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Is an Injunction always appropriate?

Public interest is at the heart of the matter

The patent system exists to balance seemingly contradictory objectives; promoting innovation and the disclosure of inventions for the public good (including in relation to the health of the public), in return for a limited monopoly period granted to the inventor that will temporarily restrict competition in the market. However, an increasing number of life sciences cases are coming before the UK Patents Court, where a party that is found to infringe a valid patent nevertheless argues that it should be able to continue those acts because it is in the public interest to do so.

In this article we discuss two such cases in which the UK Patents Court has sought to balance these competing factors and interests, comparing the recent ***Evalve & Abbott v Edwards***[1] (***Evalve***) decision and the judgment in ***Edwards LifeSciences v Boston Scientific***[2] (***Boston***), and drawing out the legal principles which determine when the public interest should be engaged in withholding or qualifying injunctive relief.

Evalve & Abbott v Edwards

Validity and infringement trial

In the first of two judgments handed down on 12th March 2020, Mr Justice Birss ruled that Abbott's two medical device patents for the treatment of a heart condition called mitral valve regurgitation were valid and infringed by Edwards' transcatheter device, PASCAL. Mitral valve regurgitation is a condition where the valve in the heart from the left atrium leading into the left ventricle is unable to close fully and prevent blood flowing the wrong way, back into the atrium. The condition is relatively common but can be serious: those patients with progressive mitral valve regurgitation have a poor prognosis and without treatment may die within a year of diagnosis.

Abbott's patents relate to a successful product called the MitraClip, which operates by clipping the leaflets of the mitral valve together to reduce the backflow of blood through the valve. Prior to the MitraClip, the only effective treatments involved open heart surgery, which carries significant risks, particularly for elderly patients, who make up a large proportion of those with the condition.

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1 *Evalve Inc., Abbott Cardiovascular Systems Inc., & Abbott Medical U.K. Limited v Edwards Lifesciences Limited [2020]* EWHC 513 (Pat) (Validity and infringement) and 514 (Pat) (Public interest)
2 *Edwards Lifesciences v Boston Scientific* [2018] EWHC 1256 (Pat)

PASCAL works in broadly the same way as the MitraClip, although it has some small but clinically relevant differences in terms of the design of the clip and the materials used to produce it.

Public interest trial

The second of the Evalve judgments dealt with the outcome of the separate trial concerning public interest issues, which took place a month after the main trial. Edwards contended that, even if the Abbott patents were held valid and infringed, no injunction should be granted. If the court did order an injunction, Edwards argued that it should be qualified so that the PASCAL device could still be provided to certain patients for whom, in the opinion of the doctor, the PASCAL was more appropriate. Finally, if the court refused this, Edwards requested that the order contain a carve-out so that the PASCAL device could be supplied to those patients for whom a MitraClip implantation had been tried but had been unsuccessful. Abbott was content for any injunction to contain such a carve-out, but did not agree with the other qualifications to the injunction proposed by Edwards.

Birss J noted that the legislature already limits patent rights in order to safeguard the public interest, including the availability of compulsory licenses (under certain conditions) as well as the power to make life saving treatments available to the public without the permission of a patentee via the Crown use scheme. He likened seeking to invoke the public interest as a reason to withhold an unqualified injunction to seeking to obtain a compulsory, royalty bearing licence, but without having established the grounds set out in the Patents Act. In this case, the relevant ground would be that there was a market demand that was not being met because there existed a category of patients for whom the MitraClip was unsuitable. However, under the compulsory licensing regime, the patentee would have three years to meet this market demand before such a licence would be granted.

Principles to be applied when assessing injunctive relief and the public interest

After considering the legislation governing the availability and enforcement of patents and the existing case law on public interest in patent decisions, the judge looked to the grant of injunctions more generally as a remedy in tort and helpfully set out a series of principles, which can be summarised as follows:

1. The starting point is that the patentee is entitled to an unqualified injunction to prevent the infringement until the expiry of its valid patent;

2. The defendant bears the burden of giving reasons why such an injunction should not be granted;

3. All the circumstances should be considered. The public interest, such as the impact on third parties, is a relevant consideration;

4. The public interest may justify refusal or carve-out from an injunction, and an award of damages *in lieu*;

5. The patent system already contains several provisions which strike balances between conflicting public interests;

6. While monopolies are generally against the public interest, the patent monopoly is something which is in the public interest to protect by the grant of an injunction, in order to further the purposes of the system as a whole, such as the promotion of investment and innovation; and

7. The legislator is better equipped than the courts to examine the tensions between different public interests. The jurisdiction of the courts to refuse or qualify a patent injunction is not there to redraw the balance and should be used sparingly and in limited circumstances.

In applying these principles to the clinical setting, the judge highlighted the fact that the patent system does not allow patents to cover methods of treatment, so that doctors are allowed the freedom to decide what treatment is best for their patients. However, the patent system *does* serve to limit the range of devices and drugs available to doctors in exercising their judgment. Birss J confirmed that while there might be clinically tangible differences between the two products, such that doctors might reasonably *prefer* the defendant's device over the patentee's product, this is not in itself sufficient to justify refusing or qualifying an injunction. In order for the public interest to be engaged in this way, the case at hand must be concerned with serious medical conditions, and in his view, perhaps only life-saving treatments.

As Birss J later explained:

"85 … What is required is sufficient objective evidence to find that there are in fact patients who ***ought not to be treated*** *using the available product from the patentee but who could, in the reasonable opinion of a body of doctors, be treated using the rival's product."*

The judge concluded that Edwards had not even sought to prove that there was an objectively defined body of patients for whom the PASCAL device would be the only suitable treatment. There was no clinical trial data available that compared the PASCAL and the MitraClip, nor any evidence demonstrating that the MitraClip could not be used for any of the categories of patients Edwards had identified. Any carve-out permitted in the circumstances would merely serve to allow doctors to exercise their clinical judgment to use the PASCAL in preference to the MitraClip, where in fact the latter would be perfectly adequate in almost all cases. To do so would result in losses for the patentee and would "undermine the purpose of the patent system itself." He granted the injunction in the terms that Abbott sought.

The sole qualification to the injunction allowed that, where implantation of the MitraClip has been unsuccessful but a doctor reasonably believes that the PASCAL would be an appropriate treatment to try after that failure, then supply of the PASCAL device for that purpose should be permitted.

Birss J considered this approach to be consistent with that adopted previously by Arnold J (as he was then) in the earlier *Boston* case.

Edwards v Boston

As in *Evalve*, the decision in *Boston* related to patents for medical devices used in repairing heart valves in particular Edwards' "Sapien 3" transcatheter heart valve. Following the dismissal of the appeal concerning the validity and infringement of one of the patents in suit, the remitted issue hearing in the Patents Court concerned:

1. the extent to which the final injunction which had been granted against Edwards should be stayed to permit clinicians to be retrained to use the patentee's (Boston's) device; and

2. the scope and duration of the final injunction.

In relation to the first issue, the evidence varied greatly between the parties on the duration needed to retrain clinicians, and thus the appropriate length of the stay. Ultimately the judge granted a stay of the injunction for 12 months, with permission for Edwards to apply to extend the stay if necessary.

In relation to the second issue, and based on the undisputed evidence relied upon by Edwards, the judge qualified the grant of an injunction on a permanent basis to protect the interests of the identified sub-group of patients for whom the Sapien 3 was the only suitable device. Boston had accepted that there should be a carve-out of the injunction in some form in order to protect this patient sub-group, but did not agree that it should be permanent.

The judge dealt with Boston's objections in a similarly practical way as he had done for the first issue, giving Boston permission to apply to terminate the carve-out if a non-infringing device became available which was suitable for all the patients in question.

What seems to be emerging from both of these public interest judgments is that it is necessary to establish, based on objective evidence, that a refusal to grant injunctive relief (at least in part) is needed to protect the health of patients for whom the defendant's product is the only suitable treatment. This evidence was relied upon (and was undisputed) in *Boston*, but this was not the case in *Evalve*. The mere identification of clinically tangible differences between the parties' devices was not enough, in itself, to refuse the grant of an injunction.

Damages *in lieu* of an injunction

While not needing to answer the question of how damages *in lieu* of an injunction should be assessed in patent cases where an injunction was refused on public interest grounds, Birss J offered some interesting *obiter* comments in *Evalve*. In particular, he considered whether it might be a necessary factor in refusing to grant an injunction that the defendant should pay only a royalty, allowing them to make a profit. While recognising that this might cause "substantial, quantifiable and uncompensated economic harm to the patentee", if the public interest lay in ensuring that the defendant's product did come to market, the patentee would need to bear those losses

In *Boston*, Arnold J acknowledged but did not need to consider in depth Carr J's judgment in ***GSK v Wyeth***[3]. This case dealt with the financial relief available where it was in the interest of public health that the defendant remain on the market and the patentee had accepted that there should be no injunction.

Carr J refused, on procedural grounds, to grant an order that the defendant should account for its profits from infringing future sales. The patentee had not sought this relief initially and had not amended its pleadings to do so. The judge also said that were it open to the patentee to make this request, he would not allow an account of profits in respect of future infringement, as a matter of discretion. He reasoned that a basic principle of accounts of profits is that there should be unconscionable conduct by the defendant. In this case, the patentee had acknowledged that the defendant should be allowed to continue supplying its product in the interest of public health and so the continuation of infringement would not be unconscionable. He suggested that an account of future profits would be equivalent to an injunction, as the defendant would either need to supply the product without making a profit or would cease to do so.

Judges have a very broad discretion when considering the award of damages *in lieu* of an injunction following the Supreme Court's judgment in ***Lawrence v Fen Tigers***[4]. However, in light of Birss J's *obiter* remarks in *Evalve* and Carr J's decision in *GSK v Wyeth*, it will be interesting to see whether the Patents Court will in future order an account of profits *in lieu* where an infringer is allowed to remain on the market because it is in the public interest for them to do so. If some element of unconscionable conduct is required (over and above the fact of it being found to infringe a patent), what would this amount to? Does a defendant have to demonstrate that its product was developed only to meet an unmet clinical need in order to resist such a claim? What if the business opportunity to compete (albeit mistaken) with the patentee's product was also a factor? Is the test objective, or dependent on the defendant's actual belief when deciding to market the infringing product?

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3 *GlaxoSmithKline UK Ltd v Wyeth Holdings LLC* [2017] EWHC 91 (Pat)
4 *Lawrence v Fen Tigers Limited* [2014] UKSC 13)

As Edwards Lifesciences awaits a further public interest trial relating to a transcatheter product, due to take place in October 2021 and where this time they are the patentee, we may see answers to some of these questions.

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