The public interest and patent injunctions: *Evalve v Edwards Lifescience* [2020] EWHC 513 (Pat)

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It is usual for a court to grant a final injunction after a finding of patent infringement. There has been some doubt about how this applied when the patents covered essential medical products. In Evalve v Edwards Lifescience [2010] EWHC 513 (Pat), the court explored the role of the public interest in withholding injunctions and awarding damages in lieu. It construed the public interest narrowly in part due to the existence of compulsory licences. This discussion explores the court's reasoning and suggests that an even greater link with compulsory licences should be adopted.

Keywords: injunctions; public interest; patent remedies; medicines; medical supplies

Introduction

A controversial issue in patent law and medicines is what role, if any, should there be for the public interest when the court grants a final[1] injunction. The normal rule is that after a finding of patent infringement the court will grant an injunction[2] provided there is a threat that the defendant will continue to infringe. In practice, it is even simpler as a finding of previous infringement is usually taken to be evidence of an intention to infringe in the future.[3] Yet recently the somewhat amorphous concept "the public interest" has been argued to have a role to play.[4] The issue has largely arisen over medical devices and drugs and while the public interest could arise in other circumstances[5] this discussion will be confined to medicine. The issue came to a head in *Evalve v Edwards Lifescience*[6] when Birss J addressed whether the public interest impowers the court to grant a qualified injunction and, if so, in what circumstances. This was the first time the role of the public interest was substantively considered; on previous occasions the parties had accepted that a qualified injunction should be granted on public health grounds.[7] The issue can also be framed slightly differently namely

[1] Sometimes called a permanent injunction although for patent infringement it will not be permanent as it lapses at the end of period of exclusivity.
[2] *Coflexip v Stolt Comex Seaway* [2001] RPC 9, [13], Aldous LJ.
[3] *Losh v Hague* (1838) 1 WPC 200 at 200-1, Shadwell VC.
[4] The role of the public interest in granting patent injunctions was firmly established in the United States some time ago with *eBay Inc. v. MercExchange, LLC*, 547 US 388 (2006).
[5] For instance, a safety device for omnibuses: *Bonnard v London General Omnibus Co Ltd* (1919) 36 RPC 307, 325–326, CA; or high unemployment in a time of economic stress: *Illinois Tool Works Inc v Autobars Co (Services) Ltd* [1974] RPC 337, 375, Graham J.
[6] [2020] EWHC 513 (Pat).
[7] *GlaxoSmithKline UK Ltd v Wyeth Holdings LLC* [2017] EWHC 91 (Pat), [11] (Meganitis B vaccine); *Edwards Lifesciences LLC v Boston Scientific Scimed Inc* [2018] EWHC 1256 (Pat), [2018] FSR 31 (a heart implant); in

whether damages should be awarded in lieu of an injunction. In other words, the defendant pays to continue infringing.

Damages in lieu of an injunction

The court has the power to award damages in addition to, or in substitution for, an injunction.[8] So it can award damages for future acts[9] that is, in the patent context, damages for infringements after the date of trial. The award of damages in lieu used to be tightly regulated as a narrow exception from a general rule that an injunction should be granted whenever a property right is infringed,[10] but the Supreme Court in *Lawrence v Fen Tigers*[11] held that there should be no strict fetters and that the determination of whether damages should be awarded in lieu was fact-sensitive.[12] In simple terms, it might be said whether to award damages instead of an injunction should be determined according to be a test of proportionality:[13] would granting an injunction for the infringement would be disproportionate[14] having regard to the requirements of efficacy and dissuasiveness[15] or, as we look at in a moment, taking into account the public interest and the wider harm it would cause.

Basis of assessment

In *HTC Corp v Nokia Corp,*[16] Arnold J suggested that damages in lieu for future infringements should be assessed on the basis of negotiating damages (the so called "user principle") that is they are quantified having regard to what would be agreed between a willing licensee and willing licensor for permission to commit the future acts. Nevertheless, in *Evalve* the court took

an earlier decision in *Edwards* [2017] EWHC 755 (Pat), [21], Hacon HHJ said if he had to decide the matter he would not have allowed the injunction to cover the cohort of patients whose life or health depended on the device.

[8] Senior Courts Act 1981, s 50; this provision is the successor to Chancery Amendment Act 1858 (Lord Cairns' Act), s 2; it is also permitted for a court to award damages in lieu of an injunction under Directive 2004/48, art 12.

[9] See *Jaggard v Sawyer* [1995] 1 WLR 269, 276-77 (Bingham MR) and 284 (Millett LJ).

[10] Based on a criteria set out in *Shelfer v City of London Lighting Co Ltd* [1895] 1 Ch 287, 322-23, AL Smith LJ; and more recently, *Jaggard v Sawyer* [1995] 1 WLR 269; one of the considerations in *Shelfer* was that the damages would be small; but following *Lawrence v Fen Tiger* [2014] UKSC 13, [2014] AC 822, the amount of money involved is not relevant: *Evalve* [2020] EWHC 513 (Pat), [73(iv)].

[11] [2014] UKSC 13.

[12] [2014] UKSC 13, [120 to 122] (Lord Neuberger), [161] (Lord Sumption), [239] (Lord Carnworth).

[13] *Edwards Lifesciences* [2018] EWHC 1256 (Pat), [16].

[14] *Cartier International v British Sky Broadcasting* [2016] EWCA Civ 658, [2017] RPC 3, [125 and 126]; maybe "grossly disproportionate": *Virgin Atlantic v Premium Aircraft* [2009] EWCA Civ 1513, [2010] FSR 15, [25].

[15] *HTC Corporation v Nokia Corporation* [2013] EWHC 3778 (Pat), [2014] RPC 30, [32], Arnold J.

[16] [2013] EWHC 3778 (Pat), [13].

the view that other methods of assessing damages should in principle be available[17] but Birss J pointed out that the difficulty with other remedies, such as awards for lost sales[18] or an account of profits, is that the infringer has no economic incentive to continue selling the product as any profit made would pass to the patentee.[19] Indeed, such an assessment of damages (or an account) might have the same effect as an injunction for which it is awarded in lieu. He therefore concludes that if the public interest is engaged then a reasonable royalty is the appropriate remedy; even if it means that a patentee is substantially out of pocket with the loss being something the patentee has to bear for the public good.[20]

For simple products where all or almost all the profits would be apportioned to the infringement (and so the infringer would break even at best) his conclusion is surely right. However, for complex products it might be that the profit from the complete product is sufficient to make the absence of profit from the infringement itself worthwhile. For instance, the lost profits from the "tin whistle" on a battleship[21] would be insignificant compared to the profits made from selling the whole ship. In the context of medicine, imagine an artificial heart was developed, which uses an infringing valve albeit the pump and the remainder of the product is lawful. It may be that damages for the lost sales of the valve could be awarded to the patentee, but the sale of the whole heart would still remain profitable for the infringer.

How payment is made

The usual rule is that when a court awards damages for future conduct, a one-off lump sum should be calculated to cover all further loss.[22] However, for patent infringement the quantum of future damages may be very uncertain (as the future demand for the infringing product might go up or down) and so a form of periodic payment could (in theory) be ordered by the court.[23] But a periodic payments would raise additional questions as how it is managed and accounted[24]

[17] In *Evlave* it was made clear that other methods of assessment would in theory be possible for future acts: *Evalve* [2020] EWHC 513 (Pat), [64] referring to *Morris-Garner v One Step (Support)* [2018] UKSC 20, [2019] AC 649, [95], Lord Reed.
[18] Where a patentee licences a patent then clearly a payment for lost licence fees would be appropriate; for the three normal ways to assess damages in patent cases (lost sales, lost licence fees, user principle): see *General Tire & Rubber v Firestone Tyre & Rubber (No.2)* [1975] 1 WLR 819, 824-827, Lord Wilberforce; for a more detailed discussion see *Roughton, Johnson and Cook: Modern Law of Patents* (4th Ed, Lexisnexis 2019), [8.91 to 8.127].
[19] *Evalve* [2020] EWHC 513 (Pat), [67].
[20] *Evalve* [2020] EWHC 513 (Pat), [67 and 68].
[21] To use Laddie J's well known example from *Celanese International Corp v BP Chemicals Ltd* [1999] RPC 203, [51].
[22] *Jaggard v Sawyer* [1995] 1 WLR 269, 280-1 (Bingham MR) and 285-6 (Millet LJ).
[23] *HTC Corporation* [2013] EWHC 3778 (Pat), [14].
[24] *HTC Corporation* [2013] EWHC 3778 (Pat), [14].

and so it becomes closer and closer to being a compulsory licence to which the discussion turns below. Before this we must consider the role of the public interest in patent law.

The role of the public interest

The modern patent system has sought to establish a balance of public interests. While there are extensive debates about whether it achieves these aims, the basic principles are clear enough as Aldous J explained in *Chiron v Organon*:[25]

> *First it [that is, the patent system] encourages research and invention; secondly, it induces an inventor to disclose his discoveries instead of keeping them a secret; thirdly, it offers a reward for the expense of developing inventions to the state at which they are commercially practical and, fourthly, it provides an inducement to invest capital in new lines of production which might not appear profitable if many competing producers embarked on them simultaneously. Those are particularly relevant to the development of medicinal products.*

In each case, Birss J said, these incentives require long-term certainty about remedies.[26] It being effective remedies which give value to the patent. Therefore, the public interest in limiting the patentee's remedies has to be greater than the public interest which led to the creation of the system in the first place.[27] So while Lord Neuberger in *Coventry v Lawrence*[28] made it clear there is always a role for the public interest in determining whether a final injunction should be granted,[29] he went on to point out that while the public interest might commonly arise in cases it will not usually begin to justify withholding an injunction. Lord Sumption went much further saying that when a judge takes account of the "public interest" it will usually be without the necessary information to do so effectively.[30] The public interest, he pointed out, is reflected by the legislative schemes in existence.[31] Put simply, the determination of the public interest should not be made by the courts, but by Parliament when enacting legislation.[32] Thus,

[25] *Chiron Corporation v Organon Teknika (No. 10)* [1995] FSR 325, 332, Aldous J.
[26] *Evalve* [2020] EWHC 513 (Pat), [53].
[27] See by analogy with the law of confidence Lord Goff's comment in *AG v Guardian Newspapers* [1990] AC 109, 282.
[28] [2014] UKSC 13, [124].
[29] Cited in *Evalve* [2020] EWHC 513 (Pat), [48].
[30] [2014] UKSC 13, [158].
[31] [2014] UKSC 13, [158].
[32] This seems to reflect his view that parliament and not the court should take account of the public interest: see Jonathan Sumption, *Trials of the State: Law and the Decline of Politics* (Profile 2019) (based on his 2019 Reith Lectures).

legislation, such as the Patents Act 1977, already internally represents the balance of the public interest.

The public interest provisions

The Patents Act 1977 is full of provisions which restrict the grant and exercise of patent rights for reasons which could be said to reflect the public interest.[33] These range from exceptions to infringement (such as for enabling research, free commerce, and farmers being able to reuse crops)[34] to restrictions on eligible subject matter.[35] More significant for the current discussion are the various provisions enabling compulsory licences to be granted,[36] for instance, where domestic demand for a product is not being met on reasonable terms,[37] or to assist with a public health problems in other countries.[38] Historically there was also a broad power to grant compulsory licenses in relation to food and medicines,[39] but Parliament (against the will of the government of the day) refused to include such a provision in the 1977 Act.[40] Additionally, there is Crown use[41] which enables the government to obtain what is in effect a compulsory licence to supply to the public a patented product. This would include the ability to provide medicines or medical devices[42] – *any* medicine[43] or *any* medical device.[44] As the National Health Service purchases the majority of drugs sold and supplied in the United Kingdom it could be said that the government refusing to authorise Crown use for a particular drug or device was a public interest decision. This, it is suggested, would be rather too blunt a

[33] Birss J identified many of the provisions which he considered relevant: *Evalve* [2020] EWHC 513 (Pat), [33]-[37]; likewise in *Chiron Corporation* [1995] FSR 325, 332-333.
[34] Patents Act 1977, s 60(5).
[35] Patents Act 1977, s 1(2) and (3), 4A, Sch A2.
[36] Patents Act 1977, s 48 to 48B; see *Roughton, Johnson and Cook: Modern Law of Patents* (4th Ed, Lexisnexis 2019), [11.22 to 11.69].
[37] The other grounds are in PA 1977, s 48A(1) (there are different grounds for patents held by persons who are not nationals or established in a WTO country (see s 48B(1)) but all major industrialised countries are now members of the WTO.
[38] Patents Act 1977, s 128A which is there to give effect to Regulation (EC) No 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.
[39] Patents Act 1949, s 41; a point made by Abbot: *Evalve* [2020] EWHC 513 (Pat), [37].
[40] For a history see, Phillip Johnson "Access to medicine: The rise of the British pharmaceutical industry" in Graeme Dinwoodie, *Methods and Perspectives in Intellectual Property* (Edward Elgar 2013), p 329 (also discusses Crown use of medicines).
[41] These provisions were recently considered in *IPcom v Vodafone Group* [2020] EWHC 132 (Pat); also see Phillip Johnson "Scoping Crown use: authorising infringement for the services of the Crown" (2020) 15 JIPLP *forthcoming*.
[42] This was confirmed in *Pfizer v Minister of Health* [1965] 2 WLR 387, HL.
[43] A medicine has to be specified in a statutory instrument before the Crown use provisions can be relied upon: Patents Act 1977, s 56(4). Thus, the only restriction is political. For instance, the UK has a large pharmaceutical sector and if the UK government started granting compulsary licences it could not complain if other countries did the same.
[44] There is no need to specify a medical devices so it is actually easier for the Crown to use medical devices.

conclusion as there are many wider policy reasons[45] (and general bureaucratic inertia) why it might not be done. Instead, the assessment of the public interest requires some consideration of the clinical setting.

The clinical setting

Any finding by a court that there is a public interest in refusing an injunction must be assessed in the context of a clinical decisions. The basic relationships between clinical decision making and patents was summarised succinctly by Birss J in *Evalve*:[46]

> *When a doctor chooses a treatment for a patient they are exercising their clinical judgment in the best interests of that patient. Patents do not cover methods of treatment, in order not to interfere with those decisions, but patent law does certainly place restrictions on those decisions by limiting the available options – in the form of patents for drugs and devices. Stated at this level of generality, as being applicable to any reasonable clinical decision about any medical condition, the fact that reasonable doctors would choose the defendant's drug or device in preference to the patentee's product cannot on its own be sufficient to invoke the public interest as a ground for refusing or putting a carve out into a patent injunction.*

He continued by highlighting that a public interest would only begin to be relevant for the most serious medical conditions.[47] Further, and somewhat critically, he went on to say that a generic version of a life-saving drug would not usually engage the public interest provided the patented product is available to meet demand.[48] The high cost of drugs cannot in itself be a reason to engage the public interest; otherwise a final injunction would never be granted.[49]

What is needed to engage the public interest, the court in *Evalve* held, was a product which infringes the patent but that is clinically different to that sold by the patentee.[50] It must be remembered that just because the defendant sells a product which infringes a patent (either

[45] For instance, the UK generally supports pharmaceutical patents as there are numerous domestic drugs companies.
[46] *Evalve* [2020] EWHC 513 (Pat), [74] and [33]; also see G 1/07 *Treatment by surgery/MEDI-PHYSICS* [2011] OJ EPO 314 at [3.3.6]; Patents Act 1977, s 4A and European Patent Convention, art 53(c).
[47] *Evalve* [2020] EWHC 513 (Pat), [75 and 87] (he clarifies he did not mean emergencies only).
[48] *Evalve* [2020] EWHC 513 (Pat), [77]; if the demand cannot be met then there are mechanisms in the 1977 Act for Crown users to step in to address the shortage: *Evalve*, [80]; he refers an exception such as a novel pandemic disease and the Crown relying on Crown use (the judgment was handed down a day after the WHO declared that Covid-19 was a global pandemic).
[49] See the reasoning of the Federal Circuit in the United States: *WBIP, LLC v. Kohler Co*, 829 F.3d 1317, 1343 (Fed. Cir. 2016).
[50] *Evalve* [2020] EWHC 513 (Pat), [78].

through a normal interpretation or by reason of equivalence[51]) does not mean it is the same product as that sold by the patentee. A patent claim may cover various embodiments of an invention most of which are not produced by the patentee. Nevertheless, Birss J went on to hold that it being a different product is not enough to engage the public interest, it is necessary that the infringing product makes a *clinical* difference to patient outcomes from that of the patentee.[52]

Thus, a doctor preferring one drug or device to another (that is a patent eliminating choice between drugs or devices) is not in itself a sufficient public interest.[53] The judge found this would simply be too wide a carve out to injunctive relief.[54] More significantly, he held that the public interest does not preclude the grant of an injunction where a doctor reasonably believes that the balance of risk for a particular patient would be more favourable with the infringing product than the patented one.[55] The reason he postulated was that such a rule would mean that the patentee might lose a sale where its product was *objectively* perfectly adequate to undertake the treatment (notwithstanding the doctor's subjective belief).[56]

The judge went on to qualify his reasoning. Doctors, he said, must make their clinical decisions based on the best data available and their own experience.[57] This means assumptions will be made based on physical or pharmaceutical properties of the device or drug. A doctor acting perfectly properly[58] might make a clinical decision which, once evidence becomes available, turns out to be wrong.[59] Indeed, patent law and medicine is littered with instances where there was an assumption or belief held by the experts of the day which turned out to be wrong.[60] The public interest threshold is crossed, Birss J held, where there is:[61]

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[51] See *Roughton, Johnson and Cook: Modern Law of Patents* (4th Ed, Lexisnexis 2019), Ch 6.
[52] *Evalve* [2020] EWHC 513 (Pat), [78-79].
[53] *Evalve* [2020] EWHC 513 (Pat), [79 and 88]; implicitly adopting *Kirin Amgen v Sanofi*, 872 F.3d 1367, 1381 (Fed Cir. 2017).
[54] *Evalve* [2020] EWHC 513 (Pat), [88]; Birss J indicated that such an exception was for Parliament.
[55] *Evalve* [2020] EWHC 513 (Pat), [81 and 82].
[56] *Evalve* [2020] EWHC 513 (Pat), [89].
[57] *Evalve* [2020] EWHC 513 (Pat), [82 – 84].
[58] ie not negligently: *Evalve* [2020] EWHC 513 (Pat), [84].
[59] As was the case for the infringing device in *Evalve* [2020] EWHC 513 (Pat), [97].
[60] Reference overcoming prejudice; one of the most famous examples outside patent law was Barry Marshall and Robin Warren's finding that *Helicobacter pylori* caused peptic ulcers, which was widely rejected including a paper rejected as unpublishable by the Gastroenterological Society of Australia in 1983; but they ultimately won the Noble Prize for the work in 2005.
[61] *Evalve* [2020] EWHC 513 (Pat), [85]; Birss J said this followed the approach of Arnold J in *Edwards Lifesciences* [2018] EWHC 1256 (Pat), [37 to 41].
[61] *Evalve* [2020] EWHC 513 (Pat), [87], [36 and 63].

> *…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.*

Thus, an injunction will be refused where the infringing product is the only option for a patient[62] and this is proved by objective evidence.[63] Furthermore, it cannot be ignored that in the future the patentee might develop a product which is as effective as the infringing product.[64] So, the court could grant a conditional injunction providing that the infringing product can be sold only until the patentee creates a clinically equivalent product.[65] In some cases this might never be possible as the infringing product might also include elements protected by defendant's own patent so that the (first) patentee making something equivalent would be infringing the defendant's patent. In any event, the standard put forward in *Evalve* is very strict. In the case itself, it restricted use of the infringing product to patients for whom the patentee's product had already been unsuccessful[66] and there was (at least initially) a restriction to treating ten patients with the device.[67] The approach Birss J adopted, as he himself acknowledged, is very similar that for compulsory licences[68] as it is fundamentally linked to the market demand not being met. It is suggested, however, that following his reasoning and the public interest this connection to compulsory licences should be strengthen further.

Compulsory licences

Even before *Evalve*, the award of damages in lieu of an injunction had been said to be a *de facto* compulsory licence[69] but without the restrictions from both international[70] and national law.[71] In this context, the relevant ground[72] for granting a compulsory licence is "where the patented invention is a product, that a demand in the United Kingdom for that product is not being met on reasonable terms"[73] which is further qualified because no application can be made

[62] *Edwards Lifesciences* [2018] EWHC 1256 (Pat), [37 to 41].
[63] *Evalve* [2020] EWHC 513 (Pat), [87]; this addresses somewhat Lord Sumption's concerns regarding the absence of evidence when judging the public interest.
[64] A slightly different view, that the availability of a new product us not relevant for injunctions, was taken in *Edwards Lifesciences* [2018] EWHC 1256 (Pat), [62].
[65] *Evalve* [2020] EWHC 513 (Pat), [90].
[66] *Evalve* [2020] EWHC 513 (Pat), [138].
[67] *Evalve* [2020] EWHC 513 (Pat), [139] (the sixth patient was to be treated imminently after the trial).
[68] *Evalve* [2020] EWHC 513 (Pat), [90].
[69] *Chiron Corporation* [1995] FSR 325, 332-3; *HTC Corporation* [2013] EWHC 3778 (Pat), [32]; *Kirin-Amgen v TKT (No. 3)* (2001) [2005] FSR 41, [27]; *Evalve* [2020] EWHC 513 (Pat), [66].
[70] Paris Convention, art 5(A)(2) (sets out the four year period for non-use); TRIPS, art 31.
[71] Patents Act 1977, ss 48, 48A and 48B.
[72] There are two other grounds in Patents Act 1977, s 48A(1)(b) and (c) but these are not relevant.
[73] Patents Act 1977, s 48A(1)(a).

for a compulsory licence until three years after the patent was granted.[74] These compulsory licences are granted[75] to address a public interest: the undersupply of products so not meeting demand. So once this time has passed any drug or device not currently available (as it is a clinically significant variant on the patented product) might be eligible for a compulsory licence provided there is *any* demand for it.

This assessment of demand for a compulsory licence should not take into account any demand that could be created by the infringer entering the market whether by reason of the price lowering[76] or otherwise.[77] Yet this matters little for a clinically significant variants as the relevant demand is for a new (infringing) product and not the existing patented product. The assessment of demand for a compulsory licence is made on the date of the application[78] and, once more, for a variant product the demand would be infinitely more than supply (unless the patentee was willing and able to expand its range to include the variant).[79]

A key public policy restriction[80] on the grant of compulsory licences is the three year prohibition on applications. In many medical cases, due to the need to obtain a marketing authorisation, this period would have long expired. In *Evalve* the three year period expired for one of the patents[81] in 2012 - long before the infringing product was first trialled in 2017[82] - but the second patent was granted in July 2017. So in March 2020, when the judgment was handed down, it was not possible to apply for a compulsory licence.[83] In future, if an application could be made for a compulsory licence it may be the court can tailor the remedies accordingly particularly in light of the previous comments on damages in lieu of an injunction. So, in appropriate cases, a court could stay the injunction pending determination of a compulsory

[74] Patents Act 1977, s 48(1) giving effect to Paris Convention, art 5(A)(2).
[75] Although, in fact, there have been no compulsory licences granted in the United Kingdom since the law was amended in 1999: see *Roughton, Johnson and Cook: Modern Law of Patents* (4th Ed, Lexisnexis 2019), [11.25, n 4].
[76] *Research Corpn's (Carboplatin) Patent* [1990] RPC 663, 680, Hoffmann J
[77] *Cathro's Patent* (1934) 51 RPC 475, 482, Comptroller.
[78] *Cathro's Patent* (1934) 51 RPC 475, 479-80.
[79] On the other hand, for damages in lieu of an injunction, by its very nature, the award is future looking and the availability of the product may change over time: *Evalve* [2020] EWHC 513 (Pat), [90].
[80] *Evalve* [2020] EWHC 513 (Pat), [90]; albeit it is one the United Kingdom must follow under due to the Paris Convention.
[81] See *Evalve* [2020] EWHC 514 (Pat), [2].
[82] *Evalve* [2020] EWHC 513 (Pat), [100]; Fabien Praz et al "Compassionate use of the PASCAL transcatheter mitral valve repair system for patients with severe mitral regurgitation: a multicentre, prospective, observational, first-in-man study" (2017) 390 (10096) Lancet 773.
[83] In *Edwards Lifesciences* the three year period for the relevant patent expired in late February 2019 (the judgment was handed down in May 2018): [2018] EWHC 1256 (Pat).

licence application to the comptroller[84] (or with an undertaking an application will be made at a certain point).

This approach would much better fit the balance that the courts (and Parliament) sought. Furthermore, if the judge has stayed an injunction to allow an application for a compulsory licence to be made it will give a strong hint to the parties to settle on similar terms. It would also mean that the issue before the court could be greatly simplified: is the public interest need for the drug or device such that there should be some form of interim remedy while the three year period runs. This would mean any injunction would usually be relatively short further focusing the question for the court. Any payment of damages in lieu would only need to last until the compulsory licence application was resolved. It would also help focus the clinical assessment as the period of the conditional injunction might be much shorter.

Conclusion

The decision in *Evalve* highlights once more that not granting an injunction to facilitate cheaper drugs and devices is not in the public interest; or more precisely, not the balance of the public interest set by Parliament for patent law. It appears that the court will allow for injunctions to be restricted in time to allow retraining[85] or to give access to a drug or device where there is no clinical alternative[86] but, more importantly, that even when there are clinical advantages to the defendant's product an injunction would last only as long as it takes for the patentee to bring its own product to market.[87]

While the link been damages in lieu and compulsory licences was made in *Evalve* as it has been before, it is submitted that this link should be strengthened further with the court tailoring its remedies to fit the compulsory licence regime. In any event, the approach in *Evalve* might increase compulsory licensing for drugs and medicines; and this might in turn reduce the amount of litigation in cases where there might be a public interest in the infringing product remaining on the market (that is the product is objectively clinically different from the patentee's product). Whatever turns out to be the case, it leaves the court with very limited scope for relaxing remedies in the public interest.

[84] Applications for compulsory licences must be made to the comptroller (Patents Act 1977, s 48(1)) and cannot and cannot be granted by the court save on appeal (Patents Act 1977, s 99).
[85] *Edwards Lifesciences* [2018] EWHC 1256 (Pat), [64 to 67].
[86] *Evalve* [2020] EWHC 513 (Pat), [138-139].
[87] Although, where a medical device incorporates a patented invention and either improvements or other patented inventions it may be somewhat more complicated than this simple case.