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Creative Strategies for Licensors Post-*MedImmune*

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A groundbreaking 2007 decision of the Supreme Court has forced licensors and their attorneys to re-examine standard licensing terms and develop new creative strategies. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), addressed the right of a licensee of an issued patent to seek a declaratory judgment stating that the patent is invalid, unenforceable or not infringed. The Court held that it is not necessary for the licensee to break or terminate its license agreement with the licensor in order to seek such a declaratory judgment.

Prior to the *MedImmune* decision, in order for the licensee to seek such a declaratory judgment, it would typically first have to break the license (for example, by refusing to make royalty payments) or terminate the license agreement. Such action by the licensee would be necessary because, with a valid license agreement in effect, the licensee would have no "reasonable apprehension" of suit in connection with its commercialization of a product covered by the patent and, thus, no standing to bring the action. Under this scenario, the licensee would have to make a difficult decision. Its failure to pay royalties could result in both the termination by the licensor of the entire license agreement (including with respect to patent rights not in dispute) and an infringement claim by the licensor against the licensee if the licensee commercializes the potentially infringing product.

Post-*MedImmune*, though, a licensee can both challenge an issued patent and still maintain an "insurance policy" in the form of the license agreement, substantially reducing the risks inherent in being required to break or terminate the license agreement in order to assert the patent challenge.

The *MedImmune* Case

MedImmune, Inc., manufactured Synagis, a drug used to prevent respiratory tract disease in infants and young children. In 1997, MedImmune entered into a patent license agreement with Genentech, Inc. (acting on its behalf and on behalf of City of Hope, its patent co-owner) pursuant to which Genentech licensed to MedImmune rights to an existing patent (Cabilly I) and a pending patent application (Cabilly II). MedImmune agreed to pay royalties to Genentech for products that, absent the license, would infringe one or more claims of the licensed patents. Thereafter, the Cabilly II application was issued as a patent and Genentech notified MedImmune that since Synagis was covered by the issued Cabilly II patent, MedImmune must commence royalty payments to Genentech. MedImmune, however, believed that the Cabilly II patent was invalid and unenforceable and that Synagis did not infringe Cabilly II, so that, in any event, no royalty was owed.

MedImmune considered the notice from Genentech to be a clear threat from Genentech of its intent to enforce the Cabilly II patent, terminate the license agreement and sue for patent infringement if MedImmune did not make the demanded royalty payments. If Genentech prevailed, MedImmune could be enjoined from selling Synagis (which accounted for 80 percent of its revenues) and required to pay treble damages and attorneys' fees

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for willful infringement. In light of the dire potential consequences for failing to pay the royalties, MedImmune decided to pay the royalties and maintain the license agreement, although it did so under protest and with a reservation of rights.

MedImmune then sought a declaratory judgment in the Central District of California that the Cabilly II patent was invalid, unenforceable and not infringed by Synagis. The District Court dismissed the case and the United States Court of Appeals for the Federal Circuit affirmed, stating that a nonbreaching patent licensee had no standing and cannot bring such an action because it does not have any "reasonable apprehension" of suit (i.e., as a licensee it does not fear that it will face an infringement suit) and thus there is no "case or controversy" for purposes of the Declaratory Judgment Act. In a stunning decision, though, the Supreme Court overruled the prior decisions in this matter and held that MedImmune did have standing to bring the action, even if the license agreement remained in effect and MedImmune continued as a licensee from Genentech.

Fallout from *MedImmune*

Following the *MedImmune* decision, licensors have favored provisions in license agreements that are designed to disincentivize licensees from challenging a licensed patent. While the Supreme Court's long-standing decision in *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969), invalidates efforts to estop a licensee from bringing a patent challenge, other drafting solutions could and should be considered. In particular, provisions that are triggered by a licensee patent challenge are helpful.

The first drafting issue to consider is the definition of a "patent challenge." A patent challenge could be defined broadly to include any challenge with respect to the validity, scope or enforceability of a licensed patent, in any country, whether in judicial or patent opposition proceedings or otherwise. Such a challenge could include, without limitation, a licensee directly or indirectly filing a declaratory judgment, citing prior art, filing or commencing any re-examination, opposition, cancellation, nullity or similar proceeding, or provoking or becoming party to an interference. More broadly, "patent challenge" could include any threat by the licensee to do any of the foregoing and could also cover actions by the licensee's affiliates and sublicensees.

To discourage a licensee patent challenge, a clause in the license agreement could provide that, as a consequence of a patent challenge, the licensor has the right to terminate the license agreement, either in whole or in part, upon notice to the licensee. The license agreement could also include a clause that permits the licensor to convert an exclusive license grant to a non-exclusive license grant, narrow the field of use (e.g., diagnostics, therapeutics, human, animal, specific indications) in which the license may be practiced or reduce the geographical territory covered by the license grant, thereby exposing a licensee to potential infringement for anything not covered by the reduced license scope.

With respect to royalties, a clause in the license agreement could provide for an increased royalty rate (or increased rates, in the case of graduated or tiered royalties) in the event of a patent challenge. The increased rates could be made retroactive to the first commercial sale of a product covered by the patent (even if this occurred prior to the date of the patent challenge) in the event that the licensor is successful on the merits of the case. Similarly, the license agreement could provide for additional or increased milestone payments in the event of a challenge. Again, retroactivity could be addressed.

Another clause to consider is one requiring the licensee to reimburse the licensor for its reasonable attorneys' fees and out-of-pocket expenses incurred in connection with the patent challenge. More reasonably, this clause would be triggered solely if the licensee is not successful with respect to the challenge. This clause could, of course, be included along with one or more of the other clauses provided above.

It should be noted that the provisions described above and many other contractual solutions have not been fully tested in the courts in a post-*MedImmune* context, and enforceability remains an open issue. For example, the enforceability of a provision allowing a licensor to terminate a license agreement in connection with a patent challenge may be looked upon as contrary to the public policy enunciated in the *Lear* decision of encouraging challenges to invalid patents. Undoubtedly, these issues will play out in the courts as post-*MedImmune* case law becomes more defined in the coming years. ■