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*A Nonrepudiating Patent Licensee's Right To Seek  
Declaratory Judgment of Invalidity or Noninfringement of  
the Licensed Patent: MedImmune v. Genentech*

Brian T. Yeh, American Law Division

August 30, 2007

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# CRS Report for Congress

## A Nonrepudiating Patent Licensee's Right To Seek Declaratory Judgment of Invalidity or Noninfringement of the Licensed Patent: *MedImmune v. Genentech*

August 30, 2007

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Prepared for Members and  
Committees of Congress

# A Nonrepudiating Patent Licensee's Right To Seek Declaratory Judgment of Invalidity or Noninfringement of the Licensed Patent: *MedImmune v. Genentech*

## Summary

According to earlier precedent of the U.S. Court of Appeals for the Federal Circuit, a suit filed by a patent licensee in good standing, seeking to declare the underlying patent invalid, unenforceable, or not infringed, is non-justiciable under the Declaratory Judgment Act because there is no actual controversy between the licensee and licensor. The Federal Circuit had asserted that a license agreement eliminates any “reasonable apprehension” that the nonrepudiating licensee will be sued for infringement and thus federal courts must dismiss such declaratory judgment actions for lack of subject matter jurisdiction under Article III of the U.S. Constitution.

In *MedImmune v. Genentech* (549 U.S. \_\_\_, No. 05-608, decided January 9, 2007), the U.S. Supreme Court rejected the jurisdictional rule adopted by the Federal Circuit, holding to the contrary that a patent licensee need *not* materially breach its license agreement (for example, by ceasing royalty payments to the patent holder) before it may bring suit to obtain a judgment that the underlying patent is invalid, unenforceable, or not infringed, in situations where the licensor-patentee has implicitly or explicitly threatened to sue for patent infringement if the licensee did not pay the demanded royalties. Payment of royalties under such “coercive” circumstances does *not* eliminate the jurisdiction of the federal courts to entertain declaratory judgment actions from patent licensees in good standing, the Court explained. Notably, this decision is limited to the procedural issue of whether federal courts have subject matter jurisdiction over these types of claims; the Supreme Court declined to express an opinion on the merits of the arguments made by the licensor-patentee in the case for denying declaratory relief to the licensee.

This report provides a summary and analysis of the Supreme Court's opinion in *MedImmune* and discusses its potential ramifications on patent law.

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# A Nonrepudiating Patent Licensee's Right To Seek Declaratory Judgment of Invalidity or Noninfringement of the Licensed Patent: *MedImmune v. Genentech*

## Introduction

In *MedImmune v. Genentech*, the U.S. Supreme Court held that, at least in instances where the licensor-patentee has implicitly or explicitly threatened to sue for patent infringement if the licensee did not pay the demanded royalties, a patent licensee need not terminate or breach its license agreement before it may bring suit to obtain a declaratory judgment that the underlying patent is invalid, unenforceable, or not infringed. The U.S. Court of Appeals for the Federal Circuit had previously adopted a procedural rule that a licensee must stop paying royalties (and thereby materially breach the agreement) before bringing suit to challenge the validity or scope of the licensed patent. The *MedImmune* decision thus repudiates the Federal Circuit's rule that had resulted in federal courts dismissing such declaratory judgment actions for lack of subject matter jurisdiction.

## Background

**Patent Licensing Agreements.** Because the Patent Act expressly provides that “patents shall have the attributes of personal property,”<sup>1</sup> patent holders may sell their patent rights in a legal transfer called an “assignment.”<sup>2</sup> Alternatively, patent holders may grant others a “license” to exercise one of the five statutory patent rights.<sup>3</sup> A license is not a transfer of ownership of the patent, but rather is the patent holder's permission to another entity to use the invention in a limited way, typically in exchange for periodic royalty payments during the term of the patent.<sup>4</sup> A patent holder may grant to a licensee the right to practice the invention through a contract (typically known as a patent licensing agreement). The terms of the licensing agreement, however, may include conditions upon the grant of rights — for example,

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<sup>1</sup> 35 U.S.C. § 261.

<sup>2</sup> ROGER SCHECHTER & JOHN THOMAS, PRINCIPLES OF PATENT LAW § 11-1 (2d ed. 2004).

<sup>3</sup> A patent holder has the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States, or importing the protected invention into the United States. 35 U.S.C. § 154(a)(1).

<sup>4</sup> SCHECHTER & THOMAS, *supra* note 2, § 11-1.

restricting the licensee from making the invention but allowing that party to sell it.<sup>5</sup> A licensee that performs an act that exceeds the scope of the license (through a violation of the limitations and conditions of the grant of rights) or refuses to comply with the terms of the license agreement (such as by refusing to pay the required royalties) is potentially liable to the patent holder for breach of contract as well as for patent infringement.<sup>6</sup>

**Licensee Estoppel.** Over the term of a patent license agreement, a licensee may wish to challenge the validity of the underlying patent because he or she discovers information suggesting that the patent had been improvidently granted by the U.S. Patent and Trademark Office (for example, if the new information demonstrates that a patent had been issued for an invention that actually fails to meet all of the statutory standards for patentability — novelty, utility, and nonobviousness). By challenging the validity of the underlying patent, the licensee could avoid paying royalties or freely pursue other activities that had previously appeared to come within the scope of the patent. However, prior to 1969, an equitable doctrine known as “licensee estoppel” prevented a patent licensee from denying the validity of the licensed patent; this doctrine was developed by courts that were interested in supporting general principles of contract law, which normally do not permit buyers to repudiate their promises to purchase goods when they become unhappy with the contract made with the sellers, at least without some form of compensation to the other party.<sup>7</sup>

In 1969, the Supreme Court overruled the licensee estoppel doctrine by announcing in *Lear, Inc. v. Adkins*<sup>8</sup> that a license agreement does *not* bar the licensee from challenging the validity of a patent. The Court explained that “the important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain” trumps “the technical requirements of contract doctrine.”<sup>9</sup> Furthermore, other policy considerations weigh in favor of abrogating licensee estoppel: “Licensees may often be the only individuals with enough economic incentive to challenge the patentability of an inventor’s discovery. If they are muzzled, the public may continually be required to pay tribute to would-be monopolists without need or justification.”<sup>10</sup>

**Subject Matter Jurisdiction and the Declaratory Judgment Act.** Under Article III of the U.S. Constitution, the jurisdiction of federal courts is limited to actual, ongoing cases and controversies.<sup>11</sup> The Declaratory Judgment Act, codified

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<sup>5</sup> *United States v. General Electric Co.*, 272 U.S. 476, 490 (1926).

<sup>6</sup> JOHN R. THOMAS, *PHARMACEUTICAL PATENT LAW* 427 (BNA Books 2005).

<sup>7</sup> SCHECHTER & THOMAS, *supra* note 2, § 11-4.

<sup>8</sup> 395 U.S. 653 (1969).

<sup>9</sup> *Id.* at 670.

<sup>10</sup> *Id.*

<sup>11</sup> U.S. CONST. art. III, § 2, cl. 1 (“The Judicial Power shall extend to all Cases, in Law and Equity, arising under this Constitution, the Laws of the United States, and Treaties made, (continued...)”)

at 28 U.S.C. § 2201, authorizes a federal court to issue a judgment declaring the legal rights of any interested party seeking such declaration, “whether or not further relief is or could be sought,” in a “case of actual controversy within its jurisdiction.” The U.S. Supreme Court has held that an action for declaratory relief qualifies as a “case or controversy” under Article III;<sup>12</sup> furthermore, it has explained: “[T]he question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.”<sup>13</sup> The Court has also stressed that Article III requires that the dispute at issue “must be definite and concrete, touching the legal relations of parties having adverse legal interests”; and that “[i]t 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>14</sup> However, the Supreme Court has previously opined that “the difference between an abstract question and a ‘controversy’ contemplated by the Declaratory Judgment Act is necessarily one of degree, and it would be difficult, if it would be possible, to fashion a precise test for determining in every case whether there is such a controversy.”<sup>15</sup>

The U.S. Court of Appeals for the Federal Circuit (Federal Circuit)<sup>16</sup> had attempted to articulate such a test. The Federal Circuit developed a two-part test to determine whether there was an “actual controversy” in a declaratory judgment action for patent non-infringement or invalidity:

There must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity which

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<sup>11</sup> (...continued)

or which shall be made, under their Authority; — to all Cases affecting Ambassadors, other public Ministers and Consuls; — to all Cases of admiralty and maritime Jurisdiction; to Controversies to which the United States shall be a Party; — to Controversies between two or more States; between a State and Citizens of another State; between Citizens of different States, — between Citizens of the same State claiming Land under Grants of different States, and between a State, or the Citizens thereof, and foreign States, Citizens or Subjects.”).

<sup>12</sup> *Nashville, Chattanooga & St. Louis Railway Co. v. Wallace*, 288 U.S. 249 (1933); *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227 (1937).

<sup>13</sup> *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941).

<sup>14</sup> *Aetna Life Ins. Co.*, 300 U.S. at 240-41 (citations omitted).

<sup>15</sup> *Maryland Casualty Co.*, 312 U.S. at 273.

<sup>16</sup> The Federal Circuit is a specialized tribunal that has exclusive jurisdiction to hear appeals from all district court judgments in civil actions arising under federal patent law. 28 U.S.C. §1295. The purpose for Congress creating the court in 1982 was to promote predictability and uniformity in the patent law. For more information on the Federal Circuit, see CRS Report RL31703, *Patent Law and Innovation: The Creation, Operation and a Twenty-Year Assessment of the U.S. Court of Appeals for the Federal Circuit*, by John R. Thomas.

could constitute infringement or concrete steps taken with the intent to conduct such activity.<sup>17</sup>

In the *Lear* case discussed above, the licensee had refused to continue paying royalties and thus was sued by the licensor-patentee for breach of contract. The lower courts in that case had applied the licensee estoppel doctrine to prevent the licensee from raising patent invalidity as a defense to the lawsuit; as previously discussed, the Supreme Court overruled those courts and expressly repudiated the licensee estoppel doctrine. In 2004, the Federal Circuit, in *Gen-Probe Inc. v. Vysis, Inc.*, opined that the *Lear* doctrine “does not grant every licensee in every circumstance the right to challenge the validity of the licensed patent.”<sup>18</sup> The appellate court in *Gen-Probe* explained:

[A] licensee ... cannot invoke the protection of the *Lear* doctrine until it (i) actually ceases payment of royalties, and (ii) provides notice to the licensor that the reason for ceasing payment of royalties is because it has deemed the relevant claims to be invalid. This language posits that a licensee must, at a minimum, stop paying royalties (and thereby materially breach the agreement) before bringing suit to challenge the validity or scope of the licensed patent.<sup>19</sup>

The question that the U.S. Supreme Court faced in *MedImmune v. Genentech* was whether a patent licensee in good standing (meaning that the licensee is complying fully with the license terms, meeting royalty payment obligations, and cannot be sued by the licensor-patentee) must terminate or breach its license agreement before it can bring a declaratory judgment action to challenge a demand to pay royalties, on the grounds that the underlying patent is invalid, unenforceable, or not infringed.<sup>20</sup>

## MedImmune v. Genentech

MedImmune, Inc. is a pharmaceutical company that manufactures a drug, Synagis, used to prevent respiratory tract disease in infants and young children. A year before the U.S. Food and Drug Administration approved Synagis for marketing to consumers, MedImmune had entered into a patent license agreement with the biotechnology company Genentech in 1997, concerning an existing Genentech patent relating to the production of “chimeric antibodies” (the Cabilly I patent) and also a then-pending patent application for “the coexpression of immunoglobulin chains in recombinant host cells.”<sup>21</sup> MedImmune agreed to pay royalties on sales of any “licensed products” that it may make or sell which would infringe the claims of either of the patents, if not for the license agreement.<sup>22</sup>

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<sup>17</sup> BP Chems. Ltd. v. Union Carbide Corp., 4 F.3d 975, 978 (Fed. Cir. 1993).

<sup>18</sup> 359 F.3d 1376, 1381 (Fed. Cir. 2004).

<sup>19</sup> *Id.* (internal citations and quotations omitted).

<sup>20</sup> *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. \_\_\_, 127 S.Ct. 764, 767 (U.S. Jan. 9, 2007).

<sup>21</sup> *Id.*

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



In December 2001, Genentech was awarded a patent on the “coexpression” application that was the subject of the licensing agreement (Cabilly II patent). Genentech sent MedImmune a letter, asserting that the Synagis drug came within the scope of the new Cabilly II patent, and that therefore it was a “licensed product” for which royalties are owed under the 1997 license agreement. MedImmune, however, believed the Cabilly II patent invalid and unenforceable or, alternatively, that Synagis did not infringe the patent’s claims. Despite this assessment, MedImmune paid the royalties “under protest,” because it considered Genentech’s letter a threat to sue for patent infringement if it failed to comply with the demands therein.<sup>23</sup> As this drug accounted for more than 80% of the company’s revenue from sales since 1999, MedImmune was unwilling to risk the consequences of losing a patent infringement suit, which included being enjoined from selling Synagis.<sup>24</sup>

MedImmune initiated a declaratory judgment action against Genentech, seeking a declaration that the patent was invalid and unenforceable. Genentech filed a defense motion pursuant to Federal Rules of Civil Procedure 12(b)(1), asserting that the federal courts lacked Article III jurisdiction over the claim because no “actual controversy” existed between the parties.

**The District Court’s Opinion.** The U.S. District Court for the Central District of California granted Genentech’s motion, dismissing the case for lack of subject matter jurisdiction.<sup>25</sup> The district court explained that it was obliged to dismiss the case<sup>26</sup> due to the controlling precedent of the Federal Circuit’s *Gen-Probe Inc. v. Vysis, Inc.* decision in 2004, which had held that “a patent licensee in good standing cannot establish an Article III case or controversy with regard to validity, enforceability, or scope of the patent because the license agreement ‘obliterates any reasonable apprehension’ that the licensee will be sued for infringement.”<sup>27</sup> Because MedImmune continued to pay royalties under the license agreement and did not otherwise breach it, it was a licensee in good standing and was not under threat or in reasonable apprehension of suit, the court reasoned.<sup>28</sup>

**The Federal Circuit’s Opinion.** On appeal, MedImmune conceded that it was free of apprehension of suit, and that it continued to pay royalties only to avoid the consequences of a successful patent infringement suit by Genentech. However,

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

<sup>24</sup> Injunctive relief in patent infringement cases is authorized by 35 U.S.C. § 283. In addition to injunctions, the following remedies are also potentially available to the patent holder in an infringement lawsuit: (1) damages adequate to compensate the patent holder for the infringement, including lost profits and costs, 35 U.S.C. § 284; (2) treble damages, 35 U.S.C. § 284; and (3) reasonable attorney fees, 35 U.S.C. § 285.

<sup>25</sup> *MedImmune, Inc. v. Genentech, Inc.*, 2004 U.S. Dist. LEXIS 28680, at \*13 (C.D. Cal. 2004).

<sup>26</sup> Dismissal of an action is required if a court lacks subject matter jurisdiction. *Ex parte McCardle*, 74 U.S. 506 (1869).

<sup>27</sup> *MedImmune*, 127 S.Ct. at 768 (quoting *Gen-Probe, Inc. v. Vysis, Inc.*, 359 F.3d 1376, 1381 (Fed. Cir. 2004)).

<sup>28</sup> *MedImmune*, 2004 U.S. Dist. LEXIS 28680, at \*13-14.

MedImmune asserted that the *Lear* case provided it with “the absolute right to challenge the validity or enforceability of the patent, whether or not it breaches the license and whether or not it can be sued by the patentee,” and appealed for *Gen-Probe* to be overruled.<sup>29</sup> In response, Genentech argued that the facts of the case did not support invocation of *Lear* (which had dealt with licensee estoppel), but rather that the threshold question for the dispute concerned Article III jurisdiction under the Declaratory Judgment Act.<sup>30</sup> The Federal Circuit agreed with Genentech and affirmed the district court’s judgment, relying on its earlier *Gen-Probe* decision in determining that there was a lack of a justiciable controversy.<sup>31</sup> The appellate court rejected the applicability of *Lear* because in that case, the licensee had ceased royalty payments, thus breaching the license, and was then sued by the patentee. In contrast, the Federal Circuit explained, here such “breach was assiduously avoided. Thus this case does not raise the question of whether patent invalidity is available as a defense to suit against a defaulting licensee — the licensee estoppel that was laid to rest in *Lear* — for there is no defaulting licensee and no possibility of suit.”<sup>32</sup>

The Supreme Court granted certiorari on February 21, 2006, to review the *MedImmune* case, in order to answer the following question:

Does Article III’s grant of jurisdiction of “all Cases ... arising under ... the Laws of the United States,” implemented in the “actual controversy” requirement of the Declaratory Judgment Act, 28 U.S.C. § 2201(a), require a patent licensee to refuse to pay royalties and commit material breach of the license agreement before suing to declare the patent invalid, unenforceable or not infringed?<sup>33</sup>

**The Supreme Court’s Opinion.** On January 9, 2007, the Supreme Court reversed the Federal Circuit’s judgment in an 8-1 decision, and remanded the case to the district court. The Court held that a patent licensee is *not* required to repudiate its license agreement before seeking a declaratory judgment in federal court that the underlying patent is invalid, unenforceable, or not infringed.<sup>34</sup>

Writing for the majority, Justice Antonin Scalia first explained that the Article III “case or controversy” requirement would have been satisfied if MedImmune had refused to make royalty payments.<sup>35</sup> At issue here, however, was whether a case or controversy still existed when MedImmune’s compliance with the license terms eliminated the immediate threat of injury from a patent infringement lawsuit. Justice Scalia offered a comparison to a situation where the government threatens legal action, in which there is no requirement that “a plaintiff [] expose himself to liability before bringing suit to challenge the basis for the threat — for example, the

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<sup>29</sup> *MedImmune, Inc. v. Genentech, Inc.*, 427 F.3d 958, 963 (Fed. Cir. 2005).

<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

<sup>33</sup> *MedImmune, Inc. v. Genentech, Inc.*, 546 U.S. 1169 (2006).

<sup>34</sup> *MedImmune*, 127 S.Ct. at 777.

<sup>35</sup> *Id.* at 771-72.

constitutionality of a law threatened to be enforced.”<sup>36</sup> In such a case, he noted, courts have not found Article III jurisdiction to be lacking despite the fact that the plaintiff’s own action (or inaction) in failing to violate the law eliminates the imminent threat of prosecution.<sup>37</sup>

Although a *private* party, rather than the government, threatened the enforcement action in *MedImmune*, this distinction does not make a significant legal difference that would eliminate jurisdiction, Justice Scalia argued.<sup>38</sup> He identified an earlier Supreme Court decision, *Altvater v. Freeman*,<sup>39</sup> that had a substantially similar fact pattern as *MedImmune*. In *Altvater*, the patentees had filed suit against their licensees to enforce territorial restrictions in the license. The licensees then filed a counterclaim for declaratory judgment that the underlying patents were invalid. However, the licensees continued to pay royalties “under protest,” although it was being required to do so under an injunction decree that the patentees had obtained in an earlier case. Yet Justice Scalia explained that the absence of an injunction in *MedImmune* does not distinguish the case from *Altvater* because if the *Altvater* licensee had stopped paying the royalties in defiance of the injunction, the licensee would have risked being liable for actual and treble damages in a patent infringement lawsuit.<sup>40</sup> The *Altvater* Court had held

[C]ertainly the requirements of [a] case or controversy are met where payment of a claim is demanded as of right and where payment is made, but where the involuntary or coercive nature of the exaction preserves the right to recover the sums paid or to challenge the legality of the claim.<sup>41</sup>

Here, Genentech had demanded that MedImmune make royalty payments under the licensing agreement and apparently threatened to bring a patent infringement lawsuit to enjoin sales of MedImmune’s Synagis drug if royalties were not paid. MedImmune’s payment of royalties under such “coercive” circumstances does not eliminate jurisdiction of a court to entertain a declaratory judgment action, Justice Scalia stated.<sup>42</sup> He opined, “The rule that a plaintiff must destroy a large building, bet the farm, or (as here) risk treble damages and the loss of 80 percent of its business, before seeking a declaration of its actively contested legal rights finds no support in Article III.”<sup>43</sup>

Justice Scalia cautioned that the Supreme Court’s decision in this case is limited to the procedural issue of whether federal courts have subject matter jurisdiction over these types of declaratory judgment actions brought by nonrepudiating licensees; the

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<sup>36</sup> *Id.* at 772.

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

<sup>38</sup> *Id.* at 773.

<sup>39</sup> 319 U.S. 359 (1943).

<sup>40</sup> *MedImmune*, 127 S.Ct. at 774.

<sup>41</sup> *Altvater*, 319 U.S. at 365.

<sup>42</sup> *MedImmune*, 127 S.Ct. at 773.

<sup>43</sup> *Id.* at 775.

Court declined, however, to express an opinion on the merits of the arguments made by the licensor-patentee for denying declaratory relief to the licensee. In its briefs filed with the Court, Genentech had appealed to a common-law doctrine that a party to a contract cannot challenge its validity while simultaneously continuing to reap its benefits.<sup>44</sup> Furthermore, Genentech had argued that the license agreement itself precluded the suit, because

[w]hen a licensee enters such an agreement ... it essentially purchases an insurance policy, immunizing it from suits for infringement so long as it continues to pay royalties and does not challenge the covered patents. Permitting it to challenge the validity of the patent without terminating or breaking the agreement alters the deal, allowing the licensee to continue enjoying its immunity while bringing a suit, the elimination of which was part of the patentee's quid pro quo.<sup>45</sup>

Justice Scalia observed, however, that these two points raised by Genentech went to the merits of the case, and not to the question of whether Article III jurisdiction is available over MedImmune's declaratory judgment action.<sup>46</sup> Finally, noting that the Declaratory Judgment Act provides that a court "*may* declare the rights and other legal relations of any interested party,"<sup>47</sup> Justice Scalia decided to "leave the equitable, prudential, and policy arguments in favor of such a discretionary dismissal for the lower courts' consideration on remand."<sup>48</sup> Similarly left for consideration on remand are any merits-based arguments for denial of declaratory relief in the case.

In lone dissent, Justice Clarence Thomas maintained that a patent licensee in good standing must breach its license prior to challenging the validity of the underlying patent.<sup>49</sup> He stated, "[T]he declaratory judgment procedure cannot be used to obtain advanced rulings on matters that would be addressed in a future case of actual controversy."<sup>50</sup> In his view, MedImmune's suit was an attempt to seek a ruling on hypothetical or conjectural matters, and thus federal courts lacked Article III jurisdiction over its claims.

**Concluding Observations.** Since *MedImmune* was decided, the Federal Circuit has acknowledged that the first prong of its "two-part test" for declaratory judgment jurisdiction, the "reasonable apprehension of suit" prong, is no longer valid because it contradicts Supreme Court precedent as explained by the *MedImmune*

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<sup>44</sup> *Id.* at 776 (citing *Commodity Credit Corp. v. Rosenberg Bros. & Co.*, 243 F.2d 504, 512 (9<sup>th</sup> Cir. 1957), and *Kingman & Co. v. Stoddard*, 85 F. 740, 745 (7<sup>th</sup> Cir. 1898)).

<sup>45</sup> *MedImmune*, 127 S.Ct. at 775-76.

<sup>46</sup> *Id.* at 776.

<sup>47</sup> 28 U.S.C. § 2201(a) (emphasis added).

<sup>48</sup> *MedImmune*, 127 S.Ct. at 777.

<sup>49</sup> *MedImmune*, 127 S.Ct. at 777 (Thomas, J., dissenting).

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

Court.<sup>51</sup> *MedImmune*, however, left open several unresolved questions whose impact on the patent law remain to be seen; lower courts' interpretations of the decision will be instructive, and the Supreme Court may well revisit the issues it declined to address in *MedImmune* during a future case. For example, the *Lear* Court had ruled that a repudiating licensee need not comply with its contract and continue paying royalties until the patent is held invalid by a court.<sup>52</sup> However, the *MedImmune* Court "express[ed] no opinion" on whether a *nonrepudiating* licensee is relieved of its contract obligations during the suit challenging the patent's validity.<sup>53</sup> Therefore, the applicability of the licensee estoppel doctrine to this situation is an open question after *MedImmune*. Also, the *MedImmune* Court had emphasized that district courts still have statutory discretionary authority to decline to hear declaratory judgment actions; it will be up to licensors-patentees to craft "equitable, prudential, and policy arguments" to successfully persuade the district court to exercise that discretion. Finally, the *MedImmune* Court did not consider the enforceability of drafting a provision in a license agreement that obliged a licensee not to challenge the validity of the underlying patent unless he or she breached the license.

Other ramifications of *MedImmune* on the patent law are significant. First, the ruling may spark an increase in patent litigation activity, as more patent licensees may find it easier to bring declaratory judgment actions to challenge the patent's validity — without having to terminate or breach their license agreements before doing so. Second, the decision promises to play a role in drafting and negotiating the terms of patent licensing agreements, as licensors-patentees may be interested in having licensees agree to the inclusion of "no challenge" clauses.<sup>54</sup> It is also likely that the decision may have an impact beyond patent law, as it may be applicable to licensing and contract law matters that do not involve intellectual property.

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<sup>51</sup> *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F. 3d 1372, 1380 (Fed. Cir. 2007). The Federal Circuit expressly chose to "leave to another day the effect of *MedImmune*, if any, on the second prong" of its test. *Id.*

<sup>52</sup> *Lear*, 395 U.S. at 673 ("[O]verriding federal policies would be significantly frustrated if licensees could be required to continue to pay royalties during the time they are challenging patent validity in the courts.").

<sup>53</sup> *MedImmune*, 127 S.Ct. at 769-70. Thus, it is uncertain whether nonrepudiating patent licensees who pay royalties "under protest" may be able to obtain a refund of those royalties when the patent is finally held invalid.

<sup>54</sup> The enforceability of such a provision, as noted above, is unclear. However, it is possible that a licensor-patentee could draft a clause providing that the patent may be challenged by the nonrepudiating licensee, on the condition that such action would "trigger a steep increase in royalty payments or a large lump sum payment (to cover the licensor's litigation expenses)," among other things. Catherine Nyarady, "*MedImmune v. Genentech*": *Unanswered Questions*, 237 NEW YORK LAW JOURNAL 22 (Feb. 1, 2007).