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Licensee Challenge

When Can A Licensee Challenge A Licensed Patent? The Supreme Court Shocks the Technology Transfer Community in *MedImmune v. Genentech*

By Irving N. Feit

A recent decision of the United States Supreme Court will have a profound impact on organizations that license intellectual property, either in or out. The decision, which was announced January 9, 2007, addresses an important issue: when can a licensee challenge a patent licensed under a technology transfer agreement?

The decision, *MedImmune v. Genentech*,¹ constitutes a departure from what was thought to be settled law, at least in the court mandated to hear all appeals relating to patents in the United States, namely, the Court of Appeals for the Federal Circuit. In the decision, the Supreme Court made it significantly easier for patent licensees to challenge patents.

First, a little historical context. Before 1969, licensees could not challenge the validity of licensed patents under any circumstances. They were prevented from doing so under the so-called doctrine of licensee estoppel. This doctrine applied even if a licensee was sued for breaching its license agreement by refusing to pay royalties.

For example, if a pre-1969 licensee had reason to believe a licensed patent was invalid, the licensee would have wanted to repudiate the license agreement, and stop paying royalties. If the licensor sued for patent infringement, however, the defense that the patent was invalid was not available to the licensee.

In 1969, the Supreme Court overruled the doctrine of licensee estoppel in its landmark decision, *Lear v. Adkins*.² After the 1969 *Lear* decision, a licensee who agreed to pay royalties during the term of a patent had the option of challenging its validity. The stated policy

behind *Lear* was to encourage validity challenges in order to weed out invalid patents.

Even under *Lear*, however, a licensee had to repudiate its license agreement before mounting a challenge to the validity of the licensed patent. The aggrieved licensor, in turn, had the option of suing the licensee in federal district court for patent infringement and breach of contract. It was at the resulting trial that licensees had the opportunity to challenge the validity of the licensed patent.

For more than seventy years, however, it has not been necessary for a repudiating licensee to wait to be sued by an aggrieved licensor. Under certain conditions, the licensee can, even before being sued, seek a declaration by a federal district court that a licensed patent is invalid, unenforceable, and/or not infringed. The basis for doing so is the Federal Declaratory Judgment Act of 1934,³ which states:

In a case of actual controversy within its jurisdiction ...any court of the United States...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.

Until the Supreme Court changed the law with its *MedImmune v. Genentech* decision, a long line

■ Irving N. Feit, Hoffmann & Baron, LLP, Partner,
Long Island, New York
E-mail: ifeit@hoffmannbaron.com

3. Federal Declaratory Judgment Act of June 14, 1934, 28 U.S.C. §2201(a).

1. *MedImmune v. Genentech*, 549 U.S.; 127 S. Ct. 764; 166 L. Ed. 2d 604; 81 U.S.P.Q.2d 1225 (2007).

2. *Lear v. Adkins*, 395 U.S. 653, 673; 162 U.S.P.Q. I (1969).

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of Federal Circuit cases had uniformly maintained a significant barrier to jurisdiction under the Declaratory Judgment Act. According to the Federal Circuit, a licensee had to be under a reasonable apprehension of an imminent law suit by a patentee in order for a federal court to have jurisdiction.⁴

Apprehension of an imminent lawsuit was said to be necessary because, under Article III of the United States Constitution, federal courts only have jurisdiction where there is a “case” or “controversy.”⁵ If there is no case or controversy, a declaration by a court is considered to be an advisory opinion, which has been held by the Supreme Court to exceed the constitutional jurisdiction of the courts.

In accordance with its pre-*MedImmune* “reasonable apprehension” test, the Federal Circuit had held that a patent licensee in good standing could not establish an Article III case or controversy. In *Gen-Probe v. Vysis*,⁶ for example, the court reasoned that a license agreement “obliterate[s] any reasonable apprehension” that the licensee will be sued for infringement.⁷

Accordingly, a balance of power had evolved between licensees and licensors. A licensee had the power to challenge a licensed patent by repudiating the license agreement and ceasing to pay royalties. To do so, however, the licensee had to risk being sued by its licensor. If the licensor prevailed, the licensee faced an injunction prohibiting future infringing activities, and risked the possibility of triple damages for past infringement.

The recent *MedImmune* decision shifted this balance of power significantly in favor of licensees. In the decision, the Supreme Court held that a licensee, *MedImmune*, could seek a declaratory judgment of patent invalidity and non-infringement in federal court under the Declaratory Judgment Act, even though it was still paying royalties, and had not otherwise breached the license agreement with its licensor, *Genentech*. It was sufficient, according to the Court, for *MedImmune* merely to pay royalties “under protest and with reservation of all of [its] rights.”⁸

4. Formally, the Federal Circuit imposed a two part test: (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit; and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such an activity. *Teva Pharmaceuticals USA v. Pfizer, Inc.* 395 F.3d 1324, 1332-33 (Fed. Cir. 2005).

5. See, for example, *Gen-Probe v. Vysis*, 359 F.3d 1376; 70 U.S.P.Q.2d 1087 (2004).

6. *Id.*

7. *Id.*, 359 F.3d at 1381.

8. *MedImmune v. Genentech*, 81 USPO2d at 1227.

Justice Scalia, writing for an almost unanimous Supreme Court, explained: “All we need to determine, is whether (*MedImmune*) has alleged a contractual dispute. It has done so.”⁹

The only dissent was that of Justice Thomas. According to Justice Thomas:

MedImmune was a licensee in good standing that had made all necessary royalty payments. Thus, by voluntarily entering into and abiding by a license agreement with *Genentech*, *MedImmune* removed any threat of suit.¹⁰

Justice Thomas further observed that the Supreme Court has “...consistently held that parties do not have standing to obtain rulings on matters that remain hypothetical or conjectural.”¹¹ He then offered the following perceptive concern about the majority’s decision:

Because neither *Genentech* nor *MedImmune* had a cause of action, *MedImmune*’s prayer for declaratory relief can be reasonably understood only as seeking an advisory opinion about an affirmative defense it might use in some future litigation. *MedImmune* wants to know whether, if it decides to breach its license agreement with *Genentech*, and if *Genentech* sues it for patent infringement, it will have a successful affirmative defense. Presumably, upon a favorable determination, *MedImmune* would then stop making royalty payments, knowing in advance that the federal courts stand behind its decision. Yet as demonstrated above, the Declaratory Judgment Act does not allow federal courts to give advisory rulings on the potential success of an affirmative defense before a cause of action has even accrued.¹²

Justice Thomas’ concern appears to be well founded. Under the majority opinion in *MedImmune*, a licensee can seek a declaration of patent invalidity, unenforceability and/or non-infringement while still paying royalties. If the licensee is successful in any of its assertions, the licensee can then stop making royalty payments, knowing in advance it will not be sued for breaching its license agreement. If unsuccessful, however, the licensee will continue making payments under the agreement, with no penalty except the cost of litigation.

Of course, the cost of litigation in the United States is high, and may act as a deterrent against overuse

9. *Id.*, 81 U.S.P.Q.2d at 1228.

10. *Id.*, 81 U.S.P.Q.2d at 1236.

11. *Id.*, 81 U.S.P.Q.2d at 1234.

12. *Id.*, 81 U.S.P.Q.2d at 1236.

of the Declaratory Judgment Act by patent licensees. However, where royalties are being paid on a very lucrative product, such as a billion dollar a year drug, the cost of litigation might appear to be a more reasonable investment, and less of a deterrent.

It should be noted that the Supreme Court did not directly overturn the Federal Circuit's "reasonable apprehension of suit" test. Rather, it stated in a footnote as dicta that the test contradicted several earlier Supreme Court decisions.¹³

Nevertheless, Supreme Court dicta was enough for the Federal Circuit. It took the Federal Circuit less than three months to abandon its long-held "reasonable apprehension" test for jurisdiction under the Declaratory Judgment Act.

In *Teva Pharmaceuticals USA v. Novartis Pharmaceuticals*,¹⁴ which was decided on March 30, 2007, and which involved the Declaratory Judgment Act in the context of an ANDA by a generic drug company under the Hatch-Waxman Act, the Federal Circuit stated:

Thus, because the Supreme Court in *MedImmune* cautioned that our declaratory judgment 'reasonable-apprehension-of-suit' test 'contradict(s)' and 'conflicts' with its precedent, these Federal Circuit tests have been 'overruled ...'¹⁵

The standard for jurisdiction under the Declaratory Judgment Act is much lower after the *MedImmune* decision than it was before. The new standard, according to the Federal Circuit in *Teva*, is determined with a "totality of the circumstances" test, *i.e.*:

...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.¹⁶

A recent, and particularly relevant, Federal Circuit case was decided on March 26, 2007. In *SanDisk v. STMicroelectronics*,¹⁷ the two parties were in discussions regarding whether SanDisk needed a license under any of fourteen patents of STMicroelectronics in order to sell certain flash memory storage products.¹⁸ During the discussions,

STMicroelectronics clearly stated that it "...has absolutely no plan whatsoever to sue SanDisk."¹⁹

Nevertheless, before these discussions ended one way or the other, SanDisk sought a declaratory judgment of invalidity and non-infringement in the US District Court for the Northern District of California.²⁰ The District Court, in an opinion rendered before the Supreme Court's *MedImmune* decision, granted STMicroelectronics' motion to dismiss SanDisk's request for declaratory judgement.²¹ According to the court, it lacked jurisdiction on the grounds that there was no actual controversy. Using pre-*MedImmune* reasoning, the court held that "... SanDisk did not have an objectively reasonable apprehension of suit."²²

The Federal Circuit reviewed the District Court's decision after *MedImmune*, and reversed. The Federal Circuit explained that, under the Supreme Court's new "totality of the circumstances" test:

... where a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, an Article III case or controversy will arise and the party need not risk a suit for infringement by engaging in the identified activity before seeking a declaration of its legal rights.²³

Under the *SanDisk* interpretation of the *MedImmune* decision, it would appear that almost any difference of opinion between a patentee and an alleged infringer or potential infringer may be sufficient to confer jurisdiction on a federal court under the Declaratory Judgment Act.

A lower standard for jurisdiction under the Declaratory Judgment Act in view of the *MedImmune* decision has also been acknowledged in Federal District Court. See *Rite-Hite Corporation v. Delta T Corporation*.²⁴

It is readily apparent from the *MedImmune*, *Teva*, *SanDisk* and *Rite-Hite* decisions discussed above that the former "reasonable apprehension of imminent lawsuit" test has been overruled, and that the new "totality of the circumstances" test will be more easily satisfied throughout the federal court system. The resulting lower barrier to jurisdiction under the Declaratory Judgment Act will make it easier for licensees to challenge the validity of patents in federal court.

13. *Id.*, 81 U.S.P.Q.2d at footnote 11.

14. *Teva Pharmaceuticals USA v. Novartis Pharmaceuticals Corp.* 482 F.3d 1330; 82 USPQ2d 1225 (Fed. Cir. 2007).

15. *Id.*, 482 F.3d at 1339.

16. *Id.*, 482 F.3d at 1337.

17. *SanDisk v. STMicroelectronics* 480 F.3d 1372; 82 U.S.P.Q.2d 1173 (Fed. Cir. 2007).

18. *Id.*, 480 F.3d at 1375, 1376.

19. *Id.*, 480 F.3d at 1376.

20. *Id.*

21. *Id.*

22. *Id.*

23. *Id.*, 480 F.3d at 1382.

24. *Rite-Hite Corporation v. Delta T Corporation*, 2007 WL 725327; 82 U.S.P.Q.2d 1272 (E. D. Wisc. 2007).

At about the same time the *MedImmune* decision made it easier for licensees to challenge patents procedurally, the Supreme Court also made it easier to invalidate patents substantively. On April 30, 2007, the Supreme Court, in *KSR International v. Teleflex*, held that the Federal Circuit's requirements for finding patent claims obvious had been too rigidly applied.²⁵

The full impact of the *KSR* decision is not yet clear. A lowering of the standard for finding obviousness in the PTO and in the courts seems inevitable. A lower standard for obviousness will make it easier to invalidate patents, and will provide further incentive for licensees to challenge licensed patents.

Accordingly, the balance of power between licensees and licensors shifted dramatically in favor of licensees in the first four months of 2007. For the reason stated above, the shift is especially pronounced in cases where profitability of the product made, used or sold under the license is very high.

It is possible that licensors may be able to restore much of the balance that existed before the *MedImmune* decision by trying to negotiate a previously untested provision into their license agreements. According to the new provision, the license would be automatically cancelled if the licensee challenges the validity of the patent.

As mentioned above, however, the policy of the Supreme Court's decision in *Lear* was to encourage challenges to invalid patents. Therefore, a provision in

a license agreement that precludes such a challenge is subject to an argument that the provision should be held unenforceable as being contrary to the policy of *Lear*.

Nevertheless, a 2001 decision of the Federal Circuit suggests that automatic cancellation of a license upon a licensee's validity challenge may be enforceable. Such a provision in an agreement to settle litigation was, in fact, enforced in *Flex-Foot, Inc. v. CRP, Inc.*²⁶

According to the Federal Circuit in *Flex-Foot*, the policy of encouraging settlements of litigation is more important than the *Lear* policy of encouraging challenges to patent validity.²⁷ The court might say the same for the policy of avoiding litigation in the first place, which is a goal of a patent license agreement.

Less drastic provisions in license agreements that might discourage licensee challenges to the validity of licensed patents have also been proposed. Such provisions include escalating royalties and the payment of the licensor's attorney fees in the case of an unsuccessful challenge to patent validity by a licensee.²⁸

Licensees appear to have won a significant battle with the Supreme Court's *MedImmune* decision. But the war goes on. ■

The opinions expressed in this article are solely the current opinions of the author, and not necessarily those of Hoffmann & Baron, LLP; any of its attorneys or agents; any of its clients; and not necessarily even the future opinions of the author.

25. *KSR International v. Teleflex*, 550 U.S.; 127 S.Ct. 1727; 167 L.Ed.2d 705; 82 U.S.P.Q.2d 1385 (2007).

26. *Flex-Foot, Inc. v. CRP Inc.*, 238 F.3d 1362, 1370; 57 U.S.P.Q.2d 1635 (Fed. Cir. 2001). The author thanks Bruce Toman of Cornell Research Foundation, Inc. for bringing this decision to his attention. Mr. Toman, in turn, thanks Gunnar Leinberg of Nixon Peabody LLP for bringing the decision to his attention. The author emphasizes that all opinions and interpretations of court decisions expressed in this article are his alone.

27. *Id.*, 238 F.3d at 1368.

28. Gary H. Levin and Aaron B. Rabinowitz, *Handbook of 23rd Annual Joint* (Connecticut, New Jersey, New York and Philadelphia Intellectual Property Law Associations) *Patent Practice Seminar*, New York City (May 9, 2007).