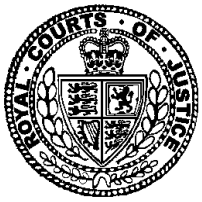

Neutral Citation Number: [2019] EWHC 3395 (Pat)

Case No: HP-2019-000003

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

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

Date: Wednesday, 6 November 2019

Before:

THE HONOURABLE MR JUSTICE MARCUS SMITH

- -

Between:

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

- -

MR JAMES ABRAHAMS QC and **MS JENNIFER DIXON** (instructed by **Taylor Wessing LLP**) for the **Claimants**

MS KATHRYN PICKARD (instructed by **Powell Gilbert LLP**) for the **Defendant**

- -

Approved Judgment

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MR JUSTICE MARCUS SMITH:

1. This is an application for specific disclosure made in a dispute between the Claimants – Evalve Inc., Abbott Cardiovascular Systems Inc. and Abbott Medical UK Limited – against the Defendant, Edwards Lifesciences Limited. I shall, for the purposes of this ruling, refer to the Claimants without differentiation as the "Claimants" and to Edwards Lifesciences Limited as the "Defendant".

2. The application for specific disclosure is made by the Claimants against the Defendant. The application notice indicates that the application is made CPR 31.12. The Defendant says that the application is wrongly made under this rule, because the "disclosure pilot" under CPR PD 51U applies. Accordingly, it is said that the application is made under the wrong provision. This matters because the rules under the disclosure pilot are considerably different from the rules that would otherwise apply. I shall, instead of referring to CPR PD 51U refer to the "Disclosure Pilot Rules".

3. During the course of hearing this application, Mr Abrahams QC who, with Ms Dixon, appeared for the Claimants, conceded that this was indeed a case under the disclosure pilot and not a case under CPR 31.12. That is the basis on which I will proceed to determine the application. It is, if I may say so, clearly right that this is a case under the disclosure pilot.

4. The facts of the case and the dispute between the Claimants and the Defendant are as follows. The Defendant manufactures a device known as the "PASCAL" device. The PASCAL device is used to treat mitral regurgitation, which is a life-threatening condition in which the mitral valve of the heart ceases to function properly. The PASCAL device enables repair of a patient's mitral valve without the need for surgery.

5. It should not be understood that the PASCAL device is the first such device to deal with this life-threatening condition of mitral regurgitation. The Claimants have, and have had for a considerable period, their own transcatheter mitral valve repair device on the market. These devices are marketed under the name "MitraClip". There have been, going back to 2008, a number of different versions of MitraClip.

6. There have been a number of clinical trials in relation to the efficacy of the earlier MitraClip devices, two of which are EVEREST I and EVEREST II. In 2018, the latest iterations of the MitraClip device, the MitraClip NTR and the MitraClip XTR, were launched. There is a further iteration, the MitraClip G4, which recently received FDA approval in the United States, but which has not yet been launched.

7. The Claimants allege that the PASCAL device infringes two of the Claimants' patents, EP 1,1408,850 (the "850 patent"), and EP 1,624,810 (the "810 patent"). The Defendant denies infringement and counterclaims that both of these patents, the 850 patent and the 810 patent, are invalid. The trial of these issues was expedited by Arnold J (as he then was) and is due to be heard in December 2019.

8. In the event that the outcome of the December hearing is against the Defendant – in other words, were it to be found that the patents are valid and infringed –the Defendant additionally contends that the grant of a permanent injunction prohibiting the supply of the PASCAL device in the United Kingdom would be disproportionate having regard to the public interest. The Defendant has pleaded, as a result, a public interest defence.

9. The public interest defence has had something of a chequered procedural history. It was raised by the Defendant in the infringement and validity proceedings and was debated before Henry Carr J in the context of an application, by the Claimants, for an interim injunction. The application for an interim injunction was refused. Various directions were made, both by Henry Carr J and other High Court Judges, regarding (amongst other things) the pleading of the issues, disclosure and evidence.

10. One of the consequences of these directions was that the public interest defence was hived off to its own expedited trial, due to be heard in January 2020, one month after the first trial. In the course of this hiving off, it is fair to say that the question of disclosure in relation to the public interest defence appears to have fallen off both parties' radar. I say that intending no criticism, but I must mention it in order to explain why we find ourselves in the position we are in today.

11. It was contended by Ms Pickard, who appeared for the Defendant, that this was a case where an order for extended disclosure had been made under paragraph 6 of the Disclosure Pilot Rules, and that what the Claimants were seeking to do by their application was to vary that order for extended disclosure under paragraph 18 of the Disclosure Pilot Rules. I do not consider that that is the correct characterisation of what has happened and, to be fair to her, Ms Pickard did not press the point very hard when I explored this question with her in the course of her submissions. She was prepared to accept that this was in fact a case where disclosure was – in relation to the public interest defence – being addressed late in the day and that the application by the Claimants was in fact an application for extended disclosure under paragraph 6 of the Disclosure Pilot Rules.

12. In short, this was not a case where the question of extended disclosure had previously been considered by the court, and an order made. Rather, this was a case where there had been no such prior consideration, and the matter of disclosure in relation to the January 2020 trial was now being addressed, effectively for the first time, before me.

13. It is necessary now for me to turn to the manner in which the public interest defence has been pleaded. That defence was inserted by way of amendment into the Defendant's Defence, at paragraph 10. This paragraph reads as follows:

> "To the extent that any of the claims of the patents are held to be valid and infringed and the Claimants are held to be entitled to relief, it would be disproportionate, having regard to the public interest, to restrain the supply of the PASCAL device in the UK. Accordingly, pursuant to section 50 of the Senior Courts Act 1981, the court should exercise its discretion to refuse the injunctive relief sought by the Claimants. In support of the foregoing, the Defendant shall rely on the following:
>
> (i) The Defendant's PASCAL device is significantly different to other transcatheter mitral valve repair devices approved for sale in the United Kingdom, including the Claimants' MitraClip device. Such differences include the following:
>
> (a) The PASCAL device includes a central spacer;
>
> (b) The PASCAL device includes a single row of teeth on each clasp;
>
> (c) The PASCAL device includes long, broad, methanol-framed paddles;

(d) The PASCAL device can adopt an elongated configuration for reposition and/or removal of the device;

(e) The clasps of the PASCAL device can be operated independently;

(f) The PASCAL device includes the PASCAL styryl delivery system.

(ii) In the premises, the PASCAL device can:

(a) Be used to successfully treat patients who could not otherwise be successfully treated with other available transcatheter mitral valve repair devices, including the Claimants' MitraClip device; and/or

(b) Provide favourable clinical outcomes in comparison to other available transcatheter mitral valve repair devices, including the claimants' MitraClip device.

(iii) For clinical reasons, clinicians prefer, and should not be prevented from, having different treatment options to treat their patients according to their clinical judgment."

14. Preparing for this hearing last night, I read this plea with great care and considered that it was clear and unambiguous. However, in the course of Mr Abrahams' very able submissions in support of the Claimants' application for extended disclosure, it became clear that there was an ambiguity latent in this pleading.

15. I read the pleading in paragraphs 10(i), (ii) and (iii) as conjunctive and not disjunctive points. Paragraphs 10(i) and 10(ii) lead up to the Defendant's central point for the purposes of the January 2020 trial, namely that it is in the public interest that clinicians should not be prevented from administering, as part of their treatment of patients, the PASCAL device because it is a clinical option that should, in the public interest, be available to them.

16. That is the point made in paragraph 10(iii), but it only works because of the pleading in paragraph 10(i) – which sets out the differences between the PASCAL device and other devices – and paragraph 10(ii) – which pleads the advantages said to arise out of these differences, and seeks to explain why a clinician might prefer one device over another. So, it is said in paragraphs 10(ii)(a) and (b) that there are two cases where the PASCAL device might be preferred by a clinician:

i) One case is where patients could not be treated by any other transcatheter mitral valve device, including MitraClip devices;

ii) The other case is to provide a more favourable clinical outcome than would be pertain if one used an alternative mitral valve repair device, again including the MitraClip device.

17. It seemed to me, both on a first reading and on later readings, that paragraph 10(ii) was actually asserting that these two cases pertained in the judgment of clinicians. In other words, the point was not whether – as a matter of court-ascertained objective fact – the PASCAL device had these advantages, but whether clinicians perceived, in their clinical judgment, the PASCAL device to have these advantages.

18. I put this reading to Ms Pickard and she accepted it as a correct articulation of the Defendant's case. For the avoidance of doubt – given the ambiguity that clearly exists, given Mr Abrahams' submissions – it seemed to me appropriate (and purely for the avoidance of doubt) to make two changes to paragraph 10:

    i) To insert, after the word "can" in the first sentence of paragraph 10(ii), the words "in the reasonable judgment of clinicians". Thus, the first line of paragraph 10(ii) will now read:

    > "In the premises, the PASCAL device can in the reasonable judgment of clinicians:"

    ii) To delete the opening words of paragraph 10(iii), "For clinical reasons", and to inserted instead the words "By reason of the facts and matters pleaded in paragraphs 10(i) and (ii) above". Thus, paragraph 10(iii) will now read:

    > "~~For clinical reasons~~ By reason of the facts and matters pleaded in paragraphs 10(i) and (ii) above, clinicians prefer, and should not be prevented from, having different treatment options to treat their patients according to their clinical judgment."

19. I have spent some time seeking to articulate exactly the nature of the Defendant's public interest defence, because it seems to me that this goes to the heart of the present application. For the avoidance of doubt, I give permission to amend paragraph 10 of the Defence in the two respects that I have articulated: indeed, given the importance that I attach to the formulation of the public interest defence, these are amendments that the Defendant will be required to make, and Ms Pickard confirmed that they would be made.

20. It is clear from paragraph 10, that the clinician preference pleaded in paragraph 10(iii) will be demonstrated by the expert opinion evidence of clinicians, supplemented by some factual evidence from the Defendant explaining the Defendant's understanding as to why some clinicians prefer the PASCAL device. This factual and expert evidence has, I should point out, already been served by the parties and filed with the court.

21. The prism through which the existence (or otherwise) of the advantages of the PASCAL device are assessed is the reasonable judgment of the clinician. It is not the Defendant's case that the court must itself determine, "from the ground up" and independent of the judgment of clinicians, whether the PASCAL device is indeed better than other devices for the reasons pleaded by the Defendant. Given the evidence served by both parties, there is no way in which this court could possibly determine, essentially from first principles, and without regard to the judgment of clinicians, whether, objectively speaking, the PASCAL device can be said to be better in the ways articulated in paragraphs 10(ii)(a) and (b).

22. It may very well be that the reasonable judgment of clinicians for preferring one product over another is insufficient to trigger the public interest defence. Mr Abrahams has made very clear that this is a point he intends to take at trial and he is, of course, entitled to do that. It is not necessary for me, in determining the Claimants' application, to articulate what would and what would not satisfy the public interest defence. I am simply concerned with the question of disclosure.

23. Carrying on with the pleadings, it is also important that I refer to a Request for Further Information made by the Claimants of the Defendant. It is relevant to note the

Defendant's answer to Request 3. Request 3 seeks to explore the sort of limits the Defendant would seek to incorporate into any injunction granted by the court in order to protect the public interest. The Defendant contended that any injunction ordered should be limited by following the proviso:

> "The Defendant shall not be restrained from disposing of, offering to dispose of, using, importing or keeping, whether for disposal or otherwise, the PASCAL device in the United Kingdom for the purposes of treating patients for whom, in the medical judgment of a clinician, the PASCAL device is the most appropriate treatment option."

Whether an injunction is granted in those terms, or in other terms, is not a matter for me. But this answer provides important further clarification of the way in which the Defendant articulates the public interest defence.

24. I was also taken to the answers to Requests 6, 7, 8 and 9. These Requests seek further information as regards the advantages, or perceived advantages, of the PASCAL device over other, rival, devices. I will not quote these answers – they are long – but I observe that if one reads the responses to Requests 6, 7, 8 and 9 on their own, one might be led to believe that a "from the ground up" evaluation of product superiority was being called for. As I have said, that is not my reading of paragraph 10 of the Defence, and it is trite that a response to a request for further information cannot be used to expand or amend a case, but merely to clarify a case that has already been pleaded.

25. I turn then to disclosure that is sought by the Claimants. By its application notice issued on 4 October 2019, the Claimants seek an order that there be disclosure of all documents within the Defendant's control recording any PASCAL implantations at which an "adverse event" occurred, including documents recording the nature of and/or reasons for any such adverse event. The term "adverse event" was a defined term in the application notice, and <u>included</u> documents relating to the following cases:

    i) Cases where the implantation of PASCAL has been abandoned and a MitraClip has been implanted instead.

    ii) Cases where a MitraClip has been implanted in addition to PASCAL.

    iii) Cases where the implantation of PASCAL has been abandoned either before or during the procedure.

    iv) Cases where the PASCAL device had become fully or partially detached from the valve leaflets.

    v) Cases where one or more of the sub-valvular chordae have been damaged during the procedure.

    vi) All other reports of suspected adverse events received from patients or physicians.

26. The list was in fact rather more extensive than this, but these six instances are sufficient to understand the nature of the Claimants' disclosure application.

27. Why is this material sought? The explanation can be found in two statements given by the Claimants' instructing solicitor, Mr Cohen. For present purposes, it is only necessary to refer Mr Cohen's ninth and tenth statements. I have obviously read the entirety of these statements, but it is only necessary to refer to certain paragraphs. Paragraph 16 of Mr Cohen's ninth witness statement says this:

> "The claimants expect that the Defendant's evidence in support of its public interest defence is likely to include selected evidence of successful PASCAL procedures. Evidence confined to such carefully selected instances of successful PASCAL implantations would give a wholly misleading picture of the efficacy of PASCAL. This evidence would only be of value to the court if placed in its proper context, which would include unsuccessful procedures and adverse events. The disclosure request would allow the Claimants to fully test the Defendant's case on the public interest defence, something it will not be able to do fully on the basis only of documents which are in the public domain."

That point is repeated in Mr Cohen's tenth statement, which (in paragraph 6) says this:

> "The reasons why the Claimants considered disclosure to be necessary in this case are set out in paragraphs 15 to 19 of Cohen 9. In summary, the Claimants expect that the Defendant's evidence in support of its public interest defence will include selected evidence of successful PASCAL procedures. Evidence confined to such carefully selected instances of successful PASCAL implantations would give a wholly misleading picture of the evidence in PASCAL. This evidence would only be of value to the court if placed in its proper context, which would include unsuccessful procedures and adverse events. The disclosure request would allow [the Claimants] to fully test the Defendant's case on the public interest defence, something which it will not be able to do fully on the basis only of documents which are in the public domain."

28. These statements give the impression that evidence from the Defendant is yet to be served. In fact, the Defendant's evidence was served between the giving of Cohen 9 and Cohen 10, and I have been referred to the material that has been adduced by all parties in relation to the public interest defence. Entirely unsurprisingly, given the case that I understood the Defendant to be running in paragraph 10 of its Defence, the evidence that has been adduced, certainly by the Defendant, relates to the perception of clinicians as to whether the PASCAL device is to be preferred for the two reasons articulated in paragraph 10(ii) of the Defence. The evidence that is deployed in support of the public interest defence essentially goes to why a clinician, in the exercise of his or her clinical judgment, would elect for good reason to use the PASCAL device either because no other device would work or because the outcome using the PASCAL device would be preferable to any other device.

29. None of the evidence that has been served to date in this case makes any reference to the adverse evidence or the adverse reports that exist in relation to either the PASCAL

device or the MitraClip devices. In other words, the Defendant does not seek to burnish the reputation of PASCAL by reference to positive event reports in its control. Neither does the Defendant refer to negative event reports regarding the MitraClip devices.

30. The reason for this approach is because the focus is on the reasonable judgment of clinicians in preferring the PASCAL device. The evidence served goes to that point which is, as I find, the pleaded point. The Claimants, by their application, seek to extract from the Defendant adverse event reports not seen by clinicians in order to put these, in cross-examination, to the witnesses being called by the Defendant. It seems to me that the disclosure such evidence in the course of the public interest trial would serve no useful purpose. The fact is that one cannot derive any form of reliable conclusion from an adverse event report, when viewed in isolation and not in context. It would be impossible for a clinician, in cross-examination, to give any sensible view as to the significance or otherwise of a single adverse event report, or, indeed, multiple adverse event reports.

31. The fact is that the trial of the public interest defence is not going to focus on what, objectively speaking and without regard to clinician understanding, is the better product. Were the court to conduct a "from the ground up" analysis of this sort, the adverse event reports, just like positive event reports, would be part – a very small part – of the material relevant to that question. That is because, to resolve that issue, this court would have to conduct in effect its own clinical trial of the PASCAL device, to determine whether the view that is alleged to exist on the part of clinicians in terms of their preference of the PASCAL device is actually objectively justified. Were that the issue, then I have no doubt that the disclosure sought by the Claimants would be given. As it is, I do not consider the disclosure sought by this application to be relevant to the issues in this dispute.

32. I turn to the Disclosure Pilot Rules. Paragraph 7(3) of the Disclosure Pilot Rules refers to "issues for disclosure" and defines these as meaning, for the purposes of disclosure, only those key issues in dispute which the parties consider will need to be determined by the court with some reference to contemporaneous documents in order for there to be a fair resolution of the proceedings. That does not extend to every issue which is disputed in the statements of case by denial or non-admission.

33. I have no hesitation in finding, for reasons that I have given, that the disclosure sought by the Claimants does not fall within this definition of issues for disclosure and that the application must be refused for that reason alone.

34. Were it necessary, I would consider the parameters of paragraph 6 of the Disclosure Pilot Rules, which in paragraph 6(4) sets out the criteria that must be borne in mind when considering whether an order for extended disclosure should be made. Paragraph 6(4) makes clear that, in all cases, extended disclosure must be reasonable and proportionate having regard to the overriding objective and the various factors that are listed in that paragraph.

35. Because I have concluded that the disclosure sought does not relate to an issue for disclosure within the meaning of paragraph 7 of the Disclosure Pilot Rules, it is unnecessary for me to consider whether the disclosure sought by the Claimants would satisfy the "reasonable and proportionate" test. Had I reached a different conclusion, however, I should make clear that I do not consider that the factors in paragraph 6(4)

of the Disclosure Pilot Rules could justify the disclosure sought by the Claimants, even if I were persuaded that in some tangential way the material went to an issue for disclosure.

36. Accordingly, and for those reasons, I dismiss the application.

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