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Case No: IP-2024-000024

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

Rolls Building
Fetter Lane
London, EC4A 1NL

26 April 2024

Before :

MISS CHARLOTTE MAY KC
(Sitting as a Deputy Judge of the High Court)

- -

Between:

WELL LEAD MEDICAL CO., LIMITED **Claimant**
(a company incorporated under the laws of China)

- and –

CJ MEDICAL LIMITED

Defendant

- -
- -

Mr Richard Davis KC and Mr Nick Zweck (instructed by **Clyde & Co LLP**) for the **Claimant**
Mr Guy Tritton (instructed by **N.J.Akers & Co Ltd**) for the **Defendant**

Hearing date: 10 April 2024

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APPROVED JUDGMENT

Remote hand-down: This judgment will be handed down remotely by circulation to the parties or their representatives by email and release to The National Archives. A copy of the judgment in final form as handed down should be available on The National Archives website shortly thereafter but can otherwise be obtained on request by email to the Judicial Office (press.enquiries@judiciary.uk).

Miss Charlotte May KC (sitting as a Deputy High Court Judge):

Introduction

1. This is my reserved judgment following the application by the Claimant for interim injunctive relief against the Defendant. The Claimant seeks an order restraining the Defendant until judgment or further order in the meantime from supplying or offering to supply, disposing or offering to dispose, using or importing in the United Kingdom a product called the "Seplou Sheath". The Seplou Sheath is an endourology device known as a ureteral access sheath (**UAS**). It is used in a procedure called endoscopic renal lithotripsy, a common urological procedure for the treatment of kidney stones.

2. The Claimant alleges that the Defendant's dealings (actual or threatened) in the Seplou Sheath in the United Kingdom infringe the patent in suit in these proceedings, EP(UK) 3 760 143 B1 (**the Patent**). The Defendant denies infringement, and counterclaims for invalidity on various grounds. There is a preliminary point of detail as to whether the Claimant is the proprietor of the Patent. There is also a dispute on this application as to what dealings the Defendant has already undertaken and when, which is relevant to the analysis of the balance of convenience and status quo. I return to these points below.

3. The Claim Form was issued on 15 February 2024, and the application for interim relief was issued the following day. After some dispute between the parties, the hearing was fixed for 10 April 2024. At the hearing, I had the benefit of written and oral submissions from Mr Davis KC who appeared on behalf of the Claimant with Mr Zweck, and from Mr Tritton on behalf of the Defendant, as well as evidence filed by both parties. I am grateful to all those who were involved in the preparation of these materials.

Background

4. The following summary comes from the evidence of Ms Lijuan Shi, Sales and Marketing Director (Endourology) at the Claimant, Mr Ralph Cox, partner at the Claimant's solicitors, Mr George Reynolds, Sales Director of the Defendant, Mr Charles Reynolds, Managing Director of the Defendant (and Mr George Reynolds' father), and Mr Noel Akers of the Defendant's patent attorneys.

5. The Claimant was founded in 1998 and became a publicly traded company in 2004 when it was listed on the Shanghai stock exchange. It is in the business of developing, manufacturing, and distributing medical devices. Its core business covers urology, anaesthesia, respiratory care, and haemodialysis. It is a substantial business with annual sales of approximately £150 million and a total asset value of approximately £262 million as at the end of 2022. Within the endourology sector, it has approximately 20 products (including UASs, ureteral stents and dilation devices) which are distributed in China and around the world.

6. As noted above, endoscopic renal lithotripsy is the procedure of crushing and removing kidney stones. There are two types of endoscopic renal lithotripsy: percutaneous nephrolithotomy (PCNL) where advancement of the endoscope is via an incision in the abdomen, and retrograde intrarenal surgery (RIRS) where advancement of the endoscope is via the ureter. An access sheath is often used in these procedures. An obturator or dilator is generally required for the safe insertion of the sheath (it provides

sufficient stiffening to allow insertion and has a dilating effect on the urethra). Once the sheath is in position, the obturator is removed and the endoscope is inserted. Irrigation is required during the procedure (normally saline) and it is delivered through the endoscope. The outflow of the irrigation fluid is through the space between the inner diameter of the sheath and the outer diameter of the endoscope. With a conventional sheath, the outflow is passive, dependent upon intrarenal pressure and gravity. The crushed stones are generally extracted using forceps or a stone basket or by use of high-pressure irrigation to flush the stone fragments out.

7. The Patent relates to a UAS with negative pressure suction functionality which is provided by a side arm oblique to the main sheath and with a longitudinal slit. The person using the suction functionality can alter the negative pressure by covering more or less of the slit. The negative pressure system allows the fragmented kidney stones to be removed with the saline solution as it passes back through the gap between the sheath and the endoscope (claim 1). In addition, the Patent also provides for a UAS with a flexible tip to allow the user to adjust the direction of suction, irrigation, instrument placement or removal of a stone (claim 3). The Patent has a filing date of 27 April 2015 and a priority date of 28 July 2014.

8. The Claimant sells two products in the UK which are said to exploit the Patent. The first product is the "ClearPetra Sheath" which was launched in 2016 after the Claimant obtained CE certification in 2015. This is said to have the features of claim 1. The second product is the "Flexi ClearPetra Sheath" which was launched in March 2023. This is said to have the features of claim 3.

9. Until recently, the ClearPetra family of products were the only UASs with negative pressure suction functionality on the market in the UK. There are competitors who also market UASs, such as Boston Scientific, Cook Medical and Rocamed, but they do not offer a suction UAS. The original ClearPetra Sheath is priced at £165 per unit, whereas the Flexi ClearPetra is priced at £125. Ms Shi explained that the Flexi ClearPetra was priced lower than the original sheath so as to be more competitive with existing conventional (i.e. non suction) UASs.

10. Ms Shi stated that the Claimant had no intention of changing the price of the Flexi ClearPetra Sheath over the next 24 months from the date of her statement (February 2024) but that it does intend to drop the price of the original ClearPetra Sheath to a similar level to the Flexi product, so that it has better access to clinical trials and procurement. She also said that the Claimant estimates that 6000 to 9000 units will be sold in the UK between February 2024 and February 2026, of which most will be the Flexi ClearPetra sheath.

11. ClearPetra is distributed in the UK through a specialist medical devices distributor called BioSpectrum Ltd.

12. The Claimant says that the ClearPetra Sheath enables a novel suction assisted procedure for kidney stone retrieval which is safe, with minimal complications and reduced need for ancillary treatment or post operative follow up, thereby resulting in costs savings for the hospital and benefits for the patient.

13. The Defendant is a private company based in Truro, Cornwall. It is a distributor of a wide range of medical and surgical devices in the UK. Its profits have grown annually between 2018 and 2023, with the latest available figures at over £2.2 million.

14. A recent addition to the Defendant's product portfolio is the Seplou Sheath, which is also a negative pressure suction UAS. There appear to be two different versions of the Seplou Sheath, one of which has a flexible bendable tip (which the Claimant says is the same as the Flexi ClearPetra). It is the flexible version of the Seplou Sheath which is in issue here.

15. The Claimant first became aware of the Defendant's involvement with the Seplou Sheath in the UK when it exhibited the product at the Eastern Urology Ground Annual Meeting on 17 November 2023. By this time, the Seplou Sheath was already known to the Claimant, since it is one of a large number (over 60) of alleged "copy" products of the ClearPetra Sheath that are produced in China.

16. There are approximately 18,000 cases of endoscopic renal lithotripsy performed annually in the UK. Of these, approximately 8400 procedures each year will be carried out using a sheath. Surgeons often prefer to conduct ureteroscopies without using an access sheath as this can result in a lower likelihood of post procedural complications. However, the use of an access sheath has the advantage of enabling the surgeon to make repeated passages of the ureteroscope into the patient. It can also improve the flow of irrigation fluid and visualisation of the procedure, as well as reduce operating time. If the surgeon uses a sheath, he or she can choose to use a conventional UAS or a suction UAS.

17. In the UK, UASs (including suction versions) are sold to the NHS and private hospitals. Sales to the NHS are made via the NHS Supply Chain once the product is listed on the NHS Framework. The current endourology Framework started on 21 June 2021 and ends on 20 June 2025. It covers "consumables used within minimally invasive endourological procedures" and gives a list of approved suppliers and product categories. The Claimant's distributor, BioSpectrum, and the Defendant are both suppliers for the current endourology Framework.

18. It is possible to apply to NHS procurement to add new endourological products to the NHS Supply Chain, but this can take up to 12 weeks to approve. The Defendant applied to add the Seplou Sheath to its range of endourological products for supply to NHS hospitals on 28 November 2023. The approval took longer than expected and the Seplou Sheath "went live" on the NHS Supply Chain website on 22 February 2024. Supply of the Seplou Sheath by the Defendant to NHS hospitals could begin only once this approval had been granted.

Applicable Legal Principles

19. There was no dispute between the parties as to the relevant legal principles, although as is often the case, each side emphasised different points from the authorities.

20. The starting point is the well-known analysis in *American Cyanamid v Ethicon* [1975] AC 396. This was summarised by Floyd LJ in *Neurim Pharmaceuticals (1991) Ltd v Generics UK Ltd (t/a Mylan)* [2020] EWCA Civ 793, [2021] RPC 7 at [15] as follows:

- Stage 1: Is there a serious question to be tried?
- Stage 2: Are damages an adequate remedy for the claimant?
- Stage 3: If not, are damages (on the cross-undertaking in damages) an adequate remedy for the defendant?
- Stage 4: If damages are not an adequate remedy for either side, where does the balance of convenience lie?

21. As Counsel for the Defendant submitted, the following additional points can also be drawn out of the Court of Appeal *Neurim* decision:

i) Damages must be an adequate remedy, not a perfect one. The boundary between adequate and inadequate is not a precise one, and it will be a matter for judicial evaluation on the evidence as to whether or not the boundary has been crossed ([16]).

ii) If the boundary between adequate and inadequate is not crossed in relation to the claimant's loss then, normally, an injunction will not be granted ([16]).

iii) It follows that the court should not assume that damages will be inadequate and move straight to consider the balance of convenience. It is important to consider Stages 1 and 2 first ([17]).

iv) It is well settled that, in deciding Stage 1, the court should not conduct a "mini trial" but confine itself to seeing whether there is a serious question to be tried on the substantive claim ([18]).

v) In tackling Stages 2-4, the court must do the best that it can on the available written evidence. Merely because the task is hard should not lead to the court abandoning the task at the outset ([18]).

vi) It can be appropriate to consider the question of damage by reference to two periods: the period up to the point (hypothetically assumed) when the patentee succeeds in getting a permanent injunction after trial (**Period 1)** and the subsequent period between that point and the expiry of the patent (**Period 2**) ([21]).

22. Counsel for the Defendant also drew my attention to paragraphs [51]-[53] of the Court of Appeal *Neurim* decision. I do not consider that these paragraphs contain any additional points of principle, since they are specific to the facts of that case.

23. Counsel for the Claimant emphasised five points in his written and oral submissions. The first was that where the other factors are evenly balanced, it is a counsel of prudence to take such measures as necessary to maintain the status quo. In this context he referred me to *Fellowes & Son v Fisher* [1976] 1QB 122CA although the point was originally made by and is more often cited from Lord Diplock in *American Cyanamid* at p.396.

24. As an aside, I note that it was common ground that the status quo should be assessed as at the time immediately before the issue of proceedings or the application notice if substantially later, rather than at the time when the conduct complained of began. See Lewison LJ in *Frank Industries Pty Ltd v Nike Retail BV* [2108] EWCA Civ 497 at [19].

25. Secondly, Counsel for the Claimant emphasised the relevance and importance of harm that may not sound in damages. He relied on the passage in the decision of Mellor J in *Neurim Pharmaceuticals (1991) Ltd & Anr v Teva UK Ltd* [2022] EWHC 954 (Pat) at [9]-[10] where the judge said:

> 9. Mr Waugh QC for Neurim made an additional point in these terms:
>
> > 'Damage for this purpose includes harm that is not normally recoverable in damages – see Terrell 19th ed'n at 14-175 - 14-178 citing SmithKline Beecham v Apotex Europe Ltd [2003] EWCA Civ 137 per Aldous LJ at [18].'
>
> 10. This needs a bit of unpacking. Carnwarth LJ (as he then was) at [43] made the same point as Aldous LJ in [18] and, to my mind, in clearer terms (see the passage I have underlined below):
>
> > 'Aldous LJ has also quoted from Lord Diplock's classic statement in *American Cyanamid Co v Ethicon Ltd* [1975] A.C. 396, 406, where he said:
> >
> > > 'The object of the interlocutory injunction is to protect the plaintiff against injury by violation of his right for which he would not be adequately compensated in damages recoverable in the action if the uncertainty were resolved in his favour at the trial …'
> >
> > The purpose of an interlocutory injunction therefore is protection, not just against 'loss which would sound in damages', but against violation of any right where damages would not be adequate compensation. An obvious example of the need for that wider formulation is the case of trespass to land. A landowner whose title is not disputed is normally entitled to an injunction to restrain trespass on his land, even if the trespass does not harm him (see *Patel v WH Smith (Eziot) Ltd* [1987] 1W.L.R. 853, 858F).'

26. Counsel for the Claimant submitted that this passage was relevant to his case on unquantifiable damage which he said the Claimant will suffer if it loses its current exclusivity in the marketplace. I shall return to this further below.

27. Thirdly, counsel for the Claimant also drew my attention to paragraphs [6]-[8] of the decision of Mellor J in *Neurim* in relation to what the judge said about price depression. I summarise the salient points from those paragraphs as follows:

i) The nature and extent of a price depression, if any, is a question of fact for each case.

ii) It may depend on the number of generic entrants in the market.

iii) Whether the price depression manifests itself in a downward price spiral is also intensely fact sensitive.

iv) Once the monopoly price previously charged by the patentee has been depressed (whether a price spiral occurs or not) it is often difficult if not impractical to restore the price to previous levels.

28. Fourthly, counsel for the Claimant reminded me of the passage in the Court of Appeal *Neurim* decision at [38] to the effect that the court should conduct a critical assessment of the evidence. In *Neurim*, the point arose in the context of the evidence about alleged consequential loss to the claimant in that case if the injunction was not granted. Floyd LJ held that the court was not bound to accept that evidence uncritically but instead should examine it with a critical eye and by reference to the relevant facts and circumstances of the case. In this case, the Claimant makes critical observations about parts of the Defendant's evidence which it submits taints the evidence generally. I shall return to that below.

29. Finally, counsel for the Claimant referred me to the decision of the Supreme Court in *Rugby Football Union v Consolidated Information Services Ltd (formally Viagogo Ltd) (in liquidation)* [2012] UKSC 55 in support of a submission that it is legitimate for the court to take account of the deterrent effect which an injunction might have on third party potential entrants. He relied on the following paragraphs of the opinion of Lord Kerr:

> 33. The appellant's challenge to the Court of Appeal's decision rests exclusively on the claim that it applied the wrong test in assessing the proportionality of the making of the *Norwich Pharmacal* order. Put succinctly, the appellant claims that, in assessing whether the order is proportionate, the court should evaluate the impact that the disclosure of the information will have on the individual concerned against the value to the applicant of the information that can be obtained about that particular individual. Expressed in simple terms which reflect the circumstances of this case, the court, according to the appellant, should confine its consideration to the individual transaction and ask, "What value will the information about this particular individual have to the RFU?"
>
> 34. Mr Howe QC, who appeared for the appellant, submitted that Longmore LJ in the Court of Appeal had been wrong to suggest that it would "generally be proportionate" to make a *Norwich Pharmacal* order once it had been shown that there was arguable wrongdoing and that there was no realistic way of discovering the identity of the arguable wrongdoers other than by obtaining an order. Rather, Mr Howe claimed, the court should have asked whether obtaining information about a particular person who had sold a ticket at more than face value would benefit the RFU to an extent that outweighed that individual's right to have his or her personal data protected from disclosure. It was suggested that the way in which the Court of Appeal had formulated the test involved a presumptive approach. On that basis it was to be assumed that the need to obtain the information in order to prosecute an action to vindicate the right to property would in virtually every instance trump any claim to privacy and protection of personal data. The appellant contended that this assumption was misplaced.

The proportionality of the interference could only be assessed by concentrating the examination on the particular circumstances of the individual transaction. In this way, the appellant claimed, the weighing exercise involved assessing how much benefit would derive from obtaining information about a single individual as against the infringement of that particular person's right to have his or her personal data protected.

…

36. Mr Howe suggested that in these passages the CJEU had prescribed a clear principle that national courts, in dealing with a claim for disclosure of personal data must weigh the potential value to the party seeking the material against the interests of the data subject. This unexceptionable claim can be readily accepted; it is its refinement and development that causes greater difficulty. Mr Howe argues that in making that assessment, the court must conduct the examination solely by reference to the particular benefit that obtaining the information relating to an individual data subject might bring. Its value as part of a broader context is not to be considered. Thus, for instance, the fact that obtaining the information might deter others from selling or buying tickets for rugby internationals could not be taken into account.

37. I find this approach somewhat artificial, not to say contrived. It is unrealistic to fail to have regard to the overall aim of the RFU in seeking this information. It is not simply to pursue individuals. It obviously includes an element of active discouragement to others who might in the future contemplate the flouting of rules which the RFU seeks to enforce. There is nothing, in my opinion, in the cited passages from the CJEU's judgment that supports a restriction of the matters to be considered by a national court in the manner suggested.

…

40. Mr Howe suggested that the use of the expression, "the facts of each case" in para 59 of the court's judgment betokened a conclusion that the individual transaction between the internet provider and the subscriber was to be considered without reference to broader considerations that might motivate the applicant for disclosure of the information. I do not accept that submission. Of course the facts of each case must be considered. But this does not mean that they should be placed in a hermetically sealed compartment so that their possible impact on issues going well beyond their significance to the person whose personal data are sought is ignored. There is no logical or sensible reason to disregard the wider context in which the RFU wants to have access to this information. Their desire to prevent the future sale of tickets for international matches at inflated prices is intimately connected to the application for the Norwich Pharmacal order. The ability to demonstrate that those who contemplate such sale or purchase can be detected is a perfectly legitimate aspiration justifying the disclosure of the information sought. There is no coherent or rational reason that it should not feature in any assessment of the proportionality of the granting of the order.

30. As these paragraphs illustrate, that case concerned the grant of *Norwich Pharmacal* relief, specifically the disclosure of the identity of individuals who had sold RFU tickets at inflated prices via the Viagogo website. That is obviously different to the grant of interim injunctive relief. Counsel for the Claimant submitted that, nevertheless, since injunctions and *Norwich Pharmacal* orders are both discretionary remedies which concern questions of proportionality, the reasoning of the Supreme Court applies equally to both types of relief.

31. I accept, of course, that proportionality is a relevant consideration in respect of injunctive relief, albeit that it is not normally raised in the context of interim injunction applications in patent disputes. However, I do not accept that the deterrent effect which granting an injunction may have on third parties should be elevated to a point of principle. In my judgment, whether there will be a deterrent effect and whether that effect is relevant in any given case will be fact sensitive.

32. However, as the Defendant submitted, in the context of an action for patent infringement, the court must be careful not to assume that the patent is valid and infringed anymore than it should assume the opposite (unless it is a rare case where the merits are considered). As a result, a deterrent effect is unlikely to be relevant in most cases (since it assumes the former and not the latter). If it is relevant, it is most likely to fit in the analysis at Stage 4, in respect of the balance of convenience.

33. I have kept all these principles and points in mind in my analysis below.

Is the Claimant the proprietor of the Patent?

34. The named inventor and original registered proprietor of the Patent is Professor Shaw P. Wan. According to Ms Shi, Professor Wan assigned his rights in the Patent to the Claimant by virtue of a written assignment dated 29 May 2023. She exhibited a copy of the assignment to her evidence. However, as Mr Akers, pointed out in his evidence, the name of the assignee is Guangzhou Well Lead Medical Co., Ltd, which is different to the name of the Claimant.

35. This apparent discrepancy was addressed by Mr Cox in his evidence in reply. He stated that the assignee is the same entity as the Claimant, even though the names are slightly different. He explained that Well Lead Medical Co., Ltd is the official name of the Claimant, a Chinese corporation. This is the name that is used, for example, on the Shanghai stock exchange. However, the Claimant's Chinese name translates to Guangzhou Well Lead Medical Co., Ltd. He also explained that Guangzhou is the city where the Claimant is located and that it is a general requirement under Chinese law that the city or municipal district where a company operates is used in front of a trading name.

36. During the hearing, I pointed out that as well as the difference in names, there was also a difference in the address of the assignee as recorded in the assignment and the address of the Claimant as recorded in the Claim Form (albeit that they are both based in Guangzhou). Counsel for the Claimant explained to me on instructions that the address on the assignment is the Claimant's registered address but the address on the Claim Form is the Claimant's trading address. To demonstrate this, he produced a copy of the Claimant's German equivalent of the CE certificate for the ClearPetra Sheath which is

in the name of the Claimant and uses its registered address (i.e. the same address as that used in the assignment). He also pointed me to the Claimant's marketing materials for the ClearPetra Sheath at Annex 2 of the Particulars of Claim which uses the same address as the Claim Form.

37. Mr Akers also noted in his evidence that the registered proprietor of the Patent as shown on the register maintained by the UKIPO is Well Lead Medical LLC, which again is a different name from the Claimant. This was explained by Mr Cox in reply on the basis that there had been an error in the form filed at the UKIPO by the Claimant's representative, Dorr IP, when registering the assignment in that it referred to "LLC" and not "Co., Ltd". He said that the Claimant will apply to the UKIPO for the entry to be corrected.

38. Based on this evidence, I am satisfied that the Claimant is the proprietor of the Patent, even if the register is defective. In this regard I note that s.60 Patents Act 1977 does not require a proprietor to be registered, and indeed s.68 of the Act expressly contemplates that an unregistered proprietor can sue for infringement.

Quality of the Defendant's evidence

39. As noted above, the Claimant criticised various aspects of the Defendant's evidence as the foundation for a submission that the rest of the evidence should be treated with particular care, especially the evidence about the impact that granting or refusing an injunction may have on future sales and prices. Three specific aspects of the evidence were said to be contradictory, grossly misleading and/or manifestly untrue.

40. First, Mr George Reynolds gave evidence about the orders of the Seplou Sheath as at the date of his statement, 19 March 2024. It was conveniently summarised in tabular form as follows:

Customer	Date of order	No. of units of Seplou Sheath	Price per unit (£)	Total price (£)
UCLH	22 Jan 2024	25	160	3125
UHS Estates	7 Feb 2024	20	125	2500
Spire Healthcare	19 Feb 2024	20	145	2900
West Cumberland Hospital	20 Feb 2024	2	125	250

41. Mr Reynolds stated that the first units of the Seplou Sheath were despatched to customers on 8 March 2024, and that a total of 57 units had been despatched to satisfy the existing orders (although this is obviously a typographical error and should read 67

units instead). He also estimated that the Defendant may sell up to a further 150 units before the hearing date in April.

42. Counsel for the Claimant submitted that this evidence was contrary to the position that had previously been conveyed by the Defendant in its communications to the court in February 2024 when the parties had been debating an appropriate hearing date for this application. The Claimant wanted the hearing to be listed in the week of 10 April, but the Defendant wanted it to be listed in mid-May. In support of its position that a May hearing was appropriate, the Defendant had sent a bullet-point list of submissions to the court via email dated 23 February 2024, which list included the following:

> - The Defendant has not sold the Seplou Sheath and is not currently in a position to begin selling the product. The Framework Agreement to register the Defendant as a supplier to the NHS is only likely to be finalised some time in March. The earliest the Defendant will be able to begin supplying the Product in the UK will be April. The projected sales volume of the Product by the Defendant once active selling begins is small – ie 50 units per month. Accordingly, if the hearing is in mid-May, it is unlikely that there will be any substantial sales at all. Thus, there is unlikely to be any real prejudice at all if the hearing is not until mid-May.

43. The email was sent to the court by the Defendant's counsel's clerk but was signed by a representative at the Defendant's patent attorneys.

44. I was initially very concerned that the Defendant had misled the court in respect of the February email. At first blush, the email certainly gives the impression that the Defendant had not commenced dealings in the Seplou Sheath and would not do so before a substantive hearing. However, on a more careful read, one can see that the Defendant only states that it has not sold the product. It does not go so far as to say that it has not already started marketing it, offering it for sale or supply, and taking orders in readiness for when it can do so.

45. Moreover, as counsel for the Defendant pointed out, in the event the hearing was listed for 10 April 2024 which was the date that the Claimant wanted. So the Defendant's email was not operative in any meaningful way.

46. I do not accept that any apparent conflict between the Defendant's email and its evidence provides a foundation for treating that evidence with particular caution. I have considered all the evidence carefully and with an appropriate level of scrutiny (in accordance with the *Neurim* guidance), but I do not consider that the Defendant's evidence should be treated differently from the Claimant's or given any less weight.

47. Second, Mr George Reynolds gave evidence that the core of the Seplou Sheath comprises a reinforced coil structure to provide optimal flexibility, maximum resistance to kinking and compression, and visibility (for example by fluoroscopy or other x-ray techniques). He explained that it is important for the surgeon to be able to see the location of the sheath during use so that it is correctly positioned into the ureter of the patient and to avoid injury (such as perforation of the ureter or other organs). By

contrast, he said that the Claimant's Clear Petra Sheath is not visible by x-ray. I refer to paragraph 61 of his Witness Statement where he said:

> 61. I understand from my discussions with urologists and surgeons in the urology field that the Claimant's Clear Petra sheaths are not visible under x-ray illumination, as they are translucent to x-rays. As a result, the sheath is not visible on a kidney, ureter and bladder (KUB) x-ray image. This in turn means that the location of the sheath of the Clear Petra products, once inserted into the ureter of the patient, cannot be readily determined using standard procedures, such as fluoroscopy. In particular, a number of surgeons have reported that it is difficult, if not impossible using fluoroscopy to see the tip of the Clear Petra sheath, within the patient, leaving the surgeon unsure about the location of the distal end of the sheath. This leads to significantly higher risks to the patient when using the Claimant's products, compared with the Seplou Sheath. In particular, I have been advised that this has led to patients experiencing severe complications following use, including post-operative haematuria. These complications are avoided when using the Seplou Sheath supplied by C J Medical.

48. He went on to suggest that the Seplou Sheath provides a safer alternative to the ClearPetra Sheath, with the result that if the Defendant was injuncted, patients could be put at increased risk.

49. This evidence is consistent with the Defendant's pleaded case in its Defence and Counterclaim, which states as follows:

> **Seplou Sheath is substantially safer than Clear Petra/Flexi Clear Petra.**
>
> 16. In particular, it is averred that no injunction should be granted even if the Seplou Sheath is found to infringe the Patent (and the same is found valid) as the Seplou Sheath has substantial advantages to patients over the ClearPetra or Flexi ClearPetra. The Seplou Sheath has an inner metal coil inside it that allows surgeons to see (using xray or other diagnostic imaging methods) the position of the sheath, in particular the distal tip of the sheath, within the patient. Visualisation of the Seplou Sheath allows the surgeon to identify the precise location of the sheath and its distal tip thereby avoiding perforation of the ureter and damage to the kidney as the sheath is advanced into the renal pelvis and avoids post-operative haematuria. Seplou has a licence for the sheath design with the metal coil which is protected by EP1819389B1 and which is owned by Cook Medical Technologies LLC. The ClearPetra and Flexi ClearPetra sheath does not have these advantages. If the Seplou Sheath is found to infringe and the Patent is valid, the Defendant would be prepared to enter into a licence whereby a reasonable royalty is paid.

50. The Defence and Counterclaim was signed with a statement of truth by Mr Charles Reynolds, Managing Director of the Defendant. It is dated 2 April 2024.

51. That is the same date as the Claimant's reply evidence in the application. In that evidence, Mr Cox explained that Mr Reynolds' evidence is wrong, and that the ClearPetra Sheath also has an internal metal coil, as most UASs on the market do. Accordingly, he said, it has the same characteristics as the Seplou Sheath of

compression resistance and visibility. He rejected any suggestion that the Seplou Sheath has any advantage over the ClearPetra Sheath, which he said work and are used in identical ways. Mr Cox supported his evidence with exhibits of x-ray images, purportedly showing a ClearPetra Sheath with a metal coil.

52. This prompted a further statement from Mr Akers dated 5 April 2024. He called into question whether the x-ray images where a metal coil was visible were of a ClearPetra Sheath.

53. Thankfully I do not have to resolve that dispute, as the Defendant has subsequently been able to inspect a Flexi ClearPetra Sheath and satisfy itself that there is a metal coil inside the sheath. According to the correspondence between the parties, that happened on Saturday 6 April 2024. I was referred to an email from the Defendant's patent attorneys dated 7 April 2024 which stated:

> "As you will be aware, there has been an acute conflict of primary fact in this case as to whether the ClearPetra and/or the Flexi ClearPetra Sheath has a metal coil in it.
>
> Following service of your client's evidence in reply, efforts were made to inspect a ClearPetra sheath. On Saturday, a representative of the Defendant managed to inspect a sample of a Flexi ClearPetra product at an exhibition. A metal coil was seen inside the sheath. It is thus accepted that the Flexi ClearPetra Sheath does indeed include a metal coil.
>
> The Defendant will therefore not be pursuing a defence or put forward any argument founded on the basis that the ClearPetra or Flexi ClearPetra sheath does not have a metal coil and/or that the Seplou Sheath offers substantial medical advantages over the ClearPetra and/or Flexi ClearPetra sheaths by reason of the former having a metal coil and the latter sheaths not having one."

54. As a result, the Defendant's counsel clearly indicated in his written and oral submissions that the Defendant no longer pursues any suggestion that the ClearPetra Sheaths do not have a metal coil or that the Seplou Sheath is better for patients as a result.

55. Nevertheless, counsel for the Claimant submitted that the statements which had been made by the Defendant in its pleadings and evidence about the ClearPetra Sheath products were derogatory, misleading and/or untrue (knowingly or otherwise). He suggested that the 7 April email had been carefully worded to avoid revealing whether this was the first time the Defendant had inspected the Claimant's products, but that since the ClearPetra Sheath had been on the market for years, it was inherently unlikely that it was.

56. I do not accept the submission that there was anything untoward about the 7 April email. This is because Mr Akers makes clear in his Second Witness Statement at paragraph 5 that the Defendant had not been able to obtain a ClearPetra or Flexi Clear Petra (at least as at the date of the statement). I also do not accept the submission that the Defendant's pleadings and evidence on this issue were knowingly untrue. There is no evidence to support that submission. To the contrary, the evidence of Mr George

Reynolds which I set out at paragraph 47. above suggests that the Defendant had a legitimate basis for believing the statements that were made, albeit that they have turned out to be wrong. The fact that the Defendant told the Claimant of its mistake on 7 April, immediately after the mistake was identified on 6 April, reinforces the impression that it was a genuine error. The allegation that the statements were derogatory is relevant to the Claimant's case on unquantifiable damage and I return to it in that context below.

57. Third, Mr George Reynolds gave evidence that the net price of the Seplou Sheath to NHS hospitals was "fixed" at £125 for at least 15 months from the date of his evidence (19 March 2024) – that is, until the Framework Agreement expires in June 2025. However, Mr Cox in reply gave evidence that he had been informed by Mr McQuilkin of BioSpectrum (the Claimant's distributor) that prices are not fixed with NHS hospitals. The Defendant now accepts that it is possible to change the price (contrary to what Mr Reynolds seems to have said in evidence) but I was told by counsel for the Defendant on instructions that it can take weeks to implement such a change and that the Defendant would not do this now that it has given a price of £125 to the NHS for the next year.

58. Counsel for the Claimant submitted that this was another example of evidence which was "simply not true". He even went so far as to say that Mr George Reynolds knew that it was not true when he signed his Witness Statement. I am not able to accept that submission. There is no evidence to support it. Moreover, it seems more likely that when Mr Reynolds said that the NHS price was "fixed" at £125, he was not saying that it could never be changed, but rather that the Defendant had no intention of changing it.

59. Overall, I do not accept the submission that these three specific aspects of the Defendant's evidence taint the rest of it.

Trial Listing

60. Before I address the stages of *American Cyanamid*, it is convenient to say something about the trial listing, as it feeds into my analysis below. At the hearing, the parties indicated that they could be ready for trial by January 2025. Counsel for the Claimant floated the idea of a speedy trial but did not make a formal application for one. After the hearing I made enquiries of IPEC listings and ascertained that it would be possible to list the trial next January even without a speedy trial. I understand that the trial date has been or is in the process of being listed for January 2025.

Stage 1: Serious issue to be tried?

61. There was no dispute between the parties that there was a serious issue to be tried. In particular, it was accepted by the Defendant that the Claimant has an arguable case of infringement. The Defendant also submitted that it had a strong case of non-infringement and/or validity, but those will be substantive issues for trial in due course, along with infringement, and I say no more about them. This was not a case where either party suggested that I should take the merits of the case into account in considering whether or not to grant the injunction.

Stage 2: Are damages an adequate remedy for the Claimant?

62. The parties addressed this analysis by reference to Period 1 and Period 2 separately, and it is convenient for me to do the same.

63. As to Period 1, it was accepted by the Defendant that a sale of the Seplou Sheath would otherwise be a sale of the Flexi ClearPetra (at least in the current market). As a result, counsel for the Claimant accepted, rightly in my view, that damages for Period 1 would be an adequate remedy.

64. In the circumstances, Period 2 was the focus of the Claimant's submissions. It was argued that there were four ways in which the Claimant would (or would likely) suffer damage in this period which could not be adequately compensated by damages if an injunction was refused: (i) loss of market exclusivity; (ii) derogatory marketing statements; (iii) price depression; (iv) quantification of damages. I shall address the points in that order.

(i) Loss of Market Exclusivity

65. I did not understand the Claimant's case to be that losing market exclusivity *per se* was the reason for alleged unquantifiable damage. If that were so, then it would be raised by the patentee in every interim injunction application to restrain alleged patent infringement, but it is not. Indeed, I am not aware of an authority where it has been argued as a free-standing point, and counsel for the Claimant did not refer me to one. In most cases, the market exclusivity which the patentee enjoys results in a monopoly over price, and it is normally arguments about the potential impact that refusing an injunction will have on price (whether in the form of price depression or a price spiral) which feature heavily in the evidence on damage.

66. However, counsel for the Claimant submitted that there were two additional features unique to this case which relate to market exclusivity (beyond arguments about price depression which are addressed as a different (third) point, considered below) and which would result in unquantifiable damage to the Claimant if an injunction was refused.

67. First, the Claimant submitted that, by virtue of the market exclusivity which it currently enjoys, it has control over the way in which the ClearPetra Sheath (and the surgical technique to which it relates) is introduced into the market and the way in which surgeons and other medical professionals are educated in relation to it.

68. There was some evidence from the Claimant about its efforts to educate the market through marketing and promotional activities, summarised as follows:

    i) Ms Shi has been involved in promoting the ClearPetra Sheath since it obtained CE certification in 2015.

    ii) The ClearPetra Sheath was launched during the European Association of Urology Congress, Munich, 12-15 March 2018 by means of a promotional flyer included in every congress attendee's bag (at a cost of €8225). It attracted significant attention and interest from urologists.

iii) Since then, Ms Shi has exhibited the ClearPetra Sheath at over 20 conferences/congresses worldwide. She provided a tabular summary of these in her witness statement. Two of them were in the UK: the European Association of Urology in 2017, and the International Alliances of Urolithiasis Conference in 2023.

iv) In addition, Ms Shi has worked to promote the ClearPetra Sheath in the UK with the Claimant's local distributor at the British Association of Urological Surgeons Meeting in 2016 and with Professor Wan visiting 7 UK hospitals.

v) Other promotional activities within the UK include direct interaction with hospital staff, as well as at trade fairs, urologist meetings, local audit training days and product evaluations, and via social media. No details of these promotional activities were provided in evidence.

69. There was also some evidence that the market for suction UASs was evolving. Mr Cox provided UK sales figures for the period from July 2023 to February 2024 (1,110 ClearPetra units, of which 815 or 73% were Flexi sheaths), and said that sales had increased since the launch of the Flexi ClearPetra Sheath. He also said that the Claimant and its distributor were continuing their efforts to establish the Flexi ClearPetra "as the gold standard" for suction UASs and that the exclusivity in educating the market as to its benefits was crucial in that regard. He did not provide any further details as to what steps were being taken to educate the market.

70. It is difficult for me to assess the extent to which the Claimant's sales have increased since the launch of the Flexi ClearPetra Sheath since I have not been provided with earlier sales figures. Nevertheless, it is entirely plausible that the market has grown since the Flexi sheath was launched and I accept that evidence in general terms.

71. However, there is no evidence that the Claimant's marketing efforts are causing the market to grow or why, assuming they are, those efforts will be in any way undermined by virtue of the Defendant also being on the market. There was no evidence that the Defendant's activities in respect of the Seplou Sheath (threatened or actual) will interfere with the Claimant's ability to market and promote the ClearPetra (original and flexi) or to educate the medical community as they see fit.

72. In my judgment, even allowing for the fact that the suction UAS market may be a growing one, there is no evidence to support an argument that loss of market exclusivity to the Claimant if an injunction is refused will damage its ability to educate the market at all, let alone in a way which is unquantifiable.

73. Second, the Claimant submitted that, by virtue of the market exclusivity which it currently enjoys, third parties are currently deterred from entering the market, but that deterrent will dissipate if an injunction is refused.

74. The evidence about possible third-party entrants can be summarised as follows:

i) A third party called MedTech UK had threatened to distribute the Seplou Sheath in the UK. The Claimant sent it a cease and desist letter on 23 September 2023. That prompted assurances from MedTech UK that it has not sold the Seplou

Sheath in the UK and has no intention of doing so in the foreseeable future. Based on those assurances, no further action has been taken against it.

ii) On 6 February 2024, the Claimant became aware that Aqua Medical Ltd were offering the Seplou Sheath for sale in the UK. The Claimant (via its solicitor) sent a cease and desist letter to Aqua Medical on 14 February 2024. Aqua Medical emailed a response the following day, in which it said that since it merely acted as a distributor for Seplou, the Claimant should take up its grievances with them instead. It also said that it would not communicate on this matter further. However, I am told by Mr Davis KC on instructions that since then, the Claimant's solicitor has had a phone conversation with a representative at Aqua Medical in which Aqua Medical confirmed that it was coming off the market. As a result, no further action has been taken against it either.

iii) A third party called Innovex Medical Co. Ltd has produced a negative pressure suction UAS which the Claimant alleges is a version of the ClearPetra Sheath. Ms Shi says that Innovex will likely exhibit its UAS at MEDICA 2024. MEDICA is one of the largest trade fairs, held annually in Germany. The Claimant has instructed a German firm, Wildanger Kehrwald Graf von Schwerin & Partner mbB to file an injunction application against Innovex in Germany. On 16 February 2024, Innovex filed a nullity action of the German designation of the Patent. It has recently come to the Claimant's attention that a medical devices distributor called Ingles Medical Ltd is offering the Innovex UAS for sale in the UK via its website www.inglesmedical.com. However, there is no evidence that this product has made it onto the NHS Supply Framework. I was told by Mr Davis KC on instructions that the Claimant had checked the NHS Supply Chain, and it was not listed. He also pointed out that this is consistent with the Defendant's evidence to the effect that the Seplou Sheath is the only other suction UAS on the market in the UK.

iv) Ms Shi gave evidence that there are over 60 imitation suction UASs in China alone, and that, in her view, it is very likely that a number of these products will enter the UK market. However, she does not identify which products are likely to come onto the UK market, or when. Nor does she explain how long they have been on the market in China, or why she thinks that they might come onto the UK market in the future when they have not done so already. It is impossible for me to place any weight on this evidence, which is only expressed in general terms and is unsupported by any details or documentation.

75. So, the upshot of this evidence is that, as things stand, Ingles Medical is the only third party who appears to be threatening to sell and supply a suction UAS in the UK (albeit that it cannot yet sell or supply to NHS hospitals as it is not on the NHS Framework). I was told by Mr Davis KC on instructions that the Claimant was in the process of obtaining a sample of the Innovex UAS. At the time of the hearing, it had not yet engaged in correspondence with Ingles Medical but intends to do so, depending on the outcome of the inspection of the Innovex UAS once one has been obtained.

76. The Claimant submitted that it was inevitable that, if the injunction was refused, third parties will be encouraged to enter the market before judgment at trial. Since there is no specific evidence about any third parties being likely to enter the UK market beyond Ingles Medical, I reject this submission at the general level at which it is made. There is

simply no way of knowing one way or the other from the evidence before me whether third parties generally will try to enter the UK market or when. The evidence fell a long way short of establishing that it was likely or inevitable.

77. As for Ingles Medical specifically, I accept that it is likely that it could enter the market in the foreseeable future with the Innovex UAS product. However, there is no evidence that it is waiting to see the outcome of this application before it decides what to do. It seems more likely that it is waiting for the Innovex UAS to get on to the NHS Framework. Similarly, there is no evidence that an interim injunction against the Defendant would serve as a deterrent against Ingles Medical; it might, but it might not. That would depend on a range of factors, including its appetite for risk. In my judgment, the potential deterrent effect that an injunction against the Defendant would have in respect of Ingles Medical is not a sufficient basis for granting it on the facts of this case. The Claimant has other mechanisms available to it to try to prevent Ingles Medical from getting on to the market if that is what it wants to do, and the court would have to consider any application against Ingles Medical on its merits.

78. The Claimant also submitted in its skeleton that, assuming it prevails at trial, third party entrants "will not be directly prevented from continuing activities and so the Claimant's present market exclusivity will be irredeemably undermined". It was said that this was just the kind of non-compensatable damage contemplated at paragraph [10] of the Mellor J *Neurim* judgment referred to above. I confess that I did not understand this submission. Whether third parties will be prevented from continuing activities or not will depend on what those activities are, whether they infringe any valid right of the Claimant and what steps the Claimant takes to prevent infringement. In my judgment, the hypothetical risk of third-party entrants *per se* cannot be enough to justify injunctive relief, certainly not on the facts of this case.

(ii) Defendant's alleged derogatory statements

79. The Claimant submitted that the Defendant has made derogatory statements about the ClearPetra Sheath to the market. These are said to concern the allegation (now accepted to be wrong) that the ClearPetra Sheath does not have an internal coil and is not as safe as the Seplou Sheath. The Claimant argued that the effect of the injunction will be to keep the Defendant off the market, with the result that the Defendant will have no real motive to make such statements in the future. Note that the Claimant does not pursue a claim for trade libel or malicious falsehood and accepts that it would be difficult to get an interim injunction for such a claim in any event.

80. In my judgment, this argument is fundamentally flawed for three reasons.

i) First, the argument is not supported by any evidence that the Defendant has made derogatory statements to the market about the ClearPetra Sheath in the past. I set out the relevant evidence from Mr George Reynolds at paragraph 47. above. In that evidence, he reports what the Defendant has been told from others, not what it has been saying to the market. When I put this to Counsel for the Claimant, he submitted that if the Defendant is willing to make "derogatory" statements in its evidence to the court, I could infer that it is what it is also telling the marketplace. However, there is no evidence to support that inference and I reject the submission.

ii) Second, the argument is not supported by any evidence that the Defendant will make derogatory statements in the future. I cannot see why it would be in the Defendant's interest to do so, since it could undermine the value of the market overall. Moreover, the Defendant now accepts that the ClearPetra Sheath comprises a coil and has abandoned its case that it is not as safe as the Seplou Sheath.

iii) Third, even if the Defendant had made or was threatening to make derogatory marketing statements about the ClearPetra Sheath (contrary to my assessment of the evidence), I do not think that this would justify the grant of an injunction to restrain its sale or supply of the Seplou Sheath. There is not a sufficient nexus between these activities. Moreover, the injunction which the Claimant seeks would not stop the Defendant making derogatory statements in any event.

(iii) Price Depression

81. The Claimant argued that if an injunction was refused, there would likely be a substantial and irreversible price depression for the Claimant's ClearPetra products. The argument was predicated on the assumptions that if there is no injunction, it is inevitable that (i) third parties will enter the market; and (ii) there will be a resulting price war.

82. I have already addressed the evidence on third parties above. That evidence does not support an assumption that multiple third parties are bound to enter the UK market.

83. As to the argument that there will be a resulting price war, that was said to be supported by the following:

i) Ms Shi stated in her evidence that since the Seplou Sheath was identical to the ClearPetra, the only basis for the Defendant to compete was on price. Mr Charles Reynolds gave evidence that the Defendant made a gross profit of approximately £60 per unit of the Seplou Sheath. The Claimant submitted that this was a high profit margin and there was clearly room to reduce the sale price whilst still making a profit.

ii) Mr Cox gave evidence that a different (but related) product had recently undergone a significant price reduction because of market competition. The product in question is called a flexible ureteroscope. This is the scope which is passed through the UAS to view and break up the kidney stones. Mr Cox explained that, according to Mr McQuilkin of BioSpectrum, the price of flexible ureteroscopes has fallen over the last 18 months or so from £900 per unit to £350 per unit as more parties have entered the market. He says that there is no reason why the same would not happen to the price of suction UASs if multiple parties were to enter the market.

84. Against that, Mr George Reynolds gave evidence that the Defendant has fixed the NHS price of the Seplou Sheath at £125 to match the price of the Flexi ClearPetra Sheath. It had entered the market in November 2023 at a unit price of £160, but Mr Reynolds explained that this was later revised down in line with the market price for UASs as set by the Claimant. He said that the Defendant's practice regarding pricing is to follow the market price established by the Claimant and its distributor. As noted above, the

Claimant's price for the Flexi ClearPetra Sheath is £125 and it intends to reduce the price of the ClearPetra Sheath so that it is similar or the same.

85. Mr Reynolds also explained that the price of products supplied to private hospitals was on a case-by-case basis, but that in general the price paid by private hospitals for the Seplou Sheath matches the NHS price. He illustrated this with one example of a private hospital who had made an inquiry for the Seplou Sheath in November 2023 at an initial price of £160. The products were shipped on 8 March 2024 at a reduced price of £125. Only about 5% of the Defendant's sales are to private hospitals.

86. The overall thrust of Mr Reynold's evidence was that if the Claimant did not reduce its price, the Defendant would not do so either. As a result, he said that there was no risk of price depression. This was backed up by an offer of an undertaking that the Defendant would not drop its price for the Seplou Sheath below £125 provided that the Claimant did not drop its price for the ClearPetra and Flexi ClearPetra Sheaths below £125. The Claimant pointed out that an undertaking in this form was potentially anti-competitive and unlawful, with the result that the Defendant's counsel modified the offer at the hearing to one whereby the Defendant undertakes not to drop its price below that of the Claimant (without fixing it at any particular price).

87. Stepping back and assessing this evidence in the round, I do not think that there is sufficient evidence for me to conclude that a price war is likely, let alone inevitable. I accept that there has been a reduction in the price of the flexible ureteroscope, but it is difficult to assess the relevance of that example to this case without knowing more information about the nature of that market and the circumstances in which parties started selling that product. For example, I do not even know whether patent protection was in issue. As a result, the example simply illustrates that multiple players in a market can lead to price competition and price reduction.

88. I also accept that the Defendant has already reduced the price of the Seplou Sheath twice (see the table at paragraph 40. above), so in theory could do so again. However, I have no reason to go behind the evidence of Mr Reynolds to the effect that the Defendant has no intention of reducing its price below that of the Claimant. That evidence is borne out by the Defendant's conduct to date. If the Defendant intended to undercut the Claimant, then surely it would have done so from the outset to gain the maximum foothold on the market as quickly as possible. However, that has not been the case at all. Moreover, it is not in the Defendant's interest to cause a price war, particularly when it is the only other supplier of suction UASs on the UK market.

89. As to whether there will be a price reduction caused by third party entrants, there was no evidence to support this beyond assertion by Ms Shi that this would likely be the case. It is difficult to place much weight on that evidence in circumstances where Ingles Medical is the only third party that has been identified as a potential entrant with the Innovex UAS but there is no evidence as to the price it would charge if it started selling. Moreover, it may choose not to sell at all, depending on the outcome of the correspondence with the Claimant. I simply do not know what Ingles Medical will do and the evidence does not allow me to make a reasonable prediction either way.

90. In the circumstances, I reject the Claimant's submission that a price war is likely or inevitable on the facts of this case. For the reasons I have given, this is not a case of

imminent market entry by multiple third parties, and the evidence indicates that the Defendant will maintain the current market price.

(iv) Quantification of damage

91. The Claimant argued that damages in Period 2 could not be quantified adequately because it will be extremely difficult for the Claimant to restore prices to their original levels after trial if an injunction is wrongly refused. This argument is predicated on the assumption that there will be a price reduction, and I address it on that basis even though I do not agree with it.

92. Ms Shi gave evidence that, in her view, the Claimant would not be able to restore its current prices if the Defendant were taken off the market after trial. She said:

> 45. The Claimant is also concerned that, if the Defendant is able to remain on the market and drops its prices to undercut ClearPetra, then it will have to drop its prices too. The lower prices will then become established over the time it will take for this action to reach trial and a final order (which I understand from Mr Cox to be in the order of 15 months away, possibly longer). I consider that it will be very difficult, probably impossible, for Well Lead (and BioSpectrum) to get NHS procurement to accept ClearPetra prices going up again after that length of time if the Defendant is held to be infringing the Patent and so has to stop selling the Seplou products (and so restoring the Claimant's market exclusivity for suction sheaths).

93. Mr Cox said something to similar effect in his reply statement, albeit that it was based on information that he had obtained from Mr McQuilkin. According to Mr Cox, Mr McQuilkin's view is that once the NHS has become used to lower prices for suction UASs, it will be challenging to increase them again just because competing products have been removed from the market. It can also take time for price changes to take effect (anywhere between 3 and 6 months) because of administrative delay or "lag".

94. Against that, Mr George Reynolds said that, in his view, the Claimant would be able to raise the price after trial even if (contrary to his evidence) there was a price depression before trial and it transpired that an injunction was wrongly refused. This is because the NHS is an experienced and knowledgeable buyer who understands the impact that an infringing product can have on price. Furthermore, it also appreciates the importance of quality products and does not select products solely on price.

95. I prefer the evidence of Mr Reynolds on this issue. I agree that the NHS is a sophisticated purchaser who understands the impact that patents can have on pricing (up or down). I was also not persuaded that it would necessarily be difficult for the Claimant to raise its prices back to original levels if there was a price reduction. In this context, I note that the Claimant's evidence assumed that the trial would not take place until at least May 2025, if not later. As I have said, it is now agreed that it will take place in January 2025. As a result, even if there is some price depression between now and trial, it will only be for a relatively short period of time (at most about 6 months). In my view, that is not sufficient time for the market to become entrenched in relation to price, particularly if, as Ms Shi says, there has only recently been widespread acceptance of suction UASs.

96. In any event, as noted in the Background section above Ms Shi also gave clear evidence about the Claimant's sales forecasts, at least until February 2026. I set out that evidence here in full:

> 40. The original ClearPetra Sheath was launched in 2016. The new Flexi ClearPetra Sheath was launched in March 2023. The Flexi ClearPetra Sheath is priced at £125 per unit in the UK whereas the original ClearPetra Sheath is priced at £165 per unit. The Flexi ClearPetra Sheath was priced lower than the original so as to be more competitive with existing conventional (i.e. non-suction) UASs. It is not intended that the price of the Flexi ClearPetra Sheath will change over the next 24 months but Well Lead is planning to drop the price of the original ClearPetra Sheath to a level similar to the Flexi so that the product has better access to trials and NHS procurement. It is presently estimated that 6,000 – 9,000 units of ClearPetra Sheaths will be sold over the next 24 months. I consider that most of these sales with be of the Flexi ClearPetra Sheath.

97. Mr Cox confirmed the accuracy of these predictions in his reply evidence, stating as follows:

> 58. … The Claimant's estimate of 6,000 to 9,000 sales is therefore realistic, provided that it retains exclusivity under the Patent, and Ms Shi has told me that the Claimant is confident in its accuracy on this basis. In fact, it considers that, with the combination of exclusivity (i.e. because it is granted the interim injunction sought by this Application), pricing at £125 and the growing interest in the Flexi ClearPetra Sheath, it should be able to increase its share of the UAS market to about 50%.

98. For completeness, I should note that Ms Shi also said that it was more difficult to predict how the market will develop beyond February 2026.

99. In my judgment, this evidence is particularly important. It means that the task of calculating damage in Period 2 if an injunction is wrongly refused will be *relatively* straightforward. I emphasise the word relatively because I accept, as the Claimant submitted, that a damages inquiry is an inherently difficult exercise because of the need to make predictions about what would have happened in the counterfactual. However, I bear in mind the guidance from the Court of Appeal in *Neurim* as set out above that damages should be adequate, not perfect. Now that the trial is listed (or will be listed) for January 2025, if the Claimant prevails it will be able to restore market exclusivity long before February 2026. As a result, by the time of any damages inquiry, the court will know the sales and price of the ClearPetra Sheaths which the Claimant has attained after trial and once its monopoly is restored, and will be able to compare that with the Claimant's forecasts. Any shortfall can be adequately calculated and compensated in damages.

100. In the circumstances, I find that damages are an adequate remedy for the Claimant on all the facts and circumstances of this case. As a result, the Claimant's application for injunctive relief fails at Stage 2.

Stage 3: If not, are damages an adequate remedy for the Defendant?

101. In light of the decision I have reached in respect of Stage 2 above, this issue does not strictly arise. However, in deference to the parties and in case this goes further, I shall set out my assessment of the evidence and the conclusions I would have drawn based on it.

102. Mr George Reynolds gave evidence that the Defendant would likely achieve approximately 5% penetration of the market and sell up to about 420 units of the Seplou Sheath in the next 12 months (assuming all UAS use is a suction sheath rather than a conventional one). This represents a possible revenue to the Defendant of up to about £52,500 for the period to April 2024. Thereafter, he predicted that the Defendant's market share would grow by a further 5% in the following 12 months, leading to total possible sales of approximately 900 units to April 2026. The counsel for the Claimant submitted, and I accept, that these forecasts provide sufficient basis for the court to quantify the damage the Defendant would suffer if an injunction was wrongly granted in respect of Period 1.

103. However, counsel for the Defendant submitted that damages would not be an adequate remedy for Period 2. He argued that this was because it would be very difficult to predict what market share the Defendant would have obtained in the counterfactual if it is wrongly injuncted in the actual. It was said that this difficulty would be exacerbated by the fact that the Claimant would have secured a stronger position in market in the interim by virtue of its extended monopoly, which would reduce the Defendant's ability to achieve sales once the injunction is lifted. As a result, the sales that the Defendant achieves in the actual once the injunction is lifted after trial could not be a relevant proxy for the sales it would have achieved in the counterfactual. The damages calculation would be further complicated if third parties enter the market after trial and the Defendant loses any first mover advantage over them.

104. Counsel for the Claimant accepted that it is "slightly more difficult" to quantify the damage to the Defendant in Period 2 if the injunction is wrongly granted than it will be to quantify the damage to the Claimant if the injunction is wrongly refused. However, he submitted that the assessment can still be performed adequately, using the Defendant's forecasts as a yardstick.

105. I agree that damages to the Defendant in respect of Period 2 would be more difficult to calculate than the damages to the Claimant. I have considered carefully whether the potential impact of third-party entrants after trial and the loss of the first mover advantage would make damages too uncertain to be adequate on the facts of this case. After some deliberation, I formed the view that it would not, for two reasons. First, the forecasts which Mr Reynolds gives of the Defendant's sales until April 2026 provide sufficient foundation for the court to make an adequate assessment of the likely sales that the Defendant would have made in the counterfactual. Just as with the Claimant under Stage 2, this makes the damages calculation relatively straightforward, albeit that it may not be perfect. In my judgment, it would not be fair or appropriate to treat the impact of parties' forecasts on the ability to calculate damages differently. Second, I was struck by the fact that the Defendant's arguments about losing the first mover advantage were not supported by any evidence. Counsel for the Defendant submitted that I could take judicial notice of the concept of the first mover advantage and that it was a "sure-footed submission" that losing it will cause damage. However, in my

judgment whether there is a first mover advantage, and the consequence of losing it, will be a question of fact for each case. If it had been a real concern for the Defendant, it would (and should) have been addressed in evidence.

106. The Defendant also argued that it would suffer damage in three other ways if an injunction was wrongly granted, and which also could not be adequately compensated in damages. These were:

i) Lost sales of convoyed goods.

ii) Reputational damage.

iii) Difficulty in enforcing in China any damages award under the cross-undertaking.

I address them briefly in turn.

(i) Lost sales of convoyed goods

107. The Defendant argued that an injunction would cause it to lose out on the sale of ureteroscopes, as convoyed goods. As explained above, a ureteroscope is inserted into a UAS and used to view and break up the kidney stone. Mr George Reynolds gave evidence that if the Defendant was injuncted, there was a risk that the Claimant (via its distributor) would start to "bundle" its ClearPetra UAS with the ureteroscope that it sells (called Urofino) but the Defendant would be denied the opportunity to do the same thing with the ureteroscope that it sells (called Pusen). He also said that bundling would enable the Claimant (via its distributor) to undercut the equivalent combined price of a ClearPetra Sheath and the Pusen ureteroscope, with the result that the Defendant would lose sales of the Pusen. He estimated that lost sales would be in the region of 4800 Pusen units a year, and that it would be difficult to restore market share if it transpired that the injunction had been wrongly granted.

108. The Claimant criticised this argument for the following reasons. First, there is no evidence that the market is currently based on bundling, even though ureteroscopes and UASs have been on the market for some time. To the contrary, the evidence from Mr Cox was that, based on Mr McQuilkin's experience, NHS hospitals buy medial products separately as they work through their purchasing lists. Moreover, neither party has sold their UASs to date as part of a bundle with other products. Second, the figures presented by Mr Reynolds simply do not stack up. This is because, on its own figures, the Defendant is only likely to sell approximately 420 Seplou Sheaths in the next 12 months. So even assuming that every sale of a Seplou Sheath also resulted in the sale of a Pusen, if the Defendant was injuncted it would only lose out on sales of approximately 420 ureteroscopes and not the thousands being alleged.

109. In my judgment, these criticisms are well founded. I would have rejected the Defendant's argument that it is at risk of unquantifiable damage from lost sales of convoyed goods.

(ii) Reputational Damage

110. The Defendant argued that an injunction would cause it reputational damage which is difficult to repair and unquantifiable in damages. This was based on the evidence of

Mr Charles Reynolds, who said that if an injunction was wrongly granted, it would tarnish the Defendant's reputation for providing products which are safe and of high quality. He also thought that the market would not understand the nuances of interim relief and would assume that the Seplou Sheath is an infringing product, particularly as it is already on the market. As a result, the product would be tainted too.

111. Against this, Mr Cox gave evidence, based on Mr McQuilkin's experience, that surgeons do not form an adverse view of companies who are required to withdraw products for patent reasons. The NHS procurement bodies also understand patent litigation. He also said that the Defendant would not suffer any damage to its reputation since it is only the distributor of the product and can make that clear to the NHS Supply Chain and private hospitals alike.

112. If it had been necessary to decide this point, I would have preferred the evidence of the Claimant and rejected the suggestion that an injunction would cause the Defendant reputational damage. As I have already said above, the NHS is a sophisticated purchaser. It is likely to understand the nuances of interim relief, including that it does not involve a finding of infringement. An injunction would not taint the reputation of the Defendant or the Seplou Sheath so as to lead to unquantifiable damage.

(iii) Difficulty in enforcing a judgment in China for damages under the cross-undertaking

113. The Defendant argued that it is difficult to enforce a High Court Order in China, and that it could take up to a year.

114. I was not impressed with this argument at all. There was no evidence to suggest that the Claimant would not meet its obligations if the court held that it was liable to pay damages under a cross-undertaking for an injunction which should not have been granted. As a result, there is no reason to consider the ease with which a damages judgment could be enforced in China. In any event, even if enforcement proceedings were necessary, the damage would be quantifiable (being the judgment debt, on this hypothesis as yet unpaid). I would have rejected this as an additional head of unquantifiable damage.

115. In conclusion, I would have found that damages would be an adequate remedy to the Defendant under Stage 3 if the analysis had got that far.

Stage 4: If damages are not an adequate remedy for either side, where does the balance of convenience lie?

116. If I am wrong that damages are an adequate remedy to the Claimant and the Defendant, then damages would have been equally unquantifiable for both sides. In that situation, the balance of convenience would have come into play.

117. Both parties concentrated their submissions on this issue by reference to the status quo. It was common ground that the status quo should be assessed as of 16 February 2024, the date of the application for interim relief (and the day after the Claim Form had been issued).

118. The evidence from the Defendant about its activities in relation to the Seplou Sheath can be summarised as follows (in chronological order):

i) In July 2023, the Defendant made its first enquiries about becoming a distributor for the Seplou range of products.

ii) On 23 October 2023, the Defendant secured registration at the MHRA for a range of products supplied to it by Seplou, including the Seplou Sheath.

iii) On 14 November 2023, the Defendant received samples of the Seplou Sheath.

iv) On 17 November 2023, the Defendant attended the annual meeting of the Eastern Urology Group where it presented the Seplou Sheath.

v) On 28 November 2023, the Defendant applied to add the Seplou Sheath to its list of endourological products available for supply to the NHS via the NHS Framework.

vi) On 29 November 2023, the Defendant responded to an enquiry from a hospital in the UK to supply the Seplou Sheath and provided a quotation. The original quotation was at a unit price of £160, but this was reduced to £125 by the time the order was received and the product despatched, in line with the NHS pricing.

vii) On 9 February 2024, the Defendant attended a meeting of the Royal Society of Medicine in London where it had discussion with surgeons about the Seplou Sheath.

viii) As of 20 February 2024, the Defendant had received four orders from 3 NHS hospitals and one private hospital as summarised in the table at paragraph 40. above. Two of these orders for 45 Seplou Sheaths were before 16 February, being the relevant date for assessing the status quo in this case. The Defendant inherited the UCLH order from a previous distributor of the Seplou Sheath after that distributor received a cease and desist letter from the Claimant. The higher price for that order had been set by the previous distributor.

ix) On 22 February 2024, the Seplou Sheath went live on the NHS Supply Chain website. The Defendant could only supply Seplou Sheaths to NHS hospitals once this approval had been granted.

x) However, the NHS Supply Chain team listed the Seplou Sheath at the wrong price (with £125 being listed as the price per box of 10 sheaths, rather than the unit price per sheath). The Defendant is liaising with the NHS Supply Chain management to have this error corrected, but it has caused delay in the Defendant's ability to despatch products to meet customer orders.

xi) On or between 8-12 March 2024, the Defendant despatched the first units of the Seplou Sheath to customers (Mr George Reynolds and Mr Charles Reynolds give different dates, but nothing turns on this as they are both after 16 February).

xii) On 12 March 2024, the Defendant started actively marketing the Seplou Sheath product.

xiii) An order for a further batch of Seplou Sheaths has been placed with the manufacturer in China and these are expected to arrive in the UK by the end of March.

119. The Claimant argued that the Defendant was not yet on the market and maintenance of the status quo weighed in favour of granting an injunction. In support of that argument, it relied on the following:

i) the evidence from Mr George Reynolds that the Defendant did not start "actively marketing" the Seplou Sheath until mid-March;

ii) the fact that, by 16 February 2024, the Defendant had only received two orders for what it described as "small numbers";

iii) the fact that the Defendant had only presented or discussed the Seplou Sheath at two meetings;

iv) the fact that the Seplou Sheath does not appear on the Defendant's website. I was not shown a copy of the website so I do not know what it looks like or if or how other products are marketed on it;

v) the fact that there was no evidence of any outstanding orders.

120. I do not think that this represents a fair characterisation of the evidence. The evidence shows that the Defendant had started dealing in the Seplou Sheath in the UK in November 2023. The Claimant was aware of that at the time. The Defendant immediately started promoting the product at clinical meetings and offering the product for sale. By 16 February 2024 it had accepted orders for sale and supply from two hospitals. Those orders were for 45 units. This amounts to a reasonable proportion of the predicted sales that the Defendant expects to make over the next 12 months (approximately 10%); it is certainly not *de minimis* in that context. In my view, the Defendant was clearly on the market by the relevant date. I would have rejected the Claimant's submission to the contrary.

121. Counsel for the Defendant submitted that the injunction which the Claimant sought would enjoin the Defendant from conduct it had already commenced. He argued that, as a result, if the injunction was granted it would not preserve the status quo.

122. I would have accepted that submission. If it had been necessary for me to reach a view in respect of Stage 4, I would have held that the Defendant had already commenced sufficient trading at the relevant date to mean that the status quo weighed in favour of refusing the injunction. Moreover, the balance of the risk of injustice would, in my view, have come down in favour of the Defendant because, as indicated above, calculating damages to the Defendant in Period 2 would have been more difficult than calculating damages to the Claimant.

Conclusion

123. Accordingly, I refuse to grant the Claimant the interim relief that it seeks on this application.