Evalve v Edwards Lifesciences [2020] EWHC 513 & 514 (Pat): The Limits of Public Interest

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On Friday 13 March 2020, Birss J handed down a pair of judgments in the litigation between Evalve (a member of the Abbott group of companies) and Edwards Lifesciences, a veteran of UK patent litigation over the past decade. In the first judgment Evalve's two UK patents, EP (UK) 1 408 850 and EP (UK) 1 624 810 ("the Patents"), were held to be valid and infringed by Edward's PASCAL device. The second judgment addressed what the parties had referred to as the "Public Interest" trial, the subject of which was whether, in the event that Edward's PASCAL device infringed a valid claim of an asserted Evalve patent, a final injunction should nonetheless be refused on grounds of public interest. The second decision is the subject of this article.

Evalve first issued proceedings against Edwards in early 2019, alleging that Edwards' PASCAL product, a trans catheter device used in the treatment of mitral valve regurgitation, infringed the Patents. Mitral valve regurgitation is a severe condition, and most untreated patients die within a year of diagnosis. In the past the condition has been treated by open heart surgery to suture the defective valve. However, the majority of patients suffering mitral valve regurgitation are of advanced age, and consequently many are not strong enough for open heart surgery. Trans catheter devices capable of replicating the required sutures are therefore a welcome alternative therapeutic approach, and Evalve successfully markets a trans catheter device called the MitraClip for the treatment of mitral valve regurgitation. The MitraClip has been used in about 100,000 procedures since the introduction of the first generation device in 2008.

The MitraClip is an embodiment of the inventions in the Patents, and in the first judgment, Birss J held that the PASCAL device infringed certain claims of the Patents, as a matter of both normal construction and on the basis of equivalence. Evalve consequently sought a final injunction under s.61(1)(a) of the Patents Act 1977 to restrain Edwards from marketing the PASCAL.
However, Edwards contended that no injunction should be granted, or alternatively any injunction which is granted should be subject to certain carve outs relating to specific clinical scenarios, on the basis that the availability of the PASCAL device serves the public interest because a reasonable doctor would select the PASCAL over the MitraClip as providing superior patient outcomes due to the difference in design and functionality of the two devices.

Birss J reviewed the law relating to injunctions as it arises from both the tortious remedy of injunctions generally and patent law specifically. He concluded that there are seven principles which apply where a party is seeking to avoid a final injunction in relation to a patent on the grounds of public interest:

1. A general injunction is the normal remedy.
2. The defendant bears the burden of showing why that injunction should not be granted.
3. All the circumstances should be considered, and public interest is such a circumstance.
4. Public interest may justify the refusal of or carve out from an injunction, and the size of damages which would then be due to the patentee is not a corrective or counterbalance to public interest. Even if the damage would be large it may be still be in the public interest to refuse to grant an injunction (or carve out from it).
5. Account must be made of the fact that public interest provisions are already engrained in the statute to strike a balance between monopoly rights and the public interest.
6. Where a patent is valid and infringed, the remedy of an injunction is itself in the public interest, as it is integral to the public bargain of protecting investment in exchange for disclosure which underlies the patent system.
7. When differing public interests are engaged, the judiciary should have in mind that the legislature is better positioned to balance between those interests through statute than the judiciary is through judgments. Therefore the discretion of a judge to refuse (or qualify) a injunction should be used sparingly and in limited circumstances.

Birss J was concerned that Edwards' argument that it should not be injuncted amounted to an argument that is was entitled to a compulsory licence by another name, but without the stringent requirements for such a statutory licence. Edwards noted that it was not entitled to a compulsory licence in any event for one of the Patents as it was not within the last 3 years of its term, which Birss J acknowledged. Consequently, he went on to consider what kind of public interest in the clinical setting would be sufficient to override the presumption that an injunction should be granted.

Taking the decision of *Arnold J in Edwards Lifesciences v Boston Scientific* [2018] EWHC 1256 (Pat) as a starting point, he held that for the question of public interest to arise in cases concerned with clinical supplies, the case "must be concerned with treatments for serious medical conditions, and perhaps only for life saving treatments" [75]. The preference of a notional doctor or class of doctors for one treatment over another is not sufficient in any circumstances. Opinion alone is not enough. What is required is sufficient objective evidence that would cause a reasonable body of doctors to find that there are in fact patients who could not be treated with the patented device but could be treated with the rival product.

Birss J concluded that *"the relevant public interest sufficient to justify a refusal, at least in part, of a patent injunction, is the need to protect the lives of patients for whom the defendant's product is the only suitable treatment, when that fact is established by objective evidence."* [87]. Birss J was satisfied that he had arrived at the same approach as Arnold J in Edwards v Boston, and further, that this test was *"not far from the test for a compulsory licence (market demand not met)"* [90].

The objective evidence in question was held to be the outcomes of clinical trials utilising the relevant devices, either in comparative studies or in individual studies where the outcomes were comparable. Reviewing the available clinical data, Birss J held that *"[t]here is no reliable clinical data which identifies any class of patients for which it is more likely than not that PASCAL is the only viable treatment. Nor is there any reliable clinical data which identifies particular classes of patients or anatomies for which it is more likely than not that PASCAL would be a better treatment than the currently available MitraClip"* [137]. It was notable from Birss J's review that the clinical data in respect of PASCAL was sparse, and it will remain open to debate whether the outcome of this hearing might have been different had it occurred in 2023, when a significant trial comparing the performance of PASCAL and the MitraClip titled CLASP IID/IIF is due to be published. However, in view of the available data the injunction was granted in full, the only carve out being where a MitraClip implantation has already been unsuccessful, a carve out with which Evalve agreed.