New Jersey Law Journal

VOL. CLXXXVIII– NO.3 – INDEX 281 APRIL 23, 2007 ESTABLISHED 1878

INTELLECTUAL PROPERTY & *Life Sciences*

Do Patent Licensees Have It Both Ways?

Impact of Supreme Court decision depends on lower court application

By Arnold B. Calmann and Katherine A.Escanlar

Until recently, a party who licensed and paid a royalty for a patent was not permitted to institute a lawsuit to challenge the validity of that patent while still reaping the benefits of the license agreement (including immunity from an infringement suit). In 2004, the Federal Circuit dismissed a declaratory judgment action for lack of subject matter jurisdiction, ruling that no "actual controversy" existed to support jurisdiction. *Gen-Probe Inc. v. Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir. 2004). The court found that the licensee continued to pay contract royalties and thus was in good standing, and that the license agreement "insulated" the licensee and therefore "obliterated any reasonable apprehension" that it will be sued for infringement.

However, that ruling was recently overturned by the United States Supreme Court in *MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764 (2007). The Court held that a patent licensee may bring a declaratory judgment action to determine whether the licensed patent is valid, enforceable or not infringed, even where the licensee is continuing to pay contract royalties (albeit under protest). Thus, to establish a justiciable case or controversy under Article III of the United States Constitution, a licensee need not terminate or breach its license agreement before instituting a declaratory judgment action challenging the licensed patent.

The *MedImmune* decision raises the issue of whether licensees may have their cake and eat it, too, because a licensee may challenge the validity of a patent while continuing to pay royalties and reaping the benefits of the license agreement at the same time (such as avoiding the risk of a patent infringement suit, damages and/or an injunction). *MedImmune* has generated critical commentary raising serious questions regarding the impact of the decision on the structure of patent license arrangements and whether a seismic shift has occurred in the relationship of the parties involved in the underlying royalty agreement. See, e.g., Nicholas Coch & Mary Richardson, "Supreme Court Ruling Leaves Issues Open Regarding Patent Licensing," *The Metro. Corp. Counsel*, Feb. 2007, at 18; Charles Barquist & Jason Crotty, "*MedImmune v. Genentech*: The Supreme Court Upends the Federal Circuit's Declaratory Judgment Jurisprudence," *The National Law Journal*, Jan. 29, 2007.

Historically, under the doctrine of "licensee estoppel," a licensee was precluded from challenging the validity of a licensed patent. See, e.g., *Automatic Radio Mfg. Co. v. Hazeltine Research, Inc.*, 339 U.S. 827 (1950). However, that doctrine was overruled by the Supreme Court in *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969), which held that a licensee

Calmann is a member of Saiber Schlesinger Satz & Goldstein and focuses his practice on intellectual property, antitrust, trade regulation and complex corporate litigation. Escanlar, an associate at the firm, focuses her practice on business litigation, trade litigation and intellectual property .

who breached the agreement by ceasing to pay royalties was not estopped from attacking the validity of the patent. The *Lear* Court recognized the important public policy in fostering the free competition in ideas that belong in the public domain and the fact that licensees often may be the only ones with the economic incentive to challenge the patentability of an invention. The Court further held that the breaching licensee could avoid payment of all royalties accrued after the patent was issued, if the licensee could prove patent invalidity.

While *Lear* upended the licensee estoppel doctrine, the Federal Circuit in *Gen-Probe* had noted that the *Lear* doctrine "does not grant every licensee in every circumstance the right to challenge the validity of the licensed patent." Indeed, *Gen-Probe* held that the licensee, who was *in compliance* with the terms of the license agreement, was barred from bringing a declaratory judgment action because there was no "reasonable apprehension" that the licensee will be sued for infringement. That court reasoned that allowing a licensee to sue without materially breaching its agreement would "discourage patentees from granting licenses" and would effectively defeat the covenant not to sue formed by the license. "[T]he licensor would bear all the risk, while [the] licensee would benefit from the license's effective cap on damages or royalties in the event its challenge to the patent's scope or validity fails."

Thus, prior to *MedImmune*, the Federal Circuit applied its "reasonable apprehension of suit" test to determine the justiciability of a declaratory judgment action, which involved a nonbreaching licensee. However, *MedImmune* changed the landscape.

MedImmune manufactures a drug called Synagis, which is used to prevent respiratory tract disease in young children. In 1997, MedImmune and Genentech entered into a license agreement in which Genentech agreed to license, among other things, its then-pending patent application. In 2001, Genentech's patent application matured into the "Cabilly II" patent. Genentech subsequently sent MedImmune a letter stating that its Synagis product was covered by the Cabilly II patent and therefore, MedImmune, as licensee, was obligated to pay royalties.

Believing that the Cabilly II patent was invalid, unenforceable and not infringed, but unwilling to risk potential treble damages, attorney's fees and an injunction resulting from unsuccessfully defending against an infringement suit, MedImmune paid the demanded royalties "under protest and with reservation of all of [its] rights." It thereafter brought a declaratory judgment action asserting patent invalidity and noninfringement. Relying on *Gen-Probe*, the district court dismissed the action for lack of subject matter jurisdiction, and the Federal Circuit affirmed. The Supreme Court reversed.

Justice Antonin Scalia, writing for an 8-1 majority, concluded that the Federal Circuit's "reasonable apprehension of suit" test for determining the justiciability of a declaratory judgment action, as set forth in the *Gen-Probe* decision, conflicts with Supreme Court precedent. Instead, the Court clarified that in determining whether a "case or controversy" existed under Article III, a dispute must be "'definite and concrete'" and "'real and substantial,'" but not one seeking an advisory opinion. According to the Court, the basic question and the test 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.

That test would have been satisfied had MedImmune refused to pay the royalties because an immediate "substantial controversy" would have arisen, resulting from the breach of the obligations under the license agreement. But in *MedImmune*, the question was whether a case or controversy existed where the licensee *continued to comply* with the agreement and paid royalties. The Court answered in the affirmative.

The Court found that declaratory judgment jurisdiction exists where threatened enforcement action "coerces" a plaintiff into taking action to eliminate that threat. According to the Court, MedImmune was effectively coerced into paying the royalties because it faced the threat of treble damages and loss of 80 percent of its business in the event of an infringement suit in which it failed to succeed. "The rule that a plaintiff must destroy a large building, bet the farm, or…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."

The Court rejected Genentech's argument that by entering into the license agreement, the parties agreed that as long as MedImmune continued to pay royalties and did not challenge the licensed patent, it would be immune from an infringement suit by Genentech. The Court concluded that "[p]romising to pay royalties on patents that have not been held invalid does not amount to a promise *not to seek* a holding of their invalidity." (emphasis in text).

The Court also found unpersuasive Genentech's contention that MedImmune's action was barred by the common-law rule that a party to a contract cannot challenge its validity while simultaneously continuing to enjoy its benefits. The Court found it "hard to see" how the rule applied to the case: "Petitioner is not repudiating or impugning the contract while continuing to reap its benefits. Rather, it is asserting that the contract, properly interpreted, does not prevent it from challenging the patents, and does not require the payment of royalties because the patents do not cover its products and are invalid." The Court further noted that even if the common-law rule barred the action, this would only mean that Genentech would win on the merits.

Importantly, Justice Scalia more

than once distinguished between rendering a decision based on jurisdictional grounds as opposed to the merits: "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 — that is, on the applicability of licensee estoppel under these circumstances." For that comment, Justice Scalia cited to *Studiengesellschaft Kohle, M.B.H. v. Shell Oil Co.*, 112 F.3d 1561, 1568 (Fed. Cir. 1997), in which the Federal Circuit held that the protections of the *Lear* doctrine would not apply unless the licensee "(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." Thus, Justice Scalia appears to have left open for a decision on remand whether *Lear*'s repudiation of the doctrine of licensee estoppel applies to a non-breaching licensee.

Lastly, the Court determined that on remand, the District Court may consider arguments based on the merits, as well as various policy arguments raised by the parties.

A question arises as to whether the Court's reference to the *Shell Oil* case contradicts the underlying reasoning in the *MedImmune* decision. If *Shell Oil* requires that a licensee actually cease its royalty payments and provide the licensor with notice of a challenge to the validity of the patent, a question arises as to whether it is worthwhile to allow a licensee to bring a declaratory judgment action only to bar that action on the merits under *Shell Oil*'s reasoning.

For example, what if on remand from the Supreme Court to the Federal Circuit and/or district court, the lower court applies the *Shell Oil* doctrine and licensee estopppel applies to a nonbreaching licensee? To further hypothesize, what if that decision led to another Supreme Court decision affirming application of the *Shell Oil* doctrine? Would that make the benefits of the *MedImmune* decision illusory? At that point, one might argue that there would be no need for a nonbreaching licensee to file a declaratory judgment action because *Shell Oil* and its progeny would bar the declaratory judgment action in the first instance. In fact, one commentator expressed the view that "the Supreme Court may have simply opened the jurisdictional door, only to allow [the licensee], once inside the courthouse, to be estopped on the merits." David L. Fox, "*MedImmune v. Genentech* and Licensee Estoppel," *IP Law 360*, Feb. 23, 2007, at http://ip.law360.com. That view is seconded where *MedImmune* is viewed as a narrow decision that "does not necessarily signal the end of patent licensee estoppel or a radical change in the relationship of licensors and licensees." Kenneth C. Bass III & Mark Fox Evens, "A Contrarian View of *MedImmune v. Genentech*," *IP Law 360*, Feb. 7, 2007, at http://ip.law360.com.

A further question arises whether the Supreme Court gave proper weight to the common-law rule that a party to a contract cannot simultaneously challenge its validity and continue to reap its benefits. One might argue that Justice Scalia's effort to distinguish the common-law rule from the issue presented in *MedImmune* could be viewed as form over substance. Arguably, asserting, as in *MedImmune*, that the contract "does not require the payment of royalties because the patents do not cover its products and are invalid" is, in fact, a challenge to the very contract to which one is a party. It would appear difficult to ignore the possible argument that seeking a declaratory judgment action challenging patent validity would be something other than "repudiating or impugning" the license agreement. Justice Scalia's reasoning on this issue could be criticized as being somewhat strained.

MedImmune also places in issue the predictability and reliability of patent license agreements. "[L]icensors will face much greater uncertainty regarding the long term enforceability of their licenses — particularly licenses entered into under threat of litigation — as they face the prospect of a licensee seeking at any time to invalidate the licensed patent(s)." Jeffrey M. Fisher & Robert H. Sloss, "MedImmune Ushers in New Era of Patent Litigation," *IP Law 360*, Jan. 12, 2007, at http://ip.law360.com.

The projected impact of *MedImmune* raises a number of other issues. For example, that licensors may argue that the "'pay and then sue' strategy is inequitable" and imprudent. Barquist & Crotty, supra. Licensors will undoubtedly contend that it is fundamentally unfair for a licensee to challenge the validity of a patent, while at the same time reaping the benefits of the license agreement, including immunity from an infringement suit.

It is likely that the *MedImmune* decision will result in an increase in the number of patent suits because licensees may challenge the validity of a patent without risking an infringement suit, enhanced damages, and/or an injunction. There also may be an increase in litigation because patentees may feel compelled to bring an infringement suit instead of entering into a license agreement knowing that the license is "not a final resolution" but rather is subject to a validity attack later on. Barquist & Crotty, supra.

"In the pharmaceutical industry, [*MedImmune*] may have a far-ranging impact." Chad A. Landmon, "Supreme Court Backhands Key Federal Circuit Test," *IP Law 360*, Jan. 10, 2007, at http:// ip.law360.com. Under the Hatch-Waxman Act, the first generic pharmaceutical company to file an Abbreviated New Drug Application (ANDA) relating to a patent listed in the FDA's publication of "Approved Drug Products With Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book"), would obtain a 180-day period of marketing exclusivity if its product does not infringe the listed patent or if the patent is declared invalid. (Ordinarily, the ANDA applicant files a "Paragraph IV" certification of noninfringement or that the listed

patent is invalid). Generic companies have attempted to bring declaratory judgment actions challenging patents listed in the Orange Book because of the potentially crippling patent damages that could be imposed if the generic company launches its product without certainty as to patent validity. Previously, the Federal Circuit has largely struck down those efforts under its "reasonable apprehension of suit" test. See *Teva Pharm. USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324 (Fed. Cir. 2005). However, in the wake of *MedImmune*, the Federal Circuit in *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, No. 06-1181, 2007 WL 942201 (Fed. Cir. Mar. 30, 2007), explicitly recognized that its "reasonable apprehension of suit" test had been "overruled" by the *MedImmune* decision.

The dispute in *Teva* centered on an antiviral medication called Famvir. Novartis listed five patents in the Orange Book for Famvir: the '937 patent, which is directed to the active ingredient in Famvir, famciclovir, and four other method-of-use patents. Teva filed an ANDA to market the generic famciclovir tablets and provided its Paragraph IV certification that the five Novartis patents were not infringed or were invalid. Subsequently, Novartis sued Teva for infringement of the '937 patent but it *did not* assert any claims regarding the four method-of-use patents. As a consequence, Teva brought a declaratory judgment action on the four method of use patents to establish "patent certainty." See 21 U.S.C. § 355 (j)(5)(C). Applying the Federal Circuit's "reasonable apprehension of suit" test, the district court had held that Teva failed to establish a justiciable controversy to support declaratory judgment jurisdiction.

However, in light of the *MedImmune* decision, the Federal Circuit reversed the district court and expressly noted that its "reasonable apprehension of suit" test "conflicts" with the Supreme Court's *MedImmune* holding. The Federal Circuit applied *MedImmune*'s "all the circumstances" test and "taken as a whole," the circumstances established that Teva had an injury-in-fact and, therefore, a justiciable controversy existed. Critical to the court was the listing of the Novartis patents; Teva's ANDA certification; the interplay of the relevant statutes; the pending Novartis suit; and the threat of future litigation against Teva.

The court concluded that "[a] justiciable declaratory judgment controversy arises for an ANDA filer when a patentee lists patents in the Orange Book, the ANDA applicant files its ANDA certifying the listed patents under paragraph IV, and the patentee brings an action against the submitted ANDA on one or more of the patents. The combination of these three circumstances is dispositive in establishing an actual declaratory judgment controversy as to all the paragraph IV certified patents, whether the patentee has sued on all or only some of the paragraph IV certified patents."

Thus, it appears that the *MedImmune* decision created a renewed opportunity for generic companies to seek declaratory judgment relief before they launch products into the market. As one commentator has noted: "[The *Teva v. Novartis*] decision eliminates a powerful weapon innovator drug companies had in their ongoing battle against generics: the uncertainty and risk that generics face when considering whether to launch their drug products before patent expiration. Now generics in Teva's position will be able to file a declaratory judgment action and obtain a court decision on the validity or infringement of Orange Book-listed patents before deciding whether to launch." A. Barkoff, "Orange Book Blog," http://feeds.feedburner.com/~r/OrangeBookBlog/~3/105443784/federal_circuit_1.html (Mar. 30, 2007).

MedImmune also may have a potential impact on the terms of future license agreements: (1) As Barquist and Crotty noted, royalty payments may be increased in order to account for potential litigation costs when the validity of the licensed patent is later challenged. Licensors may seek other ways of using the royalty payments as a protective device, e.g., creating a sliding scale of payments where the major portion of the payments are paid early in the term of the license agreement. However, strategic use of the royalty payment scheme may require further analysis under *Lear* to evaluate its validity; and (2) Licensors may also seek to contractually limit the licensee's right to challenge the validity of the licensed patent. Justice Scalia alluded to the potential for such a provision in *MedImmune*. However, it is not clear whether such clauses would be enforceable under *Lear*. Justice Anthony Kennedy, in fact, noted during oral arguments that "at some point, either in this case or some later case, [we] may have to address the question of whether or not such a provision is enforceable. If it is, we may not be talking about much. It's just going to be boilerplate in every license agreement, and that's the end of it."

MedImmune raises a number of significant strategic litigation, contractual, and policy issues. Depending upon its interpretation by the lower courts and the outcome of the questions surrounding application of the licensee estoppel doctrine to nonbreaching licensees, *MedImmune*'s impact could be far-reaching with monumental financial consequences or it could have only short-term ramifications.

On the eve of publication of this article, the United States Patent & Trademark Office declared invalid Genentech's Cabilly II patent that is the principal subject matter of the patent license agreement in dispute in *MedImmune*. The ramifications of that action are beyond the scope of this article. Suffice to say, the PTO's decision only further complicates the import of the *MedImmune* decision. ■