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Amelia Smith Rinehart

*University of Utah, S.J. Quinney College of Law*

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# PATENT CASES AND PUBLIC CONTROVERSIES

*Amelia Smith Rinehart\**

## INTRODUCTION

A patent could be described as a private solution to a public problem—the government grants to an inventor a private exclusive right to his invention for a limited time in order to encourage the promotion of progress to benefit the public as a whole.<sup>1</sup> When someone infringes that private right, the patentee enforces his exclusive right in federal court by filing a civil action for patent infringement pursuant to 35 U.S.C. § 281.<sup>2</sup> But what happens when a member of the public wishes to challenge the merits of that private right? Some members of the public might like to practice the invention without consequence—this group could include competitors, hopeful market entrants, patent licensees, or even strangers to the patent owner. Other people might believe that the patent harms them and others (including the government sovereign itself) by restricting competition and limiting innovation or by offending on moral or ethical grounds. Because the traditional Article III inquiry in such cases revolves around the reciprocal (and often hypothetical) infringement case that could be brought by the patentee against the challenging party, conventional wisdom holds that the former group, the practicing public, would be welcome in federal court while the latter group, the non-practicing public, would not.

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1 See U.S. CONST. art. I, § 8, cl. 8 (granting to Congress the power “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries”).

2 35 U.S.C. § 281 (2006) (providing a civil action for infringement); see also *id.* § 271 (defining infringement).

Despite improbable chances for justiciability,<sup>3</sup> several recent cases challenge this conventional wisdom, revealing a trend in patent litigation whereby members of the public bring suits to challenge patents, including *Ass'n of Molecular Pathology v. Myriad Genetics, Inc.* (“AMP”),<sup>4</sup> *Mama Cares Foundation v. Nutriset Société Par Actions Cimplifiée* (“Mama Cares”),<sup>5</sup> and *Organic Seed Growers & Trade Ass'n v. Monsanto Co.* (“OSGTA”).<sup>6</sup> In these public patent litigations, the declaratory plaintiffs seek to invalidate patents on a variety of grounds. In *AMP* and *OSGTA*, the declaratory plaintiffs claim the patents—gene patents in *AMP* and genetically modified food patents in *OSGTA*—are invalid on statutory subject matter grounds.<sup>7</sup> In *Mama Cares*, the declaratory plaintiffs claim that the patents, directed toward ready-to-eat therapeutic food products and processes, are invalid on other grounds of patentability (e.g., lack of novelty, non-obviousness, or inadequate disclosure).<sup>8</sup> In each case, the declaratory plaintiffs are not presently infringing the patents—the *Mama Cares* plaintiffs and some *AMP* plaintiffs desire to infringe; all of the *OSGTA* plaintiffs fear inevitable infringement sometime in the future. In all three cases, public interest groups, such as the American Civil Liberties Union and the Public Patent Foundation, support the declaratory plaintiffs in their quest for invalidation. The Court of Appeals for the Federal Circuit

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3 See *Flast v. Cohen*, 392 U.S. 83, 95 (1968) (“Justiciability is the term of art employed to give expression to this dual limitation placed upon federal courts by the case-and-controversy doctrine.”); LINDA MULLENIX ET AL., UNDERSTANDING FEDERAL COURTS AND JURISDICTION § 2.01 (1998) (explaining justiciability).

4 *Ass'n for Molecular Pathology v. USPTO (AMP)*, 689 F.3d 1303 (Fed. Cir. 2012), *aff'd in part on other grounds, rev'd in part on other grounds, sub nom. Ass'n for Molecular Pathology v. Myriad Genetics, Inc. (AMP II)*, 133 S. Ct. 2107 (June 13, 2013); see *Ass'n for Molecular Pathology v. USPTO*, 653 F.3d 1329 (Fed. Cir. 2011), *vacated on other grounds, sub nom. Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 132 S. Ct. 1794 (2012) (challenging the validity of patents for isolated DNA sequences). The Court addressed a groundbreaking question in its 2013 *Association for Molecular Pathology v. Myriad Genetics, Inc. (AMP II)* case: are human genes patentable? Without addressing the question of justiciability, the Court affirmed-in-part and reversed-in-part the Federal Circuit's refusal to invalidate the patent claims in suit directed to isolated DNA material and to cDNA (or synthetic DNA) material. The Court held that isolated DNA claims were invalid and not patent eligible subject matter under § 101 because they claimed naturally occurring phenomena. *AMP II*, 133 S. Ct. at 2117–19. The Court held that cDNA claims, in contrast, were patent eligible because they did not claim “products of nature.” *Id.* at 2119. The Court did not review a question raised by the petitioners for review of the Federal Circuit's finding of standing on behalf of just one plaintiff. See *AMP II*, 133 S. Ct. 694 (2013) (granting the petition for writ of certiorari as to question one only); *Petition for Writ of Certiorari* at i, *AMP II*, 133 S. Ct. 2107 (No. 12-398).

5 *Mama Cares Found. v. Nutriset Société Par Actions Cimplifiée (Mama Cares)*, 825 F. Supp. 2d 178, 183 (D.D.C. 2011).

6 *Organic Seed Growers & Trade Ass'n v. Monsanto Co. (OSGTA)*, 851 F. Supp. 2d 544, 547 (S.D.N.Y. 2012), *aff'd*, 718 F.3d 1350 (Fed. Cir. 2013).

7 In other words, on the grounds that the patented subject matters are not eligible for patent protection at all, per 35 U.S.C. § 101 (2006).

8 First Amended Complaint at 8, *Mama Cares*, 825 F. Supp. 2d 178 (No. 1:09-cv-02395).

(“Federal Circuit”) twice approved of jurisdiction in *AMP*<sup>9</sup> but found the *OSGTA* controversy moot.<sup>10</sup> A district court dismissed *Mama Cares* for lack of jurisdiction.<sup>11</sup> Each court came to a decision on jurisdiction (and therefore justiciability) by referring to the likelihood (or lack thereof) of an infringement suit by the patent owner and by citing the same Supreme Court and Federal Circuit precedent. However, the courts’ views of that precedent and the Supreme Court’s policy preference to encourage patent challenges raise questions regarding justiciability in patent cases and in public law cases generally.

As discussed below, *MedImmune, Inc. v. Genentech, Inc.*, the most recent case from the Supreme Court addressing declaratory judgment justiciability, instructs courts considering declaratory cases (including patent ones) to embrace the flexibility of Article III justiciability by simply asking whether a declaratory plaintiff has a sufficiently real and immediate legal dispute with the declaratory defendant.<sup>12</sup> A broad view of *MedImmune*’s Article III jurisprudence in declaratory patent cases could facilitate public litigants challenging patents in courts. Such public patent litigation would further a strong public interest in challenging invalid patents—an interest that courts, including the Supreme Court, have championed for decades.<sup>13</sup> However, despite *MedImmune*’s hint of flexibility in applying its stated standard of reality and immediacy, the question of Article III justiciability in lower courts focuses on identifying an underlying coercive action that could be brought by the declaratory defendant. (In other words, the request for anticipatory relief necessitates asking the declaratory plaintiff, “You anticipate *what exactly?*”) In a declaratory patent case, the underlying coercive action for infringement reorients the Article III inquiry toward the patentee’s intent to enforce his patent rights and the declaratory plaintiff’s desire to exploit non-infringing activity.<sup>14</sup> Thus, a contextual reading of *MedImmune* (itself a licensing dispute) and its progeny reveals a narrower view of justiciability that reiterates our federal civil litigation system’s commitment to private adjudication even in patent cases where the public stakes may be large.

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9 *AMP*, 689 F.3d at 1323; *Ass’n for Molecular Pathology*, 653 F.3d at 1348. Notably, the Supreme Court declined to address the question of justiciability presented in the petition for certiorari. See *supra* note 4.

10 *OSGTA*, 718 F.3d at 1361–61.

11 See *Mama Cares*, 825 F. Supp. 2d at 183 (dismissing the suit for lack of subject matter jurisdiction).

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

13 See, e.g., *Lear, Inc. v. Adkins*, 395 U.S. 653, 674 (1969) (stating that “enforcing this contractual provision would undermine the strong federal policy favoring the full and free use of ideas in the public domain”); *Bresnick v. U.S. Vitamin Corp.*, 139 F.2d 239, 242 (2d Cir. 1943) (“We have disposed of the patent as a whole because it has seemed to us proper that it should not remain in the art as a scarecrow.”).

14 The activity could be non-infringing because it operates outside of the claims of the patent or because the activity operates within the claims of an invalid patent.

Despite courts' doublethink<sup>15</sup> in declaratory patent cases like *MedImmune*—simultaneously promoting public patent challenges as a matter of patent policy and private litigation as a matter of law—these cases have not created an open door to federal court for public patent litigants. *MedImmune*'s reminder that rigorous rules have no place in Article III justiciability determinations appears to be disregarded in the declaratory patent case. Post-*MedImmune* cases in the Federal Circuit and in lower courts insist upon a showing of affirmative acts from the patentee indicating an intention to enforce his patent and affirmative acts from the declaratory plaintiff indicating that she is “ready, willing and able” to infringe the patents at any time in order to establish the legally cognizable interest required for justiciability.<sup>16</sup> Declaratory patent plaintiffs who allege injuries outside of the traditional harm of patentees' threatened coercive actions for infringement (what the Federal Circuit refers to as “a restraint on the free exploitation of non-infringing goods”<sup>17</sup>) remain excluded from federal courts despite arguably presenting other injuries of sufficient immediacy and reality to warrant relief. In traditional cases where the patentee explicitly or implicitly threatens to bring an infringement suit against a declaratory plaintiff making meaningful preparations to infringe (or already infringing), courts reach the same results as under the older reasonable apprehension of suit test abrogated in *MedImmune*.<sup>18</sup> In cases involving privileged parties (like licensees or covenantees) or in cases involving a member of the public seeking to challenge the patent on public interest grounds, courts struggle to identify an underlying coercive cause of action for infringement based upon such affirmative acts by the patentee and declaratory plaintiff.

The growing interest in public interest patent litigation, as evidenced by cases like *AMP* and others, suggests that there is room for improvement in the jurisprudence of justiciability in declaratory patent cases. Moreover, *MedImmune*'s long game—shifting the focus from a bright-line rule based upon the relative certainty of an infringement action to an adverse interests standard—suggests that public patent litigation could be encouraged as the

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15 “Doublethink” means a simultaneous belief in two contradictory ideas. *Doublethink Definition*, MERRIAM-WEBSTER.COM, <http://www.merriam-webster.com/dictionary/doublethink> (last visited Oct. 17, 2013). George Orwell coined the word in his novel, *1984*. See GEORGE ORWELL, 1984, at 9 (1949).

16 See *Arris Group, Inc. v. British Telecomms. PLC*, 639 F.3d 1368, 1374 (Fed. Cir. 2011); *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1381 (Fed. Cir. 2007).

17 *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1291 (Fed. Cir. 2008) (quoting *Red Wing Shoe Co. v. Hockerson-Halberstadt, Inc.*, 148 F.3d 1355, 1360 (Fed. Cir. 1998)) (internal quotation marks omitted).

18 See *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993) (noting that courts had developed a pragmatic two-part reasonable apprehension of suit test, which considered the same two factors as new post-*MedImmune* cases, namely the existence of “(1) an explicit threat or other action by the patentee . . . and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity” (citing *Jervis B. Webb Co. v. S. Sys., Inc.*, 742 F.2d 1388, 1398–99 (Fed. Cir. 1984))).

best mechanism for challenging patents that may negatively impact society. Recognizing that members of the public have an interest in invalidating patents deemed costly for society as a whole and an even greater interest in the patent system's overall legacy of legitimacy in granting the right to exclude only when deserved, this Article proposes that *MedImmune's* doublethink be resolved by allowing certain members of the public standing to sue patentees in order to invalidate patents. A limited citizen's right to invalidate a patent would supplement the private right to invalidate that is afforded to alleged infringers and would improve the overall legitimacy of the patent system.

The Article proceeds as follows. Part I summarizes the evolution of the current standard for justiciability in declaratory patent cases, including the Supreme Court's *MedImmune* opinion and its progeny in the Federal Circuit and the lower courts. Part II discusses the growing trend of public interest patent litigation and the hurdles declaratory plaintiffs face on justiciability grounds despite courts' approval of patent challenges generally on policy grounds. Finally, Part III introduces a legislative reform that promises to afford justiciability for some members of the public without compromising Article III's emphasis on private adjudication.

## I. THE EVOLUTION OF A JUSTICIABILITY STANDARD

Federal courts have exclusive jurisdiction over all suits "arising under any Act of Congress relating to patents."<sup>19</sup> The majority of patent cases satisfy this jurisdictional requirement by arising under 35 U.S.C. § 281, which grants to a patentee the "remedy by civil action for infringement of his patent."<sup>20</sup> A patentee seeking to enforce the limited, exclusive rights secured by his patent may file suit against any party who makes, uses, sells, or offers for sale the invention claimed by the patent or who imports the invention into the United States.<sup>21</sup> Because patents enjoy a presumption of validity by statute,<sup>22</sup> a patentee need not establish that his patent meets the requirements for patentability in order to proceed with his infringement suit in federal court; proving ownership suffices for a civil action brought under 35 U.S.C.

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19 28 U.S.C. § 1338 (Supp. V 2011); see 8 DONALD S. CHISUM, CHISUM ON PATENTS § 21.02[1][b]. For the history of exclusive federal jurisdiction in patent cases, see Donald S. Chisum, *The Allocation of Jurisdiction Between State and Federal Courts in Patent Litigation*, 46 WASH. L. REV. 633, 636 (1971). Conventional wisdom holds that Congress intended to promote uniformity of decision and to encourage the development of expertise on the bench. *Id.* The formation of the Federal Circuit in 1982 reiterated these goals in the context of appeals from patent cases. See Rochelle Cooper Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. REV. 1, 7 (1989).

20 35 U.S.C. § 281 (2006). Other cases that "arise under the patent laws" not involving civil actions for infringement also implicate federal question jurisprudence but are beyond the limited scope of this Article focusing on the declaratory patent case.

21 The statute further defines an infringer as "whoever without authority makes, uses, offers to sell . . . or imports into the United States any patented invention during the term of the patent therefor." *Id.* § 271.

22 *Id.* § 282.

§ 281.<sup>23</sup> Anyone sued by the patentee for infringement may challenge the validity of any patent claim in suit as an affirmative defense to liability.<sup>24</sup> If a defendant establishes with clear and convincing evidence that a patent claim is invalid, the claim cannot be infringed and will be unenforceable as to the world (meaning the patentee cannot bring future civil actions of infringement of that particular claim against anyone).<sup>25</sup>

The patent laws do not provide a statutory cause of action to citizens to contest the validity of a patent.<sup>26</sup> Prior to 1934, courts could not provide equitable anticipatory relief in any fashion; even an alleged infringer could not bring his own suit in federal court for declarations of invalidity or non-infringement.<sup>27</sup> Therefore, a member of the public seeking to challenge a patent had to wait until the patentee sued her in federal court for patent infringement.<sup>28</sup> Only accused infringers had the opportunity to invalidate patents and then only as defendants in infringement suits. If the patentee was reluctant to sue, whether because he preferred to leverage the threat of suit, because he did not have the resources to sue, because practicing the invention was done with his authority under a license, or because he was not

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23 *Lorenz v. F.W. Woolworth Co.*, 305 F.2d 102, 105 (2d Cir. 1962) (“The presumption of validity relieves the patent holder of the burden of establishing that validity as a requisite for the successful maintenance of an infringement action, and places the burden of establishing invalidity on the alleged infringer who asserts it.”); see 6 R. CARL MOY, MOY’S WALKER ON PATENTS § 17.16 (4th ed. 2012) (“[T]he patent owner in a suit for infringement need only allege that the patent in suit was duly issued.”); FED. R. CIV. P. Form 18 (providing sufficient complaint for patent infringement).

24 35 U.S.C. § 282(b).

25 See, e.g., *Microsoft Corp. v. i4i Ltd. P’ship*, 131 S. Ct. 2238, 2242 (2011) (confirming that “§ 282 requires an invalidity defense to be proved by clear and convincing evidence”); *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 332–333 (1971) (holding that a declaration of invalidity creates a collateral estoppel barrier against further litigation involving the patent unless the patent owner can demonstrate that he did not have “a full and fair chance to litigate the validity of his patent”).

26 There are several avenues for contesting patent scope or validity by petitioning the United States Patent & Trademark Office (USPTO) for further review after the patent issues. The patent owner may apply to the USPTO for a reissue of the patent with an amended claim scope if he believes that he has mistakenly under- or over-claimed his invention. The patent owner or any third party also may apply to the USPTO for reexamination of the patent on the basis that a newly discovered printed publication raises a substantial question of patentability. USPTO rules limit the applicability and participation of third parties during the administration of such challenges, which resemble the examination process itself. The USPTO examination, reissue, and reexamination processes, and any subsequent appellate procedures between the applicant or owner and the USPTO itself, provide the only truly public policing mechanism wherein the government serves as an agent for the public’s interest in avoiding burdensome patents. For an overview of policy and procedures, see the MANUAL OF PATENT EXAMINING PROCEDURE, available at <http://mpep.uspto.gov/RDMS/detail/manual/MPEP/e8r9/d0e18.xml> (last visited Sept. 10, 2013); see also *infra* Part III.

27 Edwin Borchard, *The Federal Declaratory Judgments Act*, 21 VA. L. REV. 35, 39–40 (1934).

28 *Id.*

aware of the infringement, a potential infringer who believed the patent invalid and unenforceable risked accruing damages to the patentee if he engaged in arguably infringing activity before the patentee brought suit.

This dilemma—an *in terrorem* choice between the incurrence of a growing potential liability for patent infringement and abandonment of [his] enterprises<sup>29</sup>—spurred passage of the 1934 Declaratory Judgments Act, which, for the first time, allowed potential infringers to “clear the air” by seeking declaratory relief in federal court instead of waiting for the patent owner to file an infringement suit.<sup>30</sup> This unique remedy allows for anticipatory rather than coercive relief<sup>31</sup> by providing, “[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 legal relations of any interested party seeking such declaration.”<sup>32</sup> A declaratory plaintiff seeking to maintain a patent case (with exclusive federal jurisdiction and exclusive appeals to the Federal Circuit) need only establish a “case or controversy” as required by Article III of the Constitution (also called constitutional justiciability) and statutory jurisdiction over the claims, typically by raising a substantial question of patent law.<sup>33</sup> Courts generally accept that parties who request declaratory relief in the form of declarations of invalidity

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29 *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 735 (Fed. Cir. 1988).

30 *Id.*

31 See Herman L. Trautman, *Federal Right Jurisdiction and the Declaratory Remedy*, 7 VAND. L. REV. 445, 463 (1954).

32 28 U.S.C. § 2201(a) (2006). In patent cases, alleged infringers often request declaratory relief in the form of judgments of invalidity, unenforceability, and non-infringement, whereas patent owners often request declaratory relief in the form of judgments of infringement, validity, or enforceability.

33 See, e.g., *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 807–08 (1986) (explaining federal jurisdiction); *Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1324 (Fed. Cir. 1998) (stating that for original jurisdiction to exist there must be both judicial power under Article III and statutory jurisdiction (citing *Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 471 (1982))). A party seeking to contest the validity of a patent may also raise the patent question of invalidity as a defense in another suit, for example, a contract action brought by the patent owner to collect royalties under a patent license. In state cases, the defense of invalidity would not support federal jurisdiction over the entire case. In federal cases brought on other grounds, the defense of invalidity may affect whether the Federal Circuit has appellate jurisdiction. See *Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 829–34 (2002) (finding no jurisdiction for the Federal Circuit when the defendant asserts patent infringement counterclaim). For a discussion of *Holmes* and its impact on Federal Circuit appellate jurisdiction, see Christopher A. Cotropia, “*Arising Under*” *Jurisdiction and Uniformity in Patent Law*, 9 MICH. TELECOMM. & TECH. L. REV. 253 (2003). Congress recently overruled *Holmes* by amending § 1295 jurisdiction for the Federal Circuit, but this jurisdiction remains tied to claims arising under patent law. Compare 28 U.S.C. § 1295(a)(1) (2006), with 28 U.S.C. § 1295(a)(1) (Supp. V 2011) (allowing Federal Circuit jurisdiction for “any civil action arising under, or . . . any civil action in which a party has asserted a compulsory counterclaim arising under, any Act of Congress relating to patents”).



or unenforceability of a patent raise substantial questions of patent law.<sup>34</sup> However, declaratory plaintiffs often face formidable Article III challenges based upon the general case or controversy requirement as well as the underlying doctrines of standing, ripeness and mootness, as discussed below in Section I.A.<sup>35</sup> In *MedImmune*, the Supreme Court addressed these Article III doctrines in a very specific context: that of a declaratory patent case brought by a non-breaching licensee. As described more fully below in Section I.B, the opinion in *MedImmune* offers two different readings—one narrow, the other broad—that have important implications in declaratory patent cases and public law litigation.

### A. Article III Doctrines of Justiciability

Because the Court in *MedImmune* (and its predecessors) implicitly refers to the underlying doctrines of justiciability—standing (between adverse legal interests of sufficient reality), ripeness (sufficient immediacy) and mootness (substantial controversy)—the Federal Circuit has found it helpful to use these doctrines to answer Article III’s basic question: whether the right *party* raises the right *interest* at the right *time*.<sup>36</sup>

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34 See *Zenie Bros. v. Miskend*, 10 F. Supp. 779, 781 (S.D.N.Y. 1935) (“A suit to have a patent declared invalid for want of invention is one arising under the patent laws, as plainly as the ordinary suit for infringement.”); EDWIN BORCHARD, *DECLARATORY JUDGMENTS* 809 (2d ed. 1941). In Professor Borchard’s opinion, such a case “really and substantially involves a dispute or controversy respecting the validity, consideration or effect of a law of Congress.” *Id.* (quoting *Hopkins v. Walker*, 244 U.S. 486, 489 (1917)) (internal quotation marks omitted). This general acceptance of federal question jurisdiction in declaratory patent cases occasionally may run afoul of the well-pleaded complaint rule, especially when invalidity may be raised in anticipation of a declaratory defendant’s state claims. In such cases, important federalism concerns may be implicated. See *Pub. Serv. Comm’n of Utah v. Wycoff Co.*, 344 U.S. 237, 247 (1952) (“Declaratory proceedings in the federal courts against state officials must be decided with regard for the implications of our federal system. . . . Anticipatory judgment by a federal court to frustrate action by a state agency is even less tolerable to our federalism.”).

35 The doctrine of mootness remains relevant in some declaratory patent cases but such issues are beyond the scope of this Article. For further discussion, see Kelsey I. Nix & Laurie Stempler, *The Federal Circuit’s Interpretation and Application of the MedImmune Standard for Declaratory Judgment Jurisdiction*, 19 *TEX. INTELL. PROP. L.J.* 331, 354–58 (2011) (explaining that in instances where courts apply a mootness analysis, “the *MedImmune* standard appears secondary to the constitutional analysis”).

36 See, e.g., *Caraco Pharm. Labs., Ltd. v. Forest Labs. Inc.*, 527 F.3d 1278, 1291 (Fed. Cir. 2008) (explaining the three-part framework used to establish justiciability); see also *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1338 (Fed. Cir. 2008) (denying jurisdiction on justiciability grounds by viewing Article III’s “‘immediacy and reality’ inquiry . . . through the lens of standing”); *Teva Pharms. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1336 (Fed. Cir. 2005) (denying jurisdiction because patentee’s only threats comprised listing a patent in the Orange Book and thus, “their adverse interests have not ripened into an actual controversy”).

One of the most commonly invoked justiciability doctrines,<sup>37</sup> standing, is an “essential and unchanging part” of any Article III case or controversy analysis.<sup>38</sup> In order to establish a justiciable case or controversy:

a plaintiff must show (1) it has suffered an ‘injury in fact’ that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.<sup>39</sup>

This framework, focusing on the harm to the plaintiff that she seeks to have redressed, preserves the private adjudication model in federal courts. The injury in fact, causation, and redressability requirements essentially tether an identified injury to a legally cognizable interest. Although older cases addressing what has now become known as the standing doctrine required a legal wrong, *Lujan v. Defenders of Wildlife* and its progeny have made clear that for constitutional standing the injury must be a factual one, provided the injured party claims a legally cognizable interest that demands relief from the court.<sup>40</sup> In addition to these constitutional requirements, courts also frame standing in terms of three prudential considerations: 1) if the plaintiff is alleging violation of a statute or constitutional provision, the claim must be within the zone of interests of the challenged provision; 2) parties may not assert a generalized grievance shared by all persons; and 3) a plaintiff cannot raise the interests of a third party. (Because these requirements are not thought to be constitutional, Congress can override them with legislation.<sup>41</sup>)

Although standing focuses on the proper party to bring suit, the doctrines of ripeness and mootness determine *when* litigation can be brought.<sup>42</sup> Often, as the Court in *MedImmune* noted, “standing and ripeness boil down to the same question.”<sup>43</sup> This overlap is particularly salient in declaratory

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37 See *Allen v. Wright*, 468 U.S. 737, 750 (1984) (“The Art. III doctrine that requires a litigant to have ‘standing’ to invoke the power of a federal court is perhaps the most important of these doctrines.”).

38 *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992).

39 *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180–81 (2000).

40 *Id.* For a critical analysis of the injury in fact requirement, see F. Andrew Hessick, *Standing, Injury in Fact, and Private Rights*, 93 CORNELL L. REV. 275 (2008) (arguing that the injury in fact requirement undermines the separation of powers in cases where the plaintiff alleges the violation of a private legal right).

41 *Bennett v. Spear*, 520 U.S. 154, 162 (1997). For one discussion of another facet of prudential standing in patent cases, see Xuan-Thao Nguyen, *Patent Prudential Standing*, 21 GEO. MASON L. REV. (forthcoming, 2013), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2321808](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2321808) (describing the confusion within the Federal Circuit’s “substantial rights” doctrine for determining whether exclusive licensee plaintiffs have standing to sue infringers as mirroring the problems and criticisms associated with the general standing doctrine in federal courts).

42 ERWIN CHERMERINSKY, *FEDERAL JURISDICTION* § 2.4, at 117 (6th ed. 2012).

43 *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 128 n.8 (2007); see *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1338 n.6 (Fed. Cir. 2008) (“The underlying inquiry, rooted in the requirement that Article III courts cannot issue advisory opinions, is

patent cases. When the threat of injury (e.g., a restraint on free exploitation of non-infringing activity) is remote, one could argue that no injury has been alleged (standing) or, in the alternative, that the injury would be adequate but has not yet occurred (ripeness).<sup>44</sup> Nevertheless, courts approaching the justiciability question on ripeness grounds must evaluate “both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration.”<sup>45</sup> “[A]n action is fit for judicial review where further factual development would not ‘significantly advance [a court’s] ability to deal with the legal issues presented.’”<sup>46</sup> Withholding adjudication causes hardship to the party who brings suit when the alleged injury (or uncertainty or threats) has an “‘immediate and substantial impact’” on the declaratory plaintiff.<sup>47</sup>

In contrast to ripeness and standing, which consider whether the plaintiff initially brings a case or controversy to the court, the mootness doctrine demands that the standing doctrine’s requisite personal interest exist throughout the litigation.<sup>48</sup> For this reason, like ripeness, mootness often turns on the timing of the declaratory plaintiff’s injury in fact. Standing and ripeness define justiciability at the commencement of the litigation but mootness defines justiciability throughout its existence.<sup>49</sup>

### B. *The Path to MedImmune*

The Patent Act, 35 U.S.C. § 282, creates the patentee’s right to exclude others from making, using, selling, and offering to sell the invention; this right to exclude suffices as the patentee’s legally cognizable interest necessary under Article III.<sup>50</sup> When someone “performs at least one prohibited action with respect to the patented invention that violates these exclusionary rights,” the patentee’s legally cognizable interest is injured-in-fact, thus establishing

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the same regardless of whether labeled standing, ripeness, or the requirement that the controversy have ‘sufficient immediacy and reality’ (citing *MedImmune*, 549 U.S. at 128 n.8)).

44 CHEMERINSKY, *supra* note 42, § 2.4.1, at 117.

45 *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1294–95 (Fed. Cir. 2008) (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967)).

46 *Id.* at 1295 (alteration in original) (quoting *Nat’l Park Hospitality Ass’n v. Dep’t of Interior*, 538 U.S. 803, 812 (2003)). The court might ask whether the remaining questions are purely legal ones. *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 581 (1985).

47 *Caraco Pharm.*, 527 F.3d at 1295 (quoting *Gardner v. Toilet Goods Ass’n*, 387 U.S. 167, 171 (1967)).

48 CHEMERINSKY, *supra* note 42, § 2.5.1, at 129.

49 *Id.* (citing *United States Parole Comm. v. Geraghty*, 445 U.S. 388, 397 (1980)). “[M]ootness [is] the doctrine of standing in a time frame.” *Id.* (quoting Henry Monaghan, *Constitutional Adjudication: The Who and When*, 82 YALE L.J. 1363, 1384 (1973) (second alteration in original)).

50 *Morrow v. Microsoft Corp.*, 499 F.3d 1332, 1339 (Fed. Cir. 2007) (citing *Arachnid, Inc. v. Merit Indus., Inc.*, 939 F.2d 1574, 1578 (Fed. Cir. 1991)).

the requisite standing to sue.<sup>51</sup> Not only would the case be fit for review, but refusing adjudication would cause hardship to the patentee who seeks to exercise his private right to exclude others by bringing suit.

When a declaratory plaintiff brings suit requesting anticipatory relief through the declaratory judgment procedure, the court assessing justiciability must determine whether the declaratory plaintiff (often, but not always, an alleged infringer) has shown an injury in fact to her own legally cognizable interest. The question in both cases is, does this dispute involve adverse litigants and is it likely that a favorable federal court decision will have some effect?<sup>52</sup> As noted above, prior to passage of the Declaratory Judgments Act, this was a formidable barrier that prevented courts from providing declaratory relief in any fashion.<sup>53</sup> For example, in *Willing v. Chicago Auditorium Ass'n*, the Supreme Court insisted that Article III required a plaintiff to demonstrate a legal cause of action, what the lower court in *Willing* had described as “a wrong cognizable in courts of justice under the established principles of law or equity.”<sup>54</sup> When a plaintiff, for whatever reason, sought to obtain a judicial determination of a legal relationship or a settlement of issues in dispute, he was often turned away from federal courts of equity unless he could establish “a recognizable title to legal protection.”<sup>55</sup> The declaratory judgment procedure allows for the declaratory plaintiff to request anticipatory relief without demonstrating her own cause of action. However, for this very reason, the declaratory posture of the case obfuscates

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51 *Id.* (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992)).

52 CHEMERINSKY, *supra* note 42, § 2.1, at 44.

53 Borchard, *supra* note 27, at 36–38. Borchard, a prominent Yale law professor, strongly advocated the general availability of declaratory remedies and wrote an extensive treatise on the subject after the Act’s passage. See BORCHARD, *supra* note 34. Arguably, American courts in equity had long recognized their own power to make declaratory judgments without using that terminology, for example, by issuing judgments “construing wills, interpreting deeds, trying disputed titles to property, real and personal, quieting title and declaring the non-existence of clouds thereon, declaring the nullity of instruments and legal relations, including marriage,” establishing boundaries and declaring the validity of bond issues, and judgments in an infinite variety of proceedings not requiring execution. *Id.* at xiv. Despite this availability in equitable courts of judgments involving some executory or investitive relief, American courts, even those in equity, were hesitant to award solely declaratory judgments, in other words, those judgments that simply declared the rights of parties without coercing relief (as in damages or injunctions) or creating or altering existing jural relationships (as in granting a divorce or nullifying a marriage). *Id.* at 138–149.

54 *Willing v. Chi. Auditorium Ass'n*, 8 F.2d 998, 1009 (N.D. Ill. 1925), *rev'd*, 20 F.2d 837 (7th Cir. 1927), *rev'd*, 277 U.S. 274 (1928). In *Willing*, land lessors disagreed with their tenant over whether the lease gave the tenant the right to tear down a building on the land. *Willing v. Chi. Auditorium Ass'n*, 277 U.S. 274, 285 (1928). In denying jurisdiction, the Court held that the tenant’s doubts and fears did not give rise to a cause of action— “[n]o defendant has wronged the plaintiff or has threatened to do so”—and hence, the case lacked constitutional justiciability despite the parties’ adverse interests. *Id.* at 289–90.

55 Edwin Borchard, *The Next Step Beyond Equity—The Declaratory Action*, 13 U. CHI. L. REV. 145, 157 (1946).

the justiciability analysis (as compared to the relatively straightforward infringement case).

The Supreme Court first approved of the Declaratory Judgments Act in *Aetna Life Insurance Co. v. Haworth*.<sup>56</sup> There, the Court described a justiciable controversy as one “definite and concrete, touching the legal relations of the parties having adverse legal interests[,] . . . a real and substantial controversy admitting of specific relief.”<sup>57</sup> In doing so, the *Aetna* Court emphasized that *who* presents the controversy to the courts for adjudication does not change the *character* of the controversy and of the *issue* to be determined.<sup>58</sup> Later, in *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, the Court refused to

fashion a precise test for determining in every case whether there is such a controversy. . . . [T]he question in each case 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>59</sup>

Instead of demanding a cause of action, the Court directed courts to identify an immediate and real dispute of a legal nature.<sup>60</sup> This open-ended standard preserved the flexibility needed to address the myriad ways in which cases could arrive in federal court under the Declaratory Judgments Act, yet forced plaintiffs to prove that anticipatory relief was warranted. The Court did not shelve the cause of action requirement, but opened it up to include the declaratory defendant’s cause of action accrued (perhaps threatened) but not yet initiated.<sup>61</sup>

In declaratory patent cases, just the types of cases that the drafters of the Declaratory Judgments Act had in mind when enacting the legislation,<sup>62</sup> the hypothetical patent infringement cause of action remained paramount because courts assumed it created the only legally cognizable interests at play in patent cases. As a result, the “all the circumstances” standard from *Maryland Casualty* eventually evolved into the Federal Circuit’s familiar two-part test for determining justiciability in declaratory patent cases:

There must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory

56 300 U.S. 227, 244 (1937).

57 *Id.* at 240–41 (citations omitted).

58 *Id.* at 244 (“It is the nature of the controversy, not the method of its presentation or the particular party who presents it, that is determinative.”).

59 *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941). In *Maryland Casualty*, an insurance company and an insured disputed the insurer’s liability on the policy and its duty to defend the insured in an automobile collision case pending in state court. *Id.* at 271–72. The automobile collision involved an employee of the insured driving a truck sold to him by the insured, which the insurer claimed eliminated its liability on the insurance policy. *Id.* at 271. The Court found an actual justiciable controversy between the parties and remanded for further proceedings. *Id.* at 274.

60 *Id.* at 273.

61 *Id.* at 273–74.

62 See Lisa A. Dolak, *Declaratory Judgment Jurisdiction in Patent Cases: Restoring the Balance Between the Patentee and the Accused Infringer*, 38 B.C. L. REV. 903, 910–11 (1997).

plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.<sup>63</sup>

Under this construct, the legally cognizable interest held by the patentee—the right to exclude others—has been injured or will soon be injured by the activity of the declaratory plaintiff that would constitute infringement; this creates substantial adverse legal interests in the parties (or, in the words of *Aetna*, it defines the “character of the controversy”<sup>64</sup>). But simple accrual of an infringement action on the part of the patentee lacked the immediacy sufficient to pass muster under *Aetna* and *Maryland Casualty*. By requiring a reasonable apprehension of suit, the Federal Circuit assessed the relative certainty (or, perhaps, probability) that the patentee actually would bring his coercive action for infringement against this declaratory plaintiff.<sup>65</sup> In other words, if an underlying infringement action had accrued and was relatively certain to be brought by the patentee, the case was justiciable under Article III on standing and ripeness grounds. Again, as in *Aetna*, courts cared less about who was bringing the action than about the character of the action. When a declaratory plaintiff reasonably worried that the patentee would bring suit based on his own actions, his dispute was sufficiently real and immediate to warrant adjudication. Thus the Federal Circuit test moved away from assessing only a present or future injury to the patentee’s legally cognizable interest and instead focused on both the real or threatened injury to the patentee as well as the potential for harm to the declaratory plaintiff who sought judicial resolution of the underlying cause of action for infringement in advance of the patentee bringing suit (if it was to be brought at all).<sup>66</sup>

To that end, the first part of this test asked whether the patentee intended to enforce his exclusive patent rights through a forthcoming infringement action.<sup>67</sup> Explicit threats to file an infringement suit, the sort of patentee conduct contemplated by Professor Borchard,<sup>68</sup> obviously sufficed to establish the requisite reasonable apprehension of suit.<sup>69</sup> The Fed-

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63 *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993).

64 *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 244 (1937).

65 See David I. Levine & Charles E. Belle, *Declaratory Relief after MedImmune*, 14 LEWIS & CLARK L. REV. 491, 517 (2010).

66 *Id.*

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

68 See *supra* note 27 and accompanying text.

69 See, e.g., *Capo, Inc. v. Dioptrics Med. Prods., Inc.*, 387 F.3d 1352, 1353 (Fed. Cir. 2004) (finding a reasonable apprehension of suit based upon various threats from the patentee, including that it “would have no choice but to defend its patents against infringement”); *Fina Research, S.A. v. Baroid Ltd.*, 141 F.3d 1479, 1483 (Fed. Cir. 1998) (finding a reasonable apprehension of suit based upon letters alleging infringement and threatening suit); *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 812 (Fed. Cir. 1996) (finding a reasonable apprehension of suit based upon, *inter alia*, a letter suggesting that the management of the corporate-assignee favored litigation); *Zenie Bros. v. Miskend*, 10 F. Supp. 779, 781–82

eral Circuit also approved of jurisdiction in cases involving implicit threats found in letters to customers suggesting infringement by a manufacturer and parallel litigations against similarly situated parties.<sup>70</sup> At the same time, the appellate court carefully noted that “more is required than the existence of an adversely held patent,”<sup>71</sup> that a patentee’s offer of a license, without more, is insufficient to establish the predicate for declaratory judgment jurisdiction,<sup>72</sup> and that “proposed or ongoing license negotiations” were likewise insufficient.<sup>73</sup>

The second part of the Federal Circuit’s test for justiciability required that the declaratory plaintiff demonstrate “a true interest to be protected”<sup>74</sup> by “exam[in]g whether there had been ‘meaningful preparation’ to conduct potentially infringing activity.”<sup>75</sup> Often, the parties to the litigation admitted that such activity existed.<sup>76</sup> Without such an admission, courts tended to turn away remote or speculative cases. For example, the Federal Circuit denied justiciability in cases where activities would not be infringing until a new drug application was filed with the FDA,<sup>77</sup> where the declaratory plaintiff had not built its prototype until at least a year after the suit was commenced,<sup>78</sup> where the product was “years away” from potential FDA approval,<sup>79</sup> and where the allegedly infringing device had never been used, and likely would not be used in the future.<sup>80</sup>

By examining the seriousness of the threats made by the patentee in light of the concrete steps taken by the declaratory plaintiff, the Federal Cir-

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(S.D.N.Y. 1935) (finding justiciability based upon threats from patentee to customers of declaratory plaintiff and approving of declaratory procedure in patent cases).

70 *Arrowhead*, 846 F.2d at 738 (“That a competitor is suing a third party and asking the court to find one’s company a co-infringer can hardly contribute to euphoria. The law does not require enterprises to keep their heads in the sand while a patentee picks them off one by one and at its leisure.”).

71 *BP Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993).

72 *Indium Corp. of Am. v. Semi-Alloys, Inc.*, 781 F.2d 879, 883 (Fed. Cir. 1985).

73 *Phillips Plastics Corp. v. Kato Hatsujo Kabushiki Kaisha*, 57 F.3d 1051, 1053 (Fed. Cir. 1995).

74 *Arrowhead*, 846 F.2d at 736.

75 *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 879 (Fed. Cir. 2008) (citing *Arrowhead*, 846 F.2d at 736); see *BP Chems.*, 4 F.3d at 978 (stating that the declaratory plaintiff must establish “present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity”); *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 955 (Fed. Cir. 1987) (stating that the declaratory plaintiff “must actually have either produced the device or have prepared to produce that device”).

76 See, e.g., *Arrowhead*, 846 F.2d at 739 (explaining that defendant’s brief stated “a declaratory judgment plaintiff need only show use or preparation for use of a process that ‘might at trial be found to be an infringement’”).

77 *Cat Tech*, 528 F.3d at 881 (citing *Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1346–50 (Fed. Cir. 2007)).

78 *Id.* (citing *Sierra Applied Scis., Inc. v. Advanced Energy Indus., Inc.*, 363 F.3d 1361, 1378–81 (Fed. Cir. 2004)).

79 *Id.* (citing *Teletronics Pacing Sys., Inc. v. Ventritex, Inc.*, 982 F.2d 1520, 1527 (Fed. Cir. 1992)).

80 *Id.* (citing *Jervis B. Webb Co. v. S. Sys., Inc.*, 742 F.2d 1388, 1399 (Fed. Cir. 1984)).

cuit's pre-*MedImmune* bright-line rule aimed to sort out those cases where the parties anticipated forthcoming litigation on the issue of infringement (i.e., cases in which the declaratory procedure afforded the parties an earlier resolution of a case certain to be brought in the future) and those cases where future litigation between the parties remained remote, even as to the issue of infringement. Granting jurisdiction in the former cases but not the latter fulfilled the purpose of the Declaratory Judgments Act—to provide anticipatory relief where previously none could be had until the coercive action was filed—and accomplished this with a basic test requiring both an underlying cause of action and a threat of suit by the holder of that cause of action.<sup>81</sup>

As a result, the bright-line rule worked best in the kinds of cases described by Professor Borchard in support of the Declaratory Judgments Act's equitable remedy, i.e., the "sad and saddening scenario" where a bullying patentee threatens an infringement action to strong-arm an alleged infringer into meeting his demands.<sup>82</sup> These cases typically involved competitors seeking to enter the patentee's market. Even within this category, the test was less useful when applied in cases where the patentee made few, if any, infringement overtures or where the declaratory plaintiffs had no meaningful plans for infringement. Nevertheless, courts considered the totality of the circumstances to weigh whether an actual case or controversy arose between the parties to find jurisdiction only in those cases where the dispute was "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."<sup>83</sup> In other words, courts asked whether a coercive action "arising under" the patent laws—always the patentee's hypothetical coercive action for infringement—loomed close enough on the horizon such that anticipatory relief could be granted to the declaratory plaintiff.

Unlike these factually difficult but legally coherent competitor cases, privileged party cases, where the declaratory plaintiff was a licensee or had received a covenant not to sue, offered more complexity. Prior to 1969, a patent licensee could not contest the validity of a patent subject to his license agreement in a contract suit over royalty obligations.<sup>84</sup> In *Lear v. Adkins*, the Supreme Court removed this legal barricade (referred to as licensee estop-

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81 See Borchard, *supra* note 27, at 37.

82 See *Arrowhead*, 846 F.2d at 734–35.

83 *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941); see *C.R. Bard, Inc., v. Schwarz*, 716 F.2d 874, 879 (Fed. Cir. 1983) (stating that justiciability requires "that the declaratory plaintiff has sufficient interest in the controversy and that there is a reasonable threat that the patentee or licensor will bring an infringement suit against the alleged infringer").

84 See *Automatic Radio Mfg. Co. v. Hazeltine Research, Inc.*, 339 U.S. 827, 836 (1950) (adhering to rule of licensee estoppel to prevent licensee from challenging the validity of licensed patents), *abrogated by Lear, Inc. v. Adkins*, 395 U.S. 653 (1969). In cases like *Automatic Radio*, the Court reasoned that the patent's validity was irrelevant in royalty suits—the licensee promised to pay royalties for the option to practice the patented invention regardless of validity and regardless of whether the licensee actually exercised that option. Alfred C. Server & Peter Singleton, *Licensee Patent Validity Challenges Following MedImmune: Implications for Patent Licensing*, 3 HASTINGS SCI. & TECH. L.J. 243, 269 (2011).



pel), holding that a licensee is not estopped from contesting the validity of the patent, that a contesting licensee is not required to continue paying royalties during the suit and, if the patent is declared invalid, the licensee's obligations under the license, including royalty obligations, are void as a matter of federal patent policy.<sup>85</sup> After *Lear*, the appellate courts developed a split of decision as to whether a licensee could contest the validity of the licensed patent without first breaching or terminating the license agreement.<sup>86</sup> The consolidation of patent appeals to the Federal Circuit eventually resolved the split in favor of patentees. In *Gen-Probe Inc. v. Vysis, Inc.*, the court declined to grant jurisdiction to a licensee-declaratory plaintiff who continued to pay royalties in protest.<sup>87</sup> Without a material breach of the license, the Federal Circuit deduced, the licensee could have no reasonable apprehension of an infringement suit.<sup>88</sup> In similar cases where the declaratory plaintiff received a covenant not to sue from the patentee, the Federal Circuit also refused jurisdiction (or held as moot cases already established) on the grounds that the covenant (provided it was broad enough to cover past and future allegedly infringing activity) removed any apprehension of suit on the part of the declaratory plaintiff.<sup>89</sup> In both license and covenant cases, the Federal Cir-

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85 *Lear*, 395 U.S. at 670, 673; see *Cordis Corp. v. Medtronic, Inc.*, 780 F.2d 991, 995 (Fed. Cir. 1985). For a critical analysis of *Lear* and its effect on patentees' incentives, see Rochelle Cooper Dreyfuss, *Dethroning Lear: Licensee Estoppel and the Incentive to Innovate*, 72 VA. L. REV. 677 (1986) and Rochelle Cooper Dreyfuss & Lawrence S. Pope, *Dethroning Lear? Incentives to Innovate After MedImmune*, 24 BERKELEY TECH. L.J. 971, 976 (2009) (arguing that *MedImmune* limits the reach of *Lear* by permitting licensees to be "remuzzled" when the license itself notifies the licensee that his ability to challenge is limited).

86 Emmett F. Hale, III, *The "Arising Under" Jurisdiction of the Federal Circuit: An Opportunity for Uniformity in Patent Law*, 14 FLA. ST. U. L. REV. 229, 242 n.79 (1986). The Third and Seventh Circuits required the licensee to breach the license to establish justiciability. *Id.* (citing *Thiokol Chem. Corp. v. Burlington Indus., Inc.*, 448 F.2d 1328 (3d Cir. 1971); *Milprint, Inc. v. Curwood, Inc.*, 562 F.2d 418 (7th Cir. 1977)). The Second, Ninth, and District of Columbia Circuits did not require breach as a basis for federal jurisdiction. *Id.* (citing *Warner-Jenkinson Co. v. Allied Chem. Corp.*, 567 F.2d 184 (2d Cir. 1977); *Geni-Chlor Int'l, Inc. v. Multisonics Dev. Corp.*, 580 F.2d 981 (9th Cir. 1978); *Hanes Corp. v. Millard*, 521 F.2d 585 (D.C. Cir. 1976)).

87 *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1381 (Fed. Cir. 2004).

88 *Id.* The court explained that to allow the licensee to invalidate a patent without materially breaching the license, in effect, would force the licensor (patentee) to bear all of the risk of the agreement because the licensee will receive the benefit of limited damages or royalties even if the challenge fails. *Id.* Compare *C.R. Bard*, 716 F.2d at 880-81 (finding jurisdiction when the licensee ceased payments to materially breach the license), with *Cordis*, 780 F.2d at 995 (finding no jurisdiction when the licensee placed royalty payments into escrow). Interestingly, the Federal Circuit adopted the reasonable apprehension of suit test to make constitutional justiciability determinations, yet *C.R. Bard*, its first licensee case addressing the older circuit split, decided a question of statutory jurisdiction ("arising under") rather than constitutional justiciability. See *C.R. Bard*, 716 F.2d at 880. The reasonable apprehension of suit test thus appeared to address both constitutional and statutory jurisdiction.

89 See *Super Sack Mfg. Corp. v. Chase Packaging Corp.*, 57 F.3d 1054, 1059-60 (Fed. Cir. 1995). In *Super Sack*, the covenant not to sue was promised during trial but before an

cuit held that jurisdiction would be inappropriate because anticipatory relief was not necessary to resolve a dispute between these parties.<sup>90</sup> There was no possibility that the declaratory defendant could bring an infringement action against this declaratory plaintiff—no underlying legally cognizable interest supporting an infringement cause of action existed.<sup>91</sup>

Excluding licensees in good standing from challenging patents created a quandary for courts. On one hand, no reasonable apprehension of the hypothetical coercive infringement suit can exist until the protection of the license ceases. On the other hand, a licensee, especially one in good standing, may be the party best suited to challenge the licensed patent.<sup>92</sup> The rigidity of the Federal Circuit's bright-line rule seemed at odds with the policy behind the Declaratory Judgments Act to reduce the uncertainty inherent in moving forward with potentially infringing conduct, as well as federal patent policy encouraging patent challenges (as outlined in *Lear*).<sup>93</sup> By strictly adhering to its reasonable apprehension of suit test, the Federal Circuit failed to include as justiciable those cases where an infringement suit was not probable (or even possible) but where the parties may have had a real and immediate patent dispute anyway.

### C. *The MedImmune Dispute*

The courts again faced this issue in *MedImmune, Inc. v. Genentech, Inc.*<sup>94</sup> The declaratory plaintiff, MedImmune, Inc. ("MedImmune") and the patentee, Genentech, Inc. ("Genentech"), initially entered into a license agreement contemplating patents not yet issued and products that MedImmune was already selling.<sup>95</sup> When the patents issued, Genentech informed MedImmune that it owed Genentech royalties on products Genentech believed were

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infringement verdict, which the court found to moot any jurisdiction previously established under the two-part test. *Id.* In *Fort James Corp. v. Solo Cup Co.*, 412 F.3d 1340 (Fed. Cir. 1995), the court carved out an exception to the *Super Sack* rule whereby jurisdiction is maintained over invalidity claims or counterclaims despite a promise not to sue if the jury or judge has decided the issue of infringement already. *Id.* at 1353 (Schall, J., dissenting).

90 See, e.g., *Gen-Probe*, 359 F.3d at 1381 (explaining that once a license with a covenant not to sue was formed, "[a] licensee must, at a minimum, stop paying royalties (and thereby materially breach the agreement)" in order to establish a reasonable apprehension of suit).

91 See *id.* (stating that a promise not to sue "obliterated any reasonable apprehension of a lawsuit"); *Super Sack*, 57 F.3d at 1059 (stating that a promise not to sue "removes from the field any controversy sufficiently actual to confer jurisdiction over this case").

92 *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969) ("Licensees may often be the only individuals with enough economic incentive to challenge the patentability of an inventor's discovery."). But see Dreyfuss, *supra* note 85, at 754 n.277 and accompanying text (discussing "special benefits that would accrue if patent users were encouraged to challenge patents early").

93 *Lear*, 395 U.S. at 673.

94 549 U.S. 118, 120–21 (2007).

95 *Id.* at 121.

covered by the licensed patent.<sup>96</sup> MedImmune, however, believed that the patent was invalid and that royalties were not due under the agreement.<sup>97</sup> While continuing to pay royalties, it filed a declaratory suit against Genentech seeking to have the patents declared invalid and not infringed in order to remove its own royalty obligations.<sup>98</sup> The district court applied the Federal Circuit's reasonable apprehension of suit test, citing *Gen-Probe*,<sup>99</sup> and held that MedImmune's ongoing payment of royalties prevented it from possessing a reasonable apprehension of suit, thus no case or controversy existed sufficient to establish constitutional justiciability.<sup>100</sup> The Federal Circuit agreed, affirming the district court's dismissal for lack of jurisdiction.<sup>101</sup> The Supreme Court then granted MedImmune's petition for certiorari to answer the following question:

Does Article III's grant of jurisdiction of "all Cases . . . arising under . . . the Laws of the United States," implemented in the "actual controversy" requirement of the Declaratory Judgment Act, 28 U.S.C. § 2201 (a), require a patent licensee to refuse to pay royalties and commit material breach of the license agreement before suing to declare the patent invalid, unenforceable or not infringed?<sup>102</sup>

In its opinion, the Court first questioned the nature of the dispute at hand—"whether it involve[d] only a freestanding claim of patent invalidity or rather a claim that, both because of patent invalidity and because of non-infringement, no royalties are ow[ed] under the license agreement."<sup>103</sup> The majority viewed the case as one involving a dispute over whether royalties were owed under the license agreement, implicating the federal patent questions of non-infringement and invalidity in order to resolve that contracts question.<sup>104</sup> Concluding that the dispute was really one over whether MedImmune owed royalties under the license agreement, the Court held that the dispute between MedImmune and Genentech was sufficiently real and immediate to support Article III justiciability.<sup>105</sup>

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96 *Id.* at 121–22.

97 *Id.*

98 *Id.* at 122. As *Lear* allowed, if a court declares the patent invalid, the licensee avoids all payment of royalties accruing after he challenges the patent. 395 U.S. at 673.

99 *Gen-Probe Inc., v. Vysis, Inc.*, 359 F.3d 1376, 1381 (Fed. Cir. 2004); *see supra* Section I.B.

100 *MedImmune, Inc. v. Genentech, Inc.*, No. CV 03-2567 MRP (CTX), 2004 WL 3770589, at \*4 (C.D. Cal. Apr. 26, 2004), *aff'd*, 427 F.3d 958 (Fed. Cir. 2005), *rev'd*, 549 U.S. 118 (2007).

101 *MedImmune, Inc. v. Genentech, Inc.*, 427 F.3d 958, 963 (Fed. Cir. 2005), *rev'd*, 549 U.S. 118 (2007).

102 Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit at i, *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007) (No. 05-608), 2005 WL 3067195, at \*i (alteration in original).

103 *MedImmune*, 549 U.S. at 123.

104 *Id.* ("[It] probably makes no difference to the ultimate issue of subject-matter jurisdiction, but it is well to be clear about the nature of the case before us.").

105 *Id.* at 137.

The Court found that Genentech's continuing demands for MedImmune to pay royalties for permission to use a patent MedImmune believed to be invalid created a genuine legal interest in the case that could only be resolved by adjudication.<sup>106</sup> The Court rejected the notion that MedImmune had to "bet the farm," or breach the license, in order to contest the validity of the licensed patents.<sup>107</sup> Further, the Court pointed to the *Aetna* and *Maryland Casualty* cases as examples of Article III controversies featuring contractual disputes without termination of the contract as a prerequisite to justiciability.<sup>108</sup> Importantly, MedImmune's desire to avoid accruing patent infringement damages, including the possibility of willful damages, by seeking declaratory relief before (or in lieu of) materially breaching the license persuaded the Court that this was just the sort of real and immediate dispute contemplated by Article III's case or controversy requirement.<sup>109</sup> Accordingly, in the words of the majority opinion, to decide the invalidity question was "not to decide a hypothetical case."<sup>110</sup> The Court, therefore, reversed the Federal Circuit's decision and remanded the case for further consideration.<sup>111</sup> In a footnote, the Court appeared to abrogate at least the first prong of the Federal Circuit's reasonable apprehension of suit test,<sup>112</sup> describing the requirement as contrary to Supreme Court precedent addressing constitutional justiciability, including *Aetna* and *Maryland Casualty*.<sup>113</sup>

In the lone dissent, Justice Thomas disagreed with the majority's description of the nature of the dispute. Instead, he viewed the case as one involving simply a freestanding claim for patent invalidity.<sup>114</sup> As such, neither party had a coercive cause of action (real or hypothetical).<sup>115</sup> Genentech had no cause of action for patent infringement because the contract had not been repudiated. MedImmune had no cause of action for any federal claim because patent invalidity is not a cause of action created under the patent laws. In fact, the patent laws expressly identify invalidity as a defense to an infringement cause of action.<sup>116</sup> Genentech's hypothetical coercive cause of action could not be brought because the license had not been terminated or breached; according to Justice Thomas, this meant that MedImmune did not have a justiciable case or controversy.<sup>117</sup>

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106 *Id.*

107 *Id.* at 129.

108 *Id.* at 133 n.11.

109 *Id.* at 134.

110 *Id.* at 131 n.10.

111 *Id.* at 137.

112 *Id.* at 132 n.11.

113 *Id.* The Court did not address the second prong of the test because no dispute existed as to whether MedImmune was engaged in allegedly infringing activity. *Id.* at 123.

114 *Id.* at 140–41 (Thomas, J., dissenting).

115 *Id.* at 146.

116 35 U.S.C. § 282(b) (2006).

117 *MedImmune*, 549 U.S. at 141–42 (Thomas, J., dissenting); *see Lear, Inc. v. Adkins*, 395 U.S. 653, 673 (1969) (holding that parties must be permitted to avoid the payment of all royalties accruing "during the time they are challenging patent validity"); *Studiengesell-*

#### D. *Post-MedImmune Cases*

As stated in *MedImmune*, “the question in each case 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>118</sup> Despite repeating this worn passage from *Aetna* and *Maryland Casualty*, *MedImmune*’s factual context introduced a wrinkle—the parties disputed the scope of the patent license, a dispute no less justiciable than the contractual dispute in *Aetna*,<sup>119</sup> but involving questions of patent law that also required resolution. That such a dispute failed the rigorous reasonable apprehension of suit test sounded an alarm. Plainly, the parties in *MedImmune* had immediate and real adverse legal interests involving both contract law and patent law.<sup>120</sup> Consequently, the Court could not reconcile the Federal Circuit’s reasonable apprehension of an infringement suit test with the uniquely adverse position of a licensee (like the one in *MedImmune*) who believes that a licensed patent is invalid or not infringed, yet cannot afford the risk of breaching the license and subjecting himself to damages for breach and willful infringement.<sup>121</sup> Thus the Court’s rejection of the reasonable apprehension of suit test in *MedImmune* may be narrowly read to hold that a patentee’s demand for royalty payments under a patent license suffices to establish the requisite cognizable legal interest when the declaratory plaintiff believes the patent to be invalid and not infringed by the products for which royalties have been demanded.<sup>122</sup> The hypothetical coercive action for infringement lurks behind the licensee’s anticipatory repudiation of the license by protesting royalty payments.

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schaft Kohle, M.B.H. v. Shell Oil Co., 112 F.3d 1561, 1567 (Fed. Cir. 1997) (holding that where the court has found the relevant patent claims invalid, the licensor may recover damages for breach of contract for past royalties due on processes allegedly covered by such claims, from the date of the alleged breach until the date that the licensee first challenged validity of the claims).

More likely, Justice Thomas takes issue with the outcome in *MedImmune* because he believes it violates the well-pleaded complaint rule for statutory jurisdiction (“arising under” jurisdiction) because the license, without termination, creates a legal barrier for an infringement suit even though a declaratory plaintiff disputes whether the license reaches to certain products or whether the patents are invalid. See *Cotropia*, *supra* note 33, at 263–64. The application (and wisdom) of the well-pleaded complaint rule, even in patent cases, is beyond the scope of this Article.

118 *MedImmune*, 549 U.S. at 127 (quoting *Maryland Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)).

119 *Compare* *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 242 (1937) (“The dispute relates to legal rights and obligations arising from the contracts of insurance.”), *with* *MedImmune*, 549 U.S. at 124–25 (identifying the nature of the case as revolving around the duties of each party under a license agreement).

120 Even the Court seemed confused as to what the dispute was about—contract or patent. See Transcript of Oral Argument at 11–15, *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007) (No. 05-608).

121 *MedImmune*, 549 U.S. at 132 & n.11.

122 *Id.* (abrogating any test that requires a reasonable apprehension of suit).

Approached more broadly, however, *MedImmune's* rejection of the reasonable apprehension of suit test suggests that Article III does not demand that a hypothetical coercive action for infringement be relatively certain to occur in order to establish justiciability. Instead, Article III, even in declaratory patent cases, requires a flexible inquiry into *what* has been harmed (or will be harmed) by *whom* such that anticipatory relief should be afforded to a declaratory plaintiff. Thus, the Court may be insinuating that the hypothetical coercive action for infringement should be unmoored from the justiciability analysis, which could invite plaintiffs to allege any legally cognizable injury related to the patents in suit.<sup>123</sup> Perhaps plaintiffs should be able to identify and plead legally cognizable injuries that reflect societal harms resulting from invalid patents—reduced competition, for example.

*MedImmune* highlights two competing goals: one focused on private disputes over infringement, the other on the private and public harms from invalid patents. Together these create what might best be called a double-think problem—courts openly embrace justiciability in controversies over patent infringement and validity yet limit this embrace to an identifiable underlying coercive action for infringement as the touchstone for declaratory justiciability, which constrains the availability of patent invalidity actions to would-be competitors or disgruntled licensees. Courts following *MedImmune* attempt to navigate their cases somewhere in between these two shores, emphasizing a broad, flexible inquiry for Article III justiciability yet anchoring the inquiry to a hypothetical infringement action. As one court stated, “[Post-*MedImmune*,] the trend is to find an actual controversy, at least where the declaratory judgment plaintiff’s product arguably practices a patent and the patentee has given some indication it will enforce its rights.”<sup>124</sup>

Updating its own jurisprudence to reflect *MedImmune's* retake on *Aetna*, the Federal Circuit now frames the justiciability question as “a dispute as to a legal right—for example, an underlying legal cause of action that the declaratory defendant could have brought or threatened to bring.”<sup>125</sup> “A useful question to ask in determining whether an actual controversy exists is what, if any, cause of action the declaratory judgment defendant may have against the declaratory judgment plaintiff . . . .”<sup>126</sup> Not surprisingly, even in licensee cases, the cause of action identified by the court must always involve the

123 Brief of Amici Curiae Erika R. George and Kali N. Murray in Support of the Ass’n for Molecular Pathology, et. al, at 10, Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012) (No. 2010-1406).

124 *Diamonds.net LLC v. Idex Online, Ltd.*, 590 F. Supp. 2d 593, 598 (S.D.N.Y. 2008). A more precise statement of the Federal Circuit’s new, wordier test is:

[W]here a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise and the party need not risk a suit for infringement by engaging in the identified activity before seeking a declaration of its legal rights.

*SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1381 (Fed. Cir. 2007).

125 *Arris Grp., Inc. v. British Telecomms. PLC*, 639 F.3d 1368, 1374 (Fed. Cir. 2011).

126 *Benitec Ausl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1344 (Fed. Cir. 2007).

infringement claim that could be brought by the patentee now or sometime in the near future against the declaratory plaintiff.<sup>127</sup> The Patent Act offers no other legally cognizable interest to be disputed. In fact, courts consistently refuse to recognize different legally cognizable patent rights (e.g., the right to operate in the public domain).<sup>128</sup>

Accordingly, traditional cases featuring a threatening patentee and an allegedly infringing competitor are justiciable, as should be cases identical to *MedImmune* featuring a licensee challenging patents while continuing to pay royalties (at least when the licensor has made a demand for royalties, presumably on the grounds that the demand itself would serve as an anticipatory repudiation sufficing to trigger justiciability).<sup>129</sup> That leaves cases in between—within the competitor category, cases where the patentee offers to license the patent but negotiations fail to produce an agreement or where the declaratory plaintiff has not taken any meaningful steps to infringe the patent yet; and within the privileged party cases, cases where the licensee hasn't made a protest or where the patentee has promised not to sue the declaratory plaintiff for infringement. In these cases, courts search for a legally cognizable interest on the part of the declaratory plaintiff, finding it only in those cases where it believes that the patentee's infringement cause of action has accrued through the patentee's affirmative acts toward the plaintiff hinting at enforcement and the plaintiff's affirmative acts suggesting infringement will be forthcoming—the accrual of the infringement cause of action elicits a legally cognizable right to free exploitation of non-infringing goods or processes.<sup>130</sup>

Not surprisingly, the Federal Circuit struggles with cases on the margins involving competitors (for example, cases where a competitor has negotiated for, but failed to procure, a license from the patentee). The legally cognizable interest that the Federal Circuit recognizes in declaratory patent cases—the right to free exploitation of non-infringing activity—cannot suffice for justiciability. If it did, all individuals who could be excluded by the patentee

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127 This is true even where the infringement action arises through the Hatch-Waxman Act rather than through a licensor's explicit threat of suit against a licensee. *Compare* *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988) (applying reasonable apprehension of suit test, which requires explicit acts on part of defendant to indicate intent to bring a suit for patent infringement), *with* *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1341–43 (Fed. Cir. 2007) (finding justiciability based on a controversy arising through the Hatch-Waxman Act, even though patent holder had not sued or threatened to sue).

128 *See, e.g.*, *Leatherman Tool Grp., Inc. v. Copper Indus., Inc.*, 131 F.3d 1011, 1015 (Fed. Cir. 1997) (“[T]he patent laws create no affirmative right supporting a cause of action against a competitor to assert a right to make or copy what is in the public domain . . . .”); *Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1327 (Fed. Cir. 1998) (same); *see also* *Golan v. Holder*, 132 S. Ct. 873, 889–94 (2012) (permitting Congress to restore copyright protection to works previously in the public domain).

129 *MedImmune, Inc. v. Genentech, Inc.*, No. CV 03–02567 MRP (CTX), 2007 WL 5760839, at \*2–3 (C.D. Cal. Aug. 16, 2007).

130 *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1380–81 (Fed. Cir. 2007).

would have this right merely because the patent, as private property, gives the patentee the right to exclude anyone and everyone from practicing what the patent claims—a principle the Federal Circuit has repeatedly rejected.<sup>131</sup> Therefore, courts must find some legally cognizable underlying action for infringement to find justiciable the declaratory action; they must pinpoint when the hypothetical infringement action accrued to the patentee in order to trigger justiciability. In failed negotiation cases, the Federal Circuit looks for specific affirmative acts that suggest that the hypothetical infringement action could be brought by the patentee against this would-be competitor.<sup>132</sup> In licensee cases without a failure to pay royalties, *MedImmune* may allow courts to find that a dispute over the license evinces the right to free exploitation necessary for justiciability.

Importantly, the Federal Circuit cannot allow for patent litigation brought by members of the public who may be harmed by an invalid patent, because these citizens lack a legally cognizable interest despite any identifiable injury in fact that might suffice under *Lujan*. Such a general ban on public patent litigation on the basis of justiciability likely fails to address the goal of the patent system to promote progress by balancing the public's right to free competition with the incentive to innovate. The public interest in justiciability for patent cases is discussed below.

## II. THE RISE IN PUBLIC PATENT LITIGATION

Courts often have been asked to consider public harms created by patents.<sup>133</sup> The grant of exclusive rights to patentees “carries out a public policy adopted by the Constitution and laws of the United States, ‘to promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right . . .’ to their ‘new and useful’ inventions.”<sup>134</sup> In *Pennock v. Dialogue*, Justice Story referred to the “promotion of progress” as “the ‘main object’” of the patent system, the “‘reward of inventors [being] secondary and merely a means to that end.’”<sup>135</sup> The Court continued in *Kendall v. Winsor*, “[T]he rights and welfare of the community must be fairly dealt with and effectually guarded. Considerations of individual emolument can never be permitted to operate to the injury of these.”<sup>136</sup> When patents claim old or obvious inventions, when patents claim inventions more broadly than what was invented, or when patents are granted on ineligible subject

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131 *Id.*

132 *Id.* at 1382.

133 *See, e.g.,* *Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 665 (1944) (citing cases).

134 *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 492 (1942) (alterations in original) (quoting U.S. CONST. art. I, § 8, cl. 8; 35 U.S.C. § 31 (1940)), *abrogated by* *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28 (2006).

135 *United States v. Masonite Corp.*, 316 U.S. 265, 278 (1942) (quoting *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 19 (1829)).

136 *Kendall v. Winsor*, 62 U.S. (21 How.) 322, 329 (1858).



matter, such grants of private exclusive rights are contrary to that important public policy.<sup>137</sup>

After passage of state and federal antitrust laws in the late nineteenth century, the exclusive rights granted by the patent allowed patentees to do exactly what these competition laws were designed to prohibit: unduly restrain competition through price controls, tie sales of unpatented goods to sales of patentable ones, or raise claims of contributory infringement against a supplier of unpatented goods.<sup>138</sup> At first, patentees avoided antitrust liability by virtue of the patent's limited right to exclude others.<sup>139</sup> Patent law did not afford relief when a patentee dictated restrictive licensing terms because, reasoned the courts, the patentee held the right to refuse to license on any terms.<sup>140</sup> As patentees pushed the boundaries of allowable competitive restraint by introducing licenses of all stripes, the courts began to use antitrust principles to declare tying arrangements and price restrictions illegal as a matter of patent law.<sup>141</sup>

During World War II, the Court went even further to recognize for the first time in *Morton Salt Co. v. G.S. Suppiger Co.* an affirmative defense of patent misuse to an infringement claim.<sup>142</sup> Any so-called misuse of the patent, namely undue restraints on trade (including price fixing, monopolizing, and creating tying arrangements), rendered the patent unenforceable against the alleged infringer until the patentee cured the misuse.<sup>143</sup> Reiterating the public welfare concerns of Justice Story and the early courts, the Court in *Morton Salt* explained that unenforceability in cases of misuse was in the public interest: "The patentee, like these other holders of an exclusive privilege

137 *Id.* at 328.

138 See *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 200–01 (1980) (discussing the competing policies of contributory infringement and patent misuse and the limits of patentees' exercise of control over unpatented articles used in their inventions); *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 517–18 (1917) (holding the tying of sale of unpatented goods to sale of patented ones as being "wholly outside of the patent in suit and of the patent law as we have interpreted it"); J. Dianne Brinson, *Patent Misuse: Time for a Change*, 16 RUTGERS COMPUTER & TECH. L.J. 357, 360–66 (1990) (detailing the history of the doctrine related to a fear of tying arrangements); Note, *Patent Rights and the Anti-Trust Laws*, 17 COLUM. L. REV. 538, 542 & nn.1–2 (1917). Congress enacted the Sherman Act in 1890 and subsequently enacted the Clayton Act in 1914. See Robin C. Feldman, *The Insufficiency of Antitrust Analysis for Patent Misuse*, 55 HASTINGS L.J. 399, 403 n.11 (2003).

139 See *Heaton-Peninsular Button-Fastener Co. v. Eureka Specialty Co.*, 77 F. 288, 301 (6th Cir. 1896).

140 *Id.* at 294–95.

141 See, e.g., *Carbice Corp. v. Am. Patents Dev. Corp.*, 283 U.S. 27, 31 (1931) (finding unenforceable restrictions tying a patented good to unpatented materials); *Motion Picture Patents*, 243 U.S. at 518 (finding unenforceable restrictions tying a patented good to unpatented supplies); *Bauer v. O'Donnell*, 229 U.S. 1, 17 (1913) (finding unenforceable price restrictions on downstream sales).

142 *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 493–94 (1942), *abrogated by Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28 (2006).

143 *Id.*

granted in the furtherance of a public policy, may not claim protection of his grant by the courts where it is being used to subvert that policy.”<sup>144</sup> In this and later cases, the Court held that equitably, and as a matter of patent policy,<sup>145</sup> a patentee will not be allowed to enforce his patent as long as he is “impermissibly broadening the patent grant.”<sup>146</sup> Accordingly, the patentee may cure the misuse by eliminating the offensive restraint.<sup>147</sup>

The contours of the misuse doctrine have changed since its inception (and since Congress’s explicit codification of what is not misuse in the 1952 Patent Act),<sup>148</sup> but it remains a viable (albeit uncommonly successful) defense with two surprising procedural characteristics. One, an infringer can use the misuse defense to escape all liability for infringement (akin to the unclean hands doctrine in equity).<sup>149</sup> Two, the infringer need not be harmed by the misuse in question.<sup>150</sup> The public harm created by the anticompetitive effect of the misuse suffices to immunize the alleged infringer (and others in his shoes) from infringement liability until the patentee cures the misuse.<sup>151</sup> Interestingly, no case has addressed whether a

144 *Id.* at 494; *see* *Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661, 665 (1944) (listing cases addressing patent public policy); *see also* *Automatic Radio Mfg. Co. v. Hazeltine Research, Inc.*, 339 U.S. 827, 839 (1950) (Douglas, J., dissenting) (“But what worse enlargement of monopoly is there than the attachment of a patent to an unpatentable article? When we consider the constitutional standard, what greater public harm than that is there in the patent system?”), *overruled in part by* *Lear, Inc. v. Adkins*, 395 U.S. 653, 671 (1969).

145 J. Dianne Brinson describes the policy in *Morton Salt* as one of antitrust policy. *See* Brinson, *supra* note 138, at 365 n.56.

146 *See* *Princo Corp. v. Int’l Trade Comm’n*, 616 F.3d 1318, 1328 (Fed. Cir. 2010); *see also id.* at 1331 (describing patent misuse as “‘patent leverage,’ i.e., the use of the patent power to impose overbroad conditions on the use of the patent in suit”); *Windsurfing Int’l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1001–02 (Fed. Cir. 1986) (describing patent misuse as requiring unlawful restraints of competition). The patent misuse doctrine has been criticized as outmoded and unsound in light of developments in antitrust law and amendments to the Patent Act. *See* Mark A. Lemley, Comment, *The Economic Irrationality of the Patent Misuse Doctrine*, 78 CAL. L. REV. 1599 (1990) (arguing that the misuse doctrine cannot be defended economically); Brinson, *supra* note 138 (describing the misuse doctrine as anachronistic and suggesting elimination). *But see* Feldman, *supra* note 138, at 399–402 (explaining that the Federal Circuit’s antitrust analysis of misuse questions fails to capture the policy concerns embodied in patent law).

147 *Princo*, 616 F.3d at 1328.

148 *See* 35 U.S.C. § 271(d) (2006).

149 *See* Brinson, *supra* note 138, at 366 (“[T]he Court’s decision ‘was just as shocking as if a careless motorist were able to defend the subsequent personal injury suit by proving that the pedestrian had beaten his wife before leaving home.’” (quoting Zechariah Chafee, Jr., *Coming into Equity with Clean Hands*, 47 MICH. L. REV. 1065, 1072 (1949))).

150 *See* *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 494 (1942), *abrogated by* *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28 (2006); Brinson, *supra* note 138, at 366.

151 *See* Lemley, *supra* note 146, at 1631 (arguing that “there is no reason to retain specific parts of the patent misuse doctrine, and very good reason to abolish the entire defense” on the grounds that antitrust laws sufficiently deter anticompetitive behavior).

declaratory plaintiff without plans to infringe and without threats from the patentee can allege patent misuse in support of jurisdiction.

Anticompetitive harm may be the public harm most often associated with the patent system's careful balance of competition and innovation interests.<sup>152</sup> However, in *Vitamin Technologists, Inc. v. Wisconsin Alumni Research Foundation*, the Ninth Circuit identified a different type of harm, namely, the harm to public health that may result from needy groups' lack of access to a patented invention.<sup>153</sup> In *Vitamin Technologists*, the patentee refused to license a patented process for irradiating margarine that would reduce rickets and vitamin D deficiencies in children.<sup>154</sup> The court took notice of the prevalence of rickets in poorer populations and agonized over whether the patentee's refusal to provide access to the invention to the poor supported the patentee's profitable, supracompetitive monopoly. As the court noted, "[i]t is strongly arguable that such a suppression of the patent's use is vastly more against the public interest than its use for a mere control of prices . . . or the tying [sic] of unpatented with patented material . . ." <sup>155</sup> Although it disposed of the case on invalidity grounds—finding all of the contested patent claims invalid and unenforceable on the merits—the court referred its concerns about the welfare of the public to the Attorney General.<sup>156</sup>

*Vitamin Technologists* and other misuse cases described above refer to the public policy underpinnings of the patent system as support for weighing harms to the public interest (incidences of rickets among poorer populations in *Vitamin Technologists* and anticompetitive conduct in the misuse cases) against the value to be gained from the patentee's ability to exclude others, including the alleged infringers being sued (in both cases, this value would presumably be the incentive to invent in the first place).<sup>157</sup> Therefore, unenforceability on misuse grounds necessarily redresses harm to the public

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152 See, e.g., *Capo, Inc. v. Dioptrics Med. Prods., Inc.*, 387 F.3d 1352, 1358 (Fed. Cir. 2004) ("In patent cases the court's refusal to accept a declaratory action also raises issues of public interest, for patent rights are of competitive impact as well as innovation incentive.").

153 146 F.2d 941, 945 (9th Cir. 1945).

154 *Id.* at 943.

155 *Id.* at 946.

156 *Id.*

157 As with any equitable defense, only a party with clean hands (i.e., one who has not engaged in wrongdoing) may raise it, yet courts do not consider a patent infringer an equitable wrongdoer for the purposes of standing in misuse cases. See *C.R. Bard v. M3 Sys.*, 157 F.3d 1340, 1372 (Fed. Cir. 1998); *B. Braun Med. v. Abbott Labs.*, 124 F.3d 1419, 1427 (Fed. Cir. 1997); *Tex. Instruments, Inc. v. Hyundai Elecs. Indus., Co.*, 49 F. Supp. 2d 893, 917 (E.D. Tex. 1999) (citing *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 244 (1933)). Importantly, the court does not require that the party raising a misuse or unclean hands defense suffer from the harm alleged to the public from the patentee's conduct; see *Lemley, supra* note 146, at 1618–19 ("Under current law, the patent infringer can take advantage of the patent misuse doctrine whether or not she has been injured by the patentee's misuse. . . . The lack of an injury requirement often produces situations in which parties who were not injured by misuse are the ones who benefit from the doctrine."); see also *id.* at 1631 (arguing that "there is no reason to retain specific parts of the patent

rather than individual harm to the sued infringer.<sup>158</sup> Precedent exists for two basic propositions. First, a declaratory plaintiff may raise a publicly shared harm related to patent invalidity sufficient to satisfy Article III's injury in fact requirement. Second, such publicly shared harm need not be limited to anticompetitive harms that arise from restrictive licensing practices. Several recent patent cases involving public health concerns suggest that the time has come for recognizing justiciability in patent cases where a declaratory plaintiff claims a publicly shared harm to be redressed by declaratory relief invalidating the patent (and others like it through stare decisis).<sup>159</sup>

#### A. Association for Molecular Pathologists: *Breast Cancer Gene Patents*

The declaratory plaintiffs in *AMP* collectively sought to invalidate patents claiming certain isolated genes and diagnostic methods relating to breast cancer.<sup>160</sup> Patents directed toward genetic subject matter have generated much public debate regarding whether such patents are sound ethically or morally.<sup>161</sup> Despite the public outcry, many thousands of companies have received patents on isolated gene components and methods of diagnosing diseases using DNA sequences on the grounds that this subject matter is patent eligible based on *Diamond v. Chakrabarty*, a seminal case interpreting 35 U.S.C. § 101<sup>162</sup> as allowing patenting for “‘anything under the sun that is made by man.’”<sup>163</sup> By claiming that these patents are invalid under § 101, a successful challenge would render valueless all patents directed toward similar subject matter by recasting the patent eligibility requirement of § 101 to exclude an entire class of subject matter—genetic material.

*AMP's* declaratory plaintiffs were comprised of genetic researchers, medical practitioners who referred patients to the patent owner's facility to be

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misuse doctrine, and very good reason to abolish the entire defense” on the grounds that antitrust laws sufficiently deter anticompetitive behavior).

158 See *Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, 494 (1942), *abrogated by* *Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28 (2006). In contrast, an antitrust plaintiff must demonstrate competitive harm in order to demonstrate standing to bring suit. See, e.g., *City of New York v. Grp. Health Inc.*, 649 F.3d 151, 155 (2d Cir. 2011) (“To state a claim under [the antitrust laws], a plaintiff must allege a plausible relevant market in which competition will be impaired.”); *United States v. Visa U.S.A., Inc.*, 344 F.3d 229, 238 (2d Cir. 2003) (“[T]he [plaintiff] must demonstrate that within the relevant market, the defendants' actions have had substantial adverse effects on competition . . .”).

159 See *AMP*, 689 F.3d 1303 (Fed. Cir. 2012), *aff'd in part on other grounds, rev'd in part on other grounds sub nom.* *Ass'n for Molecular Pathology v. Myriad Genetics, Inc. (AMP II)*, 133 S. Ct. 2017 (June 13, 2013); *Mama Cares*, 825 F. Supp. 2d 178 (D.D.C. 2011); *Organic Seed Growers & Trade Ass'n v. Monsanto Co.*, 718 F.3d 1350 (Fed. Cir. 2013).

160 *AMP*, 689 F.3d at 1309.

161 See *Talk of the Nation: Breast Cancer Gene Patents Challenged* (National Public Radio broadcast Dec. 11, 2009), available at <http://www.npr.org/templates/transcript/transcript.php?storyId=121343433>.

162 35 U.S.C. § 101 (2006).

163 *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting S. REP. NO. 82-1979, at 5 (1952)) (finding invented microorganisms “patentable subject matter”).

tested for certain genetic mutations identified in the patents, and patients whose insurance did not cover either the initial testing, or second testing for patients whose first results were inconclusive.<sup>164</sup> Nearly ten years before the declaratory plaintiffs filed their complaint, Myriad Genetics, Inc. (“Myriad”), the exclusive licensee of the patents challenged in *AMP*, sued one company (not a party to *AMP*) for patent infringement and sent cease-and-desist letters with license offers to several of the declaratory plaintiff researchers.<sup>165</sup> At least one researcher admitted on the record that he was ready, able, and willing to conduct arguably infringing activity if the patent were to be held invalid by the court.<sup>166</sup> On appeal, the Federal Circuit held that the willingness of this researcher to engage in potentially infringing activity, in combination with Myriad’s earlier enforcement maneuvers, created a dispute sufficiently real and immediate to establish Article III jurisdiction.<sup>167</sup>

Importantly, the court noted that the researcher need not bet the farm by engaging in the arguably infringing activity now; he could instead challenge the patents in court based on future plans to practice the patented invention.<sup>168</sup> This is a restatement of the precise wording of *MedImmune*.<sup>169</sup> But *AMP* is not a licensee case. The declaratory plaintiff’s interest is determined by his desire to practice a presumably valid patent—a desire that may be held by many individuals whom Myriad has not threatened with an infringement action. Moreover, Myriad did not reach out to many of the plaintiffs, if at all; when it did reach out to those few, it did so a decade earlier. Myriad’s hypothetical coercive action for infringement was not on the doorstep of the courthouse. However, the Federal Circuit considered all the circumstances in order to hold that the dispute was immediate and real, at least as to the one plaintiff who was ready, willing, and able to infringe upon invalidation of the patents.<sup>170</sup> By casting this individual plaintiff as a potential competitor, the court was able to frame the injury as one to the plaintiff’s right to freely operate without exclusion from the patent owner—a right that apparently did not become a legally cognizable interest until the plaintiff professed his readiness and willingness to infringe at some point.

### B. Mama Cares Foundation: *Ready-to-Eat Therapeutic Food Patents*

In *Mama Cares Foundation v. Nutriset Société Par Actions Simplifiée*, the declaratory plaintiffs, Mama Cares Foundation and Breedlove Foods (collectively, “Mama Cares”)—two non-profit companies focused on the problem of global hunger—claimed that the patentee’s refusal to license the patented process for manufacturing Plumpy’nut® ready-to-eat therapeutic food prod-

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164 *AMP*, 689 F.3d at 1308.

165 *Id.* at 1321.

166 *Id.*

167 *Id.* at 1321–23.

168 *Id.* at 1322.

169 *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 134 (2007).

170 *AMP*, 689 F.3d at 1321–22.

ucts harmed its efforts to eradicate world hunger.<sup>171</sup> In order to remedy this harm, Mama Cares requested a declaratory judgment of non-infringement and invalidity on the grounds that the patent's claims were too vague to sustain protection. After the patentee challenged justiciability on Article III grounds, Mama Cares argued that the dispute comprised a "substantial controversy . . . of sufficient immediacy and reality"<sup>172</sup> (*MedImmune's* new standard) because the patentee declined to license the patent to others in the United States and sent a warning to the therapeutic food industry that it would take steps to enforce its patent against infringers.<sup>173</sup> The court dismissed the action, emphasizing the lack of affirmative acts by the patentee directed toward these particular declaratory plaintiffs—industry warnings and a refusal to license others did not rise to the level of conduct causing an Article III prescribed injury in fact.<sup>174</sup> Like other courts using the Federal Circuit's post-*MedImmune* precedent to determine questions of justiciability, the court focused on the underlying cause of action for infringement and determined that no cause of action had yet accrued because the patentee failed to reach out to Mama Cares in order to enforce the patent against it.<sup>175</sup> The public harm alleged by the plaintiffs in *Mama Cares*—a harm similar to one identified as problematic by the court in *Vitamin Technologists*—was not considered by the court to support justiciability, despite the case's focus on the problem of global hunger.<sup>176</sup>

### C. Organic Seed Growers Trade Association: *Genetically Modified Food Patents*

Like patents covering genetic subject matter, patents claiming genetically modified food implicate the public debate regarding the harms associated with "Frankenfood" and whether such food should be sold and

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171 *Mama Cares*, 825 F. Supp. 2d 178, 180 (D.D.C. 2011). The patent claimed the preparation and use of foods or nutritional supplements in the treatment of malnutrition, and the product sold under the patent is known commonly by its brand name, Plumpy'nut®. *Id.* "Plumpy'nut® is a peanut-based product that does not need to be mixed with water, has a two-year shelf life, and does not require refrigeration. These qualities make Plumpy'nut® a particularly effective tool in combating severe malnutrition in developing countries." *Id.* Mama Cares and Breedlove developed their own peanut-based ready-to-eat therapeutic food designed to treat malnutrition. *Id.*

172 *MedImmune*, 549 U.S. at 127 (quoting *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)).

173 *Mama Cares*, 825 F. Supp. 2d at 182–83.

174 *Id.* at 183–84.

175 *Id.*

176 Courts have trimmed the reach of the patent misuse doctrine to public harms created by the abuse of market power and not by refusals to license. Therefore, the patentee's refusal to license would not have supported a claim for patent misuse to render the patent invalid. Because misuse is a statutory defense, this should say nothing about whether the harm may suffice to create standing under *Lujan*.

distributed globally.<sup>177</sup> The declaratory plaintiffs in *OSGTA*—a group of organic seed growers and organic farms—filed a declaratory complaint against Monsanto Company (“Monsanto”)—the owner of many patents directed toward genetic plant technology used in growing genetically modified food—despite a desire to *not* infringe the patents in suit.<sup>178</sup> The declaratory plaintiffs alleged that the patent was invalid for a variety of reasons, including a claim that it lacks the utility required for patent eligibility by § 101.<sup>179</sup> Although Monsanto is a well-known litigant when it comes to enforcing its genetic seed patents,<sup>180</sup> the district court held that the declaratory plaintiffs did not persuade the court that the dispute was immediate: Monsanto had not threatened any individual plaintiff with infringement litigation, and no individual plaintiff had, to its knowledge, infringed the patent.<sup>181</sup> On appeal, the Federal Circuit conceded that trace amounts of patented genetic material would infringe the patent, but held that Monsanto made the controversy moot by promising not to sue any inadvertent infringers like the organic farmers who brought the suit.<sup>182</sup>

The declaratory plaintiffs claimed that the propagation of genetically modified seeds by Monsanto would lead to inevitable contamination of general seed populations through wind dispersal, cross-pollination, and other contamination processes.<sup>183</sup> As a result, the organic farmers and seed growers—who have a strong personal and professional desire to not infringe because infringement would taint their organic seed lines with unwanted genetic characteristics—almost certainly would become infringers at some unknown point in the future.<sup>184</sup> The inevitable but undesired infringement argument failed to convince the court that the declaratory plaintiffs needed anticipatory relief—Monsanto’s assurances that it would not sue inadvertent infringers rendered any controversy moot.<sup>185</sup>

#### D. Defining the Need for Public Patent Litigation

Courts necessarily framed each of these cases as a competitive injury case—the only way to utilize the declaratory judgment procedure to obtain

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177 See Brooke Glass-O’Shea, *The History and Future of Genetically Modified Crops: Frankenfoods, Superweeds, and the Developing World*, 7 J. FOOD L. & POL’Y 1, 1 (2011) (discussing the advent of “ Frankenfoods”).

178 *OSGTA*, 851 F. Supp. 2d 544, 555 (S.D.N.Y. 2012), *aff’d*, 718 F.3d 1350 (Fed. Cir. 2013).

179 Amended Complaint at 53, *OSGTA*, 851 F. Supp. 2d 544 (S.D.N.Y. 2012) (No. 11-cv-2163); see also 35 U.S.C. § 101 (2006) (establishing utility requirement for patents).

180 See Donald L. Barlett & James B. Steele, *Monsanto’s Harvest of Fear*, VANITY FAIR, May 2008, available at <http://www.vanityfair.com/politics/features/2008/05/monsanto200805>; FOOD, INC. (Magnolia Home Entertainment 2008).

181 *OSGTA*, 851 F. Supp. 2d at 556.

182 *Organic Seed Growers & Trade Ass’n v. Monsanto Co.*, 718 F.3d 1350, 1359–61 (Fed. Cir. 2013).

183 See *OSGTA*, 851 F. Supp. 2d at 548–49.

184 *Id.*

185 *Id.* at 549.

anticipatory relief in declaratory patent cases because of the requirement of a legally cognizable interest associated with an accrued infringement cause of action.<sup>186</sup> Courts identify the injury as one to the plaintiff's right to freely practice the claimed invention, but this legally cognizable right is not available unless and until an underlying cause of action for infringement becomes cognizable, which requires proof of the patentee's affirmative acts toward the declaratory plaintiff and the declaratory plaintiff's desire and ability to infringe the patent but for the patentee's right to exclude.<sup>187</sup> The tethering of declaratory justiciability and an underlying infringement cause of action makes sense legally (as described above in Section I.C) and historically (the Declaratory Judgments Act envisioned only harassed infringers bringing suit against the harassing patentees<sup>188</sup>). However, as *MedImmune* itself demonstrates, the underlying cause of action for infringement need not have accrued, in the legal sense, in order to support justiciability; rather, the Court cautioned lower courts to make decisions based on "all the circumstances."<sup>189</sup>

This resulting doublethink creates problems at the margins for would-be competitors who have not been threatened by cautious patentees. Such would-be competitors could craft a complaint alleging justiciability without much more than vague threats and a desire and ability to infringe. Indeed, this is precisely the sort of declaratory plaintiff the *AMP* court approved.<sup>190</sup> In *AMP*, the Federal Circuit stretched the *MedImmune* standard to its broadest point yet, finding one plaintiff who was ready, willing, and able to infringe upon invalidation of the patents in suit. The affirmative acts that courts have been demanding of declaratory plaintiffs in patent cases post-*MedImmune* were lacking in *AMP*, yet justiciability remained.

Moreover, despite the doublethink of suggesting broad justiciability requirements while demanding a legally cognizable underlying infringement action, courts ignore the policy concerns raised in many patent cases as to the welfare of the public.<sup>191</sup> Accordingly, the "problem" of justiciability in declaratory patent cases, on its face, appears to be a small one—the group of would-be competitors who are not sure whether their complaint rises to the level needed to trigger justiciability. Yet a hidden problem may be much larger. Patents grant exclusive private rights to spur innovation, but these

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186 See, e.g., *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1292 (Fed. Cir. 2008) (discussing the exclusions of the declaratory plaintiff from drug market).

187 See *AMP*, 689 F.3d 1303, 1316 (Fed. Cir. 2012) (affirming the district court's finding that declaratory plaintiffs had the ability and desire to engage in infringement, as well as the belief that such testing was within their rights, but could not do so without risking infringement liability), *aff'd in part on other grounds, rev'd in part on other grounds sub nom. AMP II*, 133 S. Ct. 2107 (June 13, 2013); *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1380–81 (Fed. Cir. 2007) (requiring a showing of affirmative acts by the patentee toward the declaratory plaintiff).

188 See BORCHARD, *supra* note 34, at 812.

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

190 See *AMP*, 689 F.3d at 1321 n.8, 1321–22.

191 See *supra* text accompanying notes 15–16.



rights come with a cost to society in the form of direct costs, like reduced competition and administrative expenses, and in the form of indirect costs, like inadequate health care for those who cannot afford patented medicines and diagnostic measures or a lack of diversity in agricultural crops due to genetically modified organism dispersal.<sup>192</sup> Article III standing and other justiciability doctrines need not ignore the public harm, writ large, from invalid patents. Nor should these doctrines ignore the individual harms suffered by members of the public when unwarranted exclusive rights are given to a private party. The very existence of a patent restricts any individual's freedom to operate because a patent carries a presumption of validity and explicitly gives the patentee the right to enforce the patent against anyone, even innocent infringers.<sup>193</sup>

Normatively, it makes little sense to find justiciable those cases where would-be competitors have a very small risk of being drawn into an infringement action (as in *AMP*) yet not find justiciable those cases where the patent (or patents) in suit, through threatened enforcement against others, the chilling of competition, or lack of access for the neediest individuals, harms individual members of the public by reducing competition unnecessarily without an accompanying and more beneficial promotion of innovation (as in, possibly, *Mama Cares*). Instead of framing these cases as ones involving competitors—trying to fit them to the Federal Circuit's precedent involving competitive injury and an underlying legally cognizable interest in a future infringement action—perhaps the time has come for public patent litigation, where plaintiffs are able to raise not only the public's dual rights to competition and innovation as promised by the patent system, but other harms like the lack of access to medicines presented by the *Mama Cares* and *Vitamin Technologists* cases.

### III. A LIMITED CITIZEN'S RIGHT TO CHALLENGE PATENTS

The historical coupling of an infringement claim and its invalidity counterpart arose from pre-declaratory judgment cases wherein invalidity could only be raised as a defense to an infringement claim.<sup>194</sup> Now commonplace, the declaratory judgment procedure (as described in Part I) allows a claim

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192 See *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969) (“Licensees may often be the only individuals with enough economic incentive to challenge the patentability of an inventor’s discovery. If they are muzzled, the public may continually be required to pay tribute to would-be monopolists without need or justification.”).

193 35 U.S.C. § 282 (2006) (“A patent shall be presumed valid.”); see 35 U.S.C. § 287 (2006 & Supp. V 2011) (requiring only constructive notice of patent by patentees, thus leaving innocent infringers who have not received *actual* notice liable); see also Christopher A. Harkins, *Choosing Between the Advice of Counsel Defense to Willful Patent Infringement or the Effective Assistance of Trial Counsel: A Bridge or the Troubled Waters?*, 5 NW. J. TECH. & INTELL. PROP. 210, 221 (2007) (“Even innocent parties may be liable for patent infringement . . . an innocent infringer is no less liable than a willful infringer.” (footnote omitted)).

194 See, e.g., *W. Bickford Co. v. Merrill*, 268 F. 540, 541 (1st Cir. 1920) (“This is a patent infringement case. The defenses are invalidity and noninfringement.”).

for relief in the form of a judgment of patent non-infringement and/or invalidity, but only in those instances where the case otherwise meets Article III's justiciability requirement.<sup>195</sup> Courts have taken this to mean, at a minimum, that a legally cognizable infringement case must be *possible* for the patentee to bring suit against the declaratory plaintiff.<sup>196</sup> This possibility may be quite remote, as in licensee cases like *MedImmune* (where the licensee fears the consequences of terminating or breaching the license and so the license remains in force) but the possibility nevertheless may create a continuing dispute that sends the licensee to court to seek a remedy in the form of declaratory relief.<sup>197</sup>

When a court focuses on the declaratory defendant's underlying cause of action for infringement in order to find a legally cognizable right on the part of the declaratory plaintiff, the court essentially demands that the declaratory plaintiff raise a competitive injury in order to establish justiciability. This injury, characterized by the Federal Circuit as a restraint on the declaratory plaintiff's legally cognizable right to free exploitation of non-infringing goods, describes a large majority of the injuries in declaratory patent cases. Declaratory plaintiffs more often than not are current or future competitors of the patentee, someone for whom infringing without paying tribute to the patent owner would provide a competitive advantage.<sup>198</sup> For this reason, in cases featuring threats by the patentee and potential infringing activity, the declaratory judgment procedure can and does provide adequate relief when the plaintiff identifies as his injury a restraint on his freedom to exploit non-infringing products or processes.

Declaratory plaintiffs who do not face threats from a patentee and are not poised to infringe the patent will be turned away routinely from federal court on justiciability grounds. In *MedImmune* and elsewhere, courts have stated that Article III does not recognize such a remote or speculative infringement case in support of the claim for declaratory relief.<sup>199</sup> However, *MedImmune's* "all the circumstances" standard is not inconsistent with the normative claim that a non-infringing member of the public could be

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195 28 U.S.C. § 2201 (2006 & Supp. V 2011).

196 *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1345 (Fed. Cir. 2007) (holding that the mere possibility of a future suit was an injury sufficient to find a justiciable controversy).

197 *MedImmune, Inc. v. Genentech, Inc.*, No. CV 03-2567 MRP, 2004 WL 3770589, at \*5-6 (C.D. Cal. April 26, 2004). Interestingly, the court stated that the bringing of the invalidity suit creates the dispute sufficient for Article III, which seems a bit beyond the statement in *MedImmune*.

198 *See, e.g., Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1291 (Fed. Cir. 2008) (identifying the alleged injury in fact as a "restraint on the free exploitation of non-infringing goods" (quoting *Red Wing Shoe Co., Inc. v. Hockerson-Halberstadt, Inc.*, 148 F.3d 1355, 1360 (Fed. Cir. 1998))).

199 *See, e.g., Velvet Underground v. Andy Warhol Found. for the Visual Arts, Inc.*, 890 F. Supp. 2d 398, 408 (S.D.N.Y. 2012) (noting that the injury claimed was not "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment" (quoting *MedImmune*, 549 U.S. at 127)).

allowed to bring a declaratory judgment claim for patent invalidity separate from any immediate (and cognizable) underlying claim for infringement. The easiest mechanism for realizing this normative claim outside of the confusing declaratory judgment context involves legislative action. First, Congress could enact a statutory cause of action for invalidating a patent in order to create a legally cognizable right sufficient to create federal jurisdiction without utilizing the tortuous declaratory judgment procedure and without requiring *infringement* as a touchstone for the declaratory plaintiff's legal right. Next, courts could accept individual harms that are shared by the public as injuries in fact sufficient to support standing for such a citizen's action to invalidate a patent under the Court's *Lujan* framework. Each of these is addressed below.

#### A. *A Carefully Crafted Statutory Right to Sue*

The Constitution gives Congress the power “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”<sup>200</sup> Under this power, Congress could create a statutory right to challenge a patent in a civil action for invalidity or unenforceability. “[T]he importance to the public at large of resolving questions of patent validity”<sup>201</sup> supports making a civil action for cancelling a patent available to parties claiming a right to free exploitation of the claimed invention, a legally cognizable interest recognized by statute without the cumbersome procedure of the declaratory judgment mechanism.

The Supreme Court paved the way for a statutory right to invalidate by first recognizing the separability of a declaratory invalidity claim (or counterclaim) from an infringement claim (or counterclaim). In *Altwater v. Freeman*, the Court famously proclaimed, “[t]o hold a patent valid if it is not infringed is to decide a hypothetical case.”<sup>202</sup> However, in the very next sentence, the Court carefully distinguished invalidity as a defense (pled in an answer to a bill of infringement) from invalidity as a counterclaim.<sup>203</sup> The invalidity counterclaim, the Court suggested, could stand alone despite dismissal of the infringement bill, provided it had independent justiciability under Article III (in that case, supplied by other claims and devices in dispute).<sup>204</sup> Later, after the Federal Circuit made a practice of vacating invalidity judgments on appeal upon affirming non-infringement judgments, the Court reiterated that a non-infringement judgment did not moot an invalidity judgment, nor did it support vacating such judgments—when the district court has jurisdiction to consider the invalidity counterclaim independent of the infringement

200 U.S. CONST. art I, § 8, cl. 8.

201 *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 101 (1993) (citing *Blonder-Tongue Labs., Inc. v. University of Ill. Found.*, 402 U.S. 313 (1971)).

202 *Altwater v. Freeman*, 319 U.S. 359, 363 (1943).

203 *Id.*

204 *Id.*

charge, the Federal Circuit retains the power to decide the question of invalidity.<sup>205</sup> Thus claims for invalidating patents could stand alone, provided such claims were, in their own right, justiciable.

The first step to recognizing justiciable claims for patent invalidation for members of the public would be to delineate a legal right to free exploitation of non-infringing activity separate from, and not dependent upon, the patentee's legal right to enforce the patent.<sup>206</sup> Because the patent grants to the patentee the right to exclude all from practicing the invention in violation of 35 U.S.C. § 281,<sup>207</sup> the right to free exploitation of non-infringing activity should belong to all citizens regardless of underlying infringement threats. Therefore, Congress could model this new legal right on the legal rights granted by the citizen suit provisions found in environmental laws.<sup>208</sup> A citizen suit provision granted to members of the public in order to adjudicate a legal right to free exploitation of non-infringing activity would advance the public interest in policing patents in federal courts, a policy endorsed by the Supreme Court in misuse cases as well as in *Lear*<sup>209</sup> and, most recently, in *MedImmune*.<sup>210</sup>

Congress has the broad authority to create legal injuries sufficient to provide standing to members of the public to challenge patents in court.<sup>211</sup> In *Federal Election Commission v. Akins*,<sup>212</sup> for example, Congress created a right to bring suit to any person "aggrieved" by a Federal Election Commission decision. The right created, then, was defined as a right to information about political committees and the Federal Election Commission's decision at issue denied plaintiffs' right to that information, which was "deemed sufficient to meet Article III and to allow standing under the broad citizen suit provision for any aggrieved person."<sup>213</sup> The Court emphasized that the term "aggrieved" indicates a "congressional intent to cast the standing net

205 *Cardinal Chem. Co.*, 508 U.S. at 98.

206 Recall from Section I.C above that the declaratory judgment procedure will not allow recognizing the right to free exploitation of non-infringing activity without establishing an imminent underlying cause of action for infringement.

207 35 U.S.C. § 281 (2006).

208 Elizabeth Magill, *Standing for the Public: A Lost History*, 95 VA. L. REV. 1131, 1187–89 (2009). Magill describes the citizen suit provisions in the Clean Air Act, Clean Water Act, Marine Protection, Research, and Sanctuaries Act, Noise Control Act, Endangered Species Act, Toxic Substances Control Act, and the Surface Mining Control and Reclamation Act. *Id.* According to Magill, Congress envisioned citizens as private enforcers of the environmental laws, even against private defendants as well as federal agencies. See *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 209 (2000) (Scalia, J., dissenting) ("By permitting citizens to pursue civil penalties payable to the Federal Treasury, the Act does not provide a mechanism for individual relief in any traditional sense, but turns over to private citizens the function of enforcing the law.").

209 *Lear, Inc. v. Adkins*, 395 U.S. 653, 670–71 (1969).

210 *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 136 (2007).

211 *CHEMERINSKY*, *supra* note 42, § 2.3, at 72 (citing *Fed. Election Comm'n v. Akins*, 524 U.S. 11 (1998)).

212 524 U.S. 11 (1998).

213 *CHEMERINSKY*, *supra* note 42, § 2.3, at 72–73.

broadly—beyond the common-law interests and substantive statutory rights upon which ‘prudential’ standing traditionally rested.”<sup>214</sup> A statutory right to cancel a patent given to a person aggrieved by the grant of the patent itself appropriately constrains the availability of the civil action to only those persons who suffer an injury within the zone of interests to be protected by the provision in the first place—the harms that arise when an unwarranted right to exclude is granted to a patentee. A civil action granting a statutory right to bring suit to cancel a patent provides a mechanism for challenging patents that circumvents the tortuous declaratory judgment procedure associated with the civil action for infringement. And providing such a civil action allows Congress to make clear to courts that a policy of encouraging more patent challenges works to enhance the system already in place. By creating a legal interest in the form of a civil action, the inquiry rightfully will revolve around the injury in fact suffered by the plaintiffs in suit—is this plaintiff harmed by this potentially invalid patent in a way that supports standing to bring suit?

Some scholars have questioned congressional authority to create legal rights in the form of citizen suits on separation of powers grounds—arguing that allowing Congress to dictate law enforcement blurs the line between congressional power and executive branch power.<sup>215</sup> However, in the patent context, citizens (with Article III standing, of course) will identify and challenge suspect patents on their merits. Set within the patent system as a whole, a legal right to nullify presents a special case where citizen challenges to patents would advance the goals of the system to promote progress by granting exclusive rights, while preserving the public interest in free competition where those rights are unwarranted. Congress created the patent system to incentivize innovators; recognizing a legal right to free exploitation simply smoothes the route to ridding the system of invalid or unenforceable patents rather than tipping a balance between legislative and executive function. The citizen is not enforcing the patent laws in lieu of the USPTO, but rather providing a backstop for nullifying patents after the regulatory process of patent procurement has ended.<sup>216</sup>

A modest statute creating a legal right to free exploitation of non-infringing activity must further identify *who* can sue for a violation of this right, *when* the suit may be brought, and the *remedy* that may be sought. In one simple version, Congress could authorize anyone who is aggrieved by the

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214 *Akins*, 524 U.S. at 19.

215 See Robin Kundis Craig, *Will Separation of Powers Challenges “Take Care” of Environmental Citizen Suits? Article II, Injury-in-Fact, Private “Enforcers,” and Lessons from Qui Tam Litigation*, 72 U. COLO. L. REV. 93, 95–96 (2001); Charles S. Abell, Note, *Ignoring the Trees for the Forests: How the Citizen Suit Provision of the Clean Water Act Violates the Constitution’s Separation of Powers Principle*, 81 VA. L. REV. 1957, 1957–58 (1995).

216 This citizen-suit backstop is necessary because of the insufficiency of current post-grant procedures. See Eric Williams, Note, *Remembering the Public’s Interest in the Patent System - A Post-Grant Opposition Designed to Benefit the Public*, 2006 B.C. INTELL. PROP. & TECH. F., at 1 (discussing the “absence of a timely, inexpensive mechanism for invalidating the high number of bad patents being issued”).

existence of the allegedly invalid patent to bring a civil action to obtain a remedy in the form of a judgment of invalidity or unenforceability. In this formulation, a person may be aggrieved by harm to competition, where the invalid patent limits consumer choice or freedom to operate by competitors. A person may also be aggrieved by harm to innovation where the invalid patent prevents technological advance within an industry. Either version of harm would suffice for standing to sue to protect the legal right created by the statute and may embrace many public policy concerns.

The statute also could limit when aggrieved citizens may bring a suit to invalidate a patent. The Leahy-Smith America Invents Act has significantly changed how members of the public challenge patents through administrative procedures at the USPTO.<sup>217</sup> As of March 2013, members of the public may challenge a patent grant in a post-grant opposition procedure brought within nine months from the patent's grant.<sup>218</sup> After expiration of the nine months, members of the public may utilize the more limited *inter partes* reexamination procedures to cancel claims.<sup>219</sup> The USPTO recently proposed rules for each of these procedures, which are intended to provide a parallel path for invalidation in district courts after the patent has been granted.<sup>220</sup> Notably, the post-grant opposition procedures aspire to reduce the costs that may amass from an invalid patent over time by allowing for cancellation relatively soon after the grant. For this reason, the proposed statute should, at a minimum, require nine months to expire from the grant of the patent in order to accommodate the post-grant opposition procedures.<sup>221</sup> The *inter partes* procedures may be brought any time after the nine months expire, and would simply continue to provide a parallel path for invalidity within the USPTO. For many years, the USPTO reexamination procedures have co-existed with district court determinations of invalidity, offering a cheaper and more expeditious route to cancellation for many dubious patents.<sup>222</sup> There is no reason to believe that an additional mechanism for streamlined invalidity actions in district courts would hamper the goals of these procedures. In fact, under the proposed rules, any party who has previously filed a civil action seeking to challenge the patentability of a patent may not institute

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217 Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011).

218 See § 6(d), 125 Stat. at 299–313 (adding 35 U.S.C. § 325 for post-grant review).

219 See Pub. L. No. 112-274, § 1(d)(2), 126 Stat. 2456 (adding 35 U.S.C. § 311 for *inter partes* reviews).

220 Changes to Implement Inter Partes Review Proceedings, Post-Grant Review Proceedings, and Transitional Program for Covered Business Method Patents, 77 Fed. Reg. 48,680 (Aug. 14, 2012) (to be codified at 37 C.F.R. pt. 42).

221 The European patent rules also recognize this and require nine months to accommodate post-grant opposition of patents. See Convention on the Grant of European Patents (European Patent Convention) art. 99, Oct. 5, 1973, 1065 U.N.T.S. 199 (as amended Nov. 29, 2000), available at <http://www.epo.org/law-practice/legal-texts/html/epc/2010/e/ar99.html> (last visited Oct. 17, 2013).

222 See 35 U.S.C. §§ 305, 314 (2006) (determining that reexamination proceedings shall be conducted with “special dispatch” within the patent office).

either a post-grant review or an *inter partes* reexamination.<sup>223</sup> These features ensure that members of the public will hesitate before instituting the more expensive yet more robust district court proceedings under the proposed statute.<sup>224</sup>

Moreover, the importance of the public interest in policing allegedly bad patents suggests that *inter partes* procedures be supplemented with a right to invalidate in district courts for aggrieved persons identifying harms of public importance. The new *inter partes* procedures, as proposed by the USPTO to be implemented in 2013, allow members of the public to raise questions of substantial patentability for any and all claims of a patent, whereupon the USPTO reviews these questions to determine whether these identified claims pass muster under the Patent Act (i.e., novel, not obvious, and adequately disclosed).<sup>225</sup> Although the decisions from the Patent Trial and Appeal Board are appealable to the Federal Circuit, public interest groups may find it more desirable to bring suit for invalidity in a district court of their choosing, where appeal also may be taken to the Federal Circuit. The district court provides a more transparent forum for challenges.

One possible counterargument to providing a right to invalidate to any aggrieved person may be that a citizen suit provision would increase the number of litigations brought to invalidate patents and thus would strain our already burdened federal court dockets. As demonstrated in Part II above, public interest groups already bring suits in those cases where the public has an interest in patent invalidation and seek plaintiff members who may best get over the Article III standing hurdle. A statute creating a right to invalidate would simply make this mechanism easier for litigants who are able to establish an injury in fact by eliminating the narrower view that imminent infringement litigation provides the only route for a legally cognizable interest in invalidation. This alone would prevent any rush to the courthouse for all questionable patents. Patent litigations are very costly, which could prohibit all but the most serious suits. Despite the added expense, federal court determinations of invalidity may be more preferable despite the added expense in important public cases (high profile or critical to an entire industry, as in *AMP*). In some cases, the litigants also challenge patent policy through the federal courts—interpreting the Patent Act’s provisions and the USPTO’s regulations are functions that cannot be accommodated by the administrative proceedings available at the USPTO for amendment to or invalidation of patents.

Congress has already granted the right to bring declaratory judgment claims of invalidity, non-infringement, and unenforceability to generic com-

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223 35 U.S.C. § 315(a)(1) (2006 & Supp. V 2011).

224 The statute effectively forces those challenging a patent to choose either to utilize *inter partes* review or to pursue a remedy in the courts, to the exclusion of the other. See 35 U.S.C. § 315 (2006 & Supp. V 2011).

225 See Changes to Implement Inter Partes Review Proceedings, *supra* note 220.

panies under the amendments to the Hatch-Waxman Act.<sup>226</sup> The recent provisions in the Affordable Care Act relating to biologics also create a cause of action for declaratory challenges to patents.<sup>227</sup> Although helpful in sorting out the issues described above when determining justiciability in declaratory patent cases, this Article proposes that the declaratory judgment mechanism is a poor one for raising invalidity issues. Therefore, even these provisions could be amended to grant a legally cognizable right to bring suit to invalidate, recognizing that generic companies and competing biologics makers most likely would have standing to sue under Article III regardless of the fictional infringement mechanism found in the Hatch-Waxman Act or the Affordable Care Act.

### B. *Public Patent Injuries in Fact*

Despite its legislative power, Congress cannot statutorily create a legal interest in persons who have not suffered an injury in fact as proscribed by Article III.<sup>228</sup> Once Congress creates a legally cognizable right to free exploitation of non-infringing goods and a corresponding civil action to obtain relief, a member of the public who seeks to challenge a patent on the grounds that he shares in a public harm still must allege and prove an injury in fact caused by the defendant and redressable by the court.<sup>229</sup> Although many scholars have challenged this requirement as not constitutionally mandated,<sup>230</sup> the Supreme Court has continued to reiterate that the injury in fact requirement cannot be circumvented by legislation—it is a constitutional requirement.

A stranger to the patentee with no plans to infringe and who alleges a public harm to competition that affects general health and safety does not seem, superficially at least, very different from a taxpayer challenging expenditures of the federal coffers or one ideologically devoted to challenging environmental laws.<sup>231</sup> Although the member of the public in these cases may seem analogous to an ideological plaintiff, the better analogy may be that the member of the public seeks to raise a generalized grievance, a harm individually suffered by many people. Courts have generally prohibited

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226 Greater Access to Affordable Pharmaceuticals Act, H.R. 2491, 108th Cong. § 2(a)(2)(C) (2003); *Teva Pharms. USA, Inc. v. Pfizer Inc.*, 405 F.3d 990, 995 (Fed. Cir. 2005) (indicating that the plain language of the Hatch-Waxman Act provides an “express mechanism for generics to challenge, with declaratory actions, the claim scope or validity of listed patents”).

227 35 U.S.C. § 271 (2006 & Supp. V 2011).

228 *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 576–78 (1992) (“‘Individual rights’ within the meaning of this passage, do not mean public rights that have been legislatively pronounced to belong to each individual who forms part of the public.”).

229 *Id.* at 578.

230 See, e.g., Hessick, *supra* note 40, at 277–78 (2008); Cass R. Sunstein, *What’s Standing after Lujan? Of Citizen Suits, “Injuries,” and Article III*, 91 MICH. L. REV. 163, 166 (1992).

231 *Flast v. Cohen*, 392 U.S. 83, 102–03 (1968) (describing the nexus test for taxpayer standing); *Lujan*, 504 U.S. at 566–67 (describing the nexus required when challenging environmental laws).



plaintiffs from seeking to adjudicate generalized grievances on prudential grounds,<sup>232</sup> which means that Congress could legislate around the prohibition by creating a statutory cause of action for aggrieved persons, and such persons need only demonstrate an Article III injury in fact.

The crux of standing in these cases will be for the plaintiffs to show some particularized, concrete, and individual injury in fact.<sup>233</sup> For example, a member of the public may claim an individual injury resulting from the risk or uncertainty that her activity infringes a patent, where the uncertainty chills investment and redirects her efforts into other endeavors.<sup>234</sup> Likewise, a member of the public may claim an individual injury resulting from a lack of access to the patented invention as a result of the patentee's exclusion of others within the marketplace for the invention. Such injuries could still be characterized as competitive ones—these parties would allege a desire to infringe, or a desire that others be able to infringe, and such desires could be deemed a sufficient injury in fact without identifying an immediate underlying infringement claim.<sup>235</sup>

### C. Proposed Statute

*The courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction when any person brings a civil action under section 2201 of title 28 for a declaratory judgment that a patent is invalid or not infringed and such person alleges an injury relating to a restraint on his trade or to his health or safety. No such civil action may be brought until ninety days after the date upon which the patent issues. A civil action brought under this provision shall have no effect on any pending or future request for an inter partes review of the patent in suit, except that a court, in its discretion, may stay any or all proceedings until resolution of the inter partes review and a court may decline jurisdiction pursuant to section 2201 of title 28 on the grounds that an inter partes review remains pending.*

### CONCLUSION

In *MedImmune*, the Supreme Court opened the door for courts considering jurisdiction in patent cases to allow policy concerns to override constitutional and statutory jurisdictional constraints. A strong public policy interest in invalidating patents may suggest an expansion of justiciability to encom-

232 See Louis L. Jaffe, *The Citizen as Litigant in Public Actions: The Non-Hohfeldian or Ideological Plaintiff*, 116 U. PA. L. REV. 1033, 1033–37 (1968) (discussing that courts have traditionally required in a case that there be a “plaintiff who proffers for judicial determination a question concerning his own legal status”).

233 *Lujan*, 504 U.S. at 560–62.

234 Brief of Intellectual Property Professors as Amici Curiae in Support of Petitioner at 9, *Already, LLC v. Nike, Inc.*, 228 U.S. 618 (2012) (No. 11-982) (“When a person is deterred from undertaking valuable economic activity by the risk that the activity may encroach on another’s exclusive right, that person has incurred an actual, concrete, and particularized injury.”).

235 See *supra* note 158 for cases discussing a finding of competitive harm in antitrust cases.

pass patent cases brought by concerned citizens. Because of the potential for important public implications for allegedly invalid patents, this Article proposes that the tension between patent policy and law best be resolved by a congressional authorization of a cause of action for invalidation to be brought by aggrieved citizens, with appropriate and thoughtful contours to supplement the competitor suits already allowed under the declaratory judgment procedure.

