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Big Patent Decisions

# MedImmune: More Leverage

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MERCHANT & GOULD

The Supreme Court's recent *MedImmune* decision may revolutionize a patent licensee's ability to challenge the scope, validity, and enforceability of licensed patents. *MedImmune, Inc. v. Genentech, Inc.* 127 S. Ct. 764 (2007). The decision grants jurisdiction for licensees to challenge patents without terminating the license. This allows a licensee to eliminate the risk of facing harm well in excess of the royalties, such as treble damages, attorney's fees, and an injunction, when challenging a patent. Some may view the decision's effects as helping to defeat patents that should have never issued. While this may be true, the decision may also lead to unintended results regarding existing licenses. Moreover, any anti-patentee effect may be largely dampened, if not reversed, by new language in future licenses and by licensee estoppel.

### The Case

The *MedImmune* case centered on a 1997 licensing agreement, in which MedImmune agreed to make royalty payments related to its respiratory syncytial virus (RSV) drug Synagis to Genentech, which held rights in patents and patent applications covering antibody synthesis. Specifically, the license required royalty payments to be made "until a patent claim has been held invalid by a competent body." In 2001, Genentech demanded MedImmune pay a second royalty on Synagis, as the product also purportedly infringed a second, recently granted "Calliby II" patent. MedImmune disagreed with Genentech.

Under pre-existing case law of the Court of Appeals for the Federal Circuit, MedImmune was faced with the Hobson's choice. MedImmune could either refuse to pay licensing fees (and thus creating a risk of owing treble damages and attorney's fees for patent infringement as well as the risk of an injunction), or pay licensing fees for a patent for which it may have owed nothing. MedImmune understandably did not like either option.

Instead, MedImmune gambled on a strategy that was clearly unavailable under existing law. MedImmune paid the royalties Genentech claimed were due under the second patent, but sued Genentech anyway in 2002 for a declaration that it owed no royalties under the license due to patent invalidity, unenforceability, and non-infringement. As 80% of its sales revenue was tied up in Synagis, MedImmune chose not to run the risk of terminating its license and challenging the scope and validity of the patent, as would be required under the law existing at the time. Instead, it placed its hopes in changing the law and effectively bought an "insurance policy" by continuing to pay the royalties called for in the license agreement.

At the lower court levels, MedImmune predictably failed.

Applying well-established Federal Circuit precedent, the District Court and Federal Circuit both dismissed the declaratory judgment action for lack of subject matter jurisdiction at the pleading stage. The courts held that because MedImmune was a patent licensee in good standing, no Article III case or controversy regarding the patent's validity, enforceability, or scope existed. . In particular, the lower courts held that MedImmune had no "reasonable apprehension" of being sued for infringement. Such a "reasonable apprehension" had been held to be a prerequisite for a case or controversy.

At the Supreme Court, MedImmune main-

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tained that it continued to comply with the license only because of the high risks of terminating the license, including the potential loss of the licensed technology through an injunction on Synagis. An injunction would have been devastating for the company. Effectively, MedImmune argued, its continued compliance was coerced by the severe penalty for failing to comply with the license terms.

Genentech argued that the case should be dismissed because MedImmune had agreed to make royalty payments, although under protest. Thus, Genentech claimed, no case or controversy to establish declaratory judgment jurisdiction existed.

The Court reversed long-standing Federal Circuit precedent, holding 8-1 that a case or controversy within the meaning of Article III of the Constitution existed even though MedImmune did not breach the license. The Court compared the situation to cases in which a party is allowed to challenge a law without violating it. The Court noted that it regularly allows challenges to laws, which, for example, limit speech without forcing the challenging party to break the law and suffer the consequences, so long as they clearly seek to act in violation of the law, and effectively are coerced into compliance due to the penalties of non-compliance.

Citing *Altvater v. Freeman*, 319 U.S. 359 (1943), the Supreme Court maintained that the same approach should apply to patent licenses, even though they do not directly involve government coercion. The main point of *Altvater* was that payment of royalties under "coercive" circumstances does not eliminate jurisdiction. Invoking *Altvater,* the Court held that a licensee such as MedImmune, which faced the loss of 80% of its business if it lost its license, is similarly effectively "coerced" into compliance, and thus should be able to sue for the right not to comply. Just as a citizen need not violate certain laws to challenge them, a licensee need not cease its payment of royalties to create a controversy for purposes of a challenge to patent validity or scope in court.

Justice Thomas' dissent distinguished *Altvater* by limiting its scope to finding that a sufficient case or controversy only existed when a licensee was threatened with an injunction if it stopped payments. The majority dismissed this argument, indicating that a licensee who pays royalties for fear of treble damages and loss of business is no less coerced than a licensee who pays royalties based on fear of an injunction.

### The Effects

The full import of the *MedImmune* decision may not be known for some time as lower courts interpret and apply the Court's opinion to new facts and issues. Some courts may view *MedImmune* narrowly as a simple jurisdictional decision that will not change the underlying merits of a licensee-estoppel defense. Others may read the decision as a matter of specific contractual language giving rise to a case and controversy. Others will surely argue the decision is intended more broadly to give patent licensees the ability and encouragement to challenge patent validity while continuing to pay license fees.

Whatever the eventual limits of the *MedImmune* effect, the decision will almost assuredly have a powerful impact on existing and future patent licenses in the short term. For example, *MedImmune* gives licensees a new and unexpected advantage regarding existing licenses. Existing licensees can now potentially avoid the risks of losing a patent challenge. Few of the licensing arrangements that exist today likely have clauses that contemplate the formerly precluded option of a licensee challenging a patent while paying under the licensee. Instead, it seems that existing licensees, who may have had to pay higher royalties had the licensor known the licensee could challenge the patent, have received a windfall.

For example, *MedImmune* potentially flips the tables on patent holding companies that have traditionally had little to lose and much to gain in threatening patent litigation. Generally, a patent holding company holds a bargaining advantage against a potentially infringing company when the holding company threatens suit. The potential infringer faces the prospect of an injunction, significant (or even treble) damages, and considerable attorney fees, any of which could be potentially devastating to the company. The holding company, on the other hand, has a significantly lower downside – mainly attorney fees, which can be mitigated through contingent fee agreements. Because the holding company does not have products of its own, there is no risk of a countersuit for patent infringement.

Often, a threatened company will accept a patent license even for patents of dubious validity simply because the risks of losing a lawsuit are too high. After *MedImmune*, however, existing licensees potentially have the upper hand. The licensee has an insurance policy in that the royalty fees in the license have effectively capped its potential damages. The patent holding company, on the other hand, faces the prospect of losing its revenue stream from one (or even all) of its licensees and/or having its patent invalidated. An increase in challenges to patent validity by licensees (and especially by groups of licensees) would appear likely in the short term.

Whether such challenges will be effective is yet to be determined. MedImmune effectively allows the licensee through the front door of the courthouse to challenge the license. The Court expressly did not decide, however, whether a challenging licensee, once in court, is still precluded from challenging validity or infringement by principles of licensee estoppel. Thus, the decision may present good and bad news for licensees: you can bring a lawsuit, but you will lose. However, it is unlikely that licensee estoppel will completely bar licensee challenges. For example, relevant to *MedImmune,* a licensee who continues to pay royalties for one product but refuses to pay for a second product will likely be allowed, at a minimum, the right to challenge the need to pay royalties on the second product. Whether such challenges will be allowed, or be allowed regarding both validity and infringement, remains to be seen.

Looking forward, the terms of licensing deals will likely significantly change after *MedImmune*. Parties, especially licensors,

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will address the impact on the license when licensees sue to declare the patent invalid or not infringed. The pre-*MedImmune* barrier to licensee litigation may be replaced by contractual disincentives to litigate. For example, a patentee may request a provision that allows for termination of the license if the licensee brings suit, thus reopening the door to treble damages, attorney's fees, and an injunction if the former licensee continues to practice the patented technology. Or, the license may state that a suing licensee's royalty increases in the event of a patent challenge. Another possible arrangement is a preset penalty, such as liquidated damages or trebled royalties and attorney's fees, should the licensee lose the challenge. Such contract provisions would alleviate both the licensee's concern that it is not getting a license to a rightfully patented product and a licensor's concern that it will be unfairly subjected to suit.

One unintended consequence of the decision is that it may discourage licensing in favor of litigation. A patent owner may feel compelled to bring suit and induce counterclaims regarding validity and enforceability before entering a license, and then settle the case with a license. If there is litigation that is settled with a licensing arrangement, the accused infringer/licensee may be bound by *res judicata* principles from challenging the patent in the future. Or patentees may seek to secure admissions of validity from licensees.

Ultimately, the decision may lead to more litigation. Litigation may be initiated more often before a license is pursued, in the hopes that a later license agreement would be viewed as part of a settlement of disputed claims and thus bar future challenges to the patent. However, once the lawsuit is commenced, it may lead to litigation that would not have occurred otherwise should the parties be unable to reach a license agreement.

Because of the advantages given to licensees, licensors may be more wary of entering licenses. They may demand higher royalties or new, onerous terms to compensate them for this new risk. Potential licensees may balk at such demands, leading to an impasse. The result would be fewer instances of technology transfer, and perhaps more litigation between parties unable to reach agreement out of court.

*MedImmune* has changed the rules of the patent licensing game. The reversal may be viewed as part of a more general trend placing more pressure on patent owners. Several amicus briefs filed advocated the reversal to encourage more challenges to the scope and validity of patents. These amici contended that commerce is burdened and innovation stifled by the unchallenged enforcement of unwarranted patents on obvious inventions (such as certain business methods). Amici contended that innovation and businesses would benefit by making it easier for licensees to challenge patents. However, the change may also bring additional changes, such as more litigation.

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