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### Recommended Citation

Megan M. La Belle, Standing to Sue in the Myriad Genetics Case, 2 CAL. L. REV. CIR. 68 (2011).

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# California Law Review Circuit

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Vol. 2

November 2011

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## Standing to Sue in the *Myriad Genetics* Case

Megan M. La Belle\*

### INTRODUCTION

A short time ago, a three-judge panel of the United States Court of Appeals for the Federal Circuit issued its decision in *Ass'n for Molecular Pathology v. USPTO (Myriad Genetics)*,<sup>1</sup> one of the most important patent cases in recent history. The *Myriad* case addresses the controversial question whether isolated human genes related to breast and ovarian cancer can be patented. The case has garnered significant attention from various industries, the Department of Justice, the legal academy, the media, and the public. Features on the lawsuit have appeared in the *New York Times*, *Washington Post*, *Wall Street Journal*, and *Los Angeles Times*,<sup>2</sup> and approximately forty amicus briefs were filed with the court. So far, commentators and amici have

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\* Assistant Professor, Catholic University of America, Columbus School of Law. The author would like to thank David Orlic and Amanda Leiter for their valuable comments and suggestions. The author is also grateful to her research assistants, Chanelle Blackie and Josh Goyden, for their excellent research and editorial assistance.

1. *Ass'n for Molecular Pathology v. USPTO (Myriad)*, 653 F.3d 1329 (2011). A recording of the oral argument is available on the Federal Circuit's website. See Oral Argument, *Ass'n for Molecular Pathology v. USPTO (Myriad)*, 653 F.3d 1329 (2011) (No. 2010-1406), available at <http://www.ca9.uscourts.gov/oral-argument-recordings/2010-1406/all>.

2. Andrew Pollack, *Ruling Upholds Gene Patent in Cancer Test*, N.Y. TIMES (July 29, 2011), <http://www.washingtonpost.com/wp-dyn/content/article/2010/03/01/AR2010030102925.html>; Kari Lydersen, *Lawsuit Attacks Patent Giving Company Control Over Genetic Test for Cancer Risk*, WASH. POST (Mar. 2, 2010), [http://www.washingtonpost.com/wpdyn/content/article/2010/03/01/AR2010030102925\\_pf.html](http://www.washingtonpost.com/wpdyn/content/article/2010/03/01/AR2010030102925_pf.html); Nathan Koppel, *Genetic Research Spurs Fight Over Patents Tied to the Body*, WALL ST. J. (Dec. 10, 2009), <http://online.wsj.com/article/SB126041358100284931.html>; Eryn Brown, *Myriad Genetics: Is it Legal to Patent a Gene?*, L.A. TIMES (Apr. 4, 2011), <http://articles.latimes.com/2011/apr/04/news/la-heb-gene-patent-myriad-20110404>.

focused primarily on the substantive legal issues: Should genes be patentable subject matter? How do gene patents impact medical research and health care? Do gene patents promote innovation as required by the Constitution? Yet, the *Myriad* case also raises important questions about the justiciability of patent declaratory judgment disputes that have received surprisingly little attention.

The patents at issue in *Myriad* cover the BRCA1 and BRCA2 genes, which relate to an increased risk of breast and ovarian cancer. Twenty named plaintiffs – including various medical organizations, genetics researchers, clinicians, and cancer patients – filed a declaratory judgment action against the patent owner, Myriad Genetics (“Myriad”), and several other defendants.<sup>3</sup> Plaintiffs sought a declaration that the patents were invalid because human genes, as products of nature, are not patentable subject matter. After determining that all twenty plaintiffs had standing, the district court declared the patents invalid and granted summary judgment to plaintiffs.

On appeal, the Federal Circuit affirmed that there was standing to sue, although on far narrower grounds. The Federal Circuit held that only one of the twenty plaintiffs – Dr. Harry Ostrer – had suffered an injury-in-fact, a prerequisite for standing in federal court.<sup>4</sup> In the court’s opinion, the other plaintiffs lacked standing either because Myriad had taken no actions against them, or because their injuries were too speculative to satisfy the imminent injury requirement under *Lujan v. Defenders of Wildlife*.<sup>5</sup>

Having decided that the case was justiciable, the Federal Circuit turned to the merits. In a divided opinion, the court reversed the lower court’s invalidity ruling, holding that at least some of Myriad’s patent claims recite patentable subject matter.<sup>6</sup> The court held, in other words, that some types of genes can be patented. After the *Myriad* court issued its decision, both parties petitioned for panel rehearing. Recently, the panel denied both petitions.<sup>7</sup>

The panel’s decision may not be the end of the line for the *Myriad* case, however. The plaintiffs (and perhaps Myriad) could choose to file a petition for writ of certiorari with the United States Supreme Court.<sup>8</sup> Because of the importance of both the substantive and procedural issues at stake, there is a

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3. Complaint at ¶¶ 7–26, Ass’n for Molecular Pathology v. USPTO (*Myriad*), 653 F.3d 1329 (S.D.N.Y. 2011). (No. 09-4515).

4. *Myriad*, 653 F.3d at 1344.

5. *See id.* at 1346–47 (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992)).

6. *Id.* at 1354.

7. U.S. Court of Appeals for the Federal Circuit, Disposition Sheet (Sept. 13, 2011), <http://www.genomicslawreport.com/wp-content/uploads/2011/09/Myriad-Dispositions.pdf>.

8. Andrew Pollack, *Despite Gene Patent Victory, Myriad Genetics Faces Challenges*, N.Y. TIMES (Aug. 24, 2011), <http://www.nytimes.com/2011/08/25/business/despite-gene-patent-victory-myriad-genetics-faces-challenges.html?pagewanted=all> (stating that plaintiffs are considering seeking Supreme Court review). The parties have ninety days from the date the petition for rehearing was denied to file a petition for writ of certiorari. *See* SUP. CT. R. 13.1, 13.3. The plaintiffs’ petition for rehearing was denied on September 13 and Myriad’s was denied on September 16, which means that their certiorari petitions would be due in mid-December. *Id.*

good chance the Supreme Court will weigh in on this case.<sup>9</sup> Yet, even if *Myriad* does not reach the Supreme Court, the decision has potentially far-reaching implications for patent declaratory judgment actions that warrant closer attention.

This Essay argues that the *Myriad* court misinterpreted and misapplied Supreme Court standing precedent, fashioned a test that is far too narrow, and wrongly concluded that Dr. Ostrer was the only plaintiff with standing to sue. The Essay begins with a brief explanation of standing in the patent declaratory judgment context, focusing on the Supreme Court's recent decision in *MedImmune, Inc. v. Genentech, Inc.*<sup>10</sup> It then provides a background of the *Myriad* case, highlighting those facts which were relevant to the court's justiciability determination.

The next Part of the Essay turns to the *Myriad* decision and discusses the court's flawed standing analysis. The *Myriad* court initially identified *MedImmune*'s "all the circumstances" test as the relevant standard,<sup>11</sup> but then proceeded to apply a bright-line rule instead. The court held that in order for an alleged infringer to have standing in patent declaratory judgment actions the plaintiff must demonstrate both (i) affirmative acts by the defendant, and (ii) meaningful preparation for infringing activity by the plaintiff. Applying this two-part test (instead of *MedImmune*'s holistic standard), the court erroneously concluded that Dr. Ostrer was the only plaintiff with standing.

After examining the opinion in *Myriad*, the Essay avers that the Federal Circuit has come full circle since *MedImmune* and is once again taking a formalistic approach to standing in patent declaratory judgment actions. In *MedImmune*, the Supreme Court continued its long-standing practice of adopting flexible legal standards that facilitate lawsuits brought by parties challenging patent validity.<sup>12</sup> The Supreme Court encourages such lawsuits because of the public benefit created when potentially bad patents – like those at issue in *Myriad* – are eradicated.<sup>13</sup> Rather than following the Supreme Court's lead, however, the Federal Circuit has made it *more* difficult for plaintiffs to challenge potentially invalid patents by heightening standing

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9. Kevin E. Noonan, *Deciphering the Patent Eligibility Message in Prometheus, Myriad, and Classen*, *Patent Docs* (Sept. 20, 2011), <http://www.patentdocs.org/2011/09/deciphering-the-patent-eligibility-message-in-prometheus-myriad-and-classen.html> (noting that Supreme Court may consider *Myriad*); Dennis Crouch, *Patentable Subject Matter and the Supreme Court Myriad Preview* (Aug. 3, 2011), <http://www.patentlyo.com/patent/2011/08/patentable-subject-matter.html> (discussing potential Supreme Court review of *Myriad*).

10. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007).

11. *Myriad*, 653 F.3d at 1342–43.

12. See, e.g., *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 345 (1971) (discussing line of Supreme Court cases that "eliminate[ed] obstacles to suit by those disposed to challenge the validity of a patent").

13. See, e.g., *id.* at 331 n.21 ("It is just as important that a good patent be ultimately upheld as that a bad one be definitively stricken."); *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969) (explaining the importance of validity challenges 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").

requirements. Thus, the standing test announced in *Myriad* not only violates the letter and spirit of *MedImmune*, but it also undermines the primary purpose of the patent system: promotion of innovation to benefit the public. Had standing been analyzed under *MedImmune*'s all the circumstances test, the *Myriad* court would have concluded that at least two other plaintiffs – Drs. Kazazian and Ganguly – also had standing to bring this case.

The Essay then argues that the *Myriad* court's reliance on *Lujan v. Defenders of Wildlife*<sup>14</sup> to support its narrow interpretation of the standing doctrine was misplaced because *Lujan* and *Myriad* are distinguishable. Most importantly, the plaintiffs in *Lujan* had not yet suffered an actual injury when they filed suit, but complained only of a possible future injury. This is in contradistinction to *Myriad* where Drs. Kazazian, Ganguly, and Ostrer had all suffered an actual injury as a result of defendant's conduct. Specifically, these three plaintiffs were forced by *Myriad* to cease BRCA testing, and they continued to suffer from those injuries at the time the lawsuit was filed.

The Essay concludes by underscoring the importance of declaratory judgment actions to our patent system. Under our current patent system, litigation is the primary gatekeeper of patent quality.<sup>15</sup> When patent owners choose not to sue for patent infringement, a declaratory judgment action is often the only way to challenge a patent's validity. If patents are successfully challenged, previously patented innovations may then be used and exploited by the public. The result is enhanced consumer choice, increased competition, and lower costs, all of which bring significant economic benefits to society.<sup>16</sup> Thus, courts should be moving toward legal standards that encourage, rather than dissuade, the filing of suits like *Myriad*. If given the opportunity, the Supreme Court should review *Myriad* in order to get the Federal Circuit back on course with respect to standing in patent declaratory judgment actions.

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14. *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992).

15. On September 16, 2011, President Obama signed into law the Leahy-Smith America Invents Act ("AIA"), the most significant amendment to our patent laws since 1952. Leahy-Smith America Invents Act, Pub. L. 112-029, 125 Stat. 284 (2011). Among other things, the AIA provides for certain post-grant review proceedings to challenge patent validity at the U.S. Patent and Trademark Office (USPTO), rather than in federal court. *Id.* § 6, 125 Stat. 284, 299–313. However, these post-grant review provisions do not become effective until September 16, 2012. *Id.* § 35, 125 Stat. 284, 341. Moreover, the ability to challenge patent validity through these administrative proceedings will be more limited than in federal court. *See, e.g., id.* § 6, 125 Stat. 284, 306 (providing that petition for post-grant review must be filed within nine months of the date of the grant of the patent or issuance of reissue patent). Thus, the extent to which these new procedures will impact patent validity challenges remains unclear.

16. *MedImmune, LLC v. PDL BioPharma, Inc.*, No. C 08-5590 JF (HRL), 2011 WL 61191, at \* 23 (N.D. Cal. Jan. 7, 2011) (noting that "the public benefits from [potentially invalid] patents being challenged").

## I.

## STANDING IN PATENT DECLARATORY JUDGMENT ACTIONS

*A. The Doctrine of Standing*

Article III, Section 2 of the U.S. Constitution limits the judicial power of the United States to “cases” and “controversies.”<sup>17</sup> Courts have long recognized that various justiciability doctrines derive from this provision, including the requirement that plaintiffs have standing to sue in federal court.<sup>18</sup> One purpose of the standing doctrine is to ensure that federal courts resolve only genuine controversies between adverse parties, since Article III prohibits the issuance of advisory opinions. Another more controversial role served by the standing doctrine is to maintain the separation of powers among the three branches of our federal government.<sup>19</sup>

The Supreme Court has established that “the irreducible constitutional minimum of standing contains three elements.”<sup>20</sup> First, the plaintiff must have suffered, or been threatened with, an injury-in-fact. An injury-in-fact is a concrete and particularized invasion of a legally protected interest; it must be “actual or imminent,” as opposed to “conjectural or hypothetical.”<sup>21</sup> Second, there must be a causal connection between the injury and the defendant’s conduct, meaning at least some portion of the plaintiff’s injury is “fairly traceable” to the defendant and not to a third party.<sup>22</sup> Lastly, it must be likely that the relief requested will redress the plaintiff’s injury.<sup>23</sup> At least one plaintiff must satisfy all three of these standing requirements to proceed in an Article III court in any type of suit,<sup>24</sup> including those brought under the Declaratory Judgment Act.<sup>25</sup>

*B. The Declaratory Judgment Act and Patents*

The Declaratory Judgment Act, enacted in 1934, provides that “[i]n a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other

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17. U.S. CONST. art. III, § 2.

18. *Summers v. Earth Island Inst.*, 129 S. Ct. 1142, 1148–49 (2009).

19. *See, e.g.*, Cass R. Sunstein, *What’s Standing After Lujan? Of Citizen Suits, “Injuries,” and Article III*, 91 MICH. L. REV. 163, 215–20 (1992).

20. *Lujan*, 504 U.S. at 560.

21. *Id.*

22. *Id.*

23. *Id.* at 561.

24. *Home v. Flores*, 129 S. Ct. 2579, 2592 (2009) (“[I]n all standing inquiries, the critical question is whether at least one petitioner has alleged such a personal stake in the outcome of the controversy as to warrant his invocation of federal-court jurisdiction.”) (internal quotations omitted).

25. The Supreme Court has also identified three prudential standing principles: (i) plaintiff generally may not assert rights of a third party; (ii) taxpayer plaintiff may not sue regarding a common grievance; and (iii) plaintiff’s claim must be within the “zone of interests” of the relevant statute. *See* Erwin Chemerinsky, *FEDERAL JURISDICTION* 61 (5th ed. 2007). Since these requirements were not at issue in *Myriad*, they will not be addressed further in this Essay.

legal relations of any interested party seeking such declaration. . . .”<sup>26</sup> The Act further provides that “[a]ny such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.”<sup>27</sup>

The Supreme Court consistently has held that the Declaratory Judgment Act is “procedural only.”<sup>28</sup> So, like most procedural devices, the Declaratory Judgment Act is trans-substantive, meaning it is available in any type of federal litigation regardless of the substantive nature of the underlying claims.<sup>29</sup> And, indeed, plaintiffs have invoked the Declaratory Judgment Act in a wide range of civil suits over the years, including cases involving First Amendment claims, contractual disputes, and antitrust matters, to name just a few.<sup>30</sup>

From the beginning, though, the Declaratory Judgment Act and patents have been closely linked. The legislative history makes clear that, in deciding to pass the Declaratory Judgment Act, Congress was particularly concerned with the rights of alleged patent infringers who had been threatened with suit, but were unable to ask a court to determine their rights.<sup>31</sup> Professor Edson R. Sunderland, a proponent of the Act, testified before Congress about the plight of alleged patent infringers:

I assert that I have a right to use a certain patent. What am I going to do about it? There is no way I can litigate my right, which I claim, to use that device, except by going ahead and using it, and you [the patent holder] can sit back as long as you please and let me run up just as high a bill of damages as you wish to have me run up, and then you may sue me for the damages, and I am ruined, having acted all the time in good faith and on my best judgment, but having no way in the world to find out whether I had a right to use that device or not.<sup>32</sup>

This scenario has been described alternatively as a patent owner’s use of a “scarecrow” patent,<sup>33</sup> or a patent owner’s engagement in “a *danse macabre*, brandishing a Damoclean threat with a sheathed sword.”<sup>34</sup>

Since its enactment, the Declaratory Judgment Act has played an important role in patent cases, both because it protects alleged infringers from this *danse macabre*, and because it allows alleged infringers to challenge invalid patents. When an alleged infringer sues for declaratory relief and proves that a patent is invalid, society as a whole benefits because that

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26. 28 U.S.C. § 2201 (2006).

27. *Id.*

28. *See, e.g., Skelly Oil Co. v. Phillips Petroleum Co.*, 339 U.S. 667, 671 (1950).

29. *See* H.R. Report No. 366, 112th Cong. (2011), to accompany H.R. 5623, 70th Cong. (1928).

30. *See, e.g., North Side Lumber Co. v. Block*, 474 U.S. 931 (1985); *Schneider v. Smith*, 390 U.S. 17 (1968); *Beacon Theatres, Inc. v. Westover*, 359 U.S. 500 (1959).

31. *See Declaratory Judgments: Hearings on H.R. 5623 Before a Subcomm. of the S. Comm. on the Judiciary*, 70th Cong. 16 (1928).

32. *Id.* at 35.

33. *Cardinal Chem. Co. v. Morton Int’l, Inc.*, 508 U.S. 83, 95–96 (1993).

34. *Id.*

previously protected intellectual property enters the public domain.<sup>35</sup> Indeed, the Supreme Court has long acknowledged the public function served by these patent declaratory judgment actions, and it consistently has adopted legal standards to facilitate such lawsuits. The most recent case in this jurisprudential line, *MedImmune v. Genentech*, addressed standing in patent declaratory judgment actions – the very question at issue in the *Myriad* case.

### C. *MedImmune v. Genentech*

Standing problems arise in all types of cases, but they are much more common in cases where the plaintiff seeks an anticipatory remedy – meaning an injunction or declaratory relief – rather than damages. Thus, the very nature of patent declaratory judgment actions, where the plaintiff seeks only a declaration of rights and not monetary damages, makes them fertile ground for standing challenges.

In patent declaratory relief suits, the alleged infringer sues the patent owner and seeks a declaration from the court that its products do not infringe the patent and/or that the patent at issue is invalid. Often the alleged infringer files its lawsuit *before* it has engaged in any activity that might be considered infringing. Under these circumstances, it can be quite difficult for plaintiffs to establish the first two elements of the standing inquiry: (1) an injury-in-fact (2) fairly traceable to the defendant patent owner's conduct.<sup>36</sup>

Since the Federal Circuit was created in 1982, it has struggled to define the parameters for standing in patent declaratory relief actions.<sup>37</sup> While the court has consistently held that “[t]he mere existence of a potentially adverse patent” is insufficient for standing, it is much less clear what circumstances permit alleged infringers to sue for declaratory relief.<sup>38</sup> Yet, when the Federal Circuit has attempted to provide more structure to the standing analysis, the Supreme Court has rebuked its efforts.

For many years, the Federal Circuit required alleged patent infringers to satisfy a two-part test to establish standing in a declaratory relief action: (i) the alleged infringer must have had a reasonable apprehension of suit at the time it filed the action; and (ii) the alleged infringer must have produced, or made meaningful preparations to produce, an allegedly infringing product.<sup>39</sup> The

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35. See *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 345 (1971) (holding that “all ideas in general circulation [should] be dedicated to the common good unless protected by a valid patent”).

36. *MedImmune, Inc. v. Genentech, Inc.* 549 U.S. 118, 128 n.8 (2007) (“The justiciability problem that arises, when the party seeking declaratory relief is himself preventing the complained-of injury from occurring, can be described in terms of standing (whether plaintiff is threatened with ‘imminent’ injury in fact ‘fairly . . . trace[able] to the challenged action of the defendant’”).

37. Standing in this context is often referred to as “declaratory judgment jurisdiction.” See, e.g., *Ass’n for Molecular Pathology v. USPTO (Myriad)*, 653 F.3d 1329, 1334 (2011).

38. See, e.g., *Capo, Inc. v. Dioptrics Med. Prods., Inc.*, 387 F.3d 1352, 1355 (Fed. Cir. 2004); *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993).

39. See, e.g., *Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 887 n.2 (Fed. Cir. 1992).



“reasonable apprehension” prong of this test required alleged infringers to show either an “explicit threat” or some other conduct by the patent holder that created an objectively reasonable apprehension of an infringement suit.<sup>40</sup> The “meaningful preparations” prong, on the other hand, focused on the alleged infringer’s conduct. This second prong was intended to preclude plaintiffs from seeking advisory opinions on whether “some merely contemplated activity” might be infringing.<sup>41</sup>

In *Gen-Probe v. Vysis*,<sup>42</sup> the Federal Circuit applied this two-part test in deciding whether a non-repudiating licensee could sue for declaratory relief. Although Gen-Probe’s production of an allegedly infringing product clearly satisfied the second prong, the court concluded that plaintiff lacked standing based on the reasonable apprehension portion of the test. The court reasoned that a non-repudiating licensee does not have a reasonable apprehension of suit because the patent holder *cannot* sue the licensee for infringement since the conduct is permitted under the license.<sup>43</sup> Thus, after *Gen-Probe*, in order for a licensee in good standing to seek declaratory relief, it needed to breach the license agreement (for example by ceasing royalty payments), so as to create a reasonable apprehension of suit.

The *Gen-Probe* rule reached the Supreme Court a few years later in *MedImmune v. Genentech*.<sup>44</sup> In an eight-to-one decision, the Court reversed the Federal Circuit and held that Article III’s standing requirement does not obligate a non-repudiating licensee to terminate or breach its license agreement before seeking a declaratory judgment.<sup>45</sup> The licensee should not have to “bet the farm, so to speak, by taking the violative action.”<sup>46</sup>

The Court instructed, instead, that the question of standing in declaratory judgment actions be determined on a case-by-case basis in light of all the facts. Specifically, the inquiry 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>47</sup> In other words, in deciding whether plaintiffs have established the elements of standing – injury-in-fact, causation, and redressability – the court must look to the totality of the circumstances.

While the parameters of this test will continue to evolve, there is consensus among courts, commentators, and litigants that the *MedImmune* standard for establishing standing is significantly more lenient and favorable to alleged patent infringers.<sup>48</sup> Indeed, when measured against this new standard,

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40. *BP Chems.*, 4 F.3d at 978.

41. *Arrowhead Indus. Water, Inc. v. Ecolchem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988).

42. *Gen-Probe v. Vysis*, 359 F.3d 1376 (Fed. Cir. 2004).

43. *Id.* at 1382.

44. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007).

45. *MedImmune*, 549 U.S. at 137.

46. *Id.* at 129.

47. *Id.* at 127.

48. *See, e.g., Prasco, LLC v. Medicis Pharmaceutical Corp.*, 537 F.3d 1329 (Fed. Cir. 2008);

the Supreme Court concluded in *MedImmune* itself that standing had been established.<sup>49</sup>

But *MedImmune* did more than announce a new standard for standing in declaratory relief actions. The Court also criticized the reasonable apprehension prong of the Federal Circuit's standing test, stating that it appeared to conflict with Supreme Court precedent.<sup>50</sup> Initially, the Federal Circuit responded to *MedImmune* by abandoning the reasonable apprehension prong, and stating that it would use the all the circumstances test instead.<sup>51</sup> More recently, however, the Federal Circuit has taken a different tack. In *Prasco, LLC v. Medicis Pharmaceutical Corp.*, for example, the court held that "proving a reasonable apprehension of suit is one of multiple ways that a declaratory judgment plaintiff can satisfy the more general all-the-circumstances test to establish that an action presents a justiciable Article III controversy."<sup>52</sup>

Similarly, in *Cat Tech LLC v. Tubemaster, Inc.*,<sup>53</sup> the Federal Circuit considered *MedImmune*'s impact on the meaningful preparations prong of its now-repudiated two-prong test. The court began by acknowledging that *MedImmune* altered the standing analysis in patent declaratory relief actions and made it easier for plaintiffs to establish an Article III case or controversy. Nevertheless, the court opined, the question of meaningful preparations remains an "important element" in the standing analysis.<sup>54</sup>

It is against this legal backdrop that the Federal Circuit decided that only one of the plaintiffs in *Myriad* had standing to sue for declaratory relief. The court's standing analysis will be taken up in Part III. In order to frame the issues, however, the next Part provides a brief factual and procedural background of the case.

## II.

### BACKGROUND OF MYRIAD GENETICS

#### A. Factual Background

Myriad, a for-profit healthcare company, studies the role of genes in human disease and develops diagnostic tests for diseases found to have a genetic basis. Myriad is the co-owner or exclusive licensee of several patents related to two human genes known as BRCA1 and BRCA2 (collectively

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Ronald A. Bleeker & Michael V. O'Shaughnessy, *One Year After MedImmune – The Impact on Patent Licensing and Negotiation*, 17 FED. CIR. B.J. 401, 435 (2008) (stating that "[t]he new standard . . . makes it easier for accused infringers to bring a declaratory judgment action").

49. *MedImmune*, 549 U.S. at 137.

50. *Id.* at 132 n.11.

51. *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1381 (Fed. Cir. 2007); *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, 482 F.3d 1330, 1339 (Fed. Cir. 2007).

52. *Prasco*, 537 F.3d at 1336.

53. *Cat Tech LLC v. Tubemaster, Inc.*, 528 F.3d 871 (Fed. Cir. 2008).

54. *Id.* at 880.

“BRCA”). Certain mutations in the BRCA genes correlate with an increased risk of breast and ovarian cancer.<sup>55</sup>

The University of Pennsylvania Genetic Diagnostic Laboratory (“GDL”) is a state-of-the art facility that provides DNA-based diagnostic testing for a variety of genetic diseases. Since 1995, Arupa Ganguly, Ph.D. and Haig Kazazian, Jr., M.D. have served as the co-directors of the GDL.<sup>56</sup> In the late 1990s, Drs. Ganguly and Kazazian were researching BRCA genes and providing BRCA testing services to patients. During this time, Dr. Kazazian also received and conducted diagnostic tests on patient samples from other doctors, including Harry Ostrer, M.D., Director of the Genetics Laboratory at the NYU Langone Medical Center.<sup>57</sup>

Beginning in 1998, Drs. Ganguly and Kazazian received a series of letters from Myriad. The first letter, dated May 29, 1998, informed the doctors of Myriad’s patents and offered an extremely narrow license.<sup>58</sup> Around the same time, Dr. Ostrer received a similar letter. The letter to Dr. Ostrer stated that he was “either currently providing diagnostic testing services for BRCA1 or [was] interested in initiating such a service.”<sup>59</sup> The letter went on to offer Dr. Ostrer a license that, like the one offered to Drs. Ganguly and Kazazian, was quite limited in scope.<sup>60</sup>

On August 26, 1998, Drs. Ganguly and Kazazian received a second letter from Myriad. This letter, sent by Myriad’s attorney, asserted that Dr. Kazazian’s commercial testing activities infringed the patents-in-suit and demanded that he cease “all infringing activity.”<sup>61</sup> Soon thereafter, Myriad sued the University of Pennsylvania for patent infringement.<sup>62</sup> The suit was dismissed without prejudice because the University agreed to cease the infringing activity.

In June and September of 1999, however, the General Counsel at the University of Pennsylvania received two more cease-and-desist letters from Myriad. The letters claimed that Dr. Kazazian was continuing to conduct infringing tests and demanded that these activities cease.<sup>63</sup> Because it feared that Myriad would reinstitute the infringement suit, the University compelled Drs. Ganguly and Kazazian to cease all BRCA testing for either research or

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55. Complaint at ¶¶ 1–4, *Ass’n for Molecular Pathology v. USPTO (Myriad)*, 653 F.3d 1329 (S.D.N.Y. 2011). (No. 09-4515).

56. *Ass’n for Molecular Pathology v. USPTO (Myriad)*, 669 F. Supp. 2d 365, 372 (S.D.N.Y. 2009) (denying defendants motion to dismiss).

57. Declaration of Harry Ostrer, M.D., 1:09-cv-04515-RWS (Aug. 26, 2009) (“Ostrer Decl.”), ¶ 5.

58. Declaration of Arupa Ganguly, PhD, 1:09-cv-04515-RWS, Doc. 85 (Aug. 18, 2009) (“Ganguly Decl.”), ¶ 5, Ex. 2.

59. Ostrer Decl., ¶ 7, Ex. 2.

60. *Id.*

61. Ganguly Decl., ¶ 6, Ex. 3.

62. *Myriad Genetics v. Univ. of Penn.*, Case No. 2:98-cv-829 (D. Utah 1998).

63. Ganguly Decl., ¶¶ 7, 9 and Exs. 4, 6.

clinical purposes.<sup>64</sup> The GDL also was precluded from accepting samples from other institutions or individual doctors because Myriad contended that such activities were infringing.<sup>65</sup>

In addition to the activities outlined above regarding the GDL, Myriad has engaged in other threatening conduct with respect to its BRCA patents. Myriad has sent cease-and-desist letters to other institutions,<sup>66</sup> it has informed the director of the Yale DNA Diagnostics Laboratory that certain contemplated testing would infringe Myriad's patents,<sup>67</sup> and it has filed lawsuits regarding its BRCA patents.<sup>68</sup> It is widely understood among those in the field of genetics research that Myriad will vigorously enforce its rights with respect to the BRCA patents.<sup>69</sup>

No doubt Myriad's pattern of behavior has had a "chilling effect" on the industry.<sup>70</sup> In light of GDL's experience, Myriad's competitors have decided not to offer BRCA-related testing services.<sup>71</sup> Yet many have indicated that they would consider beginning (or, in the case of GDL, resuming) BRCA testing if Myriad's patents were to be invalidated. Dr. Ostrer, for example, stated that "[i]f the patents were invalidated, I would immediately take steps to begin clinical sequencing of the BRCA1 and BRCA2 genes."<sup>72</sup> Though a bit more tentative, Dr. Ganguly also indicated her earnest desire to "immediately consider resuming BRCA testing in [her] laboratory."<sup>73</sup> Significantly, both Drs. Ganguly and Ostrer declare that they have the capability and resources to begin BRCA testing immediately.

### B. Procedural Background

On May 12, 2009, twenty plaintiffs represented by the ACLU and the Public Patent Foundation filed a declaratory judgment action in the U.S. District Court for the Southern District of New York against Myriad Genetics.<sup>74</sup> Plaintiffs included various medical organizations, genetics researchers, clinicians, and cancer patients. Among other things, plaintiffs sought a

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64. *Id.*, ¶ 10.

65. Ostrer Decl., ¶ 5.

66. Order Denying Mot. to Dismiss, 31–32, *Ass'n for Molecular Pathology v. USPTO (Myriad)*, 653 F.3d 1329 (S.D.N.Y. 2011) (No. 09-4515).

67. *Id.* at 32–33.

68. *Myriad Genetics v. Oncormed*, Case No. 2:98-cv-35 (D. Utah 1998); *Myriad Genetics v. Oncormed*, Case No. 2:97-cv-922 (D. Utah 1997).

69. Order Denying Mot. to Dismiss, 32–33, *Ass'n for Molecular Pathology v. USPTO (Myriad)*, 653 F.3d 1329 (S.D.N.Y. 2011) (No. 09-4515).

70. Ostrer Decl., ¶ 6.

71. *Id.*

72. *Id.*, ¶ 8.

73. Ganguly Decl., ¶ 14.

74. Plaintiffs also sued the United States Patent and Trademark Office asserting certain constitutional claims. *See* Complaint, ¶¶ 102–03, *Ass'n for Molecular Pathology v. USPTO (Myriad)*, 653 F.3d 1329 (S.D.N.Y. 2011) (No. 09-4515). Those claims are not addressed in this Essay, however, because they were dismissed by the district court and are not at issue on appeal.

declaration that certain claims of Myriad's patents related to the BRCA gene were invalid because human genes, as products of nature, are not patentable subject matter.<sup>75</sup>

Defendants moved to dismiss the case on the ground that, *inter alia*, plaintiffs lacked standing because Myriad had failed to take sufficient affirmative acts to create a justiciable controversy. On November 1, 2009, the district court issued an order denying defendants' motion to dismiss. The court held that, under the *MedImmune* test, all twenty plaintiffs had alleged sufficient facts to support standing. Importantly, in reaching this decision, the court held that although patent holders must take some affirmative acts to create an Article III case or controversy, there is no "general rule that [those] actions [must be] directed towards the plaintiff" as opposed to a third party.<sup>76</sup>

Having denied defendants' motion to dismiss, the court turned to the parties' cross-motions for summary judgment. On March 29, 2010, the court issued a 156-page opinion that granted summary judgment to plaintiffs with respect to their invalidity claims. The court declared, specifically, that the patents were invalid because they are "directed to a law of nature."<sup>77</sup>

Myriad appealed the decision to the Federal Circuit, and approximately forty amicus briefs were filed with the court. The amici included medical and health organizations, pharmaceutical companies, intellectual property associations, and academics. Additionally, the United States Department of Justice ("DOJ") filed an amicus brief arguing that some types of genes are patentable, while others are not.<sup>78</sup> The DOJ's role in the *Myriad* case is remarkable for two reasons. First, the DOJ's position contradicts the broader view of gene patentability long held by other arms of the federal government, namely the Patent and Trademark Office and the National Institutes of Health.<sup>79</sup> Second, in an unprecedented move, the acting Solicitor General of the United States, Neal Katyal, wrote to the Federal Circuit and requested that the *Myriad* oral argument be scheduled for a certain date so that he could appear personally to argue on behalf of the United States.<sup>80</sup>

Per Mr. Katyal's request, the Federal Circuit heard oral arguments in *Myriad* on April 4, 2011. The panel included Judges Lourie, Bryson, and Moore. Because scholars, amici, and the media had fixed on the substantive

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75. *Id.* at ¶ 102.

76. Order Denying Mot. to Dismiss, 55 n.14, Ass'n for Molecular Pathology v. USPTO (*Myriad*), 653 F.3d 1329 (S.D.N.Y. 2011) (No. 09-4515).

77. Ass'n for Molecular Pathology v. USPTO (*Myriad*), 702 F. Supp. 2d 181, 237 (S.D.N.Y. 2010) (granting plaintiffs' motion for summary judgment).

78. Brief for the United States as Amicus Curiae in Support of Neither Party, Case No. 2010-1406 (Oct. 29, 2010), <http://patentdocs.typepad.com/files/united-states-amicus-brief-1.pdf>.

79. See, e.g., Tuma Ray, *U.S. DOJ Argues Against Patenting Isolated Genes, But USPTO Will Maintain Status Quo* (Nov. 3, 2010), <http://www.genomeweb.com/dxpgx/us-doj-argues-against-patenting-isolated-genes-uspto-will-maintain-status-quo?page=show>.

80. Letter from Neal Katyal to Jan Horably, Clerk of the United States Court of Appeals for the Federal Circuit (Feb. 10, 2011), <http://patentdocs.typepad.com/files/katyal-letter.pdf>.

issues in the case, some were surprised that the panel devoted significant time to questions concerning justiciability.<sup>81</sup> Indeed, when plaintiffs' counsel opened his argument by addressing the merits of the case, Judge Moore asked him to begin with standing instead.<sup>82</sup> The panel then proceeded to ask the parties numerous questions about standing, particularly the impact of the Supreme Court's decision in *Lujan*. Thus, after oral argument, it was unclear whether the court would reach the merits of the case or whether it would dismiss the case on justiciability grounds.

In an interesting twist, on July 27, 2011, Myriad filed a letter "to bring to the Court's attention events occurring since the April 4 [2011] oral argument that could have a bearing on the threshold jurisdictional issue presented in [the] case."<sup>83</sup> Myriad's letter explained that Dr. Ostrer was leaving his position at NYU to join the Department of Genetics at Albert Einstein College of Medicine, which, unlike NYU, "does not offer, and is not qualified to offer, clinical genetic testing."<sup>84</sup> Accordingly, Myriad argued, Dr. Ostrer no longer has the "capability and desire" to immediately begin sequencing the BRCA genes, and thus has no standing to sue.

Just two days after Myriad filed this letter, the Federal Circuit issued its much-anticipated decision in *Myriad*. In a divided opinion authored by Judge Lourie, the Federal Circuit reversed the lower court's invalidity determination and held that most of Myriad's BRCA-related gene patents claim subject matter eligible for patent protection.<sup>85</sup> Before reaching this decision on the merits, the court considered the threshold justiciability question and concluded that only one of the twenty plaintiffs, Dr. Ostrer, had standing to sue Myriad.<sup>86</sup> The court's opinion is conspicuously silent about Dr. Ostrer's departure from NYU, however, suggesting that the letter failed to reach the panel before the decision was issued.

At the end of August, both Myriad and the plaintiffs filed petitions for panel rehearing. Unsurprisingly, Myriad's petition challenged the court's standing decision for the reasons laid out in its July 27th letter.<sup>87</sup> And while the

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81. See, e.g., John Conley & Dan Vorhaus, *What We Learned from the Myriad Oral Argument*, GENOMICS LAW REPORT (Apr. 5, 2011), <http://www.genomicslawreport.com/index.php/2011/04/05/what-we-learned-from-myriad-oral-argument/>.

82. Oral Argument at 26:21, *Ass'n for Molecular Pathology v. USPTO (Myriad)*, 653 F.3d 1329 (2011) (No. 2010-1406), available at <http://www.cafc.uscourts.gov/oral-argument-recordings/2010-1406/all>. ("Mr. Hansen, would you mind starting with standing first?")

83. Letter from Gregory A. Castanias to Jan Horbaly, Clerk of the United States Court of Appeals for the Federal Circuit (July 27, 2011), <http://patentdocs.typepad.com/files/myriad-letter.pdf>.

84. *Id.*

85. *Ass'n for Molecular Pathology v. USPTO (Myriad)*, 653 F.3d 1329, 1354 (2011). On the merits, the Federal Circuit reversed the district court holding that Myriad's claims directed to isolated genes recite patentable subject matter. *Id.* at 1334. However, the Federal Circuit affirmed the lower court's invalidity determination as to some of Myriad's method claims. *Id.*

86. *Id.* at 1344.

87. Defendants-Appellants' Petition for Panel Rehearing, Case No. 2010-1406 (Fed. Cir. Aug. 29, 2011), <http://www.patents4life.com/wp-content/uploads/2011/09/Myriad-Petition-for-Panel->

plaintiffs' petition focused primarily on the merits of the case, they too asked the panel to reconsider the question of standing.<sup>88</sup> On September 13, 2011, the panel denied the plaintiffs' petition for rehearing, but asked plaintiffs to file a response to Myriad's petition regarding Dr. Ostrer's recent change of circumstances.<sup>89</sup> Plaintiffs responded with Dr. Ostrer's supplemental declaration which made clear that Ostrer's departure from NYU would not change any circumstances relevant to the standing analysis.<sup>90</sup> Accordingly, the Federal Circuit denied Myriad's petition for panel rehearing as well.<sup>91</sup>

The remainder of this Essay critically examines the Federal Circuit's standing analysis in the *Myriad* case and concludes that it should be reconsidered because it contradicts Supreme Court precedent and is unsound from a policy perspective. The Essay argues that a broader interpretation of the standing doctrine is warranted – not just in the *Myriad* case, but in patent declaratory judgment actions across the board.

### III.

#### THE PANEL'S DECISION IN *MYRIAD*

##### A. *The Federal Circuit's Post-MedImmune Jurisprudence*

In recent years, the Supreme Court has eschewed bright-line rules regarding the patent system.<sup>92</sup> For example, the Court eliminated the presumption that a patent owner who prevailed on infringement was entitled to a permanent injunction;<sup>93</sup> it rejected the motivation-to-combine test for

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Rehearing.pdf.

88. Plaintiffs-Appellees' Petition for Panel Rehearing, No. 2010-1406 (Fed. Cir. Aug. 25 2011). Plaintiffs argued that the American College of Medical Genetics has organizational standing on behalf of its member, Dr. Ostrer. *Id.* at 11–12. They additionally contended that plaintiff Ellen Matloff, the Director of the Cancer Genetic Counseling Shared Resource at the Yale Cancer Center, has standing because she was informed by Myriad that certain tests Yale geneticists were considering undertaking would violate Myriad's patents. *Id.* at 12. Although both of these arguments appear to have merit, it is beyond the scope of this Essay to address them since other plaintiffs plainly satisfied the requirements of standing under *MedImmune*.

89. U.S. Court of Appeals for the Federal Circuit, Disposition Sheet (Sept. 12, 2011), <http://www.genomicslawreport.com/wp-content/uploads/2011/09/Myriad-Dispositions.pdf>.

90. Plaintiffs-Appellees' Answer to Defendants-Appellants' Petition for Panel Rehearing, Case No. 2010-1406 (Fed. Cir. Sept. 15, 2011).

91. U.S. Court of Appeals for the Federal Circuit, Disposition Sheet (Sept. 12, 2011), <http://www.genomicslawreport.com/wp-content/uploads/2011/09/Myriad-Dispositions.pdf>. It is true that events occurring after the onset of litigation may end the controversy between the parties. *See e.g.*, *Lewis v. Continental Bank Corp.*, 494 U.S. 472, 477–78 (1990); *Golden v. Zwickler*, 394 U.S. 103, 108 (1969). The question, therefore, was whether the change of circumstances that Dr. Ostrer experienced mooted the controversy. The *Myriad* panel clearly believed that it did not.

92. Megan M. La Belle, *Patent Litigation, Personal Jurisdiction, and the Public Good*, 18 GEO. MASON L. REV. 43 (2010); Peter Lee, *Patent Law and the Two Cultures*, 120 YALE L.J. 2 (2010) (arguing that the Federal Circuit uses formalistic rules to mitigate the burden on lay judges and juries grappling with unfamiliar technologies in patent cases).

93. *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388 (2006).

obviousness;<sup>94</sup> and it held that the “machine-or-transformation” test was not the sole test for patentable subject matter.<sup>95</sup> In a similar vein, the *MedImmune* Court rejected the Federal Circuit’s two-prong test for standing in patent declaratory judgment actions and mandated that courts consider all the circumstances instead.<sup>96</sup>

Since *MedImmune*, the Federal Circuit repeatedly has stated that it now applies the all the circumstances test, and that it should be easier for plaintiffs seeking declaratory relief to establish standing.<sup>97</sup> Yet a closer look at post-*MedImmune* jurisprudence suggests something different: the Federal Circuit is reverting to a bright-line test. In *Prasco, LLC v. Medicis Pharmaceutical Corp.*, for instance, the court breathed new life into the reasonable apprehension of suit inquiry holding that it is “one of multiple ways that a declaratory judgment plaintiff can satisfy the more general all-the-circumstances test to establish that an action presents a justiciable Article III controversy.”<sup>98</sup>

An even more striking example of this regression is *Cat Tech LLC v. Tubemaster, Inc.*, in which the Federal Circuit held that, after *MedImmune*, the meaningful preparations prong of its former test remains an “important element” in the standing analysis.<sup>99</sup> The court did not stop there, however, as it went on to explain:

If a declaratory judgment plaintiff has not taken significant, concrete steps to conduct infringing activity, the dispute is neither “immediate” nor “real” and *the requirements for justiciability have not been met.*<sup>100</sup>

Thus, in actuality, the court held that the question of meaningful preparations is not merely an “important element” of standing, but a requirement. Simply put, the court appears to have reinstated the “meaningful preparations” prong of the standing test.

The *Myriad* case presented the Federal Circuit with an opportunity to reverse this retrogressive trend. Disappointingly, though, the *Myriad* panel did just the opposite: it has returned the law of standing in patent declaratory judgment actions to its status before *MedImmune*.

### B. *The Myriad Court’s Standing Analysis*

In *Myriad*, the court began its standing analysis by stating that there is no bright-line rule for standing.<sup>101</sup> The court explained that the question, instead,

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94. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

95. *Bilski v. Kappos*, 130 S. Ct. 3218, 3222 (2009).

96. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007).

97. *See, e.g., Prasco, LLC v. Medicis Pharmaceutical Corp.*, 537 F.3d 1329, 1336 (Fed. Cir. 2008); *Cat Tech, LLC v. Tubemaster, Inc.*, 528 F.3d 871, 880 (Fed. Cir. 2008).

98. *Prasco*, 537 F.3d at 1336.

99. *Cat Tech*, 528 F.3d at 880.

100. *Id.* (emphasis added).

101. *Ass’n for Molecular Pathology v. USPTO (Myriad)*, 653 F.3d 1329, 1342 (2011).



is “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>102</sup> The *Myriad* court further acknowledged that *MedImmune* relaxed the Federal Circuit’s prior test for standing in patent declaratory relief suits.<sup>103</sup>

It therefore appeared at the outset that *Myriad*’s standing analysis would be faithful to *MedImmune*; yet, that supposition was not borne out by the rest of the opinion. Despite these pronouncements about the flexible and lenient *MedImmune* standard, in the end the court applied a rigid two-part test. As the court explained:

[T]o establish an injury in fact traceable to the patentee, a declaratory judgment plaintiff must allege both (1) an affirmative act by the patentee related to the enforcement of his patent rights, and (2) meaningful preparation to conduct potentially infringing activity.<sup>104</sup>

This test is strikingly similar to the one utilized by the Federal Circuit before *MedImmune*.<sup>105</sup> In fact, the second prong is identical, and the first focuses on the patentee’s conduct just like the earlier “reasonable apprehension of suit” prong.<sup>106</sup> 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.

Applying this bright-line test, the court quickly narrowed the group of twenty prospective plaintiffs to only three: Drs. Kazazian, Ganguly, and Ostrer. In the court’s view, these were the only plaintiffs who could allege “affirmative patent enforcement actions directed at them by Myriad,” namely the cease-and-desist letters and proposed licensing agreements sent by Myriad in the late 1990s.<sup>107</sup> That is, only Drs. Kazazian, Ganguly, and Ostrer could satisfy the first prong of the Federal Circuit’s standing test.

With respect to the second prong, however, the court determined that only Dr. Ostrer had made “meaningful preparation to conduct potentially infringing activity.”<sup>108</sup> Although Drs. Kazazian, Ganguly, and Ostrer all declared that they were capable of performing the BRCA genetic testing, only Dr. Ostrer said

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102. *Id.* at 1343.

103. *Id.* at 1344.

104. *Id.* (internal citations omitted).

105. *See, e.g.,* *Teva Pharmaceuticals USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1335 (Fed. Cir. 2005) (describing pre-*MedImmune* test as “requir[ing] two core elements: (1) acts of defendant indicating an intent to enforce its patent; and (2) acts of plaintiff that might subject it or its customers to suit for patent infringement.”).

106. *See* *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988) (holding that reasonable apprehension prong of the pre-*MedImmune* test is satisfied only if defendant’s conduct indicates an intent to enforce its patent).

107. *Ass’n for Molecular Pathology v. USPTO (Myriad)*, 653 F.3d 1329, 1344 (2011).

108. *Id.*

definitively that he would resume that testing if the patents in suit were invalidated. Drs. Kazazian and Ganguly alleged only that they would “consider” resuming BRCA testing, and the *Myriad* court concluded that such “‘some day intentions’ are insufficient to support an actual or imminent injury for standing” under *Lujan*.<sup>109</sup> For those reasons, the Federal Circuit reversed the district court’s broad holding with respect to standing and held that Dr. Ostrer was the only plaintiff who could maintain a declaratory judgment action against Myriad.

Since only one plaintiff has to have standing in order for a case to be justiciable,<sup>110</sup> then why does it matter if the court’s reasoning was flawed or if there were other plaintiffs who also had standing to sue Myriad? The reasons are twofold: first and foremost, the panel’s decision creates bad precedent for future patent declaratory relief actions;<sup>111</sup> and second, Myriad may raise the standing issue in a petition for writ of certiorari to the United States Supreme Court. The next Part of the Essay aims to show that the Federal Circuit improperly analyzed justiciability in *Myriad*, and urges the Supreme Court to correct this faulty application of the standing doctrine if presented with the opportunity.

#### IV.

##### MYRIAD: A PROPER JUSTICIABILITY ANALYSIS

###### A. *MedImmune’s All the Circumstances Test Governs Standing in Patent Declaratory Judgment Actions*

At the beginning of its opinion, the *Myriad* panel pronounced that *MedImmune’s* all the circumstances test governs the standing analysis in patent declaratory relief actions. The court then held that, in order to satisfy this test, plaintiffs must demonstrate two things: (1) an affirmative act by the patentee related to the enforcement of the patent rights; and (2) meaningful preparation by the plaintiff to conduct potentially infringing activity.<sup>112</sup> In other words, the *Myriad* panel gave lip service to the *MedImmune* standard, but then applied precisely the type of bright line rule eschewed by the Supreme Court just a few years ago.

*MedImmune* provides that the question of standing depends on “whether

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109. *Id.* at 1346.

110. *Massachusetts v. E.P.A.*, 549 U.S. 497, 518 (2007) (“Only one of the petitioners needs to have standing to permit us to consider the petition for review.”).

111. Indeed, the impact of *Myriad* is quickly becoming clear. Two published district court opinions have considered *Myriad* in addressing the question of standing in patent declaratory judgment cases. *See Proofpoint, Inc. v. Innova Patent Licensing, LLC*, 2011 WL 4915847, \*1 (N.D. Cal. Oct. 17, 2011); *JIA Jewelry Importers of Am., Inc. v. Pandora Jewelry, LLC*, 2011 WL 4566118, \*1 (D. Md. Sept. 29, 2011). Unsurprisingly, both courts held that plaintiffs failed to satisfy *Myriad’s* bright-line rule, and therefore dismissed their declaratory judgment actions on justiciability grounds.

112. *Myriad*, 653 F.3d at 1343.

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>113</sup> The Supreme Court intentionally crafted this test so that it would be easier for alleged infringers to demonstrate standing.<sup>114</sup> Why? Because when private parties invalidate bad patents the public as a whole benefits from robust competition, increased consumer choice, and lower prices.<sup>115</sup> And often, declaratory relief is the only channel available for challenging potentially invalid patents.

While patent litigation certainly implicates private interests, the public is the primary intended beneficiary of our patent system. Courts, including the Federal Circuit, have recognized this for years.<sup>116</sup> Indeed, Judge Moore, one of the panelists in *Myriad*, stated the following in a recent case:

In a patent case, especially where a patent has been invalidated, the public interest is overwhelming . . . [P]atents are public rather than private rights . . . .<sup>117</sup>

Yet, in the context of patent declaratory judgment actions, the Federal Circuit consistently seems more concerned with the plight of patent owners than with the threat that potentially bad patents pose to the public.<sup>118</sup> At the oral argument in *Myriad*, Judge Moore expressed serious skepticism about the breadth of the district court’s standing analysis. Judge Moore was particularly troubled by the court’s decision to afford standing to the patent plaintiffs:

[T]o reach individual people who want cheaper access to products

113. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007).

114. *See, e.g., Myriad*, 653 F.3d at 1344 (“*MedImmune* relaxed this court’s more restrictive ‘reasonable apprehension of suit’ test for declaratory judgment jurisdiction.”); *Micron Tech., Inc. v. Mosaid Techs., Inc.*, 518 F.3d 897, 902 (Fed. Cir. 2008) (“[T]he now more lenient legal standard facilitates or enhances the availability of declaratory judgment jurisdiction in patent cases.”).

115. *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969) (explaining the importance of validity challenges 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”); *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 816 (1945) (“The far-reaching social and economic consequences of a patent . . . 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.”).

116. *See, e.g., United States v. Masonite Corp.*, 316 U.S. 265, 278 (1942) (“[T]he promotion of the progress of science and the useful arts is the main object; reward of inventors is secondary and merely a means to that end.”) (internal quotation marks omitted); *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005) (“The basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility.”) (quoting *Brenner v. Manson*, 383 U.S. 519, 535–36 (1966)); *Frischer & Co. v. Bakelite Corp.*, 39 F.2d 247, 267 (C.C.P.A. 1930) (“The essential purpose of our patent system is to benefit the public by encouraging the genius and wit of men to develop new and useful things for mankind’s benefit and enjoyment . . . .”).

117. *Ohio Willow Wood Co. v. Thermo-Ply, Inc.*, 629 F.3d 1374, 1376 (2011) (Moore, J., concurring).

118. *See La Belle*, *supra* note 92, at 47–48 (arguing that the Federal Circuit has consistently adopted personal jurisdiction standards that make it more difficult for alleged infringers to sue for declaratory relief).

seems to me . . . so broad as to allow any person that wants a cheaper product in any case to sue. . . . Apple and Microsoft and everybody else would be sued by every consumer out there.<sup>119</sup>

And she seemed equally unconvinced by plaintiffs' argument that potential competitors should have standing to sue *Myriad*:

Do you not recognize the profound impact that would have on our patent system if anyone who was ready, willing, and able to compete tomorrow could bring a [declaratory judgment] action against the patentee in any forum of their choosing without any affirmative act directed at all towards them by the patentee?<sup>120</sup>

The question of whether potential competitors and consumers should have standing to seek declaratory relief in patent cases is complex and provocative. It was unnecessary for the *Myriad* court to resolve this question since there were other plaintiffs – namely Drs. Kazazian, Ganguly, and Ostrer – whose arguments for standing were stronger. But this issue is sure to arise in future cases, especially now that public interest organizations like the ACLU and the Public Patent Foundation are using declaratory relief to challenge potentially invalid patents.<sup>121</sup> It is true that allowing such suits could negatively impact patent owners as Judge Moore suggested at the *Myriad* oral argument. What courts must remember, however, is that it is public rights – not private rights – that are of paramount importance in our patent system. A patent is a private privilege; yet it is a privilege that is “conditioned by a public purpose.”<sup>122</sup>

It was this public purpose – as well as a desire to improve accuracy and bring patent jurisprudence in line with other areas of the law – that led the Supreme Court to mandate a holistic approach to standing in patent declaratory judgment actions. Yet, just a few years after *MedImmune*, the Federal Circuit's inclination toward formalism has once again caused it to adopt a bright line rule. Had the Federal Circuit analyzed standing in *Myriad* under the proper standard, the result surely would have been different.

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119. Oral Argument at 9:07, *Ass'n for Molecular Pathology v. USPTO (Myriad)*, 653 F.3d 1329 (2011) (No. 2010-1406), available at <http://www.ca9.uscourts.gov/oral-argument-recordings/2010-1406/all>.

120. *Id.* at 31:22.

121. The Public Patent Foundation is a non-profit legal services organization “whose mission is to protect freedom in the patent system.” PUBLIC PATENT FOUNDATION, *About PUBPAT*, available at <http://www.pubpat.org/> (last visited October 22, 2011). In addition to serving as co-counsel with the ACLU in *Myriad*, the Public Patent Foundation also has filed a declaratory judgment action in the Southern District of New York on behalf of sixty family farmers, seed businesses, and organic agricultural organizations against Monsanto Company to challenge the validity of Monsanto's patents covering genetically-modified seed. See First Amended Complaint, Organic Seed Growers and Trade Association, No. 11-2163 (S.D.N.Y. June 1, 2011), available at <http://www.pubpat.org/assets/files/seed/OSGATA-v-Monsanto-Complaint.pdf>. Monsanto has moved to dismiss the case arguing that, under the bright-line test announced in *Myriad*, plaintiffs lack standing to sue. See Reply Memorandum in Support of Monsanto's Motion to Dismiss for Lack of Subject-Matter Jurisdiction at 1, No. 11-2163 (S.D.N.Y. Aug. 26, 2011).

122. *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 344 (1971).

*B. Drs. Ganguly, Kazazian, and Ostrer All Have Standing Under  
MedImmune's All the Circumstances Test*

While it is beyond the scope of this Essay to discuss all of the facts relevant to standing, this Part highlights the most significant evidence, and demonstrates that Drs. Ganguly, Kazazian, and Ostrer all had standing to sue Myriad. First, Drs. Ganguly, Kazazian, and Ostrer were all engaged in BRCA-related activity in the late 1990s, and all three were forced to cease that activity due to Myriad's conduct. After offering Drs. Ganguly, Kazazian, and Ostrer licenses that were far too narrow, Myriad sent several cease-and-desist letters and then sued the University of Pennsylvania for patent infringement. As a consequence, Drs. Ganguly and Kazazian stopped all BRCA activity, and Dr. Ostrer stopped providing samples to the GDL for testing.

Second, there is significant evidence in the record that it is widely understood in the industry that Myriad vigorously enforces its BRCA patents.<sup>123</sup> Myriad has sent threatening letters to competitors other than the University of Pennsylvania. It has also refused to allow certain laboratories, like the Yale DNA Diagnostics Laboratory, to undertake BRCA testing.<sup>124</sup> This type of conduct is an important consideration in the standing analysis.<sup>125</sup>

Finally, Myriad has refused to provide plaintiffs with a covenant not to sue. As the Federal Circuit recently held, "a patentee's refusal to give assurances that it will not enforce its patent is relevant to the determination of declaratory judgment standing."<sup>126</sup> And at oral argument Judge Moore acknowledged that the refusal to provide a covenant not to sue is particularly germane in this case "where there has been an actual threat [and] an actual modification of behavior."<sup>127</sup>

Despite this wealth of evidence, the Federal Circuit concluded that Drs. Ganguly and Kazazian lacked standing because they did not allege a controversy of sufficient reality and immediacy as required by *Lujan v. Defenders of Wildlife*.<sup>128</sup> Following a brief synopsis of the Supreme Court's decision in *Lujan*, the Essay argues that the *Myriad* panel misinterpreted *Lujan* and failed to recognize the factual differences between the two cases.

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123. Order Denying Mot. to Dismiss, 32–33, *Ass'n for Molecular Pathology v. USPTO (Myriad)*, 653 F.3d 1329 (S.D.N.Y. 2011) (No. 09-4515).

124. *Id.* at 31–32.

125. *Prasco, LLC v. Medicis Pharmaceutical Corp.*, 537 F.3d 1336, 1341 (Fed. Cir. 2008) ("Prior litigious conduct is one circumstance to be considered in assessing whether the totality of circumstances creates an actual controversy.").

126. *Arris Group, Inc. v. British Telecommunications PLC*, 639 F.3d 1368, 1381 (Fed. Cir. 2011) (internal quotations and brackets omitted).

127. Oral Argument at 6:09, *Ass'n for Molecular Pathology v. USPTO (Myriad)*, 653 F.3d 1329 (2011) (No. 2010-1406), available at <http://www.cafc.uscourts.gov/oral-argument-recordings/2010-1406/all>.

128. *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992).

C. *Lujan Does Not Bar Standing In Myriad Genetics*

1. *The Lujan Decision*

*Lujan v. Defenders of Wildlife*, one of the seminal Supreme Court cases on standing, arose under section 7(a) of the Endangered Species Act (“ESA”) of 1973.<sup>129</sup> That section of the Act requires federal agencies to consult with the Secretary of the Interior whenever they propose an action that may affect endangered or threatened species. In 1978, the Secretary of the Interior promulgated a regulation stating that the obligations imposed by section 7(a) extend to actions taken abroad. A year later, however, Interior reversed its position and revised the regulation to require consultation only for actions taken in the United States or on the high seas.<sup>130</sup>

In *Lujan*, the Defenders of Wildlife and two other environmental organizations sued Manuel Lujan, the Secretary of the Interior, challenging the revised regulation. Plaintiffs sued pursuant to the “citizen suit” provision of the ESA. That provision allows any person to “commence a civil suit on his own behalf to enjoin any person, including the United States and any other governmental instrumentality or agency . . . who is alleged to be in violation of any provision of this chapter.”<sup>131</sup>

Plaintiffs sought a declaratory judgment that the revised regulation misinterprets section 7(a), and an injunction that would require Interior to restore the original interpretation of the statute. Lujan moved to dismiss on standing grounds. In support of standing, plaintiffs submitted affidavits from Joyce Kelly and Amy Skilbred, both to prove that plaintiffs would be injured if section 7(a) of the ESA did not to apply to endangered species abroad.

In her affidavit, Kelly stated that she had visited Egypt in 1986 and “observed the traditional habitat of the endangered Nile crocodile there and intend[ed] to do so again, and hope[d] to observe the crocodile directly.”<sup>132</sup> Kelly further declared that she would “suffer harm in fact as the result of the American role in overseeing the rehabilitation of the Aswan High Dam on the Nile and in developing Egypt’s Master Water Plan.”<sup>133</sup> Similarly, Skilbred averred in her affidavit that she was in Sri Lanka in 1981 and “observed the habitat . . . of the Asian elephant and the leopard” on the site of the Mahaweli Project, a development project in which the United States was involved.<sup>134</sup> Skilbred explained that this project threatened endangered species in the area, which harmed her since she “intend[ed] to return to Sri Lanka in the future.”<sup>135</sup>

After considering the evidence, the district court granted defendant’s

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129. *Id.*

130. *Id.* at 55–59.

131. 16 U.S.C. § 1540(g) (2006).

132. *Lujan*, 504 U.S. at 563.

133. *Id.*

134. *Id.*

135. *Id.*

motion to dismiss for lack of standing. The Eighth Circuit reversed and, after remand, the case eventually made its way to the Supreme Court.

The *Lujan* Court announced that “the irreducible constitutional minimum of standing contains three elements.”<sup>136</sup> First, the plaintiff must have suffered, or been threatened with, an injury-in-fact. An injury-in-fact is a concrete and particularized invasion of a legally protected interest; it must be “actual or imminent,” as opposed to “conjectural or hypothetical.”<sup>137</sup> Second, there must be a causal connection between the injury and the defendant’s conduct, meaning at least some portion of the plaintiff’s injury is “fairly traceable” to the defendant and not to a third party.<sup>138</sup> Lastly, it must be likely that the relief requested will redress the plaintiff’s injury.<sup>139</sup> Applying this test, the Supreme Court held by a vote of seven to two that there was no standing because plaintiffs failed to demonstrate an injury-in-fact.

With respect to the injury-in-fact prong, the Court determined that plaintiffs failed to show how damage to the endangered species would produce an “imminent” injury to Kelly and Skilbred. According to the Court,

[T]he affiants’ profession of an “intent” to return to the places they had visited before – where they will presumably, this time, be deprived of the opportunity to observe animals of the endangered species – is simply not enough. Such “some day” intentions – without any description of concrete plans, or indeed even any specification of *when* the some day will be – do not support a finding of the “actual or imminent” injury that our cases require.<sup>140</sup>

What is clear from *Lujan* is that this injury-in-fact analysis was shaped by separation of powers principles. Justice Scalia, writing for the majority, proclaimed that the core purpose of the standing doctrine was to safeguard the separation of powers by limiting the circumstances in which courts may hear cases.<sup>141</sup> Separation of powers concerns are particularly implicated by citizen suits where, as in *Lujan*, Congress has bestowed on private individuals the right to sue to vindicate some public interest. The fear is that creating a private right of action permits Congress to transfer from the executive branch to the judicial branch the President’s most important constitutional duty: to “take Care that the Laws be faithfully executed.”<sup>142</sup> *Lujan* therefore held that plaintiffs could not establish an injury-in-fact solely through the citizen suit provision of the ESA.

In the face of this evidence, a majority of the *Lujan* Court concluded that plaintiffs could not satisfy the injury-in-fact prong of the standing test. To be sure, the correctness of the *Lujan* decision has been the subject of much

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136. *Id.* at 560.

137. *Id.*

138. *Id.*

139. *Id.* at 561.

140. *Id.* at 564 (emphasis in original).

141. *Id.* at 576–77.

142. U.S. CONST. art. II, § 3.

debate.<sup>143</sup> That debate is of no moment to this Essay, however, because a proper interpretation of *Lujan* proves that it is easily distinguished from *Myriad*.

## 2. *Myriad* is Distinguishable from *Lujan*

The *Myriad* panel held that Drs. Ganguly and Kazazian, unlike Dr. Ostrer, had not suffered an injury-in-fact because their injuries were not “actual or imminent” under *Lujan*. The panel drew a distinction between Dr. Ostrer, who declared that he would immediately resume BRCA testing if the patents in suit were invalidated, and Drs. Ganguly and Kazazian, who indicated that they would consider resuming such testing. The panel analogized the statements of Drs. Ganguly and Kazazian to the “‘some day’ intentions” of plaintiffs Kelly and Skilbred in the *Lujan* case, and then concluded that such “‘some day’” intentions are insufficient to support standing.<sup>144</sup> But a close reading of *Lujan* suggests that the *Myriad* court misinterpreted the injury-in-fact requirement.

*Lujan* provides that an injury-in-fact must be “actual *or* imminent.”<sup>145</sup> Yet, the Federal Circuit in *Myriad* appeared to require plaintiffs’ injuries to be actual *and* imminent:

In contrast to Ostrer, who alleges an actual and imminent injury for purposes of standing, Drs. Kazazian and Ganguly allege only that they will ‘consider’ resuming BRCA testing.”<sup>146</sup>

This misreading of *Lujan*’s imminence requirement led the *Myriad* court to the wrong result on the question of standing.

In *Lujan* the Supreme Court held that the plaintiffs had suffered neither an actual nor imminent injury, and thus could not demonstrate the requisite injury-in-fact. The plaintiff environmental groups in *Lujan* relied on standing declarations from environmental group members who had suffered no injury at the time of filing suit. The affiants, Joyce Kelly and Amy Skilbred, claimed only that they *would be injured* as a result of the challenged projects in Egypt and Sri Lanka, which would harm certain endangered species that the affiants enjoyed viewing; but they offered no evidence that those projects had already impacted the endangered species in question. In short, the complaint in *Lujan* alleged no actual injury and so the only question was whether the plaintiffs would suffer imminent harm.

The same cannot be said for *Myriad*, however. Some of the plaintiffs in *Myriad* – namely Drs. Ganguly, Kazazian, and Ostrer – had already been injured at the time the lawsuit was filed. In the late 1990s, all three of these plaintiffs were engaged in BRCA-related activities: Dr. Ganguly was conducting BRCA research; Dr. Kazazian was providing BRCA testing

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143. See generally Sunstein, *supra* note 19.

144. Ass’n for Molecular Pathology v. USPTO (*Myriad*), 653 F.3d 1329, 1346 (2011).

145. *Lujan*, 504 U.S. at 564 (emphasis added).

146. *Myriad*, 653 F.3d at 1346 (emphasis added).



services to patients; and Dr. Ostrer was supplying Dr. Kazazian with patient samples for testing. But all three plaintiffs were forced to cease their activities as a result of Myriad's threats to enforce its BRCA patents against them and its filing of an actual lawsuit. Consequently, plaintiffs suffered an actual injury-in-fact.

The plaintiffs in *Myriad*, unlike in *Lujan*, suffered a past injury. It is well settled that past wrongs are evidence bearing on the question "whether there is a real and immediate threat of repeated injury."<sup>147</sup> Yet, the analysis does not end there. The Supreme Court stated in *City of Los Angeles v. Lyons* that past injury is not necessarily sufficient to establish standing for prospective relief.<sup>148</sup> Because the plaintiffs in *Myriad* sought prospective relief in the form of a declaration of rights, *Lyons* also should have been considered.

The plaintiff in *Lyons* was stopped by a member of the Los Angeles Police Department ("LAPD") for a traffic violation, and then subjected to a life-threatening chokehold. Lyons filed a federal civil rights action against the city alleging that LAPD had a policy of using this chokehold, and that the chokehold had caused the death of sixteen people in the past eight years.<sup>149</sup> Lyons sought the following relief: (i) damages for the injury he sustained when subjected to the chokehold; (ii) a declaration that "use of the chokehold absent the threat of immediate use of deadly force is a per se violation of various constitutional rights"; and (iii) an injunction that would preclude the LAPD from using the chokehold except in very limited circumstances.<sup>150</sup>

While there was little doubt that Lyons had standing to sue for past damages based on the injuries he sustained from the chokehold, the city challenged his standing to sue for prospective relief. In deciding that question, the Supreme Court embraced the concept of "remedial standing,"<sup>151</sup> meaning a standing analysis that depends on the remedy sought.<sup>152</sup> As the Court explained, "past exposure to illegal conduct does not in itself show a present case or controversy regarding injunctive relief" unless the past injury is "[a]ccompanied by . . . continuing, present adverse effects."<sup>153</sup> Stated more simply, plaintiffs suffering from *continuing injuries* have standing to sue for prospective relief, while plaintiffs with purely past injuries do not.

Applying this remedial standing test, the Court allowed Lyons' suit for

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147. *City of Los Angeles v. Lyons*, 461 U.S. 95, 102 (1983); *O'Shea v. Littleton*, 414 U.S. 488, 496 (1974); *see also* *Kolender v. Lawson*, 461 U.S. 352, 355 n.3 (1983) (holding that plaintiff who had suffered repeated past injuries had demonstrated a "credible threat" sufficient to support standing for prospective relief).

148. *Lyons*, 461 U.S. 95.

149. *Id.* at 115–16.

150. *Id.* at 98.

151. Richard H. Fallon, Jr., *Of Justiciability, Remedies, and Public Law Litigation: Notes on the Jurisprudence of Lyons*, 59 N.Y.U. L. REV. 1 (1984).

152. *Summers v. Earth Island Inst.*, 129 S. Ct. 1142, 1149 (2009) ("[Plaintiff] bears the burden of showing that he has standing for each type of relief sought.").

153. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 563 (1992); *Lyons*, 461 U.S. at 102.

damages, but held that he lacked standing to sue for prospective relief. In the Court's view, there was no actual or present injury because, by the time Lyons filed suit, he no longer suffered any continuing injury that equitable relief could redress. What is more, there was no imminent injury since Lyons' assertion that he may again be subject to an illegal chokehold at some point in the future was "no more than speculation."<sup>154</sup> In the end, the *Lyons* Court held that the potential threat of future injury was not sufficiently likely to warrant standing for prospective relief.

The facts of *Myriad* are distinguishable from both *Lujan* and *Lyons* because Drs. Ganguly, Kazazian, and Ostrer each suffered a past injury that is "[a]ccompanied by . . . continuing, present adverse effects."<sup>155</sup> Plaintiffs' affidavits demonstrate this continuing injury: (i) Drs. Ganguly, Kazazian, and Ostrer were engaged in BRCA-related activity; (ii) they were forced to stop those activities because *Myriad* sued them for infringement; (iii) they remain interested in pursuing BRCA activities; and (iv) they have refrained from doing so because of *Myriad*'s continued threat to enforce its potentially invalid patents. Indeed, Judge Moore acknowledged this continuing threat at oral argument when discussing the cease-and-desist letters sent to Drs. Ganguly and Kazazian in the late 1990s:

I'm looking at it as [Drs. Ganguly and Kazazian are] very much laboring under the continued threat of *Myriad*. The fact that *Myriad* sent cease and desist ten years ago, twelve years ago, well they did. What reason do [Drs. Ganguly and Kazazian] have to think that *Myriad* is not still feeling very much the same way? I mean, *Myriad* had the power and authority to modify it if [*Myriad* was] no longer feeling that way. [*Myriad*] could've let the plaintiffs know, [*Myriad*] could've offered a covenant not to sue. But *Myriad* has declined to do so.<sup>156</sup>

That the plaintiffs in *Myriad* suffered from past and continuing injuries renders *Lujan* wholly inapplicable.<sup>157</sup> The only injury at issue in *Lujan* was a future – or imminent – injury, so it arguably made sense for the Court to impose a heightened injury-in-fact requirement. In other words, *Lujan*'s

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154. *Lyons*, 461 U.S. at 108.

155. *Lujan*, 504 U.S. at 563; *Lyons*, 461 U.S. at 102.

156. Oral Argument at 5:31, *Ass'n for Molecular Pathology v. USPTO (Myriad)*, 653 F.3d 1329 (2011) (No. 2010-1406), available at <http://www.ca9.uscourts.gov/oral-argument-recordings/2010-1406/all>.

157. A related reason why *Myriad* and *Lujan* are inapposite is because the separation-of-powers principles underlying *Lujan* simply were not an issue in *Myriad*. See *Lujan*, 504 U.S. at 576–77. The motivation for the *Lujan* Court's heightened injury-in-fact requirement was concern that congressionally authorized citizen suits disrupt the separation of powers by improperly transferring to the judiciary the executive's duty to "take Care that the Laws be faithfully executed." U.S. CONST. art. II, § 3; see also Heather Elliott, *Congress's Inability to Solve Standing Problems*, 91 B.U. L. REV. 159, 175–76 (2011). But *Myriad* does not involve a citizen suit provision – another ground on which it is distinguishable from *Lujan*.

language regarding “some day intentions” applies only to future injuries.<sup>158</sup> And in *Myriad* the injury was not in the future; it was continuing and “actual . . . not conjectural or hypothetical.”<sup>159</sup> Plaintiffs were not merely complaining of “possible future injur[ies];”<sup>160</sup> they described in detail repeated past injuries and continuing harm that adequately established an injury-in-fact.<sup>161</sup>

#### CONCLUSION

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 by *Myriad* – Are genes patentable subject matter? How do gene patents impact medical research and health care? Do gene patents promote innovation as required by the Constitution? – are critically important and should be addressed by the courts “sooner rather than later,” as Justice Breyer has opined.<sup>162</sup> Indeed, this point is made especially poignant by the Supreme Court’s recent decision to review *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,<sup>163</sup> another Federal Circuit case concerning patentable subject matter.

Yet, in order to reach the merits of *Myriad* and cases like it, courts must first satisfy themselves with respect to justiciability. In doing so, courts must be mindful of the essentiality of declaratory relief to a well-functioning patent system. Under our current system, litigation is the primary gatekeeper of patent quality. Patent quality is commonly raised as an affirmative defense to a patent infringement claim. But if a patent owner does not sue for infringement, then often the only way to challenge a potentially invalid patent is through a declaratory judgment action.

Because invalid patents have such a profound impact on competition, consumers, and the patent system as a whole, the ability to challenge such

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158. *Lujan*, 504 U.S. at 564.

159. *Id.* at 560 (internal citations omitted).

160. *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990); *see also* John G. Roberts, Jr., *Article III Limits on Statutory Standing*, 42 DUKE L.J. 1219, 1225 (1993).

161. *Cf.* *N.A.A.C.P. v. City of Parma*, 263 F.3d 513, 528 (6th Cir. 2001) (concluding that plaintiff had standing to sue for prospective relief because he had more than “some day intentions” of seeking employment with the defendant); *James v. City of Dallas*, 254 F.3d 551, 563–64 (5th Cir. 2001) (finding that plaintiffs established an actual and imminent injury because the defendant’s “continued threat of collection actions or foreclosures” created an “ongoing effect, which allegedly burden[ed] the Plaintiffs’ ownership of property”); *Disabled in Action of Metro. New York v. Trump Intern. Hotel & Tower*, No. 01 Civ. 5518, 2003 WL 1751785, at \*7 (S.D.N.Y. Apr. 2, 2003) (“Courts considering ADA claims have found that disabled plaintiffs who had encountered barriers [in the past] have standing to bring claims for injunctive relief if they show a plausible intention or desire to return to the place but for the barriers to access.”).

162. *Laboratory Corp. of Am. v. Metabolite Labs., Inc.*, 548 U.S. 124, 134 (2006) (Breyer, J., dissenting) (dissenting from decision to dismiss writ of certiorari as improvidently granted).

163. Kali Borkoski, *Details on Today’s Order List*, SCOTUS BLOG (June 20, 2011, 11:47 AM), <http://www.scotusblog.com/2011/06/details-on-todays-order-list-3/>.

patents is vital to the public interest.<sup>164</sup> Time and again, the Supreme Court has adopted legal standards that facilitate declaratory relief actions.<sup>165</sup> After *Myriad*, it seems the Supreme Court needs to remind the Federal Circuit of its obligation to the public when considering patent declaratory judgment actions.

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164. *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969) (explaining the importance of validity challenges 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”).

165. *See, e.g., Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 345–46 (1971) (discussing line of Supreme Court cases that “eliminate[d] obstacles to suit by those disposed to challenge the validity of a patent”).