Neutral Citation Number: [2019] EWHC 1158 (Pat)

Case No: Claim No. HP-2019-000003

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

The Rolls Building
7 Rolls Buildings
Fetter Lane
London EC4A 1NL

Date: Friday, 3rd May 2019

Before:

MR. JUSTICE HENRY CARR

- -

Between:

(1) EVALVE INC.	**Claimant**
(2) ABBOTT CARDIOVASCULAR SYSTEMS INC.	
(3) ABBOTT MEDICAL UK LIMITED	
- and -	
EDWARDS LIFESCIENCES LIMITED	**Defendant**

- -
- -

MR. RICHARD MEADE QC and **MR. JAMES ABRAHAMS QC** (instructed by **Taylor Wessing LLP**) appeared for the **Claimants.**

MR. IAIN PURVIS QC (instructed by **Powell Gilbert LLP**) appeared for the **Defendant.**

- -

Approved Judgment

Digital Transcription by Marten Walsh Cherer Ltd.,
1st Floor, Quality House, 6-9 Quality Court, Chancery Lane, London WC2A 1HP.
Telephone No: 020 7067 2900. Fax No: 020 7831 6864 DX 410 LDE
Email: info@martenwalshcherer.com
Web: www.martenwalshcherer.com

MR JUSTICE HENRY CARR:

Introduction

1. In these proceedings, the claimants (together "Abbott") allege that the defendant ("Edwards") is infringing two of Abbott's patents, which the parties have described as the '810 patent and the '850 patent. By this application, Abbott seeks an interim injunction to restrain Edwards from marketing the alleged infringement in the United Kingdom until judgment or further order.

2. Edwards' device, which it is preparing to launch, is a product known as PASCAL. PASCAL is a medical device for treating mitral regurgitation, which is a life-threatening condition in which the mitral valve of the heart ceases to function properly. PASCAL is implanted in the mitral valve via a catheter, by a procedure known as transcatheter mitral valve repair (TMVr).

3. At present, the market for TMVr products in the United Kingdom is very small. This is demonstrated by the limited sales of Abbott's own TMVr product, which is known as MitraClip. At present, there are only about 100 implantations per year in the United Kingdom. The reason why the United Kingdom market is small, in contrast, for example, to the market in Germany, is because TMVr is not currently funded by the National Health Service.

4. NHS England is in the process of considering whether to fund a particular type of TMVr operation, which could be effected either by MitraClip or by PASCAL. It is widely anticipated that a favourable decision will be made, although the date when this decision will be made, and the date when first reimbursed implantations are likely to take place, remains a matter of some speculation.

5. According to Edwards' evidence, it intends to roll out PASCAL in the United Kingdom in a controlled manner to a small number of hospitals between October 2019 and February 2020. The controlled roll-out is planned to continue thereafter until the end of June 2020. The purpose of the controlled roll-out is to enable Edwards to obtain feedback from UK clinicians, and to promote PASCAL, so as to be able properly to compete with MitraClip when reimbursement is introduced.

6. Abbott claims that if Edwards is allowed to proceed with its plans, Abbott will suffer irreparable or unquantifiable damage between now and judgment in these proceedings, whereas if Edwards' plans are put on hold for a relatively short period, it will not suffer any such irreparable or unquantifiable damage.

Procedural History

7. This claim was issued by Abbott on 28th January 2019. Edwards denies infringement and has counterclaimed for invalidity of both patents on the basis of lack of novelty and obviousness. Edwards accepts that Abbott has established that there is a serious question to be tried. In those circumstances, very sensibly, neither counsel addressed me on the merits of the claim for infringement, nor on the counterclaim for invalidity.

8. After having applied for an interim injunction, Abbott sought an expedited trial, which application was opposed by Edwards. Abbott's application for expedition was granted

by Arnold J in March 2019, and the trial will take place in December 2019. The parties estimate, and I agree, that judgment is likely to be delivered by the end of January 2020.

9. In its submissions in support of an expedited trial, Abbott recognised that expedition would have the effect of ameliorating the damage done to the losing party to the preliminary injunction application. In particular, in its written submissions to the court for the expedition hearing, Abbott said:

> "The evidence of Mr. Estay is that, if permitted, Edwards plans to undertake no more than 5 PASCAL procedures in the UK prior to the end of 2019; these are in the nature of a test-run it seems, and things will ramp up to a commercial scale thereafter. A trial in the autumn term would enable a decision before Edwards was in a position to enter the UK market on a full commercial scale, and possibly before it had done anything at all. It is possible that it would remove the need for the preliminary injunction application."

10. This does not, of course, mean that Abbott is debarred from seeking interim relief, even though they have obtained expedition. However, it does show a recognition, which is in my view inevitable, that a few procedures by Edwards, in the nature of a test run, would be considerably less damaging to Abbott than a full commercial launch of PASCAL.

MitraClip

11. In his first statement in support of this application, Mr. Maraschi, the EMEA Marketing Director for the Structural Heart Division at Abbott International BV gave evidence about the history and technical function of MitraClip. He explained that:

> "6. MitraClip is a first-in-class device marketed by Abbott which is used for the treatment of mitral regurgitation ('MR'). MR is a serious, progressive heart disease in which the mitral valve does not close properly, allowing blood to flow backwards in the heart. MR is often divided into two different sub-types:
>
> (a) degenerative (primary) mitral regurgitation ('DMR'), which is caused by a primary abnormality of the mitral apparatus; and
>
> (b) functional (secondary) mitral regurgitation ('FMR'), which occurs when the left ventricle of the heart is distorted or dilated, displacing the papillary muscles that support the two valve leaflets and stretching the valve annulus so that the valve leaflets can no longer come together to close the annulus, thereby causing the blood to flow back into the atrium.
>
> 7. MitraClip obtained CE mark approval in Europe in 2008 and was first used in patients in the UK in November 2008. In the UK and in most other countries in Europe, MitraClip is used for treatment of patients with both DMR and FMR.
>
> 8. MitraClip was also approved by the U.S. Food & Drug Administration ('FDA') in 2013. In the U.S., it is currently

indicated for the percutaneous reduction of significant symptomatic mitral regurgitation in DMR patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation (see page 3 of the U.S. MitraClip instructions for use, attached as Exhibit MDM-1).

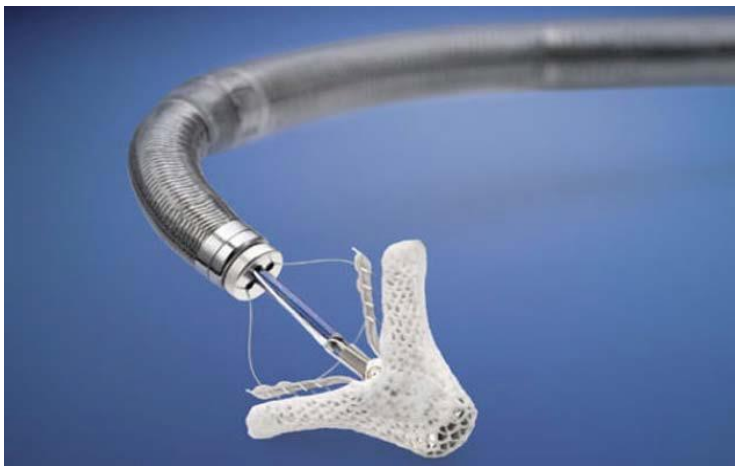

Fig. 1: MitraClip

9. The MitraClip procedure involves reconstruction of the insufficient mitral valve through tissue approximation in a technique known as 'edge-to edge' repair and MitraClip is the first and only such device approved for commercial sale anywhere in the world. Since MitraClip is a transcatheter procedure, it is less invasive than traditional open-heart surgery and is therefore particularly suitable for mitral regurgitation patients who have been classified as high risk for such surgery. MitraClip is seen as the standard of care in this market segment.

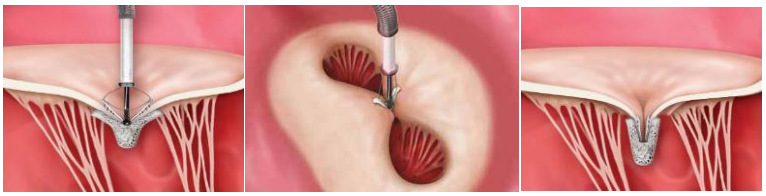

Fig. 2: Transcatheter edge-to-edge repair procedure with MitraClip

10. Edwards' PASCAL product is also an edge-to-edge transcatheter mitral valve leaflet repair device for treating the same patient population as MitraClip.

11. In 2018, Abbott launched third generation versions of MitraClip: MitraClip NTR with an improved delivery system; and MitraClip XTR which also has longer arms than the current MitraClip NT device."

12. I should add that Abbott is developing further generations of MitraClip with other new features, the details of which are said to be confidential.

13. At paragraphs 14-19, Mr. Maraschi gave an account of MitraClip's sales and reimbursement. In summary, he explained that MitraClip is a commercially important product for Abbott. In 2017, worldwide sales of MitraClip totalled hundreds of millions of dollars, the figure for which is said, for some reason, to be confidential. A small proportion of those total sales was made in the United Kingdom. UK sales of MitraClip have been lower than in other major European countries because, as I have explained, MitraClip is not currently funded by the NHS in the United Kingdom.

14. However, Mr. Maraschi said that he was optimistic that a decision would be made by NHS England later this year to reimburse MitraClip for appropriate patients. If the decision is taken and MitraClip will be funded by NHS England, Mr. Maraschi would expect UK sales of MitraClip to increase significantly, although he considered that the magnitude of such an increase was difficult to predict.

15. Mr. Maraschi also gave evidence about COAPT, which is a long-term, randomised clinical study, the results of which have recently been published by Abbott. This study demonstrates a significant overall benefit to certain patients with FMR. The study was carried out on patients with heart failure or moderate to severe secondary MR, and compared outcomes from MitraClip, plus medical therapy, with medical therapy alone.

16. The investigators found that at 24 months post procedure, the hospitalisation rate for heart failures was 35.8% for those patients in whom MitraClip was implanted, compared to 67.9% for those patients who were given medical treatment alone. The overall death rate was 29.1% compared to 46.1% and the MitraClip group had milder MR, better quality of life and fewer device-related complications.

17. The study included a large number of FMR patients. In FMR, surgical repair or replacement has not been shown to lower the rate of hospitalisation or death. However, positive results for this group of patients in the COAPT study has occasioned considerable interest in MitraClip within the relevant medical community.

18. Mr. Maraschi explained that he would expect that these results will have a positive effect on future overall sales of MitraClip, and on the transcatheter mitral valve repair market worldwide. Furthermore, the fact that the COAPT study has provided new evidence that MitraClip provides significant benefits to FMR patients would be expected to be viewed positively by the relevant panels when considering whether MitraClip should be routinely funded by NHS England.

19. Since I have not considered the prior art, I make no observations about the validity of the patents in suit. However, on the evidence before me, I can see that MitraClip is a very important medical advance, which has proved to be a life-saver. Abbott's concerns to protect its research and development are entirely understandable. Whether its claims are justified depends on the results of the trial.

PASCAL

20. Edwards contends that there are key differences between PASCAL and MitraClip. In particular, it contends that in terms of overall design, the key differences between

PASCAL and MitraClip are, first, that PASCAL paddles are significantly longer than the arms of the Mitraclip NT and NTR, and wider than any of the MitraClip devices; secondly, that PASCAL has a single row of teeth at the end of each clasp, whereas the MitraClip grippers have teeth running along their entire length; and, thirdly, that PASCAL includes a spacer, unlike MitraClip.

21. As for modes of implantation, Edwards alleges two key differences. First, PASCAL allows for each mitral leaflet to be engaged separately, a facility referred to as independent clasping. None of the MitraClips, it is said, is capable of this; they always engage both leaflets at the same time. Secondly, both devices can be repositioned during the procedure in order to optimise MR. This involves pulling the device back into the left atrium. In so doing, PASCAL adopts an elongated configuration, unlike, it is said, any of the MitraClip devices.

22. Edwards claims that PASCAL is clinically superior in certain respects to MitraClip, a claim which is hotly disputed by Abbott.

23. In its evidence and skeleton argument, Abbott characterised the PASCAL device as a copycat product, which was piggybacking on investment and training that had been carried out by Abbott. As I observed at the hearing, this type of advocacy relied on too many animal analogies. The allegation that PASCAL was a copycat product should never have been made.

24. First, it appears on the evidence before me to be entirely unjustified. Secondly, even if justified, it is irrelevant to the claim of patent infringement advanced by Abbott. If Abbott wishes to allege copying, then it should bring a claim for infringement of unregistered design right, if any such right subsists. The courts of the United Kingdom have repeatedly said that allegations of copying are irrelevant to patent infringement.

25. Whilst it is no doubt tempting, nonetheless, to assert copying, it is a sign of weakness rather than strength when this is done. Mr. Meade, wisely, did not attempt to justify this allegation for the purposes of obtaining interim relief, and I hope and expect that it will not re-emerge at trial.

Legal Principles

26. The American Cyanamid test is so well-known that it does not require repetition in this judgment. However, there is one issue that does need to be addressed. Mr. Meade laid great stress on the proposition that Edwards could not establish irreparable or unquantifiable harm if the injunction were granted.

27. That was disputed by Mr. Purvis, who additionally pointed out that before the question of irreparable harm to the defendant is addressed, the claimant needs to establish that it would suffer irreparable or unquantifiable harm itself, otherwise intervention by the court by the grant of an interim injunction would not be justified.

28. In my view, and in so far as it was disputed, Mr. Purvis is correct about this. In *National Commercial Bank Jamaica Limited v Olint Corporation Limited* [2009] UKPC 16, Lord Hoffmann considered the basis on which an interlocutory injunction had been granted by the Jamaican Court of Appeal. He said at [16] – [17]:

> "16. The second feature is the basis upon which Jones J decided to refuse an interlocutory injunction and the Court of Appeal decided to grant one. It is often said that the purpose of an interlocutory injunction is to preserve the status quo, but it is of course impossible to stop the world pending trial. The court may order a defendant to do something or not to do something else, but such restrictions on the defendant's freedom of action will have consequences, for him and for others, which a court has to take into account. The purpose of such an injunction is to improve the chances of the court being able to do justice after a determination of the merits at the trial. At the interlocutory stage, the court must therefore assess whether granting or withholding an injunction is more likely to produce a just result. As the House of Lords pointed out in American Cyanamid Co v Ethicon Ltd [1975] AC 396, that means that if damages will be an adequate remedy for the plaintiff, there are no grounds for interference with the defendant's freedom of action by the grant of an injunction. Likewise, if there is a serious issue to be tried and the plaintiff could be prejudiced by the acts or omissions of the defendant pending trial and the cross-undertaking in damages would provide the defendant with an adequate remedy if it turns out that his freedom of action should not have been restrained, then an injunction should ordinarily be granted.
>
> "17. In practice, however, it is often hard to tell whether either damages or the cross-undertaking will be an adequate remedy and the court has to engage in trying to predict whether granting or withholding an injunction is more or less likely to cause irremediable prejudice (and to what extent) if it turns out that the injunction should not have been granted or withheld, as the case may be. The basic principle is that the court should take whichever course seems likely to cause the least irremediable prejudice to one party or the other. This is an assessment in which, as Lord Diplock said in the American Cyanamid case [1975] AC 396, 408:
>
> 'It would be unwise to attempt even to list all the various matters which may need to be taken into consideration in deciding where the balance lies, let alone to suggest the relative weight to be attached to them.'"

29. Mr. Meade relied on paragraph 17, which points out that in practice the courts will often be faced with a difficult task in predicting which side will suffer greater irremediable prejudice. Therefore, the court tries to adopt a solution which will achieve the least injustice pending trial. However, paragraph 16 clearly establishes that if damages will be an adequate remedy for the claimant, then there are no grounds for interference with the defendant's freedom of action by the grant of an interim injunction.

Irreparable harm to Abbott

30. I must first consider whether Abbott's evidence has established that it will suffer irreparable harm if an injunction is not granted.

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.

32. I must therefore consider whether Abbott has shown that this very limited activity will cause it irreparable harm pending trial. There is no suggestion of a downward price spiral pending trial as no other competitors, apart from Abbott and Edwards, are anticipated to enter this market, and Edwards have indicated that PASCAL is likely to cost more than MitraClip.

33. In this regard, Mr. Meade relied on the following submissions. First, he argued that sales lost to Abbott as a result of implantation of PASCAL devices in 10 patients will be difficult to quantify. However, Edwards has accepted that for the purposes of any damage inquiry or other financial relief, each sale of PASCAL made by Edwards is a sale lost to Abbott. On that basis, quantification would appear to be very easy. However, Edwards contends that one clinical advantage of PASCAL is that fewer devices may be required for particular implantations than would be the case in respect of MitraClip. Mr. Meade relied on the existence of this contention to suggest some difficulty of quantification. I do not agree.

34. First, Abbott vigorously denies that there is any clinical advantage and its case is that fewer PASCAL devices are not required for particular implantations. Secondly, if Edwards loses at trial but succeeds on this issue, then it may have to pay more damages to Abbott in respect of lost sales. I do not consider that there is any real difficulty in quantification.

35. Recognising that that was not his strongest point, Mr. Meade relied upon a concern expressed in Mr. Maraschi's evidence that Edwards would drive sales of PASCAL by promoting this device with other mitral valve-specific products, which Mr. Maraschi called a toolbox, or with medical devices used for treating other types of heart disease which Mr. Maraschi called bundling.

36. In the light of Edwards' undertaking pending trial to limit implantations to 10 patients in two centres, I find it very difficult to see that any allegation of toolboxing or bundling is sustainable. In any event, this allegation is expressly refuted by Mr. Estay at paragraphs 18 and 19 of his second statement, where he said:

> "18. At paragraphs 25 and 26 of his statement, Mr Maraschi cites the fact that Edwards has referred to its various products for mitral and tricuspid valve repair or replacement as offering a 'toolbox' of new therapies. This simply means that Edwards is developing a portfolio of products that may be used to treat a variety of patients. For example, a particular patient may be better suited to PASCAL, rather than Cardioband, or vice versa, depending upon the underlying cause of MR and their anatomy, as per judgement of the treating heart team. Edwards seeks to offer clinicians a broad range of products required to optimally treat their various patients.
>
> "19. Edwards does not bundle such products together, or seek to offer financial incentives to cross sell any of its products. In any case, it is difficult to see how such marketing strategies could be relevant to the planned very limited launch of PASCAL, where a discrete number of implantations will be agreed with hospitals in advance, rather than being driven by sales representatives. Likewise, I do not see how the very limited launch of PASCAL could drive sales of other products, if this is what Mr Maraschi is suggesting."

37. I accept that evidence. The very limited activities planned by Edwards between now and trial do not involve salesmen selling products on the back of a market leader; rather, two centres are to be chosen for trials of this specific PASCAL product. I do not accept, in the light of Mr. Estay's evidence, that there is any risk of cross-selling.

38. Thirdly, Mr. Meade argued that the limited activities to be undertaken by Edwards between now and trial will disrupt Abbott's relationships with clinicians, which have been carefully built up over time. This concern was raised by Mr. Maraschi in his evidence. Its basis is that if Abbott succeeds at trial in circumstances where the PASCAL product has come on the market, even to a limited extent, then Abbott may be seen by some clinicians as responsible for removing a treatment option from the market and might be thought, however unfairly, to be acting against the interests of doctors and patients. Therefore, Abbott is concerned that it might reflect badly on its reputation if it was seen as seeking to restrain access to PASCAL.

39. It is common ground that Abbott has long-standing and close relationships with clinicians in the United Kingdom. It is also common ground that Abbott has a very significant presence on the ground, both in terms of training staff and its product representatives. I do not accept that, as a result of the very limited activities of Edwards between now and trial, there is any risk of damage to its reputation or these relationships. Abbott has chosen, as it is entitled to do, to seek to enforce its patent rights in the United Kingdom and to seek an injunction against marketing of PASCAL at trial. This is in respect of a product which has been the subject of clinical trials and is already on widespread sale in Germany. PASCAL is already very well known to clinicians in the United Kingdom as a result, for example, of publicity given in relation to it in conferences in the United Kingdom. If clinicians are upset by the grant of an injunction, this will happen in any event if Abbott are successful at trial. The activities in the United Kingdom that Edwards is proposing to undertake pending trial will, in my view, make no difference.

40. I further note that although this claim has been floated by Mr. Maraschi, none of the numerous clinicians who has put in evidence on behalf of Abbott on this application has given any evidence to support his concern. None of them has suggested that any clinician would think the worse of Abbott because of its decision to enforce its patent rights. Furthermore, if Abbott wins at trial, then interventional cardiologists will have no choice but to use MitraClip. For these reasons I reject this allegation.

41. A further but related aspect of alleged reputational damage advanced by Abbott was what it described as damage to the MitraClip brand. It was said that as well as the risk of a perception in the clinical community that Abbott was responsible for removing a new treatment option from the market, there was a risk that relationships would suffer in hospitals where PASCAL procedures had been planned, or where training with PASCAL has taken place. Mr. Maraschi suggested that if PASCAL comes onto the market and is later withdrawn, Abbott would have to re-familiarise clinicians who had used the PASCAL device before they could start using MitraClip again. Not only would the costs of such retraining have to be borne by Abbott, but operations would have to be postponed whilst such retraining occurred.

42. I have to say that I regard this allegation as fanciful, not least because it is firmly refuted by the evidence served on behalf of Edwards. In particular, the likelihood of such retraining being needed as a result of a maximum of 10 implantations of PASCAL over a period of a few months is far-fetched. A very small number of MitraClip implantations are carried out each year in the United Kingdom at a total of 18 hospitals. Several months must often elapse between procedures at these 18 hospitals. Yet as Mr. MacCarthy, an interventional cardiologist whose evidence was adduced on behalf of Edwards has pointed out, Abbott does not have a policy of requiring refresher training in such circumstances. Mr. Maraschi has given no evidence of how long a gap between implantations is regarded as sufficient to trigger the need for any refresher course, or how that is policed, if it is indeed required.

43. Furthermore, there is no suggestion that hospitals which are currently using MitraClip will cease to do so, and therefore I do not accept that there will be any need for retraining. Even if there was, the cost of that exercise would be quantifiable, since the number of retraining exercises would be known by the time of any damages inquiry.

44. In his second statement, Mr. Maraschi also expressed a concern about brand damage to the MitraClip brand, on the basis that without an injunction, clinicians who have been trained on PASCAL will no longer regard TMVr as synonymous with the MitraClip brand. I do not accept that this establishes any kind of irreparable harm. In particular, if Abbott succeeds at trial, then its exclusivity will be very quickly re-established and the very limited activities planned by Edwards in the interim, which will have lasted for a few months, will, in my view, make no difference.

45. Furthermore, as I have said, there is already a widespread awareness of PASCAL in the United Kingdom and the way in which it works, as pointed out by Dr. Baker on behalf of Abbott at paragraph 17 of his first expert report and Mr. Estay at paragraph 21 of his second statement. It is not possible to pretend that clinicians in the United Kingdom are currently unaware of the PASCAL option.

46. The next point advanced by Mr. Meade was that if Edwards is allowed to arrange for 10 implantations at two hospitals between now and trial, then it will seek to rely upon

the fact that it is already on the market in order to resist a final injunction if it is successful at trial. There is, in my view, nothing in this point. Whilst Edwards has made clear that in those circumstances, i.e. if it loses the trial, it will resist the grant of a final injunction, that will be on the basis that PASCAL has, it is said, significant clinical advantages, and therefore an injunction would be contrary to the public interest. Edwards has stated that it will not rely on the fact that it has arranged for 10 implantations at two centres in order to resist the grant of a final injunction.

47. Finally, Mr. Meade relied upon the fact that Edwards has failed to clear the way of patents before deciding to launch PASCAL. In particular, Edwards knew of the existence of MitraClip throughout the time that it was developing PASCAL. It would have been reasonable to assume that it was subject to patent protection, and indeed Edwards has known of the existence of the patents in suit for some time. Edwards filed an opposition against the '810 patent in April 2018, and its knowledge of the patents is evidenced by the information disclosure statement filed with its own patent applications. Edwards published clinical data for its PASCAL product in 2017 but took no steps during the long gestation of the PASCAL device to clear its route to market by bringing proceedings to revoke or establish non-infringement of Abbott's patents. The situation in which Edwards finds itself, according to Abbott, where its commercial plans may be disrupted, arises because of its deliberate decision not to clear the way.

48. When assessing this allegation, it is necessary to consider where a failure to clear the way fits into the American Cyanamid analysis. It obviously does not establish irreparable harm to the claimant. Rather, it seeks to attribute blame to the defendant for failing to take action earlier. A failure to clear the way is a material factor in cases where irreparable harm to both parties is evenly balanced. At that point additional factors are required to be considered, including the status quo. This, in my view, is made clear by the judgment of the Court of Appeal in *SmithKline Beecham Plc v Apotex Europe Limited* [2003] FSR 31. In that well-known case, Aldous LJ said at paragraph 40:

> "The factors in favour of granting an injunction and of refusing one were evenly balanced. I find no error of principle in the way that the judge exercised his discretion. The judge was, in my view entitled to take into account when deciding to maintain the status quo that Apotex walked into the situation that they find themselves in with their eyes open to the risk that they were taking. They knew the risk and decided that it was best not to remove it. To preserve the status quo as the judge did meant that Apotex would only temporarily be prevented from doing that which they have not yet done. If they are right, the court will have to do the best it can to compensate them under the cross-undertaking."

49. Similarly, in *Warner-Lambert Company, LLC v Actavis Group PTC EHF and others* [2015] EWHC 72 (Pat), Arnold J referred to the Apotex case at paragraph 132, and said at paragraph 133:

> "Counsel for Warner-Lambert submitted that this principle was applicable to the present case. He adopted my suggestion that what Actavis ought to have done was to proceed as follows.

> First, as soon as they formed the intention to market generic pregabalin for epilepsy and GAD, Actavis should have written to Warner-Lambert asking it to acknowledge that the disposal etc by Actavis of generic pregabalin with an MA, SmPC and PIL limited to epilepsy and GAD would not infringe the Patent. Secondly, when Warner-Lambert declined to give that acknowledgement, Actavis should have launched proceedings for a declaration of non-infringement pursuant to section 71 of the 1977 Act alternatively the Court's inherent jurisdiction. Counsel for Warner-Lambert submitted that, if Actavis had taken that course, the infringement issue could have been finally determined by now. I accept this submission, and I accept that, *other things being equal*, this factor would favour the grant of interim relief." (emphasis added)

50. Accordingly, if I were to reach the view that this is an evenly balanced case in terms of irreparable harm, then Edwards' failure to clear the way and preservation of the status quo would be important factors to consider. However, I do not consider that this is an evenly balanced case. On the contrary, in the light of Edwards' undertaking to limit its activities until judgment, subject to a liberty to apply, to 10 implantations in two hospitals, I do not consider that Abbott will suffer irreparable prejudice between now and judgment. I consider that damages will be an adequate remedy for Abbott, and therefore there are no grounds for interference with Edwards' freedom of action by the grant of a preliminary injunction.

Irreparable harm to Edwards

51. In case I am wrong about this, I will go on to consider whether the grant of a preliminary injunction would cause irreparable prejudice to Edwards. Mr. Meade strongly contended that there was no evidence that any irreparable prejudice would be caused to Edwards. However, in answer to this contention, Mr. Purvis relied upon certain parts of Mr. Estay's evidence. First, he relied upon paragraphs 9-13 of Mr. Estay's second statement, when Mr. Estay gave details of launch plans for PASCAL, some of which information is said to be confidential. In particular, Mr. Estay indicated that it was critical that Edwards should have the opportunity to familiarise and train at least some UK clinicians with PASCAL, ahead of reimbursement, and to take any necessary associated administrative steps. That is why Edwards has made the controlled roll-out plans that I have indicated. Mr. Estay explained that Edwards intends to continue a very limited roll-out of PASCAL into 2020. As with all of its structural heart products, in order to maximize benefit and mitigate risk to patients, Edwards will control the roll-out of PASCAL and review the experience of cardiologists before launching to the mass market. PASCAL is first being introduced elsewhere in Europe, where there is a greater body of experience of treating MR with novel transcatheter techniques. However, Mr. Estay indicated that it was important for Edwards to gain the feedback of UK clinicians whose views are respected worldwide. As part of the roll-out of PASCAL Edwards intends to introduce the product to the UK in a very controlled manner. Nevertheless, it hopes to have familiarised a small number of clinicians and their teams with PASCAL by the time reimbursement procedures can be carried out, which could happen between the end of January and mid 2020.

52. Mr. Estay stated that given that the roll-out of PASCAL would be gradual and controlled, delaying the launch of PASCAL would have a knock-on effect on Edwards' position at the time when reimbursement of these devices is available in the United Kingdom.

53. In his first statement, at paragraphs 44-49, Mr. Estay set out what he considered to be the irreparable harm to Edwards in the event that a preliminary injunction is granted. He pointed out that there is an expectation that the NHS will, at some time in the near future, begin reimbursing TMVr procedures. Whilst it was not clear exactly when that would begin, in order to benefit from this change in the market, Edwards would need to be in a position to launch PASCAL later in 2019. In the event that Edwards was restrained from launching PASCAL this year, then it would be unable to compete with Abbott for the expanding reimbursed market. MitraClip would enjoy a monopoly as the only such device available to all eligible UK sites and Edwards would face the challenge of entering the market later. Mr. Estay asserted that it could not be said that every sale of a MitraClip device in that period would have been a sale of PASCAL if it was on the market, and it would be impossible to quantify the loss of Edwards' sales for that period. Similarly, it would be impossible to predict what impact this might have on the market going forward, and thus to quantify Edwards' lost sales as a result of a wrongly granted preliminary injunction.

54. Finally, Mr. Estay said that the experience of the first clinicians to implant PASCAL in the UK would provide Edwards with valuable feedback on the use of the device in the clinical environment and Edwards anticipates that the opinion of respected UK clinicians would be influential in educating clinicians internationally about the benefits of this new product.

55. Mr. Meade contended that all this meant was that Edwards would gain the same benefits if they were delayed for a few months. I do not agree. Mr. Estay's evidence is that if Edwards is unable to compete with Abbott at the outset when the reimbursement market begins, it will not be possible, accurately, to look at its subsequent sales to estimate how many sales would have been made if it had been competing at the outset. I can see that there may be some advantage in being able to compete at the outset when the market expands, and I accept that this gives rise to a difficulty in quantification if the injunction is granted. By contrast, there is no such difficulty if the injunction is refused, because Edwards have accepted that every sale of PASCAL is a lost sale of MitraClip.

Conclusion

56. For these reasons, I consider that even if Abbott will suffer some irreparable prejudice as a result of Edwards' limited launch, then such prejudice is clearly outweighed by the irreparable harm that would be suffered by Edwards if the injunction is granted. Therefore, I intend to refuse injunctive relief.

57. I should add that both parties have served very extensive evidence as to whether PASCAL has clinical benefits when compared with MitraClip. Had the question of irreparable harm been evenly balanced, then it was Edwards' case that the public interest should be taken into account. I have not been required to resolve this issue, even if it were possible to do so on an application of this nature, as I have not found that the balance was even.

Costs

58. In relation to costs, the starting point is that Abbott brought an application for interim relief, having already obtained an expedited trial, and it lost. Therefore, without more, Abbott should pay the costs of that application.

59. However, two factors are raised which might cause me to depart from that order. The first, as reflected in my judgment, is that there was a legitimate concern as to a lack of clarity as to Edwards' intentions, which resulted in an undertaking being given at the hearing. Therefore, it is suggested that Abbott gained something by coming to court, which they would not otherwise have been offered.

60. I would have had sympathy for that argument had Abbott taken the opportunity which it was given to consider whether to proceed with the application for a preliminary injunction in the light of the undertaking, and had decided not to proceed. In that event, there would be a powerful case, either for no order as to costs or possibly that Abbott should recover its costs.

61. However, having considered the undertaking, Abbott made it perfectly clear that it was not good enough and it intended to proceed and did proceed with its application. Therefore, it would have made no difference if the undertaking had been offered in advance of the hearing, Abbott would still have rejected it.

62. Furthermore, whilst there was a lack of clarity in Mr. Estay's evidence, the overall thrust was quite clearly that Edwards intended a controlled, limited roll-out. If Abbott was concerned about lack of clarity, it could have asked for an undertaking, which it did not. So, for those reasons, the offer of the undertaking does not cause me to depart from the order I would otherwise make.

63. A second matter raised is the proliferation of evidence concerning the debate as to whether or not PASCAL is clinically superior. This evidence was put in by Edwards to cater for the possibility that I would consider the balance of irreparable harm to be even, and therefore it might come in at that point.

64. It is a somewhat unusual case, in that as Mr. Purvis has pointed out, these are life-saving devices which potentially avoid open heart surgery, and therefore the public interest could be engaged. I have not had to decide on the merits of that evidence.

65. I accept that as a matter of law the evidence is admissible. None the less, what this application has illustrated, by the numerous witness statements that have been put in by distinguished clinicians, is the very grave difficulty that a court would face in resolving this type of allegation on an interim basis. Once the clinical benefits were disputed, the evidence spiralled out of control. Indeed, Mr. Purvis suggested that the test that should be applied was the same test as for Abbott's cause of action, namely whether Edwards has an arguable case that PASCAL was clinically superior.

66. In my view, parties should think very carefully before setting this ball rolling on an interim application, and I have been told that in this case, the combined costs of this evidence alone, concerning clinical superiority, are in six figures.

67. I think that the fair result, having taken account of all these considerations, is to make an order that Edwards should recover its costs of the application but to make a significant deduction in respect of the costs of the public interest issue. I do not intend to that Edwards should pay any of Abbott's costs, but, equally, I am not inclined to allow Edwards to recover its costs of that issue.

Summary assessment

68. As I indicated, I am going to make a deduction in respect of the costs of the public interest costs but not order any of those costs to be paid by Edwards.

69. The parties are not that far apart when it comes to the percentage of the total documents that were spent on the public interest issue. The total spent on documents is just over £101,000 of Edwards' costs, of which Edwards estimates 39% was spent on the public interest issue and Abbott says 45/46%.

70. In addition, as Mr. Purvis very fairly acknowledges, there will have been additional time spent in preparing the case on the basis of the public interest issue. For example, some proportion of counsel's brief fees (one would like to believe) is attributable to that issue.

71. I do not think it is possible to do this by a precise mathematical analysis, and I have to step back and consider what the fair deduction would be. I consider that the fair deduction would be somewhat over £47,000, which brings the total costs that I intend to order to Edwards down from £247,874.10 to £200,000.

- - - - - - - - - -