Remedies for Patent Infringement in the Medical Sector

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Patent monopolies in the medical sector have always been controversial, with the need to promote and fairly compensate innovation on the one hand, and to prevent obstacles to the consequent health benefits (and further innovation) on the other. Injuncting or financially penalising a medical product may raise public health issues by having an impact on the availability of treatment. Conversely, patentees need to obtain sufficient reward for the long and expensive research effort needed to get a product to market. Recent cases show a judicial interest in engaging with these issues in a more creative exercise of discretion.

Overview

In a number of recent cases the courts have adopted a flexible pragmatic approach to remedies, seeking to strike a balance between legal rights and the public interest when granting injunctive relief. In May 2018, in *Edwards Lifesciences LLC v Boston Scientific Scimed Inc*,[1] after Boston's patent was held to be both valid and infringed by Edwards, the parties approached the court having agreed that there should be some sort of stay and subsequent qualification on any injunction restraining Edwards to accommodate public health concerns. The court:

- stayed the injunction for 12 months to allow time for clinicians to be retrained to use and adopt a non-infringing product; and
- subsequently qualified the injunction to allow Edwards to supply its infringing product to a limited number of patients for which there was no alternative treatment.

The court also made orders allowing the parties to amend the order should Edwards require a longer stay period for retraining or another non-infringing treatment option arise for the treatment of the special patient group. The case also raises interesting issues about how financial remedies might be calculated when awarded in lieu of an injunction.

When and How the Court May Grant an Injunction

Injunctive relief is an equitable remedy that is subject to the court's broad discretion. This discretion applies both to the court's decision on whether to grant an injunction at all and to the form of any injunction granted. The court may stay the injunction for a period (pending the outcome of an appeal or other time-sensitive circumstances) or qualify its application to a certain period of time or certain conduct. The court also has a discretion to award damages instead of an injunction.[2]

The court's discretion is largely unfettered provided it is exercised within the fairly wide ambit of Article 3 of the European Parliament and Council Directive 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights

[1] [2018] EWHC 1256.

[2] Senior Courts Act 1981, section 50 (and prior to its enactment, applying *Shelfer v City of London Electric Lighting Co* [1895] 1 Ch 287).

('the Enforcement Directive'). As things stand, it is expected that the requirements under the Directive will continue to apply in some form post-Brexit. This directive requires remedies to be:

(1) 'fair and equitable and … not unnecessarily complicated or costly, or entail unreasonable time limits or unwarranted delays'; as well as

(2) 'effective, proportionate and dissuasive … applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse'.

The current legal position in the United Kingdom is that an injunction should ordinarily be granted to stop or prevent violation of a claimant's rights.[3]3 This places a burden on the defendant to argue that an injunction should not be granted.

However, given the broad discretion of the court, there is scope for the defendant to resist an injunction or seek to limit its effect, including by reference to relevant public interest concerns.[4] Ultimately, whether or not an injunction will be granted and the form of that injunction is highly fact-specific and will depend on the circumstances of the case.

The US Position

By way of comparison, in the United States patentees had grown accustomed to expect an injunction as an automatic remedy for patent infringement until *eBay v MercExchange*.[5]

This case returned to the equitable origins of the remedy, requiring plaintiffs seeking an injunction to establish that it is warranted on the basis of a four-factor test. The plaintiff must show that (1) they have suffered irreparable injury for which there are (2) inadequate remedies available at law, (3) the balance of hardships favours the grant of an injunction, and (4) an injunction would not disserve the public interest.

Ultimately, though the tests vary, both the UK and the US courts will consider similar issues and leave some flexibility in granting injunctions. In the United States, given that the grant of an injunction requires the plaintiff to satisfy all four factors in *eBay,* even where damages are an inadequate remedy, it seems that if an injunction would disserve the public interest, it would not be available.

The Market for Transcatheter Heart Valves

In January 2014, Edwards[6] launched a transcatheter heart valve called 'Sapien 3' for the treatment of aortic stenosis, a narrowing of the exit to the left ventricle of the heart and a disease described in the judgment as 'the most common valvular heart disease in the developed world'. Left untreated, aortic stenosis has a very high mortality rate. Transcatheter heart valves

[3] *Coventry v Lawrence* [2014] UKSC 13, 121 (*Coventry v Lawrence*).

[4] *Coventry v Lawrence*, at 122 to 124.

[5] 547 US 388 (2006).

[6] We will refer to the patent infringing parties collectively as 'Edwards' and the patentee as 'Boston'.

are implanted using a procedure known as TAVI, a less invasive alternative to open heart surgery, where the valve is implanted percutaneously using a catheter to guide it through a patient's blood vessel and into the heart.

At the time of the judgment, there were seven transcatheter heart valves approved for use in the United Kingdom. Most valves were self-expanding but the Sapien 3 was balloon-expandable and accounted for 60.7 per cent of the total number of transcatheter heart valves implanted. A significant body of clinical opinion suggested that the Sapien 3 had the best clinical outcome for patients but there appeared to be little hard data to support this.

Boston, the patentee, was not a big player in the TAVI field. Its two transcatheter heart valve devices had been withdrawn from the market and a third, that it acquired, only accounted for a 5.5 per cent market share.

Boston had a patent titled 'Repositionable Heart Valve' that had been found valid and infringed by the Sapien 3 in previous proceedings.[7] Acknowledging that both parties had sought leave to appeal, in the primary proceedings Judge Hacon granted Boston an unqualified injunction restraining the Edwards parties from infringing its patent but stayed this injunction pending the outcome of any appeal. Both parties' appeals were dismissed and the matter of whether there should be any qualification to the original injunction was sent back to Arnold J in the Patent Court.

The court had previously alluded to the need for qualifications to any infringement remedy and the parties agreed that the injunction imposed on Edwards should be stayed for a period and subsequently qualified for a further period. The length of the stay and how the injunction should be qualified were at issue. A key consideration on both issues was one of public interest, namely, the impact that an unqualified injunction could have upon the health of aortic stenosis patients.

Balancing the Public Interest and the Rights of a Patent Owner

Given that any delay or qualification on the injunctive relief sought would partly deprive Boston of a remedy ordinarily available to it, Arnold J characterised the remedy determination as a proportionality exercise. That is, the court was required to 'strike a balance between Boston's interest in maintaining the monopoly conferred by Boston's patent and the public interest in ensuring that patients with aortic stenosis receive appropriate treatment'.

On the monopoly side, it was relevant that:

(1) there was no suggestion that Edwards' continued supply of the Sapien 3 would cause Boston harm that could not be compensated by a financial remedy; and

[7] *Edwards Lifesciences LLC v Boston Scientific Scimed Inc* [2017] EWHC 405.

(2) there was no evidence to suggest that Edwards could not meet whatever financial remedy was imposed at the quantum hearing.

On the public interest side, Edwards pointed to the need to ensure that appropriate TAVI procedures remained available to patients.

Length of the Stay

Edwards' evidence demonstrated that clinicians were experienced with the particular device they used and could not cease performing TAVI procedures with the Sapien 3 overnight. Time would be required to retrain clinicians and adopt a new non-infringing device in clinics.

As the time required for this transition was uncertain, Arnold J granted an initial stay on the injunction of 12 months and permitted Edwards to apply to extend the stay should the necessary transition require more time.

Qualification

There were a small number of aortic stenosis patients for whom the Sapien 3 was the only treatment option. To protect the health of these patients, Arnold J therefore qualified the injunction to allow Edwards to supply the Sapien 3 valve to these patients. The court proposed that a declaration should be provided by a responsible clinician, certifying that there were no alternative treatments, before the Sapien 3 would be made available. To account for a potential non-infringing treatment alternative for these patients entering the market, Arnold J permitted Boston to apply to terminate the exception should these circumstances arise.

Where To Next?

Tailored remedies are a positive judicial development in facilitating the adaptation of traditional legal concepts to changing social issues. The courts have demonstrated that injunctions can be very flexible for this purpose but they are very fact-dependent.

In *Regeneron Pharmaceuticals Inc v Kymab Ltd*,[8] the court qualified a final injunction to allow Kymab to use infringing antibody-producing transgenic mice to make non-infringing mice to preserve a number of technical advances that were not related to the Regeneron's patented invention. Further, the court stayed the final injunction and order for delivery up or destruction, pending Kymab's appeal, on the basis that these orders would cause serious loss and damage to Kymab, including a serious disruption to collaborations for the development of antibodies to treat a number of diseases for which there was a significant unmet clinical need, and diseases affecting developing countries. Acknowledging that certain collaborations represented a lost opportunity for Regeneron, the court made the stay conditional on an undertaking from Kymab not to commercialise any product developed under these partnerships prior to the determination of its appeal and not

[8] [2018] EWCA Civ 1186.

to enter into any new collaborations. In the event that Kymab's appeal was unsuccessful, the court granted Regeneron liberty to apply for an injunction to restrain Kymab from securing any springboard commercial advantage from its interim infringing activities upon expiry of Regeneron's patents.

An injunction has also been refused in a case involving a generic where, due to the variability in production, only a small number of products would be infringing.[9] Ultimately, in that case, the court determined that the number of infringing products that would be produced was *de minimis* and therefore there was no threat that the parties would infringe the patent. The court commented that, had the number been small but not *de minimis*, the court would refuse an injunction on the basis that the harm to the patentee was much less than the harm to a defendant if an injunction was granted and an injunction would be a barrier to legitimate trade.

In another medical case, if a patentee had a significant market share, the balancing of interests might lead to a different result from that in *Edwards v Boston*. However, there does seem to be a trend in the courts to seek to protect the interests of patients. If the patentee has recently launched a product with potential but low market share, an injunction might be important to preserve the opportunities to lead the market. However, if a competitor could get a product to patients faster or in an improved form, that might weigh against an injunction.

Tailored Financial Remedies

The courts are able to grant financial remedies in lieu of an injunction, in other words, compensation for future infringement. Where compensation for future acts is to be awarded, it is clear that damages can be sought but not currently clear whether an account of profits is available. Further decisions in the *Edwards v Boston* case may clarify this.

Damages for Future Infringement

Jaggard's case[10] held that damages for future infringement should be decided on a 'once and for all basis', suggesting a lump sum would be the appropriate reward. The reason for this was so that all future acts would be dealt with and could not be the subject of future litigation.

An assessment of such a lump sum would generally apply the same principles as those applied to damages for past infringement, that is, by considering what amounts would have been agreed between a willing licensor and licensee, what Arnold J has called 'negotiation damages' or what could reasonably be demanded.[11] Damages for future infringements, however, attract the additional burden of considering what amount would be agreed between a willing licensor or

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[9] *Napp Pharmaceutical Holdings Ltd v Dr Reddy's Laboratories (UK) Ltd* [2016] EWHC 1517.

[10] [1995] 1 WLR 269.

[11] *Force India Formula One Team Ltd v I Malaysia Racing Team Sdn Bhd* [2012] RPC 29, 386.

licensee for any future infringing acts that a defendant might commit.[12]

The courts have recognised in *HTC Corporation v Nokia Corporation*[13] (a telecoms case) that it is difficult to decide on a lump sum when the patent has a long way to run before it expires; the sum would most likely be too high or too low. The judge in *HTC v Nokia* suggested that a possible solution is to order a running royalty. The judge acknowledged that awarding an ongoing royalty would raise the difficulty of the court having to decide on other terms of the licence, such as audit provisions. Nonetheless, in the later Unwired Planet case,[14] the High Court grappled with a similar issue and found a way of guiding the parties as to what licence terms are acceptable by approving a particular form of licence.

An Account of Profits for Future Infringement

In *GSK v Wyeth*,[15] the court entertained the idea of an account of profits for future infringement. In that case, the court refused to order an account of profits for future infringement because the patentee had not originally sought an injunction (given public health issues) and was therefore not entitled to apply later for an account of profits in lieu of an injunction where the defendant would have had no warning that this remedy was sought. Interestingly, this reasoning did not apply to the claim for compensation for past infringement and the court considered it would be wrong to deprive the patentee of its election of an account for past infringement by reason of its decision not to seek an injunction in these circumstances. The court considered whether an account of profits would be available for future infringement assuming it had the power to award this remedy but it did not decide the point.

Carr J indicated that a basic principle relevant in awarding an account of profits is some unconscionable or improper conduct. Given that the continuing supply of the infringing medical product was in the public interest, Carr J concluded that continued sales were not unconscionable, opening up the possibility that an account would not be available where an injunction was stayed, qualified or refused on public interest grounds.

These comments may also be relevant to compensation for past infringement. Normally the patentee has the right to elect between damages and an account of profits (having had some access to the infringer's figures to inform that decision).

There has been limited judicial consideration of the impact of the public interest but Carr J's comment suggests a court might refuse an account of profits in respect of future or past infringement if conduct had not been unconscionable. This is a useful reminder that, despite the election, an account remains a

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[12] *HTC Corporation v Nokia Corporation* [2013] EWHC 3778 at [13].

[13] 2013] EWHC 3778.

[14] *Unwired Planet v Huawei* [2017] EWHC 711.

[15] [2017] EWHC 9.

discretionary remedy, so a patentee should consider all the circumstances and any grounds on which a remedy might be refused before making its election.

Interestingly, Carr J also observed that the effect of an account might be the same as an injunction, noting that where all or a substantial proportion of the profits have to be handed over, the infringer will either need to continue making the product without profit or will have to cease selling it. Arguably, where an injunction is inappropriate on the basis of public interest concerns, it would not be in the public interest to grant a financial remedy that would cause the infringer to cease the necessary infringing conduct because they could not afford to continue.

The court in GSK v Wyeth concluded that it was for the trial judge (who originally heard the case) to decide whether damages for future infringement might be awarded in the form of:

- lump sum;
- periodical payments;
- deferred retrospective award; or
- some other mechanism.

In *Edwards v Boston*, damages (or an account of profits) for both past and future infringement will be assessed at a future hearing but the court made an interim award of 5 per cent of net interim sales.

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