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Kenyon & Kenyon LLP

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The implications of *MedImmune v Genentech*

By **Jeffrey M Butler** and **Ashton J Delauney**,
Kenyon & Kenyon LLP, New York

“You can’t have it both ways.” Not so (at least if you are a patent licensee), declared the United States Supreme Court in its 9th January 2007 decision in *MedImmune Inc v Genentech Inc*. In its eagerly anticipated opinion, an eight-to-one majority of the Court decided that a patent licensee can sue to challenge the validity of the underlying patent even while continuing to comply fully with the terms of the licence. This decision eviscerated the bright-line rule previously formulated by the Court of Appeals for the Federal Circuit, the specialised court that is the exclusive US appellate court in patent cases, which held that a patent licensee needed to materially breach its licence agreement (such as by terminating royalty payments) and thereby possess a reasonable apprehension of a suit for patent infringement before it could challenge the validity of the patent in a US district court. The Supreme Court’s decision significantly impacts the bargaining leverage that patent owners and potential licensees bring to the table in licensing negotiations.

The road to the Supreme Court

In 1998, MedImmune Inc developed an antibody drug, marketed as Synagis®, to treat respiratory tract diseases in infants. MedImmune had earlier entered into a licence agreement with Genentech Inc covering an existing Genentech patent and a then-pending application relating to technology for producing therapeutic antibodies.

Shortly after Genentech’s pending application issued as the “Cabilly II” patent in 2001, Genentech requested that MedImmune also pay royalties under that patent. MedImmune believed that the Cabilly II patent was neither valid nor enforceable nor infringed by Synagis®. Nevertheless,

failure to pay the demanded royalties would mean that Genentech could terminate the licence agreement and sue for patent infringement. Were Genentech to prevail in that suit, MedImmune potentially could face trebled damages for wilful patent infringement, an order to pay Genentech’s attorney fees and an injunction to stop sales of Synagis®. Unwilling to assume these potentially catastrophic risks, MedImmune proceeded to pay the demanded royalties “under protest and with reservation of all of [its] rights”. MedImmune also filed suit under the Declaratory Judgment Act (a DJ action), seeking, among other things, a declaration from the District Court of Central California that Cabilly II was invalid, unenforceable and/or not infringed by Synagis®.

In order for a US federal court to have jurisdiction to adjudicate a DJ action – and declare the rights of the party seeking such declaration – there must be a “case of actual controversy”. This requirement, set forth in the Declaratory Judgment Act, effectuates Article III of the United States Constitution, which authorises the courts to hear only justiciable cases or controversies. Courts are not empowered to give advisory opinions. Genentech moved to dismiss the MedImmune suit on the ground that, because MedImmune was a licensee in good standing – ie, it had not breached its licence agreement and could not, therefore, be sued for patent infringement – there was no actual controversy. Genentech’s argument was based on a series of decisions by the Federal Circuit, most recently in *Gen-Probe Inc v Vysis Inc*, which held that, for an actual controversy to exist, thereby vesting a court with jurisdiction to entertain a DJ action by the licensee, the licensee must have materially breached the agreement and consequently possessed a reasonable apprehension of a lawsuit by the licensor.

Though it expressed reservations about the Federal Circuit’s *Gen-Probe* decision, the

district court was obliged to follow the appellate court's precedent and dismissed MedImmune's DJ action for lack of jurisdiction. On appeal, the Federal Circuit affirmed the district court's decision, and the Supreme Court accepted review of the Federal Circuit's ruling.

The Supreme Court's opinion

Writing for the Court, Justice Scalia reasoned that there was a substantial controversy of sufficient immediacy to trigger court jurisdiction, even though MedImmune continued to make royalty payments under the licence agreement. Justice Scalia relied on *Altwater v Freeman*, a previous Supreme Court decision on a DJ action, which held that, although a licensee had maintained payments of royalties, a DJ claim of invalidity of the licensed patent still presented a justiciable case or controversy. The Federal Circuit had not followed the *Altwater* ruling on the basis that the licensee in that case had continued paying royalties under the compulsion of a court injunction decree, rather than freely choosing to paying royalties as MedImmune had done. However, Justice Scalia reasoned that *Altwater* still applied, and concluded that the reasonable-apprehension-of-suit rule espoused by the Federal Circuit which required that a plaintiff "bet the farm, or (as here) risk treble damages and the loss of 80 percent of its business, before seeking a declaration of its actively contested legal rights finds no support in Article III". Accordingly, the Court held that MedImmune was not required to breach its licence agreement before seeking a declaratory judgment that the underlying patent was invalid, unenforceable or not infringed.

Justice Thomas dissented. Noting that MedImmune was under no threat of being sued by Genentech for patent infringement and that patent invalidity is an affirmative defence to patent infringement, not a freestanding cause of action, he expressed the view that MedImmune was merely seeking an advisory opinion from the courts: "MedImmune wants to know whether, if it decides to breach its licence agreement with Genentech, and if Genentech sues it for patent infringement, it will have a successful affirmative defence." Justice Thomas noted that the Supreme Court itself had "consistently held that parties do not have standing to obtain rulings on matters that remain hypothetical or conjectural".

Implications of the Supreme Court's decision

The Supreme Court's decision in *MedImmune v Genentech* has profound business

implications for patent owners and licensees. A licensee often has the greatest interest and economic incentive to challenge the validity of a patent since, in a typical case, it is the party that felt a need to obtain a licence and that is burdened by paying royalties for the patented technology. The *MedImmune* decision effectively gives a licensee *carte blanche* to contest the validity of the licensed patent, while ensuring only potential upside to such action: if the patent is declared invalid, the licensee is freed of its royalty obligations; if the patent's validity is upheld, the licensee merely continues paying the royalties that it had contracted to pay. Previously, a licensee would be less inclined to sue, since under the Federal Circuit's rubric it would first have to breach the agreement and thereby risk being sued by the patent owner for patent infringement. Under *MedImmune*, the licensee's right to sue to invalidate the patent is in many respects unilateral since, by virtue of the licence, the patent owner can neither sue for patent infringement nor assert a counterclaim of patent infringement in defence of the invalidity suit. The decision seems, therefore, to decisively favour licensees (many of which may be smaller companies that rely on licensed technologies) over patentees (many of which may be larger patent-owning corporations, as well as universities and research institutions that generate revenues by licensing their patented inventions).

The incentive to sue provided by the *MedImmune* decision will likely lead to an increase in litigation as licensees more frequently seek to contest the validity of licensed patents. In many cases, the licensee will have acquired information under the licence that it can then use to challenge the validity of the underlying patent. It may also have used the licensed technology to produce and sell a commercial product(s), thereby building up its financial resources in order to more effectively challenge the patent. *MedImmune* and various *amicus curiae* argued that many questionable or 'weak' patents have issued. Whether it was intentional or not, an effect of the *MedImmune* decision will be to incentivise challenges to 'weak' licensed patents. However, it seems doubtful that the benefit to society at large in having some number of dubious patents invalidated will outweigh the improvidence of an upsurge in unsuccessful challenges to valid patents that result from the inevitable attempts of certain licensees to escape their contractual obligations.

For its part, and in view of *MedImmune*, a patent owner may be less willing to grant

licences since it bears all the risk of increased litigation. This may have a chilling effect on the exploitation and commercialisation of patented inventions. Moreover, when it does grant a licence, a licensor likely may demand a royalty premium to compensate for the increased risk and expense of defending an invalidity challenge by the licensee. However, the pricing of this premium will be tricky due to the uncertainties inherent in trying to accommodate cooperative licensees versus those that will be inclined to challenge the validity of the licensed patent. In addition, the transaction costs associated with licence agreements might increase if, as is likely, both patent owner and licensee expend more resources on evaluating the validity of a patent prior to licensing. Patent owners might also be incentivised to settle licensing disputes on terms they might not otherwise have found acceptable in order to avoid a patent invalidity challenge.

The impact of the *MedImmune* decision on patent litigation may extend beyond the licensee-licensor relationship, and, for example, into the area of generic drugs. Generics manufacturers were among the parties that filed amicus briefs in the *MedImmune v Genentech* case in support of *MedImmune*. This was not surprising, considering that a decision favourable to *MedImmune* could be very helpful to generics companies. The Supreme Court's *MedImmune* ruling opens up the possibility that would-be Abbreviated New Drug Application (ANDA) filers will be able to establish jurisdiction in a DJ action to challenge drug patents. This would effectively eliminate the risk to the generic company of having to launch a generic product under the threat of a patent infringement suit.

Filing of an ANDA triggers a 45-day period during which the patent-owning drug company must initiate patent litigation to resolve validity and/or infringement issues, or have the FDA begin the approval process for the generic drug. However, because a generic company that had not yet commercialised its product would not be liable for damages, drug companies often chose to delay filing a suit until after the generic drug had been approved by the FDA and was being marketed. The 2003 Medicare Modernization Act (MMA) provided for a generic company to bring a DJ action, "to the extent allowed by [Article III of] the Constitution", against a pioneer drug company that declined to sue within the 45-

day period. However, the Federal Circuit's reasonable-apprehension-of-suit requirement for standing to bring DJ actions also renders that MMA provision ineffectual. The Supreme Court's repudiation of the reasonable-apprehension-of-suit test in *MedImmune* may facilitate the ability of generic manufacturers to bring DJ actions against pioneer drug companies that fail to sue on their patents within the 45-day window.

The first generic company to file an ANDA also obtains a 180-day period of marketing exclusivity for its generic drug. The clock on this 180-day period is triggered by the first commercial marketing of the generic product, but under the MMA, the exclusivity period is forfeited if the generic company does not commence marketing within 75 days of a final, non-appealable decision that the underlying patent is invalid or not infringed. The *MedImmune* decision may give a subsequent ANDA filer standing to obtain a final court decision on a drug patent, forcing the first ANDA filer to either launch its product or forfeit its exclusivity period. Overall, therefore, *MedImmune* may facilitate the marketing of generic drugs and increase the public's access to lower-cost medications.

Practical tips to protect licensors negotiating licence agreements

The Supreme Court's *MedImmune* decision appears to have considerably strengthened the hand of the party seeking a licence from a patent owner, placing the onus on the licensor to try and ameliorate the impact of this decision. One apparent solution would be for the licensor to insist on a provision in the licence agreement that precludes a licensee in good standing from filing a DJ action alleging patent invalidity, unenforceability or non-infringement. Indeed, during oral proceedings in the *MedImmune* case, Justice Scalia opined that such a provision "would be enforceable... [T]he licensor could raise that contractual provision as a basis for dismissing the suit". Justice Kennedy astutely noted, however, that if such a provision is enforceable, "we may not be talking about much. It's just going to be boilerplate in every licence agreement, and that's the end of it".

In fact, such a provision is unlikely to be enforceable in view of the Supreme Court's 1969 decision in *Lear Inc v Adkins*. In *Lear*, the Supreme Court acknowledged that contract law forbids a purchaser from repudiating a promise because he later becomes dissatisfied with the bargain he made, but noted that this principle needed

to be balanced against the mandate of federal law and patent policy that all ideas in general circulation be freely usable by the public unless protected by a valid patent. Weighing these competing demands, the Court in *Lear* held that “the technical requirements of contract doctrine must yield to the demands of the public interest”. In so doing, the Court abolished the longstanding doctrine of “licensee estoppel”, under which a licensee was prevented from challenging the validity of a licensed patent. Thus, the *Lear* ruling suggests that a provision in a licence agreement depriving a licensee of freedom to contest the validity of a licensed patent will not be enforceable.

On the other hand, a provision that any legal challenge to the patent by the licensee, such as a DJ action asserting patent invalidity, unenforceability or non-infringement, is a condition that allows the licensor to terminate the licence agreement and sue the former licensee for patent infringement may pass muster under the *Lear* ruling. Thus, patent owners would be advised to include such a protective clause in the licence agreement. Another option is the inclusion of a provision specifying that any legal challenge of the licensed patent triggers payment of a higher royalty. The licensor may also require an upfront, lump-sum payment that is forfeited in the event that the licensee launches a challenge to the validity of the patent. The licensor also may require adjustment – to the benefit of the licensor – of other “pre-challenge” licence terms in the event of a challenge by the licensee. It can be anticipated that licensees will contend that such provisions fall foul of *Lear*. Indeed, during oral arguments in the *MedImmune* case, Justice Ginsburg specifically inquired whether the imposition of higher royalty fees if the licensee sued might be an effective way to protect a patent owner from suit by a licensee. Counsel for *MedImmune* responded that such a proposal raised problems as to the scope of the *Lear* decision. In its *MedImmune* decision, the Supreme Court acknowledged that the enforceability of such provisions is an “open question”, but the Court suggested that such provisions may be a fair compromise under *Lear*.

The above strategies, provided they are enforceable under *Lear*, may assist a patent licensor in mitigating the effects of the Supreme Court’s *MedImmune* decision and ensure that a licensee cannot have his cake and eat it too. However, while the licensor may be afforded some protections in future

licence agreements, existing agreements that lack such protective provisions may be destabilised by the *MedImmune* decision, with potentially billions of dollars in lost royalties at stake.

**Kenyon & Kenyon LLP**

One Broadway
New York, NY 10004-1007, USA
Tel: +1 212 425 7200
Fax: +1 212 425 5288

www.kenyon.com

Jeffrey M Butler

Partner
jbutler@kenyon.com

Jeffrey Butler is an attorney at law and a registered patent attorney with extensive experience in litigation and adversarial matters concerning all aspects of intellectual property, including patents, trademarks, copyright, antitrust, unfair competition and trade secrets. He also has significant experience in domestic and international IP licensing, acquisition and exploitation. Mr Butler holds a JD from George Washington University. He has authored and co-authored articles and presented papers, seminars and symposia on numerous IP and litigation topics.

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Ashton J Delauney

Associate
adelauney@kenyon.com

Ashton Delauney has significant experience in a variety of patent-related matters, particularly the preparation and prosecution of US and PCT international patent applications in the biological and pharmaceutical sciences, development of patent portfolios, opinion work and client counselling. Prior to embarking on a legal career, he was a senior lecturer at the University of the West Indies, Barbados, lecturing and conducting research in biochemistry and molecular biology.

Kenyon & Kenyon LLP

One Broadway

New York, NY 10004-1007, USA

Tel: +1 212 425 7200

Fax: +1 212 425 5288

www.kenyon.com