

# *MEDIMMUNE, INC. v. GENENTECH, INC.*: A PATENT LICENSEE DOES NOT NEED TO TERMINATE OR BREACH A LICENSE AGREEMENT IN ORDER TO CHALLENGE ITS VALIDITY OR ENFORCEABILITY

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## I. INTRODUCTION

*MedImmune, Inc. v. Genentech, Inc.*, asks whether Article III’s restriction on the jurisdiction of the federal courts only to “cases” and “controversies,”<sup>1</sup> as required by the “actual controversy” limitation of the Declaratory Judgment Act,<sup>2</sup> necessitates that a patent licensee terminate or breach its license agreement before seeking a declaratory judgment to hold the underlying patent invalid, unenforceable, or not infringed. The Court of Appeals for the Federal Circuit, the appellate court responsible for hearing all patent appeals, had established that a company licensing a patent must infringe a patent, which risks subjecting the licensee to treble damages, in order to challenge the validity of that patent in court to prevent a licensee from hedging its bets by simultaneously paying for the patent license and challenging the patent’s validity.<sup>3</sup>

Justice Scalia, writing for an eight-member majority, rejected the argument advanced by Genentech—that MedImmune, Inc., could not sue because it had voluntarily entered into the licensing agreement with Genentech and continued to pay all required royalty payments—

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1. U.S. CONST. art. III, § 2.

2. 28 U.S.C. § 2201(a) (1993).

3. See generally *Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004) (patent licensee must breach or terminate license to challenge the validity of the licensed patent).

and overruled the Federal Circuit's precedent.<sup>4</sup> Instead, the Court held that a challenge to the validity of a patent is now a justiciable controversy for which a federal court has subject matter jurisdiction, regardless of whether the licensee first breaches the licensing agreement.<sup>5</sup>

## II. FACTS AND PROCEDURAL HISTORY

MedImmune, Inc., the petitioner, is a biotechnology company that produces and markets a drug used to prevent potentially fatal respiratory disease in infants and young children.<sup>6</sup> This drug, distributed under the trademarked name "Synagis," accounts for more than eighty percent of petitioner's sales revenue since 1999.<sup>7</sup> In 1997, one year before Synagis was marketed, petitioner entered into a licensing agreement with the respondent, Genentech, Inc.<sup>8</sup> Under the licensing agreement, the petitioner agreed to pay royalties to the respondent if it sold any products covered by one of the licensed patents, including the "Cabilly II" patent held by the respondent, which was ultimately challenged and resulted in this case.<sup>9</sup>

Following the signing of the licensing agreement, Genentech delivered a letter to MedImmune stating its belief that the product Synagis fell under the Cabilly II patent and, therefore, royalties should be paid in accordance with the terms of the licensing agreement.<sup>10</sup> This letter *clearly* threatened that Genentech would seek to enforce the Cabilly II patent. Although MedImmune did not believe the Cabilly II patent was valid and enforceable, it feared the potential costs if Genentech succeeded in enforcing the license agreement or enjoining the sale of Synagis. MedImmune was confronted with a difficult decision: continue to pay royalties despite feeling that they were not owed or breach the licensing agreement and challenge the validity of the patent. Fearful of the serious consequences associated with breaching or terminating the licensing agreement, especially the risk of treble damages, MedImmune paid all

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4. MedImmune, Inc. v. Genentech, Inc., 127 S. Ct. 764, 777 (2007).

5. *Id.*

6. *Id.* at 767.

7. *Id.* at 768.

8. *Id.* at 767–68.

9. *Id.*

10. *Id.* at 768.

royalties requested by Genentech, but did so “under protest and with reservation of all [its] rights.”<sup>11</sup>

MedImmune subsequently filed suit against Genentech in the United States District Court for the District of Central California, seeking a declaratory judgment to declare the Cabilly II patent unenforceable or invalid. At the same time, MedImmune continued to pay all demanded royalties under protest.<sup>12</sup> The district court granted Genentech’s motion to dismiss the declaratory-judgment claims for lack of subject-matter jurisdiction.<sup>13</sup> In doing so, the district court relied on *Gen-Probe, Inc. v. Vysis, Inc.*<sup>14</sup> The Federal Circuit had held in *Gen-Probe* that a patent licensee in good standing cannot establish an Article III case or controversy with regard to validity, enforceability, or scope of a patent because the presence of a license agreement “obliterate[s] any reasonable apprehension” that the licensee will be sued for infringement.<sup>15</sup> Although the district court intimated that it had “serious misgivings” about the practical application of the *Gen-Probe* rule, it concluded there were not sufficient facts to distinguish the case from the facts of *Gen-Probe*.<sup>16</sup> Therefore, the court was obligated to follow precedent and dismissed MedImmune’s case.<sup>17</sup> On appeal, the Federal Circuit affirmed, also citing *Gen-Probe* as the binding precedent.<sup>18</sup>

The Federal Circuit’s 2004 *Gen-Probe* decision required a licensee to breach or terminate the licensing agreement in order to bring a challenge to the patent’s validity because this was seen as creating an actual controversy.<sup>19</sup> However, a landmark 1969 Supreme Court case, *Lear v. Adkins*, held that patent licensees are not barred from challenging the validity of the patents they have licensed simply by virtue of the contractual relationship created by the licensing

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11. *Id.* at 768 (quoting Joint Appendix 426).

12. *Id.* at 767–68.

13. MedImmune, Inc. v. Genentech, Inc., No. CV 03-2567 MRP (CTX), 2004 WL 3770589 (C.D. Cal., Apr. 26, 2004).

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

15. *Id.* at 1381.

16. See MedImmune, Inc. v. Genentech, Inc., No. CV 03-2567 MRP (CTX), 2004 WL 3770589, at \*6 (C.D. Cal., Apr. 26, 2004) (“Even if it has serious misgivings about the panel’s conclusion, this Court is not free to reconsider policy ramifications that Gen-Probe rejected. There are no relevant facts that distinguish this case from the facts of Gen-Probe.”).

17. *Id.*

18. MedImmune, Inc. v. Genentech, Inc., 427 F.3d 958, 964–965 (Fed. Cir. 2005).

19. *Gen-Probe*, 359 F.3d at 1382.

agreement.<sup>20</sup> *MedImmune, Inc. v. Genentech, Inc.* provided an opportunity to reconcile these differences.

### III. HOLDING

The Supreme Court granted *certiorari* in order to decide if termination or breach of a licensing agreement is a necessary precondition to bring a suit challenging the validity or enforceability of a patent. *MedImmune, Inc. v. Genentech, Inc.* offered the Supreme Court an opportunity to clarify the legal landscape in an evolving area of intellectual property law. In amicus briefs, many large companies with extensive portfolios of patented intellectual property argued the licensor's position that a licensee cannot retain the benefit of the licensing agreement by paying all necessary fees while simultaneously challenging the agreement's validity in court. On the other side, the U.S. Patent and Trademark Office, the Justice Department, the General Pharmaceuticals Association, and the Natural Resources Defense Council filed amicus briefs for the licensee.<sup>21</sup> The Justice Department argued that invalid patents hurt efficient licensing, hinder competition, and undermine incentives for innovation.<sup>22</sup> The efficiency arguments were persuasive and led eight members of the Court to find for the licensee. However, the opinion focused almost entirely on the jurisdictional issue. An eight-member majority opinion found that courts have jurisdiction in this case. The sole dissenter was Justice Thomas.

The main issue before the Court was whether MedImmune alleged a contractual dispute.<sup>23</sup> In order to discuss subject matter jurisdiction, the majority opinion first clarified the underlying "nature

20. *Lear v. Adkins*, 395 U.S. 653, 673-74 (1969).

21. Alex Lash, *Patent Ruling Roils Biotech World*, DAILY DEAL, Jan. 11, 2007.

22. Brief for the United States as Amicus Curiae Supporting Petitioners at 4, *MedImmune*, 127 S. Ct. 764 (No. 05-608); see generally Federal Trade Comm'n, "To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy" (2003), available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf> (last visited January 10, 2007); U.S. Dep't of Justice & Federal Trade Comm'n, "Antitrust Guidelines for the Licensing of Intellectual Property" (1995), available at <http://www.usdoj.gov/atr/public/guidelines/0558.pdf> (last visited January 10, 2007); see also U.S. Dep't of Justice, "Report of the Department of Justice's Task Force on Intellectual Property" (2004), available at [http://www.usdoj.gov/olp/ip\\_task\\_force\\_report.pdf](http://www.usdoj.gov/olp/ip_task_force_report.pdf) (last visited January 10, 2007).

23. Brief for the United States as Amicus Curiae Supporting Petitioners at 5, *MedImmune*, 127 S. Ct. 764 (No. 05-608).

of the case.”<sup>24</sup> Although not an issue for the Court, Scalia’s opinion dismisses Genentech’s contention that no factual dispute existed regarding whether Synagis infringed the Cabilly II patent.<sup>25</sup> Furthermore, Justice Scalia challenged the respondent’s allegation that royalties are due under the licensing agreement for an infringing product whether or not the underlying patent is valid.<sup>26</sup>

Delving into the jurisdictional question, the Court discussed the requirements of Article III and the Declaratory Judgment Act. Article III of the Constitution limits judicial power for the adjudication of cases only to “cases” or “controversies.” In the past, the Court interpreted this requirement as limiting federal court jurisdiction only to cases in which resolution is “in a concrete factual context conducive to a realistic appreciation of the consequences of judicial action” and “outside “the rarefied atmosphere of a debating society.”<sup>27</sup> In other words, the judiciary’s function is not to opine on hypothetical disputes. The Declaratory Judgment Act, in accordance with the strictures of Article III, permits federal court decisions only “[i]n a case of actual controversy.”<sup>28</sup> The Supreme Court upheld the constitutionality of the Declaratory Judgment Act in *Aetna Life Ins. Co. v. Haworth*, where it limited justiciability to controversies that “are such in the constitutional sense.”<sup>29</sup> A constitutionally justiciable controversy is not abstract, hypothetical, academic, or moot.<sup>30</sup> There must be adequate circumstances to prove “there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a

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24. *MedImmune*, 127 S. Ct. at 769.

25. *Id.* (“The first point simply does not comport with the allegations of petitioner’s amended complaint. The very first count requested a ‘DECLARATORY JUDGMENT ON CONTRACTUAL RIGHTS AND OBLIGATIONS,’ and stated that petitioner ‘disputes its obligation to make payments under the 1997 License Agreement because [petitioner’s] sale of its Synagis product does not infringe any valid claim of the [Cabilly II] Patent.’) (citations omitted).

26. *Id.* at 769–70 (“We express no opinion on whether a *nonrepudiating licensee* is similarly relieved of its contract obligation during a successful challenge to a patent’s validity.”) (emphasis in original).

27. *Valley Forge Christian College v. Ams. United for Separation of Church and State, Inc.*, 454 U.S. 464, 472 (1982).

28. 28 U.S.C. § 2201(a) (1993).

29. *Aetna Life Ins. Co. v. Hayworth*, 300 U.S. 227, 240 (1937).

30. *Id.* at 240–41 (citing *U.S. v. Alaska S.S. Co.*, 253 U.S. 113, 116 (1920)).

declaratory judgment.”<sup>31</sup> In other words, there must be a real, immediate legal dispute between adverse parties.

The crux of this case was whether there was an actual controversy sufficient to meet the requirements of Article III and the Declaratory Judgment Act. The Court pointed out that petitioner clearly would have met these requirements “if petitioner had taken the final step of refusing to pay royalty payments under the 1997 license agreement.”<sup>32</sup> Theoretically, if MedImmune continued to make royalty payments it would not yet be vulnerable to immediate harm by way of a suit for enforcement or an injunction of the sale of its products. Without the immediacy of harm, the matter’s justiciability was uncertain because no actual controversy creating subject matter jurisdiction had yet arisen.<sup>33</sup> But for the petitioner continuing to make royalty payments under protest, there would be an actual controversy and all of the necessary elements were present for proper judicial resolution of the dispute.

Justice Scalia drew an analogy to this problem by comparing it to a more familiar occurrence, a suit for a declaratory judgment under threat of action by the government. Often, such actions occur in the First Amendment context. For example, a petitioner need not breach a law banning the distribution of handbills before bringing a suit to challenge its basis.<sup>34</sup> In such a circumstance, the challenge is justiciable regardless of whether the handbills were ever distributed or if the petitioner ever faced prosecution. This is because “the declaratory judgment procedure is an alternative to pursuit of the arguably illegal activity.”<sup>35</sup> Thus, an individual seeking declaratory relief against government action can continue to abide by the law while simultaneously challenging the validity of that law.

Although declaratory judgments by private parties against the government in the mentioned example, there are few Supreme Court cases interpreting the Declaratory Judgment Act as applied to two

31. *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941).

32. *MedImmune, Inc. v. Genentech, Inc.* 127 S. Ct. 764, 771–72 (2007).

33. *Id.* at 772 n. 8 (“The justiciability problem that arises, when the party seeking declaratory relief is himself preventing the complained-of injury from occurring, can be described in terms of standing . . . or in terms of ripeness.”).

34. *Id.*

35. *Id.* (citing *Steffel v. Thompson*, 415 U.S. 452, 480 (1974) (J. Rehnquist, concurring)).

private parties. In fact, the majority only located one case, *Altwater v. Freeman*,<sup>36</sup> which was decided over sixty years ago.

*Altwater*'s fact pattern bears striking similarities to *MedImmune*. Like *MedImmune*, *Altwater* involved a licensee who paid royalties under protest and simultaneously sought a declaratory judgment to find the underlying patents invalid. The Court held there was a justiciable case or controversy despite the fact that royalties were being paid. If the licensee were not allowed to challenge the patent while continuing to pay royalties, the only alternative would be to bring suit and "risk not only actual but treble damages in infringement suits."<sup>37</sup> The Court held that requiring a licensee to breach a licensing agreement in order to challenge the validity of the underlying patent was too burdensome on the licensee. If payments are made in response to coercive behavior, those payments are not seen as eliminating all controversies. *Gen-Probe, Inc. v. Vysis, Inc.* was decided with this case in mind. In *Gen-Probe*, the Federal Circuit limited the scope of *Altwater*'s holding to only those situations where a threat of injunction exists. In *MedImmune*, the Court determines that the Federal Circuit read the *Altwater* holding too narrowly.<sup>38</sup>

Like the suit against the government, the Court held that a dispute between two private parties over the validity of a licensing agreement meets the jurisdictional requirements of Article III and the Declaratory Judgment Act. The parties' dispute is real and immediate because both sides disagree about their legal obligations to one another.<sup>39</sup> Although the petitioner continued to pay the royalties that were allegedly due under the licensing agreement, it only did so because of the enormous gamble associated with having to breach the agreement in order to challenge the validity of the underlying patent. To require the petitioner to "bet the farm, or (as here) risk treble damages and the loss of 80 percent of its business before seeking a declaration of its actively contested legal rights finds no support in Article III."<sup>40</sup>

Furthermore, the existence of a licensing agreement does not preclude the contracting party from challenging the validity of the

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

37. *Id.* at 365.

38. *MedImmune*, 127 S. Ct. at 774.

39. *Id.* at 768-69.

40. *Id.* at 775.

intellectual property at issue. A valid licensing agreement memorializing a promise to pay royalties does not represent a guarantee that the licensee will not seek a court order holding the underlying patents invalid.<sup>41</sup>

Finally, the majority declined to apply the common law principle of contracts that one “cannot at one and the same time challenge [a contract’s] validity and continue to reap its benefits.”<sup>42</sup> The Court found that to reach this common law doctrine would be to decide the case on the merits, while the case before the Court in *MedImmune* simply dealt with the jurisdictional question.

#### IV. IMPACT AND CONCLUSION

*MedImmune, Inc. v. Genentech, Inc.* takes an aggressive stand in favor of policing the patent system by allowing the courts to grant declaratory relief before a licensee ceases to pay royalties. Some observers have alleged that the Patent and Trademark Office is overburdened, causing it to grant many patents of questionable validity.<sup>43</sup> By allowing licensees to challenge these questionable patents without having to “bet the farm,” *MedImmune* encourages the use of litigation and market mechanisms to establish the validity of patents and intellectual property. Although less efficient than denying a patent outright at the application stage, the decision removes some of the deadweight loss associated with patents whose validity is never challenged because licensees would rather play it safe than risk treble damages. Because licensees are often the only parties with the financial incentives to challenge a patent’s validity, they are likely the most appropriate party to bring a challenge. This is consistent with a rising tide of patent “reform” bills that have recently been proposed at the congressional level, which are aimed at increasing the availability of post-grant review of patents.<sup>44</sup>

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41. *Id.* at 776.

42. *Id.*

43. Press Release, Cooley Godward Kronish LLP, “*MedImmune v. Genentech*: A Dilemma Removed for Patent Licensees” (Feb. 15, 2007), available at <http://www.cooley.com/news/alerts.aspx?ID=40494620>.

44. See, e.g., H.R. 2795, 109th Cong. (2005) (“Patent Reform Act of 2005”) (which would strengthen allowable procedures for the review of patents after they are granted by the Patent and Trademark Office).



By removing a procedural hurdle, the decision also helps protect smaller companies who may be exploited by larger companies with stronger patent portfolios. Typically, licensees are small businesses or start-up companies that, in order to enter a given market, must license the patents of larger companies, who have substantial research and development budgets. Often, the licensing agreements group together a large collection of patents. These groupings can prevent the smaller licensee companies from examining or challenging each patent's validity or applicability due to limited financial resources. High business risks often dissuade smaller and newer companies from breaching a licensing agreement in order to challenge a patent's validity. A judgment of willful infringement of a patent may lead to treble damages or punitive damages. Arguably, the pre-*MedImmune* incentive structure punished companies who lacked power or financial resources by chaining them to invalid patents.

The Court's decision in *MedImmune* shifts the balance of power from bigger patent-owning companies to the smaller start-up companies that rely on obtaining licenses for patented technology.<sup>45</sup> Now, patent licensees may be more inclined to reevaluate the patents for which they are paying royalties and decide to challenge the validity of those patents while paying the royalties under protest. The Court's holding is limited, however, because licensees must be under sufficient threat of litigation by the licensor in order to create a case or controversy before challenging the validity of the patent at issue via litigation. A letter threatening enforcement of obligations under a licensing agreement was deemed sufficient in *MedImmune* to create a controversy for purposes of Article III. Presumably, notice of termination of a licensing agreement would also meet this requirement. This could lead to an interesting situation in which a licensee attempts to induce a licensor to threaten suit by sending a notice of termination of the licensing agreement to force the licensor to abandon the licensing agreement or else risk a challenge to the patent's validity.

The tension between patent owners and licensees led to vociferous debate among the many amicus in the case. According to the numerous amicus briefs presented on behalf of the respondent, a

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45. Linda Greenhouse, *U.S. Supreme Court Favors Companies that Rely on Others' Patents*, INTERNATIONAL HERALD TRIBUNE, Jan. 10, 2007.

decision for the licensee would serve to diminish the value of intellectual property owned by big-branded drug makers, universities, and other companies.<sup>46</sup> Amicus briefs on behalf of the respondent cited examples including the impact on research universities and other non-commercial enterprises, suggesting that substantial harm would ensue if licensees are permitted to challenge a patent's validity without breaching the underlying licensing agreement.<sup>47</sup> Universities and non-commercial research entities might become discouraged from licensing their inventions because they cannot afford the potential liability associated with a challenge to the patent's validity. Because universities are major contributors to intellectual property, an event that dissuades them from licensing their inventions could harm the availability of many important technological advances. In other words, inventors will become wary of licensing their inventions and the public will suffer.

Both *MedImmune's* critics and supporters believe that the decision will change the nature of licensing agreements. Leading patent attorneys predict that patent owners may include provisions in their licensing agreements that will invalidate the agreement if the licensee challenges one of the licensed patents.<sup>48</sup> In fact, during the oral arguments, Chief Justice Roberts suggested that there might be some way of legally structuring licensing agreements to diminish the threat of a lawsuit by the licensee.<sup>49</sup>

The enforceability of such contract provisions is the source of great debate. In the past, U.S. courts generally have favored parties' private agreements that avoid or limit litigation, but covenants promising not to challenge the validity of a patent run counter to the underlying policy reasons animating the decision in *MedImmune*. However, the enforceability of such provisions was not addressed in the opinion, and this will most certainly be an area of contention in the future.

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46. Patti Waldmeir, *Supreme Court Acts on Patents Legal Challenges*, THE FINANCIAL TIMES (UK), Jan. 10, 2007.

47. *Id.*

48. *High Court Plows Barrier Generics Encounter Challenging Patents*, FDA WEEK, Jan. 12, 2007, Section 2.

49. Transcript of Oral Argument at 4, *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (No. 05-608).

The Court did not determine the underlying validity of the Cabilly II patent, but simply gave the petitioner the right to pursue its lawsuit in lower courts. MedImmune, Inc., in a press release following the decision, promised to pursue its original complaint “vigorously” at the lower court level.<sup>50</sup>

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50. Press Release, MedImmune, Inc., “MedImmune Issues Statement Regarding Supreme Court Decision” (Jan. 9, 2007), *available at* <http://phx.corporate-ir.net/phoenix.zhtml?c=83037&p=irol-investornewsArticle&ID=948671&highlight=> (last visited January 10, 2007).