Column
IP Lawyer

Written by
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More freedom for licensees after Supreme Court decision

With their recent *MedImmune v Genentech* judgment, the nine Supreme Court justices have changed the licensing landscape in the US

The United States Supreme Court issued a decision in *MedImmune Inc v Genentech Inc* on 9th January 2007, holding that a patent licensee was not required to terminate or breach the licence agreement prior to seeking declaratory judgment of patent invalidity or non-infringement.

MedImmune manufactures Synagis, a drug used to prevent respiratory tract disease in infants and young children, using monoclonal antibody technology licensed from Genentech. The patent licence agreement with Genentech covered an existing patent (Cabilly I), and a then-pending patent application which eventually issued as the Cabilly II patent. Upon issuance of the Cabilly II patent, Genentech delivered a letter to MedImmune indicating that Synagis was subject to royalty payments in accordance with the licence agreement. In an effort to avoid potential infringement litigation, MedImmune informed Genentech that it planned to pay the royalties, but only under explicit protest and with reservation of all rights. Subsequently, MedImmune filed a declaratory judgment action, seeking to have the Cabilly II patent declared invalid, unenforceable or not infringed.

The United States Declaratory Judgment Act permits a court to declare prospectively the rights, duties or obligations of the parties to a dispute, provided there is a "case of actual controversy". The issue presented in *MedImmune* (or any declaratory judgment case) ultimately becomes one of standing under Article III of the US Constitution, ie, whether there exists a "controversy" in the absence of a material breach of a patent licence agreement.

The district court, as well as the United States Court of Appeals for the Federal Circuit, dismissed MedImmune's claims on the grounds that a licensee in good standing is prohibited from filing a declaratory judgment action against its licensor due to failure to satisfy the Article III "case or controversy" requirement because the patent licence agreement, and the licensee's compliance with it, removes any reasonable apprehension that the licensee will be sued for infringement.

The Supreme Court reversed, holding that a plaintiff threatened with possible harmful action does not surrender the right to challenge the legal basis for that action when the steps it takes to avoid the harm are coerced. Justice Scalia further opined that the very purpose of the Declaratory Judgment Act was to ameliorate coercion that would force a challenger to make the difficult choice to abandon his defences or risk being sued. If Genentech were to prevail in an infringement action following a breach of the licence by MedImmune, MedImmune could be held liable for treble damages and attorney fees, and sales of Synagis (which account for more than 80% of MedImmune's revenue) could be enjoined. This being so, the royalty payments to Genentech were, the Court found, effectively coerced, thereby allowing jurisdiction for a declaratory judgment action.

Thus, the court found the requirement of a case or controversy is met whenever payment is demanded as of right, because "the involuntary or coercive nature of the exaction" operates to preserve the licensee's legal rights.

Implications of the decision

The *MedImmune* case required the Court to weigh a number of countervailing public policy considerations regarding licence agreements and patent policy. For instance, there is a significant public policy in favour of patent licensing as a means to reduce litigation and foster judicial efficiency. Conversely, there is an equally compelling policy consideration in favour of helping expunge invalid patents by permitting licensees to challenge the validity of a licensed patent.

Having examined this conundrum, the Court decided that "the promise to pay royalties on patents which have not been held invalid does not amount to a promise not to challenge their validity". Consequently, the *MedImmune* decision may render patentees susceptible to a greater number of validity disputes initiated by non-breaching licensees, thereby increasing the uncertainty, risk and litigation expenses associated with patent enforcement. This in turn may induce patentees prospectively to demand greater royalty fees, or to develop variable fee structures, in order to compensate for the increased risk of litigation.

The increased cost of litigation to the patentee and the increased royalty fee to the licensee could serve as a market barrier to some entities or could ultimately be incorporated into the price of licensed products. Alternatively, patentees may begin including standard language in licence agreements requiring licensees to waive their right to challenge validity. Whether such a provision would be enforceable has yet to be determined.

The *MedImmune* decision may well have further ramifications with respect to communications directed towards potential infringers because an additional footnote to the decision included comments broadly but non-specifically critical of the Federal Circuit's overall jurisprudence on what statements by a patentee gave rise to a "reasonable apprehension of suit", as required for jurisdiction under the Declaratory Judgment Act. Patentees may need to use precise and guarded language in demand letters or licence offers in order to prevent the potential infringer from construing the communication as creating a reasonable apprehension of litigation, thereby exposing the patentee to a declaratory judgment action. The potential infringer, as nominal plaintiff in the declaratory suit, would be entitled to choose the forum of the suit, which could impose additional expenses on the patentee such as travel expenditures and local counsel fees, and could further face it with unfavourable local procedures or jury pools.

Likewise, the due diligence involved in an assignment or patent purchase agreement will require further scrutiny of any outstanding licence agreements to assess the extent to which a licensee is entitled to challenge validity.

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