Neutral Citation Number: [2018] EWHC 1256 (Pat)

Case No: HC-2015-004574

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

Rolls Building
Fetter Lane, London, EC4A 1NL

Date: 24 May 2018

Before :

MR JUSTICE ARNOLD

- -

Between :

EDWARDS LIFESCIENCES LLC	**Claimant**
- and –	
BOSTON SCIENTIFIC SCIMED INC	**Defendant**
- and	
(1) EDWARDS LIFESCIENCES SA	**Fourth Party**
(2) EDWARDS LIFESCIENCES LIMITED	**Seventh Party**
(3) EDWARDS LIFESCIENCES (SINGAPORE) PTE LIMITED	**Eighth Party**

- -
- -

Iain Purvis QC and **Piers Acland QC** (instructed by **Powell Gilbert LLP**) for **Edwards**
Geoffrey Hobbs QC and **Kathryn Pickard** (instructed by **Simmons & Simmons LLP**) for **Boston**

Hearing date: 16 May 2018

- -

Judgment Approved

MR JUSTICE ARNOLD :

Introduction

1. These proceedings were commenced by the Claimant ("LLC") on 9 November 2015 seeking revocation of European Patents (UK) 2 249 254 ("254") owned by the Defendant ("Boston"). Boston counterclaimed alleging infringement of 254 and 2 926 766 ("766") by LLC, the Third Party (Edwards Lifesciences Corporation, "ELC"), the Fourth Party ("ELSA") and the Seventh Party ("ELL") (collectively, together with the Eighth Party ("ELS"), "Edwards") through dealings in a transcatheter heart valve ("THV") called the Sapien 3 which had been launched by Edwards in January 2014. In a judgment dated 3 March 2017 ([2017] EWHC 405 (Pat)) His Honour Judge Hacon sitting as a High Court Judge held that 254 was invalid, but that 766 was valid and had been infringed by ELSA and ELL.

2. On 24 March 2017 Judge Hacon made an order giving effect to his conclusions, paragraphs 8, 9 and 24 of which were in the following terms:

> "8. The Edwards Parties [defined as LLC, ELC, ELSA and ELL] and each of them, whether acting by their directors, officers, servants, employees, agents or any of them or otherwise however, be restrained from infringing [766].
>
> 9. The Edwards Parties and each of them deliver up to the Defendant or, at the Defendant's option, destroy upon oath all material within their possession, custody, power or control, the continued possession of which would constitute a breach of the foregoing injunction.
>
> 24. Paragraphs 8 and 9 of this Order are stayed pending the outcome of the Edwards' Parties' appeal to the Court of Appeal …"

3. It can be seen from the judgment which Judge Hacon gave on 24 March 2017 ([2017] EWHC 755 (Pat)) that Boston had sought an injunction in the usual way, whereas Edwards had resisted the grant of an injunction at least without qualification on the ground that there was a public interest in patients continuing to receive the Sapien 3. Judge Hacon expressed the view that, if the matter were going no further, he would "certainly be limiting that injunction by reference to the cohort of patients whose lives or health would potentially be put at risk by the grant of an injunction". Since he had decided to grant both sides permission to appeal to the Court of Appeal, however, he decided that the simplest course was to grant an unqualified injunction, but to stay it pending appeal, with a view to the question being revisited once the appeal had been determined in the light of the clinical circumstances then prevailing and any other factors which should be taken into account.

4. Judge Hacon also made orders for the provision of *Island v Tring* disclosure by ELSA and ELL and for an account of profits or an enquiry as to damages by reason of the infringement of 766 by ELSA and ELL at Boston's election. There were subsequently a series of disputes arising out of the *Island v Tring* disclosure, which among other things led to the joinder of ELS and the discontinuance of Boston's claim against ELC. On 10 May 2018 Boston elected for an account of profits. Issues as to the liability of LLC and ELS for infringements of 766 will be determined as part of the account. No directions have yet been made for the taking of the account, but I was told that directions were being discussed by the parties which contemplated a hearing estimated at 6-7 days with 1-2 days' pre-reading. No hearing date has been fixed, but it seems clear that the earliest likely window is June-July 2019. During the course of the hearing before me, counsel for Boston submitted that the injunction granted by Judge Hacon should be extended to ELS. Boston must apply on notice in the ordinary way if it wants such relief.

5. On 28 March 2018 the Court of Appeal handed down a judgment ([2018] EWCA Civ 673) deciding that both sides' appeals against Judge Hacon's decision should be dismissed. On 11 April 2018 the Court of Appeal made an order giving effect to its conclusions, paragraph 6 of which was in the following terms:

> "The issue 'what, if any exception or limitation should be made to paragraphs 8 and 9 of [the order dated 24 March 2017] to allow for Edwards to continue to supply the Sapien 3 valve' be remitted to a judge of the Patents Court."

6. This is my judgment on the remitted issue. At the hearing, it was common ground that the injunction granted by Judge Hacon should be stayed for a period, and then qualified for a further period, with respect to supplies of the Sapien 3 in the public interest having regard to the impact that the injunction would have upon the health of patients with aortic stenosis. The disputes were as to (i) the length of the stay and (ii) the scope and duration of the qualification. It was also common ground that (unless 766 is subsequently revoked or limited in a material way due to opposition proceedings which are pending before the European Patent Office) Boston should receive a financial remedy in respect of future supplies of the Sapien 3, but that the nature (i.e. whether there should be an account of profits or damages) and quantum of that remedy should be determined at a future hearing. As I think both sides accepted, the most convenient and cost-efficient procedure will be for that issue to be determined in parallel with the account of profits in respect of past supplies. It was also common ground that, between now and that hearing, Edwards should make payments in respect of supplies of the Sapien 3 into a nominated account, but there was a dispute as to the quantum of such payments. I will refer to these for convenience as "payments on account". Finally, it was also common ground that the order for delivery up does not require separate consideration, since it is ancillary to the injunction.

7. In addition, I must deal with an application by Boston for the supply of samples of a new THV called the Sapien 3 Ultra ("the Ultra") which Edwards are presently seeking approval for and hope to be in a position to launch by December 2018. Edwards contend that it is clear that the Ultra does not infringe 766, while Boston contends that it is strongly arguable that it does. To date, neither side has commenced proceedings or made any application to determine that issue. Originally, Boston's application had sought disclosure as well as the provision of samples, but during the course of the hearing Edwards agreed to provide a Product Description in respect of the Ultra on or before 30 May 2018. As I made clear at the hearing, I consider it desirable that any dispute as to whether the Ultra infringes 766 should be determined expeditiously, that is to say, before the current planned launch date.

The evidence

8. Both sides filed a substantial volume of written evidence, although some of this was directed to Boston's application. In particular, both parties filed evidence from clinical witnesses. Much of this evidence was factual in nature, but some of it was expert opinion. Edwards rightly applied for permission to adduce expert evidence from the witnesses whose statements formed part of its evidence in chief, although it omitted to do so in respect of the witness whose statement formed part of its evidence in reply. Boston made no such application in respect of its clinical witness. At the hearing both sides proceeded on the assumption that the Court would grant them permission to rely upon the expert evidence which had been adduced. I will do so. Neither side applied to cross-examine any witness called by the other side. Rather, both sides proceeded on the basis that the Court would assess and weigh the evidence without the assistance of cross-examination.

9. The experts whose statements Edwards relied upon as part of its evidence in chief are representative of the range of cardiac units performing transcatheter aortic valve implementation ("TAVI") procedures in the UK:

    i) Professor Simon Redwood is a Professor of Interventional Cardiology and Consultant Cardiologist and Director of the Cardiac Catheter Laboratories at Guy's and St Thomas' NHS Foundation Trust. Together with Professor Bernard Prendergast, he leads one of the largest centres for interventional cardiology in the UK at St Thomas' Hospital, where some 200 TAVI procedures were performed in 2017. Prof Redwood is the immediate Past President of the British Cardiovascular Intervention Society ("BCIS").

    ii) Professor Philip MacCarthy is a Professor of Interventional Cardiology at King's College London and Consultant Interventional Cardiologist at King's College Hospital, at which 130-150 TAVI procedures are currently performed every year. Prof MacCarthy is a member of the Council of the BCIS.

    iii) Dr John Rawlins is a Consultant Cardiologist at University Hospital Southampton ("UHS"), a mid-sized TAVI centre currently performing 100-130 TAVI procedures per year.

    iv) Dr Rajesh Aggarwal is a Consultant Cardiologist at Basildon and Thurock University Hospital. Together with Dr Rohan Jagathesan, Dr Aggarwal established the TAVI unit at Basildon. They performed their first TAVI procedure in May 2017. Since then they have performed about 20 TAVI procedures.

10. Boston's expert is Professor Stephen Brecker. He is Chief of the Cardiology Clinical Academic Group at St George's University Hospitals NHS Foundation Trust and St George's University of London. He is a Consultant Cardiologist at St George's Hospital and leads the TAVI program there and he is a Professor of Cardiology at St George's London. He is a Fellow of the BCIS and has been a global proctor for Medtronic since 2010.

11. Edwards adduced evidence in reply from Dr Martyn Thomas, who was director of Cardiology Services at King's College Hospital from 2003 to 2006 and Director of Cardiovascular Services at St Thomas' Hospital from 2007 to 2014. He was also President of the BCIS from 2004 to 2008. Since 2014 he has been employed by LLC as Vice President of Medical Affairs.

The law applicable to the remitted issue

12. The Court has jurisdiction under section 50 of the Senior Courts Act 1981 to "award damages … in substitution for an injunction". I considered the principles which should be applied when considering an application for damages to be awarded in lieu of an injunction in a patent case in *HTC Corporation v Nokia Corporation* [2013] EWHC 3778 (Pat), [2014] Bus LR 217 at [3]-[32]. As counsel for Edwards pointed out, however, that was not a case in which it was contended that the injunction should be withheld or qualified on the ground of public interest.

13. Since then, there have been two main developments which call for attention. First, in *Lawrence v Fen Tigers Ltd* [2014] UKSC 13, [2014] AC 822 the Supreme Court held that the approach to be adopted by a judge when being asked to award damages in lieu of an injunction should be more flexible than that suggested by earlier Court of Appeal authorities. As Lord Neuberger of Abbotsbury explained:

> "120. The Court's power to award damages in lieu of an injunction involves a classic exercise of discretion, which should not, as a matter of principle, be fettered … And as a matter of practical fairness, each case is likely to be so fact-sensitive that any firm guidance is likely to do more harm than good …"
>
> 121. … while the discretion is not fettered, its manner of exercise is as predictable as possible. I would accept that the prima facie position is that an injunction should be granted, so the legal burden is on the defendant to show why it should not …
>
> 122. … it is right to emphasise that, when a judge is called on to decide whether to award damages in lieu of an injunction, I do not think that there should be any inclination either way (subject to the legal burden discussed above): the outcome should depend on all the evidence and arguments…
>
> 123. … it would, in the absence of additional relevant circumstances pointing the other way, normally be right to refuse an injunction if [A L Smith LJ's fourth tests in *Shelfer v City of London*] are satisfied. [But] the fact that those tests are not all satisfied does not mean that an injunction should be granted.
>
> 124. As for … public interest, I find it hard to see how there could be any circumstances in which it arose and could not, as a matter of law, be a relevant factor …"

14. Secondly, in *GlaxoSmithKline UK Ltd v Wyeth Holdings LLC* [2017] EWHC 91 (Pat), where the patentee accepted that there should be no injunction because of the potential impact on public health, the patentee sought an order that the defendant should account for its profits from infringing sales to be made in the future as to opposed to paying damages. Henry Carr J refused this both on procedural grounds and in the exercise of his discretion, while leaving open the question of whether the Court had jurisdiction to make such an order. Counsel for Boston submitted that Henry Carr J's reasoning for refusing the order in the exercise of his discretion was flawed, while counsel for Edwards supported it. Fortunately, it is not necessary for me to express any view on this question for the reasons explained in paragraph 6 above.

15. It was common ground between the parties that, in determining the issues as to (i) the length of the stay and (ii) the scope and duration of the qualification, the Court should have regard to the public interest and should exercise its discretion in accordance with Article 3 of European Parliament and Council Directive 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights ("the Enforcement Directive"), which provides:

"*Article 3*

General obligation

1. 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.

2. 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."

16. As I have observed in another context, the key consideration in Article 3 is proportionality and consideration of the other factors feeds into the proportionality analysis.

Factual background

Aortic stenosis

17. Aortic stenosis is the narrowing of the exit of the left ventricle of the heart where the aorta begins. It may occur at the aortic valve as well as above and below this level. It is the most common valvular heart disease in the developed world. Around 50% of patients suffering from severe symptomatic aortic stenosis die within 9-12 months if untreated. Almost 100% of such patients die within two years if not treated.

THVs

18. THVs are replacement heart valves that can be implanted percutaneously, by inserting a catheter into a patient's blood vessel (most commonly the femoral artery) and then using the catheter to guide the replacement heart valve into position in the patient's heart. The patient's native heart valve is not excised: the THV is positioned to push the patient's diseased heart valve leaflets out of the way and take over the job of the native heart valve. In their most basic form, THVs comprise an expandable metal frame (either balloon-expandable or self-expanding) on which is mounted a replacement heart valve made up of artificial valve leaflets.

19. There are two basic types of THV device: those that self-expand within the aortic annulus (self-expanding) and those that are implanted with the assistance of a balloon catheter (balloon-expandable).

TAVI procedures

20. The procedure of implanting a THV is known as TAVI. TAVI is used as an alternative to surgical heart valve replacement for patients suffering with aortic stenosis. TAVI is a relatively recent procedure. The first TAVI was in 2002, and the first regular TAVI procedures started around decade ago. The number of TAVI

procedures performed in the UK grew from approximately 1,800 in 2014 to nearly 4,000 in 2017.

21. Until three years ago, TAVI was only used for "high-risk" patients, i.e. those patients who were too sick to withstand open heart surgery and so would die if untreated. It is now also approved for "intermediate risk" patients ("IRPs"), i.e. those for whom surgery remains a viable option. IRPs currently account for 30-40% of TAVI procedures carried out by Prof Redwood, and he expects this proportion to grow to 50% within the next two years. There is no suggestion that his practice is untypical in this respect.

THVs approved for use in the UK

22. Seven types of THV are currently approved for use in the UK:

Manufacturer	Device	Type
Edwards	Sapien XT	balloon-expandable
	Sapien 3	balloon-expandable
	Centera	self-expanding
Medtronic	Evolut R	self-expanding
	Evolut Pro	self-expanding
Boston	Acurate	self-expanding
St Jude	Portico	self-expanding

23. The Edwards Sapien XT is only used for niche procedures such as valve-in-valve replacements (where a second valve is inserted within an existing device) or by some TAVI units where cost is a factor. Only 23 TAVI procedures in the UK in 2017 used Sapien XT devices (0.6%).

24. The Edwards Sapien 3 is the successor to the Sapient XT and provides improved performance, particularly in relation to paravalvular leakage. 2,382 Sapien 3 devices were implanted in the UK in 2017. Edwards' evidence, which I find persuasive, is that this represents approximately 60.7% of the total number of THVs implanted.

25. The Edwards Centera received CE mark approval for high risk patients in February 2018, but is not yet commercially available in the UK. Boston accepts that the Centera does not infringe. Edwards intend to use the Centera to target the self-expanding THV market. It is not approved for IRPs.

26. The Medtronic Evolut R has been used in the UK since 2007. It has a small delivery system and is used where the femoral access route is borderline and is sometimes used for valve-in-valve replacements. 1,064 Evolut R devices were implanted in 2017 (27.1%).

27. The Evolut Pro was launched in the UK in July 2017. It has a larger delivery system than the Evolut R and is only available in a limited number of UK TAVI centres. 66 Evolut Pro devices were implanted in 2017 (1.7%).

28. Boston is a relatively small player in the TAVI field. Its earlier devices, the Lotus and Lotus Edge, were withdrawn in February 2017 and October 2016 respectively due to safety concerns. Boston has announced that the Lotus Edge will not be available in

Europe until at least 2019. There is a dispute as to whether or not the Lotus and the Lotus Edge fall within the claims of 766, but this does not matter given that they are not on the market. In 2017 Boston acquired Symetis SA, which previously manufactured the Acurate. Edwards' unchallenged evidence is that 215 Acurate devices were implanted in 2017. On Edwards' evidence, that represents a market share of 5.5%. This is despite the Acurate being less expensive than the Sapien 3. Boston does not dispute that the Acurate falls outside the claims of 766.

29. The St Jude Portico is not generally used by interventional cardiologists due to lack of high quality clinical trial data and concerns regarding thrombosis. 75 devices were implanted in 2017 (1.9%).

30. It follows from the above that, for most clinicians in the UK, the choice is between the Sapien 3 (balloon-expandable) and the Evolut R or Evolut Pro (both self-expanding). In the case of IRPs, these are the only choices, because they are the only ones approved for IRPs.

31. It is pertinent to note that it is common practice to supply THVs on consignment terms, meaning that the device is only sold when it is implanted.

Clinical outcomes of the devices

32. Prof Redwood, Prof McCarthy, Dr Rawlins and Dr Aggarwal all express the opinion that the Sapien 3 provides the best clinical outcomes for most patients.

33. Prof MacCarthy gives the following reasons for this:

    i) very low paravalvular leak rate;

    ii) very low pacemaker rate;

    iii) a very low profile, steerable delivery system which translates to low vascular injury rate;

    iv) low stroke rate;

    v) easy native valve crossing without pre-balloon aortic valvuloplasty;

    vi) by far the most robust evidence base for its use compared to surgery; and

    vii) suitability for most anatomies.

34. Prof Brecker makes three points. First, all of the THVs available have been approved for use after rigorous clinical trials. Secondly, there have been no randomised studies comparing the Sapien 3 with the Evolut R or Pro and therefore it is not possible to state with complete confidence that one valve is better than another. In Prof Brecker's view the most recent studies which have been released for the Sapien 3, Evolut Pro and Acurate indicate broad clinical equivalence between the devices, particularly on the primary outcomes of mortality and strokes at 30 days. Thirdly, clinicians have an understandable preference for the THV with which they are most familiar, but this does not necessarily mean that they are in fact superior.

35. Counsel for Edwards submitted that the best evidence available was a meta-analysis of data from 30 studies by Denise Todaro *et al*, "Current TAVR devices", *Cardiac Interventions Today*, 11, 2, 53 (2017) exhibited by Prof Brecker. Figure 3 of this paper showed that the Sapien 3 had superior outcomes than the Evolut R on every measure reported. As counsel for Boston pointed out, however, it is not clear whether these differences are statistically significant. Moreover, the authors do not comment on the apparent superiority of the Sapien 3, as might be expected if it were statistically significantly superior in every respect.

36. The conclusion which I draw from this is that, although there is a significant body of clinical opinion which regards the Sapien 3 as giving the best clinical outcomes, there is little in the way of hard data to substantiate that opinion.

Patients for whom the Sapien 3 is the only option

37. Most TAVI devices (around 95%) are delivered percutaneously via the femoral artery (referred to as the transfemoral route). Patients whose femoral arteries are too narrow or too calcified for this procedure (i.e. the remaining 5%) are generally treated via one of three other routes: through the heart (transapical), through the aorta (transaortic) or via the subclavian vein (subclavian). Of these, the transapical predominates, accounting for just over half of non-transfemoral deliveries.

38. Five devices are approved for non-transfemoral delivery: the Sapien XT, Sapien 3, Evolut R, Evolut Pro and Acurate. For IRPs, the options are confined to the following:

Device	**transapical**	**transaortic**	**subclavian**
Sapien 3	+	+	
Evolut R		+	+
Evolut Pro		+	+

39. Thus there exists a group of patients (IRPs requiring transapical delivery) for whom the Sapien 3 is the only option. As Prof Redwood explains, the number in this group is growing due to the increasing use of TAVI. Prof Brecker expresses the opinion that the total number of such patients is probably less than 20 per year in the UK, because in other cases delivery by an alternative route is possible or surgery would be preferable to transapical delivery. He does not dispute that, for some patients, the Sapien 3 is the only option, or that their numbers are growing.

40. There are three other groups of patients for whom the Sapien 3 is the only option:

    i) Patients who need a balloon-expandable valve, but for whom the Sapien XT would not be suitable.

    ii) IRPs under the age of 75 (the Sapien 3 is the only THV approved for such patients).

    iii) Patients who have a significant allergy to nickel (the Sapien 3 is the only device which does not use a nickel-based stent).

41. It appears that the number of patients in each of these groups is small, but they exist.

Adoption of a new THV

42. Clinicians working in a TAVI centre cannot unilaterally adopt a new medical device without having overcome a number of internal governance hurdles. Each hospital has its own procedures. By way of example, Dr Rawlins explains that the proposal to introduce the Evolut R device at UHS (in addition to the existing Sapien 3) required the approval of a technical committee, two ethical committees and a number of finance committees. The process took eight weeks.

The number of clinicians who will require re-training

43. Clinicians require training to use a THV. It is therefore common ground that a number of clinicians who are currently trained to use the Sapien 3 will need to be re-trained to use another device. (Edwards have undertaken not to train any new UK clinicians to use the Sapien 3, apart from three who have already had training arranged for 29-30 May 2018.) An important factual issue between the parties is as to the number of such clinicians. Boston estimates it at 16, whereas Edwards estimate it at 60.

44. Boston's figure is based on three assumptions. First, that there are eight TAVI centres at which clinicians will have to be retrained – four which currently use only the Sapien 3 and four at which the clinicians will need to be trained to use one of the Medtronic devices in order to treat IRPs. Secondly, that there are two clinicians at each such TAVI centre. Thirdly, that none of the clinicians working at TAVI centres in which Medtronic devices are currently implanted will need training.

45. Edwards' evidence, which I accept, is that each of these assumptions is unreliable. As to the first, there are eight (not four) TAVI centres in the UK which only implant the Sapien 3 and three (not four) TAVI centres which do not currently implant one of the Medtronic devices. Accordingly, there are eleven TAVI centres at which the clinical team will need to be retrained.

46. As to the second assumption, there is no reason to suppose that each TAVI centre only employs two clinicians. For example, there are three clinicians at UHS. The Royal Stoke University Hospital has four clinicians trained on the Sapien 3. A similar picture emerges in other affected units.

47. As for the third assumption, the fact that a TAVI centre implants Medtronic devices does not mean that all of the clinicians working there are certified in respect of such products. It is relatively common in multi-device centres for individual clinicians to be trained to use only one device. By way of example, the Royal Papworth Hospital implants Sapien 3 and Medtronic devices. One of the clinicians working there is only certified to implant the Sapien 3, whereas other members of the team are certified on Medtronic devices.

48. Furthermore, as Prof Brecker explains, it is best practice for clinicians to be trained to use at least two THVs. According to Boston's evidence, withdrawal of the Sapien 3 will leave some 15 TAVI centres in the UK (accounting for 36.7% of all implantations in 2017) with a Medtronic device as the only available device. Some of these centres have very substantial patient throughputs, and are therefore likely to employ more than two clinicians.

49. For these reasons, I consider that Edwards' estimate of 60 clinicians who are likely to need re-training is a reasonable one, and certainly more likely to be accurate than Boston's estimate of 16.

The time which will be required for re-training

50. Another important factual issue between the parties concerns the time which will be required to re-train clinicians to use another THV. As Edwards point out, this partly depends on the number of clinicians that will require re-training. Furthermore, it is not just the clinicians who need to be trained, but also the specialist catheter nurses who will participate in the procedure.

51. For clinicians, the initial training takes several days, involving lectures and observation of a TAVI procedure. Dr Rawlins explains that the training programme for the Evolut R required two days of on-site training, attendance at three off-site meetings and an off-site observation of a TAVI implantation. There are three interventional cardiologists at UHS. In order to maintain continuity of care for existing patients, the training of each clinician had to be staggered over a period of months.

52. The next phase, referred to as "proctoring", involves direct supervision by another clinician who is already experienced in the use of the particular device. The required number of proctored implantations will vary from clinician to clinician. Prof Brecker says that clinicians who are already proficient on Sapien valves generally require 5-10 proctored implantations before they are certified to use the Evolut R and Evolut Pro.

53. The duration of the proctoring phase is of course subject to the availability of suitable proctors. For some devices, it also depends on the availability of other specialists such as prep nurses. Boston requires its own prep nurses to be present. Although this is not the case for Medtronic, Prof Brecker acknowledges that it can take some time to treat nurses how to load a valve.

54. The duration of the proctoring phase is also affected by the throughput of the TAVI centre and the number of clinicians working there. Dr Rawlins explains that UHS undertakes approximately three TAVI procedures per week. With three interventional cardiologists requiring up to 30 proctored interventions, the proctoring phase for the Evolut R will take up to 10 weeks. However, this would require all patients to be treated with the new device, even those for whom the Sapien 3 is judged to be the preferred (or indeed the only) option.

55. Dr Rawlins believes that it might take between 6 months and one year for an individual team of interventional cardiologists which currently uses only the Sapien 3 to complete training and proctoring in relation to a new device such as the Evolut R. If this coincides with the same training and proctoring of other Sapien 3-only clinicians, the process could take well over a year.

56. Expediting such training and proctoring will inevitably disrupt waiting lists. Patients waiting to be treated by clinicians who have to be diverted into training will suffer. So too will patients who would otherwise be treated by the proctor.

57. Even after certification, the attendance of a proctor may still be required, for example where the clinician does not feel sufficiently comfortable dealing with a complex case.

58. Increasing familiarity with a new device leads to improvements in outcome. Prof Brecker explains that complication rates are higher amongst lower volume users but this effect disappears over time with increased experience. He is in little doubt that individual operators will feel uncomfortable at not being able to use a device that they have become familiar with and may feel less confident at first in treating patients with a new device. Dr Rawlins (who is already familiar with the Sapien 3) considers that it will take approximately 50 implantations to become fully familiar with the Evolut R and to maximise clinical outcomes using it.

General points

59. In considering both the duration of the stay of, and the nature and duration of the qualification to, the injunction, the starting point, as counsel for Boston rightly emphasised, is that the Sapien 3 has been found to be an infringing device. It follows that, ordinarily, Boston would be entitled to an injunction to prevent further sales of that device until the expiry of 766 on 22 December 2024. Although counsel for Boston also relied upon the fact that an injunction had already been granted, I am unimpressed with that point because the Court of Appeal's order leaves open the question of what (if any) limitation or qualification there should be to that injunction, and as I have explained it is agreed there should be a stay and a qualification.

60. Given that a stay and a qualification of the injunction, albeit on terms that Boston receives a financial remedy in respect of future sales of the Sapien 3, will partly deprive Boston of the remedy to which it would ordinarily be entitled, the length of the stay and the nature and duration of the qualification must be proportionate, that is to say, they must strike a balance between Boston's interest in maintaining the monopoly conferred by 766 and the public interest in ensuring that patients with aortic stenosis receive appropriate treatment. Rightly, Edwards do not rely upon their own interests except in so far as they coincide with the public interest.

61. In considering the proportionality of the parties' respective proposals, a striking factor is what Boston's evidence does not say. There is no suggestion that continued sales of the Sapien 3 will cause Boston irreparable harm, that is to say, harm that cannot be fully compensated by a financial remedy against Edwards. This is unsurprising given that the Sapien 3 has been on the market since January 2014, that the Sapien 3 has some 60% of the market and that the Acurate only has 5-6% of the market. Indeed, it seems likely that the major beneficiary of the more limited stay and qualification proposed by Boston would be Medtronic. Nor is there any suggestion that Edwards will not be able to pay whatever sum may be determined to be payable in respect of future sales of the Sapien 3. Furthermore, as discussed above, Boston is not currently exploiting 766 in the UK.

62. On the other hand, I agree with counsel for Boston that the potential future availability of the Ultra is not a material factor. At present, it is not certain that Edwards will obtain approval for the Ultra. Even if they do, I cannot assume that the Ultra does not infringe 766. Even if the Ultra does not infringe, that in itself would not justify a stay or qualification of the injunction with respect to the Sapien 3.

63. I also agree with counsel for Boston that there is insufficient objective evidence of clinical superiority of the Sapien 3 to justify a stay or qualification of the injunction on that ground alone.

Duration of the stay

64. Boston proposes a stay of two to three months. The basis for this proposal is Prof Brecker's opinion that that period should be sufficient to enable clinicians who need to be re-trained to be trained to use another THV. Edwards seeks a stay of 18 months. The basis for this is Edwards' evidence as to the number of clinicians who are likely to need re-training and the length of time that this is likely to take.

65. Prof Brecker does not explain very clearly the basis for his opinion that two to three months should suffice. I infer, however, that it is based upon Boston's estimate as to the number of clinicians who need to be re-trained. For the reasons given above, however, I consider that that estimate is significantly too low. It also appears to be based on the assumption that all the clinicians who need to be re-trained can be re-trained simultaneously and that this will take no longer than two to three months. For the reasons explained above, this appears to me to be unrealistic.

66. Equally, however, Edwards' evidence does not explain very clearly how the figure of 18 months has been arrived at. It appears to be primarily based on a combination of the number of clinicians who need to be re-trained and Dr Rawlins' evidence that the process could take well over a year and that further time will be required before clinicians are fully comfortable with it.

67. In my view there is considerable uncertainty as to how long the re-training process is going to take. I think that the truth is that no-one will really know until the necessary arrangements have been made. On the present evidence, it seems to me that the process is likely to take at least a year, but I am unsure as to whether it will take any longer than that, or if so, how much longer. In those circumstances I have concluded that the best course is to grant an initial stay of the injunction to permit continued implantation of the Sapien 3 for a period of 12 months and to grant Edwards permission to apply to extend the stay if it turns out that the period required for re-training is longer than that.

Nature and duration of the qualification

68. There is no real dispute that, for the reasons explained above, there is a small but growing number of patients for whom, at present, the Sapien 3 is the only suitable device. Edwards contend that the provision of Sapien 3 valves for such patients should be excepted from the injunction without limit of time.

69. Boston accepts that there should be an exception to the injunction for this reason, but contends that it should only last for six months after the end of the stay. Counsel for Edwards submitted that there was no basis for this limitation. I agree with this. The exception is justified by the need to protect the health of those patients for whom the Sapien 3 is the only suitable THV. That need will not necessarily cease to exist six months after the end of the stay. On the other hand, I accept that one cannot predict what devices will became available between now and the expiry of 766. It is possible that in, say 2021, a device will become available which is both non-infringing and

suitable for all the patients in question. It seems to me that the way in which to address this is to give Boston permission to apply to terminate the exception in such circumstances.

70. It is common ground that the supply of Sapien 3 valves to the patients in question should be permitted where there is an appropriate declaration from the responsible clinician, but there is a dispute between the parties as to the form the declaration should take. Edwards contend that Boston's proposal is unduly complex. I agree with this, and thus I think the starting point should be Edwards' proposed declaration. On the other hand, I consider that Edwards' wording is too vague. In my view the declaration should certify that, in the clinician's judgment, the patient falls into one of the groups for whom there is no alternative to the Sapien 3 for the reasons given above. I would add that some of the drafting of Edwards' proposed declaration is infelicitous (e.g. "the following conditions are or have been reasonably fulfilled"). I will hear further argument on that aspect when this judgment is handed down.

71. It is also common ground that Edwards should be required to send clinicians an approved form of communication to inform them of the outcome of the litigation pursuant to Article 15 of the Enforcement Directive. Edwards were agreeable to part of a communication proposed by Boston, but not the remainder. Broadly I agree with Edwards' position, but again I will hear further argument on the details.

Payments on account

72. Edwards propose a payment on account of 2% of the net sales value of TAVI kits incorporating the Sapien 3. Boston proposes 50% of the total gross sums received or receivable from sales of the Sapien 3. It seems to me that Edwards' figure may be too low, while Boston's figure is almost certainly too high. Since it is agreed that the payments are simply on account of whatever figure may be awarded in future, however, I see no need to consider the rival justifications for these figures. Rather I propose to fix a figure which I consider reasonable, which is 5% of the net sales value of kits.

Boston's application for the provision of samples of the Ultra

73. During the hearing Edwards offered to permit Boston's independent experts to inspect a sample of the Ultra, and submitted that it was premature to require provision of samples prior to provision of the Product Description and inspection by the experts, since those steps might render the provision of samples unnecessary. I agree with this, subject to the proviso that the experts should be permitted to inspect the sample together with Boston's solicitors and counsel at the premises of Boston's solicitors.