sup>123</sup> *Id.* at 1380. The *SanDisk* court, however, noted that, while *MedImmune* rejected the reasonable apprehension test, it is unclear what effect that decision had on the second prong of the Federal Circuit’s pre-*MedImmune* patent declaratory judgment standing test. *Id.* at 1380 n.2 (“In this case, we address only the first prong of this court’s two-part test. There is no dispute that the second prong is met. We therefore leave to another day the effect of *MedImmune*, if any, on the second prong.”).

<sup>124</sup> *Id.* at 1380–81.

<sup>125</sup> *Id.* at 1382 (“These facts evince that the conditions of creating ‘a substantial controversy, between parties having adverse legal interest, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment’ were fulfilled.” (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941))).

<sup>126</sup> *Id.* at 1381.

<sup>127</sup> *Id.* at 1385 (Bryson, J., concurring).

*MedImmune*'s rejection of the reasonable-apprehension-of-suit test in favor of the all-the-circumstances test.<sup>128</sup>

More recently, in *Prasco, LLC v. Medicis Pharmaceutical Corp.*, the Federal Circuit held that proving a reasonable apprehension of suit was one of several ways to satisfy the all-the-circumstances test.<sup>129</sup> This approach does not conflict with the Supreme Court's criticism of the reasonable-apprehension-of-suit test in *MedImmune*, since a reasonable apprehension of suit could be a sufficient but not necessary condition to satisfy the all-the-circumstances test. However, the Federal Circuit's use of the reasonable-apprehension-of-suit test as a sub-test within the all-the-circumstances analysis might be challenged in future decisions if invocation of the latter becomes a mere tool to reinstitute the former.<sup>130</sup>

Even more recently, in *Myriad*, the Federal Circuit considered whether isolated genes constituted patentable subject matter under 35 U.S.C. § 101.<sup>131</sup> In order to reach the patentable subject matter question, however, the Federal Circuit first had to determine whether physicians who intended to practice the genetic diagnostic test for breast cancer covered by the gene patents at issue had standing to bring a declaratory judgment action against the patent holder, *Myriad*.<sup>132</sup> The Federal Circuit began its standing analysis by identifying *MedImmune*'s all-the-circumstances test as the applicable test for determining standing in patent declaratory judgment actions.<sup>133</sup> While the court acknowledged that *MedImmune* did relax the Federal Circuit's more stringent reasonable-apprehension-of-suit test, and noted that there is no bright-line rule for assessing declaratory judgment standing, it went on to require a potential infringer to allege "both (1) an affirmative act by the [patent holder] related to the enforcement of his patent rights, and (2) meaningful preparation to

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<sup>128</sup> *Id.*

<sup>129</sup> 537 F.3d 1329, 1336 (Fed. Cir. 2008).

<sup>130</sup> In other words, if the Federal Circuit treats a reasonable apprehension of suit as a necessary condition (as opposed to merely a sufficient one) for patent declaratory judgment standing, it contradicts *MedImmune*.

<sup>131</sup> *Ass'n for Molecular Pathology v. U.S. Trade & Patent Office (Myriad)*, 689 F.3d 1303 (Fed. Cir. 2012), *cert. granted sub nom. Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 694 (2012).

<sup>132</sup> *Id.* at 1317. The *Myriad* court briefly discussed a second standing issue, which the plaintiffs had declined to pursue, namely that certain patients had standing to bring suit based on their "inability to gain access to affordable *BRCA* genetic testing because of *Myriad*'s patent dominance of such services." *Id.* at 1319 n.7. The court noted that, "[w]hile denial of health services can, in certain circumstances, state a judicially cognizable injury, . . . we fail to see how the inability to afford a patented invention could establish an invasion of a legally protected interest for purposes of standing." *Id.* (citing *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 40–41 (1976)).

<sup>133</sup> *Id.* at 1318.

conduct potentially infringing activity.”<sup>134</sup> Such a requirement encapsulates the Federal Circuit’s pre-*MedImmune* standard, demanding both an affirmative act by the patent holder and meaningful preparation by the accused infringer.<sup>135</sup>

Applying this formalistic approach, the *Myriad* court dismissed seventeen of the initial twenty plaintiffs, finding that only three of the plaintiffs satisfied the first prong of its test by alleging that Myriad enforced its patent against them.<sup>136</sup> Next, the court determined that of the remaining three plaintiffs only one, Dr. Ostrer, alleged sufficiently real or imminent injury to support standing.<sup>137</sup> Contrasting Dr. Ostrer’s intention to immediately perform the genetic testing in question with the other doctors’ statements that they would merely consider resuming the genetic testing, the court cited *Lujan* for the proposition that “[t]hese ‘some day intentions’ are insufficient to support an ‘actual or imminent’ injury for standing ‘without . . . any specification of *when* the some day will be.’”<sup>138</sup> As a result, the *Myriad* court held that only Dr. Ostrer had standing to pursue his claim.<sup>139</sup> On the merits, the majority reversed the district court, finding that isolated genes were patentable subject matter.<sup>140</sup>

The Supreme Court has subsequently granted the potential infringers’ petition for a writ of certiorari, but has limited its review to the patentability of human genes.<sup>141</sup> While the Court should certainly resolve the issue on the merits, it might also wish to address the standing issue. In Part III.A, I argue that the Supreme Court should reaffirm its all-the-circumstances test in light of the Federal Circuit’s attempts to revert back to a pre-*MedImmune* standard. Although the issue might seem moot given that the Federal Circuit found one plaintiff to have standing, the Supreme Court should consider the standing issue in order to clarify the current state of standing doctrine in patent

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<sup>134</sup> *Id.* (citing *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 880 (Fed. Cir. 2008), and *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1380–81 (Fed. Cir. 2007)).

<sup>135</sup> As Professor Megan La Belle notes:

This test is strikingly similar to the one utilized by the Federal Circuit before *MedImmune*. In fact, the second prong is identical, and the first focuses on the [patent holder’s] conduct just like the earlier ‘reasonable apprehension of suit’ prong. Thus, the panel’s decision in *Myriad* crystallized what had been hinted at in *Prasco* and *Cat Tech*: the Federal Circuit has come full circle with respect to standing in patent declaratory judgment actions and has returned to its pre-*MedImmune* formalistic approach.

La Belle, *supra* note 84, at 83 (footnotes omitted).

<sup>136</sup> *Myriad*, 689 F.3d at 1319.

<sup>137</sup> *Id.*

<sup>138</sup> *Id.* at 1321 (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 564 (1992)).

<sup>139</sup> *Id.* at 1319.

<sup>140</sup> *Id.* at 1337.

<sup>141</sup> *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 694 (2012).

declaratory judgment actions. Moreover, because Dr. Ostrer has allegedly transferred to a hospital that does not offer the genetic test covered by Myriad's patents<sup>142</sup>—a change in circumstances that might affect the standing determination under the Federal Circuit's analysis—the Supreme Court should find it necessary to consider the standing issue before it reaches the merits of the case.

### III EXPANDING STANDING IN PATENT DECLARATORY JUDGMENT ACTIONS

If we accept the need for greater consideration of public policy arguments in patent law,<sup>143</sup> expanding standing in patent declaratory judgment actions offers a potentially attractive solution.<sup>144</sup> By including more parties who lack the pro-patent bias that typifies modern-day patent litigation, expanding standing could infuse the common law rulemaking of patent courts<sup>145</sup> with novel policy arguments that otherwise would not be aired. Because courts depend on litigants to raise policy arguments, the Federal Circuit might consider the extent to which a particular litigant raises novel public policy arguments, as well as the degree to which such a litigant is the only potential party to raise such claims, when determining standing. While such an expansion of standing must necessarily be tailored to avoid the risk of stifling innovation by upsetting the basic *quid pro quo* upon which our patent system is premised,<sup>146</sup> failure to address this issue risks

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<sup>142</sup> Letter from Gregory A. Castanias, Attorney for Defendants-Appellants, to Jan Horbaly, Clerk, U.S. Court of Appeals for the Federal Circuit (July 27, 2011) (on file with the *New York University Law Review*).

<sup>143</sup> See *supra* Part I.

<sup>144</sup> Of course, other potential solutions exist—including congressional adjustment of substantive patent statutes and granting the PTO substantive rulemaking authority. I propose only that expanding standing in patent declaratory judgment actions provides one potential mechanism through which public policy arguments might be aired. That said, expanding standing may be preferred as it allows novel policy arguments to be continually raised, which is especially important in a rapidly changing field like technology. Moreover, see BURK & LEMLEY, *supra* note 7, at 95–108 for an argument that judicial decisionmaking is superior to legislative action in this area.

<sup>145</sup> See, e.g., *id.* at 103 (noting that the Patent Act delegates broad authority to the courts, and that judge-made doctrines play a major role in its implementation).

<sup>146</sup> In U.S. patent law, patents are often viewed as a time-limited exclusive right granted to the patentee in return for disclosure of the underlying invention through publication of the patent. See, e.g., *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001) (“The disclosure required by the Patent Act is the *quid pro quo* of the right to exclude.” (internal quotation marks omitted)).

silencing input from the very constituency that the patent system was created to benefit in the first place: the public as a whole.<sup>147</sup>

### A. *Expanding Standing Within the Existing Framework*

The first—and most realistic—option for expanding standing in patent declaratory judgment actions is to argue that the Federal Circuit has misapplied the all-the-circumstances test required by the Supreme Court in *MedImmune*.<sup>148</sup> If a potential infringer is denied standing based on the lack of a personalized threat or reasonable apprehension of suit, such an individual might argue along the lines of the petitioners in *Myriad*<sup>149</sup> that these rigid requirements contradict *MedImmune*'s flexible all-the-circumstances test. As discussed in Part II.B.1, even if a potential infringer lacks a reasonable apprehension of suit, standing is not precluded under *MedImmune* if the potential infringer herself eliminated the threat of suit through involuntary or coerced action.<sup>150</sup> Moreover, other factors might justify standing under *MedImmune*'s broad all-the-circumstances test. Such an argument would allow plaintiffs who wish to practice an invention covered by a suspect patent, but who nonetheless refrain from doing so for fear of risking treble damages, to raise public policy concerns regarding the validity of a patent that otherwise may not be heard.

*Myriad* provides a case in point. The potential infringers seek to question the patentability of isolated genes generally and have brought a declaratory judgment action on the grounds that, although they wish to perform a genetic test covered by the patented invention, they have chosen not to for fear of an infringement action.<sup>151</sup> The definitive resolution of this issue either way will profoundly impact

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<sup>147</sup> See *supra* Part I.C. Although individuals' concerns may, of course, also be heard through Congress, the degree to which Congress has deferred to the courts in the area of patent law, combined with the infrequency of congressional intervention, suggests that the public's recourse should be bolstered.

<sup>148</sup> For a detailed analysis of the Federal Circuit's application of the all-the-circumstances test in *Myriad*, see La Belle, *supra* note 84, at 82–93.

<sup>149</sup> Petition for Writ of Certiorari at 31, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012) (No. 11-725), 2011 WL 6257250 at \*31 (“*MedImmune* instructs that bright line rules and steadfast requirements are inappropriate when analyzing a plaintiff's standing in a declaratory judgment action.”).

<sup>150</sup> *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 131 (2007); see also *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 96 (1993) (“Merely the desire to avoid the threat of a ‘scarecrow’ patent . . . may therefore be sufficient to establish jurisdiction under the Declaratory Judgment Act.”).

<sup>151</sup> *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office (Myriad)*, 689 F.3d 1303, 1316–17, *cert. granted sub nom. Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 694 (2012).

the public interest.<sup>152</sup> Moreover, if courts do not allow this issue to be raised in the first place, patent holders like *Myriad* will be allowed to continue exploiting their monopolies without the patents' legitimacy ever being tested.<sup>153</sup>

A declaratory judgment defendant could respond that expanding standing in patent declaratory judgment cases would flood courts with litigation and disrupt the basic quid pro quo of patent law,<sup>154</sup> stifling innovation. Potential infringers may counter that the fear of endless litigation is mitigated by the self-limiting nature of bringing such claims: Because the remedy being sought by a potential infringer is often the invalidation of a patent, successfully raising such claims precludes future patent infringement suits. Although patent declaratory judgment actions in which the patent is eventually upheld may increase the burden on courts, successful patent declaratory judgment actions invalidating a patent will reduce this burden. As a whole, the two effects may offset one another.

The concern that allowing such suits would disrupt the quid pro quo of patent law, thereby stifling innovation, is more troubling. Potential infringers can respond, consistent with Professor La Belle, that long-standing Supreme Court precedent supports the adoption of "flexible legal standards that facilitate lawsuits brought by parties challenging patent validity."<sup>155</sup> As discussed in Part I.C, the Supreme Court has encouraged such suits because the public benefits when bad patents are invalidated.<sup>156</sup> Moreover, *Lear, Inc. v. Adkins* emphasized

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<sup>152</sup> "While all patent litigation implicates the public interest, *Myriad* is a particularly high-stakes case with potentially far reaching consequences for society. The substantive questions posed in *Myriad* . . . are critically important and should be addressed by the courts 'sooner rather than later,' as Justice Breyer has opined." La Belle, *supra* note 84, at 93 (quoting *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 134 (2006) (Breyer, J., dissenting)).

<sup>153</sup> *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 734–35 (Fed. Cir. 1988) (explaining that the Declaratory Judgment Act was enacted, in part, to resolve situations in which "a patent owner engages in a *danse macabre*, brandishing a Damoclean threat with a sheathed sword"), *overruled on other grounds* by *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007).

<sup>154</sup> See *supra* note 146 and accompanying text (discussing the basic quid pro quo of U.S. patent law). A patent declaratory judgment defendant would also likely claim that the public interest has already been sufficiently considered when the PTO initially approved the patent. However, as the Supreme Court in *Lear, Inc. v. Adkins* noted, "A patent . . . simply represents a legal conclusion reached by the Patent Office. . . . Yet the Patent Office is often obliged to reach its decision in an *ex parte* proceeding, *without the aid of the arguments which could be advanced by parties interested in proving patent invalidity.*" 395 U.S. 653, 670 (1969) (emphasis added).

<sup>155</sup> La Belle, *supra* note 84, at 70 (citing *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 345 (1971)).

<sup>156</sup> *Id.* (citing *Blonder-Tongue*, 402 U.S. at 331 n.21, and *Lear*, 395 U.S. at 670). In particular, in *Lear*, the Supreme Court recognized the importance of patent declaratory

the dangers of muzzling a potential infringer who is the only prospective plaintiff with sufficient economic incentive to challenge a patent's validity.<sup>157</sup> Therefore, a potential infringer who does not meet the Federal Circuit's restrictive interpretation of *MedImmune* could argue that courts should confer standing on the grounds that he is a member of the only group that has sufficient economic incentive to bring suit, particularly when resolution of the patent's validity would be valuable to the public.

Still, Judge Moore stated a valid concern in *Myriad* regarding the profound impact on the patent system of allowing "anyone who was ready, willing, and able to compete tomorrow" to bring a declaratory judgment action "against the [patent holder] in any forum of their choosing without any affirmative act directed at all towards them by the [patent holder]."<sup>158</sup> In order to address this concern, I propose the following solution: While would-be plaintiffs who have avoided the threat of suit by refraining from potentially infringing conduct should not automatically be granted standing to challenge a patent's validity, courts should consider (1) the extent to which potential infringers are the only prospective challengers of a patent's validity and (2) the degree to which such a determination would potentially affect the public interest within *MedImmune*'s all-the-circumstances test.<sup>159</sup> Analyzing these factors within the all-the-circumstances test would conform to *MedImmune*'s decision to eschew bright-line rules in determining declaratory judgment standing. Courts would then have leeway to balance the competing interests in invalidating bad patents

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judgment actions in light of the "public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain." 395 U.S. at 670.

<sup>157</sup> *Lear*, 395 U.S. at 670.

<sup>158</sup> Oral Argument at 31:30, *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406), available at <http://www.cafc.uscourts.gov/oral-argument-recordings/2010-1406/all>.

<sup>159</sup> While my analysis of *MedImmune*'s all-the-circumstances test in Part II.B.2 revealed the existence of at least two relevant factors in determining the standing of potential infringers—namely, the reasonable-apprehension-of-suit test and the coercion principle—the *MedImmune* Court's reluctance to adopt a bright-line rule suggests that these are not the only relevant factors. In addition to the further considerations I have outlined above, courts may also wish to consider the extent to which a potential infringer's claim of invalidity, *as opposed to noninfringement*, might implicate the public interest. As the Federal Circuit hinted at in *Prasco, LLC v. Medicis Pharmaceutical Corp.*, "[The declaratory judgment plaintiff] had sued only for a declaratory judgment of non-infringement. We thus have no opportunity to consider whether similar facts would be sufficient to establish jurisdiction if, instead, [the declaratory judgment plaintiff] had conceded infringement and was only arguing invalidity." 537 F.3d 1329, 1342 n.12 (Fed. Cir. 2008).

on the one hand, and protecting legitimate patent holders on the other.<sup>160</sup>

*B. Expanding Standing by Focusing on Underlying Justifications*

Courts may also wish to expand standing in patent declaratory judgment actions by reassessing the existing principles that justify standing doctrine generally.<sup>161</sup> As discussed in Part II.A, standing is a judicially created doctrine rooted in Article III's "case or controversy" clause. Although few question the fundamental need for a standing doctrine, the current regime has been criticized by scholars and courts as "incoherent,"<sup>162</sup> "permeated with sophistry,"<sup>163</sup> and "a word game played by secret rules."<sup>164</sup> Perhaps most accurately, the doctrine has been characterized as a meaningless "litany" of requirements recounted before "the Court . . . chooses up sides and decides the case."<sup>165</sup> According to Judge William Fletcher, discontent with modern standing doctrine stems from a mismatch between its formal structure and underlying purpose.<sup>166</sup>

The need for a standing requirement has been justified on several grounds, including the need for adverse and energetic parties in litigation,<sup>167</sup> the desire that the most affected parties be adequately represented,<sup>168</sup> the necessity for concrete facts to inform courts'

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<sup>160</sup> However, simply allowing courts to consider these factors in the first place might disrupt this tenuous balance because declaratory judgment defendants would have to expend considerable resources challenging standing under such a broad test. In order to correct for this, courts might implement a fee-shifting provision in which potential infringers who invoke standing based on these factors, but who are found to have a meritless claim, would be required to pay the defendant's reasonable attorneys' fees. Such a compromise would promote patent declaratory judgment suits in the public interest, while deterring suits that are likely to stifle innovation.

<sup>161</sup> For one argument that standing should be broadened outside of the context of patent law, see *Sierra Club v. Morton*, 405 U.S. 727, 757 (1972) (Blackmun, J., dissenting). In *Sierra Club*, Justice Blackmun calls for "an imaginative expansion of our traditional concepts of standing in order to enable an organization such as the Sierra Club, possessed, as it is, of pertinent, bona fide and well-recognized attributes and purposes in the area of environment, to litigate environmental issues." *Id.*

<sup>162</sup> Fletcher, *supra* note 93, at 221.

<sup>163</sup> 4 KENNETH CULP DAVIS, ADMINISTRATIVE LAW TREATISE § 24:35, at 342 (2d ed. 1983).

<sup>164</sup> *Flast v. Cohen*, 392 U.S. 83, 129 (1968) (Harlan, J., dissenting).

<sup>165</sup> Abram Chayes, *The Supreme Court 1981 Term—Foreword: Public Law Litigation and the Burger Court*, 96 HARV. L. REV. 4, 22–23 (1982).

<sup>166</sup> Fletcher, *supra* note 93, at 221.

<sup>167</sup> *Flast*, 392 U.S. at 101; *Baker v. Carr*, 369 U.S. 186, 204 (1962).

<sup>168</sup> *Diamond v. Charles*, 476 U.S. 54, 62 (1986); *Warth v. Seldin*, 422 U.S. 490, 498–99 (1975); *Sierra Club v. Morton*, 405 U.S. 727, 740 (1972); cf. ERWIN CHERMERINSKY, FEDERAL JURISDICTION 57 (6th ed. 2012) ("[T]he insistence on a personal stake in the outcome of the litigation is a very uncertain guarantee of high-quality advocacy.").

decisions,<sup>169</sup> and the belief that generalized injuries should be addressed by the political process.<sup>170</sup> The standing requirement has also been justified on judicial efficiency grounds.<sup>171</sup>

While each of these rationales plays a role in justifying the need for a standing requirement, the Supreme Court observed in *Allen v. Wright* that “the law of Art. III standing is built on a single basic idea—the idea of separation of powers.”<sup>172</sup> The separation of powers concern is that if courts hear cases brought by too broad a class of individuals, the judiciary will usurp the executive branch’s constitutional duty to faithfully execute the laws.<sup>173</sup>

The separation of powers justification underlying standing doctrine, however, is especially weak in the context of patent litigation. As many scholars have noted, the Patent Act is a broad enabling statute akin to the antitrust laws and in contrast to the regulatory nature of modern copyright law.<sup>174</sup> The Act lays out in broad language the requirements for obtaining a patent—including the requirements of utility, novelty, and nonobviousness—but leaves courts to flesh out the details.<sup>175</sup> While the Executive certainly plays a crucial role in the granting of patents, the PTO lacks substantive rulemaking

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<sup>169</sup> *Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 477–78 (1982); *Schlesinger v. Reservists Comm. to Stop the War*, 418 U.S. 208, 222 (1974); *Baker*, 369 U.S. at 204.

<sup>170</sup> FALLON ET AL., *supra* note 88, at 114–15 (citing *Lewis v. Casey*, 518 U.S. 343, 357 (1996), and *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 576 (1992)).

<sup>171</sup> See, e.g., CHEMERINSKY, *supra* note 168, at 50 (claiming that standing doctrine promotes judicial efficiency by reducing lawsuits on purely ideological grounds).

<sup>172</sup> 468 U.S. 737, 752 (1984); see also *Valley Forge*, 454 U.S. at 473 (“The exercise of the judicial power . . . affects relationships between the coequal arms of the National Government.”); *Laird v. Tatum*, 408 U.S. 1, 15 (1972) (monitoring the wisdom of executive action is the appropriate role of the Congress rather than of the judiciary); La Belle, *supra* note 84, at 89 (citing *Lujan*, 504 U.S. at 576–77) (describing *Lujan*’s standing analysis as “shaped by separation of powers principles”); Antonin Scalia, *The Doctrine of Standing as an Essential Element of the Separation of Powers*, 17 SUFFOLK U. L. REV. 881, 881 (1983) (“[T]he judicial doctrine of standing is a crucial and inseparable element of [the principle of separation of powers], whose disregard will inevitably produce . . . an overjudicialization of the processes of self-governance.”).

<sup>173</sup> See U.S. CONST. art. II, § 3. Such considerations are particularly important where Congress grants individuals the right to bring suit in the public interest. In such circumstances, as Justice Scalia explained in *Lujan*, “[t]o permit Congress to convert the undifferentiated public interest in executive officers’ compliance with the law into an ‘individual right’ vindicable in the courts is to permit Congress to transfer from the President to the courts the Chief Executive’s most important constitutional duty . . .” *Lujan*, 504 U.S. at 577.

<sup>174</sup> See BURK & LEMLEY, *supra* note 7, at 103 (explaining that statutes exist on a continuum of specificity); Joseph P. Liu, *Regulatory Copyright*, 83 N.C. L. REV. 87, 102–05 (2004) (describing characteristics of the regulatory model of copyright legislation); *id.* at 105–25 (detailing specific instances of “regulatory” copyright law).

<sup>175</sup> 35 U.S.C. §§ 101–103 (2006).

authority.<sup>176</sup> Rather, courts create substantive patent law, similar to the statutory tailoring role played by courts in antitrust law.<sup>177</sup> Moreover, while the Patent Act does afford patents issued by the PTO a presumption of validity,<sup>178</sup> courts routinely overrule the PTO's determinations.<sup>179</sup>

Because the Executive already plays a relatively minor role in ensuring the faithful execution of patent laws, we should be less concerned about the separation-of-powers implications of granting standing to a broader class of individuals in patent declaratory judgment actions than we might be in other areas of law.<sup>180</sup> Moreover, several of the other justifications supporting standing doctrine are particularly inapplicable to patent declaratory judgment suits. As discussed in Part III.A, judicial efficiency arguments in support of a strict standing requirement are blunted by the self-correcting nature of patent declaratory judgment suits: A potential infringer's success in court eliminates future patent infringement litigation regarding the patent-in-suit. Similarly, while courts must "protect[ ] democratic

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<sup>176</sup> According to the Federal Circuit, the PTO lacks "any general substantive rulemaking power." *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549–50 (Fed. Cir. 1996); *see also* *Eli Lilly & Co. v. Bd. of Regents of Univ. of Wash.*, 334 F.3d 1264, 1269 n.1 (Fed. Cir. 2003) (citing *Merck & Co.*, 80 F.3d at 1549). In particular, the PTO may not issue rules that "effect[ ] a change in existing law or policy which affect[s] individual rights and obligations." *Animal Legal Def. Fund. v. Quigg*, 932 F.2d 920, 927 (Fed. Cir. 1991) (internal quotation marks omitted).

<sup>177</sup> Indeed, the dynamic in patent law places even more emphasis on the courts than in antitrust law where guidelines issued by the Department of Justice and the Federal Trade Commission are viewed as highly influential on judicial decisionmaking. *See* Hillary Greene, *Guideline Institutionalization: The Role of Merger Guidelines in Antitrust Discourse*, 48 WM. & MARY L. REV. 771, 856 (2006) (concluding that "the courts have ceded significant responsibility to interpret the law to the antitrust agencies"). Moreover, Congress itself has played a relatively minor role in shaping patent law over the past century. *But see* *United States v. Richardson*, 418 U.S. 166, 179 (1974) ("Slow, cumbersome, and unresponsive though the traditional electoral process may be thought at times, our system provides for changing members of the political branches when dissatisfied citizens convince a sufficient number of their fellow electors that elected representatives are delinquent in performing duties committed to them.").

<sup>178</sup> 35 U.S.C. § 282 (2006).

<sup>179</sup> Between 1989 and 1996, for instance, district courts and the Federal Circuit invalidated forty-six percent of challenged patents. Allison & Lemley, *supra* note 49, at 205.

<sup>180</sup> For a similar argument, *see* La Belle, *supra* note 84, at 92 n.157, which notes that separation of powers concerns should not arise in cases not involving congressionally authorized citizen suits. A more nuanced approach suggested by Professor Cass Sunstein argues that when a plaintiff "establishes that an agency has enforced the law in an unlawful way," the President has violated his constitutional duty under the Take Care Clause, thereby rendering judicial enforcement permissible. Cass R. Sunstein, *What's Standing After Lujan? Of Citizen Suits, "Injuries," and Article III*, 91 MICH. L. REV. 163, 212 (1992). In this way, one might argue that when the PTO improperly issues a patent, the President has failed to "take Care that the Laws be faithfully executed," justifying standing and relieving our separation of powers concern. U.S. CONST. art. II, § 3.

prerogatives” by ensuring that generalized injuries are addressed by the political process,<sup>181</sup> the degree to which Congress has delegated the fashioning of substantive patent law to the courts suggests that courts should play a larger role in addressing generalized grievances in patent law than in other fields.

The remaining justifications for standing doctrine—the benefits from adverse and energetic parties, the desire that the most affected parties be adequately represented, and the need for concrete facts to inform courts’ decisions—exist in patent litigation just as they do in other areas of law. However, these concerns should be addressed *directly* by assessing the degree to which the case at hand implicates these concerns, rather than indirectly through the enigmatic wordplay that so typifies modern standing doctrine. Doing otherwise imports into patent law potentially over-restrictive standing requirements premised on justifications—separation of powers in particular—that are inapplicable in the patent context. Instead, the Supreme Court could formulate a new context-sensitive framework for determining standing in patent declaratory judgment actions, one that takes into account both the degree to which each of the standing doctrine’s justifications is implicated in the case at hand and the importance of declaratory judgment actions for the patent system as a whole.<sup>182</sup>

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<sup>181</sup> FALLON ET AL., *supra* note 88, at 114–15 (citing *Lewis v. Casey*, 518 U.S. 343, 357 (1996), and *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 576 (1992)). The Supreme Court echoed this concern in *Diamond v. Chakrabarty*, noting:

The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot. That process involves the balancing of competing values and interests, which in our democratic system is the business of elected representatives. Whatever their validity, the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts.

447 U.S. 303, 317 (1980). *See also Lujan*, 504 U.S. at 576 (“Vindicating the *public* interest . . . is the function of Congress and the Chief Executive.”).

<sup>182</sup> Professor Kali Murray also argues for a reassessment of standing in patent litigation to more fully incorporate the concerns of third parties. According to Murray:

[The] reliance on a private interest model [stemming from the traditional understanding of the Patent Act] leads to a reluctance to fully accord standing to parties seeking to protect broader public interests, such as an error by the patent office that implicates an entire class of technologies. A reassessment of standing is necessary if patent law is to be sensitive to these broader concerns of third party constituencies.

Kali N. Murray, *Rules for Radicals: A Politics of Patent Law*, 14 J. INTELL. PROP. L. 63, 77 (2006) (footnote omitted). The current regime’s “[r]eliance on competitors to prove or disprove patent validity can be problematic as competitors may have compelling business reasons for not pursuing a challenge to a particular patent.” *Id.* at 80. In particular, competitors will often settle a patent dispute to the detriment of consumers—even if a potentially infringing competitor has a particularly strong case—in order to avoid the cost of

### C. Congressional Action to Relax Standing in Patent Cases

Even if courts recognize the disconnect between the justifications for standing doctrine and patent declaratory judgment actions, they may refrain from reassessing the current framework because of the uncertainties that may arise during such reform. Just as uncertainty in substantive patent law reduces the value of patents and thereby the incentive to innovate, so too does uncertainty in standing doctrine because patent holders would be unsure of which parties might bring declaratory judgment actions against them. Insecure patent holders will discount the value of obtaining a patent, potentially disrupting the balance between incentivizing innovation and protecting the public domain.

In order to remedy this, Congress could statutorily amend the requirements for standing in patent declaratory judgment actions, relaxing the standard while still providing clarity. The Supreme Court addressed a similar issue in *Lujan v. Defenders of Wildlife*, in which several environmental organizations challenged the procedure through which the Departments of Interior and Commerce issued regulations.<sup>183</sup> Prior to *Lujan*, the Supreme Court had on several occasions held that Congress could authorize citizen suits to defend the public interest through statutory enforcement.<sup>184</sup> Although the Court held in *Lujan* that Congress may not dispense with the concrete injury requirement for standing altogether, the Court emphasized that “[statutory] broadening [of] the categories of injury that may be alleged in support of standing is a different matter from abandoning the

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litigation. “For example, increasingly, a generic producer may derive significant benefits by settling with a conventional producer; indeed, the potentially collusive practices between generic and conventional producers of pharmaceuticals have been the subject of increasing judicial and administrative scrutiny.” *Id.*

Still, according to Murray, few cases question the limited standing that patent law affords to third parties other than competitors. *Id.* at 79–80. For this reason, third parties might argue for third-party standing resulting from a procedural injury under the Administrative Procedure Act, 5 U.S.C. §§ 500–504, 551–559, 701–706 (2006). Murray, *supra*, at 80–81. While Murray notes that the Federal Circuit has generally rejected such third-party standing claims, he argues that recent changes in the statutory landscape “provide an opportunity to revisit the ability of third parties to claim procedural injury in fact under the Patent Act.” *Id.* at 83.

<sup>183</sup> *Lujan*, 504 U.S. at 558–59.

<sup>184</sup> See, e.g., *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 373–74 (1982) (granting standing to an African-American “tester” to seek relief under section 804 of the Fair Housing Act of 1968, 42 U.S.C. § 3604 (2006)); *Trafficante v. Metro. Life Ins. Co.*, 409 U.S. 205, 211 (1972) (conferring standing on a white tenant and an African-American tenant under section 810 of the Civil Rights Act of 1968, 42 U.S.C. § 3610, and stating that “the complainants act not only on their own behalf but also as private attorneys general in vindicating a policy that Congress considered to be of the highest priority” (internal quotation marks omitted)).

requirement that the party seeking review must himself have suffered an injury.”<sup>185</sup> Indeed, Justice Scalia, writing for the majority, noted that “[t]he . . . injury required by Art. III may exist solely by virtue of ‘statutes creating legal rights, the invasion of which creates standing.’”<sup>186</sup>

Still, as Professor Richard Fallon notes, the precise ways in which Congress may define judicially cognizable injuries is uncertain after *Lujan*.<sup>187</sup> Two more recent Supreme Court decisions suggest that the scope of congressional power to create judicially cognizable injuries is quite broad. In *Federal Election Commission v. Akins*,<sup>188</sup> the Court conferred standing upon a group of voters who sought to challenge the Federal Election Commission’s ruling that the American Israel Public Affairs Committee was not a “political committee” under the Federal Election Campaign Act of 1971 (FECA).<sup>189</sup> Within FECA, Congress provided that any person who believed that a violation of the Act had occurred could file a complaint with the Federal Election Commission. The Commission’s decision would be reviewable in district court.<sup>190</sup> Although Justice Breyer recognized that the political branches are often the more appropriate venue to remedy widely shared grievances, he found the plaintiffs to have standing because the harm alleged was “sufficiently concrete and specific such that the fact that it is widely shared does not deprive Congress of constitutional power to authorize its vindication in the federal courts.”<sup>191</sup>

Similarly, in *Massachusetts v. EPA*, the Supreme Court held that Massachusetts had standing to challenge the Environmental Protection Agency’s refusal to regulate greenhouse gas emissions from cars.<sup>192</sup> Quoting *Lujan*, Justice Stevens stated:

[A] litigant to whom Congress has ‘accorded a procedural right to protect his concrete interests . . . can assert that right without meeting all the normal standards for redressability and immediacy[.]’ When a litigant is vested with a procedural right [by Congress], that litigant has standing if there is some possibility that

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<sup>185</sup> *Lujan*, 504 U.S. at 578 (second alteration in original) (quoting *Sierra Club v. Morton*, 405 U.S. 727, 738 (1972)).

<sup>186</sup> *Id.* (alteration in original) (quoting *Warth v. Seldin*, 422 U.S. 490, 500 (1975)); see also *id.* at 580 (Kennedy, J., concurring) (“In my view, Congress has the power to define injuries and articulate chains of causation that will give rise to a case or controversy where none existed before, and I do not read the Court’s opinion to suggest a contrary view.”).

<sup>187</sup> FALLON ET AL., *supra* note 88, at 142.

<sup>188</sup> 524 U.S. 11 (1998).

<sup>189</sup> Pub. L. No. 92-225, 86 Stat. 3 (1972) (codified as amended at 2 U.S.C. §§ 431–455 (2006)).

<sup>190</sup> *Id.* at 19 (quoting 2 U.S.C. §§ 437g(a)(1), 437g(a)(8)(A)).

<sup>191</sup> *Id.* at 25.

<sup>192</sup> 549 U.S. 497 (2007).

the requested relief will prompt the injury-causing party to reconsider the decision that allegedly harmed the litigant.<sup>193</sup>

*Massachusetts v. EPA* might also stand for the proposition that congressional authority to confer standing upon individuals depends on a balance between the imminence and graveness of the potential harm<sup>194</sup>—although potentially distinguishable by the fact that the Court also relied on *Massachusetts*'s “quasi-sovereign interests.”<sup>195</sup>

Taken together, these cases suggest that the power of Congress to statutorily grant standing to particular individuals is quite broad even in cases of widely shared grievances. Therefore, were Congress inclined to broaden standing in patent declaratory judgment actions, it could do so without violating the separation of powers by creating a legal right for individuals to challenge patents (1) that they believe to be invalid and (2) that cover inventions that they seek to practice. Creating such a statutory right would allow Congress to tailor standing requirements by providing further guidance on how courts should interpret “injuries” in patent declaratory judgment actions. For instance, Congress might confer standing by finding that the mere communication of a patent's existence from the patent holder to a potential infringer satisfies the injury requirement. Or Congress could statutorily require courts to consider other factors—including the extent to which the potential infringers are the only prospective challengers of a patent's validity and the degree to which such a determination would potentially affect the public interest<sup>196</sup>—in determining standing. By explicitly defining the circumstances in which a potential infringer would have standing, Congress could broaden the standing requirement to better reflect patent law's need for greater consideration of public policy while simultaneously avoiding the uncertainty that would result from judicial revision of the doctrine.

## CONCLUSION

Even if we accept the need for greater consideration of public policy arguments in patent litigation, expanding standing in patent

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<sup>193</sup> *Id.* at 517–18 (citations omitted).

<sup>194</sup> FALLON ET AL., *supra* note 88, at 145; see also Jonathan Remy Nash, *Standing and the Precautionary Principle*, 108 COLUM. L. REV. 494, 511 (2008) (advocating “precautionary-based standing,” in which “the ‘injury’ prong of standing is satisfied where the plaintiff can show that the harm that it might suffer would be catastrophic and irreversible, and that its occurrence is subject to great uncertainty”).

<sup>195</sup> *Massachusetts v. EPA*, 549 U.S. at 519–20.

<sup>196</sup> See *supra* notes 158–60 and accompanying text (describing why consideration of such factors is desirable). The fact that Congress has failed to pass such legislation does not counsel against my proposal, given the difficulty of drawing such a negative inference in a field in which Congress seldom legislates.

declaratory judgment actions may be unnecessary given a new set of procedures created by the Leahy-Smith America Invents Act (AIA), which was signed into law by President Obama on September 16, 2011.<sup>197</sup> Section 6 of the AIA creates “post-grant review proceedings” that will allow individuals to challenge the validity of a patent at the PTO as an alternative to instituting a suit in federal court.<sup>198</sup> These new post-grant opposition procedures will allow for patent challenges based on nearly any issue affecting a patent’s validity.<sup>199</sup> Moreover, the new procedures will likely grant standing on a broad basis to nearly any individual.<sup>200</sup>

Still, the ability to challenge a patent’s validity through the AIA’s post-grant review proceedings will be significantly more restricted than through the federal court system.<sup>201</sup> Most importantly, section 6 of the AIA provides that petitions for post-grant review must be filed within nine months of a patent’s issuance.<sup>202</sup> Because potential infringers are often unaware of the relevance of a patent within nine months of issuance, this provision is likely to limit significantly the effectiveness of the new post-grant opposition procedures. Additionally, the new procedures allow the PTO Commissioner to authorize a review only if, based on the information presented in the request for review, “it is more likely than not that at least [one] of the claims challenged in the petition is unpatentable.”<sup>203</sup> While a review may also be authorized if “the petition raises a novel or unsettled legal question that is important to other patents or patent applications,”<sup>204</sup>

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<sup>197</sup> Pub. L. No. 112-29, 125 Stat. 284 (2011) (to be codified in scattered sections of 35 U.S.C.).

<sup>198</sup> § 6, 125 Stat. at 299–313 (to be codified at 35 U.S.C. §§ 311–319). Currently, the PTO employs two types of reexamination procedures for issued patents. Ex parte proceedings allow any third party to request the reexamination of an issued patent; however, third parties are extremely limited in the proceeding itself. Inter partes proceedings allow for greater participation from challengers. Still, both procedures have been used rarely since their creation due to several significant limitations, including the restriction that challengers can only question the validity of a patent based on novelty and nonobviousness. See CARRIER, *supra* note 3, at 212.

As a result, the potential infringers in *Myriad*, for instance, would not be able to challenge *Myriad*’s gene patents based on their patentable subject matter contention. For a more complete description of both inter partes and ex parte proceedings, see *id.* at 211–13.

<sup>199</sup> See Changes to Implement Post-Grant Review Proceedings, 77 Fed. Reg. 7060, 7060–61 (proposed Feb. 10, 2012) (to be codified at 37 C.F.R. pt. 42) (providing broad statutory grounds supporting post-grant review).

<sup>200</sup> Standing is conferred to any individual who “certif[ies] that the patent for which review is sought is available for post-grant review and that the petitioner is not barred or estopped from requesting a post-grant review of the patent.” *Id.* at 7079.

<sup>201</sup> See *id.* at 7061 (listing requirements for seeking post-grant review).

<sup>202</sup> § 6, 125 Stat. at 306.

<sup>203</sup> *Id.*

<sup>204</sup> *Id.* at 307.

this preponderance of the evidence standard in order to engage in a full-fledged review will likely reduce the utility of the new procedures.<sup>205</sup> As a result, the AIA's post-grant review proceedings are unlikely to relieve the concerns expressed in this Note.

Given the increase in patent protection over the past three decades, combined with modern-day patent litigation's lack of concern for public policy considerations, patent law needs a counterbalance to avoid the dangers posed by overprotection. One potential solution is to expand standing in patent declaratory judgment actions to allow parties likely to raise public policy arguments to have their day in court. While courts may draw from the Supreme Court's *MedImmune* decision to grant standing to a broader class of plaintiffs, the Supreme Court may also wish to reassess the framework for standing in patent declaratory judgment actions by focusing on the justifications for the standing doctrine in general. Additionally, Congress could statutorily broaden standing and outline specific instances in which courts should hear cases from potential infringers. Because the AIA's post-grant opposition procedures are unlikely to allow most potential infringers to challenge suspect patents, any of the above solutions for broadening standing in patent declaratory judgment suits would provide a remedy for the lack of public policy considerations in U.S. patent law.

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<sup>205</sup> This threshold showing is significantly higher than the required "substantial new question of patentability" showing for current ex parte and inter partes PTO reviews. 35 U.S.C. §§ 303(a), 312(a) (2006). This differential suggests that, while the new post-grant opposition procedures can be used in a broader class of challenges, a smaller percentage of petitions will actually result in reviews.

