



Neutral Citation Number: [2019] EWHC 955 (Pat)

Case No: HP-2019-000003

**IN THE HIGH COURT OF JUSTICE**  
**BUSINESS AND PROPERTY COURTS**  
**INTELLECTUAL PROPERTY LIST (CHANCERY DIVISION)**  
**PATENTS COURT**

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

Date: Tuesday, 9<sup>th</sup> April 2019

**Before:**

**MR. JUSTICE HENRY CARR**

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**Between:**

(1) EVALVE INC.  
(2) ABBOTT CARDIOVASCULAR SYSTEMS  
INC.  
(3) ABBOTT MEDICAL UK LIMITED

**Claimants**

- and -

**EDWARDS LIFESCIENCES LIMITED**

**Defendant**

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**MR. TOM MITCHESON QC and MR. MICHAEL CONWAY** (instructed by **Taylor Wessing LLP**) for the **Claimants**.

**MR. PIERS ACLAND QC** (instructed by **Powell Gilbert LLP**) for the **Defendant**.

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**Approved Judgment**

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## **MR. JUSTICE HENRY CARR:**

### **Introduction**

1. I have before me a dispute of a very common nature concerning which individuals should be admitted to a confidentiality club which has been agreed between the parties in this case.
2. There were, at the start of this hearing, two applications before the court; one made by the claimants, (“Abbott”), and the other made by the defendants, (“Edwards”).
3. In relation to Abbott's application, Edwards' confidential information has been disclosed under terms of confidence to the following individuals: Ms. Embry, who is Abbott's Senior Counsel Intellectual Property Litigation; and Mr. Maraschi, who is Abbott's EMEA marketing director. Edwards has agreed that its information may also be disclosed to three other members of Abbott's legal team: Namely, Hubert Allen, Executive Vice President, General Counsel and Secretary; David Mendelson, Divisional Vice President and Associate General Counsel; and Gary Schneiderman, former Division Counsel, Patent Litigation and exclusive consultant.
4. The outstanding dispute in relation to Abbott's application is whether the information should also be made available to two additional members of its legal team, namely, Paul Yasger, Divisional Vice President and Associate General Counsel, and Ron Devore, Division Counsel, Patents.
5. On 5th April, Edwards served its own application because at that stage, Abbott had only admitted one individual from within Edwards to review the information which it had designated confidential, namely, its business manager, Rodolfo Estay, who is Vice President, Transcatheter Mitral and Cuspid Therapies, Europe. The outstanding dispute was whether, as Edwards contended, three individuals from its legal team should be included in the confidentiality club, namely, Aimee Weisner, Corporate Vice President, General Counsel; Ryan Lindsey, Senior Patent Counsel; and Avi Schwartz, Director IP Litigation Counsel.
6. Wisely, Abbott have now consented to the admission of those three individuals to the confidentiality club. Had it not done so, I might well have taken a very different attitude to Abbott's application. The position now is that Edwards has its chosen in-house legal team included in the confidentiality club.

### **Background**

7. This is a claim for infringement of two of Abbott's patents which are for devices used in the percutaneous treatment of mitral regurgitation, where the mitral valve of the heart does not close properly. Abbott has sued Edwards for infringement of related patents in several other jurisdictions, including in the US District Court of Delaware.
8. The only device which is currently on the market is Abbott's MitraClip. The alleged infringing product is a device called PASCAL, which Edwards is planning to launch later this year in the UK, as recorded in a judgment of Arnold J, where he ordered that the trial should be expedited and fixed in the window from the 9th-20th December 2019.

9. Abbott has applied for a preliminary injunction, supported by a statement of Mr. Maraschi, certain limited parts of which have been currently designated "Confidential". Edwards' responsive evidence includes a witness statement of Mr. Estay. Again, certain limited parts of that statement have also been designated "Confidential".
10. For the purposes of the Delaware proceedings, the parties have agreed a confidentiality regime, as set out in a protective order. The order identifies two categories of information; namely, confidential and highly confidential information. Information designated "Highly confidential" may be disclosed only to Ms. Embry, Mr. Allen, Mr. Mendelson and Mr. Schneiderman on Edwards' side. Mr. Yasger and Mr. Devore are entitled to see information which is designated "Confidential" rather than "Highly confidential". My understanding is that there was an objection to Mr. Yasger and Mr. Devore seeing information which might be relevant to patent prosecutions in which they are potentially involved. The information with which I am concerned is not relevant to patent prosecutions.

### **Legal principles**

11. The applicable principles are very well-known and were summarised by Aldous LJ in *Roussel Uclaf v ICI*, [1990] RPC 45 at 54. In brief, Aldous LJ said that each case has to be decided on its own facts and the broad principle must be that the court has the task of deciding how justice can be achieved, taking into account the rights and needs of the parties. The object to be achieved is that the applicant should have as full a degree of disclosure as will be consistent with adequate protection of its secret. The court will be careful not to expose a party to unnecessary risk of its trade secrets leaking to, or being used by, competitors. What is necessary or unnecessary will depend on the nature of the secret, the position of the parties and the extent of the disclosure ordered. Essentially, it is a balance between the degree of risk of prejudice if the relevant information is disclosed to named individuals as against the risk of prejudice if it is not. If disclosure is unduly restricted, it may be that the defence or prosecution of the proceedings may be impeded.

### **Discussion**

12. In the present case, Edwards' confidential information describes its marketing strategy for PASCAL in the United Kingdom, including the identity of the target clinical centres, the number of planned implementations, the pricing of the product, and the resources to be deployed. Whilst, as a matter of generality, the fact that PASCAL is due for a limited launch in the United Kingdom is not confidential, I accept that the detail of this information certainly is. Therefore, it is extremely important that it should not be made public by deliberate or inadvertent disclosure.
13. Mr. Acland QC, who appeared on this application on behalf of Edwards, disclaimed any suggestion that there would be deliberate disclosure by Mr. Yasger or Mr. Devore. Therefore, the question is whether there is prejudice by risk of inadvertent disclosure.
14. Edwards' position may be summarised as follows: first, it is said that Abbott's evidence does not, or does not properly, address the need for Mr. Yasger and Mr. Devore to be included in addition to the other members of the legal team, who

have already been included. It is said that Abbott has an ample legal team in the form of Messrs. Embry and Allen, Mendelson and Schneiderman, to give instructions to Taylor Wessing for the forthcoming preliminary injunction application. It is said that there is no justification, nor any need for Mr. Yasger or Mr. Devore to be included in Abbott's confidentiality club.

15. Looking at the other side of the balance, Mr. Acland submitted that there is a risk of inadvertent disclosure simply by an increase in the numbers of in-house lawyers on Abbott's side from four to six. He postulated the possibility of a document being left in a room accidentally or a chance conversation which might lead to one of Abbott's sales force learning of the plans which Edwards have disclosed for its UK launch.
16. The other potential prejudice which has been canvassed on this application is in relation to collateral use of the information. For example, it was said that Abbott might use the fact that Mr. Yasger and Mr. Devore have been included in the confidentiality club and have received this confidential information in order to re-open the position in the United States and seek a variation of the protective order there.
17. As to the first question, namely is there a need for Mr. Yasger and Mr. Devore to see this information, that is addressed in the evidence of Ms. Embry in support of the application. She explains in her first witness statement how Abbott instructs its legal team in the context of global litigation of which the UK is, I would suggest, a relatively modest part. Ms. Embry is able to provide instructions on straightforward matters to Taylor Wessing, but strategic decisions are made by a team of lawyers. The legal team meets on a regular basis and sign-off from the team as a whole is required on all important decisions. She says (and I accept) that such an arrangement is unsurprising in an organisation the size of Abbott and in relation to litigation of this nature.
18. Mr. Hubert Allen is the senior member of the team. On Mr. Allen's senior staff are Mr Mendelson, who is head of litigation, and Mr. Yasger, who is head of intellectual property. Both have responsibility for this litigation, each providing complementary expertise and experience; both are Divisional Vice Presidents and Associate General Counsels, reporting to Hubert Allen, Abbott's General Counsel. Organisationally, Ms. Embry is one step below, and she reports to both Mr Mendelson and Mr. Yasger. Ms. Embry says that, under the circumstances, it would make it untenable for the legal team to function properly if Ms. Embry had access to information and Mr. Allen did as well, but Mr. Yasger did not.
19. Mr. Devore is a Divisional Counsel at Abbott, with specific expertise in relation the field of devices with which we are concerned. Both Mr. Yasger and Mr. Devore are US attorneys and, as Ms. Embry explains (and even without her explanation, I would accept) they understand their duties to keep material confidential.
20. Mr. Mitcheson QC, who appeared for Abbott on this application, submitted that their inclusion in the confidentiality club will not increase the risk of inadvertent disclosure. On the contrary, the risk of inadvertent disclosure might be higher if there were members of the same legal team with different levels of access to certain information. I see the force of that submission and I believe that it is correct.

21. In a second witness statement, served shortly before this hearing, Ms. Embry explained further the need for Mr. Yasger and Mr. Devore to be included in the confidentiality club. She explained that Abbott does not have a separate IP litigation group within its in-house legal structure, and patent litigations such as this case are dealt with by drawing expertise from the separate IP and litigation groups. Mr. Yasger heads the IP group of which Mr. Devore is a member, and Mr Mendelson heads the litigation group of which Ms. Embry is a member. The inclusion of Mr. Devore and Mr. Yasger in the confidentiality club, according to Ms. Embry, ensures that there are members in each of the layers of management for both the litigation team and the IP team. Without the inclusion of Mr. Devore and Mr. Yasger, there is no representation of the IP in-house Abbott team in the confidentiality club, which Ms. Embry states is impairing Abbott's conduct of the litigation.
22. She also explains that Mr. Devore has detailed in-depth knowledge of the commercial background of the MitraClip device and of the commercial field of devices for edge-to-edge treatment of mitral valve disease generally. His commercial input, she says, will be very valuable for the strategic decisions required in relation to the preliminary injunction application. She states that by unreasonably resisting Mr. Devore's inclusion in the UK confidentiality club, Edwards are hindering the efficient function of the legal team.
23. I accept that evidence and I accept that there is prejudice, or at least potential prejudice, to Abbott, if none of its in-house IP team are included in the confidentiality club. This establishes, in my view, a *prima facie* case that Mr. Yasger and Mr. Devore should be admitted.
24. As against that, I need to balance a potential risk of inadvertent disclosure. The inadvertent disclosure raised by Edwards in its evidence was the possibility that a competitor might learn of the information. In fact, there is no competitor to Abbott or Edwards who, according to the evidence, would be interested. The information is primarily of interest to the legal teams seeking to resist the injunction application and also, potentially, to Abbott's sales force.
25. The question of disclosure to Abbott's sales force was not raised by Edwards in its evidence, and therefore has not been addressed by Abbott. Mr. Mitcheson rightly points out that this issue could well have been the subject of evidence from Abbott, because it may well be that the individuals concerned do not communicate with the sales force and do not share relevant premises.
26. In any event, I regard the possibility of inadvertent disclosure by Abbott's lawyers as vanishingly small. If inadvertent disclosure were made by any of Abbott's lawyers or, indeed, any of Edwards' lawyers, that would be an extremely serious matter, both for Abbott or Edwards, and for the individuals concerned. Those individuals will be fully aware of their obligations and of the consequences if they were breached. Therefore, I would expect and believe that adequate precautions will be taken.
27. Weighing up all the circumstances, I consider that Mr. Yasger and Mr. Devore should be permitted access to the information, subject to the confidentiality undertakings that they are willing to give.

28. I should add that I was also concerned about the possibility raised in Edwards' evidence that the fact that these individuals had been included in the confidentiality club might be used for a collateral purpose; namely, to seek to vary the protective order in the United States where Mr. Yasger and Mr. Devore have not hitherto been allowed access to highly confidential information. However, on instructions, Mr. Mitcheson has made clear that Abbott are willing to offer an undertaking to the UK court not to seek to vary the protective order in that way, which satisfies my concerns in that respect.
29. Therefore, I intend to grant Abbott's application.

**Abbott's undertaking**

30. I am asked to resolve a relatively small dispute in relation to the terms of an undertaking that Abbott are willing to give, one part of which is agreed and one part of which would require further instructions to be given to Mr. Mitcheson, which is not yet agreed.
31. Abbott are prepared to undertake not to use the provision of Edwards' confidential information to Mr. Yasger and Mr. Devore to seek to re-open the US protective order. The part that Abbott are not currently in a position to agree to is whether to offer an undertaking not to use the fact that Edwards' confidential information has been provided to those individuals to challenge the designation under the US protective order by Edwards of information as "Highly confidential" or "Confidential".
32. My concern, as expressed earlier in this judgment, was that Abbott should not be in a position to use the inclusion of Mr. Devore and Mr. Yasger in the UK confidentiality club for a collateral purpose, such as to gain an advantage in other proceedings. Therefore, I consider it is appropriate, if Abbott wish to take advantage of the opportunity to include Mr. Yasger and Mr. Devore within the UK confidentiality club, for Abbott's undertaking to make clear that they will use the fact that the information has been provided to Mr. Yasger and Mr. Devore to gain an advantage in the US proceedings. However, I accept that it is a matter for Abbott's election. If they offer the undertaking that Mr. Acland has requested, then Mr. Yasger and Mr. Devore will be added to the confidentiality club; if they do not, then they will not. I also accept that it is appropriate for Abbott to be given an opportunity to consider whether to offer this undertaking.

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