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The Supreme Court Changes the Rules on When a Licensee Can File a Declaratory Judgment

MedImmune, a biotechnology company, sells a product called Synagis®, which is a drug used to prevent respiratory tract disease in infants. In 1997, MedImmune entered into a patent license agreement with Genentech Inc. and City of Hope, a nonprofit health care provider. The license agreement covered, among other things, a pending patent application that eventually issued as a patent. After the patent issued, Genentech sought royalties from MedImmune alleging that Synagis® was covered under that patent.

Although MedImmune believed no royalties were due because it believed Synagis® did not infringe the patent's claims and further because it believed that the patent was invalid and unenforceable, MedImmune considered the letter a clear threat to enforce the patent, terminate the license agreement, and bring a patent infringement action if it did not pay. Such an action could have resulted in MedImmune being ordered to pay damages (potentially treble damages and attorney's fees) and be enjoined from selling Synagis®, which accounts for more than 80 percent of its sales revenue. As a result, MedImmune paid the royalties under protest and filed a declaratory judgment ("DJ") action for declaratory relief. DJ actions are often used by potential defendants to obtain a declaration that a patent is invalid, unenforceable and/or not infringed.

The District Court dismissed the DJ claims for lack of subject matter jurisdiction because, under Federal Circuit precedent, a patent licensee in good standing cannot establish an Article III case or controversy with regard to the patent's validity, enforceability or scope. The Federal Circuit affirmed based upon its precedent in *Gen-Probe Inc. v. Vysis*, 359 F.3d 1376 (Fed. Cir. 2004), where the Federal Circuit held that a licensee must breach its licensing agreement to create a "case of actual controversy" over the validity of a patent. Without an apprehension of suit, the Federal Circuit held that the DJ action would not rise to an actual controversy as required by the Constitution.

The Federal Circuit's reasoning was that a licensor chooses to avoid litigation as an avenue of enforcing its rights by voluntarily relinquishing its statutory right to exclude by granting a license. Allowing an action to proceed would effectively defeat such contractual covenants and would discourage patentees from granting licenses. In other words, the licensor would bear all the risk, while the licensee

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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. As such, it would be inequitable for a patent holder, having contracted away its right to sue for infringement, to be "in continuing risk of attack on the patent whenever the licensee chooses"..."while the licensee can preserve its license and royalty rate if the attack fails." The Gen-Probe decision distinguished prior Supreme Court precedent (*Altvater v. Freeman*, 319 U. S. 359 (1943)), which held that a licensee's failure to cease its payment of royalties did not render nonjusticiable a dispute over the validity of the patent on the ground that Altvater involved the compulsion of an injunction.

On January 9, 2007, the U.S. Supreme Court, by an 8-1 vote, reinstated the lawsuit by MedImmune challenging the Genentech patent. The opinion in MedImmune v. Genentech states that patent licensees no longer have to breach the license in order to have standing to challenge the licensed patent. Now a patent can be challenged by a licensee while still honoring the license and paying royalties -- just as MedImmune did in the instant case.

Under the old rules, a license agreement amounted to an insurance policy against litigation over patent validity or infringement. Now, as a result of this ruling, patent challenges will be safer and easier to file without fear of retaliation by the licensor. Licensees can now raise challenges on patents that both parties previously thought were settled and protected by the license agreement.

There are a few lessons that can be taken from this decision. The first lesson is that the opinion is broader than patents. This decision extends to other licensing issues and potentially to contracts whether or not they involve patents or intellectual property. The Supreme Court stated:

> "The rule that a plaintiff must destroy a large building, bet the farm, or (as here) risk treble damages and the loss of 80% of its business, before seeking a declaration of its actively contested legal rights finds no support in Article III."

The second lesson is that the opinion may also indicate that a contractual prohibition against challenging the validity of the patents may serve to block challenges by licensees in good standing. Specifically, the Supreme Court stated:

> "To begin with, it is not clear where the prohibition against challenging the validity of the patents is to be found. It can hardly be

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