Neutral Citation Number: [2021] EWHC 2415 (Pat)

Case No: HP-2021-000028

IN THE HIGH COURT OF JUSTICE
CHANCERY DIVISION
PATENTS COURT
SHORTER TRIALS SCHEME

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 31/08/2021

Before :

THE HON MR JUSTICE MELLOR

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Between :

(1) ADVANCED BIONICS AG (a company incorporated under the laws of Switzerland) (2) ADVANCED BIONICS UK LIMITED	**Claimants**
- and -	
MED-EL ELEKTROMEDIZINISCHE GERATE GmbH (a company incorporated under the laws of Austria)	**Defendant**

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Andrew Lykiardopoulos QC and **Thomas Lunt** (instructed by **Kirkland & Ellis International LLP**) for the **Claimants**
Michael Silverleaf QC (instructed by **Osborne Clarke LLP**) for the **Defendant**

Hearing date: 19th August 2021

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Approved Judgment

I direct that pursuant to CPR PD 39A para 6.1 no official shorthand note shall be taken of this Judgment and that copies of this version as handed down may be treated as authentic.

COVID-19: This judgment was handed down remotely by circulation to the parties' representatives by email. It will also be released for publication on BAILII and other websites. The date and time for hand-down is deemed to be 10.30am on Tuesday 31st August 2021.

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THE HON MR JUSTICE MELLOR

Mr Justice Mellor:

Introduction

1. The Claimants ('AB') apply for expedition of the trial of this action against the Defendant ('Med-El'). AB seek to invalidate Med-El's EP (UK) 3,138,605 B (the Patent or 605) and/or to establish that their 3D device does not infringe. Not surprisingly, Med-El has indicated it will bring a counterclaim for infringement. Once again, the circumstances which give rise to this application stem from the ability of a patentee to obtain a swift decision from a German court on infringement and before any court has examined the validity of the patent. As I indicated in a recent judgment (*Abbott Laboratories Limited v Dexcom Inc* [2021] EWHC 2246 (Pat) at [28] and [30]) the position which the so-called 'injunction gap' creates in Germany is a matter for the German courts. The task for an English Court on an application of this type is to examine the effects that an early injunction in Germany may have on the UK market to the disadvantage of a party who believes the EP is invalid and/or not infringed, and to decide whether those effects justify expedition of a trial in this country.

2. There may be many cases where the effect of a German injunction on the UK market is slight or even non-existent. Equally, a case may reveal a real risk that a party in the position of AB will suffer real damage in the UK market caused by knowledge that a German court has granted an injunction over their flagship product and the fact that it may be difficult if not impossible to overcome concerns in the UK market as to whether it is safe or prudent to take that party's product for fear that an injunction in the UK may well follow, even if in time that party secures a finding from the English court that the EP(UK) is invalid (and/or not infringed). If such damage is suffered, there is no redress against the patentee, it is truly irreparable damage.

3. This application was issued on 14.07.21, followed by service of the first witness statements of Ms Coltart (from AB's solicitors) and Ms Carr-Brendel (Global President of AB), comprising some 24 pages of statements, in support on 16.07.21. The application was initially listed in the interim applications court on 27.07.21 (as it happened, before me). Med-El could not be ready in time, so the parties agreed to stand the application over to be heard by me in the Vacation. Med-El served extensive evidence on 16.08.21 (some 42 pages of statements, unnecessarily lengthened by the inclusion of various submissions), from Mr James (from Med-El's solicitors) and from Mr Konegger (Med-El's Head of IP). This was only three days before this hearing, so AB had to prepare its evidence in reply in a hurry and served short second witness statements from Ms Coltart and Ms Carr-Brendel in reply on 18.08.21. The 'evidence' did not end there, because Mr Silverleaf QC for Med-El sought to interest me in a series of points he relayed on instructions. The written evidence was already overly detailed and it is not necessary for me to relate Mr Silverleaf's additional points or to take them into account.

4. More generally, I was assisted by Skeleton Arguments from each side and 2 ½ hours of oral submissions. In the expectation that the following day in the vacation interim applications court would be somewhat quieter, I proposed to give judgment at noon on Friday 20 August, but that did not prove possible due to the arrival of more urgent applications. Having reached a firm view, I announced the result with reasons to follow. The result was that I directed the trial of this action to be listed before an assigned Judge or suitably qualified deputy in February 2022 if at all possible, with an

estimate of 4 days in the Shorter Trials Scheme, category 3. The reasons are contained in this judgment.

Applicable principles

5. The applicable principles were not in dispute:

   i) So far as expedition generally is concerned, I find the relevant principles in *Gore v Geox* [2008] EWCA 622 at [25] and in *James Petter v EMC Europe* [2015] EWCA Civ 480 at [10]-[14], [16]-[17] & [22]. It is not necessary to set out those passages. I reminded myself of them in *Abbott v Dexcom* at [6]-[7].

   ii) Expedition of a patent claim has generated a few additional important points which were usefully gathered together by Birss J. (as he then was) in *Nicoventures Trading Ltd v Philip Morris & or* [2020] EWHC 1594 (Pat). In *Abbott* at [8]-[9], I drew attention to three particular points made by Birss J. which are equally applicable here. Due to a particular point taken by Med-El in this case, counsel for AB drew my attention to a further point made by the Judge in *Nicoventures.* This is best explained in context, below.

6. I also found useful the way in which Meade J. characterised the interplay between the various *Gore* factors in *Teva v Janssen* [2021] EWHC 1922 (Pat) at [6]:

> All of these matters are to be assessed on a sliding scale. There could be a good reason for expedition or a really, really good reason for expedition. There can be a requirement for a modest degree of expedition or there can be a requirement for a lot of expedition. None of these things, therefore, is a binary consideration.

7. Leaving aside the legal principles, much of the explanation of how the German courts operate when dealing with patent cases which I related in *Abbott* was also covered in the evidence before me in this case. To avoid repeating all this material, I take into account the matters related in *Abbott* at [20], [22], [23, third sentence], [24, second and third sentences] and [28].

The Patent

8. The Patent is entitled 'MRI-Safe Disk Magnet for Implants'. It was filed on 21.04.2011, claiming a priority date of 23.04.2010 and proceeded to grant on 10.04.2019. Although it relates to implantable medical devices generally, it has particular application for cochlear implants. These devices typically comprise an internal implanted component and an external component. As the Patent explains by reference to a prior art system, attachment magnets are used to hold the external component magnetically in place over the implant. Then signals from a microphone as part of the external component can be transmitted transcutaneously to the internal component which includes an electrode to stimulate the auditory nerve in the cochlear.

9. The problem addressed by the Patent is that patients who require cochlear implants frequently have to undergo MRI examinations. An MRI scanner exerts a powerful magnetic field which can cause pain and injury to a patient with an implanted magnet

which is essentially fixed in place, but can also alter the magnetisation of the implanted magnet. The implanted magnet can also affect the MRI image. The magnetic field can also induce a voltage in the transmission system, causing hearing artifacts.

10. This has been a recognised problem for some years. Indeed, the Patent discusses a prior proposal (from Med-El) in a PCT application (WO 03/081976 A2), one of the co-inventors of which is also a co-inventor of the Patent. This PCT application ('Zimmerling') is the sole piece of prior art pleaded by AB. The idea in Zimmerling was to use spherical magnets which can swivel to align with the applied magnetic field so that the torque which would exert itself on a fixed magnet disappears.

11. The Patent explains that the typical prior art arrangement had the magnetic dipoles perpendicular to the skin, so that, for example, the South end of the N-S magnet in the external magnet was attracted to the North end of the N-S magnet in the internal magnet. The solution in the Patent involves two modifications: first, arrange the magnetic dipoles so they lie parallel to the skin and second, make the internal magnet rotatable in the plane of the skin. Claim 1 claims such an arrangement. The 14 other claims are all dependent on claim 1 and add further points of detail.

12. AB's Grounds of Invalidity plead lack of inventive step over Zimmerling and also some fairly routine insufficiency squeezes.

13. AB's product which is alleged to infringe has been on the UK market since late 2018. It is called the Hi Res 3D device (the '3D device'). The arrangement of magnets in its internal component gives rise to certain non-infringement and construction arguments and is likely also to result in arguments for infringement by equivalence: there is an array of four slim parallel cylindrical magnets, each rotatable about its longitudinal axis, in a rotatable circular frame.

The litigation background

14. AB announced its 3D device product in June 2018. Shortly thereafter, Med-El say they warned AB of its patent rights (but the Patent had not yet been granted). The 3D device was launched in the US in September 2018 with Med-El starting an infringement action in the US in October 2018 on various patents which include the US equivalent of 605. Although progress has been somewhat delayed by the pandemic, the trial of the US action is expected to take place in mid-2022. In Europe, a CE mark was obtained in November 2018 and the 3D device launched shortly thereafter.

15. In Europe the Patent in suit proceeded to grant on 10.04.2019. AB filed opposition in January 2020, at the end of the 9-month opposition period. The Opposition Division gave a preliminary opinion that the Patent was invalid for added matter in September 2020, but, at the hearing of the Opposition on 19.03.2021, the Patent was held valid and not obvious over Zimmerling. The OD handed down its written reasons on 11.05.2021 and AB filed its appeal on 18.05.2021. Med-El criticised AB for not having sought expedition of its appeal, but AB countered by saying (a) when their appeal was filed, Med-El's proceedings in Germany had not yet started and (b) in any event, they would request expedition when they file their grounds for the appeal in September 2021.

16. At least until June 2021, there was some basis for thinking that the dispute over the 3D device was being fought out in the US and via the EPO proceedings. However on

02.06.2021, Med-El launched an infringement action based on the German designation of the Patent in the Landgericht Mannheim, a court known to be quick to decide infringement claims. Med-El sought the earliest possible hearing, not least by requesting that the Mannheim court sever its claim against the first claimant from its claim against AB's German subsidiary in the event that international service on the Swiss-domiciled entity would delay the proceedings, to avoid the latter claim being delayed by service on the first claimant in Switzerland. The Mannheim court has set the hearing of the infringement claim for 18.01.2022. In the usual way, judgment is likely to be issued some 6 weeks later i.e. around the end of February 2022.

17. AB learnt of the Mannheim action on 15.06.2021. That led to the issue of the Claim form in this action on 13.07.2021 in the Shorter Trials Scheme, served with the Particulars of Claim and Grounds of Invalidity. This application was issued the following day. Two days after that, AB served particulars of the 3D device in respect of which AB seek a declaration of non-infringement of the Patent. Med-El suggested the particulars were inadequate in various respects. However, it is clear that Med-El has a very good understanding of the 3D device and any issues over the particulars should be readily resolvable.

18. Returning to the proceedings in Europe, even with expedition, AB's appeal to the EPO Technical Board of Appeal is unlikely to be decided until after June 2022. As I explained in *Abbott* at [23], a German nullity action cannot be commenced until after the conclusion of the EPO Opposition proceedings (including appeals). Thus, in Germany, the possible injunction gap may last from around the end of February 2022 to the conclusion of a nullity action which can only be commenced in June 2022 at the very earliest: the period is likely to be well over a year and could be two.

19. Initially, AB's application sought a trial of this action in December 2021. This would have required a very compressed timetable down to trial. Furthermore, the lists are very congested in December 2021 and at the start of the hearing I indicated that a listing in December 2021 was not possible and that, if expedition was justified, a more realistic trial date would be in February 2022. The parties had already anticipated this, so although some of the evidence was directed specifically at a December 2021 trial, it also covered other possibilities.

20. In its evidence, Med-El sought to establish this action as requiring a 5-7 day, category 4 trial which should receive a listing in the normal course, i.e. in October 2022. I will discuss the reasons put forward in Med-El's evidence below, but in his oral submissions, Mr Silverleaf QC based his opposition to expedition on the basis of a 5 day trial being listed in the ordinary course in June 2022, from which judgment *might* be handed down by the end of July 2022. In this way, the focus in submissions was on the effect in the UK of the German court granting an injunction at around the end of February 2022 until possibly the end of July 2022, when the UK Court would decide validity (and infringement). From my understanding of the state of the Patents Court lists, even listing this trial in June 2022 would require some expedition, but I will proceed on the basis that the period in dispute is between February and June 2022.

21. I can deal here with Med-El's attempts to say this action would require a 5-7 day trial with a category 4 complexity rating. There was discussion in Med-El's evidence of the possibility of complex vector analysis of magnetic fields and the need for experiments to be conducted. I am unconvinced of the need for the former because the Patent and

its claims are expressed at a level of detail which seems to me to be far removed from requiring vector analysis. Both sides said they currently saw no need for experiments, but I was warned that the situation might change as the issues develop. All experiments in patent actions should come with a government health warning, but again, if experiments need to be conducted (e.g. for the purposes of the infringement case), I do not see them as being particularly complex. For example, if an issue arose as to the orientation of each of the four cylindrical magnets in the internal component of the 3D device, I do not conceive it would be difficult to arrange to observe markings on each cylinder to indicate its orientation under various applied magnetic fields.

22. I am well aware of the tendency of the issues in a patent action to become increasingly complex through the exchanges of expert evidence, but having reviewed the Patent, the alleged infringement and Zimmerling, I agree with AB that the appropriate complexity rating for this action is category 3, which means it can be heard by a Deputy Judge if necessary. Since this action involves a single (relatively short) Patent, with one independent claim (at the moment), one piece of prior art and one alleged infringement, I also agree with AB that it should be possible for this trial to be completed in 4 days. In the Shorter Trials Scheme, I envisage 1 day for the Judge's pre-reading (with any short opening submissions taking place at the end of that one day), essentially one day for the cross-examination of each side's experts and one day for closing submissions.

23. Med-El submitted that more than one expert would be required: a biomedical engineer and a clinician. I do not rule out the need for some evidence from an expert clinician, largely to provide the court with relevant CGK, but I doubt whether any of that type of evidence will be the subject of serious dispute or require extensive cross-examination, leaving the bulk of time for cross-examination for focus on the magnetic aspects of this case.

24. All of these points must be kept under review by the parties and, when I announced the result on 20th August, I directed that a CMC be held (before me) in early October this year to review the trial length, complexity rating and any other directions which the parties cannot agree. Since all these points were the foundation for Med-El's cross-application to transfer this case out of the Shorter Trials Scheme, I also adjourned that application to the CMC in October.

Factual background

25. It was not in dispute that the relevant product market has some unusual characteristics, all of which are explicable in light of the fact that half of the product has to be surgically inserted. I need to explain various aspects of the market in order to examine what effect, if any, an injunction in Germany might have on the UK market. The evidence established the following.

26. Hearing loss affects over a billion people worldwide and a significant proportion of those were born with a hearing impairment or began to experience hearing loss as a child. Children who are pre-lingually deaf (i.e. before they acquire speech) have serious difficulty in learning speech and speech recognition. Thus, as well as enabling adults with hearing loss to regain a perception of sound, cochlear implants can assist pre-lingual children to develop speech and speech recognition.

27. As Ms Carr-Brendel explained:

> 5. Cochlear implants enable people with permanent hearing loss to perceive sound. An external component placed behind the ear houses a microphone and electronics which convert sound into electrical signals. The external housing transmits the electrical signals into a device which has been surgically implanted underneath the patient's cranial skin. The implanted device conveys the signals to an electrode which is located in the cochlea, being a bony aspect of the inner ear. These electrical signals directly stimulate the auditory nerve.

28. In terms of the internal component of AB's 3D device in issue, Mr Konegger explained that:

> The 'internal component' comprises an assembly containing a removeable attachment magnet, a coil for signal transmission, a stimulator housing unit containing the implant electronics and an electrode array that is surgically implanted within the cochlear for electrical stimulation.

29. So far as the external component of the 3D device is concerned, Mr Konegger described it thus:

> The external part of AB's device is made up of three discrete sub-components. These are a microphone at one end (the "**Microphone**") which is connected to a behind-the-ear sound processor (the "**Processor**"), that is connected to an external headpiece/transmitter coil (the "**External Coil Housing**") at the other. The Processor is a battery powered device and contains, amongst other parts, a signal processor to convert sound into stimulation signals that are transmitted to the 'internal component' (via the External Coil Housing) and a plug socket to receive a connecting cable (to the External Coil Housing). The External Coil Housing comprises a replaceable attachment magnet, a coil to transmit signal and power to the internal component and a socket to receive a connecting cable which connects the Processor with the External Coil Housing. In one known variant of AB's device, the External Coil Housing includes a further microphone.

30. Ms Carr-Brendel explained the role of the attachment magnets:

> 6. Both the implanted and external components of a cochlear implant system contain attachment magnets and/or magnet assemblies. When the external component is brought close to the implanted magnet, the magnetic attraction holds the external component in place over the patient's skin. This transcutaneous magnetic coupling enables the patient to remove the external component (including microphone) when, for instance, sleeping or swimming.

31. Implantation requires a surgical procedure. As Ms Carr-Brendel explained:

> 10. Cochlear implants are generally implanted for the lifetime of the product which can exceed 20 years. Patients have to undergo surgery to implant the receiver coil underneath the cranial skin, and to introduce the electrode into the cochlear. Side effects and risks of the surgery may include temporary dizziness, a temporary increase in tinnitus, and facial nerve bruising. Surgery also necessarily entails a risk of infection and other complications. Understandably, there is hesitation among patients with progressive hearing loss to undergo the surgery.

32. Although the bulk of the internal component lies between the cranial skin and the cranium, the internal component also includes a wired connection to the electrode which must be carefully positioned in the cochlea, a bony aspect of the inner ear.

33. Furthermore (Ms Carr-Brendel at [11]):

> It is common that after long term implantation of the electrode a fibrotic capsule forms around the electrode within the cochlea which is dimensioned to the implanted electrode. The sizes of electrodes vary between the brands of cochlear implants. Thus, if a patient is re-implanted at a later date, it may not be possible to accommodate the electrode of another brand suitably or without the electrode buckling because of resistance by the fibrotic capsule.

34. The external component will be replaced more frequently than the implanted component. There was a mini-dispute as to whether replacement of the external component occurs every 5-6 years on average or more frequently. Ms Carr-Brendel's evidence was that around 50% of patients require a replacement headpiece around the 2 year mark, due to damage or day to day wear and tear.

35. It was common ground that patients who have cochlear implants also have an increased need for MRI scanning. It seems to be part of the territory.

36. Although the electrical signals from the electrode directly stimulate the auditory nerve, the signals sensed by the auditory nerve are not perceived by the brain as meaningful sounds, but, with a period of intensive auditory training which is typically between 6-12 months, the individual learns to interpret the stimuli as speech.

37. An important aspect of this for present purposes is that different devices produce different stimuli. Thus if a patient switches to a new device, they have to re-train their brain to interpret the different set of stimuli as meaningful sound. Furthermore, reimplantation of the same device can require a degree of re-training because the positioning of the electrode is unlikely to be precisely the same as before.

38. When customers display a loyalty to a particular product or brand, they are sometimes described as 'sticky'. Ms Carr-Brendel described patients in this field as demonstrating a 'stickiness' for the hearing experience on which they have been trained and to which they are accustomed. She explained that it is also AB's experience that, even when undergoing re-implantation, patients usually stick with the same manufacturer. None of this was disputed and is entirely understandable in this unusual product market.

39. Ms Carr-Brendel also explained that cochlear implants are Class 3 products for the purposes of the EU's framework for obtaining a CE mark. It is clear that both sides expend significant sums on research & development. Products of this nature are subject to occasional recall notices – these may be minor issues but, if serious, may require removal of an implanted device and re-implantation. Ms Carr-Brendel explained that:

> In my experience, patients are strongly deterred from selecting a cochlear implant which has a perception of likely recall or low quality. Taking an example from AB's perspective, the 2020 product recall noted in the post contributed to a noticeable fall in market share in the following financial year.

40. Her reference to 'the post' was to a blog called 'Cochlear implant HELP' which contains regular updates on product reviews or developments in the market. She describes this blog as 'well-maintained' and exhibited a detailed review from that blog in March 2021. She said that blog also displays historic product recall data for the three major cochlear implant suppliers, dating back to 1995. This blog seems to be one of a number of online resources providing detailed information and reviews for prospective or actual cochlear implant patients. Ms Carr-Brendel also described other resources on social media including Facebook groups for cochlear implant users, naming three with 9,400, 35,300 and 13,000 members respectively.

41. Ms Carr-Brendel went on to explain that the decision as to which product a patient will receive is generally audiologist led, with input from the patient. She explained that audiologists who prescribe cochlear implants advise their patients in detail on the merits and demerits of different products. It is entirely understandable that a prospective patient (and/or their parent or guardian for a child) for an implant would have great interest in selecting an implant in which they had confidence and, in addition to taking advice from their audiologist, in this day and age would consult online resources as well. It is clear that in this market, patients wish to and do make well-informed choices about which product to have implanted and this has given rise to their desire for information being met in various ways, including through online resources.

42. Ms Carr-Brendel describes the revenues associated with a single patient as significant:

> The current price of one 3D Device system (comprising the internal implant and the external sound processor kit is around £12,000-£13,000 (one system = 1 ear). Additionally, the external part of the device (the sound processor kit) is upgraded every 5-6 years at a (current) cost of around £5,000 (or £9,000 if bilateral). Furthermore, the maintenance fees associated with each individual patient are around £12,000 per annum.

43. Ms Coltart calculated that the revenues from a patient with bilateral implants over a 20 year period amount to around £300,000.

The current state of the market

44. In the market for cochlear implants, there are three main competitors. Prior to the onset of the COVID pandemic, Cochlear held around 70% of the UK market, with AB holding around 20% and Med-El around 5%.

45. AB have two cochlear implant products on the market. The older product is called the HiRes Ultra. Undoubtedly the newer 3D device is AB's flagship product and accounted for a very large proportion of AB's UK sales in the 2019/2020 financial year.

46. AB in their evidence point to two factors impacting on the current state of the market and AB's position in it.

47. First and by far the most important factor is the effect of the COVID pandemic.

48. Due to and during the COVID pandemic, the evidence is that the UK market shrank by around 50% as elective surgeries were postponed and patients avoided seeking implants. AB's evidence suggested this delay has created a latent population of patients who are forecast to undergo implantation over the next 18 months and that the catch-up is expected to cause a surge by around 70% in market demand over the next 18 months. Thus, AB submit, the market is approaching an inflexion point. If one market participant is able to corner a substantial proportion, they could significantly reconfigure the commercial landscape in the cochlear implant field.

49. The second point which affects AB is a voluntary product recall they issued in respect of the first version of the 3D device in 2020. This recall notice applies to all patients who were implanted with that first version down to February 2020. Malfunction will require re-implantation with another device, but AB estimate that only a small proportion of patients will require re-implantation. Understandably, AB did not wish to major on this point, but it seems, as Mr Silverleaf submitted, to be the or a reason for the drop in AB's market share during the pandemic to around 11%. So, it would seem that even as the market has shrunk by 50%, AB's revenues have shrunk still further due to having their share of that shrunken market very nearly halved. This second point perhaps makes AB's position all the more vulnerable at this 'inflexion point', if it is not able to compete or is hindered in competing for its share in the forecast 70% market growth over the next 18 months or so. Understandably, AB hopes to achieve a strong recovery of market share and hopes to grow its sales and revenues to above pre-COVID levels within a very few years, but I am sure that the other participants in this competitive market have similar ambitions.

AB's case for expedition and Med-El's arguments against

50. AB put forward three reasons for expedition. The third was 'to inform business decisions in the UK which have to be taken over the next year', in view of AB's spend on R&D at 25% of its revenues. I regard this third point as something of a makeweight. AB's first and second points appeared to me to amount to one, which can be summarised thus: expedition is required to avoid AB suffering possibly severe irreparable damage in the UK market caused by those in the market learning that a German court has injuncted AB's 3D device and steering clear of that device.

51. There was a mini-dispute whether an injunction in Germany would be seen in the UK as akin to a product recall. This precise point does not matter. What matters is what the effect is likely to be.

52. Med-El took a number of points in opposition but its overall submission was that no good reason for expedition had been put forward by AB. Med-El even submitted that the only justification for expedition was so that AB could demonstrate to the Mannheim

court that the English Patents Court had formed a different view on validity to that of the Opposition Division of the EPO. Mr Silverleaf submitted that this was the original justification set out in AB's evidence in chief and AB's justification changed in its reply evidence. I am satisfied this submission is incorrect. It has always been the case that the primary focus of AB's application has been to protect its market position in the UK. However, in order to protect the market in the UK from the consequences of an injunction being granted in Germany, one cannot escape from the fact that a by-product of a successful (from AB's point of view) judgment from the English court may influence the Mannheim court into not granting an injunction which would result in a significant benefit for AB's business in Germany. As I observed in *Abbott* at [28] & [30], the position in the German market is a matter for the German courts. On this application I am concerned with the position in the UK market.

53. Before I return to consider the effect in the UK market, there are a number of other points taken by Med-El that I should deal with.

54. Med-El's first point was that AB has advanced no reason why the English Court is going to disagree with the reasoned decision of the OD that the Patent discloses an inventive step over Zimmerling. Since Med-El seemed to have so much confidence in the validity of the Patent, I wondered why Med-El were not supporting the application for expedition: surely Med-El would want to get the 3D device off the UK market as quickly as possible by establishing infringement of its valid patent in this court. When I put that point to Mr Silverleaf, his response rested on the alleged unfairness of not being able properly to prepare for the trial here. This is a point I deal with below, but suffice to say I did not find his response convincing.

55. Med-El's second point was that it was open to AB to bring a revocation action in the UK to 'clear the way' ever since the Patent was granted in April 2019. Med-El point out that AB had been sued in the US and had been warned of Med-El's patent rights. There was perhaps also an implicit criticism from Med-El that AB should not have opposed at the EPO because then AB would have been able to bring nullity proceedings in Germany much earlier than otherwise.

56. A similar point to the main one was taken (albeit in different circumstances) in *Nicoventures*, so Mr Lykiardopoulos QC for AB drew my attention to the way in which Birss J. dealt with it:

> 38. BAT's fourth point is to focus at Philip Morris' past approach. It is said that they must have known, and do not deny that they have known, about the '460 patent for well over a year. After all it was granted in July 2019, but in fact the public Notice of Intention to Grant by the EPO was in November 2018. Therefore one can say that they have already had to factor in the risk associated with this product.
>
> 39. In my judgment, that submission is unreal. Philip Morris submits the risks changed when they were sued in Germany. I think that is credible and I accept it. From the position of an international group like Philip Morris, there is a major difference between the risk presented by a rival who has patents which may or may not present a risk to your business in a given jurisdiction

> such as the UK but which are not being litigated, and the risk which eventuates when that rival then initiates infringement proceedings under another designation of the same EP patent.
>
> 40. The fact that Philip Morris was obviously prepared to make decisions about its future UK launch in before BAT had sued on the '460 patent, but knowing that patent was going to grant, does not undermine the cogency of its case that now that it is being sued in Germany, there is a higher need for speed and a higher need for certainty in the UK.

57. I, too, regard Med-El's points (as summarised in paragraph 55 above) as unreal. The advantages of the central EPO Opposition procedure are obvious. Furthermore, it is clear the risks changed when Med-El decided to sue in Germany and in the Mannheim court in particular. None of this undermines the cogency of AB's case for expedition here, now that it is being sued in Germany.

58. Med-El's third and fourth points were that there was little prospect of the Mannheim court staying the grant of an injunction even if there was a finding of obviousness by the English Court, and that the English judgment would in any event be too late. These points rather assume the correctness of Med-El's characterisation of the justification for expedition, a point which I rejected in paragraph 52 above. In any event, whether either point is valid or not is a matter for the German court to decide. I am satisfied that there are various mechanisms by which an English Judgment can be drawn to the attention of the Mannheim court even after the infringement hearing, and, as Henry Carr J. indicated in *Takeda UK Ltd v F Hoffmann-La Roche AG* [2018] EWHC 2155 at [11]-[12], all courts deciding patent cases across Europe are interested to see judgments rendered by courts in other EPC contracting states on the equivalent EP.

59. Turning to the position in the UK, Med-El submitted:

    i) AB has not shown any need for commercial certainty in the short term (but this was a repeat of Med-El's point that AB should have sought to clear the way back in April 2019 or soon thereafter).

    ii) It is very unlikely that patients and clinicians will become aware of the legal proceedings in Germany (I note the careful way in which this point is phrased, based on 'legal proceedings' rather than the consequences of an injunction being granted in Germany).

    iii) All of AB's fears about the effect of a German injunction on the UK market are exaggerated and/or not objectively justifiable. This is the key point.

60. Further, to bolster its position and arguments, Med-El offered the following undertakings:

    i) That it will not seek an interim injunction in the UK;

    ii) That it will not seek to enforce an injunction (I think in the UK) to prevent a patient receiving replacement external components for the life of his or her implant; and

iii) That it will not publicise in the UK the result of its infringement action in Germany or that it has an injunction against the 3D device in Germany (if that is granted).

61. In support of Med-El's second point above, Mr Konegger included a whole section in his witness statement which was designed to establish that patients and clinicians would not get to hear of legal proceedings between the parties. In that section, he gave evidence that Med-El's policy is not to comment on any *ongoing* legal proceedings. Such a policy is laudable and sensible, but, as I observed in the course of argument, it does not mean that Med-El would not make known the result it had achieved in the German infringement action. My observation led to the offer of the third of the undertakings mentioned above.

62. In response to this section of Mr Konegger's witness statement, Ms Carr-Brendel gave evidence in reply of a specific example of a clinician being well aware of a potential patent dispute. She said:

> … in July 2018, AB received a communication from an Austrian-based clinician suggesting that AB's introduction of its 3D Device would be delayed or affected by a patent dispute with Med-El.

63. In recognition of the importance of the point, Mr Silverleaf QC almost invited me to disbelieve this piece of evidence but retreated somewhat to submit that I should be extremely cautious about placing any weight on it. I do not understand why. It will be recalled that in June 2018, AB announced their new 3D device and I assume the warning of Med-El's patent rights followed shortly thereafter. This piece of evidence is entirely consistent with those events. I am sure that certain clinicians and audiologists know representatives of each side well and will either talk about what is going on or raise questions, notwithstanding Med-El's stated company policy.

64. Even if I assume that no audiologists in the UK would become aware of the German infringement action, I find it very difficult to understand how UK audiologists would not hear very quickly that the 3D device was off the market in the major German market i.e. as soon as an injunction was granted in Germany. I am satisfied that word would go round the industry very quickly indeed. Many would then speculate whether the same was going to happen in the UK. This would lead both audiologists and patients to doubt whether it was advisable to have a 3D device implanted and to discussions to that effect on the blogs. In the unusual circumstances of this product market, I conclude that the grant of an injunction in Germany around the end of February 2022 (assuming Med-El's infringement action succeeds) is highly likely to cause significant damage to AB and to the prospects of its 3D device recovering the market share AB had before the pandemic. Audiologists would be put off from recommending and patients would be put off from choosing implantation of the 3D device. For the reasons explained above, even the loss of a single patient results in very significant and long-lasting financial loss.

65. Mr Silverleaf suggested that any doubts in the UK market could be dispelled by AB going out and reassuring audiologists. This is another point which I regard as unreal. If AB's representatives have to go out and explain to audiologists that it is safe (at least for the time being i.e. until the English Court has given judgment) to recommend the

implantation of a 3D device because Med-El has undertaken to permit AB to continue to supply replacement external components for the life of the implant, that would only, in my view, increase the doubts in the market about the 3D device.

66. Furthermore, even if a trial here took place in June 2022 with judgment before the end of July, a judgment in favour of AB would not immediately rectify the situation. Once doubts about the advisability of having a 3D device implanted take hold, they are likely to persist for some months beyond the handing down of a favourable judgment from this court.

67. For these reasons, I concluded that AB had shown a good reason for expedition (the first of the *Gore* factors).

68. Reverting for a moment to Med-El's submission about the purpose of this application (the point I rejected in paragraph 52 above) being to influence the Mannheim court, Med-El made a series of points as to why any English judgment might not exert any influence, including if, for example, the claims in Germany were amended and were therefore different from those considered in the UK, or vice-versa. However, none of these points really matter since the good reason for expedition arises from the consequences for AB in the UK.

69. As to the second of the *Gore* factors, whether expedition would interfere with the good administration of justice, AB recognised and accepted they were jumping the queue. However, I envisage the listing of this trial in February 2022 will not displace any other litigant. I directed that, if possible, this trial should be listed in February 2022, but if that is not possible (because no Patents Judge or suitably qualified Deputy Judge can be lined up to hear it) then it may have to be listed in March 2022. I directed that the parties must liaise with the Listing Office to identify a more precise trial listing, and in the meantime to seek to agree directions with a view to a trial taking place in February 2022.

70. On the third factor, Med-El complained about the unfairness of a trial being expedited to be heard in December 2021 and those points had some validity, although I suspect that Med-El could have been ready for such a trial. Med-El is obviously very familiar with the 3D device (having filed a 70-page infringement brief in Germany), and with the Patent and Zimmerling. Med-El stressed the difficulty of finding a suitable expert and the time needed to undertake the sequential unmasking of the case. Those points had much more force regarding a December 2021 trial date, but I am satisfied that a timetable down to a February 2022 trial is eminently achievable with no prejudice being caused to Med-El.

71. As for whether there are any special factors for or against expedition, AB sought to make a series of points about the unique benefits to patients of the 3D device, which Mr Silverleaf sought to counter. I do not propose to embark on any discussion of the claimed merits or demerits of either the 3D device or Med-El's Synchrony device. I am sure that audiologists and clinicians in this field have a range of opinions about the available devices, some favouring one device over others based on their own personal experiences.

72. AB also claimed there was a special medical need for the 3D device to be available for pre-lingual children. Mr Silverleaf countered by saying those sorts of considerations were only relevant following judgment (as in *E-valve v Edwards*).

73. In short, I do not see that there are any other special factors in favour or against expedition. Overall, the aim of the expedition I ordered was to allow audiologists, clinicians and patients to make their choice of device without, as far as possible, being concerned by the fact that the 3D device was off the market in Germany, concerned that the same might occur in the UK, and steering clear of the 3D device as a result, at least until the English court has examined this case itself.

74. Looking at the situation from AB's stance, I ordered expedition of the trial into February 2022 in order to avoid what I concluded was a serious risk of AB suffering severe and potentially long-lasting damage to the prospects for its 3D device on the UK market, damage for which it would never be compensated. Of course, if this court concludes the Patent is valid and infringed, then, subject to arguments over special medical needs, the 3D device is likely to be removed from the UK market.