Neutral Citation Number: [2020] EWHC 1524 (Pat)

Case No: HP-2019-000003

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF ENGLAND AND WALES
INTELLECTUAL PROPERTY LIST (ChD)
PATENTS COURT

Royal Courts of Justice
The Rolls Building
7 Rolls Buildings
Fetter Lane
London EC4A 1NL

Date: 18/06/2020

Before :

MR JUSTICE BIRSS

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Between :

(1) EVALVE INC.	**Claimants**
(2) ABBOTT CARDIOVASCULAR SYSTEMS INC.	
(3) ABBOTT MEDICAL U.K. LIMITED	
- and -	
EDWARDS LIFESCIENCES LIMITED	**Defendant**

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Richard Meade QC, James Abrahams QC, Michael Conway and Jennifer Dixon (instructed by **Taylor Wessing**) for the **Claimants**
Piers Acland QC and Kathryn Pickard (instructed by **Powell Gilbert**) for the **Defendant**

Hearing dates: 21st April 2020

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Approved Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

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MR JUSTICE BIRSS

Mr Justice Birss :

1. This judgment deals with an aspect of the form of the order to be made following judgment in a patent action which was handed down on 12th March 2020. The action is about two patents: EP (UK) 1 408 850 entitled "Devices for capturing and fixing leaflets in valve repair" and EP (UK) 1 624 810 entitled "Fixation devices and systems for engaging tissue". The patents are held by the claimants Abbott. The 850 patent was filed on 27th June 2002 and granted on 23rd September 2009. The 810 patent was filed on 18th May 2004 and granted on 5th July 2017.

2. As the main judgment explains ([2020] EWHC 514 (Pat)), the patents relate to medical devices used to treat mitral valve regurgitation by a transcatheter technique. The patents protect a successful Abbott product called MitraClip which has been on the market since 2008. Starting from before the earliest priority date of the patents, Edwards also sought to develop a transcatheter treatment for the disorder. Its original product was called MOBIUS, which worked in a different way. The MOBIUS project was stopped. Then Edwards produced a new product called PASCAL. PASCAL achieved CE mark approval in 2019.

3. These proceedings began in January 2019. On 4th February Abbott applied for an interim injunction. In March 2019, Arnold J ordered that the trial be expedited. On 3rd May 2019, Henry Carr J dealt with the injunction application. One of the issues was the scale of the activity Edwards proposed in the UK pending trial. At paragraph 31 the judge said this:

> "31. First, Mr. Meade contended that the evidence of Mr. Estay on behalf of Edwards was vague as to Edwards' intentions pending trial and in particular as to the scale of its launch between now and judgment. To put it another way, while suggesting that Edwards' current intention is to provide for a few implantations at a few hospitals, Edwards reserves the right to itself fully to launch PASCAL onto the market pending judgment. I understood Abbott's concerns in this respect. A full-scale launch pending trial would raise different considerations from a controlled testing of the market. However, during the hearing, and no doubt in response to some indication from the bench, Mr. Purvis, on behalf of Edwards, stated that Edwards was prepared to offer an undertaking until judgment or further order, only to arrange for the implantation of PASCAL devices in 10 patients in two hospitals in the UK. That, I should say, is subject to a liberty to apply to discharge or vary the undertaking, for example, if reimbursement is granted sooner than is currently expected."

4. Instead of granting an interim injunction, Henry Carr J accepted the undertaking from Edwards to limit their supplies of PASCAL in the UK to no more than 2 hospitals for the purpose of treating no more than 10 patients.

5. Directions for the trial of validity and infringement of both patents in December 2019 were given by Arnold J on 13th June 2019. Not long after that, an issue arose about a "public interest" defence which Edwards contended would apply even if the PASCAL product was found to infringe a valid claim. On 25th July 2019, directions were given by Arnold J for the public interest issues to be tried at a hearing at the beginning of the new term in January 2020.

6. I heard both trials. The two judgments were both handed down on 12th March 2020. The main judgment [2020] EWHC 514 (Pat) dealt with validity and infringement, finding that both patents were valid and that PASCAL infringed each of them. The other judgment [2020] EWHC 513 (Pat) dealt with Edwards' public interest defence and substantially rejected it. The only exception to the injunction was a narrow one, which had been offered by Abbott, to cater for the case when a MitraClip implantation had already been unsuccessful.

7. The hearing to determine the consequential orders to make was on 21st April 2020. There were a number of issues to be resolved: (a) a dispute about the terms of the exception, (b) permission to appeal, (c) a stay pending appeal, (d) costs and interim payments, and (e) CPR 31.22.

8. The dispute about the terms of the exception was really a further attempt by Edwards to craft a much wider exception to the injunction, having failed at the public interest hearing, and without giving Abbott the opportunity to test the evidence on which that application was based in cross-examination. I rejected it.

9. I gave permission to appeal and dealt with costs and CPR 31.22.

10. In relation to a stay of the injunction pending appeal, Edwards sought an order staying the injunction altogether pending appeal, contending that the number of PASCAL implantations likely to take place before an appeal was heard was small. At most between 30 and 40 by the end of Q1 2021. Abbott contend that this amounted to Edwards in effect coming on to the UK market in a real sense within the period and was likely to cause substantial and unquantifiable harm to Abbott.

11. I decided to grant a stay of the injunction, but only if Edwards gave an undertaking which was in the same terms as the undertaking they had given to Henry Carr J, that is to say to limit PASCAL to ten implantations in the two centres. At the hearing I gave reasons for the decision in abbreviated form, indicating that either party could ask for a fuller judgment if they wished. After the hearing there were further written submissions to resolve the form of the order itself. The order was sealed on 5th May 2020.

12. The undertaking given by Edwards pending appeal are in this form:

    i) Between the date of this Order and the making of the final order of the Court of Appeal on Edwards' appeal against this Order, Edwards will limit its supply of PASCAL in the United Kingdom to the 2 hospitals referred to in paragraph 1 of Schedule B to the Order of Mr Justice Henry Carr dated 3 May 2019 (the "Hospitals") for the purpose of treating no more than 10 patients in total (such treatments being the "Procedures").

ii) Edwards will not invite any clinician not based at the Hospitals to assist, attend or observe the Procedures (subject to paragraph iii below).

iii) Edwards may invite its employee representatives and up to 2 PASCAL proctors to attend each Procedure.

iv) For this purpose, "PASCAL proctor" means a physician with prior experience carrying out the PASCAL implantation procedure and who is attending the Procedure for the sole purpose of training the clinical team to carry out the Procedure.

v) Edwards will not broadcast any of the Procedures outside the Hospitals.

13. I was asked to give a judgment on the issue and so this is it.

Legal principles

14. The principles to be applied where the claim succeeds and the grant or stay of injunctive relief is being considered pending appeal were set out by the Court of Appeal in ***Minnesota Mining and Manufacturing Co v Johnson & Johnson Ltd*** [1976] RPC 671, 676 (Buckley LJ):

> It is not in dispute that where a plaintiff has at first instance established a right to a perpetual injunction, the court has a discretion to stay the operation of that injunction pending an appeal by the defendant against the judgment. On what principles ought such a discretion to be exercised? The object, where it can be fairly achieved, must surely be so to arrange matters that, when the appeal comes to be heard, the appellate court may be able to do justice between the parties, whatever the outcome of the appeal may be. Where an injunction is an appropriate form of remedy for a successful plaintiff, the plaintiff, if he succeeds at first instance in establishing his right to relief, is entitled to that remedy upon the basis of the trial judge's findings of fact and his application of the law. This is, however, subject to the defendant's right of appeal. If the defendant in good faith proposes to appeal, challenging either the trial judge's findings or his law, and has a genuine chance of success on his appeal, the plaintiff's entitlement to his remedy cannot be regarded as certain until the appeal has been disposed of. In some cases the putting of an injunction into effect pending appeal may very severely damage the defendant in such a way that he will have no remedy against the plaintiff if he, the defendant, succeeds on his appeal. On the other hand, the postponement of putting an injunction into effect pending appeal may severely damage the plaintiff. In such a case a plaintiff may be able to recover some remedy against the defendant in the appellate court in respect of his damage in the event of the appeal failing, but the amount of this damage may be difficult to assess and the remedy available to the appellate court may not amount to a complete indemnity. It may be

> possible to do justice by staying the injunction pending the appeal, the plaintiff's position being suitably safeguarded. On the other hand it may, in some circumstances, be fair to allow the injunction to operate on conditions that the plaintiff gives an undertaking in damages or otherwise protects the defendant's rights, should he succeed in his appeal. In some cases it may be impossible to devise any method of ensuring perfect justice in any event, but the court may nevertheless be able to devise an interlocutory remedy pending the decision of the appeal which will achieve the highest available measure of fairness. The appropriate course must depend on the particular facts of each case.

15. This was followed by the Court of Appeal in ***Novartis AG v Hospira UK Ltd*** [2013] EWCA Civ 583, [2014] RPC 3, which considered the converse case of a patentee having lost at trial and seeking an interim injunction pending appeal.

16. Briefly put the test is the balance of justice. The court considering the terms of any stay pending appeal will endeavour to arrange matters so that the Court of Appeal is best able to do justice between the parties once the appeal is heard.

17. Abbott also invited me to take into account my opinion of the relative strength of the parties' cases as a way of gauging the likelihood that whatever order I make turns out to have been wrongly made, based on paragraphs 17-18 of the judgment of Lord Hoffmann in ***National Commercial Bank Jamaica Ltd v Olint Corp Ltd (Jamaica)*** [2009] UKPC 16, [2009] 1 WLR 1405.

Edwards' evidence and submissions

18. Edwards submitted that the appeal is likely to be heard and determined within 12 months and could, in fact, be heard as early as the end of this year (2020). The listing of the appeal is a matter for the Court of Appeal but I believe it is realistic to consider the issues on the footing that the appeal is likely to take about a year to come on.

19. Edwards' main evidence in support of the stay is given by Dr Jochen Reinöhl. He is Director, Medical Affairs & Professional Education, Transcatheter, Mitral & Tricuspid Therapies at Edwards Lifesciences in Switzerland.

20. In support of Edwards' case about the likely numbers of PASCAL implantations in the period up to the end of Q1 2021, Edwards relied on Dr Reinöhl's evidence as follows:

    i) TMVr procedures are currently suspended due to Covid-19. As such, Edwards does not anticipate being able to re-commence training until the end of July 2020 at the earliest;

    ii) To date, and even before Covid-19 hit, Edwards' PASCAL training had proceeded at half the rate expected. Having given an undertaking to the Court in May 2019 not to conduct more than 10 PASCAL procedures across two sites in the UK pending judgment at first instance (which, at the time of the

undertaking, was anticipated in January 2020), Edwards had only conducted 5 by the end of January 2020 and none since;

iii) Assuming that normal (or near-normal) NHS activity commences towards the end of Q3 2020, Edwards plans to complete the training that it has started at two sites (King's and the Brompton) and commence initial training at three further sites (Bart's, Manchester and Bristol);

iv) This training activity would involve an estimated 15 PASCAL procedures before the end of December 2020, with a further 15 before the end of Q1 2021 i.e. 30 in total;

v) If, as is possible (though difficult to predict with any certainty at this stage), a further four centres are named as NHS reimbursement centres in Q1 2021, Edwards will also want to start initial training at those centres. Assuming a similar rate of training at these new centres as at the established centres, and that the further four reimbursed centres do not include King's or St. Barts, Dr Reinöhl estimates that a further 10 procedures may occur by the end of Q1 2021, bringing the total number to 40.

21. Edwards then argues that these numbers are relatively small and, to the extent that they exceed the numbers that would have been expected to be carried out (subject to the argument about the terms of the exception to the injunction), any damage caused to Abbott as a consequence of permitting this limited roll-out would be readily susceptible of quantification in monetary terms. Further, as Dr Reinöhl explains, as reimbursement prices are fixed at a certain level, there is no prospect of Edwards' presence impacting on Abbott's prices. In contrast, if an injunction is granted pending appeal and Edwards is successful on its appeal, Edwards will suffer unquantifiable damage as a consequence of having to make up for lost time on the market at a time when NHS reimbursement is taking effect. Further unquantifiable damage will be suffered if key opinion leaders in the UK are prevented from having access to PASCAL and educating clinicians internationally about its qualities.

22. Finally Edwards suggested that they did not detect in Abbott's evidence any serious opposition to a stay of the injunction pending appeal and said that was unsurprising, given the findings of Henry Carr J at the preliminary injunction hearing when considering the balance of irreparable harm to the parties in the light of Edwards' limited launch plans until trial, and in particular the Judge's dismissal of the various types of irreparable harm Abbott argued it would suffer by reason of the presence of PASCAL on the market.

Abbott's evidence and submissions

23. In fact Abbott did oppose the stay. Abbott argued as follows:

i) Abbott is entitled to an immediate injunction, unless Edwards can establish proper grounds for a stay.

ii) There is a clear risk of unquantifiable harm to Abbott, and none to Edwards.

iii) Edwards made no attempt to clear the way, and has no excuse for failing to do so.

iv) The relevant status quo is that MitraClip, through Abbott's early initiative, ingenuity, and investment in clinical medicine, has been the only such product serving the UK market for the 12 years since its CE Mark approval in 2008. Edwards is not in any real sense in the market in the UK. That was the status quo prior to the claim form being issued and prior to the hearing before Henry Carr J. The 10 procedures were permitted on the basis that they would make no commercial impact. Therefore the status quo in fact as well as in law remains where it was.

24. Abbott argued that the prospect of Edwards succeeding on appeal in relation to both patents is very remote. So the way to arrange matters pending appeal, which is least likely to result in any injustice, is to grant an immediate injunction.

25. Abbott submitted that any stay of the injunction would be likely to cause Abbott real, substantial but unquantifiable damage. In reply to Dr Reinöhl, Abbott relied on evidence from Mr Gervais. At trial his evidence had described the potential impact on Abbott's business of PASCAL being able to enter the UK market prior to May 2024. I described Mr Gervais as a good witness. Abbott submitted that what Mr Reinöhl's evidence in fact amounts to is that if the injunction is stayed, Edwards will proceed with a full commercial launch of PASCAL, more or less immediately. In the period pending appeal that means training up teams in up to 9 centres, and carrying out up to 40 procedures in those centres. According to Mr Gervais that would amount to a substantial portion of the UK market even in normal (i.e. non-pandemic) times.

26. Abbott referred to its evidence at the Public Interest Trial which explained in detail how such a commercial launch would damage Abbott in ways which could not be quantified. Abbott pointed out that unlike on an interim injunction application, the court had seen this evidence tested by cross-examination, and had concluded that the relevant Abbott witnesses (Mr Gervais and also Mr Townsend) were good witnesses whose evidence could be accepted. Aspects of unquantifiable harm to Abbott caused by the launch of PASCAL in the UK include the loss of the opportunity to build the market for MitraClip and to develop new relationships with new centres/clinicians via MitraClip. Given Edwards' strength in this sector, MitraClip is the only way in which Abbott can get a foothold in many centres. Another dimension relied on was that Abbott has a pipeline of future products whose future would be adversely affected in the same way.

27. Abbott characterised Edwards' evidence of the alleged harm that it would suffer if injuncted pending appeal as exiguous and unconvincing. While Dr Reinöhl said that it was important for Edwards to have access to the UK market during the changes that are currently underway, in fact it was clear that the UK is not a priority for Edwards. It rolled out PASCAL in 10 countries in Europe before the UK. So far, it had only carried out 5 of the 10 permitted procedures in the UK, despite telling Henry Carr J that it was essential that it be able to carry out 10 procedures prior to judgment.

28. Abbott referred to what they called the general unreliability of Edwards' evidence about its commercial plans. Abbott contended that Mr Estay's evidence to Henry Carr J was that Edwards would suffer serious harm if it was not able to carry out 10

procedures before trial, but that has turned out to be wrong since Edwards has not carried out that number of procedures. Abbott also referred to my views on Mr Estay's evidence, submitting that there is no reason to think his replacement, Dr Reinöhl, is any more reliable.

29. In relation to Covid 19, Abbott did not dispute that elective procedures have been suspended pending resolution of the crisis, but argued that this meant that the number of e-e TMVr procedures in the short and medium term will be much lower and that this therefore reduces even further any claimed need for Edwards to commence a full scale commercial launch at this stage.

30. Abbott submitted that the fact that the patents are approaching expiry (in 2022 and 2024) makes the damage more serious. NHS reimbursement (itself the result of years of investment in R&D, physician training, and clinical trials by Abbott), together with the vindication of its patents (also at considerable cost and effort), presents a unique opportunity for Abbott to benefit from its innovation and recoup some of its R&D costs. A stay of the injunction for 12 months or so would very substantially reduce the period of time in which Abbott will be able to do this.

Assessment

31. The commercial evidence relied on by Edwards before Henry Carr J and at the public interest trial was given by Mr Estay. In the public interest judgment I said:

> "Rodolfo Estay is Edwards' Vice President of Transcatheter Mitral and Tricuspid Therapies in Europe. His evidence focussed on the commercial launch of PASCAL in other European countries, and the clinical feedback received from its users. The cross-examination exposed that Mr Estay's written evidence about clinician feedback relating to PASCAL was incomplete and selective. I do not believe Mr Estay thought he was being misleading, but that was the effect of his written evidence. I am not satisfied I can rely on Mr Estay's uncorroborated evidence."

32. No doubt that is one reason why Edwards decided now to ask a different individual to give evidence about its commercial plans for PASCAL. However there is no reason why I should not treat Dr Reinöhl's evidence in just the same way as the court will treat any evidence given by witness statement on an occasion in which it will not be cross-examined.

33. I accept Dr Reinöhl's evidence that Edwards would be likely to carry out 30-40 procedures in the period up to the appeal if a stay was granted. However, I reject Edwards' characterisation of this as "small". I agree with Abbott that what Edwards proposes to do amounts to a commercial launch of the PASCAL product in the UK, full scale or close to it. That would be the result of granting the stay.

34. There will certainly be substantial irreparable harm to Abbott if I allow Edwards to do that. There will be an impact which is difficult to quantify on its MitraClip market in that Abbott will lose opportunities to capitalise on the existing market now that reimbursement is in place and to build relationships. The effect will not only be on

MitraClip because if Edwards are able to move PASCAL into more centres than the two in which they already have carried out procedures then that is likely to have an impact on the position of other Abbott devices such as Portico, with which Edwards are a strong competitor. That impact itself will be significant but hard to quantify. There was some argument about this at the public interest trial. Although I held that Abbott's structural heart business is arranged so that MitraClip and Portico are dealt with by distinct groups or silos, that did not mean that it undermined Abbott's case that there could be an impact on Portico sales caused by competition between PASCAL and MitraClip.

35. Also relevant in relation to Abbott's opportunities is that, after the Court of Appeal, there will be a relatively short period until the 850 patent expires (in June 2022). So if Abbott wins the appeal but in the meantime, between now and that result, Edwards has done what it says it wishes to do, Abbott will have lost almost half of the period in which MitraClip was entitled essentially to the market to itself.

36. From Edwards' point of view, an injunction now would delay its commercial launch. That does deprive it of the opportunity to build relationships in a context in which reimbursement is now available but if Edwards had really wanted to come to market earlier it could have brought proceedings to clear the way. Nevertheless, I recognise that, if I refuse a stay altogether, there will be unquantifiable harm to Edwards.

37. Also relevant is the status quo. Despite Abbott's submissions, the true status quo today is not simply that MitraClip is on the market and PASCAL is not. Rather PASCAL has been used in 2 centres for a number of patients (somewhat fewer than 10) within the scope of the undertaking given to Henry Carr J.

38. In my judgment, the fair way to hold the ring is to take a course between the extremes proposed by each party, by allowing Edwards to continue to carry out that activity at those centres, with a fresh limit of 10 patients up to the hearing of the appeal. The period of this order will be similar to the period covered by Henry Carr J's order. I recognise it delays the launch which Edwards wishes to undertake. However this approach will allow Edwards to maintain the relationships it has already built up relating to PASCAL in the UK and maintain a UK presence, without expanding it significantly until after the appeal.

39. That is my decision.