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A REASONABLE APPREHENSION OF LAWSUIT:  
A RESTRICTIVE THRESHOLD FOR FEDERAL COURT  
JURISDICTION IN PATENT DECLARATORY JUDGMENTS

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I. INTRODUCTION.....	1
II. BACKGROUND .....	2
III. DEVELOPMENT OF THE REASONABLE APPREHENSION OF LAWSUIT STANDARD IN PATENT DECLARATORY JUDGMENTS .....	9
A. <i>Declaratory Judgments May Not be Advisory Opinions</i> .....	9
B. <i>Declaratory Judgments Must Involve a Case or Controversy</i> ..	16
C. <i>Development of Patent Declaratory Judgments in the Circuits</i>	21
IV. FEDERAL COURT STANDING .....	26
A. <i>Reasonable Apprehension of Lawsuit is Not Coextensive With Constitutional Standing</i> .....	30
B. <i>Uncertainty as an Injury in Fact</i> .....	34
C. <i>Applying Reasonable Apprehension and Standing Tests</i> .....	39
V. CONCLUSION .....	42

I. INTRODUCTION

Under Federal Circuit patent law, a person injured by an adverse patent may not bring a declaratory judgment action against a patent owner to obtain a judgment of patent validity or non-infringement unless the potential infringer has a reasonable apprehension of imminent suit by the patent owner. When the patent owner does not threaten the potential infringer, or when there is no possibility that the patent owner will sue, then the potential infringer fails the reasonable apprehension of lawsuit test and has no standing to bring suit.

While the Federal Circuit considers the reasonable apprehension of lawsuit test the constitutional threshold for standing,

the test may be a higher standard than the Constitution requires. This article will explore the requirements for a controversy under the Declaratory Judgment Act and will discuss possible differences between the reasonable apprehension of lawsuit test and the constitutional test for standing as they apply to patent infringement and invalidity actions.

## II. BACKGROUND

A federal court must have both statutory jurisdiction and constitutional jurisdiction to adjudicate a dispute.<sup>1</sup> Article III, Section 2, Clause 1 of the U.S. Constitution grants federal courts the jurisdiction to hear cases arising under the Constitution, federal laws, and treaties, as well as other cases and controversies enumerated by Article III of the Constitution.<sup>2</sup> Naturally, Congress provides the statutory jurisdiction, primarily through Title 28 of the United States Code.<sup>3</sup> The Declaratory Judgment Act grants statutory authority for federal courts to confer declaratory judgments in “case[s] of actual controversy.”<sup>4</sup>

Prior to the enactment of the Declaratory Judgment Act in 1934, a patent owner controlled when a controversy between a potential patent infringer and the patent owner would go before a judge.<sup>5</sup> The patent owner could threaten to sue potential infringers and the potential infringers’ customers, whether or not the patent owner intended to sue, because the patent owner was within his rights to use “all lawful means to protect [his] monopoly.”<sup>6</sup> At that time, federal courts normally would not allow a potential patent infringer to sue a patent owner when the patent owner threatened suit.<sup>7</sup> A court would allow a potential infringer to sue the patent owner for unfair competition when the patent owner was acting not only to protect the owner’s patent rights, but to stifle competition or to destroy the

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<sup>1</sup> Exxon Mobil Corp. v. Allapattah Servs. Inc., 125 S. Ct. 2611, 2616-17 (2005).

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

<sup>3</sup> 28 U.S.C.A. §§ 1331-69 (2006).

<sup>4</sup> 28 U.S.C.A. § 2201 (2006).

<sup>5</sup> *Developments in the Law*, 62 HARV. L. REV. 787, 863 (1949).

<sup>6</sup> A.B. Farquhar Co. v. Nat’l Harrow Co., 102 F. 714, 714 (3d Cir. 1900).

<sup>7</sup> *E.g.* Clip Bar Mfg. Co. v. Steel Protected Concrete Co., 209 F. 874, 875 (E.D. Pa. 1913); Mitchell v. Int’l Tailoring Co., 169 F. 145, 146 (S.D.N.Y. 1909).

potential infringer.<sup>8</sup> Potential infringers had difficulty proving unfair competition due to the requirement that potential infringers show the patent owner was acting in bad faith.<sup>9</sup> Consequently, a patent owner could exploit his patent rights by convincing infringing and non-infringing competitors to settle or buy licenses to stop the patent owner's harassment.<sup>10</sup> The Declaratory Judgment Act of 1934 gave potential infringers the ability to sue patent owners<sup>11</sup> by giving federal courts authority to confer declaratory judgments in "case[s] of actual controversy."<sup>12</sup>

The Supreme Court considers actual controversies in declaratory judgment cases to be those that are controversies within the meaning of the U.S. Constitution.<sup>13</sup> The Federal Circuit asserts that the actual controversy requirement for a declaratory judgment of patent non-infringement or patent invalidity requires the declaratory plaintiff to satisfy a reasonable apprehension of lawsuit test.<sup>14</sup> Using

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<sup>8</sup> *E.g.* *Racine Paper Goods Co. v. Dittgen*, 171 F. 631, 636 (7th Cir. 1909); *A.B. Farquhar Co. v. Nat'l Harrow Co.*, 102 F. 714, 716 (3d Cir. 1900). These causes of action required diversity of citizenship.

<sup>9</sup> *Developments in the Law*, *supra* note 5, at 863.

<sup>10</sup> *Wembly, Inc. v. Superba Cravats, Inc.*, 315 F.2d 87, 89 (2d Cir. 1963). *Wembly* characterized a patent owner's abusive practice of threatening potential infringers with suits without intending to sue as a "racket" because the patent owner could coerce a potential infringer into a settlement without ever knowing whether the patent was valid. *Id.* If the patent owner did sue the potential infringer, the patent owner could dismiss the complaint without prejudice if the potential infringer challenged the validity of the patent. *Id.* Thus, a patent owner never had to subject a patent's validity to the judgment of a court. *Id.*

<sup>11</sup> *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 735 (Fed. Cir. 1988).

<sup>12</sup> 28 U.S.C.A. § 2201(a) ("In a case of actual controversy within its jurisdiction, except with respect to Federal taxes other than actions brought under section 7428 of the Internal Revenue Code of 1986, a proceeding under section 505 or 1146 of title 11, or in any civil action involving an antidumping or countervailing duty proceeding regarding a class or kind of merchandise of a free trade area country (as defined in section 516A(f)(10) of the Tariff Act of 1930), as determined by the administering authority, 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, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such." (emphasis added)).

<sup>13</sup> *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239-40 (1937) ("The Declaratory Judgment Act of 1934 . . . is operative only in respect to controversies which are such in the constitutional sense."); *see also* S. Rep. No. 73-1005 (1934), as reprinted in EDWIN BORCHARD, DECLARATORY JUDGMENTS 1047-48 (2d ed., Banks-Baldwin Law Publ'g Co., 1941).

<sup>14</sup> *Jervis B. Webb Co. v. S. Sys.*, 742 F.2d 1388, 1398 (Fed. Cir. 1984) (the

this test, the Federal Circuit has repeatedly held that in patent declaratory judgments, a declaratory plaintiff cannot sue a patent owner unless the declaratory plaintiff is under a reasonable apprehension of lawsuit.<sup>15</sup> A “reasonable apprehension of lawsuit” means that the declaratory plaintiff reasonably believes that the patent owner was going to sue the declaratory plaintiff imminently, had the declaratory plaintiff not sued first.<sup>16</sup>

The problem with the Federal Circuit’s reasonable apprehension of lawsuit test is that it bars some declaratory judgments between adverse parties where a declaration would resolve a dispute and prevent a declaratory plaintiff from taking actions that accrue damages. *Medimmune, Inc. v. Genentech, Inc.* is an example of how the Federal Circuit applies the reasonable apprehension of lawsuit standard.<sup>17</sup>

In *Medimmune*, the declaratory defendant Genentech owned two patents<sup>18</sup> pertaining to methods of producing functional immunoglobulin.<sup>19</sup> Medimmune and Genentech entered into a license agreement in 1997 for the first Genentech patent, U.S. Patent Number 4,816,567, and under the terms of the license Medimmune would receive a license for the second Genentech patent when it issued.<sup>20</sup> When the second patent issued as U.S. Patent Number 6,331,415 in

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“controversy requirement for a patent invalidity declaratory judgment action requires” a reasonable apprehension of lawsuit); *Teva Pharm. USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324, 1335 (Fed. Cir. 2005) (the reasonable apprehension of lawsuit standard determines “whether there is an actual controversy in suits requesting a declaration of patent non-infringement or invalidity” (quoting *EMC Corp. v. Norand Corp.*, 89 F.3d 807, 811 (Fed. Cir. 1996))).

<sup>15</sup> *E.g.* *C.R. Bard, Inc. v. Schwartz*, 716 F.2d 874, 879 (Fed. Cir. 1983) (adopting and applying the reasonable apprehension of lawsuit because some “[c]ourts have interpreted the controversy requirement in the patent field” to require it); *Jervis B. Webb*, 742 F.2d at 1398-99; *Arrowhead*, 846 F.2d at 736; *B.P. Chem. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1995); *Teva*, 395 F.3d at 1332.

<sup>16</sup> *Arrowhead*, 846 F.2d at 736.

<sup>17</sup> *Medimmune, Inc. v. Genentech, Inc.*, 427 F.3d 958, 961 (Fed. Cir. 2005).

<sup>18</sup> *Id.* Genentech co-owned patents with City of Hope; Recombinant Immunoglobulin Preparations, U.S. Patent No. 4,816,567 (filed Apr. 8, 1983) (issued Mar. 28, 1989); Methods of Producing Immunoglobulins, Vectors and Transformed Host Cells for Use Therein, U.S. Patent No. 6,331,415, (filed June 10, 1988) (issued Dec. 18, 2001).

<sup>19</sup> U.S. Patent No. 4,816,567, *supra* note 18; U.S. Patent No. 6,331,415, *supra* note 18. Immunoglobulin is any group of structurally related proteins which function as antibodies. THE OXFORD AMERICAN DICTIONARY AND THESAURUS 735 (Oxford Univ. Press 2003).

<sup>20</sup> *Medimmune*, 427 F.3d at 962.

2001,<sup>21</sup> Genentech asserted that the license for the 6,331,415 patent covered a Medimmune product called Synagis®,<sup>22</sup> and thereafter Medimmune made royalty payments to Genentech.<sup>23</sup> However, Medimmune objected to paying the royalty on the 6,331,415 patent, and Medimmune sued Genentech seeking a declaratory judgment that the 6,331,415 patent was invalid or unenforceable.<sup>24</sup> There was not a breach of contract throughout the litigation, and Medimmune continued to pay royalties.<sup>25</sup>

The district court dismissed the case for lack of jurisdiction on the ground that there was no actual controversy as required by the Declaratory Judgment Act.<sup>26</sup> The Federal Circuit affirmed the district court by holding that there was no controversy to support Medimmune's declaratory judgment action because the patent license precluded a reasonable apprehension of lawsuit.<sup>27</sup>

*Medimmune* held that jurisdiction under the Declaratory Judgment Act requires a reasonable apprehension of lawsuit.<sup>28</sup> The Federal Circuit reasoned that because Medimmune continued to pay royalties and because there was no other breach of the license agreement, patent owner Genentech could not sue Medimmune.<sup>29</sup> As Genentech had no cause of action against Medimmune, Medimmune consequently could not possibly have a reasonable apprehension of

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<sup>21</sup> Genentech's 6,331,415 patent issued following a complex prosecution. *Id.* at 961-62. An interference was declared between the Genentech application and U.S. Patent Number 4,816,397 owned by Celltech, another defendant in *Medimmune*. *Id.* at 961. The interference resulted in a U.S. Patent Office decision favoring Celltech, and Medimmune later licensed Celltech's patent. *Id.* After the interference, Genentech appealed the decision to the district court in the Northern District of California. *Id.* Celltech and Genentech settled before trial, agreeing that the Genentech application had priority. *Id.* at 962. The Federal Circuit entered a judgment favoring Genentech based on the parties' resolution, and the U.S. Patent Office issued the 6,331,415 patent in 2001. *Id.* The Patent Office Board of Patent Appeals and Interferences asserted that the Celltech patent was cancelled by operation of law because the district court judgment giving Genentech priority was final and not appealed. *Id.*

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

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

<sup>26</sup> *Id.*

<sup>27</sup> *Id.* at 964-65.

<sup>28</sup> *Id.* at 965. The court ruled that Medimmune did not have standing under the Declaratory Judgment Act without a reasonable apprehension of lawsuit. *Id.*

<sup>29</sup> *Id.* at 963.

lawsuit.<sup>30</sup> Medimmune argued that by barring the declaratory judgment action, the Federal Circuit was effectively applying licensee estoppel,<sup>31</sup> a practice disapproved of by the Supreme Court in *Lear, Inc. v. Adkins*.<sup>32</sup> The Federal Circuit distinguished *Lear* by characterizing the licensee in *Lear* as a defaulting licensee, contrasted with Medimmune being a licensee in good standing.<sup>33</sup> *Medimmune* held that *Lear, Inc. v. Adkins* only provided a patent invalidity defense in a suit against a defaulting licensee, not as the ground for a declaratory judgment action.<sup>34</sup>

As *Medimmune* suggests, the Federal Circuit applies the reasonable apprehension of lawsuit strictly. The existence of an adverse patent alone is not enough to create an actual controversy for a declaratory judgment.<sup>35</sup> Nor will the mere presence of adverse legal interests create an actual controversy, in the Federal Circuit's view, regardless of how adverse the interests are.<sup>36</sup> When there is no reasonable apprehension of lawsuit, the Federal Circuit will not grant

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<sup>30</sup> *Id.* at 964-65.

<sup>31</sup> *Id.* at 962-63. The doctrine of licensee estoppel “establishes that so long as a licensee is operating under a license agreement he is estopped to deny the validity of his licensor’s patent . . .” *Lear, Inc. v. Adkins*, 395 U.S. 653, 656 (1969).

<sup>32</sup> *Lear*, 395 U.S. at 671. In *Lear*, *Lear, Inc.* hired inventor Adkins to design improvements for gyroscopes. *Id.* at 655. Adkins and *Lear* signed an agreement that Adkins would be the owner of the improvements Adkins developed, but *Lear* would have a license to practice them. *Id.* at 657. A second agreement gave *Lear* the right to terminate the license if the U.S. Patent Office did not issue a patent or if a court held the patent invalid. *Id.* Adkins developed improvements that *Lear* incorporated into its production. *Id.* at 655. Adkins patented the improvements, but during a long patent prosecution, *Lear* stopped making royalty payments. *Id.* at 659. Adkins sued *Lear* for royalties, and *Lear* tried to assert patent invalidity as a defense. *Id.* at 660. All of the California courts in the litigation, from the California Superior Court through the California Supreme Court, held that licensee estoppel barred *Lear* from challenging the patent. *Id.* at 660-61. The U.S. Supreme Court disagreed, holding that the trial court had to give *Lear* the opportunity to avoid royalties by showing patent invalidity and overruling *Automatic Radio Manufacturing Co. v. Hazeltine Research, Inc.*, 339 U.S. 827 (1950), which held that licensee estoppel was the general rule. *Lear*, 395 U.S. at 674.

<sup>33</sup> *Medimmune*, 427 F.3d at 963.

<sup>34</sup> *Id.*

<sup>35</sup> *BP Chemicals Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993); BORCHARD, *supra* note 13, at 807 (“[T]he mere existence of the patent is not a cloud on title...”).

<sup>36</sup> *Teva Pharm. USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324, 1333 (Fed. Cir. 2005) (adverse legal interests not sufficient to confer jurisdiction absent a reasonable apprehension of lawsuit).

jurisdiction over a declaratory judgment.<sup>37</sup>

Why does the Federal Circuit interpret the Declaratory Judgment Act so narrowly? Congress passed the Declaratory Judgment Act in part to avoid the social and economic waste incurred by accruing damages, or breaking a contract, or violating a statute in order to create a justiciable controversy.<sup>38</sup> The Federal Circuit requirement in *Medimmune* that Medimmune breach its contract with Genentech<sup>39</sup> appears to be contrary to the congressional intent of the Declaratory Judgment Act.

Some have asserted that the patent owner should be the one to decide whom to sue, suggesting that a patent owner has a right to be left alone.<sup>40</sup> But when there is an actual controversy, even when there is not a reasonable apprehension of lawsuit, it is likely that the parties will end up in court anyway. It should not matter who initiates the suit.<sup>41</sup> If the patent owner does not object to the declaratory plaintiff's activities, or the patent owner does not want to enforce the patent, a simple settlement would quickly resolve the matter.

Public policy supports a declaratory plaintiff who seeks a judgment against a patent owner in the presence of an actual controversy. While one goal of the patent system is to encourage innovation,<sup>42</sup> the "ultimate goal of the patent system" is for inventors to put new technology into the public domain by their disclosures in patents.<sup>43</sup> An inventor receives a limited monopoly in exchange for its disclosure of the invention.<sup>44</sup> As important as a patent monopoly is to a patent owner, it is equally important to the public that worthless patents not interfere with competition.<sup>45</sup> Patent monopolies have

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<sup>37</sup> *Id.*

<sup>38</sup> S. Rep. No. 73-1005 (1934), as reprinted in BORCHARD, *supra* note 13, at 1044.

<sup>39</sup> *Medimmune*, 427 F.3d at 964-65.

<sup>40</sup> BORCHARD, *supra* note 13, at 807; see also *Zenie Bros. v. Miskend*, 10 F. Supp. 779, 782 (S.D.N.Y. 1935) ("The defendant's fears that patent owners will be harassed by actions for declaratory judgment on the part of those who may or may not be infringers have not been overlooked.").

<sup>41</sup> *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 244 (1937) (when summarizing what makes a justiciable controversy, the Court reasoned that "[i]t is the nature of the controversy, not the method of its presentation or the particular party who presents it, that is determinative").

<sup>42</sup> *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989).

<sup>43</sup> *Id.* at 151.

<sup>44</sup> *Id.* at 150-51.

<sup>45</sup> *Lear, Inc. v. Adkins*, 395 U.S. 653, 663-64 (1969) (citing *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892)).

significant economic effects because patents curtail access to a free market.<sup>46</sup> The Supreme Court reasoned that because of the economic impact of patent monopolies, the public has a “paramount interest” in keeping patent monopolies “within their legitimate scope.”<sup>47</sup> As Justice O’Connor explained in *Bonito Boats v. Thunder Craft Boats*, “free exploitation of ideas will be the rule.”<sup>48</sup> One valuable benefit of the Declaratory Judgment Act is allowing potential infringers to weed out “scarecrow” patents without waiting for the patent owner to sue.<sup>49</sup>

The Federal Circuit insists that the reasonable apprehension of lawsuit test establishes the constitutional threshold for jurisdiction over declaratory judgments,<sup>50</sup> but the Federal Circuit has never clearly explained the rationale for its opinion.<sup>51</sup> The Federal Circuit’s constitutional threshold is not the same as the Supreme Court’s constitutional threshold. The Supreme Court has held that the doctrine of constitutional standing establishes the constitutional threshold for jurisdiction in any federal court action, including declaratory judgments.<sup>52</sup> If constitutional standing and a reasonable apprehension of lawsuit were synonymous, then there could be no complaint. However, it appears that the reasonable apprehension of lawsuit is more limiting than constitutional standing, and thus bars some actions unnecessarily.

One might argue that the test used to determine whether to confer jurisdiction over a declaratory action is largely immaterial because there is no requirement that a district court hear any declaratory judgment action.<sup>53</sup> A district court has substantial

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<sup>46</sup> *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945).

<sup>47</sup> *Id.*

<sup>48</sup> *Bonito Boats*, 489 U.S. at 151.

<sup>49</sup> *Societe de Conditionnement en Aluminium v. Hunter Eng’g. Co., Inc.*, 655 F.2d 938, 943 (9th Cir. 1981) (citing *Bresnick v. U. S. Vitamin Corp.*, 139 F.2d 239, 242 (2d Cir. 1943)).

<sup>50</sup> *Teva Phrm. USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324, 1335.

<sup>51</sup> While it seems the Federal Circuit has not explained the connection between a reasonable apprehension of lawsuit and Article III, the Circuit has acknowledged such a connection. *See, e.g., id.* (“[W]e developed the [reasonable apprehension of lawsuit test] to determine whether there is an actual controversy in suits requesting a declaration of patent non-infringement or invalidity.”).

<sup>52</sup> *Allen v. Wright*, 468 U.S. 737, 750 (1984). In *Allen*, parents of black children in public school sought a declaratory judgment that the I.R.S. failed to deny tax-exempt status to racially discriminatory private schools. *Id.* at 739-40. The Court dismissed for lack of standing. *Id.* at 766.

<sup>53</sup> *Teva*, 395 F.3d at 1331 (“Even if there is an actual controversy, the district court is not required to exercise declaratory judgment jurisdiction . . . .”) (citing *EMC*

discretion over whether to decline declaratory judgment jurisdiction, even in cases of actual controversy.<sup>54</sup> Thus, one might argue that the court's substantial discretion easily absorbs any difference between constitutional standing and the reasonable apprehension of lawsuit test. However, given Congress' important goal of preventing social and economic waste,<sup>55</sup> it is beneficial to use declaratory judgments to the full extent granted by the Constitution.

### III. DEVELOPMENT OF THE REASONABLE APPREHENSION OF LAWSUIT STANDARD IN PATENT DECLARATORY JUDGMENTS

#### *A. Declaratory Judgments May Not be Advisory Opinions*

The United States began considering whether to allow declaratory judgments in federal court in the early twentieth century.<sup>56</sup> Early U.S. development of the declaratory judgment considered when a declaratory judgment would be justiciable under Article III.<sup>57</sup> As Article III extends federal jurisdiction to cases and to controversies,<sup>58</sup> it followed that declaratory judgments should be allowable when parties were embroiled in a case or controversy within the meaning of the Constitution.<sup>59</sup> Unfortunately, it is not always clear when a case or controversy is within the meaning of the Constitution.

The case and controversy requirement of the Constitution grants judicial power to the federal courts, but also limits federal judiciary power.<sup>60</sup> One purpose of the case and controversy requirement as a limitation is to maintain the separation of powers between the judicial, executive, and legislative branches.<sup>61</sup> Separation of powers assures that the federal courts will not intrude into the roles

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Corp. v. Norand Corp., 89 F.3d 807, 810 (Fed. Cir. 1996)).

<sup>54</sup> *Id.*

<sup>55</sup> S. Rep. No. 73-1005 (1934), *reprinted in* BORCHARD, *supra* note 13, at 1044.

<sup>56</sup> BORCHARD, *supra* note 13, at 132. New Jersey enacted a declaratory judgment statute in 1915, and by 1939 approximately forty states had declaratory judgment statutes. *Id.* at 132-33. A federal declaratory judgment bill was introduced in Congress for the first time in 1919. *Id.* at 134 n.39.

<sup>57</sup> *See infra* notes 81-124 and accompanying text.

<sup>58</sup> U.S. CONST., art. III, § 2, cl. 1.

<sup>59</sup> *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 327, 239-40 (1937) (“The Declaratory Judgment Act of 1934 . . . is operative only in respect to controversies which are such in the constitutional sense.”).

<sup>60</sup> *Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 476 (1982).

<sup>61</sup> *Allen v. Wright*, 468 U.S. 737, 750 (1984).

assigned to the executive and legislative branches.<sup>62</sup>

An important consequence of the separation of powers principle is the federal court's ban on advisory opinions.<sup>63</sup> An advisory opinion is a decision based on hypothetical facts or abstract issues that does not finally resolve a matter.<sup>64</sup> A case is not an advisory opinion when it involves a dispute between adverse litigants, and when a court's decision would have an effect on the parties.<sup>65</sup> Erwin Chemerinsky traces these requirements through two situations early in Supreme Court history: *Hayburn's Case* in 1792,<sup>66</sup> and correspondence between the Supreme Court and Thomas Jefferson in 1793.<sup>67</sup>

*Hayburn's Case* involved an act of Congress that instituted a procedure whereby war veterans could petition a federal circuit court to receive a pension from the United States.<sup>68</sup> Under the Act, the Secretary at War and Congress could suspend or revise the court's decision in any such case.<sup>69</sup> In *Hayburn*, the Attorney General for Pennsylvania filed a motion seeking a writ of mandamus to force the circuit court to hear a pension petition from William Hayburn.<sup>70</sup> The Justices did not grant the motion.<sup>71</sup>

The Justices would not allow the motion because the circuit court's decision in Hayburn's pension case would be subject to

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<sup>62</sup> *Valley Forge Christian College*, 454 U.S. at 474 (citing *Flast v. Cohen*, 392 U.S. 83, 95 (1968)).

<sup>63</sup> *Flast*, 392 U.S. at 96 (the "rule against advisory opinions implements the separation of powers prescribed by the Constitution and confines federal courts to the role assigned them by Article III"); *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 101 (1998) (advisory opinions have been ". . . disapproved by this Court from the beginning").

<sup>64</sup> *Fund for Animals v. Williams*, 311 F.Supp.2d 1, 5 (D.D.C. 2004) (defining advisory opinions as those "decisions based on hypothetical facts or abstract issues"); *Ill. ex rel. Barra v. Archer Daniels Midland Co.*, 704 F.2d 935, 941 (7th Cir. 1983) (defining an advisory opinion as a "decision that does not resolve an actual case or controversy").

The term advisory opinion comes from an old English practice in which the King and the House of Lords would consult with judges about questions of law. WALTER H. ANDERSON, *ACTIONS FOR DECLARATORY JUDGMENT* 26-27 (West Publ'g Co. 1940). The English advisory opinions had no binding force or effect. *Id.*

<sup>65</sup> ERWIN CHEMERINSKY, *FEDERAL JURISDICTION* § 2.2, 49-51 (3d ed., Aspen Law & Bus., 1999).

<sup>66</sup> *Id.* at 51.

<sup>67</sup> *Id.* at 50.

<sup>68</sup> *Hayburn's Case*, 2 U.S. 409, 410 (1792).

<sup>69</sup> *Id.*

<sup>70</sup> *Id.* at 409.

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

revision and control by the Executive and Legislative branches.<sup>72</sup> Such an Executive or Legislative review of a federal court decision would have been inconsistent with the separation of powers of the Constitution.<sup>73</sup> Congress had essentially delegated an administrative function to the courts.<sup>74</sup>

In 1793, President George Washington sent Secretary of State Thomas Jefferson to the Supreme Court for advice regarding how the Executive branch should act with respect to the ongoing war between France and England.<sup>75</sup> In his request, Mr. Jefferson acknowledged that he presented his request outside of a recognized justiciable controversy.<sup>76</sup> The Supreme Court declined to render any advice.<sup>77</sup> In a letter to President Washington, Chief Justice Jay asserted that the constitutional separation of powers prevented the Supreme Court from deciding cases “extra-judicially.”<sup>78</sup> Chief Justice Jay may have used “extra-judicially” to mean those cases falling outside of the traditional adversarial judicial process.<sup>79</sup> However, the Supreme Court later interpreted Chief Justice Jay’s response to indicate that the constitutional separation of powers prohibits all advisory opinions.<sup>80</sup>

After the Supreme Court analyzed federal jurisdiction in a declaratory judgment for the first time<sup>81</sup> in 1927,<sup>82</sup> it was not clear whether the Supreme Court considered all declaratory judgments to be advisory opinions.<sup>83</sup> In *Liberty Warehouse Co. v. Grannis*, a

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<sup>72</sup> *Id.* at 410.

<sup>73</sup> *Id.*

<sup>74</sup> *Id.*

<sup>75</sup> CHEMERINSKY, *supra* note 65, at 50. The Executive branch sought advice in interpreting treaties and laws, and sought an opinion on such matters as whether the U.S. could sell ships and weapons to both England and France. *Id.*

<sup>76</sup> Thomas Jefferson recognized that the Court would be giving such advice under circumstances which “do not give a cognizance of them to the tribunals of the country.” *Muskrat v. United States*, 219 U.S. 346, 354 (1911) (citing *Correspondence & Public Papers of John Jay*, vol 3, 486).

<sup>77</sup> *Id.*

<sup>78</sup> *Id.*

<sup>79</sup> CHEMERINSKY, *supra* note 65, at 50.

<sup>80</sup> *Vieth v. Jubelirer*, 541 U.S. 267, 302 (2004) (the Justices’ response to Mr. Jefferson indicated that separation of powers dictates that advisory opinions are beyond the Court’s jurisdiction).

<sup>81</sup> BORCHARD, *supra* note 13, at 176.

<sup>82</sup> *Liberty Warehouse Co. v. Grannis*, 273 U.S. 70 (1927).

<sup>83</sup> *Pub. Serv. Comm’n. of Utah v. Wycoff Co., Inc.*, 344 U.S. 237, 241 (1952) (“Previous to [the Declaratory Judgment Act’s] enactment there were responsible expressions of doubt that constitutional limitations on federal judicial power would permit any federal declaratory judgment procedure.”); Donald L. Doernberg &

declaratory plaintiff, Liberty Warehouse, sued Commonwealth Attorney Grannis as a representative of Kentucky in federal district court.<sup>84</sup> Liberty sought a declaration that a 1924 Kentucky statute regulating the sale of leaf tobacco was unconstitutional.<sup>85</sup> Liberty alleged that the Commonwealth Attorney had threatened the plaintiff with civil and criminal punishments for violation of the statute, and that he had prepared indictments against Liberty.<sup>86</sup> Liberty, however, did not seek an injunction, only a declaration of its rights under the Kentucky act.<sup>87</sup> The Supreme Court held that the federal courts had no jurisdiction over the action because there was no Article III case or controversy.<sup>88</sup>

First, the Court found that the parties were not in an adversarial posture because Commonwealth Attorney Grannis *as an individual* was not adverse to Liberty because he had not threatened Liberty.<sup>89</sup> The Court recognized the fact that Liberty sued Grannis in a representational capacity,<sup>90</sup> but the Court seemed to ignore the indictments against Liberty in its analysis and opinion.<sup>91</sup> Second, Liberty did not present the case in a “regular” form wherein a judgment would enforce rights or redress or punish wrongs.<sup>92</sup> The Court broadly held that federal courts could not proceed under the Kentucky Declaratory Judgment Act because it provided a form of proceeding that violated Article III of the U.S. Constitution.<sup>93</sup>

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Michael B. Mushlin, *The Trojan Horse: How the Declaratory Judgment Act Created a Cause of Action and Expanded Federal Jurisdiction While the Supreme Court Wasn't Looking*, 36 UCLA L. REV. 529, 566-67 (1989); *see also* S. Rep. No. 1005 (1934).

<sup>84</sup> *Liberty*, 273 U.S. at 72.

<sup>85</sup> *Id.*

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

<sup>87</sup> *Id.* at 73.

<sup>88</sup> *Id.* at 76.

<sup>89</sup> *Id.* at 73. It is not clear why the Court pointed to Grannis in an individual capacity. BORCHARD, *supra* note 13, at 176.

<sup>90</sup> *Id.* at 72.

<sup>91</sup> Doernberg & Mushlin, *supra* note 83, at 558 n.131 (citing Hearings on H.R. 5623 Before a Subcomm. of the Senate Comm. on the Judiciary, 70th Cong., 1st Sess., at 2-9 (1928)). Professor Borchard appeared before the Subcommittee of the Senate Committee on the Judiciary in 1928, testifying that Professor Borchard's investigation revealed that the State Attorney General had indicted Liberty Warehouse, but the Court did not seem to take this fact into account. *Id.*

<sup>92</sup> *Liberty*, 273 U.S. at 74.

<sup>93</sup> *Id.* The question whether a federal court could proceed under the Kentucky Declaratory Judgment Act was an issue because of the Federal Conformity Statute, R. S. § 914. *Id.* According to a summary of the Federal Conformity Statute found in

Professor Edwin Borchard found the Supreme Court's prior treatment of cases with parties seeking injunctions particularly insightful when analyzing *Liberty*.<sup>94</sup> Only two weeks<sup>95</sup> before hearing arguments in *Liberty*, the Court ruled in *Village of Euclid, Ohio v. Ambler Realty Co.* that the mere existence and maintenance of an ordinance constituted a present invasion of property rights which was sufficient to establish jurisdiction.<sup>96</sup> Likewise, in *Pierce v. Society of Sisters*, the Court ruled that a statute was enough of a threat to the plaintiff to establish jurisdiction, even though the plaintiff filed the complaint more than two years before the statute was to go into effect.<sup>97</sup> Professor Borchard opines that had Liberty Warehouse filed

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*S. Pac. Co. v. Denton*, 146 U.S. 202, 208 (1892), federal district and circuit courts were to follow the "practice, pleading, and forms" of the state where the district or circuit court was located. Thus, under the Federal Conformity Statute prior to the Supreme Court's ruling in *Liberty*, the federal district court in Kentucky was to follow the Kentucky Declaratory Judgment Act.

The Supreme Court in *Liberty* described the Kentucky declaratory judgment statute as providing "in any action in a court of record of the Commonwealth having general jurisdiction wherein it is made to appear that *an actual controversy exists*, the plaintiff may, by means of a petition on the laws or equity side of the court, as the nature of the case may require, ask for and obtain 'a declaration of rights, either alone or with other relief; and the court may make a binding declaration of rights, whether or not consequential relief is or could be asked;' and that further relief, based on such declaratory judgment, may be granted by the court whenever necessary or proper, either in the same proceeding or in an independent action, upon notice to any adverse party whose rights have been adjudicated by the declaratory judgment." *Liberty*, 273 U.S. at 71. (Emphasis added)

<sup>94</sup> BORCHARD, *supra* note 13, at 177.

<sup>95</sup> The Supreme Court heard *Liberty* on December 7, 1926, *Liberty*, 273 U.S. at 70, and decided *Village of Euclid, Ohio v. Ambler Realty Co.*, 272 U.S. 365 (1926) on November 22, 1926, a difference of about two weeks. The Court decided *Liberty* on January 3, 1927. *Liberty*, 273 U.S. at 70.

<sup>96</sup> *Vill. of Euclid, Ohio*, 272 U.S. at 386. In *Village of Euclid*, Euclid had adopted an extensive zoning scheme to the detriment of a property owned by Ambler Realty. *Id.* at 379-80. The zoning ordinance had the potential of reducing Ambler Realty's property value by \$100 per frontage foot. *Id.* at 384. Ambler did not seek a building permit, nor did it seek a zoning exception under the ordinance. *Id.* at 386. Ambler sued Euclid seeking an injunction preventing enforcement of the statute. *Id.* at 384. Euclid made a motion to dismiss the case as premature, but the trial court denied the motion. *Id.* at 386. The Supreme Court ruled that the trial court properly denied the motion because the existence of the statute alone was enough of a threat to establish jurisdiction. *Id.*

<sup>97</sup> *Pierce v. Soc'y of Sisters*, 268 U. S. 510, 535 (1926). In *Pierce*, the state of Oregon passed a statute essentially requiring all children to attend public schools. *Id.* at 530. The statute passed in 1922, and was to go into effect in September 1926. *Id.* The Society of Sisters, who operated a private school, sued the state for an injunction barring enforcement of the statute, naming Governor Pierce and others as

its case as an action seeking an injunction against enforcement of the Kentucky statute instead of seeking a declaratory judgment, the Court would not have complained of jurisdiction.<sup>98</sup> In an action for injunction, the presence of the Kentucky statute regulating the sale of leaf tobacco should have been enough of a threat of irreparable injury to Liberty to establish jurisdiction for an injunction because the statute was directly applicable to Liberty, and because Commonwealth Attorney Grannis had authority to enforce the statute.<sup>99</sup>

*Liberty* left the constitutionality of declaratory judgment actions unclear because the Court's analysis was not clear about why the Court objected to declaratory judgments. While it was possible that the *Liberty* Court merely objected to the lack of federal statutory authority to hear declaratory judgments,<sup>100</sup> the broad "denunciatory"<sup>101</sup> language in *Liberty* made it equally possible that the Supreme Court majority believed that declaratory judgments necessarily were advisory opinions violating Article III.

Doubts about whether declaratory judgments were constitutional continued after the Court's opinion<sup>102</sup> in *Willing v. Chicago Auditorium Ass'n*.<sup>103</sup> In *Willing*, the plaintiff, the Chicago Auditorium Association, was a lessee that wanted to tear down an old building that the Association leased in order to construct a modern building.<sup>104</sup> While the lessee believed that the lease supported its plans, one of the lessors, *Willing*, did not agree.<sup>105</sup> In "an informal, friendly, private conversation," *Willing* asserted that the lessee could

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representatives of the state. *Id.* at 532. The state of Oregon moved to dismiss the complaint as premature, as the plaintiff filed the complaint more than two years before the statute was to go into effect. Brief of Appellant at 4a, *Pierce*, 268 U.S. 510, No. 583 (October Term, 1924). The Supreme Court stated that "[t]he injury to appellees was present and very real, not a mere possibility in the remote future. If no relief had been possible prior to the effective date of the Act, the injury would have become irreparable. Prevention of impending injury by unlawful action is a well recognized function of courts of equity." *Pierce*, 268 U.S. at 536.

<sup>98</sup> BORCHARD, *supra* note 13, at 178.

<sup>99</sup> *Id.*

<sup>100</sup> See *Willing v. Chi. Auditorium Ass'n*, 277 U.S. 274, 290 (1928) (Stone, J., concurring).

<sup>101</sup> Doernberg & Mushlin, *supra* note 83, at 568 (citing the testimony of Charles Taft, Hearings on H.R. 5623 Before a Subcomm. of the Senate Comm. on the Judiciary, 70th Cong., 1st Sess., at 7 (1928)).

<sup>102</sup> *Id.* at 558.

<sup>103</sup> *Willing*, 277 U.S. at 274.

<sup>104</sup> *Id.* at 285.

<sup>105</sup> *Id.* at 285-86.

not tear down the building.<sup>106</sup> Consequently, the lessee's financiers were fearful that the lessee's plans would violate the lease and had second thoughts about financing the project.<sup>107</sup> The lessee sued to remove the cloud caused by Willing's opposition from its leasehold interest and for an injunction barring the lessors from opposing the project.<sup>108</sup> The Court dismissed the case for lack of jurisdiction, holding that the Judicial Act did not authorize the proceeding.<sup>109</sup>

The Court ruled that there was no evidence that the lessors had opposed the project or claimed a right amounting to a cloud on title.<sup>110</sup> The Court reasoned that the action was not a cloud on title case at all because the lessors had not hampered the lessee's present use and occupancy of the property, and there were no hostile acts or threats to form an adverse assertion of right.<sup>111</sup> Instead, the Court stated the plaintiff sought "simply a declaratory judgment," which the Court asserted was beyond the power of the federal courts.<sup>112</sup>

While the Court held that the proceeding did not fall within the scope of the Judicial Code,<sup>113</sup> the Court also ruled that the case was not justiciable under Article III.<sup>114</sup> As in *Liberty*, the Court's constitutional analysis in *Willing* was not clear about why the action was not an Article III case or controversy. The Court acknowledged that the case had nearly every element of a genuine controversy: the question before the court was not moot or administrative, would fall under familiar forms of equity, and was capable of final judgment.<sup>115</sup> The plaintiff's interests were definite, specific, and not abstract, and the parties' interests were adverse.<sup>116</sup> However, the Court seemed to reason that the proceeding did not involve an Article III case or

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<sup>106</sup> *Id.* at 286.

<sup>107</sup> *Id.* at 287.

<sup>108</sup> *Id.* at 287-88.

<sup>109</sup> *Id.* at 289-90.

<sup>110</sup> *Id.* at 288. A cloud on title action fell under the equity jurisdiction of federal courts when the plaintiff was in possession of property having a clear title, and when the defendant claimed a right or title that was clearly invalid or inequitable. *Chi. Auditorium Ass'n v. Cramer*, 8 F.2d 998, 1005-06 (N.D.Ill 1925). Under equity principles, mere oral claims of ownership were generally insufficient to obtain equity jurisdiction. *Id.*

<sup>111</sup> *Willing*, 277 U.S. at 288.

<sup>112</sup> *Id.* at 289. The Court cited *Liberty*, in support of this assertion, but did not clarify whether the lack of jurisdictional authority was statutory or constitutional. *Id.*

<sup>113</sup> *Id.* at 290.

<sup>114</sup> *Id.* at 289-90.

<sup>115</sup> *Id.* at 289.

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

controversy because the plaintiff's doubts and fears could not confer a cause of action, and because the defendant had neither wronged nor threatened the plaintiff.<sup>117</sup>

Justice Stone's concurring opinion in *Willing*<sup>118</sup> appears to be a turning point in resolving the declaratory judgment's murky constitutional position. Justice Stone did not agree with the majority's broad constitutional analysis in *Willing*.<sup>119</sup> Instead, Justice Stone asserted that the Court could simply resolve *Willing* by observing that there was no statutory authority to hear the case.<sup>120</sup>

The Supreme Court largely resolved the question of whether declaratory judgments were unconstitutional<sup>121</sup> in *Nashville, Chattanooga & St. Louis Railway v. Wallace* in 1933.<sup>122</sup> In *Nashville*, the Supreme Court characterized a declaratory judgment as a procedure, not a substantive form of relief.<sup>123</sup> The Court reasoned that because the declaratory judgment was merely a procedure, a federal court would have jurisdiction over a declaratory judgment if the issues constituted a justiciable case or controversy raised in an action for injunction or other procedural form of relief.<sup>124</sup>

### *B. Declaratory Judgments Must Involve a Case or Controversy*

The Declaratory Judgment Act of 1934 emphasized the Article III case or controversy requirement by limiting the Act's scope to

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<sup>117</sup> *Id.* at 289-90.

<sup>118</sup> *Id.* at 290 (Stone, J., concurring).

<sup>119</sup> *Id.* at 290-91 (Stone, J., concurring).

<sup>120</sup> *Id.* at 290 (Stone, J., concurring).

<sup>121</sup> S. Rep. No. 73-1005 (2d Sess. 1934), reprinted in BORCHARD, *supra* note 13, at 1047.

<sup>122</sup> *Nashville, Chattanooga & St. Louis Ry. v. Wallace*, 288 U.S. 249, 259-65 (1933). In *Nashville*, the railroad sued the Comptroller of the Treasury of Tennessee seeking a declaratory judgment that a Tennessee tax on fuel storage was unconstitutional. *Id.* at 258. The railroad stored fuel in Tennessee to power trains on interstate routes through Tennessee, Kentucky, Alabama, and Georgia. *Id.* at 265. Tennessee imposed a tax on the fuel, the state had demanded payment of the taxes, and the state had threatened to enforce the tax. *Id.* at 262. The court ruled that the issue raised was unquestionably a case or controversy because the railroad could have sued to enjoin collection of the tax instead of to obtain a declaratory judgment. *Id.* at 261.

<sup>123</sup> *Id.* at 264.

<sup>124</sup> *Id.* at 262 (the Court summarized the "narrow question" presented in *Nashville* as whether a controversy that is justiciable when raised in a suit for an injunction is also justiciable when presented as a declaratory judgment).

actual controversies.<sup>125</sup> However, there is no universal definition for a constitutional case or controversy.<sup>126</sup> The text of the U.S. Constitution does not clearly define what the Framers meant by the words “cases” and “controversies.”<sup>127</sup> The fact that the Constitution enumerates several types of cases and controversies reveals that the Framers at least discussed forms of cases and controversies falling within federal jurisdiction.<sup>128</sup> But it does not appear that the Framers specifically debated the underlying meaning of cases and controversies.<sup>129</sup>

During the Constitutional Convention, James Madison argued that federal court jurisdiction should be limited to matters of a judiciary nature.<sup>130</sup> Madison asserted that it was “generally supposed that the jurisdiction given was constructively limited to cases of a Judiciary Nature.”<sup>131</sup> Madison made this comment during a debate over judicial review of legislation.<sup>132</sup> Judicial review was a controversial subject, invoking debate during and after the Constitutional Convention.<sup>133</sup> The context of Madison’s comment

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<sup>125</sup> LARRY W. YACKLE, *RECLAIMING THE FEDERAL COURTS* 110 (Harvard Univ. Press, 1994).

<sup>126</sup> *Id.* at 75-76.

<sup>127</sup> U.S. CONST., art. III, § 2, cl. 1.

<sup>128</sup> 4 *THE FOUNDERS’ CONSTITUTION* 220-27 (Philip B. Kurland & Ralph Lerner, eds., The Univ. of Chic. Press, 1987). The Framers debated proposals granting power to hear cases involving piracies and felonies on the high seas (May 29, 1787), cases relating to the collection of national revenue, questions of national peace and harmony, impeachment of national officers, and others including those that remained in the final draft of the Constitution (July 18, 1787). *Id.* at 220-22.

<sup>129</sup> Cass R. Sunstein, *What’s Standing after Lujan? Of Citizen Suits, “Injuries,” and Article III*, 91 MICH. L. REV. 163, 173 (1992) (“There is relatively little explicit material on the Framers’ conception of “case of controversy.”); Gene R. Nichol, Jr., *Justice Scalia, Standing, and Public Law Litigation*, 42 DUKE L.J. 1141, 1150 (1993) (“[T]he Framers gave almost no indication of what the phrase meant.” (referring to “case or controversy”)); YACKLE, *supra* note 125, at 76 (“As best anyone can tell, very little was said at the Constitutional Convention about the circumstances in which federal courts might act.”).

<sup>130</sup> Ralph A. Rossum, *The Courts and the Judicial Power*, in *THE FRAMING AND RATIFICATION OF THE CONSTITUTION* 235-36 (Leonard W. Levy & Dennis J. Mahoney eds., Macmillan Publishers Co. 1987) (Debate on August 27, 1787).

<sup>131</sup> *Id.* at 236 (citing James Madison, *Remarks on Mr. Jefferson’s Draft of a Constitution* in 5 *THE WRITINGS OF JAMES MADISON* 294 (Galliard Hunt ed., 1900-1910)).

<sup>132</sup> Rossum, *supra* note 130, at 236. Madison’s comment came during a debate over whether the judiciary should have jurisdiction over all cases arising under the Constitution. *Id.* Madison was opposed to giving one branch more authority to mark out the limits of the Constitution. *Id.*

<sup>133</sup> The exchange of writings between Alexander Hamilton in *The Federalist* #78-81 and Anti-Federalist Brutus in the *New York Journal* regarding the judiciary and

regarding judiciary nature may suggest that Madison was only expressing his opinion that review of legislation was not among matters of a judiciary nature.<sup>134</sup>

Professor Raoul Berger interpreted Madison's reference to "cases of a Judiciary Nature" to mean the judicial practices known and used prior to the framing of the Constitution.<sup>135</sup> Would declaratory judgments have been matters of a judicial nature at the time of the framing of the Constitution? Analogs to declaratory judgments have existed for centuries, dating to Roman law.<sup>136</sup> The judicial practice in the U.S. at the time of the framing of the Constitution largely reflected that in England.<sup>137</sup> At that time, matters of a judiciary nature in America included actions in law and in equity.<sup>138</sup> State courts rendered judgments that were essentially declaratory in cases of questions of status, quieting title and other equitable actions.<sup>139</sup> It would be difficult to argue that the Framers were unaware of such actions, but it is not clear whether the Framers would have considered such actions justiciable in federal court.

The Supreme Court's first opportunity to interpret the meaning of a case or controversy under the Declaratory Judgment Act was in *Aetna Life Insurance Co. v. Haworth* in 1937.<sup>140</sup> In *Aetna*, the declaratory plaintiff, Aetna Life Insurance Company, sought a declaration that insurance policies were void for nonpayment of premiums, and that Aetna was not obliged to pay disability payments

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judicial review further emphasized how controversial the subject was. Rossum, *supra* note 130, at 239. In Brutus' 15th essay of March 20, 1788, Brutus recognized that the federal courts would have the power of judicial review, and was concerned that the federal courts held too much power. *Id.* Hamilton responded in the *Federalist Papers #78-81*, outlining the reasons for and benefits of an independent judiciary. *Id.*

<sup>134</sup> Raoul Berger, *Standing to Sue in Public Actions: Is it a Constitutional Requirement?*, 78 YALE L.J. 816, 829 (1968-1969).

<sup>135</sup> *Id.* at 816-17.

<sup>136</sup> BORCHARD, *supra* note 13, at 87.

<sup>137</sup> Berger, *supra* note 134, at 816; William T. Quillen & Michael Hanrahan, *A Short History of the Delaware Court of Chancery 1792-1992*, 18 DEL. J. CORP. L. 819, 824 (1993).

<sup>138</sup> Quillen & Hanrahan, *supra* note 137 at 822-24.

<sup>139</sup> 1 WALTER H. ANDERSON, ACTIONS FOR DECLARATORY JUDGMENT § 3, 14 (2d ed., The Harrison Co. 1951); BORCHARD, *supra* note 13, at 148. Borchard distinguishes matters such as divorce, partition, forfeiture, etc. as not declaratory because they do not merely declare the prior existence of a right but establish new rights. *Id.* at 139.

<sup>140</sup> *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239-41 (1937).

under the policy.<sup>141</sup> In the events leading up to the suit, declaratory defendant, Haworth, purchased five policies from Aetna for life and disability coverage.<sup>142</sup> If Haworth suffered a disability while covered under the policies, Haworth could stop making payments and collect the benefit.<sup>143</sup> Haworth allegedly experienced a disability in 1930 and stopped making payments.<sup>144</sup> Subsequently, Haworth sent a written claim to Aetna asserting the disability and asserting that Haworth did not owe premium payments because of the disability.<sup>145</sup> Haworth did not make any threats to Aetna, nor did he sue Aetna.<sup>146</sup> However, Haworth had a cause of action against Aetna for payment of disability benefits,<sup>147</sup> and the statute of limitations for an action on the policies would not lapse until ten years after his death.<sup>148</sup> Aetna sued Haworth seeking a declaratory judgment that the policies were void for nonpayment.<sup>149</sup> The district court granted Haworth's motion to dismiss for lack of a controversy.<sup>150</sup> The Eighth Circuit majority affirmed the district court's dismissal after the Eighth Circuit reasoned that the facts did not show that Haworth was presently invading any of Aetna's rights, nor were Aetna's rights imminently affected by Haworth.<sup>151</sup> The Eighth Circuit held that there was no justiciable controversy in the absence of a defendant invading or threatening to invade a plaintiff's rights.<sup>152</sup> The Supreme Court reversed.<sup>153</sup>

The Court defined actual controversies under the Declaratory Judgment Act to be those controversies that Article III permitted the federal courts to hear.<sup>154</sup> Consequently, the Court held that a justiciable controversy must be definite and concrete, as opposed to hypothetical or abstract.<sup>155</sup> The Court held that a controversy must be "real and substantial," affect the legal interests or relationships of

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<sup>141</sup> *Id.* at 239.

<sup>142</sup> *Id.* at 237.

<sup>143</sup> *Id.*

<sup>144</sup> *Id.*

<sup>145</sup> *Id.* at 237-38.

<sup>146</sup> *Aetna Life Ins. Co. v. Haworth*, 84 F.2d 695, 698 (8th Cir. 1936), *rev'd*, 300 U.S. 227 (1937).

<sup>147</sup> *Aetna*, 300 U.S. at 243.

<sup>148</sup> *Aetna*, 84 F.2d at 699 (Woodrough, J., dissenting).

<sup>149</sup> *Aetna*, 300 U.S. at 239.

<sup>150</sup> *Id.* at 236.

<sup>151</sup> *Aetna*, 84 F.2d at 698.

<sup>152</sup> *Id.* at 697.

<sup>153</sup> *Aetna*, 300 U.S. at 244.

<sup>154</sup> *Id.* at 239-40.

<sup>155</sup> *Id.* at 240.

adverse parties, and must be one capable of resolution by a conclusive judgment.<sup>156</sup> The Court reasoned that there was a controversy in *Aetna* because Aetna and Haworth had taken adverse positions, each claiming a present right.<sup>157</sup> The parties' rights turned on questions of fact, and a judicial determination would be conclusive.<sup>158</sup> The Court recognized that had Haworth brought the action, there would have been a justiciable controversy.<sup>159</sup> The Court stated that the character of the controversy is the same regardless of whether Aetna or Haworth brought the action.<sup>160</sup> The Court reasoned that "[i]t is the nature of the controversy, not the method of its presentation *or the particular party who presents it*, that is determinative."<sup>161</sup>

The *Aetna* Court did not directly impose a requirement that the defendant's actions be an invasion of rights, or that such invasion of rights be imminent.<sup>162</sup> Instead, the Court appears to have focused on the adverse positions of Aetna and Haworth in reaching its holding.<sup>163</sup> It is notable that the Supreme Court's opinion did not include any analysis or acknowledgment of the Eighth Circuit's rationale.<sup>164</sup>

The Supreme Court later summarized the *Aetna* analysis in *Maryland Casualty Co. v. Pacific Coal and Oil Co.*<sup>165</sup> The Court reasoned that "[t]he question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between the parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."<sup>166</sup>

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<sup>156</sup> *Id.* at 241 (a declaratory judgment must be a "real and substantial controversy admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts").

<sup>157</sup> *Id.* at 242.

<sup>158</sup> *Id.*

<sup>159</sup> *Id.* at 243-44. Haworth could have sued in equity for a determination that the repudiation of the insurance contracts was unjustified because of his disability. *Id.* at 244.

<sup>160</sup> *Id.*

<sup>161</sup> *Id.* (Emphasis added).

<sup>162</sup> *See id.* at 240-41.

<sup>163</sup> *Id.* at 242.

<sup>164</sup> *See Aetna*, 300 U.S. at 239-44.

<sup>165</sup> *Maryland Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270 (1941).

<sup>166</sup> *Id.* at 273 (*summarizing Aetna v. Haworth*, 300 U.S. 227 (1937)).

*C. Development of Patent Declaratory Judgments in the Circuits*

A patent does not convey a right to make, use, offer to sell, or sell.<sup>167</sup> Instead, a patent owner enforces a patent by excluding others from making, using, offering to sell, selling or importing the claimed invention.<sup>168</sup> Consequently, a patent owner does not assert rights under the patent until the owner takes steps to enforce the patent.<sup>169</sup> Some courts<sup>170</sup> and commentators<sup>171</sup> have applied this principle to assert that a patent is not a cloud on a potential infringer until the patent owner exercises his right to exclude others. Under this line of reasoning, the patent owner would not be in a position adverse to the potential infringer until the patent owner takes steps to enforce the patent.<sup>172</sup>

Commentator Edmund H. O'Brien similarly analyzed the controversy requirement in patent declaratory judgment cases in 1935.<sup>173</sup> Mr. O'Brien drew an analogy between the lessors in the cloud on title action, presented in *Willing v. Chicago Auditorium Ass'n*, and patent owners in a patent infringement declaratory judgment action.<sup>174</sup> He emphasized the Court's ruling that the *Willing* lessor's opinion that the lessee's plans violated the lease was not an adverse claim of right creating a cloud on title.<sup>175</sup> By analogy, Mr. O'Brien suggested that a patent owner's opinion that a potential infringer's actions infringed a patent likewise would not create an adverse claim of right.<sup>176</sup> With this rationale, Mr. O'Brien argued that an adverse claim of right would only arise when the patent owner moved to exert its right to exclude others by demanding that infringement cease or by threatening to sue.<sup>177</sup> Supporting this

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<sup>167</sup> *Prima Tek II, L.L.C. v. A-Roo Co.*, 222 F.3d 1372, 1379 (Fed. Cir. 2000).

<sup>168</sup> 35 U.S.C. §§ 271, 281 (2004).

<sup>169</sup> Edmund H. O'Brien, *Restrictions on the Usefulness of Declaratory Judgments in Patent Suits*, 17 J. PAT. OFF. SOC'Y 270, 278 (1935).

<sup>170</sup> *Teva Pharm. USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324, 1333 (Fed. Cir. 2005) (“[M]ore is required for an actual controversy than the existence of an adversely held patent...”); *Tremond Co. v. Schering Corp.*, 122 F.2d 702, 706 (3d Cir. 1941) (“[T]he mere existence of the patent is not a cloud on title...”).

<sup>171</sup> BORCHARD, *supra* note 13, at 807 (Professor Borchard asserted that “the mere existence of the patent is not a cloud on title.”); O'Brien, *supra* note 169, at 278-79.

<sup>172</sup> O'Brien, *supra* note 169, at 278.

<sup>173</sup> *Id.*

<sup>174</sup> *Id.* at 278-79.

<sup>175</sup> *Id.* at 278.

<sup>176</sup> *Id.* at 278-79.

<sup>177</sup> *Id.* at 279.

conclusion was the *Willing* Court's denial of a cause of action because the defendants had not threatened or wronged the plaintiffs.<sup>178</sup>

The early patent infringement declaratory judgments considered by federal courts coupled two elements: manufacture or sale of a potentially infringing product and a charge of infringement or threat by the patent owner.<sup>179</sup> In 1941, the Third Circuit considered the requirement for an actual controversy in patent declaratory judgments in *Tremond Co. v. Schering Corp.*<sup>180</sup> In *Tremond*, the declaratory defendant, Schering Corporation, held a patent for certain chemicals.<sup>181</sup> Schering contacted several customers of the declaratory plaintiff, Tremond, and then put an advertisement in a trade journal asserting that any use of the chemicals without Schering's consent would be a violation of Schering's patent.<sup>182</sup> Responding to the advertisement, Tremond sued Schering for a declaratory judgment that Schering's patent was invalid or not infringed.<sup>183</sup> The district court dismissed for lack of a controversy,<sup>184</sup> and the Third Circuit reversed.<sup>185</sup>

The *Tremond* court held that there was a justiciable controversy on the facts of the case. The court cited Mr. O'Brien's analysis when asserting that "[t]here can be no doubt" that there is not a controversy before the patent owner makes a charge of infringement.<sup>186</sup> However, while the Third Circuit required a charge

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<sup>178</sup> *Willing*, 277 U.S. at 288.

<sup>179</sup> BORCHARD, *supra* note 13, at 807; P. J. Federico, *Operation of the Federal Declaratory Judgment Act in Patent Cases*, 19 J. PAT. OFF. SOC'Y 489, 500 (1937). As one example, *Zenie Brothers v. Miskend*, was an early patent declaratory judgment action under the Declaratory Judgment Act. 10 F.Supp. 779, 782 (S.D.N.Y. 1935). In *Zenie Bros.*, the defendant Miskend had recently obtained a patent for a garment seam that the plaintiff Zenie Brothers had been using for many years. *Id.* at 780. Subsequently, Miskend threatened to sue Zenie Brothers and their customers for patent infringement. *Id.* After being threatened, Zenie Brothers sought a declaratory judgment that the patent was invalid. Miskend moved to dismiss the complaint for failing to state a claim. *Id.* The *Zenie Bros.* court denied the motion to dismiss, reasoning that the case presented an adversary proceeding, was an actual controversy, and would provide finality of judgment. *Id.* at 780-81.

<sup>180</sup> 122 F.2d 702, 705 (3d Cir. 1941).

<sup>181</sup> *Id.* at 703. Schering owned U.S. Patent No. 2,096,744, Hildebrandt, et al., *Hydrogenation Products of Follicle Hormones and Methods of Producing Same* (issued Oct. 26, 1937).

<sup>182</sup> *Tremond*, 122 F.2d at 703.

<sup>183</sup> *Id.*

<sup>184</sup> *Id.*

<sup>185</sup> *Id.* at 706.

<sup>186</sup> *Id.* at 705 (citing Edmund H. O'Brien, *Restrictions on the Usefulness of*

of infringement, the charge did not have to be formal, nor did the patent owner have to charge the declaratory plaintiff directly.<sup>187</sup> The court found Schering's advertisement to be a threat of lawsuit, forming a sufficient indirect charge of patent infringement against Tremond.<sup>188</sup>

Several circuits discussed the threshold for a controversy through the late 1960's and 1970's, although none delved into the foundations beneath the charge of infringement requirement.<sup>189</sup> By 1982, most<sup>190</sup> circuits had adopted a threat or reasonable apprehension of lawsuit or a charge of infringement requirement to show the presence of a controversy.<sup>191</sup> As one exception, the Ninth Circuit

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*Declaratory Judgments in Patent Suits*, 17 J. PAT. OFF. SOC'Y 270, 278 (1935)).

<sup>187</sup> *Tremond*, 122 F.2d at 705.

<sup>188</sup> *Id.*

<sup>189</sup> *See eg.*, *Super Prods. Corp. v. D P Way Corp.*, 546 F.2d 748, 753 (7th Cir. 1976); *Sherwood Med. Indus., Inc. v. Deknatel, Inc.*, 512 F.2d 724, 727-28 (8th Cir. 1975); *Sweetheart Plastics, Inc. v. Illinois Tool Works, Inc.*, 439 F.2d 871, 874 (1st Cir. 1971); *Muller v. Olin Mathieson Chem. Corp.*, 404 F.2d 501, 504 (2d Cir. 1968).

<sup>190</sup> I found no appellate cases that definitively hold that a charge of infringement is sufficient or necessary in patent cases in the Fourth, Fifth, Tenth, and D.C. Circuits. *See eg.*, *U.S. Galvanizing & Plating Equip. Corp. v. Hanson-Van Winkle-Munning Co.*, 104 F.2d 856, 860 (4th Cir. 1939) (the Fourth Circuit applied a generic *Aetna Life Ins. Co. v. Haworth* analysis here, but there was a charge of infringement cementing the controversy); *Dahlgren Mfg. Co. v. Harris Corp.*, 399 F.Supp. 1253, 1254-56 (N.D.Tex. 1975) (a controversy existed without a direct charge of infringement when a controversy between the parties was sufficiently substantive and immediate); *Acme Feed Mills, Inc. v. Quaker Oats Co.*, 313 F.Supp. 1156, 1158 (M.D.N.C. 1970) (dismissing declaratory judgment for lack of controversy when there was no charge of infringement in trademark case); *Fash v. Clayton*, 78 F.Supp. 359, 361 (D.N.M. 1948) (a controversy does not exist unless the declaratory defendant threatens to sue).

The Ninth Circuit adopted a reasonable apprehension of liability test. *Societe de Conditionnement en Aluminum v. Hunter Engineering Co., Inc.*, 655 F.2d 938, 944 (9th Cir. 1981) (adopting a reasonable apprehension of liability test, *see infra* notes 191-201).

<sup>191</sup> *See, eg.*, *Int'l Harvester Co. v. Deere & Co.*, 623 F.2d 1207, 1210 (7th Cir. 1980) (a controversy exists when there is a reasonable apprehension of lawsuit, either by an express charge of infringement or apprehension based on defendant's conduct); *Sherwood Med. Indus., Inc. v. Deknatel, Inc.*, 512 F.2d 724, 727-28 (8th Cir. 1975) (an actual controversy exists when the patent owner makes a charge of infringement, but the charge of infringement can be implied by conduct that would lead a reasonable man to believe that he or his customers face an infringement suit); *Robin Prods. Co. v. Tomecek*, 465 F.2d 1193, 1195-96 (6th Cir. 1972) (whether a reasonable man would regard the patent owner's course of action as a charge of infringement or threat of suit); *Sweetheart Plastics, Inc. v. Illinois Tool Works, Inc.*, 439 F.2d 871, 874 (1st Cir. 1971) (required a charge of infringement, but the charge

examined and rejected a threat of lawsuit requirement in *Societe de Conditionnement en Aluminum v. Hunter Engineering Co., Inc.* in 1981.<sup>192</sup>

In *Societe de Conditionnement en Aluminum*, an employee of Hunter Engineering Company called a Hunter customer who was also a customer of Societe de Conditionnement en Aluminum (SCAL), and the Hunter employee threatened to sue this customer for patent infringement if the customer bought machinery from SCAL.<sup>193</sup> The Hunter employee did not have any authority from Hunter to make the threat, but neither the customer nor SCAL were aware of this.<sup>194</sup> The customer subsequently bought the machinery from SCAL, and SCAL sued Hunter seeking a declaratory judgment for patent invalidity.<sup>195</sup> When SCAL sued, Hunter repudiated the unauthorized threat.<sup>196</sup> Even though Hunter repudiated its threat, the Ninth Circuit held that SCAL made a prima facie case showing that there was a justiciable controversy.<sup>197</sup>

The Ninth Circuit acknowledged the presence of the threat of lawsuit test, but dismissed it because the threshold was much too high for a constitutional controversy.<sup>198</sup> According to this court, the better way to characterize a controversy was by a real and reasonable

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of infringement requirement is a flexible one; a charge of infringement may be found in a reasonable apprehension of lawsuit); *Muller v. Olin Mathieson Chem. Corp.*, 404 F.2d 501, 504 (2d Cir. 1968) (required a threat of lawsuit or charge of infringement, with a charge of infringement given liberal interpretation); *Treemond Co. v. Schering Corp.*, 122 F.2d 702, 705 (3d Cir. 1941) (“[t]here can be no doubt” that there is not a controversy before the patent owner makes a charge of infringement); *Tubeco, Inc. v. Crippen Pipe Fabrication Corp.*, 402 F.Supp. 838, 844 (E.D.N.Y. 1975) (a controversy exists when the plaintiff has a reasonable apprehension of lawsuit caused by the defendant); *Japan Gas Lighter Ass’n v. Ronson Corp.*, 257 F.Supp. 219, 237 (D.N.J. 1966) (a declaratory judgment controversy must be based on a reasonable apprehension that the plaintiff faces an infringement suit if he continues to conduct the activity in issue); *E.W. Bliss Co. v. Cold Metal Prods. Co.*, 137 F.Supp. 676, 678 (N.D. Ohio 1955) (a controversy exists when the patent owner directly or indirectly fosters the plaintiff’s reasonable apprehension of lawsuit).

*E.W. Bliss* is the earliest published reasonable apprehension of lawsuit case that I have found, and *Japan Gas Lighter* appears to be the second.

<sup>192</sup> *Societe de Conditionnement en Aluminum v. Hunter Eng’g Co.*, 655 F.2d 938, 943 (9th Cir. 1981).

<sup>193</sup> *Id.* at 941.

<sup>194</sup> *Id.*

<sup>195</sup> *Id.* at 938, 941.

<sup>196</sup> *Id.*

<sup>197</sup> *Id.* at 946.

<sup>198</sup> *Id.* at 944.

apprehension of liability if the declaratory plaintiff continued its conduct.<sup>199</sup> The court reasoned that in a reasonable apprehension of liability test, the focus is on the potential infringer, not the patent owner.<sup>200</sup> The court held that SCAL had made a prima facie case of jurisdiction because it was reasonable for the listener to believe that the employee of the patent owner had authority to make its threats, and thus there was a reasonable apprehension of liability.<sup>201</sup>

The Ninth Circuit was alone in its reasonable apprehension of liability test for patent cases, and because the Ninth Circuit adopted it in 1981, the test as applied to patent cases was short lived. The Federal Circuit assumed jurisdiction over appeals from district court patent cases in 1982,<sup>202</sup> and adopted the threat of lawsuit requirement.<sup>203</sup>

The first Federal Circuit case considering the requirements for a constitutional controversy in a declaratory judgment action was *C.R. Bard, Inc. v. Schwartz*.<sup>204</sup> The declaratory plaintiff, C.R. Bard, and inventor, Boris Schwartz, entered into an agreement licensing Schwartz's intravenous catheter patent.<sup>205</sup> Over the next ten years, C.R. Bard manufactured catheters according to the invention, and paid royalties to Schwartz.<sup>206</sup> However, in 1982 Schwartz sued C.R. Bard in a New Jersey state court for failure to use best efforts and failure to pay royalties.<sup>207</sup> C.R. Bard subsequently stopped making royalty payments and sued Schwartz in federal court seeking declaratory judgment that the patent was invalid and unenforceable.<sup>208</sup> The district court dismissed the declaratory judgment action on the ground that there was no controversy because Schwartz had not terminated the license agreement.<sup>209</sup> The Federal Circuit reversed, holding that Schwartz did not have to terminate the license in order for C.R. Bard to bring a declaratory judgment action.<sup>210</sup>

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<sup>199</sup> *Id.*

<sup>200</sup> *Id.* at 945.

<sup>201</sup> *Id.* at 946.

<sup>202</sup> 28 U.S.C. § 1295(a)(1) (2004) (enacted under the Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 25 (1982)).

<sup>203</sup> *C.R. Bard, Inc. v. Schwartz*, 716 F.2d 874, 879 (Fed. Cir. 1983).

<sup>204</sup> *Id.* at 879.

<sup>205</sup> *Id.* at 875. (C.R. Bard licensed U.S. Patent No. 3,599,637 to Schwartz, *Intravenous Catheter Assembly* (issued Aug. 17, 1971)).

<sup>206</sup> *Id.*

<sup>207</sup> *Id.*

<sup>208</sup> *Id.* at 876.

<sup>209</sup> *Id.*

<sup>210</sup> *Id.* at 882.

The *C.R. Bard* court defined a constitutional controversy as one where there is a reasonable threat that the patent owner will sue for patent infringement.<sup>211</sup> The court recognized that there was a split among the circuits over whether a licensee could seek a declaratory judgment before a licensor terminated the license.<sup>212</sup> However, the court rejected the view that there could never be a reasonable apprehension of lawsuit while the license was in effect.<sup>213</sup> Because *C.R. Bard* had breached the license by stopping royalty payments, he had a reasonable apprehension that Schwartz would sue for patent infringement.<sup>214</sup>

Ever since *C.R. Bard*, the Federal Circuit has applied the apprehension of lawsuit test.<sup>215</sup> While the court asserts that a constitutional controversy cannot exist without a reasonable apprehension of lawsuit,<sup>216</sup> the Federal Circuit seldom expressly links the reasonable apprehension test with standing.<sup>217</sup> However, it is probable that the Federal Circuit considers the reasonable apprehension test as a proxy for standing.<sup>218</sup>

#### IV. FEDERAL COURT STANDING

A plaintiff in federal court must have standing.<sup>219</sup> Under the modern standing doctrine,<sup>220</sup> the party seeking federal jurisdiction

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<sup>211</sup> *Id.* at 879 (a controversy exists when “there is a reasonable threat that the patentee or licensor will bring an infringement suit against the alleged infringer”).

<sup>212</sup> *Id.*

<sup>213</sup> *Id.* at 880.

<sup>214</sup> *Id.* at 881.

<sup>215</sup> *See, e.g.,* *Jervis B. Webb Co. v. Southern Sys. Inc.*, 742 F.2d 1388, 1398-99 (Fed. Cir. 1984); *Arrowhead Indus. Water, Inc. v. Ecolchem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988); *B.P. Chem. Ltd. v. Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1995); *Teva Pharm. USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324, 1332 (Fed. Cir. 2005); *Medimmune, Inc. v. Genentech, Inc.*, 427 F.3d 958, 964-65 (Fed. Cir. 2005).

<sup>216</sup> *Medimmune, Inc. v. Centocor, Inc.*, 409 F.3d 1376, 1379 (Fed. Cir. 2005).

<sup>217</sup> The cases explicitly linking the reasonable apprehension of lawsuit to standing are: *B.P. Chemicals*, 4 F.3d at 981 (a declaratory judgment action is justiciable when a plaintiff meets the elements of standing); *Medimmune*, 427 F.3d at 965 (“*Medimmune*, since under no threat or apprehension of suit, did not have standing to bring a declaratory” judgment action); *Teva*, 405 F.3d at 992 (Gajarsa, J., dissenting) (a declaratory judgment action is justiciable when a plaintiff meets the elements of standing).

<sup>218</sup> *See B.P. Chemicals*, 4 F.3d at 981.

<sup>219</sup> *Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 475-76 (1982).

<sup>220</sup> The modern doctrine of standing is a late-twentieth century development.

must establish standing in every federal case.<sup>221</sup> In a declaratory judgment action, the declaratory plaintiff has the burden of establishing the elements of standing.<sup>222</sup>

Standing includes both constitutional requirements and prudential considerations.<sup>223</sup> Prudential considerations are judicially imposed limitations, such as a requirement that a plaintiff's grievance be within the zone of interest protected by the law under which the plaintiff is suing.<sup>224</sup> Constitutional standing, however, is "an essential and unchanging part of the case-or-controversy requirement" of the Constitution.<sup>225</sup> The Supreme Court has repeatedly held that constitutional standing determines whether there is a case or controversy within the meaning of Article III.<sup>226</sup> A party without constitutional standing may not sue in federal court.<sup>227</sup>

The Supreme Court's requirements for constitutional standing include three elements at an "irreducible constitutional minimum."<sup>228</sup> First, there must be an injury in fact.<sup>229</sup> Second, there must be a traceable causal connection between the defendant's actions and the plaintiff's injury.<sup>230</sup> And third, the injury must be conclusively redressable by the court.<sup>231</sup> These elements are the core of the Article III case or controversy requirement.<sup>232</sup> By applying the standing doctrine, courts are able to distinguish a case or controversy from an advisory opinion.<sup>233</sup>

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Cass R. Sunstein, *What's Standing after Lujan? of Citizen Suits, "Injuries," and Article III*, 91 MICH. L. REV. 163, 169 (1992). By 1992, 117 Supreme Court cases discussed standing in terms of Article III, and 109 of the 117 cases were decided after 1965. *Id.* The first Supreme Court case to discuss standing in terms of Article III was *Stark v. Wickard*, 321 U.S. 288 (1944). The Court decided *Aetna Life Ins. Co. v. Haworth* in 1937, before *Stark v. Wickard*. See *Aetna*, 300 U.S. 227 (1937).

<sup>221</sup> *Elk Grove Unified Sch. Dist. v. Newdow*, 542 U.S. 1, 7 (2004).

<sup>222</sup> See *id.* (The party bringing the action must establish standing.)

<sup>223</sup> *Id.*

<sup>224</sup> *Id.*

<sup>225</sup> *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992).

<sup>226</sup> See, e.g., *Elk Grove Unified Sch. Dist.*, 542 U.S. at 7; *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 102 (1998); *Lujan*, 504 U.S. at 560; *Allen v. Wright*, 468 U.S. 737, 751 (1984); *Valley Forge Christian Coll.*, 454 U.S. at 472.

<sup>227</sup> *Valley Forge Christian Coll.*, 454 U.S. at 475-76.

<sup>228</sup> *Lujan*, 504 U.S. at 560.

<sup>229</sup> *Id.*

<sup>230</sup> *Id.*

<sup>231</sup> *Id.* at 561.

<sup>232</sup> *Id.* at 560.

<sup>233</sup> *Steel Co.*, 523 U.S. at 102 (standing "is a part of the common understating of what it takes to make a justiciable case"); Gene R. Nichol, Jr., *Ripeness and the*

In a declaratory judgment action brought by a potential infringer, the plaintiff should readily satisfy the redressability element of standing.<sup>234</sup> If the declaratory judgment holds that the patent is valid and infringed, the infringer must cease their conduct. If the patent is invalid or not infringed, the declaratory plaintiff may continue to conduct business. In either case, a judgment settles the question.

The injury in fact analysis is more difficult in patent declaratory judgments. When does a potential infringer have an injury in fact? Under a constitutional standing analysis, the injury in fact element is satisfied when a plaintiff has suffered or will imminently suffer a violation of a legally protected right; a right that is specific, not abstract or hypothetical.<sup>235</sup> In 1992, the Supreme Court reaffirmed this definition of injury in fact in *Lujan v. Defenders of Wildlife*.<sup>236</sup>

In *Lujan*, the Secretary of the Interior had eliminated a requirement that federal agencies issue reports of the effects agency projects have on endangered species in foreign countries.<sup>237</sup> The plaintiffs alleged that if federal agencies did not analyze and report the impact of their projects on endangered species, certain endangered species would reach extinction sooner.<sup>238</sup> The plaintiffs sued the Secretary of the Interior over the Secretary's failure to enforce the Endangered Species Act.<sup>239</sup> The plaintiffs argued that the government caused them injury because they would not be able to return to Sri Lanka and Egypt to see animals affected by federal projects after they became extinct.<sup>240</sup> Further, the plaintiffs argued they had standing because the Endangered Species Act contained a "citizen-suit" provision which allowed "any person" to sue to enjoin violations of the Act.<sup>241</sup> The Court held the plaintiffs did not have standing to sue because there was no injury in fact.<sup>242</sup> Further, even if there was injury, the Court could not redress such an injury.<sup>243</sup> A judgment

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*Constitution*, 54 U. CHI. L. REV. 153, 155 (1987).

<sup>234</sup> See *Teva Pharm. USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324, 1343 (Fed. Cir. 2005) (Mayer, dissenting) (a declaratory judgment would have resolved the entire controversy between the parties).

<sup>235</sup> *Lujan*, 504 U.S. at 560.

<sup>236</sup> *Id.*

<sup>237</sup> *Id.* at 558-59.

<sup>238</sup> *Id.* at 562.

<sup>239</sup> *Id.* at 558-59.

<sup>240</sup> *Id.* at 563-64.

<sup>241</sup> *Id.* at 571-72.

<sup>242</sup> *Id.* at 564.

<sup>243</sup> *Id.* at 568.

would not bind the funding agencies because they were not parties to the suit, and there was no evidence that a judgment would ultimately affect the government projects that were allegedly harming these animals.<sup>244</sup> The Court also held that a statute which provides a procedure for citizens to sue does not confer standing in the absence of constitutional standing.<sup>245</sup>

The Court reaffirmed the requirements for constitutional standing to include injury in fact, causation, and redressability.<sup>246</sup> Next, the Court recognized that while wanting to see endangered animals was “undeniably” a cognizable interest,<sup>247</sup> the plaintiffs had not shown that any injury to this interest was imminent.<sup>248</sup> The *Lujan* Court then distinguished between cases involving actual harm and those where harm had not yet occurred.<sup>249</sup> The Court asserted that when there is actual harm, the “existence of standing is clear.”<sup>250</sup> However, when the injury has not yet occurred, the plaintiff must show that the injury will occur imminently.<sup>251</sup>

The *Lujan* majority noted that immanency is an “elastic concept,”<sup>252</sup> but asserted that in a case of future injury, the threatened injury must be “certainly impending” to be an injury in fact.<sup>253</sup> The Court suggested that if the plaintiffs had made concrete plans for trips to Sri Lanka and Egypt, or had identified when the injury would occur, there might have been an injury in fact.<sup>254</sup> However, even if the plaintiffs had purchased tickets for a future trip, it is not clear whether they would have had standing. The Court noted that injuries which are too speculative would not pass the imminent injury rule.<sup>255</sup>

An injury generally must be concrete and particularized.<sup>256</sup> A plaintiff that claims a generalized grievance will not normally have standing in federal court.<sup>257</sup> The plaintiff must have suffered a

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<sup>244</sup> *Id.* at 569-71.

<sup>245</sup> *Id.* at 576-77.

<sup>246</sup> *Id.* at 560-61.

<sup>247</sup> *Id.* at 562.

<sup>248</sup> *Id.* at 564.

<sup>249</sup> *Id.* at 564-65 n. 2.

<sup>250</sup> *Id.*

<sup>251</sup> *Id.*

<sup>252</sup> *Id.*

<sup>253</sup> *Id.* (citing *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990)).

<sup>254</sup> *Id.* at 564.

<sup>255</sup> *Id.* at 564 n. 2.

<sup>256</sup> *Id.* at 560.

<sup>257</sup> *Id.* at 573-74. Standing for claims of generalized grievances has been denied by the Supreme Court for both Constitutional and prudential reasons. *FEC v. Akins*,

particular harm distinct from harm common to the general population.<sup>258</sup>

The Federal Circuit held that in patent cases, a particularized harm suffered by a declaratory plaintiff must be more than merely “the existence of an adversely held patent.”<sup>259</sup> The mere existence of a patent may resemble a generalized grievance when the declaratory plaintiff’s injury mirrors the public interest of keeping invalid patents from interfering with competition generally,<sup>260</sup> because such an interest is somewhat abstract and indefinite.<sup>261</sup> However, when the declaratory plaintiff is a manufacturer that is creating or planning to create a product that may infringe a patent, the declaratory plaintiff’s injury is distinguishable from the generalized grievance. The potentially infringing manufacturer faces a particularized harm because the manufacturer would be accruing potential damages with every product made.

*A. Reasonable Apprehension of Lawsuit is Not Coextensive  
With Constitutional Standing*

When a patent owner makes a charge of infringement, it necessarily raises a controversy by causing an injury in fact.<sup>262</sup> A charge of infringement from the patent owner essentially creates the same type of controversy as in an ordinary patent infringement case, where a patent owner makes a charge in a complaint and a potential infringer refutes that charge.<sup>263</sup> The Federal Circuit reasons that a

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524 U.S. 11, 23 (1998). A generalized grievance lacks Constitutional standing when the generalized grievance pertains to an abstract injury, “for example, injury to the interest in seeing that the law is obeyed.” *Id.* at 24.

<sup>258</sup> *Lujan*, 504 U.S. at 575. However, the mere fact that many people suffer the same concrete and particularized injury (appearing to be a generalized grievance) does not defeat standing. *Akins*, 524 U.S. at 24.

<sup>259</sup> *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1333 (Fed. Cir. 2005).

<sup>260</sup> *See Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945) (“The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope.”).

<sup>261</sup> *See FEC v. Akins*, 524 U.S. 11, 23 (1998).

<sup>262</sup> *Cardinal Chem. Co. v. Morton Int’l Inc.*, 508 U.S. 83, 96 (1993) (“[T]here is, necessarily a case or controversy” when the patent owner makes a charge of infringement. (Emphasis in original)).

<sup>263</sup> P. J. Federico, *Operation of the Federal Declaratory Judgment Act in Patent Cases*, 19 J. PAT. OFF. SOC’Y 489, 499 (1937). In an ordinary patent infringement case, the patent owner charges a potential infringer with infringement, and

charge of infringement is justiciable because the charge of infringement creates a reasonable apprehension of lawsuit.<sup>264</sup>

One problem with the Federal Circuit's reasonable apprehension test as a sole measure of a constitutional controversy is that it is an incomplete replacement for the standing analysis. The reasonable apprehension of lawsuit test has prevented plaintiffs from presenting injuries in fact other than their reasonable apprehension of a lawsuit. It is likely that there are situations where a declaratory plaintiff will suffer an actual injury caused by the patent owner's acts or omissions, but where there is no apprehension of lawsuit.

One example is *Teva Pharm. USA, Inc. v. Pfizer Inc.* where a patent owner strategically refused to sue or threaten to sue despite the fact that the declaratory plaintiff was prepared to manufacture a potentially infringing product.<sup>265</sup> In *Teva*, the Federal Circuit addressed jurisdiction over declaratory judgments in the context of U.S. Food and Drug Administration ("FDA") approval of generic drugs under the Hatch-Waxman Act.<sup>266</sup>

To appreciate *Teva*, it is helpful to understand part of the generic drug approval scheme. The Hatch-Waxman Act<sup>267</sup> and its subsequent Medicare Amendments<sup>268</sup> provide a mechanism for drug manufacturers to obtain FDA approval for generic drugs. Under one facet of the statute, a generic drug manufacturer can apply for FDA approval of a generic version of a previously approved patented drug.<sup>269</sup> While a new drug application requires extensive

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subsequently, the potential infringer denies infringement and challenges the validity of the patent.

<sup>264</sup> *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, 736 (Fed. Cir. 1988). In *Arrowhead*, patent owner Ecolochem sent a letter to Arrowhead asserting that if Arrowhead used the Ecolochem process, Ecolochem would sue. *Id.* at 733. Arrowhead sued Ecolochem seeking a declaratory judgment that Ecolochem's patent was invalid and not infringed. *Id.* The district court dismissed the action for lack of a controversy on the ground that Ecolochem's letter was conditional. *Id.* The Federal Circuit reversed and remanded, stating that even though there was no express charge of infringement, Arrowhead had a reasonable apprehension of lawsuit. *Id.* at 737-39.

<sup>265</sup> 395 F.3d at 1326-27.

<sup>266</sup> *Id.* at 1327.

<sup>267</sup> *Drug Price Competition and Patent Term Restoration Act of 1984*, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 15 U.S.C. §§ 68, 70, 21 U.S.C. §§ 355, 360cc, and 35 U.S.C. §§ 156, 271, 282).

<sup>268</sup> *Medicare Prescription Drug, Improvement, and Modernization Act of 2003*, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified at 26 U.S.C. §§ 139, 223, 4980 and 42 U.S.C. §§ 299, 1395, 1396).

<sup>269</sup> 21 U.S.C. § 355(j) (2003).

documentation showing the drug's effectiveness and safety,<sup>270</sup> the generic drug application requires much less information if the active ingredient of the generic drug is the same as the previously registered drug.<sup>271</sup> Reduced documentation saves the generic manufacturer a significant amount of time and money.<sup>272</sup> As a further benefit, the first manufacturer to apply for FDA approval of a generic drug utilizing a particular patented active ingredient may have a six-month exclusivity period to market its generic drug.<sup>273</sup> To enforce the six-month exclusivity period, the FDA will not approve other generic drug applications filed for that active ingredient until 180 days after the first applicant's product goes on sale, or 180 days after a court finds the patent invalid or not infringed.<sup>274</sup>

Merely filing a generic drug application before an original drug patent expires is an infringement of the patent.<sup>275</sup> The generic drug applicant must notify the patent owner of the generic drug application as part of the application process.<sup>276</sup> If the patent owner sues the generic drug applicant for patent infringement within forty-five days of receiving notice, the FDA is required to delay the application for thirty months.<sup>277</sup> If the patent owner does not sue the generic drug applicant within forty-five days, the FDA may approve the generic drug application immediately.<sup>278</sup> Furthermore, the generic drug applicant may then seek a declaratory judgment that the patent is invalid or not infringed by the generic drug.<sup>279</sup> The availability of the declaratory judgment procedure to the generic drug applicant provides it with a practical means of preventing a subsequent suit by the patent owner after the production process has already begun.

In *Teva*, Teva Pharmaceuticals filed a generic drug application in July 2002 to produce a generic version of sertraline hydrochloride, a drug patented by Pfizer.<sup>280</sup> However, Ivax Pharmaceuticals was the

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<sup>270</sup> 21 U.S.C. § 355(b)(1) (2003).

<sup>271</sup> Compare 21 U.S.C. § 355(b)(1) (2003), with 21 U.S.C. § 355(j)(2)(A) (2003).

<sup>272</sup> Henry H. Gu, *The Hatch Waxman Act and the Declaratory Judgment Action: Constitutional and Practical Implications*, 57 RUTGERS L. REV. 771, 780-81 (2005).

<sup>273</sup> 21 U.S.C. § 355(j)(5)(B)(iv) (2003). To qualify under this provision, the first applicant must notify the patent owner of the generic drug application. 21 U.S.C. § 355(j)(5)(B)(iii) (2003).

<sup>274</sup> 21 U.S.C. § 355(j)(5)(B)(iv) (2003).

<sup>275</sup> 35 U.S.C. § 271(e)(2)(A) (2004).

<sup>276</sup> 21 U.S.C. § 355(j)(2)(B)(i) (2003).

<sup>277</sup> 21 U.S.C. § 355(j)(5)(B)(iii) (2003).

<sup>278</sup> *Id.*

<sup>279</sup> 35 U.S.C. § 271(e)(5) (2004).

<sup>280</sup> *Teva Pharm. USA, Inc., v. Pfizer Inc.*, 395 F.3d 1324, 1326 (Fed. Cir. 2005).

first to file a generic drug application challenging Pfizer's sertraline hydrochloride patent.<sup>281</sup> Pfizer sued Ivax for patent infringement, and Pfizer subsequently granted a license to Ivax to settle the action.<sup>282</sup> The FDA granted a six-month exclusivity period to Ivax,<sup>283</sup> and the FDA consequently stayed Teva's application until the Ivax product was on sale for 180 days.<sup>284</sup> The Ivax license was to go into effect when Ivax started producing and selling the drug in June 2006,<sup>285</sup> ensuring that its six-month exclusivity period would not expire until December 2006. This effectively stayed Teva's application until the end of Ivax's exclusivity period in December 2006, some fifty-three months after its original date of filing. Because Pfizer did not sue Teva within the forty-five day period after Teva gave Pfizer notice of the application, Teva sought a declaratory judgment on the basis of patent invalidity and non-infringement in an attempt to accelerate its FDA approval.<sup>286</sup> The Federal Circuit held that the action between Pfizer and Teva did not contain a justiciable controversy, and dismissed the case for lack of jurisdiction.<sup>287</sup>

The *Teva* majority strictly adhered to the reasonable apprehension of lawsuit standard.<sup>288</sup> Pfizer did not sue or threaten to sue, and was careful to avoid any conduct that Teva could construe as a threat.<sup>289</sup> Further, it would likely be years before the FDA would approve Teva's sertraline hydrochloride application, because the FDA had stayed Teva's application to accommodate Ivax's exclusivity period.<sup>290</sup> As Teva would not be able to sell the drug without FDA approval, Pfizer would not have grounds to sue Teva for infringing sales for an indeterminate amount of time.<sup>291</sup> Accordingly, the Federal Circuit found that there could not possibly be a reasonable apprehension of lawsuit before the FDA approved Teva's generic drug application, which was likely to be years away.<sup>292</sup> Without a reasonable apprehension of lawsuit, the court reasoned, there could not

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<sup>281</sup> *Id.* at 1330.

<sup>282</sup> *Id.*

<sup>283</sup> *Id.*

<sup>284</sup> *Id.*

<sup>285</sup> *Id.*

<sup>286</sup> *Id.*

<sup>287</sup> *Id.* at 1338.

<sup>288</sup> *Id.* at 1332.

<sup>289</sup> *Id.* at 1333.

<sup>290</sup> *Id.* at 1334.

<sup>291</sup> *Id.*

<sup>292</sup> *Id.*

be a constitutional controversy.<sup>293</sup>

The Federal Trade Commission (“FTC”) filed a brief of amicus curiae in support of Teva.<sup>294</sup> Teva and the FTC argued that the basic elements of standing, including an injury in fact caused by Pfizer’s conduct, were sufficient to create a constitutional controversy.<sup>295</sup> The FTC’s brief also alleged that Pfizer’s actions caused injury by frustrating and delaying Teva’s launch of the generic drug.<sup>296</sup> Because Pfizer settled the infringement action with Ivax, a court would not adjudicate the validity of the patent, ensuring that the FDA would continue to stay Teva’s application.<sup>297</sup> Since Teva could not sell the drug without FDA approval, the delay completely deprived Teva of the ability to sell the drug for profit.<sup>298</sup> Teva would have suffered further economic harm if its investment in research and capital equipment had been lost because of the delay in FDA approval.<sup>299</sup> The FTC brief of amicus curiae cited Judge Gajarsa of the Federal Circuit as reasoning that “the inability to market a product without a court decision may create sufficient case or controversy for the purposes of a declaratory judgment action.”<sup>300</sup> The Federal Circuit never acknowledged Teva’s standing argument.<sup>301</sup>

### *B. Uncertainty as an Injury in Fact*

Uncertainty is an important injury that the reasonable apprehension of lawsuit test ignores in patent cases.<sup>302</sup> While case law suggests that an abstract uncertainty would not be a sufficient injury in fact,<sup>303</sup> the better rule may be that a particularized uncertainty causes a

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<sup>293</sup> *Id.* at 1338.

<sup>294</sup> Brief for Federal Trade Commission as Amicus Curiae Supporting Appellant, *Teva Pharm. USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324 (Fed. Cir. 2005) (No. 04-1186).

<sup>295</sup> *Teva*, 395 F.3d at 1335.

<sup>296</sup> Amicus Brief Supporting Appellant, *supra* note 294, at 8-9.

<sup>297</sup> *Id.* at 7.

<sup>298</sup> *Id.*

<sup>299</sup> *See Teva*, 405 F.3d 990, 994 (Fed. Cir. 2005) (Gajarsa, J., dissenting).

<sup>300</sup> Amicus Brief Supporting Appellant, *supra* note 294 at 9 (citing *Minn. Mining and Mfg. Co. v. Barr Labs., Inc.*, 289 F.3d 775, 791 (Fed. Cir. 2002) (Gajarsa, J., concurring)).

<sup>301</sup> *Teva Pharm. USA, Inc. v. Pfizer, Inc.*, 395 F.3d 1324, 1335-36 (Fed. Cir. 2005).

<sup>302</sup> *See* Daniel A. Farber, *Uncertainty as a Basis for Standing*, 33 HOFSTRA L. REV. 1123, 1125-26 (2005) (Uncertainty has real and immediate economic costs. Mr. Farber’s note primarily concerns environmental issues, however, his observations may appropriately apply to patent law.).

<sup>303</sup> *See, e.g.,* *Willing v. Chi. Auditorium Ass’n.*, 277 U.S. 274, 289-90 (1928)

justiciable controversy when the uncertainty unreasonably increases the risk of harm. Consider an example of a manufacturer who is producing, or about to produce, a product when the manufacturer discovers an adverse patent. The adverse patent creates uncertainty about the manufacturer's position, causing an increase in the manufacturer's risk. If the manufacturer continues to produce the product with knowledge of the patent, the manufacturer may be at risk of paying treble damages in an infringement action by the patent owner.<sup>304</sup> Worse yet, the manufacturer may face the prospect of an injunction stopping production of a profitable product or service.<sup>305</sup> Because of the manufacturer's potentially infringing conduct, the adverse patent causes harm by increasing the manufacturer's risk of injury.

An increased risk of future injury has satisfied the injury in fact requirement for Article III standing in circumstances other than patent infringement.<sup>306</sup> In *Baur v. Veneman*, the Second Circuit considered increased risk of harm as an injury in the context of food safety.<sup>307</sup> The plaintiff, Michael Baur, sued the Secretary of Agriculture and the U.S. Department of Agriculture ("USDA") alleging a violation of the Federal Meat Inspection Act. Baur alleged that a USDA policy permitting the slaughter of downed livestock for human consumption increased his risk of contracting mad cow disease.<sup>308</sup> The district court dismissed the complaint for lack of standing because Baur's exposure to meat from downed cattle caused a harm too remote to be an injury in fact.<sup>309</sup> Further, the district court ruled that Baur's complaint was a grievance shared by the population as a whole.<sup>310</sup> The Second Circuit reversed, holding that an increased risk of disease transmission was an injury in fact sufficient to establish standing.<sup>311</sup>

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("The fact that the plaintiff's desires are thwarted by its own doubts, or by the fears of others, does not confer a cause of action."); *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990) (alleged injury cannot be merely abstract).

<sup>304</sup> *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 826 (Fed. Cir. 1992) (under 35 U.S.C. § 284, a court may increase a damage award up to three times for willful patent infringement).

<sup>305</sup> *MercExchange, LLC v. eBay, Inc.*, 401 F.3d 1323, 1338 (Fed. Cir. 2005) (because the right to exclude is a fundamental patent right, the general rule is that a court should issue a permanent injunction after holding a patent valid and infringed).

<sup>306</sup> *See Baur v. Veneman*, 352 F.3d 625, 634 (2d Cir. 2003).

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

<sup>308</sup> *Id.* at 628.

<sup>309</sup> *Id.* at 631.

<sup>310</sup> *Id.*

<sup>311</sup> *Id.* at 633-34.

The Second Circuit reasoned that even though harm from exposure to dangerous products is probabilistic, an exposure to a risk could be an injury.<sup>312</sup> The court compared Baur's asserted injury to other increased risk injuries that have garnered standing,<sup>313</sup> including increased risk of air pollution,<sup>314</sup> exposure to second-hand smoke,<sup>315</sup> and increased financial risks caused by changes to an employee benefit plan.<sup>316</sup> The court recognized that Baur's injury was widely shared, but reiterated that standing does not fail simply because many others

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<sup>312</sup> *Id.* at 634.

<sup>313</sup> *Id.* at 633-34.

<sup>314</sup> *LaFleur v. Whitman*, 300 F.3d 256, 270 (2d Cir. 2002). In *LeFleur*, the plaintiffs objected to the issuing of Environmental Protection Agency (EPA) permits that allowed construction of a waste treatment plant. *Id.* at 259. The planned waste facility would convert waste to ethanol, *id.*, but in the process would emit small amounts of sulfur dioxide. *Id.* at 270. The amount of sulfur dioxide emission calculated was well below the EPA allowed amount. *Id.* The company seeking the permit argued that because the amount of sulfur dioxide was below the regulated amount, the plaintiff could not have an injury. *Id.* The Second Circuit disagreed, reasoning that a possible increase in exposure to sulfur dioxide was enough to confer standing because the chemical smells like rotten eggs and might impair health. *Id.*

<sup>315</sup> *Helling v. McKinney*, 509 U.S. 25, 35 (1993). While this opinion did not include an analysis of the elements of standing, the Court held that risk of future harm was enough to maintain standing in an Eighth Amendment Claim. *Id.* at 35. In *Helling*, the plaintiff, McKinney, who was an inmate in a Nevada prison, sued prison officials claiming that exposure to second hand tobacco smoke from his cellmate was an unreasonable risk to health under the Eighth Amendment, and that the prison was indifferent to the plaintiff's current medical problems caused by the smoke. *Id.* at 28. The lower court concluded that the plaintiff did not have a constitutional right to a smoke-free environment, and that the plaintiff failed to prove his indifference claim. *Id.* at 28-29. The Ninth Circuit reversed the constitutional claim on the ground that the exposure endangered future health. *Id.* at 29-30. The Supreme Court agreed that the risk of damage to future health caused by exposure to smoke was sufficient to continue the Eighth Amendment claim. *Id.* at 34-35.

<sup>316</sup> *Johnson v. Allsteel, Inc.*, 259 F.3d 885, 888 (7th Cir. 2001). In *Allsteel*, the plaintiff, Johnson, was an employee of Allsteel. *Id.* at 887. The original benefit plan provided that Allsteel could only make amendments to the plan with agreement of the local union. *Id.* Allsteel amended the plan to give Allsteel the unilateral right to amend, interpret, construe, and administer the plan. *Id.* Johnson sued Allsteel challenging the amendments under the Employee Retirement Income Security Act. *Id.* at 886. The district court dismissed on the ground that Johnson had not suffered an injury in fact sufficient for standing. *Id.* at 886-87. The Seventh Circuit reversed. *Id.* at 891. The Seventh Circuit reasoned that when Allsteel increased its discretion in the plan, the participants in the plan incurred higher risks because it was possible for the plan to change at any time. *Id.* at 888. The court reasoned that the risk that the plan could change made the plan benefits uncertain, causing an injury in fact sufficient to confer standing. *Id.* at 890.

have the same injury.<sup>317</sup> However, the Second Circuit asserted that for an enhanced risk to be an injury in fact, the plaintiff must allege a credible degree of risk.<sup>318</sup>

In some ways, a potentially infringing manufacturer may be in a position analogous to a prisoner exposed to environmental cigarette smoke. The prisoner has few practical options available to avoid a cellmate's cigarette smoke. The prisoner can try to negotiate with the cellmate, but a person addicted to smoking cigarettes may not be motivated to stop smoking for another person's wellbeing. The prisoner can request a transfer to a different cell, but is at the mercy of the jailor. Or, the prisoner can ignore the smoke and accept the risk of expensive, potentially life threatening health problems caused by the smoke. Similarly, the potentially infringing manufacturer can attempt to negotiate with a patent owner, but the patent owner may not be motivated to negotiate, especially if the patent holder is a competitor. The potentially infringing manufacturer can attempt to redesign its product or service away from the patent, but this option may be expensive or time consuming, or may be impractical or impossible due to financial, market, or technical constraints. Or, the manufacturer can ignore the patent and accept the risk of expensive litigation, and the risk of an injunction stopping its production, potentially causing an extensive loss of profits and start-up investment.

In *Helling v. McKinney*, the Supreme Court held that a prisoner subjected to a cellmate's cigarette smoke had standing to bring an Eighth Amendment claim because the risk of future harm to the prisoner was unreasonable.<sup>319</sup> In *Helling*, the plaintiff McKinney, who was an inmate in a Nevada prison, sued prison officials claiming that exposure to second hand tobacco smoke from his cellmate was an unreasonable risk to health under the Eighth Amendment, and that the prison was indifferent to the plaintiff's current medical problems caused by the smoke.<sup>320</sup> The lower court concluded that the plaintiff did not have a constitutional right to a smoke-free environment.<sup>321</sup> The Ninth Circuit reversed the constitutional claim on the ground that the exposure endangered future health.<sup>322</sup> The Supreme Court agreed that the risk of damage to future health caused by exposure to smoke

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<sup>317</sup> *Baur v. Veneman*, 352 F.3d 625, 635 (2d Cir. 2003) (citing *United States v. Students Challenging Regulatory Agency Procedures*, 412 U.S. 669, 687 (1973)).

<sup>318</sup> *Id.* at 637.

<sup>319</sup> 509 U.S. at 35.

<sup>320</sup> *Id.* at 28.

<sup>321</sup> *Id.* at 28-29.

<sup>322</sup> *Id.* at 29.

was sufficient to bring the Eighth Amendment claim.<sup>323</sup>

The Supreme Court did not explicitly apply a standing argument in *Helling* when holding that McKinney had a cause of action. However, as every plaintiff must have standing to be in federal court,<sup>324</sup> it is probable that the Court's emphasis on the unreasonable risk of future harm<sup>325</sup> was an injury in fact analysis.

Similar to the prisoner's unreasonable risk of future harm in *Helling*, an unreasonable risk of future harm can exist in patent cases when a manufacturer creating a product discovers an adverse patent. A manufacturer who is producing or about to produce a potentially infringing product may suffer injury in several ways including delays to market, unavailability of insurance, contractual liability, and increased risks of an injunction and damages. But when does a risk of future harm rise to an unreasonable level? A reasonable apprehension of lawsuit has been the modern measure of when an adverse patent causes an unreasonable risk of an injunction and infringement damages. However, the reasonable apprehension of lawsuit should not be the exclusive measure.

A delay in bringing a product to market injures a manufacturer by causing delayed, and likely reduced, revenue.<sup>326</sup> Further, depending on how the manufacturer responds to the delay, the manufacturer may lose its investments in start-up research and capital equipment if the product never goes to production, or product changes render equipment unusable. Teva's situation in *Teva Pharmaceuticals USA, Inc. v. Pfizer Inc.* is an example of the creation of a delay in bringing a product to market. Pfizer's refusal to act caused the FDA to delay Teva's generic drug application for an unknown number of months. Teva's delay to market was an injury in fact that should have been sufficient to confer standing.

The potentially infringing manufacturer may be injured when an adverse patent makes insurance unavailable. While a manufacturer likely has a commercial general liability insurance policy, the general liability insurance policy may not cover patent infringement.<sup>327</sup> Even if the insurance does cover infringement, it may exclude coverage if

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<sup>323</sup> *Id.* at 35.

<sup>324</sup> *Elk Grove Unified Sch. Dist. v. Newdow*, 542 U.S. 1, 11 (2004).

<sup>325</sup> *Helling*, 509 U.S. at 33-34.

<sup>326</sup> Armin Töpfer, *New Products- Cutting the Time to Market*, 28 No. 2 Long Range Planning 61, 63 (1995) (A ten percent delay in launch schedule leads to a twenty-five to thirty percent reduction in total project revenue.).

<sup>327</sup> *Bank of the W. v. Superior Court*, 833 P.2d 545, 560-61 (Cal. 1992) (patent infringement not covered under infringer's commercial general liability policy).

the infringement was willful.<sup>328</sup> The manufacturer may find that insurance is unavailable when an adverse patent is discovered, or may find that its insurance rates have increased.<sup>329</sup> Commentator Daniel Farber asserts that it would be “silly” to deny that increased insurance rates and unavailability of insurance are injuries in fact.<sup>330</sup>

Contract liability may cause further injury to a manufacturer of a potentially infringing product. The manufacturer may have indemnified its customer from liability for patent infringement,<sup>331</sup> increasing the manufacturer’s exposure. If the manufacturer stops shipping products, the failure to deliver products may be an expensive breach of contract. Additionally, the adverse patent may put future customer contracts at risk, jeopardizing the manufacturer’s potentially significant investment made in preparing for production.

In the example of the potentially infringing manufacturer, the manufacturer does not have a generalized grievance shared by the public at large; instead, the manufacturer suffers from a particularized injury caused by uncertainty and increased risk of harm. A plaintiff who suffers economic harm caused by future risks should have standing to sue the defendant.<sup>332</sup>

### *C. Applying Reasonable Apprehension and Standing Tests*

In *Aetna Life Ins. Co. v. Haworth*, the Supreme Court found a justiciable controversy because the dispute between the parties was real and substantial, affected the legal interests of adverse parties, and was capable of resolution by a conclusive judgment.<sup>333</sup> Conversely, in *Medimmune, Inc. v. Genentech, Inc.*, the Federal Circuit did not find a justiciable controversy because there was no reasonable apprehension of lawsuit.<sup>334</sup> It is interesting to consider *Aetna* and *Medimmune* under the Federal Circuit’s reasonable apprehension of lawsuit and the Supreme Court’s standing analyses.

In *Aetna*, Haworth had a cause of action to sue Aetna for

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<sup>328</sup> Melvin Simensky and Eric C. Osterberg, *The Insurance and Management of Intellectual Property Risks*, 17 *CARDOZO ARTS & ENT. L.J.* 321, 327, 329 (1999).

<sup>329</sup> *See id.* at 330, 339 (The insurance company may deny insurance unless the manufacturer has opinions indicating non-infringement.).

<sup>330</sup> Farber, *supra* note 302, at 1123.

<sup>331</sup> 48 C.F.R. § 27.203-1(a) (2005) (The federal government requires indemnification in contracts for goods or services that are also sold to the public.).

<sup>332</sup> *See* LARRY YACKLE, *FEDERAL COURTS* 302 (2d ed., 2003).

<sup>333</sup> *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240-41 (1937).

<sup>334</sup> *Medimmune, Inc. v. Genentech, Inc.*, 427 F.3d 958, 964-65 (Fed. Cir. 2005).

payment of benefits, but Haworth or his wife could bring the action for an unknown number of years into the future,<sup>335</sup> because the statute of limitations would not run until Haworth died.<sup>336</sup> Further, Haworth did not sue or threaten to sue Aetna.<sup>337</sup> It is apparent, then, that Aetna was not facing an imminent lawsuit because Haworth did not sue or threaten to sue,<sup>338</sup> and it seems unreasonable to believe that Haworth could meaningfully threaten Aetna's rights without suing. If the Federal Circuit were to hear *Aetna*, the court would dismiss the case for failure to present a reasonable apprehension of lawsuit.

*Aetna* may also be justiciable under a modern constitutional standing analysis. Aetna would have had to keep reserves in excess of \$20,000 until it resolved the matter.<sup>339</sup> Additionally, Aetna cited its concern that over time there could be a loss of evidence if the case was not resolved.<sup>340</sup> Both the current economic harm of maintaining reserves and the enhanced risk of losing evidence caused by Haworth's failure to take legal action may be injuries in fact sufficient to support Aetna's declaratory judgment.

Significantly, *Medimmune* is justiciable under an Article III standing analysis, notwithstanding the lack of reasonable apprehension of a lawsuit. As the Supreme Court reasoned in *Altwater v. Freeman*, a licensee suffers an injury sufficient to establish standing<sup>341</sup> when a licensor demands royalties as a right and the licensee pays royalties under protest in a coercive situation.<sup>342</sup> Recall that *Medimmune*

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<sup>335</sup> *Aetna Life Ins. Co. v. Haworth*, 84 F.2d 695, 699 (8th Cir. 1936) (Woodrough, J., dissenting) (noting that the statute of limitations ran ten years after the insured died, and of course, it was not known at the time when Haworth would die).

<sup>336</sup> *Id.*

<sup>337</sup> *Id.* at 697.

<sup>338</sup> *Teva Pharm. USA, Inc. v. Pfizer Inc.*, 405 F.3d 990, 996-97 (Fed. Cir. 2005) (Dyk, J., dissenting) (characterizing the facts in *Aetna* as a situation where Aetna was not facing an imminent risk of lawsuit.).

<sup>339</sup> *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 239 (1937).

<sup>340</sup> *Id.*

<sup>341</sup> See *Altwater v. Freeman*, 319 U.S. 359, 365 (1943) ("And certainly the requirements of case or controversy are met . . .").

<sup>342</sup> *Id.* In *Altwater v. Freeman*, an owner of a reissued patent, sued *Altwater*, a licensee under the original patent, for royalties under the reissued patent, and an injunction ordering specific performance of the license agreement. *Id.* at 360. *Altwater* filed a counterclaim seeking a declaratory judgment that the reissued patent was invalid. *Id.* The district court found that *Altwater's* product did not infringe the reissued patent, and that the license agreement was terminated. *Id.* at 362. The district court dismissed *Freeman's* claim and granted a petition to hear the declaratory judgment counterclaim. *Id.* The Eighth Circuit held that there was no controversy, and hence no jurisdiction to hear the declaratory judgment because

continued to pay license royalties because it was concerned that Genentech would terminate the license upon a breach.<sup>343</sup> If Genentech were to terminate the license, Medimmune would risk treble damages in an infringement suit for continuing to sell Synagis®.<sup>344</sup> The prospect that Genentech would terminate the license upon a breach coerced Medimmune to continue to pay royalties, which is an injury under *Altvater v. Freeman*.<sup>345</sup> Allowing Medimmune to seek a declaratory judgment would not justify an advisory opinion because the case would not turn on hypothetical or abstract issues. Similarly, the definite and concrete nature of the controversy would avoid separation of powers concerns by keeping the court from delving into abstract legislative issues. *Medimmune* is an actual controversy that should be heard.

The Supreme Court recently granted Medimmune's petition for certiorari.<sup>346</sup> The question presented to the Supreme Court was whether the actual controversy requirement of the Declaratory Judgment Act requires a licensee to breach its license agreement in order to seek a declaratory judgment action for patent invalidity.<sup>347</sup> It does not seem possible that the Court could reach this question without addressing the Federal Circuit's reasonable apprehension test. If the Court allows Medimmune to bring its declaratory judgment action without breaching its license agreement, the Court will have to pierce the Federal Circuit's heretofore immutable<sup>348</sup> reasonable apprehension of lawsuit test.

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Altvater's product did not infringe and there was no license agreement. *Id.* The Supreme Court reversed, holding that a licensee suffers an injury sufficient to establish a controversy when a licensor demands royalties as a right and the licensee pays royalties under protest and in a coercive situation. *Id.* at 365.

<sup>343</sup> See *supra* notes 19-34.

<sup>344</sup> See *Medimmune*, 427 F.3d 958, 962 (Fed. Cir. 2005) (Medimmune wanted to avoid the risk and consequences of an infringement suit). A court may increase damages by three times for willful infringement. 35 U.S.C. § 284 (2003).

<sup>345</sup> See *Altvater*, 319 U.S. at 365.

<sup>346</sup> *Medimmune*, 427 F.3d 958 (Fed. Cir. 2005), *cert. granted*, 126 S. Ct. 1329 (U.S. Feb. 21, 2006) (No. 05-608).

<sup>347</sup> *Medimmune*, 427 F.3d 958, *petition for cert. filed*, 2005 WL 3067195 (U.S. Nov. 10, 2005) (No. 05-608).

<sup>348</sup> To date, there have been no patent declaratory judgment cases where the Federal Circuit has allowed an exception to the reasonable apprehension test.

## V. CONCLUSION

The reasonable apprehension test is analogous to a canary in a mine. The dead-or-alive canary provides primitive feedback about air safety under certain conditions. But the canary's binary output does not provide any information about air quality in many other situations. As one example, coal miners suffer and die from the effects of silica dust exposure,<sup>349</sup> a harm not detected by a canary. Likewise, the reasonable apprehension of lawsuit test is an incomplete analysis of whether there is an Article III controversy.<sup>350</sup>

According to the Hatch Waxman Act, courts should assert jurisdiction in generic drug declaratory judgments such as *Teva* "to the extent consistent with the Constitution."<sup>351</sup> While a reasonable apprehension of lawsuit test identifies one form of constitutional controversy, *Aetna* is evidence that the test is not coextensive with constitutional jurisdiction. As discussed above, *Aetna* was a justiciable controversy without any apprehension of lawsuit.<sup>352</sup> In cases like *Teva*, the difference between "the extent consistent with the Constitution" and the reasonable apprehension of lawsuit can make a substantial difference. While there was no reasonable apprehension of lawsuit in *Teva*, the court dismissed an arguably justiciable controversy, preventing *Teva* from having its injuries redressed.

To avoid the limitations of the reasonable apprehension of lawsuit test, the Federal Circuit should use a proper standing analysis. In a patent declaratory judgment action, the elements of standing are more meaningful and appropriate as a constitutional threshold than the reasonable apprehension of lawsuit test.<sup>353</sup> As cases such as *Teva* and *Medimmune* illustrate, a reasonable apprehension of lawsuit is not the only possible injury in fact facing patent declaratory plaintiffs.<sup>354</sup> The reasonable apprehension of lawsuit is one injury in fact, but it is incomplete as a sole measure of constitutional controversy. It is time

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<sup>349</sup> See 20 C.F.R. 718.305 (2005) (establishing a presumption that a coal miner employed for fifteen years is totally disabled or has died from pneumoconiosis upon a showing of prescribed conditions).

<sup>350</sup> *Id.*

<sup>351</sup> 35 U.S.C. § 271(e)(5) (2004) ("[T]he courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.") (Emphasis added)

<sup>352</sup> *Teva Pharm. USA, Inc. v. Pfizer Inc.*, 405 F.3d 990, 996-97 (Fed. Cir. 2005) (Dyk, J., dissenting).

<sup>353</sup> See *id.* at 995 (Gajarsa, J., dissenting).

<sup>354</sup> *Id.* at 994 (Gajarsa, J., dissenting).

to supplement the reasonable apprehension test with a proper standing analysis.