Neutral Citation Number: [2020] EWHC 513 (Pat)

Case No: HP-2019-00003

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: 12/03/2020

Before :

MR JUSTICE BIRSS

- -

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: 15th, 16th, 17th, 21st and 22nd January 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 what the parties called the Public Interest trial. It was scheduled to come after the main patent trial. The issue to be decided is Edwards' submission that even if Edwards' PASCAL product is found to infringe a valid claim of one of Abbott's patents, nevertheless no final injunction should be ordered because to do so would be contrary to the public interest. At the time the Public Interest trial was heard, the main trial had taken place but no judgment had been given. In fact as things have turned out I have finished both judgments at the same time and they are handed down on the same day. The main patent judgment is [2020] EWHC 514 (Pat). In it I conclude that PASCAL infringes both patents.

2. The patents, EP (UK) 1 408 850 and EP (UK) 1 624 810 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. An explanation of the anatomy of the heart and the disorder these devices treat is given in the main judgment. Importantly, mitral valve regurgitation is a common disorder with the prevalence rising sharply with age. Before the MitraClip there was no effective transcatheter treatment available. The only effective treatments involved open heart surgery. Those patients with progressive mitral valve regurgitation have a poor prognosis and without treatment many will die within a year of diagnosis. However a significant number of the elderly patients with mitral valve regurgitation are not strong enough to be able to have open heart surgery. That is why the ability to treat the disorder by a transcatheter technique, which does not involve open heart surgery, is so significant.

3. In fact today there are two kinds of MitraClip on the market, the NTR and XTR. This pair of products is the third generation of MitraClips on the market and a fourth generation (G4) has been approved in the USA. Approval for the G4 is being sought in Europe.

4. Edwards' PASCAL product is another transcatheter treatment for mitral valve regurgitation. Both PASCAL and MitraClip operate in essentially the same way, clipping the two leaflets of the valve together, hopefully leading to a reduction in mitral valve regurgitation. The general technique is called edge to edge valve repair. PASCAL and MitraClip are the only transcatheter edge to edge devices approved in Europe today. The term "eeTVR" refers to edge to edge transcatheter valve repair.

5. Edwards' case can be put a number of ways. One way of putting it is that there is a body of doctors in the UK whose reasonable clinical opinion is that, at least for certain patients, PASCAL would be a better device to use for that patient than any of the MitraClip products and therefore given that, it would not be in the public interest toprevent these doctors from doing this by an injunction preventing sales of PASCAL. Another way of putting it is that there are doctors who prefer, on reasonable grounds, to use PASCAL in certain cases instead of MitraClip. Although it is possible to think of differences between these two ways of putting it, in this case nothing turns on that sort of distinction.

6. Edwards advances a set of particular circumstances for which it contends that, if any one or more of them are applicable to a given patient, then given the differences in design and functionality between MitraClip and PASCAL, a reasonable doctor would

(or some reasonable doctors do) decide that the PASCAL would be better than the MitraClip in that case. In this respect Edwards relies on a set of defined medical criteria which relate to the circumstances and also a set of features of the PASCAL product. Although Edwards' primary case is that no injunction at all should be granted for this reason, Edwards also advances a fall back position amounting to a conventional injunction to be granted but qualified by carving out from the injunction supplies of PASCAL for use in patients to whom one or more of the defined medical criteria apply. A mechanism is proposed whereby the doctor would make a declaration about those circumstances in order to be permitted to be supplied with a PASCAL device.

7. Note that Edwards' primary case that no injunction at all should be granted would mean that PASCAL products could be sold for use in any patients, irrespective of the medical criteria referred to. There is evidence that when the two products are both available side by side then PASCAL represents 30-40% of the eeTVR market. Although the numerical evidence was very sparse, doing my best having heard the evidence I have little doubt that that sort of market share is much bigger than would be represented purely by the application of the defined medical criteria.

8. At times in argument there was reference to the idea of trying to identify the reasonable opinion of a single notional reasonable doctor instead of referring to a class of doctors holding a certain reasonable view. The distinction between these two ideas does not matter in this case.

9. Edwards also says that there are patients for which in the reasonable opinion of the doctor, in what I will call extreme cases within the defined medical criteria, no MitraClip would be able to treat the patient but a PASCAL would be able to treat them, or at least would be likely to do so.

10. Finally Edwards says that in cases in which MitraClip implantation has been unsuccessful but a doctor reasonably believes a PASCAL would be an appropriate treatment to try after that failure, then supply for that purpose should be permitted. Abbott agrees with this and is willing to accept a carve out from the injunction on that basis. Nevertheless Abbott contends that the likelihood of this taking place is very small because if one device has not been successful the likelihood that the other one would work is remote.

11. Abbott's position is that an injunction should be granted with the sole qualification just referred to. No other carve outs should be granted nor should the court accept Edwards' case that no injunction be granted. There are some disputes on the law and also disputes on the facts. Abbott contends that the fact that there are some doctors today who would prefer to use PASCAL over MitraClip (and are not negligent in having that view) does not justify refusal of the injunction. Abbott argues that Edwards has not established, and indeed has not tried to establish, that there is any class of patient for whom PASCAL is objectively the only viable treatment or is objectively a better treatment than MitraClip. Abbott contends that on the evidence, while there are patients for whom the transcatheter edge to edge technique cannot be used, there has not been shown to be any patients for whom it can be said, before attempting treatment, that PASCAL would or could work when MitraClip would not. In other words, according to Abbott, on the evidence before the court all patients who could be treated at all by eeTVR can be treated using MitraClip and that is so both

objectively and in the reasonable opinion of doctors as it stands today. It may be in the future that reliable evidence will emerge to show that there are patients who can only be treated by PASCAL or for whom PASCAL is objectively better, but Edwards has not attempted to prove it in this case and it has not emerged yet in the clinical literature. In relation to Edwards' defined medical criteria, Abbott contends the evidence does not make that case good either individually or in combination.

12. Abbott argues that while it is apparent that there are some doctors today who would prefer to use PASCAL over MitraClip and are not negligent in having that view, on the state of the evidence available, that is a "mere" preference and is not founded on a sufficient objective evidence to justify a carving out from the injunction (or outright refusal) on public interest grounds.

The witnesses

13. Abbott called five fact witnesses: Santosh Prabhu, Hugues Gervais, Martin Townsend, Erwan Donal, and Joanne Barrette.

14. Santosh Prabhu is the Divisional Vice President of Product Development within the Structural Heart Division of the Abbott group of companies. The focus of his evidence dealt with the details of the four generations of MitraClip. Mr Prabhu was cross-examined and gave his evidence fairly. He explained that the independent grasping feature of MitraClip G4 was developed in part in response to clinical feedback, including requests from users. The PASCAL has an independent grasping feature and I infer that one reason for the feature's introduction into MitraClip was a response to PASCAL.

15. Hugues Gervais is the Divisional Vice President of Abbott Vascular Inc.'s Structural Heart business unit in EMEA. His evidence described the potential impact on Abbott's business of PASCAL being able to enter the UK market prior to May 2024. Mr Gervais was cross-examined. He was a good witness.

16. Martin Townsend is the Regional Therapy Manager of an Abbott division called Abbott Structural Heart. He had been at Evalve from 2009 and joined Abbott when Evalve was acquired. From 2009 his role has been to train physicians in using MitraClip and to act as a proctor for MitraClip procedures. A proctor is an individual from the medical device supplier who advises clinicians in the use of device such as MitraClip both before and during implanting. Proctors often attend the implanting itself. This happens both for MitraClip, with Abbott proctors and PASCAL, with Edwards proctors.

17. Mr Townsend gave his oral evidence fairly. Edwards' criticised the evidence in his witness statement about an episode at Royal Brompton concerning an implanting of a PASCAL device. Mr Townsend's written evidence was an accurate portrayal of the information available to him but further information was in an email from the doctor at the hospital to staff at Edwards which presents further details about what happened. Mr Townsend did not quarrel with the further detail. This episode does not lead me to place less weight on Mt Townsend's written evidence.

18. A further point taken by Edwards was that Mr Townsend accepted that Abbott's structural heart business was divided into silos. This was potentially relevant to an

issue about whether competition between PASCAL and MitraClip could cause not only lost sales of MitraClip devices but lost sales of other Abbott products, particularly Portico, a TAVI device. This in turn got into the issue of proctoring, since even if one company's proctor was at a hospital to advise on their ee-TVR product, the presence of that proctor might help with sales of other products from the company's portfolio. I did not find it necessary to get into this issue in that level of detail. In case it matters, I would hold that it is true that Abbott's structural heart business is arranged so that MitraClip and Portico are dealt with by distinct groups ("silos"), but it does not follow from this that that undermines Abbott's case that there could be an impact on Portico sales caused by competition between PASCAL and MitraClip.

19. Professor Erwan Donal is Head of the Echocardiography Unit and the Imaging Core Lab at the Centre Hospitalier Pontchaillou, France. He specialises in the treatment of valvular and structural heart disease, including the treatment of mitral regurgitation. He gave an account of his experience using PASCAL, and his team's decision to discontinue its use. Professor Donal's evidence was given under a hearsay notice, made pursuant to s2 of the Civil Evidence Act 1995 and to CPR Rule 33.

20. Joanne Barrette is Abbott's Structural Heart Division Regional Sales Director for New York. Her evidence was limited to a factual account of events relating to a patient who had been treated by Dr Kipperman, but whose MitraClip procedure had not been successful. Ms Barrette was not cross-examined.

21. Abbott called Dr Moody Makar as an expert witness. Dr Makar is the Director of Interventional Echocardiography at Cedars Sinai Medical Centre in Los Angeles, California. His evidence focussed on his own experience of MitraClip procedures, which is very extensive, as well as some, limited, experience of using PASCAL. Dr Makar addressed the arguments about MitraClip's suitability for use in patients with certain challenging anatomies, and provided his own experience of having treated such anatomies with the MitraClip.

22. Dr Makar is an echocardiographer and cardiac anaesthesiologist. Edwards pointed out that when an implant procedure is performed, a different person, the interventional cardiologist, controls the device and takes ultimate responsibility for the treatment decisions. So, they submitted, despite his expertise, Dr Makar has no hands on experience of actually implanting a device. That is true but it understates the relevance of Dr Makar's experience. Echocardiography is the imaging technique used in the procedure. Abbott submitted that the respective roles of the echocardiographer and the interventional cardiologist can be thought of as the eyes and the hands of the team. Although the metaphor is not exact, I agree it does convey the point that Dr Makar has relevant experience to bring to bear on the issues I have to decide.

23. Dr Makar made clear in cross-examination that he regarded robust clinical data from randomised clinical trials as critical. However he also accepted that real doctors have to make treatment decisions without always having the benefit of such data. For example he accepted that the early decisions to use the MitraClip XTR, based on inferences drawn from patient anatomy and device characteristics, were reasonable even though there was no robust clinical data to support them.

24. Dr Makar was asked about risk, and his answers were generally that there were no or much reduced risks if clinicians took care. Edwards submitted that in this context and in relation to a comparison between data, he had a tendency to argue Abbott's case. Dr Makar did have that tendency to a degree, although I am sure he was always seeking to explain his sincerely held opinions. I will take that into account.

25. Edwards called two fact witnesses: Stephan Windecker and Rodolfo Estay.

26. 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.

27. Professor Stephan Windecker is the Chairman of the Department of Cardiology at Bern University Hospital, Switzerland. He has experience treating patients with all iterations of the MitraClip, and also with the PASCAL, following its launch in Switzerland. His evidence described circumstances in which he or his team had taken a decision to use PASCAL where MitraClip implantation was unlikely to be successful and set out the design differences between the two devices that made it so. Professor Windecker's evidence was given under a hearsay notice. Edwards contended it was not expert evidence. I disagree. The fact that the Professor supports the opinions he expressed by reference to his own experience does not mean it is not expert evidence. I will not rely on his evidence, save for the simple point, self evident from the evidence as a whole, that there are doctors who will use PASCAL and therefore believe it is in the best interests of their patients to do so.

28. Edwards called Dr Robert Kipperman as an expert witness. He submitted three expert reports. Dr Kipperman is an interventional cardiologist at Morristown Medical Centre, New Jersey, with significant experience over 15 years of using both MitraClip and PASCAL devices to treat mitral regurgitation. Dr Kipperman provided a detailed comparison of the physical characteristics of both devices, and set out circumstances in which, in his opinion, use of a PASCAL device would be more appropriate due to the anatomical features of the patient. Mr Kipperman was cross-examined extensively. He gave his evidence entirely fairly, aiming to assist the court. I am grateful to him for his evidence.

29. One aspect of Dr Kipperman's evidence concerned a patient of his for whom he asked Abbott if they could make available a MitraClip G4 on compassionate use grounds. Compassionate use is a way in which devices which are in trials may be used before regulatory approval has been given. Abbott pointed out that there was more to that episode than appeared in Dr Kipperman's written evidence. So there was, but I do not criticise Dr Kipperman for that. Another aspect of Dr Kipperman's evidence was about the number of PASCAL devices used per patient. His clear evidence was that he rarely uses more than one. This was relevant because two MitraClips are used in 40% of cases. Abbott pointed out that the average given for PASCAL in a paper by Lim et al relating to the CLASP study (of which Dr Kipperman is one of a number of authors) was 1.5. On the facts I am satisfied that the true comparison of averages overall based on information today is that MitraClip and PASCAL have very similar

averages (simplistically, the use of 2 in 40% of cases equates to an average of 1.4). The fact that as an individual doctor Dr Kipperman uses a lower number of PASCAL devices than the average in that data is no reason to criticise him or place less weight on his evidence.

The law

30. The case engages two areas of law – patent law and the general law concerning injunctions as a remedy in tort. I will start by identifying the general principles applicable to taking into account the public interest in relation to a patent injunction. There is a fair bit of legal material to address on that. Then I will turn to the specifics of how the court should approach a case put on the basis that Edwards do here, i.e. about the choice exercised by clinicians in the best interests of their patients, as to which very little legal learning has been identified from the researches undertaken by the parties.

31. The most relevant recent decision is that of Arnold J in ***Edwards Lifesciences v Boston Scientific*** [2018] EWHC 1256 (Pat). The judge there addressed the terms of injunctive relief in relation to Edwards' Sapien 3 TAVI device, which had been held to infringe Boston's patent. In that case, the existence of an injunction and the idea of a carve out of some kind had been agreed between the parties, on the basis that there was objective evidence that the Sapien 3 was the only option in some cases. Although it is close to this case, the starting point in ***Edwards v Boston*** was common ground and the court was not being asked to refuse an injunction altogether based on the public interest. Moreover the summary of the law used in ***Edwards*** was based on the decision in ***HTC v Nokia*** [2013] EWHC 3778 (Pat) but that was on a slightly different point and a judgment which I believe is relevant in the present case (***Chiron v Organon No 10*** [1995] FSR 325) was not cited in ***HTC v Nokia*** because it was not relevant in that case and so did not feed into the summary of the law. Therefore I will review the law as a whole before coming back to ***Edwards v Boston***.

The Statutory Framework

32. A patent is personal property (section 30(1) Patents Act 1977). The patentee's right to remedy for infringement is set out at section 61(1) of the 1977 Act, which provides that a claim may be made:

> "(a) for an injunction or interdict restraining the defendant or defender from any apprehended act of infringement;
>
> (b) for an order for him to deliver up or destroy any patented product in relation to which the patent is infringed or any article in which that product is inextricably comprised;
>
> (c) for damages in respect of the infringement;
>
> (d) for an account of the profits derived by him from the infringement;
>
> (e) for a declaration or declarator that the patent is valid and has been infringed by him."

33. There are a number of aspects of the 1977 Act in which the public interest plays a part, for example section 1(2)-(4) which provides a list of non-patentable subject matter. They have various public policy based justifications, not relevant to the present case. However section 4A is relevant. This provision specifically excludes from patentability any methods of treatment and diagnosis. It is based on Art 53(c) EPC. The principle has always been in the Act and the EPC, although the provisions have moved since they were enacted. The policy justification for this exclusion was stated by the EPO Enlarged Board of Appeal in G1/07 (within paragraph 3.3.6) as:

> "Medical and veterinary practitioners should be free to use their skills and knowledge of the best available treatments to achieve the utmost benefit for their patients uninhibited by any worry that some treatment might be covered by a patent."

34. Another place in which relevant aspects of the public interest explain certain features of patent law is in the definition of what constitutes infringement. Section 60 sets out circumstances in which an act which would otherwise constitute an infringement shall not do so. They include:

i) extemporaneous preparation of a medicine for an individual (section 60(5)(c));

ii) use in clinical trials (section 60(5)(i)); and

iii) activity for the purpose of obtaining medicinal product marketing authorisations (sections 60(6D) and (6E)).

35. Yet another place where the public interest explains certain provisions is in the compulsory licencing regime (sections 46-54). In the present case, the relevant provisions are found at section 48A(1), pursuant to which the "relevant grounds" are:

> "(a) where the patented invention is a product, that a demand in the United Kingdom for that product is not being met on reasonable terms;
>
> (b) that by reason of the refusal of the proprietor of the patent concerned to grant a licence or licences on reasonable terms–
>
> (i) the exploitation in the United Kingdom of any other patented invention which involves an important technical advance of considerable economic significance in relation to the invention for which the patent concerned was granted is prevented of hindered, or
>
> (ii) the establishment or development of commercial or industrial activities in the United Kingdom is unfairly prejudiced;
>
> (c) that by reason of conditions imposed by the proprietor of the patent concerned on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of

> materials not protected by the patent, or the establishment or development of commercial or industrial activities in the United Kingdom, is unfairly prejudiced."

36. Finally the Crown use scheme set out at sections 55-59 provides a set of circumstances in which a government may be able to decide that the public interest requires products to be made available to the public without the patentee's permission (see the recent judgment of Mr Campbell QC in ***IPcom v Vodafone*** [2020] EWHC 132 (Pat)).

37. In support of its argument that the 1977 Act provides an exhaustive list of scenarios in which a court is entitled to derogate from the requirement to grant an unqualified injunction, Abbott rely on the fact that many of the provisions set out in the 1977 Act address medical products and methods, and that those sections are kept under review and subject to regular amendments. Abbott also submitted that since s41 of the 1949 Patents Act, which expressly provided that all patents for medicines and medical devices were subject to compulsory licencing, was omitted from the 1977 Act, it follows that Parliament's intended that such patents no longer be subject to such a derogation and instead be treated as any other patent.

Enforcement Directive

38. Remedies for infringement of patents and other intellectual property rights are addressed in the Enforcement Directive 2004/48/EC (the "Directive"). Article 3 of the Directive imposes a general obligation on Member States:

> "General obligation
>
> Member States shall provide for the measures, procedures and remedies necessary to ensure the enforcement of the intellectual property rights covered by this Directive. Those measures, procedures and remedies shall be fair and equitable and shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays.
>
> Those measures, procedures and remedies shall also be effective, proportionate and dissuasive and shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse."

39. Proportionality is a relevant factor, so in ***Cartier v British Sky Broadcasting*** [2016] EWCA Civ 658, the Court of Appeal cited the CJEU's dicta in Case C-2/10 ***Azienda Agro-Zootecnica Franchini Sarl v Regione Puglia*** (2011).

40. Article 3 of the Directive was considered by the Court of Appeal in ***Virgin Atlantic Airways Ltd v Premium Aircraft Interiors Group*** [2009] EWCA Civ 1512, [2010] FSR 5, with Jacob LJ finding at paragraph 25 that the test for whether or not a permanent injunction should be withheld in that case was "whether enforcement would be 'grossly disproportionate'."

41. Edwards also referred to Recital 32 of the Directive, which confirms that it "observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union." Article 17.1 of the Charter of Fundamental Rights of the European Union provides that "no one may be deprived of his or her possessions, except in the public interest…".

The TRIPS Agreement

42. Also relevant is the Agreement on Trade-Related Aspect of Intellectual Property ("TRIPS"). Article 28(1) TRIPS provides that:

> "1. A patent shall confer on its owner the following exclusive rights:
>
> where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;
>
> where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process."

43. Exceptions to Article 28 are set out at Article 30, which provides that:

> "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

44. Article 31 provides for other use without the authorisation of the patentee, where such use is permitted by the law of a Member State. This is subject to a number of provisions, set out at Art 31(a) – (l), which do not fall to be considered in the instant case.

Availability of Damages in Lieu of an Injunction

45. Section 37(1) of the Senior Courts Act 1981 sets out a power to grant an injunction, where it is just and convenient to do so. By section 37(2) that injunction may be made unconditionally or on such terms and conditions as the Court thinks just. A key component of the court's discretion is set out at section 50 of the Senior Courts Act 1981. This is the modern expression of the power first set out in Lord Cairns' Act to award damages "in addition to or in substitution for" an injunction.

46. The previous reluctance of the courts to award such damages stemmed, for the most part, from the decision in ***Shelfer v City of London Electric Lighting Co*** [1895] 1 Ch 287. The Court there found that, prima facie, a party whose legal right had been

invaded would be entitled to an injunction, with damages being awarded only in cases where four criteria were satisfied:

> "… the injury to the plaintiff's legal rights is small;
>
> And is one which is capable of being estimated in money;
>
> And is one which can be adequately compensated by a small money payment; and
>
> The case is one in which it would be oppressive to the defendant to grant an injunction."

47. The application of section 50 SCA was reviewed by the Supreme Court in ***Coventry v Lawrence*** [2014] UKSC 13 (sometimes called ***Lawrence v Fen Tigers***). The conclusion was that a more flexible approach should be taken to determining whether an order for damages would be appropriate.

48. Edwards' primary case was that ***Shelfer*** was now of limited relevance but as a fall back Edwards did argue that the ***Shelfer*** criteria were satisfied in this case and that therefore following ***Coventry v Lawrence***, it would "normally be right" for the court to refuse an injunction. Edwards also relied on the emphasis the Supreme Court placed on considering the public interest in such cases. Lord Neuberger stated, at paragraph 124 that he found it "hard to see how there could be any circumstances in which [*the public interest*] arose and could not, as a matter of law, be a relevant factor".

49. Part of Abbott's submission seemed to be that really the ***Shelfer*** criteria continued to apply but simply with the modification following ***Coventry v Lawrence*** that the public interest in general, and therefore the impact of the injunction on third parties, should always be considered. I will say now that I do not accept that way of reading ***Coventry v Lawrence***. Lord Sumption at paragraph 161 and Lord Clarke both described the decision in ***Shelfer*** as out of date and Lord Carnwath at paragraph 239 described the case as an opportunity to move away from the strict criteria in ***Shelfer***. Lord Neuberger's judgment, which was the leading judgment, makes it clear that the discretion is a wide one, albeit that this does not prevent the courts from laying down rules as to what can and cannot be taken into account. Lord Neuberger specifically held that prima facie an injunction should be granted, and the legal burden was on the defendant to show why it should not (paragraph 121). In particular, the guidance provided by Lord Neuberger at paragraph 123 is:

> "First, the application of the four tests [in *Shelfer*] must not be such as to be a fetter on the exercise of the court's discretion.
>
> Secondly, it would, in the absence of additional relevant circumstances pointing the other way, normally be right to refuse an injunction if those four tests were satisfied.
>
> Thirdly, the fact that those tests are not all satisfied does not mean that an injunction should be granted."

The application of Coventry v Lawrence to patent cases

50. Abbott emphasised that ***Coventry v Lawrence*** (and ***Shelfer***) were cases in the law of nuisance and that while those cases may be instructive, an important factor to take into account when exercising the court's discretion in this case is the nature of the rights being infringed. Abbott argued that patent rights are different from the right in land protected by nuisance. They have a distinct rationale and are governed by a separate scheme to those rights. I agree.

51. Abbott referred to judgments of Aldous J in the Patents Court in ***Biogen v Medeva*** [1993] RPC 475 and ***Chiron v Organon*** (cited above). In the latter Aldous J reconsidered the question he had already addressed in ***Biogen*** because by then ***Jaggard v Sawyer*** [1995] 1 WLR 269 had just been decided. Although both cases were decided pre-***Coventry v Lawrence***, Abbott submitted that they were, in substance, already applying a looser interpretation of the ***Shelfer*** four criteria test explained by the Supreme Court. I do not need to grapple with the difference if any between the way Aldous J approached the test and ***Coventry v Lawrence***. What I believe is relevant is that in ***Chiron*** Aldous J gave detailed consideration to the protection of the public interest in the context of patents when an infringer is seeking to invoke that public interest as a reason to withhold an injunction. His conclusion was that any attempt to dissuade the court from granting an unqualified injunction was effectively seeking to obtain a compulsory licence without having established the grounds set out in the 1977 Act. Neuberger J followed this aspect of ***Chiron*** in ***Kirin-Amgen v TKT (No. 3)*** [2005] FSR 41 at paragraph 27.

52. I highlight two passages from ***Chiron*** at this stage (a third arises below). The first at p332 explains the balance of public interests inherent in the patent system and the way it incorporates safeguards to protect the public interest:

> "A patent system, for what the Statute of Monopolies called new manufacturers, has been adopted by nearly every country in the world, because it is generally accepted that the opportunity of acquiring monopoly rights in an invention stimulates technical progress in at least four ways. First it encourages research and invention; secondly, it induces an inventor to disclose his discoveries instead of keeping them a secret; thirdly, it offers a reward for the expense of developing inventions to the state at which they are commercially practical and, fourthly, it provides an inducement to invest capital in new lines of production which might not appear profitable if many competing producers embarked on them simultaneously. Those are particularly relevant to the development of medicinal products.
>
> It is inherent in any patent system that a patentee will acquire a monopoly giving to him a right to restrict competition and also enabling him to put up or at least maintain prices. That affects the public and is contrary to the public interest, but it is the recognised price that has been accepted to be necessary to secure the advantages to which I have referred.

> Ever since the Statute of Monopolies certain safeguards have been recognised to be necessary to protect the interests of the public against abuse by a patentee of his monopoly rights. Such safeguards, as are considered necessary to safeguard the public, are now contained in the Patents Act 1977."

53. I would only add that the incentives Aldous J refers to, in particular in the investment of capital, need to operate many years before the inventor is likely to be asking the court to enforce the patent by an injunction and thereby safeguard that investment. Accordingly long term certainty about the principles on which such relief is to be determined is an important end in itself.

54. Aldous J then went on to address the presence in the 1977 Act of various provisions (set out already above) which reflect the public interest in limiting patent rights: compulsory licensing; Crown use, and exceptions in s60(5). The judge noted that with Crown use the Act made provision for making life saving drugs available in the National Health Service. Next follows the second passage from ***Chiron*** which I highlight (at p333-334):

> "… it is necessary, when exercising the discretion, to take into account the basic nature of patent monopolies and the steps that the legislature has taken to protect the public from the effect of the grant of such monopolies. Thus the mere fact that the grant of an injunction to restrain infringement of a patent will restrict competition and tend to maintain prices, does not suggest that the injunction is contrary to the public interest. It is in the public interest that patent monopolies be enforced with the resulting restrictions upon competition that are inherent in the patent system. It is also necessary to bear in mind that the legislature envisaged that in certain situations the public interest required a fetter upon patent rights and took appropriate steps to safeguard the interest of the public. For instance, the Crown can authorise the use of the patent in certain circumstances. That suggests that the interests of the public will normally be protected by the provisions of the Patents Act 1977 and an injunction should normally be granted restraining infringement unless the contrary is indicated in the Act. Thus it is a good working rule that an injunction will be granted to prevent continued infringement of a patent, even though that would have the effect of enforcing a monopoly, thereby restricting competition and maintain prices. Something more should be established before the Court will depart from the good working rule suggested in the *Shelfer* case."

55. Although Aldous J there expressed himself by reference to ***Shelfer***, in my judgment the point remains a good one under the modern approach. When the court is considering withholding an injunction on public interest grounds, it is relevant to have regard to the fact that the patent legislation itself already places limits on patent rights in order to safeguard the public interest. That includes a power to make life saving treatments available to the public without the permission of the patentee.

56. As I said already, none of the ***Chiron*** line of cases (***Biogen***, ***Chiron*** nor ***Kirin-Amgen***) seem to have been cited to Arnold J in ***HTC v Nokia*** when he considered and rejected an application by the defendant for an award of damages under section 50 in lieu of a final injunction restraining patent infringement. The reason will no doubt have been that the ***Chiron*** line of cases are focussed on the public interest as a ground to award damages in lieu while that was not the basis of the argument in ***HTC v Nokia***. From paragraph 3 onwards Arnold J reviewed the legal principles starting with the legislative background, ***Shelfer*** and ***Jaggard v Sawyer***. At paragraphs 14 and 15 the judge noted that the effect of the order sought was almost indistinguishable from a compulsory licence and raised the question of the possible need for things like a duty to account which one would see in licences. At paragraphs 16 to 18 the judge dealt with intellectual property cases in this jurisdiction before the Enforcement Directive, but as I say the ***Chiron*** line of authority was not cited. From paragraph 19 onwards the judge addressed the Enforcement Directive and concluded at paragraph 32:

> *"32. Conclusion*. Drawing these threads together, I consider that Article 3(2) of the Enforcement Directive permits and requires the court to refuse to grant an injunction where it would be disproportionate to grant one even having regard to the requirements of efficacy and dissuasiveness. Where the right sought to be enforced by the injunction is a patent, however, the court must be very cautious before making an order which is tantamount to a compulsory licence in circumstances where no compulsory licence would be available. It follows that, where no other countervailing right is in play, the burden on the party seeking to show that the injunction would be disproportionate is a heavy one. I suspect that the practical effect of this approach is little different to Pumfrey J's test [*in Navitaire v EasyJet [2005] EWHC 282 (Ch)*] of "grossly disproportionate"."
>
> [reference to *Navitaire* added]

57. I agree with this statement of the law. It was not a case in which the public interest was advanced as a factor and Arnold J himself made the same point in ***Edwards v Boston*** at paragraph 12 when referring back to ***HTC v Nokia***, before then going on to deal with ***Coventry v Lawrence*** at paragraph 13, a judgment of Henry Carr J in ***GlaxoSmithKline v Wyeth*** [2017] EWHC 91 (Pat) (which it is not necessary for me to address) at paragraph 14, and then setting out Art 3 of the Enforcement Directive and emphasising the factor of proportionality.

58. In my judgment when the court is considering the public interest relating to a medical device or treatment as a ground for refusal of a patent injunction, it is also relevant to have in mind the factors identified by Aldous J in ***Chiron***. I believe that applies when considering the wide discretion following ***Coventry v Lawrence*** and/or under the Enforcement Directive's requirement that remedies be "just and equitable" and "effective, proportionate and dissuasive". In terms of the Enforcement Directive it bears pointing out that the provisions in Art 3 are general and are applicable to all intellectual property rights. The balancing of public interest factors for copyright and trade marks will differ from the balance relating to patents because their public

interest justifications are different. That is why it is relevant to highlight the particular way the public interest operates in the patent system as a whole when exercising this discretion.

Assessment of Damages in Lieu of an Injunction

59. One factor which must be considered is the adequacy of damages in lieu as a remedy. The case came to trial before me on the footing that an inquiry as to the damages in lieu would be ordered if an injunction was refused or qualified. I questioned whether this was the right approach. In fact it was a consequence of the way both sides had arranged things. Given that in this case (unlike ***Edwards***) the defendant is contending that no injunction at all should be granted, I believe it was a mistake. The reasons why are explained by Aldous J in the third passage from ***Chiron*** which I highlight (at p335). The judge there pointed out that for a decision to be taken about the adequacy of financial compensation to the patentee:

> " … the court must have sufficient information before it to be able to estimate the compensation and decide whether the defendant can pay it. The suggestion that the court should refuse the injunction and order that there be an inquiry as to the amount of compensation should not be accepted. To do so, would mean that the court would refuse the injunction without being able to conclude that the compensation was adequate and small. Further at the inquiry, which might not take place for many months, the court might conclude that the compensation could not be properly estimated or that the amount was not adequate or was large. Determination of the amount and sufficiency of the compensation is part of the decision whether to refuse the injunction and needs to be undertaken at the same time."

60. Again the language is couched in terms of ***Shelfer*** ("small" compensation) but in my judgment the observations remain applicable. The need to examine this sort of detail now is not just because the law, based on ***Shelfer*** and pre-***Coventry v Lawrance***, was that the damage had to be small. I can see that it may not have been necessary in the present case to examine the finances in sufficient detail to actually settle the amounts to be paid but I believe more focus on this sort of evidence ought to have been given. One obvious piece of information is the level of profitability of these products relative to their prices. To be fair to Edwards the absence of this evidence arises from decisions both parties made and so it would not be fair to simply refuse to award damages in lieu because I cannot undertake the exercise based on sufficient financial information.

61. Edwards contends that a reasonable royalty assessed on a future inquiry would be appropriate as damages in lieu of the injunction. Abbott contended that such damages would be neither capable of quantification nor adequate. To address this I need to look a bit further into the law.

62. The basic compensatory principle applicable to damages for patent infringement was explained in ***General Tire*** [1975] 1 WLR 819, 824C-D (Lord Wilberforce):

> "As in the case of any other tort (leaving aside cases where exemplary damages can be given) the object of damages is to compensate for loss or injury. The general rule at any rate in relation to "economic" torts is that the measure of damages is to be, so far as possible, that sum of money which will put the injured party in the same position as he would have been in if he had not sustained the wrong (*Livingstone v Rawyards Coal Co* (1880) 5 App Cas 25, per Lord Blackburn, at p. 39)."

63. In the same case, at page 824 G to page 827 B, Lord Wilberforce established three measures of damages, depending on the facts of the individual case:

> "Cases where 'the benefit of the invention in such cases is realised through the sale of the article or product… [where] the measure of damages will then normally be the profit which would have been realised by the owner of the patent if the sales had been made by him.'
>
> Cases where the patent is 'exploited through the granting of licences for royalty payments…[where] the measure of the damages he must pay will be the sums which he would have paid by way of royalty if, instead of acting illegally, he had acted legally.'
>
> Cases not falling into the above categories, where the Court should 'consider what would have been the price which – although no price was actually quoted – could have reasonably been charged for [permission to use the invention], and estimate the damage in that way'."

64. Damages in the third category, sometimes called user damages, negotiating damages (see also ***HTC v Nokia*** paragraph 12) or ***Wrotham Park*** damages have recently been considered by the Supreme Court, in ***Morris-Garner v One Step (Support) Ltd*** [2018] UKSC 20. The court in ***Morris-Garner*** was concerned with the availability of negotiating damages as a remedy for breach of contract and considered their availability in other contexts including intellectual property infringements and awards of damages in lieu. I think part of the justification for Edwards' case that a reasonable royalty should be awarded as damages in lieu in this case was because that basis of assessing those damages is referred to extensively in ***Morris-Garner***. It is not hard to see why negotiating damages might well be the right way to assess damages in lieu on the facts of many cases. However I do not read that decision as authority for the proposition that the only measure of damages when assessing damages in lieu of an injunction is by way of negotiating damages (aka a reasonable royalty). Lord Reed at paragraph 95 makes clear that the task would be to provide a monetary substitute for what is lost by withholding the relief. In my judgment the court is not bound only to consider negotiating damages as the appropriate measure of damages in lieu of an injunction, although there may be more to this point than meets the eye, as I shall try to explain.

65. Although there had been a view that negotiating damages were restitutionary in nature, the Supreme Court there held that they were compensatory. If no injunction

was granted in the present case then it is obvious that many sales of PASCAL devices would take place as substitutes for MitraClip. Following ***General Tire***, the proper compensation for those would be the patentee's lost profit. Even without any financial details, I can safely assume that given the nature of this market the proper royalty, whatever it might be, would be a large sum of money in absolute terms. However I can also safely assume that the amount of lost profit to Abbott per product will be greater than the reasonable royalty. That is one reason why Abbott contends that the offer of a reasonable royalty (unspecified) by Edwards will grossly undercompensate Abbott. Abbott also contends that an account of profits should be available but it is not necessary to grapple with that.

66. These considerations illustrate again why what Edwards is seeking ought properly to be regarded as a kind of compulsory, royalty bearing licence. No doubt similar terms would need to be provided for dealing with accounting, royalty bearing events and perhaps whether the supplies amount to franking of the goods.

67. Neither party addressed this but I am concerned about the following. What if the court decided that the level of payment necessary to properly compensate Abbott for what is lost by withholding the injunction was lost profit damages on all or substantially all sales of PASCAL? Of course they are not identical but one can assume for this purpose the two parties' levels of profitability are much the same, after all Edwards have confirmed they intend to sell at the same price (essentially). On that basis Edwards might end up with no economic incentive to sell the PASCAL in the UK at all since it would make no profit. The same consequence could flow from an account of profits (I do not have to get into the debate today whether an account of profits would be available in lieu of an injunction). But the point of the public interest argument for refusal of the injunction is that it would be in the public interest that PASCAL products actually come onto the UK market.

68. Therefore perhaps it is a necessary component of this sort of public interest ground for refusal of an injunction that the defendant should indeed only pay a royalty, and therefore still be able to make a profit, even though that means that the patentee will be substantially out of pocket. In other words perhaps the right approach is to consider what is in some ways a hard case. If a public interest that a defendant's product comes onto the market is invoked, in order to ensure the defendant does come on the market, the damages in lieu perhaps have to be a royalty even though that may necessarily cause substantial, quantifiable and uncompensated economic harm to the patentee. The patentee would just have to bear those losses, in the public interest.

Comparative Law

69. Both parties have drawn the Court's attention to a significant body of foreign case law relating to the issue at hand. None of that case law, though instructive, is capable of being applied directly to the instant case.

70. Abbott emphasised the importance of looking at the approach in other European jurisdictions. In particular, they have pointed to jurisprudence from Switzerland (***Evalve, Abbott v Edwards*** Federal Patent Court case S2019_002 of 15th August 2019, a preliminary injunction case), Germany (the ***Herzklappen*** case 4a O 137/15 LG Düsseldorf) and the Netherlands (***Boehringer v Kirin-Amgen*** Supreme Court 21-04-1995 no. 15623; ***Nikon v ASML*** Hague District Court 18 July 2018). In each of

those cases, the courts have rejected the invocation of the public interest as a defence to an injunction, usually referring to the availability of compulsory licences. Edwards submitted that the approaches of these courts involves little or no discretion in the grant or refusal of an injunction and that compulsory licences are expressly available on public interest grounds, with no three year period as there is in the UK.

71. In the United States, a common law jurisdiction, the public interest is relevant to the grant of an injunction in the context of the test set out in ***eBay, Inc v MercExchange, LLC*** (2006) 547 US. Abbott sought to qualify this by reference to the decision in ***Amgen Inc v Sanofi*** (2017) 872 F.3d, a biosimilars case in which the Court of Appeals for the Federal Circuit rejected the suggestion that availability of a choice of drugs was sufficient to "disserve the public interest" (in the language of ***eBay***) and thereby outweigh the right to a permanent injunction. On the other hand Edwards referred to a decision of the CAFC in ***Cordis v Boston*** 99 Fed.Appx 928 (2004), a preliminary injunction case decided before ***eBay***, in which the court recognised in the context of cardiac stents that "*a strong public interest supports a broad choice of drug-eluting stents, even though no published study proves the superiority of either [*the patentee's*] or [*the defendant's] *stent*".

72. Edwards also raised the fact that the compulsory licencing regime provides that a three year time period must lapse before an application can be made. It is therefore available in respect of EP 850. In respect of EP 810, that period ends in mid-2020.

Summary of general principles

73. Drawing all this together, I attempt to summarise the applicable principles as follows:

i) A general injunction to restrain future infringements is the normal remedy for the patentee.

ii) The burden is on the defendant to give reasons why such an injunction should not be granted.

iii) All the circumstances should be considered. The public interest, such as the impact on third parties, is a relevant consideration. This applies under domestic law (***Coventry v Lawrence***) and under Art 3 of the Enforcement Directive.

iv) In a proper case the public interest may justify refusal of or carve out from injunction, and an award of damages in lieu. Smallness of the damages in lieu is not determinative. Even if the damages were a large sum of money and/or one which was difficult to calculate, it might still be in the public interest to refuse an injunction or carve scope out of it.

v) The starting point of any consideration of the public interest in relation to a remedy after a patent trial is that the patent system as a whole is already criss-crossed with provisions which strike balances between different public interests.

vi) The availability of an exclusionary injunction is an important manifestation of the monopolistic nature of a patent right. While monopolies in general are

against the public interest, once a patent has been found valid and infringed, the patent monopoly is something which it is in the public interest to protect by an injunction in order to further the purposes of the system as a whole, such as to promote investment in innovation.

vii) Therefore when, as here, various public interests are engaged and pull in different directions, one should have in mind that the legislator is better equipped than the courts to examine these issues and draw the appropriate broad balance. The jurisdiction to refuse or qualify a patent injunction on public interest grounds is not there to redraw the broad balance of public interests set by Parliament in the patent system. The power should be used sparingly and in limited circumstances.

The application of these principles to the clinical setting

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

75. For this kind of public interest to begin to be relevant, it must be concerned with treatments for serious medical conditions, and perhaps only for life saving treatments. That does not have to mean only for treating clinical emergencies. It will include treatments of the kind in this case. For many patients these eeTVR devices are life-saving therapies. However even then things can be complicated. The true balance of risk will differ between individual patients.

76. However there are many life-saving drugs and medical devices. If the legislator had thought the balance of public interests justified it then patent law could but does not contain an express limitation preventing injunctions in that sphere or providing for compulsory licences to any competitor in every such case. And indeed it is not hard to think of reasons why the legislator did not institute a broad exception like that, after all society no doubt most of all wishes to have incentives to invest the vast sums necessary to make and develop life-saving drugs and devices.

77. Another factor must be the nature of the competitive product. I doubt a generic version of a life-saving drug would usually engage the public interest in this way at all. I say "usually" because one can think of special cases, such as a novel pandemic disease; but if that happened then the Government could invoke Crown use.

78. However this case is about a product which is different from the patentee's embodiment of the invention protected by the patent. The differences are tangible clinically even if they are not significant in terms of patent law. The two products are both embodiments of the same inventions, protected by the patents. The product in this case happens to be a medical device but could just as well be a biosimilar drug. Biosimilars are necessarily very similar to but not identical with the

patentee/originator's product and that might make a clinical difference in some patients.

79. The existence of these clinically tangible differences will inevitably mean that some doctors are likely, non-negligently, to prefer to employ one product in preference to the other if they are presented with a choice. In doing so they will be acting in the best interests of their patients. In my judgment this does not engage a relevant public interest, not least because it does not necessarily carry with it the idea that if the choice had not been available, all the patients could not have been treated adequately with the patentee's product. This is, I think, what the US CAFC referred to in the ***Kirin-Amgen*** case (above).

80. If one examined the previous example in terms of market demand (see s48A(1)(a) of the 1977 Act about compulsory licences), then the example I have just described is one in which the market demand – i.e. all patients in need of the treatment – is met by the patentee's product and so no compulsory licence would be available either in the UK.

81. Now what if reasonable doctors believe that the differences between the life-saving products mean that there are some patients for whom the patentee's product is not an adequate treatment but the rival product is? And of course in the real world these things are not black and white, but matters of risk – so a doctor may reasonably believe that the balance of risk for a particular patient would be more favourable with the rival's product than it would be for the patentee's product.

82. This is a harder case but in my judgment it is still not sufficient to engage the public interest justification for refusing or limiting a patent injunction. The reason why not is because it does not examine the basis for the reasonable views of doctors. It is obvious, but the evidence of Dr Kipperman and Dr Makar also makes clear, that doctors are required to make clinical decisions on the basis of whatever evidence they have. When a new medical product comes on the market, the evidence supporting its use will have been sufficient to obtain clinical approval but that is a long way from amounting to a firm body of evidence covering all the circumstances which doctors will encounter.

83. The experience with the third generation MitraClip XTR and NTR devices illustrates the point. When the devices were approved and launched, doctors tended to use the XTR as a default choice. They had in good faith inferred, based on the device's physical characteristics and their own clinical knowledge, that the XTR's wider arms would offer benefits in term of leaflet grasping. Data from the EXPAND study proved that, in fact, the default should have been the NTR, with use of the XTR being reserved for certain anatomies. Conversely, an assumption was made that the XTR's larger size may give rise to a larger stenotic effect than the NTR. Again, this was proved to be incorrect by the EXPAND data.

84. There is no suggestion that doctors were negligent at any stage. Good faith reasonable clinical decisions were made at the start based on the available evidence. With better evidence we now know that the right approach is different.

85. In other words, merely because the choices or opinions are reasonable in their own context is not enough. Not all reasonable opinions are equal from this perspective. In

my judgment in order to engage the public interest in these circumstances it will be necessary to examine the evidential basis for the clinical judgments relied on. What is required is sufficient objective evidence to find that there are in fact patients who ought not to be treated using the available product from the patentee but who could, in the reasonable opinion of a body of doctors, be treated using the rival's product.

86. I believe this is the approach Arnold J took in ***Edwards v Boston***. He rejected a stay of the qualification of the injunction on the ground advanced by the rival that its Sapien 3 product provided the best clinical outcomes for most patients, even though he found that there was a significant body of clinical opinion that this was true, because there was "little hard data to substantiate that opinion" (paragraph 36 and see paragraph 63). On the other hand the judge did allow a permanent carve out for patients for whom the Sapien 3 was the only option.

87. In other words the relevant public interest sufficient to justify a refusal, at least in part, of a patent injunction, is the need to protect the lives of patients for whom the defendant's product is the only suitable treatment, when that fact is established by objective evidence. This is taken from paragraph 69 of ***Edwards v Boston***. In that passage Arnold J used the word "health" rather than "lives". I agree that the same principle will apply to protect against serious risks to health, which is what the replacement heart valves in that case were for. I am doubtful it applies more widely.

88. It is in the public interest that doctors should have freedom to exercise clinical judgment and choice however that is not the only public interest engaged when a final injunction restraining infringement of a valid patent would restrict clinical choice. I am not persuaded that the public interest in allowing doctors to exercise their clinical judgments in the best interests of their patients is sufficient to justify the refusal or carving out from a patent injunction. It would be a wide exception. To give effect to that interest in that way would mean that throughout the field of inventions of life saving products, just because the defendant's embodiment of the patentee's invention happened to have some clinically tangible differences from the patentee's own commercial embodiment of their invention, then there would be no exclusionary monopoly. In my judgment balancing the public interests to reach that result would be a matter for Parliament and should not be created by the courts. The patent system is set up in such a way that it does restrict the choice open to doctors by restricting the products available to them from which they can choose. That restriction is in the public interest overall because it promotes innovation.

89. A different, and lesser point, is to have regard to the difficulties such a refusal would cause. These are illustrated by Edwards' approach in this case. Initially Edwards contended that no injunction should be granted at all in the public interest. That is logical if the basis for it is to allow doctors to exercise their clinical judgment freely. However it would inevitably lead to patients for whom MitraClip is, objectively, a perfectly adequate treatment receiving PASCAL instead, with consequent losses for the patentee. That would seriously undermine the purpose of the patent system itself. Edwards' fall back list of medical criteria is designed to meet that point. It could work if the criteria defined patients for whom PASCAL was objectively the only suitable treatment. However Edwards did not attempt to establish that because the state of the evidence available today does not allow that to be decided.

90. The public interest I have identified which would justify refusal or a carve out is not far from the test for a compulsory licence (market demand not met) but as Edwards pointed out the three year period in section 48 of the 1977 Act means they cannot obtain such a licence at this stage at least under patent EP 810. It would justify a carve out pending an application for a compulsory licence. That is not because the three year period should just be overridden. The period itself reflects a decision by the legislator balancing various public interests. It would allow the patentee three years to meet market demand. An example here is the introduction of the independent grasping feature of the MitraClip G4, one reason for which was the spur of PASCAL. It could operate pending an application because on the relevant hypothesis, in the meantime there was no other option to save the lives of patients.

91. Accordingly I find that Edwards' application must fail in any event. The most Edwards set out to prove is not enough to justify refusal or a carve out from the patent injunction in this case.

The facts

92. Given my conclusion, it is not strictly necessary to examine the facts but in case this matter goes further I will do so and make my findings. The issues turn on two things – the physical features of PASCAL and the medical criteria relied on by Edwards.

93. Before getting into the detail I will summarise the state of the clinical trial data available for the devices. Both devices have been subject to a number of clinical trials.

MitraClip

94. A trial called EVEREST I was the first feasibility trial in the USA. It was subject to strict exclusion criteria including patients with certain mitral valve anatomies and pathologies, treating a total of 107 patients. EVEREST II was a randomised controlled trial, also in the USA. EVEREST II compared MitraClip to surgical repair in terms of death rate, safety profile, and efficacy in reducing mitral regurgitation. EVEREST II was subject to the same exclusion criteria as EVEREST I. EVEREST II treated 178 patients. The EVEREST trial results were announced in 2009 and 2011.

95. The COAPT study was a randomised controlled trial of 302 patients with functional mitral regurgitation for whom surgery had not proven effective, comparing outcomes with MitraClip used alongside medical therapy, as against outcomes with medical therapy alone. The COAPT study found a lower hospitalisation rate, milder mitral regurgitation, and a better quality of life for patients treated with the MitraClip. These results had a positive reception when announced in 2018, with the study being described as a "game changer".

96. The Mitra-FR study was similar to COAPT in that it was a study of MitraClip in functional mitral regurgitation patients, of whom 152 were treated. However, unlike COAPT, Mitra-FR did not show a statistically significantly different effect versus medical therapy alone. Nevertheless, on the strength of the COAPT data MitraClip is now used to treat functional mitral regurgitation. It may be that the explanation for the different results between the two studies relates to the different exclusion criteria applied in each and possible differences in follow up.

97. The EXPAND study is the most recent MitraClip study: an all-comers, single-arm, multi-centre study conducted in the USA and in Europe, which reviewed the use of MitraClip NTR and XTR devices in over 1,000 patients. Follow up was taken at discharge, 30 days, 6 months and 12 months, with numerous outcome measures taken for severity of mitral regurgitation, presence of major adverse events, and quality of life, amongst others. The EXPAND study demonstrated that the initial ideas about how to use the XTR and NTR had been wrong. Since EXPAND, detailed criteria for the use of XTR and NTR have been promulgated by the study's Steering Committee. Edwards referred to the Steering Committee's recommendations that XTR not be used in cases of (i) short, restricted leaflets, (ii) calcification of the annulus or leaflet, (iii) a smaller mitral valve area; and (iv) regurgitation in the commissures, for which the NTR would be more suitable. Conversely, Abbott relies on the same recommendations as evidence that either the NTR or XTR could be used in any case.

98. There have also been a number of other studies of MitraClip including industry sponsored multicentre registries: ACCESS Europe 2009-2011, EVEREST High Risk Registry 2007-2008, REALISM 2009 Onwards, and EXPAND 2018-2019; industry independent registries: TRAMI Registries 2009-2014 and 2010-2013, Pilot Sentinel European Registry 2011-2012, GRASP Registry 2008-2013, and STS/ACC TVT 2013-2015; and numerous single centre cohort reports.

99. In total MitraClip has been used in over 100,000 procedures, with about 40,000 performed with the third generation XTR/NTR MitraClip devices.

PASCAL

100. The results of the first-in-man study of PASCAL, a multicentre compassionate use trial involving 23 patients, were published in The Lancet in 2017. The patients chosen for that study were all ones for which MitraClip use would be off label or who had anatomical complexity such as to make successful implantation of MitraClip unlikely. However, as Abbott points out, the study predated the introduction of the third generation MitraClip, with new features including the longer arms of the XTR. Edwards retorts that the NTR is the same as the previous generation while the XTR has its own problems. Abbott's answer to that is that the NTR is not identical to its predecessor and the XTR has been proven to be a successful product. It would not be meaningful to try and attempt to resolve those arguments in order to decide whether they could explain the results in the Lancet article. The Lancet article was an important milestone in the launch of PASCAL but in my judgment it does not prove that PASCAL is objectively superior to the current MitraClip products either generally or in any particular anatomies.

101. PASCAL is currently the subject of a clinical study called CLASP, which could be regarded as a number of distinct trials. CLASP itself is a study into the safety and performance of the PASCAL system. 30 day results in respect of 62 patients were reported in the 2019 Lim article which noted that:

> "The PASCAL system provides several unique technical and procedural advantages that may allow the treatment of patients not well addressed by other therapies. For example, regurgitation is addressed by a combination of the central spacer that fills the regurgitant orifice area and broad contoured

> paddles that maximise coaptation around the spacer, thereby limiting the stress on the leaflets from the device…the independent clasp control allows leaflet capture in complex anatomies".

102. 6-month outcomes were presented in May 2019 by Spargias et al and one year outcomes in respect of the first 30 patients presented in September 2019 (Kar et al) and November 2019 (Ng et al). Edwards referred to feedback from the one year outcomes which has described PASCAL as "a novel and differentiated therapy for patients" and as having "considerable safety enhancements over the MitraClip."

103. Earlier in the proceedings there was a dispute between the parties about the provision of data relating to approximately 900 commercial PASCAL procedures in Europe. Abbott had sought and been refused disclosure of documents recording PASCAL implantations at which an adverse event had occurred. Mr Estay's evidence related to feedback from this commercial use.

Comparative Data

104. Currently, the only trial comparing PASCAL and MitraClip against one another is CLASP IID/IIF. It is a randomised controlled trial comparing the two in terms of safety and efficacy. The CLASP IID/IIF has two arms: a trial arm and a registry arm. Eligibility criteria for the trial arm is aligned with the anatomical inclusion criteria set out in the MitraClip Instructions For Use (IFU): those being, generally speaking, patients with less complex anatomies. By 31 October 2019, 51 patients were enrolled in the trial arm. The registry arm is open to patients that do not meet the MitraClip IFU criteria, whose physicians consider PASCAL to be the best device for them. 8 patients were enrolled in the registry arm as at 31 October 2019.

105. Results of CLASP IID/IIF are due to be published in December 2023. There is no other trial data comparing the performance of PASCAL and MitraClip in patients presenting with complex anatomies.

The state of clinical trial data overall

106. It is manifest that there is a wealth of data underpinning the use of MitraClip, by contrast there is much less data on PASCAL. I find that overall there is, at least yet, no hard clinical data from which to infer any objectively superior performance by PASCAL over MitraClip in any circumstances in any patients.

107. I now turn to address the design features of the PASCAL.

Design Features of the PASCAL

108. The PASCAL device has a number of design features that, on Edwards' case, make it more suitable for use in certain anatomies than the MitraClip. Those design features are summarised and addressed briefly below. I will then assess their relevance when running through the various medical criteria. It is not realistic to fill this judgment with photographs but to help with orientation I include in the annexes 1 and 2 some representative images of MitraClip and PASCAL respectively.

Distal Elements

109. Each distal element of the PASCAL device is made up of two parts: an Inner Paddle and an Outer Paddle. The distal elements of MitraClip are simply the clip arms. PASCAL has a "wingspan" of 23-25mm, which is approximately 8mm and 3mm larger than the MitraClip NTR and XTR, respectively. Its paddles are also wider than those of the MitraClip devices, by which I mean they extend further in the plane perpendicular to the page as shown in the images in the annexes. Or, putting it another way, the paddles will extend further than MitraClip along what would be the line of coaptation of the two leaflets.

110. Edwards contends that these features of the paddles would make the PASCAL more suitable for use in cases where the patient presented with a wide coaptation gap, large prolapse/flail, a short posterior leaflet, fragile leaflets, or leaflet clefts.

Existence of the central spacer

111. Another difference between the two devices is the presence of a central spacer in the PASCAL, against which its paddles hold the mitral leaflets when the device is in the closed configuration. Edwards argues that the existence of the central spacer causes less stress on the leaflets when the device is in the closed configuration, thus reducing the risk of damage and/or device detachment. This is said to be particularly beneficial in cases of fragile or calcified leaflets. Abbott contended that there was no clinical evidence for that hypothesis, and that the detachment rate for MitraClip was, in any event, very low. This was contrasted with identified cases of the PASCAL detaching.

Independent grasping

112. This has been mentioned already. The PASCAL device provides the user with the ability to control the clasps independently. Edwards submits that independent grasping would make it easier to grasp the leaflets, particularly in cases of a flail leaflet, significant valve prolapse, short posterior leaflet, or tethered leaflets. Abbott submits there was little evidence in support of any alleged benefits associated with independent grasping. Dr Makar expressed the view that it may in some cases cause damage or lead to asymmetric grasping. Mr Estay accepted that Edwards has previously issued guidance to clinicians, providing that the default method of use should be simultaneous leaflet grasping. Abbott also argues that independent grasping is a feature provided for in the new G4 range of MitraClip devices.

Use of nitinol as a construction material

113. PASCAL is constructed from memory-set nitinol alloy, which Edwards submits offers more flexibility than the cobalt-chromium alloy used to construct the MitraClip. This is said to offer advantages in treating patients with calcified or damaged leaflets by reducing stress on the tissue. Dr Kipperman also suggested that the use of nitinol may be beneficial in reducing the rate of post-implantation stenosis.

Reposition/Removal configuration

114. Edwards assert that the elongated, low profile configuration of the PASCAL device during repositioning and/or removal has the potential to assist in avoiding chordal

entanglement, trauma to the sub-valvular apparatus, leaflet perforation, and potentially other damage to the cardiac anatomy. Dr Makar's view was that such complications were rare, and unlikely to arise in cases where the MitraClip was used according to the IFU. Edwards submitted these are recognised risks potentially encountered by interventional cardiologists, based on Dr Kipperman's evidence and as seen in the literature.

Frictional elements

115. Both devices have proximal elements referred to as grippers or clasps. Each gripper closes against the corresponding distal element to grip the leaflet. In PASCAL the grippers feature a single row of teeth which grip the leaflets. In MitraClip the grippers have more rows of teeth. The NTR and XTR have 4 and 6 rows respectively. Edwards suggested that the increased number of teeth (or rows of teeth) had the potential to increase the risk of entanglement or otherwise becoming caught on the mitral valve anatomy during positioning. Dr Makar denied that this was an issue he had encountered with MitraClip, and stated that only having a single row of teeth on each clasp instead had the potential to constitute a disadvantage of the PASCAL device, increasing the risk of leaflet detachment. Dr Kipperman's view was that having fewer teeth would constitute an advantage in that, once the device passed the valve, the device's frictional elements would be partially below the leaflet edges, and therefore not exposed to the chords.

The medical criteria

116. I now turn to the medical criteria which specify the complex anatomies which Edwards alleges have improved outcomes with PASCAL over MitraClip, owing to the effect of the physical features described above. These are the situations in which, it is submitted, there is a body of reasonable medical opinion which would favour PASCAL over MitraClip.

Wide coaptation gaps

117. The argument is that PASCAL's spacer and longer paddles may assist in patients presenting with a wide coaptation gap. Both Dr Kipperman and Dr Makar gave multiple examples of use of MitraClip devices (in particular, of use of the XTR device), in such cases. Mr Makar also gave a detailed description of use of a technique called "zipping and clipping" when implanting MitraClip in a large coaptation gap. This involves placing an initial clip close to the commissures, and then a further, subsequent clip (or clips) working towards the centre of the mitral valve. This allows the large gap to be bridged, in effect in stages. Zipping and clipping will always involve using at least two clips but not every case in which more than one clip has been implanted was a case of zipping and clipping. The latter could be done because the valve has two jets, in other words two places in which a leak is occurring.

118. Edwards disputed the advisability of using the zipping and clipping technique as standard practice. Neither expert had experience using the PASCAL in such a case. In my judgment the evidence establishes that zipping and clipping is a safe and effective technique which can be used with the MitraClip system for large coaptation gaps. There is a plausible argument that as a result of its geometry one PASCAL

device might be able to handle some wide coaptation gaps which currently requiring zipping and clipping with MitraClip but that is very far from proven to an objective standard. It may turn out that there is no clinically significant difference between the two. This is a paradigm example of the state of affairs in which some doctors today may very well, in their reasonable clinical judgment, choose PASCAL over MitraClip for at least some of those cases. However if PASCAL was not available, those same doctors would use MitraClip with zipping and clipping. I am not satisfied that the risk of the latter procedure, objectively and based on the evidence today, are any higher.

Severe prolapse or flail

119. Edwards submitted that the PASCAL's paddles and independent grasping would assist in leaflet capture where there was a prolapsed leaflet or what is called a flail leaflet. Dr Kipperman described the independent grasping feature as a significant advantage of PASCAL. He used it in about half the cases in which he had used PASCAL. Although the G4 MitraClip has independent grasping, it is not (yet) approved for use in Europe whereas the third generation MitraClip does not have that feature.

120. Dr Makar described these as fairly common morphologies, which he had successfully treated on multiple occasions with a MitraClip and which use had been supported by a number of clinical studies. I accept that. Nevertheless in my judgment it is obvious that independent grasping may well have advantages in some cases. Today at least some doctors reasonably expect that it may be useful for challenging anatomies such as a large flail or prolapse gap and (see below) those with a short posterior leaflet. They also reasonably expect that it may lead to better outcomes. However I am not satisfied that the evidence today establishes anything other than reasonable expectations. There is not objective evidence that these challenging anatomies cannot be safely treated with the current MitraClip. Moreover if a doctor really did believe that the only safe and effective treatment for a patient was by using a clip with independent grasping, the G4 MitraClip could be made available on compassionate use grounds.

Short posterior leaflets

121. The valve consists of an anterior and posterior leaflet. The posterior leaflet is generally shorter in length than the anterior. Edwards submitted that PASCAL's paddles and the independent grasping capability would assist in a case in which the posterior leaflets were short in length. However the experts agreed that such cases could effectively be treated with MitraClip. Neither Dr Makar nor Dr Kipperman had direct experience of treatment of these cases using the PASCAL. Furthermore Dr Kipperman's view was based on inferences drawn from the CLASP study, but this anatomy was one of the exclusion criteria for that study.

Tethered, flimsy, fragile or calcified leaflets

122. Edwards submitted that the spacer, the longer paddles, and the flexibility of the device (due to nitinol) would make PASCAL more suitable in such cases. However the experts agreed that MitraClip could be used in such situations, subject to the caveat that the XTR is not recommended for use where there was calcification of the annulus and leaflets. In such circumstances, however, the NTR would be suitable.

Significant disruption of the sub-valvular apparatus, such as broken, thickened, or damaged chordae

123. PASCAL's single row of teeth and elongated reposition configuration are said to reduce risk to patients with significant disruption of their sub-valvular apparatus. Again, the experts agreed that a MitraClip could be used successfully in such cases. Nevertheless Dr Kipperman did express reservations as to the risk of chordal entanglement. I am sure this is an entirely reasonable view for a clinician like Dr Kipperman to have and it is something on which it is his duty to act in the best interests of his patients. It may turn out in future that a clinically significant difference between MitraClip and PASCAL emerges from robust clinical data but that is not the case today.

Leaflet clefts

124. Leaflets can have significant clefts which run away from the line of coaptation. Dr Kipperman's view was that where a patient presents with a leaflet cleft, the broad paddles of PASCAL are likely to assist because they grasp a wider segment than do the clip arms of MitraClip. This means that they may be able to grasp leaflet tissue either side of the cleft, thereby covering it. The authors of The Lancet article expressed a similar view. However both experts agreed that treatment with MitraClip would be possible in patients presenting with leaflet clefts. There is no hard data to show that any particular patient with a leaflet cleft, who could be treated with PASCAL, could not be safely and effectively treated with MitraClip.

Small valves

125. The flexibility of the PASCAL device is said by Edwards to reduce the risk of post-implantation mitral stenosis, particularly in patients with a small mitral valve area. Dr Makar's view was that there was no evidence of the PASCAL being less likely to cause stenosis than the MitraClip. Dr Kipperman gave the example of having successfully treated a patient with a very small valve with the PASCAL, but accepted on cross-examination that that patient could also have been treated with a MitraClip.

Commissural mitral regurgitation

126. The argument is that PASCAL's single row of teeth and elongated configuration would assist in placement near the commissures. These are the outer edges of the valve, looking along the line of coaptation. To the contrary however, Dr Makar's view was that PASCAL's larger size may make it more suitable for use in the A2/P2 region (i.e. in effect the middle of the valve) than near the commissures. Dr Kipperman agreed with a similar view (expressed by another doctor and put in cross-examination) that PASCAL's size meant it was not well suited to treatment outside the A2/P2 region.

127. On the other hand a feature of the commissures is that they have a high density of chordae and Dr Kipperman thought that that the reposition configuration of the PASCAL may provide safety advantages when there was a risk of chordal entanglement. He said he would prefer to use PASCAL first in such a case and if that was not successful he would probably try a MitraClip NTR.

SLDA - single leaflet device attachment

128. Another issue that Edwards claim could be addressed with use of the PASCAL is single leaflet device attachment ("SLDA"). A 2019 study by Praz et al identified higher than expected rates of SLDA associated with leaflet damage, and of leaflet tearing, in using the MitraClip XTR. Though the study concluded that the risk of leaflet damage may be accidental, it also concluded that it could be the result of the additional tension exerted on the valve leaflets associated with the grasping of more tissue. Dr Makar agreed that these conclusions were reasonable. Those findings were ultimately taken into account by the EXPAND Steering Committee in making recommendations as to the use of the XTR and NTR devices.

129. Edwards rely on this as evidence of one of the advantages of using PASCAL in the types of complex anatomies that had the potential to give rise to a higher risk of SLDA. In such cases, however, it is likely that the MitraClip NTR device could be used instead. Equally, there is little evidence of PASCAL's own performance in such cases being superior. In cross-examination it became apparent that Dr Kipperman agreed with the view that it was too early to make any firm conclusions about PASCAL's performance on that parameter.

Combinations

130. Edwards argues that in reality patients will often present with a combination of anatomical features, which fall to be considered by the clinician "in the round". The argument is that PASCAL is more suitable for use in patients presenting with combinations of the anatomical features referred to above.

131. Abbott objected to the way Edwards' case was pleaded in that it made a general reference to any and all combinations of a list of the criteria without specifying any particular combination. If the point had been taken before trial then I do not doubt Edwards would have been required to be more specific, but since Edwards did plead the point, I will permit it to rely on any specific combination for which it called evidence.

132. In fact the furthest the evidence goes is to address one or two specific combinations with any specificity. As a more general point, the evidence does not come close to establishing anything concrete.

133. Dr Kipperman's evidence identified one combination by reference to recommendations from the EXPAND Steering Committee as to NTR v XTR MitraClip usage. The suggestion was that MitraClip could not treat a patient with a combination of a large flail (for which the Steering Committee recommends an XTR), and poor quality leaflets (for which it recommends an NTR). In that situation, Dr Kipperman suggested that a PASCAL may be more effective: the independent leaflet grasping would assist with the large flail, and the long, broad paddles would place less stress on the captured leaflets. He may be right but that is not a sufficient basis to establish a case to justify a carve out from an injunction.

134. The only other attempt at specific combinations was the potential to have to deal with a large coaptation gap or flail leaflet where the patient also has a short/restricted leaflet, a frail leaflet, a non-A2/P2 pathology, a smaller mitral valve area, annular

calcification, or commissural disease. But the highest this goes is that PASCAL may be more appropriate than the current version of MitraClip. However then again it may not. In terms of evidence these combinations relate to the 23 compassionate use cases of PASCAL in the Lancet article. However the MitraClip at that time was the older MitraClip NT and not the current product.

The facts – findings overall

135. There is a body of doctors today who would prefer to use PASCAL for patients rather than MitraClip. They think PASCAL would be better for the individual patient. Some have this preference irrespective of the medical criteria relied on by Edwards. Most also take the view that there are particular anatomies for which they would, if they had the choice, choose PASCAL. Those anatomies correspond to the medical criteria relied on by Edwards above.

136. This medical opinion is based on the information available to the doctors in question – which amounts to the clinical approval of PASCAL, its physical features and inferences drawn from those features, and the limited clinical literature on the use of PASCAL. Those views are based on all the available evidence and in that sense are reasonable. However these views are provisional in the sense that as information about PASCAL usage increases it will be possible to support or falsify inferences about medical criteria and the effect of physical features.

137. There is no reliable clinical data which identifies any class of patients for which it is more likely than not that PASCAL is the only viable treatment. Nor is there any reliable clinical data which identifies particular classes of patients or anatomies for which it is more likely than not that PASCAL would be a better treatment than the currently available MitraClip. The closest Edwards comes is in relation to the use of independent grasping in cases where there is a large flail or prolapse, tethered or restricted leaflets, or a short posterior leaflet, but the evidence is simply not there. Even if evidence does emerge in due course that PASCAL with independent grasping is better that third generation MitraClips without it, it may well be that the G4 MitraClip devices with their own independent grasping will be available by then.

Conclusion

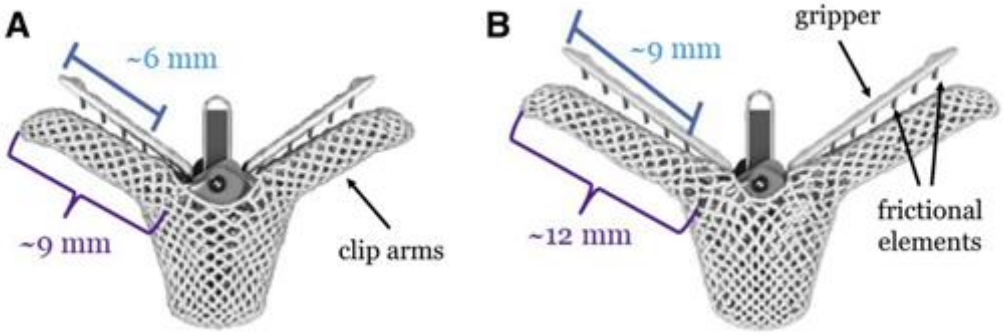
138. I will grant an injunction on the terms sought by Abbott. In other words the only carve out will be in the case when a MitraClip implantation has already been unsuccessful. I reject Edwards' case that the injunction should be refused or should contain any wider carve outs.

139. The undertaking accepted by Henry Carr J on 3rd May 2019 holds the ring between the parties for the period prior to judgment being handed down. On one view it therefore expires the instant these two judgments are given. The undertakings limited the number of the supplies of PASCAL to enough for 10 patients. My understanding from correspondence is that by 2nd March 2020 PASCAL devices had been used to treat a total of 5 patients with a further one to be used very soon (which raised a point on the undertaking, hence the correspondence). Therefore I infer no serious harm would be done by continuing the terms of the 3rd May 2019 order and undertaking over until a hearing to resolve the various consequences of the judgments, as long as that took place before Easter. If the parties are prepared to consent to an order and

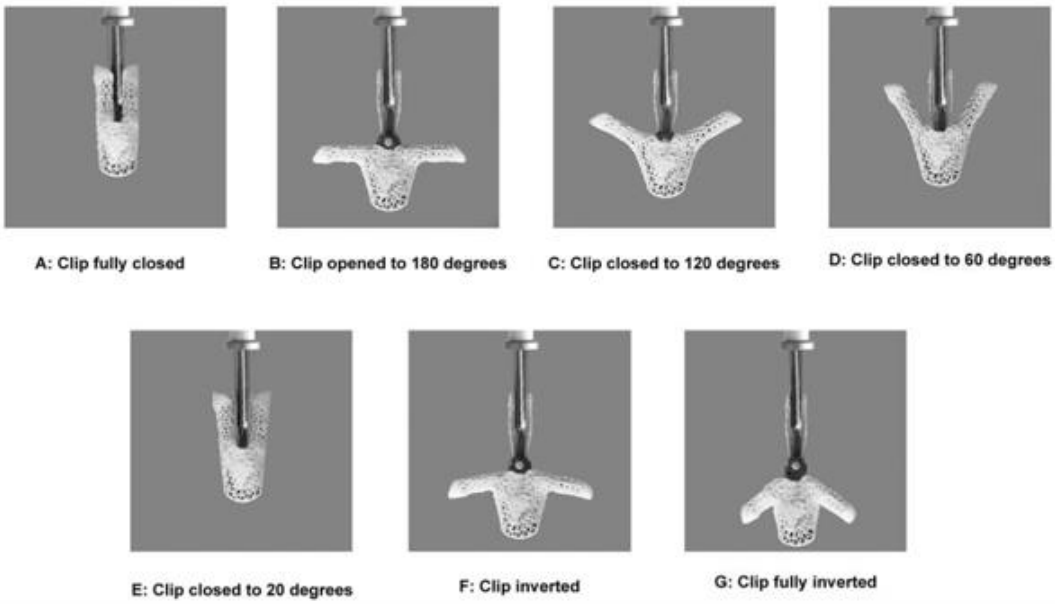
undertaking along those lines, they can inform me in writing. If they wish to argue for a different order, they will need to attend court when these judgments are given.

Annex 1

Current MitraClip NTR (left) and XTR (right)



MitraClip: the various positions:



Annex 2

PASCAL (taken from Edwards' website Mr Estay's exhibit RE-14)

Closed | Open with grippers closed | Elongated