Neutral Citation Number: [2022] EWHC 1345 (Pat)

Claim No: HP-2021-000028

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS OF ENGLAND & WALES
PATENTS COURT (ChD)
SHORTER TRIALS SCHEME

The Rolls Building
7 Rolls Buildings
Fetter Lane
London EC4A 1NL
Date: 1 June 2022

Before:

Mr CAMPBELL FORSYTH

(SITTING AS A DEPUTY JUDGE OF THE HIGH COURT)

- -

Between:

(1) ADVANCED BIONICS AG
(a company incorporated under the laws of Switzerland)

(2) ADVANCED BIONICS UK LIMITED

Claimants

- and -

MED-EL ELEKTROMEDIZINISCHE GERÄTE GMBH
(a company incorporated under the laws of Austria) **Defendant**

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ANDREW LYKIARDOPOULOS QC and **EDWARD CRONAN** (instructed by **Kirkland & Ellis International LLP)** appeared for the **Claimants**

BRIAN NICHOLSON QC and **BEN LONGSTAFF** and **CALLUM BEAMISH** (instructed by **Powell Gilbert LLP)** appeared for the **Defendant**

Hearing dates: 15, 16, 17, 18 February and 2 March 2022

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APPROVED JUDGMENT

I direct that no official shorthand note shall be taken of this judgment and that copies of this version as handed down may be treated as authentic. This judgment was handed down by the judge remotely by circulation to the parties' representatives by e-mail and release to The National Archives. The date and time for hand-down is deemed to be 4pm on 1 June 2022.

DEPUTY JUDGE FORSYTH:

INTRODUCTION

1. This is a matter tried under the Shorter Trials Scheme. The case was originally brought by Advanced Bionics AG and Advanced Bionics UK Limited, the Claimants ("**AB**") for the revocation of European Patent (UK) 3,138,605 (the "**Patent**"), and for a declaration of non-infringement in relation to AB's HiRes Ultra 3D cochlear implant device. The product is defined in paragraph 109 below and referred to as the Ultra 3D. The Defendant, Med-El Elektromedizinische Geräte GmbH ("**Med-El**") is the proprietor of the Patent. Med-El counterclaimed for infringement.

2. The Patent is entitled "*MRI-safe disk magnet for implants*". The Patent was granted on 10 April 2019. It has a priority date of 23 April 2010 ("**the Priority Date**"). This is the relevant priority date for these proceedings.

3. Med-El has applied to amend the claims of the Patent unconditionally. The proposed amended claim set is set out in Annex A to this Judgment. The issues are to be decided by reference to these unconditionally amended claims. The amendments are not opposed by AB.

4. Med-El relies on three claims: claims 1 and 10 of the Patent as granted and claim 14 as proposed to be amended.

5. AB's product, the 3D Device, which is alleged to infringe the Patent has been on the UK market since late 2018. Med-El asserts that AB has been infringing the Patent on a normal construction of the relevant claims and on the basis of the doctrine of equivalents. Indirect infringement is also alleged in relation to separate external components (including replacement headpieces and replacement headpiece magnets).

6. AB denies infringement and claims the Patent is invalid based on a single piece of prior art WO 03/081976 A2 ("**Zimmerling**") and insufficiency.

7. The Patent was opposed in the European Patent Office and I understand upheld on the claims in the form proposed to be amended. I have been told the opposition was based on the same prior art as in this case, Zimmerling. I understand the decision is being appealed. I have not been addressed on the decision in any detail. Reference was made in passing to AB using the Figure 4A embodiment of Zimmerling as the starting point at the EPO. I do not know why I was not addressed in more detail on the EPO decision. A national court is not bound by the EPO decision. There are multi-factorial and procedural differences with the EPO proceedings. In any event, in the circumstances, I have not considered or investigated the EPO decision in this Judgment. I was also informed there was a related patent case in the USA but again I was not addressed on this in any detail.

8. Med-El pleaded that the two AB entities to these proceedings were joint tortfeasors. For the purpose of these proceedings only, the first claimant, Advanced Bionics AG, accepted joint and several liability for relevant acts of the second claimant, Advanced Bionics UK Limited.

9. Andrew Lykiardopoulos QC appeared for AB, with Edward Cronan. Brian Nicholson QC appeared for Med-El, with Ben Longstaff and Callum Beamish.

CONDUCT OF THE TRIAL

10. The trial was conducted in person over 5 hearing days. This was a case with an ambitious timetable for the Shorter Trial Scheme. Even with discipline on timings, to accommodate the hearing the court sat longer than the normal court day. I would like to thank the court staff and shorthand writers for helping with these longer and unpredictable hours. In addition, due to two counsel becoming Covid positive at different times during the hearing this timetable was also delayed twice to accommodate availability. The two clinical experts gave evidence remotely from the USA.

11. With the helpful assistance of the parties, counsel and expert witnesses adapting to the circumstances, despite these issues noted above, the trial was completed with only modest delay. The complexity and volume of issues, material and witnesses combined with the limited time in Court under the Shorter Trials Scheme has resulted in a longer period post trial being needed.

12. At the start of the trial I heard a contested application regarding the admission of evidence relied upon by AB: (1) the Third Expert Report of Professor John Louis Parker, and (2) the Third Expert Report of Professor Jay Tal Rubinstein. Both reports were served on Med-El on 4 February 2022. In short, Med-El referred to the Order of Mr Justice Mellor of 29 September 2021 and its directions for expert reports. There was no provision made for a

third round of expert evidence. Med-El further noted that, as this matter is governed by Practice Direction 57AB under the Shorter Trial Scheme, paragraph 2.50 of that PD notes:

> "*Save in exceptional circumstances, the court will not permit a party to submit material at trial in addition to that permitted at the CMC or by later court order."*

13. I heard oral arguments on the application and gave an extemporaneous decision at the start of the hearing providing permission for the noted evidence to be admitted into the proceedings.

14. Following a decision of the Regional Court of Mannheim, Germany, on the German designation of the Patent, the parties provided post-trial submissions on 18 March 2022.

THE ISSUES

15. Pursuant to PD 57AB paragraph 2.38 a list of issues for trial was approved by the Court in Schedule 1 to Mr Justice Mellor's Order of 19 October 2021. These are set out below and are addressed in the Judgment:

1.*What were the relevant aspects of the common general knowledge of the Skilled Team as at the Priority Date?*

2. Are claims 1, 10 and 14 (as proposed to be amended) of the Patent obvious over Zimmerling read together with the common general knowledge?

3. Do claims 1, 10 and 14 (as proposed to be amended) of the Patent cover embodiments which owe nothing to the technical contribution of the Patent?

4. Does the 3D Device infringe any of claims 1, 10 and 14 (as proposed to be amended) of the Patent on a normal construction?

5. Does the 3D Device infringe any of claims 1, 10 and 14 (as proposed to be amended) of the Patent by reason of equivalence?

6. Does the supply or offer of supply of the Accessory Items (and each of them), including in the manner identified in §11 to the Reply and Defence to Counterclaim, constitute infringement of any of claims 1, 10 and/or 14 (as proposed to be amended) of the Patent pursuant to section 60(2) of the Patents Act 1977?

7. Is the Defendant's application to amend unconditionally the Patent in the manner identified in its Statement of Grounds for Amendment dated 7 October 2021 allowable?

THE WITNESSES

16. Each party relied on two experts, a clinician and a biomedical engineer. AB also relied on the evidence of two further witnesses of fact. James Smith is the Manager of Implant Design at Advanced Bionics. He comments on matters relating to the PPD and the 'means essential' infringement case. He gave his evidence fairly and was a helpful witness. To the extent the evidence is in issue, no criticism has been made of his evidence by Med-El. Tiziano Caldera is the Vice President of Sales of Advanced Bionics. His two statements set out information on the supply of the allegedly infringing 3D Device and its component parts in relation also to the 'means essential' case. He was not called to give evidence at the trial.

17. Med-El called clinical expert evidence from Professor Crane. Professor Crane is a doctor at the University of Rochester Medical Center specialising in otolaryngology (including otology) and neurotology. From 2007 to 2009, shortly before the Priority Date, he was at the Johns Hopkins School of Medicine Department of Otolaryngology specialising in neurotology.

18. AB called Professor Rubinstein as its clinical expert. Professor Rubinstein is a doctor at the University of Washington School of Medicine's Department of Otolaryngology. By the Priority Date he had extensive experience in implanting cochlear implants and preparing such patients for MRIs. He has served on the medical and surgical advisory boards of both AB and Med-El.

19. Both clinical experts had relevant experience and provided helpful evidence in an uncontroversial manner. Both parties accept this. However, in the end their evidence only dealt with a relatively small number of material issues, with limited areas of dispute.

20. For its biomedical engineer, Med-El called Professor Suaning. He was employed by Cochlear Ltd ("**Cochlear**") from 1992 to 1997, working on all aspects of cochlear implant development. Cochlear is one of the three main companies operating in the field of cochlear implant devices. Leading up to the Priority Date Professor Suaning took a PhD in visual prosthesis. Since 2004 he has collaborated with Cochlear on projects involving bionic eyes and cochlear implants. At times I found Professor Suaning to be too controlled and overly careful in his answering questions to the point it came across as slightly partisan to the Med-El case. However, he was a good educator to the court and made sensible concessions as appropriate.

21. AB called Professor Parker as its biomedical engineer. Professor Parker has extensive experience as a medical device engineer, with 20 years' experience designing cochlear implants at Cochlear. He was their Chief Technical Officer until 2007 – shortly before the Priority Date of the Patent. As such he was very familiar with the relevant subject matter. I found him an extremely open and helpful expert. He was also a good educator for the court. He came across as willing to answer fully and conceded points where relevant.

22. Med-El's counsel do not criticise Professor Parker personally as a witness. It was accepted he is well-qualified to assist the court and that he did so in giving his evidence at the trial. However, his evidence is criticised on the basis that his instructions or his understanding of those instructions were flawed such that he did not appreciate his role and that of the notional unimaginative skilled person in the art. The result, Med-El's counsel argue, is that his evidence is of very little probative value. This is said to manifest in concerns including: his reasoning in the evidence, his approach to obviousness (and the need to avoid hindsight), the impact of Professor Parker's own skills as a clever and inventive individual and the importance of the Priority Date. Additionally, there are also criticisms relating to precisely what matters were in Professor Parker's knowledge with regards to infringement and certain post priority devices.

23. Professor Parker's evidence contains the standard instructions and information for an expert in a patent case. He was taken to the documents in the case in the usual sequential manner as set out in *Medimmune v Novartis* [2011] EWHC 1669 (Pat). Med-El's counsel does not dispute this but rather argues his evidence demonstrates he failed to understand or follow these instructions.

24. In cross-examination Professor Parker confirmed his understanding of these instructions and his application of these in his evidence. As this is an important issue I set out below some of the relevant materials in my assessment of this point.

25. At the start of paragraph 85 in his first report Professor Parker states:

> "*When I was first shown Zimmerling and asked what the skilled person would do and before I had seen the patent, it immediately struck me that there were other straightforward shapes which could be used to take advantage of the rotatable design disclosed by Zimmerling. In particular, the first suggestion I made was the use of a flat, disk-shaped magnet instead of the bulkier magnets shown in Zimmerling, The reason I thought of this is because flat disk-shaped magnets were the most commonly used type in the common general knowledge (indeed, almost universally to my knowledge) and so the easiest way to implement Zimmerling would be to use the designs and components already being used."*

26. Med-El argues that in this paragraph and other examples the use of "me" or "I" by Professor Parker in the context of describing his views mean he was providing a personal (inventive) view rather than that of the skilled person. When challenged on this in cross examination Professor Parker responded noting:

> "*So then it may be a poor choice of phrasing in terms of how this is written, because I would have thought that the definition in the first sentence would have been read as carrying forward through the rest of the paragraph. When I am saying, when I was first shown Zimmerling and I do believe I was thinking as a skilled person would have at that time and answering with the word "I" instead of adding the extra language "a skilled person would have". So I apologise for that, but I do not see any inconsistency and I do not agree with your premise I suspect that you are making, that I am not trying to behave as a skilled person would have*."

27. Med-El's assertions on this issue went further to suggest that despite the statements in the reports and confirmation of Professor Parker that he was addressing the evidence from the perspective of the skilled person his evidence contradicted these statements. Following on from the above exchange, Med-El submitted as follows in cross examination:

> *"9 Q. To be clear, I am not accusing you of doing anything wrong.*
> *10 One of the issues that one has with experts in cases like this*
> *11 is that it is incredibly difficult to put yourself back,*
> *12 particularly when you are an inventive person to think, "Am I*
> *13 doing this right, am I giving my opinion or am I assisting the*
> *14 court as to how the Skilled Team, the unimaginative skilled*
> *15 team would work"? I respectfully will be saying to his*
> *16 Lordship that the proof is in the pudding. You can write as*
> *17 many times as you like, "through the eyes of the skilled*
> *18 person", "The question I was asked was through the eyes of the*
> *19 skilled person", but if it was at the forefront of your mind,*
> *20 "Not me, I am the skilled person", then why do we not see you*
> *21 saying that?*
> *22 A. I did not understand that that was -- I would have said that*
> *23 the first sentence covered that and apologies if that is not*
> *24 very clear**. I do think though that in that particular***
> ***25 situation, I did not actually consider that and worry about***
>
> ***2 that at the time and throughout the process**. But we are*
> *3 talking about one simple geometric transformation. We are not*
> *4 talking about a huge leap of intuition to go from Zimmerling*
> *5 to a rotating diametrically opposed magnet. We are talking*
> *6 about flipping an axis and of magnetisation. **So I do not see***
> ***7 how my particular background and my career and things that I***
> ***8 have done impacts the thought process to get from that one***
> ***9 step to the next**."*

28. I have left in the emphasis added by Med-El. Dealing with these points in turn. I do not agree with Med-El that the noted statement of Professor Parker somehow means he did not think it mattered if he was thinking from his own personal perspective or that of the skilled person throughout the process. Rather, in context I find this is nothing more than a statement following on from his earlier comments – that he had the points about his role and the skilled person in mind but did not consider it necessary to worry about repeating that statement continuously throughout the process. Regarding the second point, this is a matter of expert views on the obviousness case. Taking into account the proper context, I do not find it indicative of any malfeasance. I will deal with this and other related points and any weighting of the evidence as appropriate later in the Judgment.

29. A further submission about Professor Parker's approach made in cross examination was as follows:

> *"25 Q. Thank you. What about no inventive capacity? We discussed*
> *2 earlier that you are a very inventive person. How did you*
> *3 control your thinking to decide what an uninventive skilled*
> *4 person would do, looking at various documents?*
> *5 A. I do not know how to answer that question. I am sorry, but it*

6 is -- is there some kind of thought process or some kind of

7 way of -- ***I do not know how you stop yourself leading to a***

8 logical conclusion if that is what "invention" is, so I

9 suspect it is a definitional issue. If the invention itself

10 is non-inventive, than no inventive step was applied, whether

11 I have applied it or somebody else. Sorry, I do not

12 ***understand."***

30. Med-El submit this evidences its contention that Professor Parker does not appreciate the distinction between what was inventive to him and to the skilled person. Rather, in the context and with the overall evidence in mind I find that this simply reflected his somewhat philosophical thought process of questioning whether in 'approaching the matter as the skilled person' there is a particular way or process that should logically be followed when applying his instructions in his reaching any views. Again, I do not accept the use of the first person in his statement means he is not following the process correctly. This statement does not somehow create a broader implication that he was ignoring the contextual instructions on how to approach such an analysis from the perspective of a skilled person. His evidence is littered with references to the skilled person and their approach to the relevant matters.

31. I do not address every example raised by Med-El in this conclusion. However, I have considered them in the context of the submissions and evidence. In my view, for the reasons noted, in the clear context and responses on the issue from Professor Parker the fact that in his evidence he referred to his views in the first person at times did not mean he was not following the standard rubric of a notional uninventive skilled person at the Priority Date without hindsight. I also conclude that Professor Parker was aware of and applied his instructions regarding the uninventive skilled person at the Priority Date in approaching his evidence. In the circumstances, this line of questioning was unfair. The over-meticulous analysis of the reports put forward could even go so far as to put off experts providing reasonable analysis in their own words. In my view, Professor Parker was a fair witness and in cross-examination came across as keen to assist, educate and willing to make concessions as appropriate.

32. All the experts were helpful in assisting me in understanding the case and the technology. I do not accept everything said by the experts but will deal with relevant issues where they arise later in my Judgment.

THE SKILLED TEAM

33. As a general statement, a patent specification is addressed to those likely to have a real and practical interest in the subject matter of the invention (which includes making it as well as putting it into practice). The law identifying the skilled addressee and their attributes is set out in *Garmin (Europe) Ltd v Koninklijke Philips NV* [2019] EWHC 107 (Ch), expanded upon in *Illumina Cambridge Ltd v Latvia MCI Tech SIA* [2021] EWHC 57 (Pat) and cited and applied recently in *Alcon v Actavis* [2021] EWHC 1026 (Pat).

34. There was no dispute about these basic principles. The parties agree the Patent is addressed to a team consisting of a biomedical engineer and a clinician. Professor Parker had referred to this Skilled Engineer as a skilled medical device engineer. He accepted there is no relevant difference between the different descriptions used. Both Professors Parker and Suaning accepted the Skilled Engineer could be a mechanical engineer or a biomedical engineer and they would have a background in industry involved in designing cochlear implants. Professor Parker considered the Skilled Engineer may alternatively have an electronic engineering undergraduate background and a post-graduate course in bio-medical engineering. Again, that distinction was not put forward as one that made any difference. Similarly, the length of any relevant industrial experience - a few years to 5 years - was not specifically challenged and did not impact on the submissions. In the end nothing turns on these modest differences.

35. The parties also agreed that the Skilled Team would include a clinician. It was common ground the team would have been led by the Skilled Engineer. The Skilled Clinician would be a specialist in otolaryngology and neurotology. Otolaryngology is the area of medicine focused on the ear, nose and throat. Neurotology is a specialism within otolaryngology relating to pathological conditions of the ear and skull base. There is no dispute that the clinician would be a surgeon with a number of years' experience in cochlear implants. Professors

Rubinstein and Crane both viewed the Skilled Clinician as having training in neurotology or paediatric otolaryngology with at least a few to 5 years relevant clinical experience. There were some small differences in the views on the precise training and levels of experience but nothing the parties submitted had any material impact on the case.

36. There was also agreement that the role of the clinician in the Skilled Team was to input on issues the device manufacturers had with their existing devices or further developments. This could be via their role on medical advice boards to these cochlear device manufacturers or more directly.

THE COMMON GENERAL KNOWLEDGE

37. The law relating to the common general knowledge ("CGK") is well known and was not the subject of debate between the parties.

38. The classic statement on CGK is set out in ***General Tire v Firestone*** [1972] RPC 457 [481]-[483]. I set out below the approach to CGK noted by the Court of Appeal in ***Idenix v Gilead*** [2016] EWCA Civ 1089:

> *"70. ... I must begin with some basic principles as to what does and what does not form part of the common general knowledge. These were explained by Aldous LJ in Beloit Technologies Inc v Valmet Paper Machinery Inc [1997] RPC 489 at pages 494 to 495:*
>
> *"It has never been easy to differentiate between common general knowledge and that which is known by some. It has become particularly difficult with the modern ability to circulate and retrieve information. Employees of some companies, with the use of libraries and patent departments, will become aware of information soon after it is published in a whole variety of documents; whereas others, without such advantages, may never do so until that information is accepted generally and put into practice. The notional skilled addressee is the ordinary man who may not have the advantages that some employees of large companies may have. The information in a patent specification is addressed to such a man and must contain sufficient details for him to understand and apply the invention. It will only lack an inventive step if it is obvious to such a man.*
>
> *It follows that evidence that a fact is known or even well-known to a witness does not establish that that fact forms part of the common general knowledge. Neither does it follow that it will form part of the common general knowledge if it is recorded in a document. As stated by the Court of Appeal in General Tire & Rubber Co v Firestone Tyre & Rubber Co Ltd [1972] R.P.C. 457, at page 482, line 33:*
>
> *The two classes of documents which call for consideration in relation to common general knowledge in the instant case were individual patent specifications and "widely read publications".*
>
> *"In my judgment it is not sufficient to prove common general knowledge that a particular disclosure is made in an article, or series of articles, in a scientific journal, no matter how wide the circulation of that journal may be, in the absence of any evidence that the disclosure is accepted generally by those who are engaged in the art to which the disclosure relates. A piece of particular knowledge as disclosed in a scientific paper does not become common general knowledge merely because it is widely read, and still less because it is widely circulated. Such a piece of knowledge only becomes general knowledge when it is generally known and accepted without question by the bulk of those who are engaged in the particular art; in other words, when it becomes part of their common stock of knowledge relating to the art."*
>
> *And a little later, distinguishing between what has been written and what has been used, he said:*
>
> *"It is certainly difficult to appreciate how the use of something which has in fact never been used in a particular art can ever be held to be common general knowledge in the art."*
>
> *Those passages have often been quoted, and there has not been cited to us any case in which they have been criticised. We accept them as correctly stating in general the law on this point, though reserving for further consideration whether the words "accepted without question" may not be putting the position rather high: for the purposes of this case we are disposed, without wishing to put forward any full definition, to substitute the words "generally regarded as a good basis for further action".'"*
>
> *71. In Raychem Corporation's Patents [1998] RPC 31, Laddie J provided this important further guidance at page 40:*
>
> *"The court is trying to determine in a common sense way how the average skilled but non-inventive technician would have reacted to the pleaded prior art if it had been put before him in his work place or laboratory. The common general knowledge is the technical background of the notional man in the art against which the prior art must be considered. This is not limited to material he has memorised and*

has at the front of his mind. It includes all that material in the field he is working in which he knows exists, which he would refer to as a matter of course if he cannot remember it and which he understands is generally regarded as sufficiently reliable to use as a foundation for further work or to help understand the pleaded prior art. This does not mean that everything on the shelf which is capable of being referred to without difficulty is common general knowledge nor does it mean that every word in a common text book is either. In the case of standard textbooks, it is likely that all or most of the main text will be common general knowledge. In many cases common general knowledge will include or be reflected in readily available trade literature which a man in the art would be expected to have at his elbow and regard as basic reliable information."

72. It follows that the common general knowledge is all that knowledge which is generally regarded as a good basis for further action by the bulk of those who are engaged in a particular field. It is that knowledge which those working in that field will bring to bear when they are reading or learn of a piece of prior art. It is not necessary that those persons have that knowledge in their minds, however. The common general knowledge includes material that they know exists and which they would refer to as a matter of course if they cannot remember it and which they understand is generally regarded as sufficiently reliable to use as a foundation for further work."

Agreed common general knowledge

39. The parties provided a helpful Agreed Statement of Common General Knowledge which I incorporate into this Judgment. It is set out at Annex B. In this section I deal with further CGK which is relevant to the issues to be decided and was discussed during the proceedings.

Disputed common general knowledge

40. In Med-El's opening skeleton an attempt was made to set out what may be disputed as regards relevant CGK. In the end this did not wholly deal with the points of dispute and I therefore deal with the issues raised below as relevant. Some of the points raised by the parties on CGK are more appropriate to questions on obviousness and I will deal with those points later where they arise.

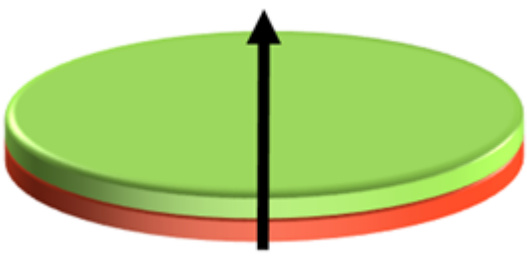
41. There was some debate about whether a legal 'mindset' case was being run by Med-El. It was confirmed no such case was being put forward.

Magnets and rotation

42. There was significant debate about what magnets may be known in the CGK and what may be CGK regarding the ability of certain magnets to rotate in response to an external magnetic field.

43. Permanent magnets have a magnetic moment which describes the strength and orientation of the magnetic field of the magnet. This is called the magnetic dipole. It is a vector quantity (it has direction). The magnetic fields of two magnets (whether permanent or electromagnetic) will interact with one another. The force induced from that interaction (called torque) will depend on the shape and strength of the magnetic fields. The force between the two magnets will vary according to the shape of the magnetic fields. However, force is proportional to the magnetic field strength and inversely proportional to the square of the distance between them. The tesla ("T") is the standard unit for magnetic flux density – a measure of the strength of a magnetic field.

44. It is accepted that the Skilled Engineer knew that magnets were available at the Priority Date in any reasonable basic shape and that they could be magnetised in a variety of different ways. At the Priority Date it was CGK that the permanent magnets used in cochlear implants were thin, disk shaped and axially magnetised. The availability of axially and diametrically magnetised permanent magnets was CGK. Axially magnetised means their magnetic dipole was positioned in the axial direction (magnetised along the geometric axis) – shown below:

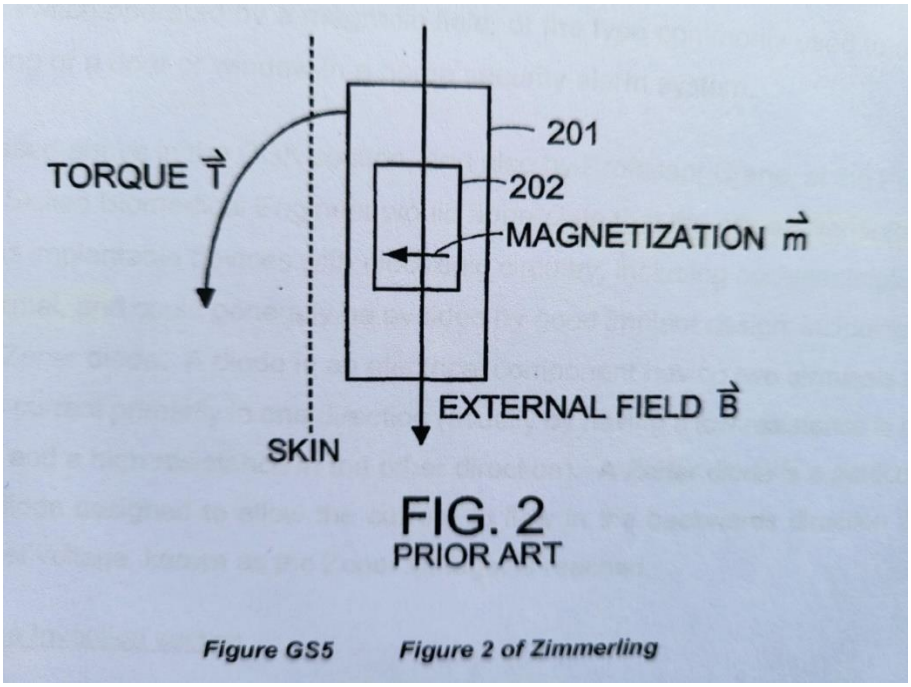


45. Diametrically magnetised permanent magnets (magnetised across their diameter) were also known in the CGK. This means the magnet is magnetised across its face as shown below. The diagram shows a disk shaped permanent magnet as an example only but the principle is of general application. With a spherical magnet whether it is considered diametric or axial would depend on its orientation.

46. Where a permanent magnet (other types of magnets were discussed but it was accepted permanent magnets were CGK) has an external magnetic field applied to it this interacts with the magnetic field produced by the permanent magnet.

47. Magnetic resonance imaging ("MRI") is a non-invasive technique in which magnetic fields are used to scan and image soft tissue for clinical use. MRI machines are effectively large electromagnets which produce a very significant magnetic field. These machines are classified by the strength of their static magnetic field (measured in tesla (T)). There are two main types of MRI machines in clinical use – closed bore and open bore systems. In a closed bore machine the static (main – there are others noted in the CGK at Annex B) magnetic field lines (B_0) are aligned from head to toe with a patient in the machine. In an open bore machine the field lines are vertical. This, main, static magnetic field normally remains turned on in a hospital.

48. At the Priority Date it was CGK that the internal disk axially magnetised permanent magnet of a cochlear implant would, when in close proximity to the external magnetic field of an MRI machine (for example when a patient gets an MRI scan) experience torque. Due to the strength of the MRI main magnetic field the magnitude of this torque when the magnetic dipole of the implanted axial permanent magnet is not aligned with this external field can cause the implanted magnet in CGK cochlear implants at the Priority Date to be dislocated, causing improper function of the device, and pain and potentially tissue damage to the patient. The below diagram is from the prior art document Zimmerling (and is also reproduced as Figure 2 of the Patent). I deal with this further below but note that this diagram shows the external MRI field B interacting with the magnetic field of the disk shaped axially magnetised permanent magnet as found in the CGK cochlear implant devices. The interaction of the field lines is shown to be perpendicular. The torque created by the interaction is shown by the arrow indicating the movement / rotation of the permanent magnet. The precise strength of the torque will depend on the component of the interaction of the respective magnetic fields - the extent to which they are aligned (or not). The permanent magnet pictured could for example be a disk-shaped implant magnet in a cochlear implant system. I do not believe these elements to be disputed by the parties and this is CGK. In any event, the submissions and cross examination on these points and elements depicted support these matters being CGK.



49. There was considerable debate in cross examination about whether it was CGK that a diametrically magnetised permanent magnet could rotate when interacting with an external magnetic field. Professor Suaning felt the skilled mechanical or electrical engineer would only have a couple of lectures on magnets and their properties. Professor Parker's view was that this was all basic science. Professor Suaning did not appear to readily accept this position on the rotation characteristics of these magnets initially and instead postulated a number of alternative ways of thinking about the issue. Some of his responses on this point in cross-examination appeared blinkered. At times he came across as trying to justify his positions rather than answering the questions in cross examination. In the end counsel for Med-El noted "*...in so far as a magnet has a polarity and you start exposing it to a field, the torques that are involved in them and therefore the possibility to use them for rotation and the like, that is part of the CGK".* In cross examination, it was accepted by Professor Suaning that using a diametric magnetic stirrer, its rotation caused by an external magnetic field, to stir mixtures in laboratories would also be CGK. In the end after extensive cross examination I do not believe Professor Suaning really disagrees with these positions and the understanding of the principles. To the extent he did then I rely on the submissions of Med-El and the evidence of Professor Parker to support my view that this is CGK. A key point that I will focus on below when I deal with obviousness is whether the skilled person would have thought of a CGK disk implant in this context at all.

Design considerations for cochlear implants

50. The primary driving force on design of a cochlear implant is to enable the user some level of hearing. By the Priority Date significant improvements had been made to the primary concerns on hearing performance, such as improving auditory performance and signal processing. The Skilled Engineer would have been familiar with the cochlear implant products from the three main producers: Cochlear, AB and Med-El at the Priority Date. By the early to mid-2000s advancements in improving these primary considerations had slowed.

51. By the Priority Date the designs of commercialised cochlear implant had effectively converged into a flat, thin and planar coil housing (containing the receiver coil, implanted permanent magnet and a silicon chip for sound processing) and the section containing the electronics which was also flat and of broadly similar depth. The two elements of the implant are angled to each other in order to conform to the curve of the skull (see below).

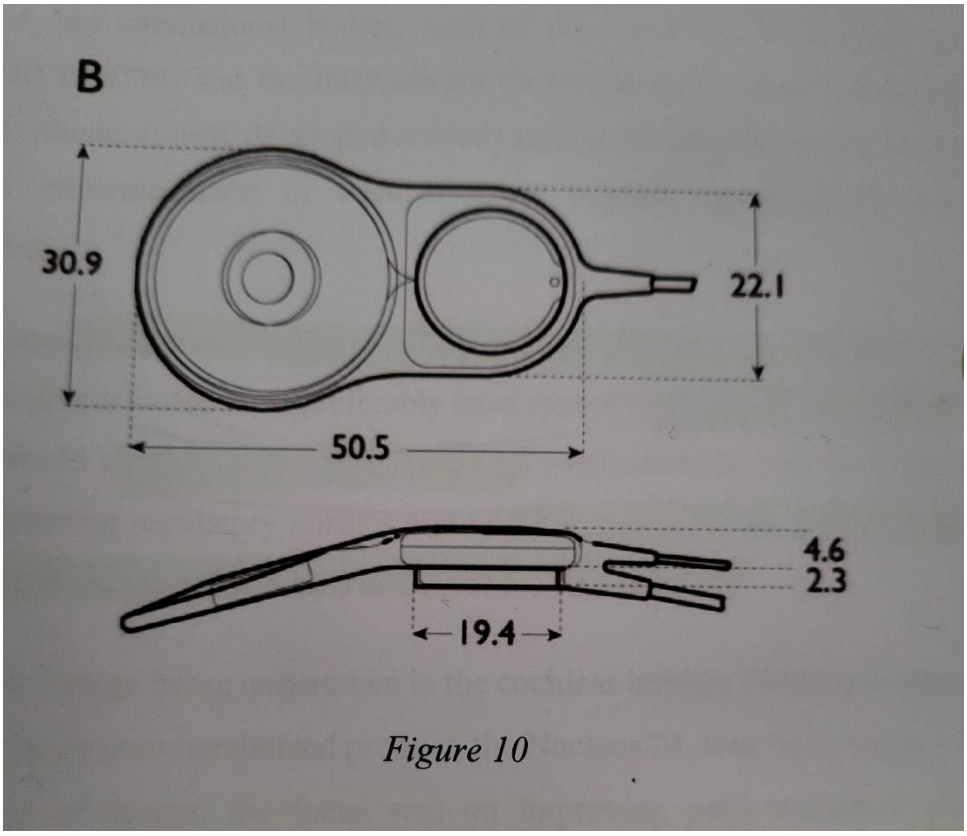


Figure 10

52. There were a number of secondary design drivers for manufacturers. For example, at and before the Priority Date the Skilled Team were aware of the compatibility issues between cochlear implants and MRI machines. Dealing with this issue was one of the design considerations at the Priority Date.

53. Other CGK design drivers for cochlear implants accepted by the experts in varying degrees at the Priority Date include: (i) ensuring a sufficiently low profile, (ii) securing the device adequately, and (iii) ensuring overall reliability of the implant. These had been achieved to some extent by the Priority Date but were still relevant.

54. As a medical device, regulatory approval for cochlear implants is necessary and would be a factor considered in any new design. The evidence on this supports the view that the Skilled Engineer would have considered the regulatory framework when considering design modifications to the implant device. Med-El's position appears to be that such regulatory concerns would not dissuade the Skilled Engineer from taking forward a magnet design based on Zimmerling. Balancing this with the positively stated position from AB I conclude that the regulatory impact would be a relevant CGK consideration to any new design and therefore the Skilled Person would try to minimise this impact to avoid regulatory hurdles where possible.

55. After cross-examination there was mainly agreement between the Skilled Clinicians on the need for reliability and concerns about complexity in new implant designs – particularly in relation to the number of internal moving parts. There was still some dispute on the evidence about how the Skilled Team would approach this issue but in the end this was more nuanced. Complexity in a new design may be acceptable with enough of a clinical benefit. In my judgment it was CGK that the Skilled Team would understand that in any developmental design that engineering and mechanical simplicity is preferable. This will be a trade-off balancing the potential benefits (clinical) of any complexity against its potential disadvantages.

56. The length of any regulatory approval process would depend on a number of factors depending on what is being changed in any existing regulated cochlear implant design. The experts disagreed on timing for the regulatory processes and its importance as a factor as a design consideration. Professor Parker had a better grasp of the issues, perhaps due to his greater personal experience. Again, in the end there was not much of substance on this point between the parties. It could be from months to about 4-5 years for a totally new product (Professor Parker) or 5-10 years (Professor Suaning). Understanding how this regulatory framework operated would have been CGK for the Skilled Team. Understanding how long it may take for a new incremental design is a more complex multifactorial question and is unlikely to be CGK.

Thickness of the implant

57. The evidence is fairly consistent on this point. In the lead up to the Priority Date there has been a successful drive towards thin implants. The thickest part of the device being the relevant thickness in this consideration. The main driving force for this was to minimise or remove the need for bone excavation – particularly as a high proportion of patients being implanted were children. Any move back to a thicker device requiring bone drilling would be resisted and need strong clinical reasoning.

58. The external part of the cochlear implant system included microphones, speech processing electronics, batteries and an RF coil to transmit sound and power to the implanted device and a permanent magnet. The magnet in the external component could be interchangeable so the strength of magnet (and the attractive forces with the internal magnet) could be adjusted – for example depending on skin thickness.

Issues of scanning someone with a cochlear implant

59. As set out at paragraph 36 of the Agreed Common General Knowledge there were a number of problems arising from internal magnets in cochlear implants being placed inside the magnetic field of an MRI machine – whether this is inside the machine or simply near it. There was general agreement on the evidence that demagnetisation and RF heating were not a significant concern. The issue of artifacts is more complex. First, the metal in the cochlear implant can impact on the magnetic field of the MRI and in turn distort the image. This will occur even if the internal permanent magnet has been removed, albeit to a lesser extent. Second, the internal magnet and the magnetic field it generates interferes with the magnetic field of the MRI and distorts the image further. These artifacts are limited in impact to an area around and in close proximity to the implant. The distortions do not impact the image in other parts of the head or the rest of the body of the patient. The main issue as recognised in the evidence is the torque. As noted above, torque is caused by the internal magnet's magnetic field creating a force upon interaction with the external MRI magnetic field such that the internal magnet moves to in order to try to align with the MRI field. This can cause discomfort, pain and may even (although the evidence indicates this is rare) damage the device. This was all CGK.

Prevalence of MRI Imaging

60. The number of MRI machines available for clinical use and also the use of these machines increased rapidly in the 1990s and 2000s. This rate slowed between 2005 and 2010. The Skilled Clinicians would be aware of and be concerned about the increasing number of circumstances they would encounter where a patient had a cochlear implant and an MRI scan was needed. The Skilled Team was aware that in the circumstances a better solution for cochlear implants would be needed. This is dealt with in more detail later in the Judgment. The Skilled Team understood the MRI issues with cochlear implants at least from the mid 2000's. It was also a perceived concern by Skilled Clinicians that the stronger 3T MRIs (which were relatively rare at the Priority Date) may be on their way to becoming more common. Professor Crane explained that none of the cochlear implants available at the Priority Date were approved for 3T machines (even with the internal magnet removed). Although it was not really a dispute in the end I am not convinced the evidence was sufficient to show any slowing of the rate of growth of MRI usage was CGK. The rest was CGK.

Removable magnets, head wrapping and not scanning

61. Professor Crane's uncontested evidence explains that Cochlear and AB had implant products on the market Pre-Priority Date that used silastic sleeves (soft silicon pouches) enabling surgeons to remove the internal magnet for an MRI scan and for it to be replaced afterwards. Professor Crane confirmed that Med-El devices were approved by regulators for use in MRI scanning in patients with the internal magnet in place on 0.2T MRI and 1.5T MRI. AB and Cochlear devices had regulatory approval for up to 1.5T machines after surgical removal of the internal magnet. Both clinical experts' evidence agrees that clinicians could also (and did) scan patients with cochlear implants without removing the internal magnet (or the implant device itself) before the Priority Date where clinically appropriate even where there was no regulatory approval. Devices with removable implant magnets had an advantage that in some instances it may otherwise have been required to remove the entire device by surgery. Perhaps unsurprisingly, the clinical experts agreed that surgery should be avoided where possible.

62. Where a patient was imaged using an MRI with the implant containing the internal magnet one of the options available was that the head could be tightly wrapped to reduce the risks of pain, discomfort and magnetic displacement. Such wrapping did not impact the artifact or demagnetisation issues. There is a dispute between the clinical experts on the degree to which clinicians were aware of and used head wrapping before the Priority Date. Professor Rubinstein believes the technique was well known and practised by clinicians well before the Priority Date. Professor Crane felt it was much more restricted in its use. The point is accepted as CGK in the Agreed CGK. I will rely on that.

63. These approaches to patients with cochlear implants were in the CGK. It is less clear on the evidence whether the Skilled Team would have been aware of all this regulatory information on the cochlear implant products being marketed. It is not clear this point is disputed. On balance, if disputed, and bearing in mind the relevant evidence on this, the limited nature of the main competition in the field and the importance and public nature of regulated medical devices I assess this information was also in the CGK.

THE PATENT

Overview

64. The Patent title is "MRI-SAFE DISK MAGNET FOR IMPLANTS". The Priority Date of the Patent is 23 April 2010. One of the named inventors, Martin Zimmerling, is also a named inventor of the prior art PCT application in this case. Paragraph [0001] describes the field of invention:

"*The present invention relates to implantable medical devices, and specifically, to magnetic elements in such devices that allow for magnetic resonance imaging*"

65. The Patent discusses prior art cochlear implant systems and focuses on the configuration of the external magnet with its conventional coin-shape and a north-south magnetic dipole that is perpendicular to the skin of the patient to produce external magnetic field lines and the internal magnet which is also coin-shape and has a north-south dipole that is perpendicular to the skin of the patient to produce internal magnetic field lines. The external transmitter housing is placed over the skin covering the internal receiver assembly and held in place by interaction between the internal magnetic field lines and the external magnetic field lines as described in [0002]. Fig.1 below depicts the set up described:

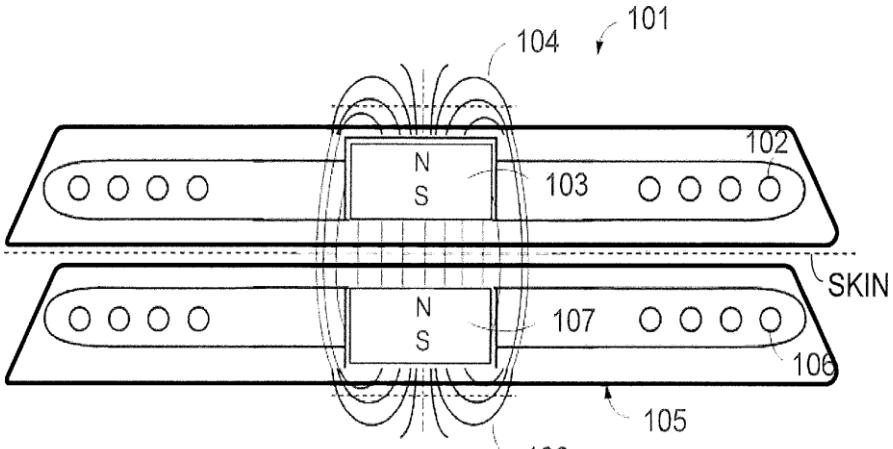


FIG. 1

66. A problem which arises for a patient who undergoes an MRI is described in [0003] explaining that interactions occur between the implant magnet and the applied external magnetic field for the MRI. Fig. 2 (as set out above at paragraph 48) is described demonstrating how the external magnetic field for the MRI creates a torque on the internal magnet. It explains some prior art issues for a patient with an implant undergoing an MRI. The torque may displace the internal magnet or the whole implant housing out of proper position and this could damage adjacent tissue in the patient. Additionally, it notes the MRI field interaction may reduce or remove the magnetisation of the implant magnet. It may also cause imaging artifacts in the MRI image and may induce voltages in the receiving coil, and hearing artifacts due to the interaction of the external magnetic field of the MRI with the implanted device.

67. Prior art is set out in paragraphs [0004] - [0006] including a design using non-conductive and conductive coatings on the implant housing to form non-shielding patterns to minimise interaction with the coil signal. Various prior art solutions are noted relating to the issues of interactions between the implant system and the MRI field – including using low field strength MRI, avoiding MRIs and surgical removal of the internal magnet. The prior art document Zimmerling is introduced in paragraph [0004]. It introduces how spherical implant magnets may assist without the need for surgery. It goes on to note various practical downsides to this solution.

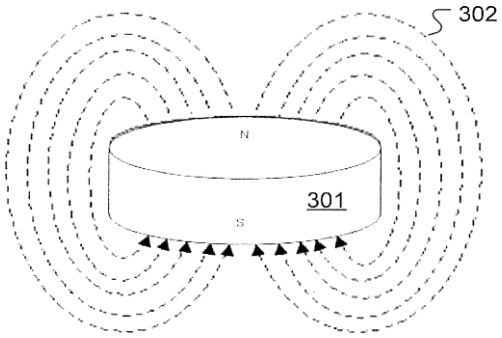
Summary of the Invention

68. The invention is summarised in paragraph [0007]. It is directed to an implant system generally and introduces the rotatable planar disk shape internal magnet and has a magnetic dipole parallel to the plane of the coil housing for transcutaneous magnetic interaction with a corresponding second attachment magnet. Paragraph [0011] explains this system may be a cochlear implant system.

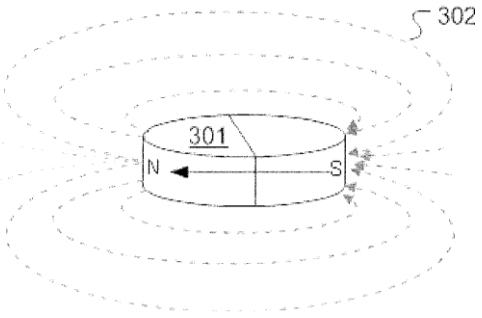
69. Paragraphs [0008]-[0009] describe further embodiments. Paragraph [0010] is important and sets out the invention in more detail:

> ***[0010]*** *The first attachment magnet may be adapted to rotate within the coil housing in response to an external magnetic field, and there may be a lubrication coating covering at least a portion of the first attachment magnet and reducing friction between the first attachment mag-net and the coil housing to promote the rotation of the first attachment magnet. At least one of the attachment magnets may have a planar disk shape, a rectangular beam shape, a cylindrical beam shape, or a cut away disk shape. Or at least one of the attachment magnets may comprise a pair of complementary cylindrical attach-ment magnets, which optionally may further include a magnetic flux guide connecting the pair of complemen-tary cylindrical attachment magnets.*

70. Paragraph [0012] provides a brief description of the figures. The Patent goes on from paragraph [0013] to set out detailed embodiments and explains the noted magnetic arrangements are directed to implant systems which are compatible with MRI systems. In paragraph [0013] the Patent sets out differences between the typical existing magnet arrangements for implant attachment magnets. Figures 3A-B are used to compare the perpendicular magnetic dipole arrangement typical in existing implant attachments magnets with the parallel magnetic dipole arrangement in an attachment magnet according to an embodiment of the Patent.



(A)



(B)

Fig. 3

71. The importance that such an arrangement has both the internal implant receiver attachment magnet and the external transmitter attachment magnet magnetised in the same orientation in the plane of the coil housing (i.e. parallel to the skin) is explained in paragraph [0014]. When this is done and the external coil housing is placed onto the patient's skin over the implant coil housing the Patent explains that the two attachment magnets turn around their axis so that the north and south poles of one attachment magnet are adjacent to the south and north poles of the other attachment magnet to maximise attractive magnetic forces.

72. Figures 4 A-B are described in paragraph [0015] and detail the features of an embodiment for a cochlear implant.

73. [0015] Figure 4A shows an elevated perspective view and Figure 4B shows a side cross-sectional view of a cochlear implant (labelled 400) having a planar coil housing (402) that contains a signal coil for transcutaneous communication of an implant communication signal. It goes on to describe the rest of the system. A first attachment magnet (401) is located within the plane of the coil housing (402) and rotatable therein (e.g., a planar disk shape) and has a magnetization direction with a magnetic dipole parallel to the plane of the coil housing (402). An external transmitter coil housing (405) has a corresponding second attachment magnet (404) with a similar magnetic dipole direction parallel to the plane of its coil housing (405) so that when placed on the skin of the recipient patient, their respective magnetic fields cause the two attachment magnets (401) and (404) to self-orient as described above to form a magnetic attraction connection between them. In specific embodiments, the coil housing (402) may have a titanium case with the attachment magnet 401 located outside the titanium case, for example, embedded in a silicone coil assembly.

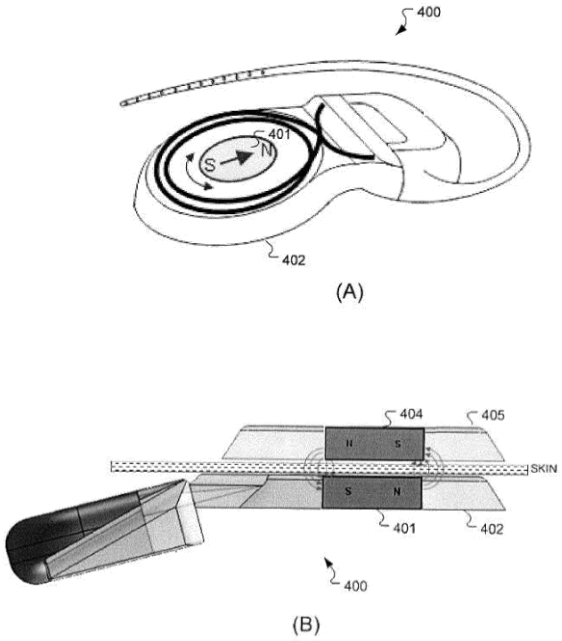


Fig. 4

74. The Patent goes on in paragraph [0016] to describe how the patient will use an embodiment when undergoing an MRI. It recognises that as the patient is brought into the MRI scanner, the attachment magnet may have a component of its magnetization which is perpendicular to the external magnetic field of the scanner. The paragraph refers to how this will result in the attachment magnet turning around on its axis to align the magnetization direction of its magnetic dipole with the static field of the MR scanner. The paragraph refers to this effect occurring for both MRI scanners with closed and open bores. Having explained this paragraph [0017] explains in more detail what happens when the attachment magnet cannot completely align with the external static magnetic field. The paragraph provides calculations and explanation that there would be a reduction in torque and low risk of weakening of the attachment magnet. This is shown in Figures 7 A-B.

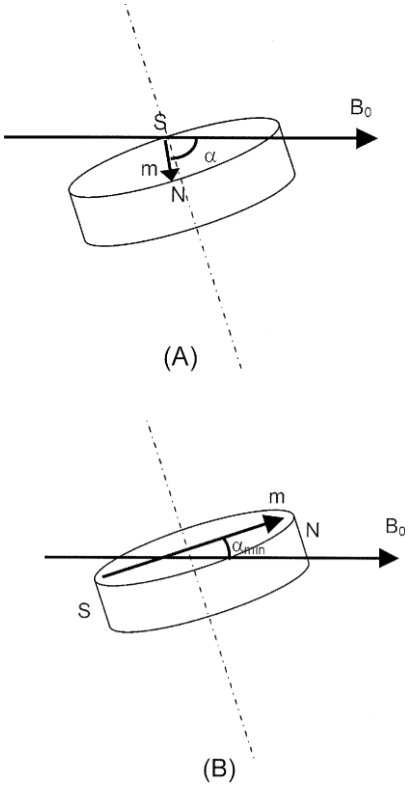


Fig. 7

75. Paragraphs [0018]-[0024] describe various embodiments illustrated by the figures. Paragraphs [0022]-[0025] go through different shapes of and set up for the attachment magnet. Paragraph [0022] notes that although the embodiments described in the earlier paragraphs are disk-shaped (cylindrical) any shape could be implemented so long as the magnetisation is parallel to the coil housing and the skin. It is explained that as well as attachment magnets that have a magnetization axis that is perpendicular to the rotational axis of the disk as set out in the earlier embodiments, in other embodiments the attachment magnets may more generally have a magnetization axis that is not parallel to the rotational axis. Paragraph [0023] considers the use of multiple attachment magnets. Paragraph [0025] refers to optimising the external attachment magnet and in the final sentence of that paragraph "*Some embodiments may have similar implant attachment magnet arrangements*."

76. Paragraph [0026] importantly deals with known spherical magnet designs and contrasts this with the Patent:

> *[0026] Non-spherical shaped magnets with a magnet field oriented in the plane of the coil housing (i.e., parallel to the skin) basically the same advantages with regards to MR systems as with spherical magnet designs, with the main limitation being that the disk-shape attachment magnet design described above allows for rotation of the magnet in only one plane. Still when the implant is placed inside the body in a sagittal plane orientation (as with a hearing implant) and with a standard MRI examination position of the patient (i.e. in supine position with the head kept straight), the implant attachment magnet can align quite well with the static magnetic field both in closed MR scanners (with a horizontal main magnetic field) as well as is open MR scanners (with the main magnetic field in vertical direction).*

77. Paragraph [0027] emphasises the benefits of the embodiments of the invention which presents attachment magnets with a slim profile and which is safe for MRI field strengths of up to and beyond 3 tesla without the need for surgical removal of the implant magnet (but that embodiments can be adapted to allow for surgical removal if desired to reduce MRI artifacts). Paragraph [0028] continues to explain the benefits of the invention and contrasts the spherical design attachment magnet with the flat bottom of the Patent attachment magnet embodiment which means there is no need to drill a recess into the bone during implantation of the device – which makes this especially suited to young children. Finally, the Patent states MRI imaging artifacts may be smaller due to the different magnetisation direction (closer alignment of the different magnetic fields). Paragraph [0028] explains that embodiments with attractive forces at both poles will require a higher shear force between the external and internal attachment magnets in the direction of magnetisation axis of the two magnets (than a conventional disk magnet with axial magnetisation).

78. Paragraph [0029] discusses advantages of embodiments of the invention having attractive forces over both poles compared to conventional disk magnets and the benefits this provides – for example in shear force. Paragraph [0030] discusses some further issues encountered depending on the patient position that torque could still remain high with the invention.

CLAIM CONSTRUCTION AND AMENDMENTS

79. There was no dispute between the parties on the law of claim construction. This is set out conveniently by Jacob LJ in *Virgin Atlantic Airways Ltd v Premium Aircraft Interiors Ltd [2009] EWCA Civ 1062* at paragraph [5] (set out below) and as applied by Floyd LJ at paragraphs [18] and [19] *in Saab Seaeye Limited v Atlas Elektronik GmbH* [2017] EWCA Civ 2175.

"*The task for the court is to determine what the person skilled in the art would have understood the patentee to have been using the language of the claim to mean. The principles were summarised by Jacob LJ in Mayne Pharma v Pharmacia Italia [2005] EWCA Civ 137 and refined by Pumfrey J in Halliburton v Smith International [2005] EWHC 1623 (Pat) following their general approval by the House of Lords in Kirin-Amgen v Hoechst Marion Roussel [2005] RPC 9. An abbreviated version of them is as follows:*

(i) The first overarching principle is that contained in Article 69 of the European Patent Convention;

(ii) Article 69 says that the extent of protection is determined by the claims. It goes on to say that the description and drawings shall be used to interpret the claims. In short the claims are to be construed in context.

(iii) It follows that the claims are to be construed purposively—the inventor's purpose being ascertained from the description and drawings.

(iv) It further follows that the claims must not be construed as if they stood alone—the drawings and description only being used to resolve any ambiguity. Purpose is vital to the construction of claims.

(v) When ascertaining the inventor's purpose, it must be remembered that he may have several purposes depending on the level of generality of his invention. Typically, for instance, an inventor may have one, generally more than one, specific embodiment as well as a generalised concept. But there is no presumption that the patentee necessarily intended the widest possible meaning consistent with his purpose be given to the words that he used: purpose and meaning are different.

(vi) Thus purpose is not the be-all and end-all. One is still at the end of the day concerned with the meaning of the language used. Hence the other extreme of the Protocol—a mere guideline—is also ruled out by Article 69 itself. It is the terms of the claims which delineate the patentee's territory.

(vii) It follows that if the patentee has included what is obviously a deliberate limitation in his claims, it must have a meaning. One cannot disregard obviously intentional elements.

(viii) It also follows that where a patentee has used a word or phrase which, acontextually, might have a particular meaning (narrow or wide) it does not necessarily have that meaning in context.

(ix) It further follows that there is no general "doctrine of equivalents."

(x) On the other hand purposive construction can lead to the conclusion that a technically trivial or minor difference between an element of a claim and the corresponding element of the alleged infringement nonetheless falls within the meaning of the element when read purposively. This is not because there is a doctrine of equivalents: it is because that is the fair way to read the claim in context.

(xi) Finally purposive construction leads one to eschew the kind of meticulous verbal analysis which lawyers are too often tempted by their training to indulge."

80. This must be read in the context of the Supreme Court's decision in *Actavis UK Limited and others v Eli Lilly and Company [2017] UKSC 48*. I will first consider the 'normal' approach to construction of the Patent on a 'purposive construction' as approved in *Generics (UK) Ltd v Yeda Research and Development Co Ltd [2017] EWHC 2629 (Pat) [138]* and *Icescape Ltd v Ice-World International BV [2018] EWCA Civ 2219 at [60]*. I will then consider equivalents where necessary.

81. The claims in issue are product claims 1, 10 and 14 (as proposed to be unconditionally amended). I use the renumbered format in this Judgment. Annex A contains the proposed amended claim set subject to Med-El's application dated 7 October 2021. For convenience, the claims set out below broken down into integers and labelled for the purpose of the analysis only.

82. Aspects of the interpretation of the claims were disputed by the parties. I set out my conclusions on these points where relevant below. The expert evidence has assisted me in understanding the technology. However, it is the court's task to determine what the person skilled in the art would have understood the patentee to have been using the language of the claim to mean. In this context understanding the nature of the alleged infringement is useful to confine the questions to be considered on construction. However, as usual, once it has been identified where the 'shoe pinches' the correct approach is to approach construction of the Patent and claims absent knowledge of the alleged infringement.

Claim 1

(a) An implant system for a recipient patient, said implant system comprising:

(b) a planar implant coil housing (402) for implanting under the skin of said patient

(i) containing a receiver coil for transcutaneous communication of an implant communication signal, and

(ii) containing a first attachment magnet (401) within the plane of the implant coil housing (402),

(c) an external coil housing (405) for placement on the skin of the patient over said implant coil housing (402),

(i) said external coil housing (405) comprising a second attachment magnet (404);

characterised in that

(d) said first attachment magnet (401)

(i) is rotatable in said plane of the implant coil housing (402), and

(ii) has a magnetic dipole parallel to the plane of the implant coil housing (402) for transcutaneous magnetic interaction with said second attachment magnet (404) allowing to form a magnetic attraction connection between them in which the magnetic dipole of said first attachment magnet (401) is parallel to said plane of the implant coil housing (402).

83. Other than the meaning of 'first attachment magnet' there is no dispute about the labelled sections of claim 1 (a), (b) (i), (ii), (c) (i). It is normal that claims can start with and general description prior to the phrase 'characterised in'. After which, the features listed are often more important.

"*For*"

84. Normally, the use of the language "for" in a claim means is it "suitable for" a particular function, and no more. The precise meaning here will depend on the context and purposive construction.

"*Comprises*"

85. The normal meaning of these words in this context are that the claim must include the feature which follows but can include other features.

(a) (ii) "*...first attachment magnet...*"

86. AB contends in its submissions and Statement of Case on Non-infringement that the Skilled Engineer would interpret the first attachment magnet, here the implant magnet, to be a single (monolithic or homogeneous) magnet

with a fixed direction and magnitude of magnetic dipole and not a plurality of magnets capable of separate or independent movement. Professor Parker considers (recognising his role here is to assist with technical meanings/functions) that this implant magnet must be strong enough in its magnetic field to be able to hold the external second attachment magnet in place.

87. In aid of this construction AB relies on the undisputed point that the first attachment magnet will have a "magnetic dipole". The reason Professor Parker says this is relevant is "*... the magnetic dipole is a vector quantity which describes the orientation and strength of a magnetic field. For a permanent magnet (subject to becoming de- or re-magnetised), the strength of the dipole is essentially a fixed value as is its orientation (relative to the physical orientation of the magnetic material).*"

88. A permanent magnet, such as the one envisaged here, has a magnetic moment which describes the strength and orientation of the magnetic field of the magnet. This is called the magnetic dipole. It is a vector quantity (it has direction). The argument is that the reference in the claims to this dipole would be interpreted as a fixed dipole. Professor Suaning's view on the technical meaning in context was the same as Professor Parker's that a magnet will have its own individual dipole. However, the experts diverged on whether the technical meaning in this context was therefore restricted to a single magnet or could encompass more than one magnet. Professor Suaning's view was that multiple magnets in close vicinity would behave as a single magnet. It was common ground that the interacting fields (dipoles) of magnets can be summed (the magnetic moments and their vectors). The Patent teaches that the external magnet can be multiple magnets at paragraphs [0010], [0023] and figures 11 and dependent claim 4.

89. AB say if the construction is more than one magnet there would be complex considerations (for example, how closely packed the magnets are to each other) that would not arise on its more simple construction. Med-El's position is that the Patent expressly teaches multiple external magnets and therefore the external magnet cannot be limited to a single magnet. The claims use the same language to describe the "*first attachment magnet*" and the" *second attachment magnet"* and it would therefore be wrong to construe the meaning of the 'attachment magnet' to have different meanings in this context. They also rely on Paragraphs [0010], [0018] and [0025] of the Patent as teaching in the description that contemplates both attachment magnets being multiple magnets.

90. The meaning of *first attachment magnet* needs be read with the inventor's purpose in the context of the Patent specification and figures. In my view the purpose is to provide an implant system that allows the external attachment to fit securely and comfortably over the internal attachment by way of a magnetic fixing. The implant magnet has other functions – in particular to rotate to minimise interaction with external magnetic fields – for example in an MRI. This purpose is entirely supported by the description. The parties also accept that when viewed functionally, whether there are one of two or more magnets inside the implant magnet housing, this would not change the function of the implant magnet. The individual magnet dipoles would merge into one net dipole. It may be technically precise to say a magnet's dipole can only be defined as intrinsically linked to that magnet but that does not matter in this context.

91. I prefer the evidence and submissions of Med-El. To limit the role here to a single magnet in the invention would in this context be artificial and an arbitrary limitation on their purpose and function. For the reasons noted and in the context of the claims I construe this integer such that the first and/or second attachment magnets can comprise multiple magnets.

(d) "*said first attachment magnet* (401)"

92. This is the internal magnet.

(d) (i) "*is rotatable in said plane of the implant coil housing*" ("rotation integer") and (d) (ii) "*has a magnetic dipole parallel to the plane of the implant coil housing"* ("dipole integer")

93. I will consider these integers at the same time as some of the evidence and arguments are interlinked. In considering the construction of these integers it is important to properly assess the context – that can mean in the context of the whole patent when viewed by the skilled person and their understanding of the CGK.

94. These integers are disputed by the parties. AB argues the rotation integer should be interpreted to mean the implant (internal) magnet is rotatable only in the plane of the implant coil housing. Med-El's position is that adding in such a limitation would be amending the claims rather than construing them and this is not permitted.

95. AB argues that the below elements of the claim integers need to be considered in combination to arrive at its construction (AB emphasis added).

(b) (ii) containing ***a first attachment magnet*** ***within the plane of the implant coil housing****,*

(d)(i) ***is rotatable in said plane of the implant coil housing*** *and*

(d) (ii) ***has a magnetic dipole parallel to the plane of the implant coil housing for transcutaneous magnetic interaction with said second attachment magnet***

(d) (ii) ***allowing to form a magnetic attraction connection between them in which the magnetic dipole of said first attachment magnet (401) is parallel to said plane of the implant coil housing***

96. AB submits the correct construction of the combination of these integers requires that the internal magnet only be (capable of) rotating parallel to the plane of the coil housing. It is not disputed that the point (d)(ii) above means that the first attachment magnet (implant/internal magnet) has a dipole parallel to the plane of the implant coil housing when it is magnetically connected to the second attachment magnet (the external magnet). Med-El argues that when the first attachment magnet (internal) is not so connected then the claim is indifferent as to what happens to the dipole (and thereby the plane of rotation) of the internal magnet.

97. The influence on the construction of the part of integer (d) (ii) after the 'for' is also disputed. On its own, and before I discuss my views on the broader context, this seems to me a straightforward use of standard language in a claim that a skilled person would understand. The product described preceding the 'for' statement is 'suitable for' the purpose that follows the statement. It is not disputed the system noted proceeding the 'for' is suitable for *"transcutaneous magnetic interaction with said second attachment magnet allowing to form a magnetic attraction connection between them in which the magnetic dipole of said first attachment magnet is parallel to said plane of the implant coil housing.".* In my view it does not by implication then mean that the preceding phrase "*has a magnetic dipole parallel to the plane of the implant coil housing"* is only operative in conjunction with the specific situation following the 'for' in the integer.

98. The embodiments in the Patent do not on their own limit the construction of the claim more generally. However, the embodiments are part of the context of the Patent. All the embodiments in the Patent show the internal magnet as restricted to being rotatable only in the implant housing parallel to the plane of the implant coil – not in other orientations. Med-El are correct in saying the Patent teaches that other shapes (than the disk-magnet) can be used in the implant. This is where context is important. The Skilled Person would understand this Patent is about providing a rotating implant magnet that aligns with an external magnetic field and reduces torque (in an external magnetic field / MRI) to achieve the useful configuration of using a slim profile and contrasting this position with the prior art. Relevant prior art (Zimmerling) is set out at the start of the Patent and the benefits that flow from the differences (see for example Patent [0027] and [0028]). Paragraph [0026] explains how the Patent is better than the prior art spherical shaped magnets " *with the main limitation being that the disk shape attachment magnet design described above allows for rotation of the magnet in only one plane*". It achieves this largely "*due to the different magnetization direction"* of the implant magnet. This is referring to the magnetic dipole of the implant magnet being parallel to the plane of the coil housing. In this context [0016] teaches that what rotates the implant magnet to align with the external field is the component of its magnetization which is perpendicular to the external magnetic field. Paragraph [0017] provides an explanation of how the magnetic field of the implant magnet and the external field in MRIs interact at clinically relevant angles to minimise the torque (it was also accepted these calculations are something within the toolkit of the Skilled Person). For these integers the Patent therefore teaches a useful compromise of the implant magnet rotating in the plane of the coil housing which has sufficient alignment with the external magnetic field with a dipole parallel to the coil housing that keeps the implant thin.

99. By following the teaching this compromise with this configuration reduces the torque enough for the patient to avoid the problems with an MRI. The Skilled Person would understand and factor in the Patent's teaching about improvements (thin housing/better magnetic attachment) over the noted prior art magnetic spheres which could rotate in any direction and therefore have their magnetisation in any direction and achieve a full alignment with the external magnetic field but with a bulky profile and potential issues with magnetic volume for external attachment. In my view for these reasons the interpretation of the rotation and dipole integers is to have a restriction of the rotation of the implant magnet to the plane of the implant coil housing and the need for the magnetisation of the implant magnet to be in the same plane are important aspects of the teaching of the Patent. The natural consequence of this construction is a good level of consistency between the description and the claim. It also provides the geometrical alignment with the external magnet as required in the final integer of the claim. This is not, as argued by Med-El, an impermissible construction that 'amends' the claim rather a standard approach to construing the meaning of the claim language with a purposive construction.

100. As a final comment, when considering the purpose of the invention it is important that in coming to this construction the magnetisation here should not be construed 'mathematically' as a point in space– i.e. when considering terms such as 'plane' and 'parallel' the real practical circumstances must be considered. The implant magnet does not have 'straight lines' for its magnetic field. It radiates from the physical magnets and has vector components in any direction. Therefore 'parallel' in context and bearing in mind the overall function of the magnetic field here it should be understood to mean substantially parallel.

101. I considered the argument of AB on these integers which dealt with the thought experiment on Figure 11 and separate axial magnets and why the invention would not work if construed according to Med-El's instruction. I did not find the analysis helpful and it seemed too far removed a consideration in context for the skilled person in looking at the construction.

102. There was discussion about how the scope of claim 10 could impact on the construction of claim 1. The argument being it could encompass both external diametric and axial magnets. Figure 11 of the Patent shows two external axial magnets for attachment. AB argue claim 1 must therefore be broader. As I have considered above the function of such multiple external magnets is to behave as a composite attachment magnet. Claim 10 states expressly that the external magnet is "magnetised parallel to the skin". The overall net dipole of the two axial magnets in the Figure 11 is consistent and should achieve this function. This goes to the interpretation that the specification teaches to exclude any magnet which rotates out of the plane housing. Again, although the logic may be persuasive, on my finding in context, the circumstances are not likely to present as indicated. In my view the more appropriate construction is that all the external attachment magnets require a dipole parallel to the skin when attached.

103. There is no comment from the parties that the construction of the amended claim 14 has any impact on the construction of the claims upon which it is dependent. For this case I only need to consider claim 14 as amended as dependent on claim 1 and claim 10 (which in turn is dependent on claim 1). Claim 14 has two expressed limitations added to the claims upon which it is dependent; (i) that the first attachment magnet (internal) is non-spherical, and (ii) that the implant coil housing has a flat bottom. Further, the final two integers in (c) (i) and (ii) are in a form which is a construction where the functional requirements in integer (b)(i), (ii) are always required for the implant system to be suitable for the purposes in (c) (i), (ii). I am not aware that this construction is disputed or causes any difficulty.

AMENDMENT

104. Med-El made an application to amend the Patent under s.75 PA 1977 on 7 October 2021 ("Amendment Application"). Mr Justice Mellor ordered that this Amendment Application would be heard at the trial of this action. The proposed amendments (to claims 11, 13 (deletion), 15 (now claim 14) have been reviewed by the Comptroller of Patents. AB filed a Statement of Objections but at trial did not oppose these amendments to the claims. They did maintain that the amendments would not cure their case on invalidity. I have considered the documents relating to the proposed Amendments and the Comptroller's response which considered the proposed amendments in the context of clarity, added matter and support. The Comptroller found the proposed amended claims *prima facie* allowable in so far as the amendments to the claim clearly define the subject matter for which protection is sought and are supported by the description.

105. The Comptroller also noted:

> "*It is considered that the skilled person would understand from the application as filed – and particularly from the passages identified above – that the invention generally extends to any magnet shape that has a magnetic dipole arranged parallel to the plane of the coil housing and that allows for the rotation of the magnet in the coil housing. This being regarded as the essential features of the invention, allowing for the improved suitability of the device for use during MRI examination of a user thereof."*

106. The law on lack of clarity/sufficiency and disclosure of additional matter under sections 76(3) and s.14(5) of the Patents Act 1977 is not in dispute. The law on amendments including added matter is usefully set out in *Bonzel v Intervention* [1991] RPC 553 [574] and *Conversant Wireless Licensing Sarl v Huawei Technologies Ltd* [2020] EWCA Civ 1292. Considering the proposed amendments in the context of the application as filed and the Patent as sought to be amended and bearing in mind the helpful report of the Comptroller I conclude the skilled person would not learn anything from the Patent as amended that they would not learn from the application as filed. Claims 11 and 14 do not add matter or extend the scope of protection.

107. I also conclude there is support for the proposed amendments to claims 11 and 14 and no issues of clarity/sufficiency with respect to these amendments to claims 11 and 14. The deletion of claim 13 does not affect the clarity of the remaining claims.

108. The Patent may therefore be amended in accordance with the unconditional amendments attached to the Statement of Grounds for Amendment dated 7 October 2021 and attached at Annex A.

INFRINGEMENT

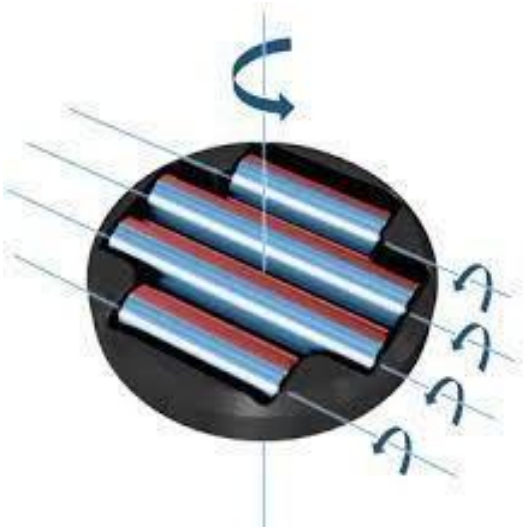
109. This case started as a request for a declaration of non-infringement by AB in relation to its HiRes Ultra 3D cochlear implant system – the implant and external headpiece ("**Ultra 3D**"). During the pleading stage Med-El counterclaimed under s.60(1) of the Patents Act 1977 for infringement of the Ultra 3D Device finally settling on claims 1, 10 and 14 (as amended) and also s.60(2) of the Patents Act 1977 for infringement of: (1) replacement headpieces compatible with the Ultra 3D cochlear implant system, and (2) replacement headpiece magnets compatible with headpieces of the Ultra 3D cochlear implant system.

110. A PPD was provided by AB and further information was contained in a Part 18 exchange (which in turn cross refers to an AB patent EP 3389771 ("**771**")) and Statement of Case on Non-infringement. I set out below a summary of some of the main parts from the documents describing the product.

Ultra 3D

111. The Ultra 3D product is a cochlear implant device suitable for use in human patients. It comprises two main parts – the implantable part which is surgically implanted subcutaneously between the patient's skull and the skin by the ear and the external part which is attached to the patient's head when in use. The distal end of the electrode is introduced into the cochlea to stimulate the auditory nerve. A picture of the Ultra 3D is below:

112. Paragraphs 4-10 of the PPD refer to the implant components. The receiving coil is set up to receive electromagnetic signals which are transmitted transcutaneously from the external component of the Ultra 3D. The received signals are processed and conveyed to the electrodes which provide electrical stimulation to the auditory nerve. The housing is non-magnetic titanium and accommodates a non-magnetic frame which is rotatable relative to the housing with its rotation axis perpendicular to the plane which is parallel to the base of the magnet assembly housing. An arrangement of four separate cylindrical permanent magnets are located in this frame. The longitudinal axes of each magnet is within the plane which is parallel to the base of the magnet assembly housing. The diagram below shows these cylinder magnets in the housing and the different axis of rotation.



113. Each of the magnets is surrounded by a sleeve composed of PEEK polymer and is rotatable with its respective sleeve about its longitudinal axis. Each of these magnets is diametrically magnetised such that the magnetic dipole of each magnet is perpendicular to the longitudinal axis of the magnet (the red and blue halves of the cylinders in the picture are the north and south poles of the magnet). As can be seen in the diagram the entire magnet assembly housing can rotate in the plane of the housing and separately each individual cylinder magnet is able to rotate about its longitudinal axis. Where a strong enough external magnetic field is experienced this will overcome the mutual attraction of the individual cylindrical magnets and the individual cylinder magnets can rotate (depending on the strength of the interaction) to try to align with the external field. Professor Parker noted it would be a mistake to underestimate the mutual attraction of these cylinders. AB confirmed the cylinder magnets align with one another in the absence of a relatively strong external magnetic field. AB accepted in its submissions that in relation to the housing containing the internal cylinder magnets; "*...In the MRI field, which actually is what the patent is all about, at its heart, our product can move in two planes or rotation...*", "*...that is right, in the orientation that the patent does, that is right, because we have our moving housing, but we also have the cylinders that can move in the MRI field.".*

114. The individual magnetic dipole moments of the cylindrical magnets are not constrained to always be parallel to the plane of the magnetic assembly housing. The evidence on this (I deal with the relevant Tysome and Eerkens papers below) is quite qualitative. It is effectively what the experts would expect to happen. There is not really any dispute about the principle of the rotating action of the cylinder magnets in a relatively strong magnetic field. There is a dispute about any more empirical/quantitative findings on the subject. Additionally, the magnet assembly housing (the non-magnetic titanium frame containing the cylindrical magnets) will rotate about its axis of rotation in the presence of the external magnetic field to also try to align the magnetic dipole moment optimally.

115. Paragraphs 11-17 deal with the external component. The external part of the Ultra 3D device contains the Naida CI Q Series sound processor and accessories (see below):

116. This headpiece contains a microphone, permanent magnet and a transmitter coil. The external magnet is diametrically magnetised. The headpiece is placed over the patients' skin when used such that the transcutaneous magnetic attraction is made to hold the headpiece in place with the internal magnet assembly. <u>At the point the headpiece is attached its external magnet is substantially parallel to the base of the housing. The orientation of</u>

the magnetic dipoles of the internal cylinder magnets align approximately with local direction of the magnetic field of the external permanent magnet. This interaction competes with the magnetic interaction between the neighboring cylinder magnets. AB's Response ("**Response**") to Med-El's Part 18 request ("**Request")** dated 13 October 2021 provides further details to the PPD. AB confirms (with the qualification it is only a concession for these proceedings) that 'at rest' ("**At-Rest Alignment"**) i.e. with no external magnetic fields influencing the internal magnet's alignment of these internal cylinder magnets is "*...substantially as suggested in fig.2 of the PPD (above) and as described in [0018]* [see below] *of the 771 Patent and as shown in the lower half of fig.9 of the 771 Patent*.". AB also explains in this Response that (once again with the qualification the concession is only for the purpose of these proceedings) during magnetic connection of the internal Ultra 3D system with the external component (and by reference to paragraph 14 of the PPD and my summary on this point – underlined above) the alignment of the cylindrical magnets ("**In-use Alignment**") "*...is substantially as suggested in fig.2 of the PPD and as described in [0019]* [see below] *of the 771 patent and as shown in the lower half of fig.9 of the 771 Patent.*". I understand this to mean the cylinder magnets in the implant remain substantially in the positions shown in fig.9 (below) in these At Rest and In-Use positions. The interactions between the cylinder magnets apparently are strong enough that when they are connecting to and connected with the external component and magnet the interaction with that external field does not substantially change the orientation of these cylinder magnets. This internal interaction between the cylinder magnets aligns the North-South pole of the different cylinder magnets such that they are parallel to the plane of the frame. The impact of any stronger external magnetic field was a matter of debate which I deal with further as relevant below. For completeness, I have set out the noted paragraphs from the 771 patent and fig.9. I note that although the fig.9 representation shows cylinder magnets with 'flattened' tops and bottoms, it is not disputed that the cylinder magnets in the Ultra 3D are fully cylindrical in shape.

> ***[0018]*** *Given the ability of each magnet 110 to freely rotate about its longitudinal axis A2, the magnets 110 align with one another in the N-S direction in the absence of a relatively strong external magnetic field (e.g., the MRI magnetic field discussed above), and the at rest N-S orientation of the magnets 110 will be perpendicular to the central axis A1, as is illustrated in FIGS. 9 and 14 . So oriented, the magnetic fields of the diametrically magnetised magnets 110 are aligned with the magnetic field of the diametrically magnetised disk-shaped positioning magnet 410.*
>
> ***[0019]*** *It should also be noted here that the magnetic field of the positioning magnet 410 is not strong enough to cause the magnets 110 to rotate out of the illustrated at rest N-S orientation. Although the frame 108 will rotate as necessary, the magnets 110 will remain in the N-S orientation illustrated in FIG. 9 and will continue to function as a magnetic unit in the presence of a headpiece magnet. As a result, when the associated headpiece is initially misaligned in the manner illustrated in FIG. 9A , the magnetic retention force will be strong enough to pull the headpiece 400 (and its antenna) into alignment over the implant 200 (and its antenna).*

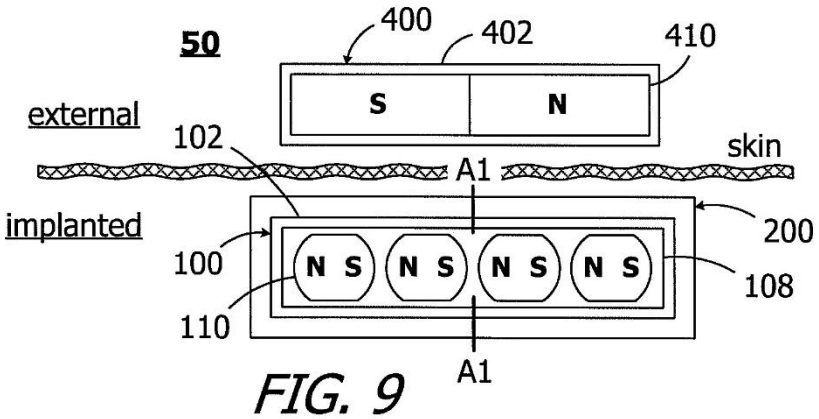
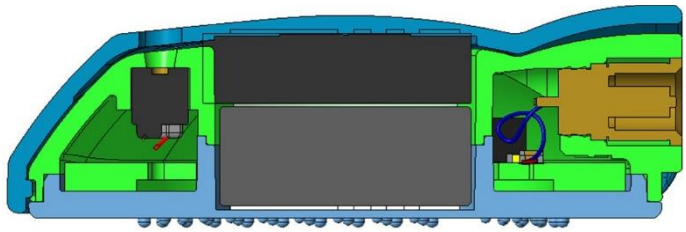
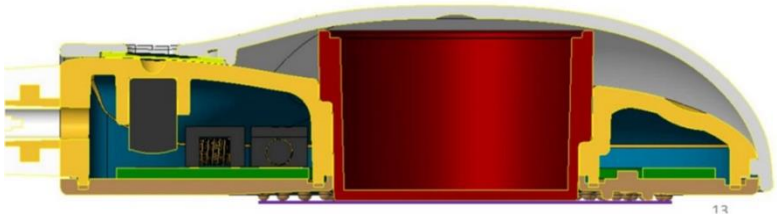


FIG. 9

117. The Response from AB also provides information on the shape and configuration of the external magnet and its position within the external part of the Ultra 3D system. The Response provides details on specific headsets. For current purposes I set out below the two images provided for the different designs. AB explains these headpieces can be "*...fitted with magnets of different sizes, each having the same diameter but of different axial length. All such magnets are fitted into their respective headpiece in the same orientation illustrated in the [below] diagrams, and the magnetic dipole of the external magnet is orientated diametricall*y."





118. The external and internal coils lie substantially parallel on top of each other (separated by the skin). The PPD goes on to note in paragraph 17 a number of headpieces which could be used with the Ultra 3D and that all are materially the same as this description.

119. Med-El's counsel provides in their closing a convenient summary of the main issues on infringement described as:

(i) the CGK axial external disk magnet has been replaced by a diametric external disk magnet, and,

(ii) the CGK axial internal magnetic disk has been replaced with a rotatable magnet assembly.

The Law

120. Section 60 of the Patents Act 1977 contains the relevant statutory provisions. The Supreme Court decision *Actavis v Eli Lilly* [2017] UKSC 48 sets out how to assess infringement. The Court in *Actavis* clarified that the scope of the claims of a patent need not necessarily be co-extensive with the construction of the claim. The introduction of a new form of doctrine of equivalents creates a further step in the process of assessing the scope of a claim. Finally, the result of this approach is that the previous principle applied - that a claim should be interpreted in the same manner, and had the same scope for the purposes of considering both novelty and infringement – is unclear. Lord Justice Birss referred to this issue in his *obiter* assessment of the matter in *Facebook v Voxer* [2021] EWHC 1377 (Pat) at [209] - [217]. The parties confirmed this '*Formstein*' defence was not being raised in this case.

121. In *Icescape Limited v Ice-World International BV & Ors* [2017] EWHC 42 (Pat) Lord Kitchin (sitting in the Court of Appeal) having reviewed the law on infringement and applying the *Actavis* decision considered at [66] the two main steps on how to approach the process for assessing infringement. The first such step is to construe the claims purposively to assess their normal interpretation. The second step is to assess if, despite there being no infringement on this normal interpretation there may still be infringement as any differences are immaterial.

> 66. "*The whole approach to interpretation and scope of protection therefore involves the following steps, considered through the eyes of the notional addressee:*
>
> *(i) Does the variant infringe any of the claims as a matter of normal interpretation?*
>
> *(ii) If not, does the variant nevertheless infringe because it varies from the invention in a way or ways which is or are immaterial? This is to be determined by asking these three questions:*

a) *Notwithstanding that it is not within the literal (that is to say, I interpolate, normal) meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, i.e. the inventive concept revealed by the patent?*

b) *Would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention?*

c) *Would such a reader of the patent have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?*"

122. The approach to assessment of the doctrine of equivalents set out above at [66 (ii) (a), (b), and (c)] was helpfully re-stated and explained by Lord Kitchin in *Icecape*.

123. In order to assess any material difference between an allegedly infringing product and the invention, the court should focus on the 'inventive concept' as described in *Icescape* [62]. Referred to as the first *Improver* question.

124. Lord Kitchin reviewed at [63] how the second recast *Improver* question should be approached and in [64] set out below the third recast Improver question:

> 64. *The third Improver question, namely whether the notional addressee would have understood from the language of the claim that the patentee intended that strict compliance with the primary meaning was an essential requirement of the invention, was considered by Lord Neuberger at [65]. He thought this was acceptable provided it was properly applied. Here he made four points:*
>
> "*i)* *Although "the language of the claim is important", consideration of this question does not exclude the specification of the patent and all the knowledge and expertise which the notional addressee is assumed to have.*
>
> *ii)* *The fact that the language of the claim does not on any sensible reading cover the variant is certainly not enough to justify holding that the patentee does not satisfy the third question.*
>
> *iii)* *It is appropriate to ask whether the component at issue is an "essential" part of the invention, but that that is not the same thing as asking if it is an "essential" part of the overall product or process of which the inventive concept is part. Here regard must be had to the inventive concept or the inventive core of the patent.*
>
> *iv)* *When one is considering a variant which would have been obvious at the date of infringement rather than at the priority date, it is necessary to imbue the notional addressee with rather more information than he might have had at the priority date. Here Lord Neuberger had in mind the assumption that the notional addressee knows that the variant works.*"

SECTION 60(1)

125. Applying a purposive construction, I have construed the relevant claims above. I now consider whether the Ultra 3D device infringes the patent on a normal construction.

126. I briefly note that it was confirmed during the hearing that Professor Parker had not been provided with the Med-El Request for Information (he had the Response) or the internally referenced '771 patent in the Request which was used to explain parts of the Request and fed into the Response. This is not really a criticism of Professor Parker. He confirmed in his evidence that he understood the nature of the mutual attraction of the implant magnet cylinders, their orientation in different contexts and that these matters were explained to him in the course of the case. This is what the missing information really goes to. In the end this is a limited point. I have taken particular care in assessing where Professor Parker gives evidence on this point and have not identified anything which gives any material concern to the issues on infringement. I will, of course, be careful to weigh this information appropriately in coming to my conclusions.

Claim 1

127. Med-El's position is that AB have taken no non-infringement points separate to those it takes in relation to claim 1 and therefore if claim 1 is infringed so are claims 10 and 14 as amended. This did not appear to be contradicted. However, out of caution, I will deal with each claim in turn –although the key disputed issues are common to

each of these claims. AB's arguments on normal infringement were significantly tied to its position on construction. The construction I have interpreted means that many of the arguments of each party leave little dispute on normal infringement. The elements of the claim which have not been dealt with below are satisfied for the purpose of infringement based on the above description and evidence (and in any event are not disputed).

128. The issues on infringement are:

(a) Is there a first attachment magnet within the plane of the implant coil housing?

(b) Is this rotatable in said plane of the implant coil housing?

(c) Does the first attachment magnet have a magnetic dipole parallel to the plane of the implant coil housing?

Is there a first attachment magnet within the plane of the implant coil housing?

129. I have construed claim 1 such that "*a first attachment magnet*" can include multiple magnets which have a net magnetic dipole.

130. As noted above and in the PPD the Ultra 3D implant has four separate cylindrical magnets used for attachment to the external component. There is no dispute between the experts (or the parties) that they will display a net magnetic moment or dipole.

Rotatable in the plane of the coil housing?

131. This is clearly present from the description above, the PPD and the evidence on the Ultra 3D device. It is not disputed that the Ultra 3D internal housing containing the four implant cylinder magnets will rotate in the plane of the implant coil housing and attach to the external magnet in the Ultra 3D device. The Ultra 3D implant coil housing continues to rotate when interacting with an external magnetic field. I deal further below with the point relating to any additional 'rotation' of the individual internal cylinder magnets along their long axis in a relatively strong magnetic field.

132. The parties each introduced a research paper relating to comparisons of the torque various cochlear implant devices (their implant magnets) would undergo in a variety of conditions in an external magnetic field (Professor Parker exhibited "*Assessment of a Novel 3T MRI compatible Cochlear Implant Magnet; Torque, Force, Demagnetisation and Imaging"* by *inter alia* Tysome ("Tysome") and Professor Suaning exhibited "*Cochlear Implant Magnet Dislocation: Simulations and Measurements of Force and Torque at 1.5T Magnetic Resonance Imaging* by *inter alia* Eerkens ("Eerkens")). Tysome compares two models of cochlear implants – the Ultra 3D and a version where the implant magnet does not rotate. Eerkens compares six cochlear implant models – some with fixed and some with rotatable implant magnets. There was extensive debate on what these papers show. Really it comes down to two results. First, the assessment that cochlear implants are susceptible to lower torque in an external magnetic field (MRI) when the implant disk magnet can rotate to try to align with the external magnetic field compared to the situation where the implant magnet cannot rotate. There is nothing in that by way of dispute between the parties. Secondly, and this I believe is the real point, whether the Ultra 3D implant can reduce its response to torque in an external magnetic field more than other cochlear implants which have rotatable implant magnets. In other words, does the ability for the implant cylinder magnets to rotate along their long axis to further align with the external magnetic field provide an additional benefit?

133. I have assessed these documents as being of limited usefulness in this context and therefore only deal with them in general terms below. Tysome demonstrates that Ultra 3D reduces torque in an MRI by rotation of its implant magnet assembly. The analysis by the experts is that Eerkens is a flawed paper or at least should be taken with caution. In particular, Eerkens has limited data points and both accept it would not be good to try to draw quantitative conclusions from the results. Qualitatively, I believe there is consensus that at some point during the experiments in the external magnetic field causes the Ultra 3D implant magnetic cylinders to rotate on their main axis to some degree to further align with the external magnetic field (the PPD notes these cylinders can rotate on this second axis but not when). There was no agreement on whether this provided a significant quantitative benefit. On the evidence presented there is nowhere near sufficient veracity or specifics in the underlying documents to come to any quantitative conclusions on the relative benefits. The parties have not chosen to undertake any experiments in this case. I do not criticise that but if there was a serious intent to provide quantitative data on this point more would have been needed.

134. When At Rest (no external magnetic field) and when In Use (attached to the external headpiece) the Ultra 3D implant cylinder magnets are in line (see above paragraph [116] internal referenced figure 9) - with their magnetic dipole parallel to the plane of the coil housing. This is agreed and in the PPD/Response to the RFI. It is also

agreed (and if not I would find it was the case on the evidence) that the cylinders will remain in this position in some relatively weaker external magnetic fields. This must be the case as it is accepted the interaction of the external magnetic field of the external attachment magnet does not overcome the implant cylinders' mutual attraction – they do not start to rotate. They continue to operate as an implant magnet with its net magnetic dipole parallel to the plane of the implant coil housing when rotating the housing assembly to attach to the external magnet.

135. If the external magnetic field strength increases then at some point the individual cylinder magnets start to rotate on their long axis. Quite when, as I note, has not been shown with any specific detail. The cylinders do not move out of the plane of the coil housing. Rather, they spin within that plane and the orientation of the individual and net magnetic dipoles of the cylinder magnets would change as a result. I deal with that aspect below.

136. In the end, the entire debate about the degree of rotation of the implant cylinder magnets 'out of the plane' is effectively redundant. As explained, the implant magnet housing containing the cylinder magnets and the cylinder magnets themselves remain physically in the plane of the implant coil housing at all times. This remains the case whether or not at points in time the cylinder magnets in the Ultra 3D implant also rotate on their longitudinal axis. If I am wrong on this then, in any event, on attachment to the external magnet or in the presence of a relatively weak external magnetic field (including the MRI – see below) the individual cylinder magnets do not rotate or do not rotate significantly and act as a single unit. The Ultra 3D system therefore falls within this integer of the claim due to the rotation (and its ability to rotate) of the implant magnet (the cylinder magnets) in the plane of the implant coil housing.

Does the first attachment magnet have a magnetic dipole parallel to the plane of the implant coil housing?

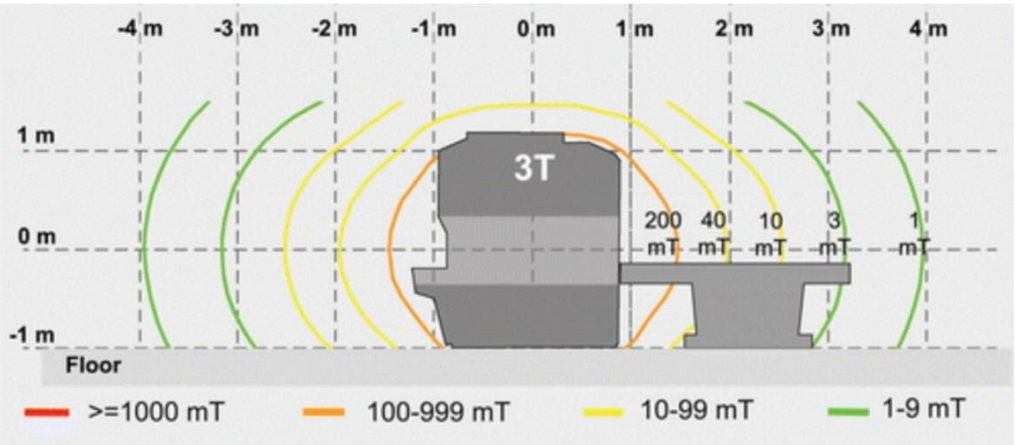
137. In the end I am also not convinced much of the extensive analysis on this point matters for similar reasons to those noted above. However, I have gone into these issues in some detail to respond to the main positions taken on submissions on this important point. Due to the lack of experiments or quantifiable evidence on the issue I have addressed points I feel assist from the evidence. The PPD confirms the following regarding the implant magnet cylinders in the Ultra 3D system:

> *"9. The magnets are able to rotate both (as an assembly) in the plane of the magnet Assembly housing and (each individually) about their respective longitudinal axes. The orientation of the individual magnetic dipole moment of each of the four magnets is not mechanically constrained to lie only in the plane of the magnet assembly housing.*
>
> *10. When an external magnetic field is applied to the cylindrical magnets, the interaction of the external magnetic field with the magnetic dipole moment of each cylindrical magnet causes each magnet to rotate about its longitudinal axis to align with the external magnetic field. Further, the frame comprising the cylindrical magnets rotates within the non-magnetic titanium housing about its rotation axis so as to permit the optimal alignment of the individual magnetic dipole moments within the external magnetic field."*

138. Mr Smith's evidence explains that "*...the magnetic dipoles of the four implant magnets of the 3D Device align parallel to the skin (except when the device is introduced into a large magnetic field, such as in an MRI machine)…*". This point about cylinders only rotating when they are inside an MRI machine was put to Mr Smith in his examination. His response was: "*That is not quite true. It is possible to rotate those four bar magnets using a headpiece magnet that is not as strong as an MRI, but you would have to align all of the poles correctly in order to achieve that and it is possible that a headpiece magnet, when it is brought in close proximity to those four bar magnets, would cause individual bar magnets to rotate slightly*." Mr Smith is the signatory of the AB Response to the Request for Information. Contrary to his statement, in the Response to Request 2 he noted that in the Ultra 3D Device the internal cylinder magnets would not rotate in the presence of a headpiece magnet. AB's counsel confirms what must be right (ignoring the language about rotating out of the plane that I have dealt with above) in the context of the pleaded Response to the Request for Information - noting "*It says that the diametric external magnet used is not strong enough to cause them [the cylinder magnets] to rotate out of plane."* I therefore assess that in his comments on examination Mr Smith was not deviating from his earlier positions that the internal cylinder magnets all align parallel to skin – including when attached to the external magnet in the Ultra 3D Device. In any event, even if there were slight movement of the cylinders as indicated this would on the evidence be a minimal movement and therefore still in my view on balance be covered by my construction that the magnetic dipole needs to be substantially parallel.

139. Finally, the Agreed Statement on CGK contains a figure which shows (below) how the external static magnetic field strength reduces with distance from the MRI machine. A patient will experience a gradient of external magnetic field strength. There will be a range of strengths of external magnetic field that will not rotate the

implant cylinders on their longitudinal axis and therefore their net dipole moment remains parallel to the plane of the implant coil housing. There will be a further range of field strengths which start to rotate the cylinders but where the net dipole will substantially remain in the plane of the implant coil housing. There appears also to be a range of strengths of external magnetic field which would rotate the individual cylinders such that their net magnetic dipole is no longer parallel to the plane of the implant coil housing.



140. Therefore the Ultra 3D product infringes the asserted claims of the Patent (for these purposes based on my assessment of the parties' positions there is no distinction between the claims in issue). It infringes when it is At Rest and the magnetic dipole is parallel to the implant coil housing. It infringes when the implant is In Use (is attached to the external magnet). It infringes for a range of external magnetic field strengths. There will also be a range of external magnetic strengths where it does not infringe. The evidence on the degree and frequency to which the Ultra 3D system would infringe when in an external magnetic field is not sufficient for this to be determined on the evidence. I have determined the Ultra 3D does infringe on normal infringement. The fact that in some circumstances (a sub-set of circumstances – it must infringe at least some of the time) it does not infringe does not matter. It also does not matter if, which was not in my view proven to the necessary standard, the Ultra 3D offers some additional benefit by better alignment through the rotation of its individual cylinder magnets. It is still benefiting from the underlying invention.

Infringement by equivalence

141. I have found infringement on a normal construction. On this basis and in the light of my finding below on validity it would not be necessary to consider infringement by equivalence but it is prudent to do so.

142. This requires me to consider the three questions set out in *Actavis v Eli Lilly* [2017] UKSC 48 at [66] (below) and as restated in *Icescape v Ice-World* [2018] EWCA Civ 2019 [58]-[67]:

i) Notwithstanding that it is not within the literal meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, ie the inventive concept revealed by the patent?

ii) Would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, that it does so in substantially the same way as the invention?

iii) Would such a reader of the patent have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?

143. The first question – does the alleged equivalent achieve substantially the same result in substantially the same way? In *Edwards Lifesciences Corporation v Meril GmbH* [2020] EWHC 2562 [222] - [223] Mr Justice Birss (as he was) considered what was meant by 'inventive concept'.

144. The inventive concept of claim 1 is a compromise achieving an acceptable degree of alignment with an external magnetic field (MRI compatibility) while keeping a thin housing and therefore avoiding bone drilling (while having sufficient magnetic volume to attach externally). This is the problem underlying the invention. The Patent

solves this problem by using non-spherical magnets which rotate in the plane of the implant coil housing and has its magnetic dipole parallel to the coil housing.

145. The variant is that in addition to the implant containing a housing with the implant magnets that can rotate in the plane of the coil housing these magnets also have the ability to rotate along their long axis. The argument from AB is that this additional feature means it is providing an improved clinical benefit by reducing the torque experienced in an external magnetic field due to this further ability of the individual cylinders to rotate and is therefore not using the inventive concept. As noted above, the degree of off-parallel alignment and any clinical advantage has not been demonstrated. The evidence also supports the view that the compromise noted would still be present even if this benefit had been demonstrated – the Ultra 3D does not achieve perfect alignment with the external magnetic field– for example, due to the equilibrium of forces between the external magnetic field and the mutual attraction of the cylinder magnets. Even if the evidence had supported that there was a relevant difference in torque reduction, the result is that the variant continues to rely at all times on the rotatability of the implant magnet housing in the plane of the implant coil to reduce the torque. Any additional benefit created by an off-parallel magnetic dipole would not alter this or the fact that utilising the claimed features enables it to keep a sufficiently thin MRI-compatible implant housing.

146. In my judgment the Ultra 3D provides the same advantages as the claimed invention in the same way.

147. As regards the second question there is no issue on how the Ultra 3D works or that that the skilled person would understand how it works (subject to the points noted above). There is no further finding of fact necessary.

148. The Patent acknowledges the teaching of Zimmerling as relevant prior art and teaches why and how the solution in the Patent resolves the problem of bulky housing versus alignment. The Skilled Person understands from the Patent teaching that to reduce torque in an external magnetic field (MRI) the internal magnet can rotate to align. The Patent teaches an important compromise to allow enough reduction in torque but to also maintain a thin housing this should use an implant magnet planar to the implant coil housing and which keeps its magnetic dipole parallel to that housing. The Patent specification teaches the importance and benefit of this compromise, including at [0022] *"It is worth noting that while the embodiments described above are disk shaped (cylindrical) but that is not necessarily required. Rather, any shape could be implemented so long as the magnetization is parallel to the coil housing and the skin.*" and [0026] that the *"...main limitation being that the disk-shaped attachment magnet design described above allows for rotation of the magnet in only one plane*.".

149. In the circumstances, I would conclude the patentee intended strict compliance with the meaning of the normal construction of the claim language which provides for the implant magnets to maintain a magnetic dipole parallel to the coil housing and that this was an essential requirement of the invention. If my finding on this is not right, to the extent it could have been argued the Patent teaching was wider, allowing the implant magnet and its magnetic dipole to rotate in all orientations, I would have come to the same conclusion on the basis that my construction of the claim was limited to this implant magnet rotating in the plane of the coil housing and its magnetic dipole being parallel to that. For the reasoning for this assessment I refer to the Judgment of Mr Justice Meade in *Optis v Apple* [2021] EWHC 1739 (Pat) [263] "*If a specification lists A and B and then only claims (as a matter of language on normal interpretation) A, then that might well be an indication that strict compliance at least so as to exclude B was intended. I think it is clearly implicit in the judgment of Birss J in Illumina v. Latvia [2021] EWHC 57 (Pat) e.g. at [338] that this sort of argument is a legitimate one and may be a powerful one, although it did not arise on the facts before him."*

150. I conclude that the Ultra 3D would not infringe claim 1 under the doctrine of equivalents. In my view and considering the parties' positions, no separate issues arise for dependent claims 10 and 14 as amended.

SECTION 60(2)

151. On the basis that the Ultra 3D Device falls within the asserted claims of the Patent, Med-El argue that AB have committed further infringing acts covered by s.60(2) of the Patents Act 1977. I have considered the law on s.60(2) indirect infringement. I set out below the relevant statutory provisions and main case law relating to the interpretation of this type of infringement.

Section 60 of the Patents Act 1977:

> *"(2) Subject to the following provisions of this section, a person (other than the proprietor of the patent) also infringes a patent for an invention if, while the patent is in force and without the consent of the proprietor, he supplies or offers to supply in the United Kingdom a person other than a licensee or other person entitled to work the invention with any of the means, relating to an essential element of the*

invention, for putting the invention into effect when he knows, or it is obvious to a reasonable person in the circumstances, that those means are suitable for putting, and are intended to put, the invention into effect in the United Kingdom.

(3) Subsection (2) above shall not apply to the supply or offer of a staple commercial product unless the supply or the offer is made for the purpose of inducing the person supplied or, as the case may be, the person to whom the offer is made to do an act which constitutes an infringement of the patent by virtue of subsection (1) above."

152. In his Judgment in *Nestec SA v Dualit Ltd* [2013] EWHC 923 [155]-[156] Mr Justice Arnold (as he was) also set out the relevant elements of Section 130(7) of the Patents Act 1977 relating to this section on infringement and its derivation from Article 26 of the Community Patent Convention. In the case of *Grimme Landmaschinenfabrik GmbH v Scott* [2010] EWCA Civ 1110 Lord Justice Jacob considered the background to Article 26 and s.60(2) at [82]-[98].

The alleged infringements

153. Med-El argue that there is s.60(2) infringement in respect of the supply by AB of external parts suitable to be used with the Ultra 3D implants where AB know that they are going to be used with the Ultra 3D implants. The external parts identified are: (1) certain AB headpieces (which may or may not include the external magnet(s)) compatible with the Ultra 3D Device, and (2) the external magnet(s) compatible for use in the Ultra 3D Device (external headpiece).

Means relating to an essential element of the invention

154. In the *Nestec* case the Judge set out the relevant principles to consider [168]–[176]:

"168.The next issue is whether the NX capsules constitute "means relating to an essential element of the invention". There appears to be no English authority as to the correct approach to this requirement which is directly in point, but it has been considered by the courts of a number of other countries which have implemented Article 26 CPC in their law, notably the courts of the Netherlands and Germany. Unhappily, the Supreme Court of the Netherlands and the Bundesgerichtshof (Federal Court of Justice) in Germany have adopted different approaches to this question.

169. In Impeller Flow Meter [Case X ZR 48/03] the reasoning of the Federal Court of Justice in relation to section 10 of the German Patents Act, which implements Article 26 CPC, was as follows:

"The criterion of the suitability of the means to interact functionally with an essential element of the invention in the implementation of the protected inventive idea excludes such means that – such as the energy needed for the operation of a protected device – might be suitable for being used in the exploitation of the invention but which contribute nothing to the implementation of the technical teaching of the invention. If a means makes such a contribution, it will, on the other hand, generally not depend on the feature or features of the patent claim that interact with the means. For, what is an element of the patent claim is, as a rule for this reason alone, also an essential element of the invention. The patent claim defines the protected invention and limits the protection granted to the patent holder to forms of exploitation that implement all the features of the invention. As a mirror image of each individual feature's function to limit protection in this way, each individual feature is fundamentally also an appropriate point of reference for the prohibition on the supply of means within the meaning of Sec. 10 of the Patent Act. In particular, it is not possible to determine the essential element of an invention according to whether they distinguish the subject matter of the patent claim from the state of the art. It is not infrequently the case that all the features of a patent claim as such are known in the state of the art. For this reason, this does not provide a suitable criterion for differentiation."

170. Thus the Court proceeded on the basis that the means in question must contribute to implementing the technical teaching of the invention. It rejected the contention that a feature could only be an essential element of the claim for this purpose if it served to distinguish the subject matter of the claim from the prior art i.e. was novel in its own right.

171. This reasoning was amplified by the Court in Pipette System (Case X ZR 38/06) as follows:

"18. In accordance with the case law of the Senate, a means refers to an essential element of the invention if it is suitable to interact in a functional way with one or several features of the patent claim when implementing the protected thought behind the invention (BGHZ 159, 76, 85 - Impeller Flow Meter). Means that can be used during the application of the invention but

which however contribute nothing to the implementation of the teachings of the patent are not covered by these criteria. If a means provides such a contribution, it does not in principle matter with which feature or features the means interacts. This is because what is a part of the patent claim is regularly already therefore an essential element of the invention (BGHZ 159, 76, 86). The Appeal Court has correctly assumed this.

19. The nozzles in dispute relate to an essential element of the invention. The nozzle is part of the object according to the invention, which consists of the combination of a hand pipette and nozzle, which forms the protected 'system' (feature 1). With the fastening section and nozzle piston, the nozzle itself is designed in accordance with feature 2 and, as a result, suitable to interact with the pipette in a functional way when implementing the thought behind the invention, in that the retention device in accordance with feature 5 grips and fix in the mountings of the fastening section of the pipette housing and the piston collar of the nozzle in accordance with the features 7 and 9 grip and release again by activating the activation arms, without the nozzle itself having to be touched.

20. This is sufficient in itself for functional interaction. In this respect, it does not matter wherein the core of the invention lies. However, a feature that has a completely subordinate importance for the technical teachings of the invention can be seen as a non-essential element of the invention; such an irrelevancy for the inventive concept cannot be explained by stating that these features are known in prior art (BGHZ 159, 76, 86). The viewpoint argued as the centrepiece of the appeal on points of law, namely that the features of the nozzle contained in the patent claim relate to conventional commercially-available nozzles, is therefore insignificant. A lack of 'essentiality' can only result in a feature not contributing anything to the performance of the product, i.e. to the solution of the technical problem on which the patent is based in a accordance with the invention, whereby a contribution that is practically meaningless can be left out of consideration. This comes into consideration if, for an invention that is concerned with the continuation of a certain function of a device known as such, features are included in the patent claim that concern another function of the device not affected by the invention. Such a situation is out of the question in the present dispute, in which the relationship of the nozzle as an essential element of the invention already results from the fact that it is precisely the nozzle, its fixing to the fastening section and nozzle pistons in a certain position that serve the design in accordance with the invention.

21. The second appeal can therefore also not succeed with the objection that that patent claim should have been aimed at a hand pipette instead of a system consisting of pipette and nozzle. The patent applicant cannot be prescribed on how to formulate the patent claims. Instead it can basically demand the grant of the patent in each way that corresponds to the technical teachings and is patentable (BGHZ 166, 347 349 et seq. - Microprocessor). Since the invention deals with the problem of improving the mechanics of coupling the nozzle to the pipette and disconnecting the nozzle from the pipette, it is possible and not a breach of law to include the syringe in the definition of the patented object."

17., Again the Court emphasised that the fact the element was known in the prior art did not prevent it being an essential element of claim, but did accept that if a feature was of completely subordinate importance for the technical teaching of the invention it could be regarded as a non-essential element.

173. In Sara Lee v Integro (Case C02/227HR), on the other hand, the Dutch Supreme Court upheld the conclusion of the Court of Appeal that an essential element must be one which distinguished the invention from the prior art:

"Insofar as the part complains about the explanation that the Court of Appeal thus gave to the patent, it miscarries due to what has already been considered under 3.3.2. It also miscarries otherwise. The mere circumstance that a fitting coffee bag is needed for putting the patented mechanism into effect does not automatically mean that this bag is a means relating to an essential part of the invention. Evidently and in light of the explanation that the Court of Appeal has given to the patent, the Court of Appeal was of the opinion that the coffee bag fitting the holder does not comprise an element by which, according to the patent specifications, the doctrine of the patent distinguishes itself from the state of the art. That opinion does not show any incorrect interpretation of the law."

174. In addition to these cases, I was referred to decisions of French and Belgian courts which appear to be more consistent with the German approach than the Dutch one.

175. In my judgment the German approach is more consonant with the apparent purpose of Article 26(1), which is that third parties should not be allowed to benefit from the invention by supplying

means the market for which has been created by the invention, than the Dutch one. Furthermore, I consider that the Dutch approach is difficult to reconcile with Article 26(2), which makes it clear that a staple commercial product may constitute means relating to an essential element. Accordingly, I propose to follow the German approach.

176. Applying that approach, I consider that the capsule does constitute means relating to an essential element of claim 1 of the Patent. In my view the capsule does contribute to the implementation of the technical teaching of the invention, and is not of completely subordinate importance. Although the invention takes the capsule as a given, and claim 1 only requires the capsule to have a guide edge in the form of a flange, the flange of the capsule plays a significant role in the way in which the claimed invention works."

155. AB's position is that whether it is the headset containing magnets which is used as the external headset in the Ultra 3D system or the external attachment magnet which is used in this headset, neither is an essential feature of claim 1. They submit claim 1 is indifferent to the characteristics of the external magnet (it could be a diametric magnet or two separate axial magnets). Before I deal with the broader point below I note that based on the evidence and the claims in the case I do not agree that it is correct the Patent is indifferent to the set-up of the external magnet in the headpiece. Claim 1 requires that the internal and external magnets "*form an attraction connection between them...*" and the use of a magnet with a "*...dipole parallel to the plane of the implant coil housing...*". The Patent explains the advantages of this approach and the evidence supports the position. This means the external attachment magnet in the headpiece needs to match the dipole of the implant magnet. Whether this is using a diametric magnet or two axial magnets to replicate the effect of a diametric magnet, the set-up is taught.

156. The broader point is whether the headpiece with the magnets/or replacement external magnets alone satisfy the requirement of an "*essential eleme*nt" of the invention. The evidence of Professor Parker notes:

> *"I was asked by Kirkland & Ellis whether the external headpiece contributes to the implementation of the technical teaching of the Patent. I have explained above what I believe to be the main thrust of the Patent. In summary, it achieves MRI compatibility but does so using a disk-shaped magnet in preference to the prior art spherical magnet. Therefore, it achieves a degree of MRI compatibility (albeit limited to rotation in the plane, rather than in three dimensions) but achieves a thinner design compared with the prior art.*
>
> *In my view, the external headpiece does not affect the capability of the implantable component in the Patent to achieve its MRI compatibility. Indeed, the external headpiece is removed before the patient enters the MRI room. The MRI compatibility comes from the rotatability of the implant magnet rather than any feature of the external magnet or headpiece. I recognize that the external component contains a magnet which interacts with the implantable component and is used to hold the headpiece over the patient's head, but that is a feature of all such cochlear implant devices and not a contribution to the MRI compatibility."*

157. I have underlined part of the statement where I want to focus. The headpiece part of the Ultra 3D system is removed before a patient enters the MRI room. When being scanned for an MRI the implanted part of the system alone is subject to the problems identified in the Patent –for example, the torque created by the MRI external magnetic field interacting with the implant device and its magnet. The external headpiece takes no part. What needs to be considered in this context is whether the headpiece and/or its magnets contributes to the implementation of the technical teaching of the invention and is not of completely subordinate importance. The function of the headpiece is the same as its function in the prior art (in this context I note the Judge in *Nestec* acknowledged the German situation as the preferred approach and that if the relevant element was known in the prior art this did not prevent it being an essential element of the claim). The only relevant difference in the design of the headpiece is the external magnet(s) which is made such that it will attach in a certain way to the type of implant magnet used. The external headpiece and its magnets do not contribute to the way the core invention operates to solve the problems the Patent identifies. That is done by the implant part of the Ultra 3D system. However, the test here is not one of considering whether the 'essential element' includes any aspect of the inventive concept of the Patent. This point was addressed by the Mr Justice Arnold (as he was) in *Nestec* in a related context when considering whether under s.60(2) the "*means were suitable for putting the invention into effect*":

> [203] *"...the capsule does not embody the inventive concept of the Patent. It is true that, as I have held, the flange of the capsule plays a significant role in the way in which the claimed invention works. Nevertheless, it remains the case that the inventions takes the capsule as a given and that the specification explicitly states that the invention can be used with any type of capsule (provided it has a flange). The invention is all about the way in which the machine operates. The fact the claims require*

the presence of the capsule is an artefact of clever claim drafting. In my view, it may be inferred that the reason why the granted claims require the presence of the capsule … is precisely in order to enable Nestec to argue that the mere supply of capsules constitutes infringement and this enable Nestec to continue to control the market in capsules..."

158. As the Judge explained in *Nestec* "*... third parties should not be allowed to benefit from the invention by supplying means the market for which has been created by the invention...*". I also take into account that the relevant design of the external headset and its magnets is set out in claim 1. This is another relevant consideration and is in line with the German decisions referred to in the *Nestec* case. The fact is the design of the external headpiece and the precise form (magnetisation) of the external magnet contribute to the implementation of the teaching of the Patent. In the circumstances, my view is the external headpiece with the magnets or the external magnet(s) alone, both of which interact in effectively a functional way with the implant element of the Ultra 3D system, contribute to the implementation of the technical teaching of the invention and are not of completely subordinate importance.

Staple commercial products

159. In a line of its closing submissions AB note that the external magnets used in the Ultra 3D headpieces are staple commercial products. This is a standalone defence to infringement under s.60(3) of the Patents Act 1977. AB have not pleaded this as part of its defence or provided any material evidence directly on this issue. AB in its closing oral submissions appear to expect the burden to be on Med-El to demonstrate (despite the lack of notice) that the magnets used in the relevant headpieces are not staple commercial products. For all these reasons, I do not believe AB have properly raised this as a defence to infringement in this action and it is too late to raise it now. I reject it on that basis. However, in case I am wrong on that, I would have decided that the defence was not made out for the following reasons. I note that the PPD and evidence provide some insight into the make-up of these magnets. They are a very particular size, shape, magnetisation, make up (Professor Parker thinks likely strong ones using rare earth materials) for use in this regulated medical device. I have also considered the relevant discussion of the Judge on this matter in *Nestec* on this point. The evidence, such that there is on this, is a long way from satisfying me it is a commercial product supplied for a variety of uses.

Means suitable for putting the invention into effect

160. I have considered the law on this point including the helpful review of the law by the Judge in *Nestec* [184]-[198], *United Wire Ltd Screen Repair Services (Scotland) Ltd* [2001] RPC 24 and as reviewed in *Schutz (UK) Ltd v Werit UK Ltd* [2013] UKSC 16.

161. AB appear to be arguing (in the context of claim 10 but I understand they contend the same position for the other claims in issue) a 'right to repair' case in the context of a consideration of infringement under s.60(2) of the 1977 Patents Act. This position was not foreshadowed in the pleadings or the Statement of Case on Non-infringement and as a result received very limited attention in the parties' submissions.

162. The cases U*nited Wire Ltd Screen Repair Services (Scotland) Ltd* and *Schutz (UK) Ltd v Werit UK Ltd* both deal with making or repairing a product that fell within the claims of the patent. I have set out some of the most relevant sections from *Schutz* below. Mr Justice Arnold in *Nestec* also usefully reviews these decisions at [183] - [199].

"Repairing and making

48. The reasoning of Lord Bingham and Lord Hoffmann in United Wire emphasises that one must avoid basing a decision on the point at issue by simply contrasting the two concepts of making and repairing, not least because "the notions of making and repair may well overlap" – para 71 per Lord Hoffmann. However, it was a contrast which Buckley LJ drew, and apparently found helpful, in this context in Solar Thomson Engineering Co Ltd v Barton [1977] RPC 537, 555 (in a passage quoted and approved by Lord Hoffmann in United Wire at para 72), and which Aldous LJ appears to have approved in his judgment in United Wire at paras 21-22 and 26-27.

49. The approach of Buckley LJ supports the notion that, subject to the overriding point that it should not obscure the central issue of whether the alleged infringer "makes" the patented article, it may sometimes be useful to consider

whether the alleged infringer is repairing rather than "making" the article. I am fortified in that view by the fact that the BGH also plainly considers this distinction to be a useful one in this field.

50. The mere fact that an activity involves replacing a constituent part of an article does not mean that the activity involves "making" of a new article rather than constituting a repair of the original article. Repair of an item frequently involves replacement of one or some of its constituents. If there are broken tiles on a roof, the replacement of those tiles is properly described as repairing the roof, and such replacements could not be said to involve rebuilding, or "making", the roof. Indeed, replacing the whole of a deteriorated roof of a building could be regarded as repairing the building, taken as a whole, rather than reconstructing the building. There are many cases concerned with repairing obligations in leases which illustrate this point - see e.g. the discussion in Woodfall on Landlord and Tenant (October 2008), Vol 1, paras 13.32 to 13.037.12.

51. In the more directly relevant context of chattels rather than buildings, the normal use of "making" and "repairing" demonstrates the same point. Works to a ship or a motor car, which involve removal and replacement of defective significant constituent parts, could be substantial in terms of physical extent, structural significance, and financial cost, without amounting to "making" a ship or motor car, as a matter of ordinary language: in such a case, they would be "repair" of the existing ship or motor car. Thus, in Coleborn & Sons v Blond [1951] 1 KB 43, 49-50, Denning LJ said, in a case concerned with purchase tax, that "[s]peaking generally, … if you replace an old engine by a new one, or an old body by a new body, you are not making a different vehicle: you are altering and improving an old one …". On the facts of that case he held "a new thing was made out of two parts - … the old chassis and … the new body – [which] when assembled together make a different thing from either of them separately."

52. The approach of Lord Hoffmann in the remarks at the end of his judgment in United Wire, quoted at the end of para 35 above, appear to me to be consistent with the approach of Denning LJ in Coleborn. On the facts of United Wire, Lord Hoffmann concluded (or said that the Court of Appeal was entitled to conclude) that the totality of the work described in his para 64 amounted to "making" a new article, because the removal of the meshes and the stripping down and repairing of the frame resulted merely in a component of the patented article "from which a new screen could be [and was] made".

53. Returning to the theme of the "normal" meaning of a word, observations about the meaning of "make" in a different legal or factual context from that under consideration should be approached with caution. The examples given above are referred to primarily to emphasise the somewhat slippery nature of the meaning of the word, and the very important role which context plays in determining whether a particular activity involves "making" an article. In general terms, in a case under section 60(1)(a) the particular contextual features are those identified in paras 26 to 29 above.

163. The further requirement of s.60(2) being considered here is that the means relating to an essential element of the invention must be "*suitable for putting the invention into effect*". This depends on whether the person who obtains and uses the external headpiece (with magnet(s), or these external magnet(s) alone) for use in the Ultra 3D Device is thereby 'making' a product falling within the claims of the Patent under s.60(1) of the Patents Act 1977.

164. This case is different to the above noted cases at least in that the Ultra 3D system alleged to infringe was not originally purchased from the Patentee. Med-El note any argument on 'repair' cannot begin to run unless the original product was made with the consent of the patent proprietor. As the party in *Schutz* had purchased the original product from the patent proprietor the point was dealt with only in passing by Lord Neuberger:

"66. ... *As Lord Hatherley LC said in Betts v Willmott (1871) LR 6 Ch App 239, 245, in a passage cited by Lord Hoffmann in United Wire at para 68:*

"When a man has purchased an article he expects to have the control of it, and there must be some clear and explicit agreement to the contrary to justify the vendor in saying that he has not given the purchaser his licence to sell the article, or to use it wherever he pleases as against himself."

In principle, a purchaser of a patented article, as I see it, should be taken as entitled to make such an assumption, subject to section 60(1)(a)."

165. In the earlier cases referenced where the original patented item was purchased from the patent proprietor they will therefore have consented to its use. I have held that when the original Ultra 3D system was supplied that was an act of infringement (subject to my decision on validity). The difference between these situations is that under s.60(2) there may be a second or further infringing acts by, subsequently, 'making' the infringing product again. Alternatively, where a patented product which had been obtained from the patent proprietor was repaired – no further infringing act has occurred. The point raised is whether the 'repair' principle can still operate on a product that has been obtained through an act of infringement. The simple answer must be, yes, it can. The principle at play here is whether these later activities, as a matter of fact and degree, are judged to be 'making' a patented product. In that context if they are not considered to be 'making' the term that has been given to the alternative position is 'repair' but really it is simply the case that the activity would not trigger s.60(1).

166. There seems no point of legal principle dividing the situations here – (1) where the original act of obtaining the product was an infringing one, and (2) the situation in the earlier cases where it was with the consent of the patent proprietor. The analysis remains identical. As it is, in this case, Med-El has confirmed it will not seek an injunction preventing the supply of any of these "*external accessory components*" relating to Ultra 3D Devices already supplied and that it will accept damages instead. On this analysis, Med-El are in the same position (albeit belatedly) as the earlier situations where the patent proprietor has received compensation for the original supply. The question therefore is whether there is a further infringing act.

167. The external headpiece and the external magnet(s) it contains (or may contain) for attachment to the implant part of the system are clearly a significant component of the overall Patented system in claim 1. The external magnet(s) being a more modest component but more closely linked to the invention, the headpiece without the external magnets being a complex piece of equipment and a more significant part of the overall system (I have no information on relative values) but less relevant to the patent and together the headpiece and external magnet comprise both these facets. Deciding this issue is an exercise of judgment.

168. The exercise of my judgment here is in assessing the question in context and is one of fact and degree. Taking into account the general principles set out at [26]-[29] in *Schutz* I have therefore considered the following:

(i) Based on the evidence I consider the headpiece and the external magnet(s) as subsidiary to the main part of the system. In coming to this view I take into account; (a) the common ground that the implant is intended to stay in place for 20 years or so but the headpiece (which I understand would normally include the magnet(s)) are replaced every 2-3 years and are therefore 'relatively' perishable items. It could be reasonably assumed that a patient (I don't believe the route of supply is material here i.e. if via a clinician) would expect to be able to replace external parts which are expected to wear out/take more of a 'bashing' from their day-to-day use, and (b) the significance of the operation of the system as impacted by these external accessories – without the presence of the headpiece the patient cannot hear, without the external magnet(s) the headpiece cannot attach to the implant.

(ii) The implant in the Ultra 3D Device and the headpiece are two parts of a system which comprises a regulated medical device.

(iii) The headpiece/external magnets do not, in my view, embody the inventive concept. As noted above I have held that the headpiece/external magnet(s) play a role in the way the claimed invention works sufficient to classify it as means relating to an '*essential element*' of the claimed invention. However, the inventive concept at its core is a compromise to allow enough reduction in torque to make it MRI safe but that in order to maintain a thin housing this should use a rotatable implant magnet which is planar to the coil housing and which keeps its magnetic dipole parallel to that housing (while maintaining sufficient magnetic volume for attachment). The headpiece and the external magnet(s) are a standalone piece of equipment in the patented system. Their design is either entirely unrelated to the inventive concept or – in the case of the external magnet(s) - an inevitable 'knock-on' requirement based on the

inventive concept and the chosen specification for the implant magnet (see further reasoning below on the 'knock-on' nature of the choice of external magnet).

(iv) Over the life of the implant the owner of the headpiece may replace it as a damaged/lost external item but presumably could also be upgrading the headpiece or the external magnet(s).

(v) Replacing a component of the headpiece looks more like repair than replacing the entire headpiece with a new one.

(vi) Replacing a damaged or lost external magnet is a relatively small component in the external headpiece and the whole system.

169. In my view this point is finely balanced. Applying these factors to the law and carefully weighing them all up, my decision is that the alleged infringer does not 'make' the patented system under claim 1 when supplying any of these external accessories – the headset, with or without the external magnet(s) or the external magnet(s) separately. I am not persuaded there is any difference based on the express element of dependent Claim 10 regarding the external magnet being magnetised parallel to the skin. I have dealt with this above in construction of the claims. There is also nothing material to this decision in claim 14 as amended.

When he knows, or it is obvious to a reasonable person in the circumstances, that those means are suitable for putting, and are intended to put, the invention into effect in the United Kingdom

170. I was not addressed on this issue in any detail. It is of less importance based on my decision above. However, for completeness I refer to paragraph 11 of the AB Amended Reply and Defence to Counterclaim. There it pleads that the noted Slim Headpieces and related external magnets are not compatible with the Ultra 3D system. This went unchallenged.

171. In the situation where a headpiece or a piece of regulated medical device technology could be used by a patient either as part of an Ultra 3D system or another cochlear system it would seem in the circumstances this should satisfy the requirement that the supplier knows (or it must be obvious to them in all the circumstances) that some ultimate users will use the headpiece with the Ultra 3D system (see *Grimme Landmaschinenfabrik GmbH & Co KG v Scott* [2010] FSR 7 [107]-[132], *KCI Licensing Inc v Smith & Nephew Plc* [2011] FSR 8 [53] and *Actavis UK Ltd v Eli Lilly & Co* [2016] EWHC 234 [32]).

DECISION OF THE REGIONAL COURT OF MANNHEIM, GERMANY

172. Subsequent to the trial I was provided with a (not agreed) translation of the decision of the Regional Court of Mannheim on infringement of the DE equivalent patent to that in suit here. I understand the same Ultra 3D Device was in issue. The decision of 8 March 2022 dealt with both direct (literal and equivalence) and indirect infringement. I am not bound by any decision of the Mannheim Regional Court in this regard. However, this is a respected Court with experienced Judges familiar with patent disputes. In this context I am aware of the statement of Lord Neuberger in *Schütz (UK) Ltd v Werit (UK) Ltd* [2013] UKSC 16:

> 40. "*However, there can be no question of the courts in this jurisdiction feeling obliged to follow the approach of the German courts, any more than the German courts could be expected to feel obliged to follow the approach of the English and Welsh courts. Unlike the EPO, both this court and the BGH are national courts. As such, while they have a great deal, including many principles, in common, they have inevitably developed somewhat different techniques and approaches in relation to many issues, including many which arise in the field of patents. While complete consistency of approach may be achieved one day, it is not a feasible or realistic possibility at the moment. Nonetheless, given the existence of the EPC (and the CPC), it is sensible for national courts at least to learn from each other."*

173. I have considered the decision of the Regional Court of Mannheim ("**RCM**") and the parties' submissions. The arguments made in the German proceedings are not identical but they do seem to overlap with those in this case. There appears to have been different evidence (for example on the positions of the cylindrical magnets in the external Ultra 3D headpiece – in these proceedings there was an agreed position in AB's Response to the Med-El RFI – in the German case this appear to have been a live issue) and procedurally the Judges will have the case presented in a different manner. Despite this, there is considerable consistency in their decision and my Judgment on the conclusion and on a number of reasons relating to the construction and the 'literal' direct infringement of Claim 1. We have come to different views on the point of indirect infringement.

174. In reviewing the decision of the RCM I note the integers of Claim 1 focused on are in the main those of significance in this case, namely; "*said first attachment magnet*", and "*has a magnetic dipole parallel to the plane of the implant coil housing*".

"*said first attachment magnet*"

175. The RCM adopted a construction that the first attachment magnet (the implant magnet) "*cannot be limited to the fact that this first attachment magnet must be formed in one piece*" and "*may consist of a plurality of individual or partial magnets*". The reasoning included considering various subsidiary claims showing that claim 1 must implicitly cover this arrangement. It also referred to paragraph [0010] of the Patent noting: "*The fact that the figures ultimately only show embodiments that make use of this possibility with regard to the second attachment magnet is irrelevant in view of the broad formulation of para. [0010] - "one of the attachment magnets." the possibility of using a plurality of individual magnets for both the first and second attachment magnets.".*

"*has a magnetic dipole parallel to the plane of the implant coil housing*"

176. The construction regarding this integer comes to effectively the same conclusion but for slightly varied reasons. As part of its reasoning the RCM notes that; "*The term dipole must also be understood in light of the teaching of M3 shown, namely, to rotate the geometrical alignment of the first attachment magnet and its magnetic field in space.*" Although the German decision focuses on the attachment of the implant and external magnets this does appear to be a recognition that it is this dipole with the magnetization changed from the prior art to one parallel to the coil housing that has the role of rotating the implant magnet to align with an external magnetic field.

177. The Court also recognises the compromise in the Patent that; "*... to provide an implant system in which the "bulged" housing necessary for the use of a spherical magnet is avoided. However, the patent in suit does not seek to solve all possible problems associated with an MRI exam. Rather, the description openly concedes that the solution according to the patent in suit – namely, the parallel arrangement of the dipole of the first attachment magnet with a simultaneous rotatability in the plane of the coil housing (= one degree of freedom) - leads to completely satisfactory results only in certain, but not all, examination situations."*

178. The reasoning in relation to the indirect infringement point by the Ultra 3D headsets and external magnet(s) is that; "*All components mentioned are central components of the challenged systems, which - as has been explained above - directly infringe the patent in suit*.". My finding on this point noted above comes to a different conclusion for the reasons given.

INSUFFICIENCY

179. AB pleads on three separate grounds that the Patent is insufficient *"the specification of the patent does not disclose the invention clearly and completely enough for it to be performed by a skilled person in the art."* (s.72(1) (c) Patents Act 1977). Each ground is related to the main point, where the claims in issue cover implant systems in which the first attachment magnet is able to rotate in any direction other than the plane of the implant coil housing and that as a result it would not be enabled across the breadth of the claim and be invalid for insufficiency. The second and third pleaded grounds deal with ancillary points – that the claims should be limited to the teaching in the figures in the Patent and including [0013] of the Patent and that the technical benefit of the Patent is in the reduction in profile of the first attachment magnet over the prior art. AB argue this is not a Patent teaching a general point of application.

180. The parties referred me to *Regeneron v Kymab* [2020] UKSC 27 [56] and *Anan Kasei v Neochemicals and Oxides* [2019] EWCA Civ 1646.

181. Whether these are 'squeeze' arguments or not, on my construction it does not seem to be relevant anymore. The parties acknowledge this is only in issue where the construction was that proposed by Med-El in the case. I have concluded the claims as interpreted cover rotation of the 'first attachment magnet' (substantially) in the plane of the implant coil housing and not a magnet that can rotate in other planes. The sufficiency arguments therefore either fail or fall away.

OBVIOUSNESS

182. There is a single prior art document in this case and it is relevant only to the issue of obviousness.

The law

183. Section 3 of the Patents Act 1977 provides: "*An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art…"*

184. The law on obviousness is extensive. A helpful review was set out in the Supreme Court *Actavis Group PTC EHF v ICOS Corp* [2019] UKSC 15 [52] - [73] at Lord Hodge stated [60]:

"*In addressing the statutory question of obviousness in section 3 of the 1977 Act it is common for English courts to adopt the so-called Windsurfing/Pozzoli structure which asks these questions:*

> *"(1)(a) Identify the notional 'person skilled in the art';*
>
> *(b) Identify the relevant common general knowledge of that person;*
>
> *(2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;*
>
> *(3) Identify what, if any, differences exist between the matter cited as forming part of the 'state of the art' and the inventive concept of the claim or the claim as construed;*
>
> *(4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?"*

(Pozzoli SPA v BDMO SA [2007] EWCA Civ 588; [2007] FSR 37, para 23 per Jacob LJ). The fourth question is the statutory question and the first three questions or tasks, the second and third of which involve knowledge and consideration of the invention, are a means of disciplining the court's approach to that fourth question …"

185. The task is to approach the prior art with care and as the skilled person would have done at the Priority Date, in the light of the CGK and to "… *evaluate all the relevant circumstances in order to answer a single and relatively simple question of fact.*" Medimmune Ltd v Novartis Pharmaceuticals UK Ltd & Ors [2012] EWCA Civ 1234 at [93], per Kitchin LJ.

186. The Court must come to its decision on whether an invention is obvious based on a review of the totality of the evidence in the case. In *Conor v Angiotech* [2007] UKHL 49 [42] Lord Hoffmann approved the statement on this point of Kitchin J (as he was) in *Generics (UK) limited v Lundbeck A/S*:

> *"As Kitchin J said in Generics (UK) Ltd v H Lundbeck A/S [2007] RPC 32, para 72:*
>
> *"The question of obviousness must be considered on the facts of each case. The court must consider the weight to be attached to any particular factor in the light of all the relevant circumstances. These may include such matters as the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research, the effort involved in pursuing them and the expectation of success."*

187. The Court of Appeal explained in Molnlycke AB v Procter & Gamble Ltd [1994] RPC 49 (CA) at page 112, line 40 that the Court will be assisted by the evidence of the expert witnesses as to whether or not the relevant step would have been obvious to the skilled person in the light of the state of the art. Other evidence may also be relevant, but the evidence of the experts takes the primary role and must be carefully assessed to identify what the notional skilled person would have regarded as obvious.

188. As summarised by Jacob J in Unilever PLC v Chefaro Proprietaries Ltd [1994] RPC 16, at page 580:

"*… the test is that set out in the statute and none other. Any other verbal formula leads to danger. In operating the test, the Windsurfing logical structure is helpful. The question is one of overall fact. Inferences from secondary evidence are relevant.*"

189. The CGK and Skilled Team have been identified earlier in this Judgment.

190. Each of the claims in issue has also been construed. In this context and considering 'step 2' of the above structured model for approaching the assessment of obviousness the point was commented on by Floyd LJ in *Generics (UK) Limited v Yeda* [2014] RPC 4 [39]:

> *"Prior art will be read with the prejudices, preferences and attitudes that the skilled person had at the priority date as explained in Asahi Medical Co Ltd v Macropharma (UK) Limited [2002] EWCA Civ 466 at [21] per Aldous LJ. Although the skilled person is assumed to be interested in the relevant field of technology there is no assumption of knowledge before reading the patent that any particular piece of prior art solves the problem under consideration. It is therefore possible that, having read the prior*

art, the skilled person would not have found the document useful or worth further development as stated by Laddie J in Inhale Therapeutic Systems Inc v Quadrant Healthcare Plc [2002] RPC 21 at [47]."

The prior art – Zimmerling

Abstract

191. Zimmerling was published on 9 October 2003. Its heading is "Reducing effect of Magnetic and Electromagnetic Fields on an Implant's Magnet and/or Electronics". The abstract explains that it discloses an "*implantable magnet that can freely turn in response to an external magnetic field, thus avoiding torque and demagnetization on the implantable magnet*".

Background Art

192. This section describes a prior art cochlear implant system shown in Figure 1:

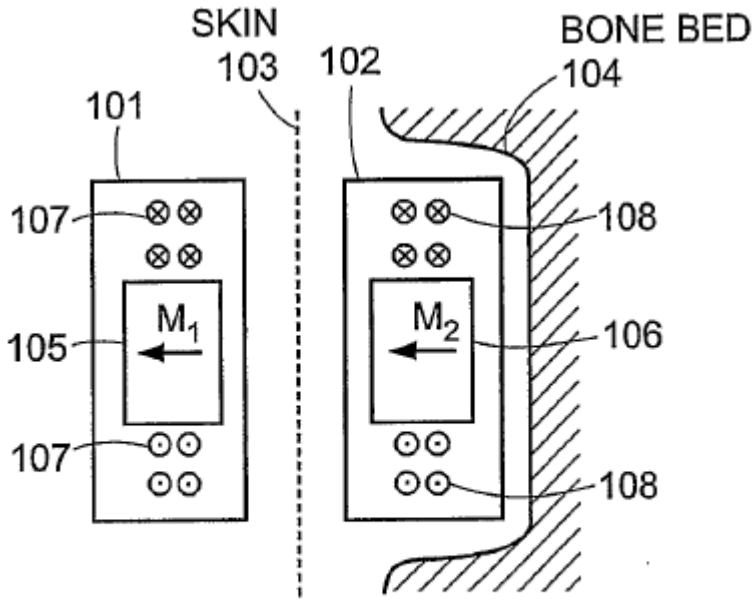


FIG. 1
PRIOR ART

193. This Figure shows the implantable component of a cochlear implant (102) under the skin, with its implanted magnet (106). The external magnet (105) is shown as positioned over the internal magnet.

194. Zimmerling describes how a patient with a cochlear implant that has an MRI scan can have interactions between the implanted magnet and the external MRI magnetic field (above about 1 tesla). Figure 2 (reproduced above at paragraph 48) demonstrates the first problem Zimmerling identifies that arises when these cochlear implant systems are introduced into the strong magnetic field of an MRI machine. This shows that the implanted magnet may experience torque that can twist the magnet and the implant out of position, potentially injuring the wearer. The second problem identified is that due to a strong external magnetic field the implant magnet may become partly demagnetised and therefore not be strong enough to hold the external part of the system in place. Further problems identified are; potential RF pulses emitted by the MRI unit inducing voltages in the implant coil/circuit and which may damage circuitry and artifacts may appear in the MRI image, caused by the local magnetic field of the implant magnet which distorts the homogeneous MRI field.

195. Zimmerling describes some ways these issues could be avoided: (1) not to undergo MRI with strong fields but this may exclude the patient from important diagnostic examination, (2) implant magnets which can be removed and re-inserted for an MRI scan but this approach has the downsides that a patient has to undergo surgery. Other alternatives noted are to use identical implant magnets with opposite orientation or to use a magnetically soft material.

Summary of the Invention

196. Zimmerling describes two general concepts within the specific embodiments which are intended to deal with the prior art problems identified in cochlear implant. The first relates to a magnetic switch. This switch is responsive to an external magnetic field. It is to provide overvoltage protection as a function of orientation of the external magnetic field. The aspects of Zimmerling dealing with switch mechanisms in essence utilise the rotation of the internal magnet in an external magnetic field to provide protection from RF overvoltage. I have not set out the disclosure on the magnetic switches as both parties and their experts felt that the Skilled Engineer would not be very interested in this issue by the Priority Date. The second relates to "*... at least one magnet is free to turn in the housing such that the at least one magnet is capable of aligning partially with an external magnetic field.".*

Detailed Description of Specific Embodiments

197. Figure 3 depicts a spherical magnet for implantation that is held in the implant in such a way that the magnet "*can turn into the direction of an externally applied magnet field.*". The magnet "*of whatever shape*" is held inside the housing so it can turn – possibly with some restrictions – into the external magnetic field lines. This is noted as preventing it experiencing *any* torque as a result of the external magnetic field – nor will it become de-magnetised. It goes on to discuss materials for the construction of the housing (titanium) and how to make the housing work with the magnet inside – leaving a small gap around the outside/lubricant etc..

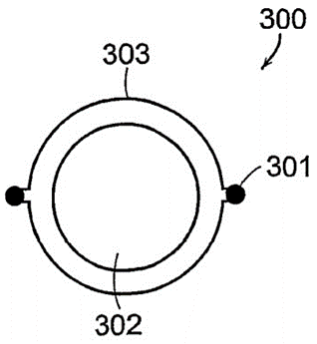


FIG. 3

198. Zimmerling acknowledges that other shapes can be accommodated within the housing and likewise permitted to rotate to suit the MRI field. Fig. 9 shows a cylinder which can rotate on its axis and is magnetised with its dipole "*normal to its axis*" (perpendicular).

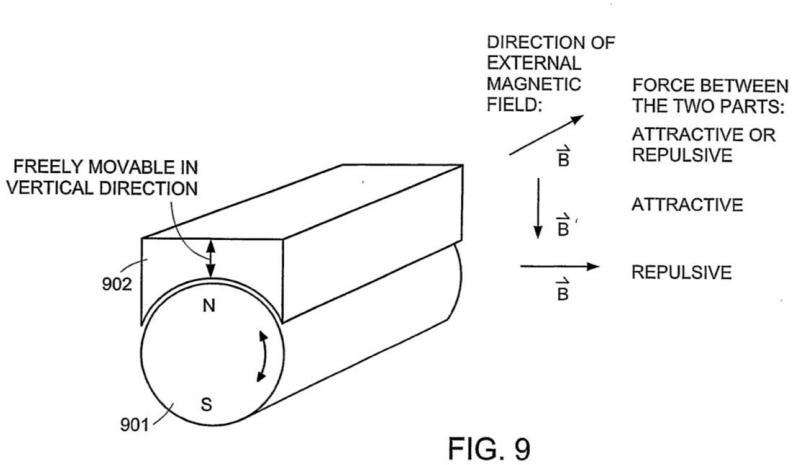


FIG. 9

199. Zimmerling explains that this cylindrical magnet can be arranged horizontally parallel to the skin in the plane of the implanted coil so that it can "*turn its magnetic moment either towards the external holding magnet*" to attach the external headpiece, or "*so as to align with the field generated*" like an MRI machine. It explains that in a typical MRI machine, the external magnetic field lines "*run along the patient's axis*" (i.e. the field goes head to toe when lying down). An alternative arrangement is discussed where the cylinder is still mounted in the plane of the implant coil but at approximately 45 degrees off the horizontal plane to be able to partially adjust to (lower field) MRI machines whose magnetic fields are vertical. The advantage noted is that a cylinder of necessary

diameter and length can be chosen such that the given volume is enough to generate an adequate holding force (for the magnet in the external headpiece) and also provides a thickness of magnet smaller than that of a spherically shaped magnet.

200. Figures 4A and 4B describe an embodiment with three, smaller spherical magnets. As Zimmerling explains this arrangement allows for a "*thinner design*" of the implant. These the magnets may be arranged "*some distance apart… thus facilitating the orientation of magnets*" primarily along the lines of an external holding magnet.

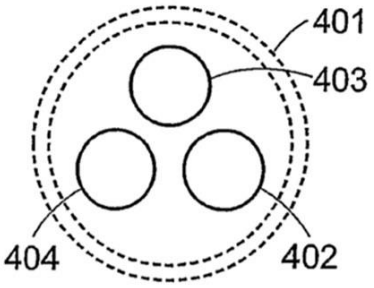


FIG. 4A

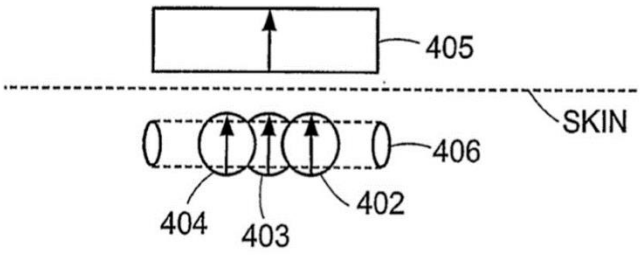


FIG. 4B

201. Figures 5A and 5B shows an implant magnet partially surrounded by magnetically soft material to create a low reluctance path for magnetic flux – this is said to partly shield the magnet from external magnetic fields – reducing the torque and demagnetization.

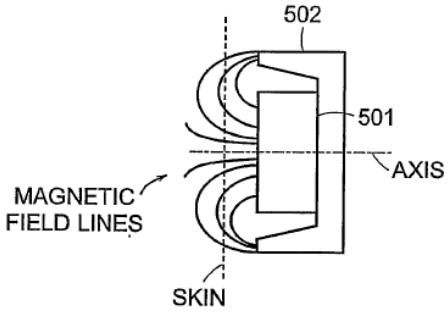


FIG. 5A

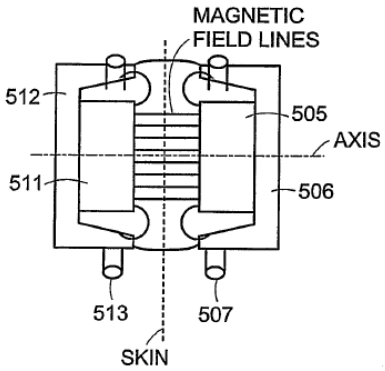


FIG. 5B

202. Figures 6A and 6B show embodiments using a ferrofluid as the implant magnet. A ferrofluid is a liquid-state material which contains tiny magnetic particles suspended in a fluid. This magnet can magnetize in the direction of an external magnetic field and experience no torque in an MRI. It will also not demagnetize. However, to get a required holding force for attachment the volume of the implant magnet may have to be comparatively larger.

203. Figure 7 shows how a "low-reluctance" part can be added to an embodiment to improve magnetic flux from the implant to external magnet and also to act as a shield to external magnetic fields to minimize torque and artifacts – especially at the implant facing side.

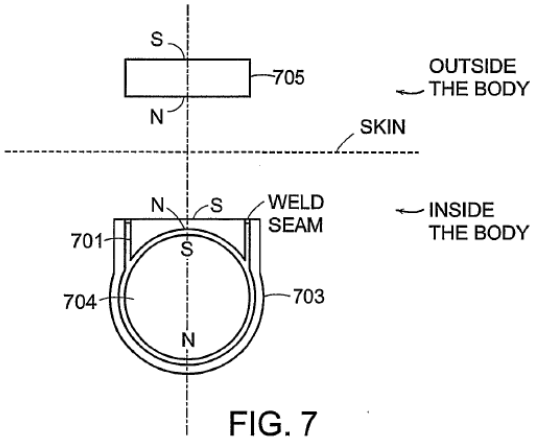


FIG. 7

204. Figures 12A and 12B disclose a rotatable implant magnet and switching function.

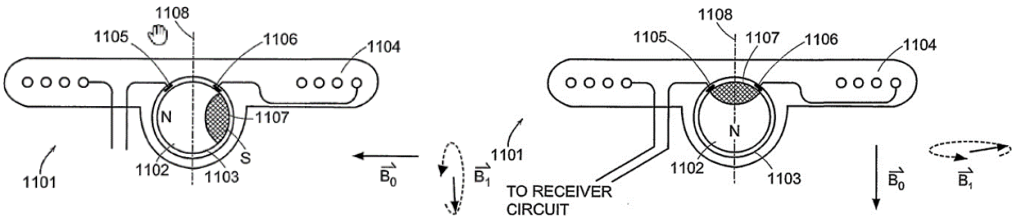


FIG. 12A FIG. 12B

Zimmerling disclosure

205. The parties agree that there is little disagreement between the experts on what Zimmerling would teach the Skilled Team. The dispute mainly focuses on what the Skilled Engineer would do in the light of this teaching. I set out below some of the main features disclosed by Zimmerling – either where agreed by the parties or based on my findings in all the circumstances and carefully weighing the information including from the evidence, documents and submissions.

206. Zimmerling is about problems that can arise when a patient with a cochlear implant has an MRI. The solutions taught are: (1) a magnetic switch that functions in response to an external magnetic field, and (2) that the implant magnets can rotate to align with an external magnetic field. By the Priority Date both parties for similar but not identical reasons dismiss the over-voltages switching teaching as being of interest to the Skilled Engineer for cochlear implants.

207. I have summarised below some of the most relevant disclosure from Zimmerling

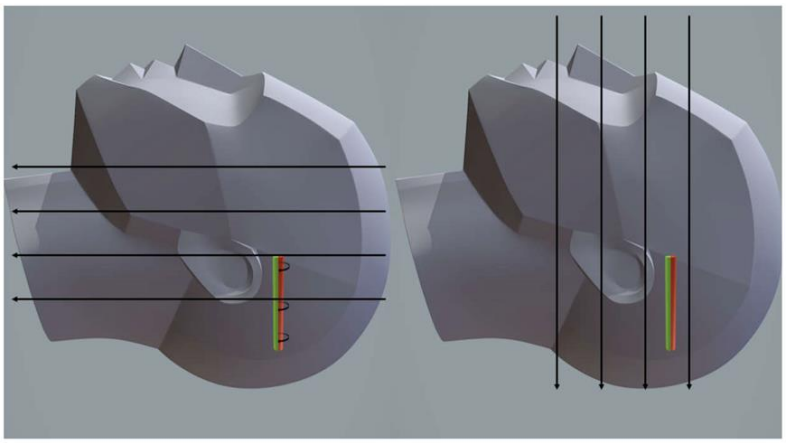
208. Zimmerling discloses the 'perfect' internal magnet for dealing with torque. The reason is that a sphere is the only shape that can fully align with an external field in any direction. With a sphere the definitions used for axial and diametric magnets – which are contextual definitions – become less helpful. It can be both.

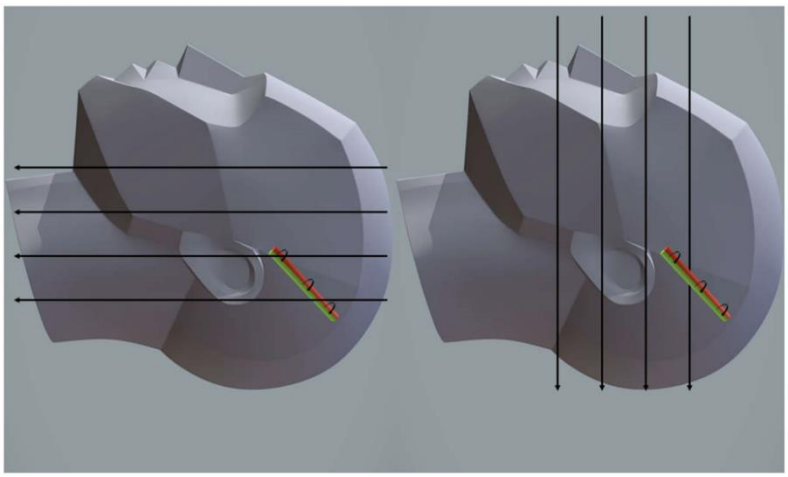
209. It is CGK that the Skilled Team would know of the need to calculate and/or test that any internal (or external) magnets have the relevant holding force to attach to each other. Zimmerling also teaches this need to factor in a given volume of magnetic material.

210. It is also CGK that the cochlear implant products on the market containing the implant magnet housing had converged to a fairly similar thin, flat design by the Priority Date. Zimmerling also taught (Figure 4) that using multiple spheres each of which was smaller would allow for a thinner design. It provides teaching on the use of a housing as a form of 'gimbal' along with explanations on friction reduction and spacing allowing the internal magnet to freely rotate.

211. Zimmerling also acknowledges the need to consider how the rotation of the internal magnet interacts with different types of MRI external magnetic fields with different directions of field lines (these types of MRI – open and closed bore - and their different operating field line directions are CGK). It teaches that a variety of shapes of internal magnets can be used. Also that varying the orientation of the axis of the rotation of an internal magnet (here a cylinder) to 45 degrees off the horizontal plane provides a compromise position that would rotate sufficiently in an external magnetic field to partially adjust to align with the directions of the different external

MRI fields of the two noted MRI systems and provide a thinner magnet than a spherical one. The Skilled Person would recognise that this cylindrical magnet set-up foregoes the ability to rotate in three dimensions and so achieve complete alignment with the external magnetic field. Med-El closing reproduced some of AB's diagrams which help to orientate what the MRI field lines and the internal cylinder magnet could look like in these two noted orientations:





212. Zimmerling teaches that the external magnets for attaching to the internal rotating one all have an axial magnetic orientation. It is not common ground that Zimmerling teaches this to be a requirement.

213. Zimmerling presents the CGK position with fig. 2 showing an axial magnet and the problem of torque twisting/rotating the axial magnet. Although unclear, I believe Professor Suaning ultimately accepted in cross examination that the Skilled Person would understand that magnets with their dipoles perpendicular to their axis were needed for rotational movement. He later accepts that diametric magnetic stirrers are CGK. This is all basic understanding of magnetic forces as commented on by Professor Parker. Although not the question being asked by AB's counsel, in responding I believe Professor Suaning was likely focusing on his key point in the case in answering these questions – the choice of a diametric disk magnet as an obvious shape to try – something he does not believe would have been considered. I have explained earlier I was concerned that in some of these responses Professor Suaning gave me the impression he was not assisting the court as I would expect. His answers could come across as evasive and at times contradictory. However, Med-El's counsel did accept the point in general terms (see above at paragraph 48). This type of movement resulting from the interaction of the magnet and external magnetic forces (although not necessarily rotation) is effectively what fig. 2 is teaching in both Zimmerling and in the Patent as prior art. That is accepted. AB's expert agrees this would be well known. The Skilled Person would understand the forces at work and know CGK examples of diametric magnets operating to rotate in an external magnetic field. As noted above, I have assessed therefore that the key to rotating a permanent magnet in an external magnetic field is to have the magnetic dipole across the axis of rotation and that this is CGK.

214. In the circumstances, this may not matter if Zimmerling teaches that changing the orientation of the magnetic dipole to one that is across the axis of rotation allows the magnet to turn in an external magnetic field. This is

what AB says it does. Med-El's counsel appears to accept this also. In cross examination Professor Suaning accepts this in the context of the cylinder magnet:

> "*Q. He is also teaching there, the skilled person, to the extent they did not already know, that in order to get this to work he has got to make sure that the shape is magnetized so that it is able to rotate in the external field."*
>
> *A. Yes*
>
> *Q. For this one, that means magnetizing diametrically, which is perpendicular to its axis of rotation?*
>
> *A. Correct."*

215. So, Zimmerling teaches how to arrange and rotate a variety of shapes of magnets in an external magnetic field such that they are arranged with their dipole across their axis of rotation and are trying to align to some extent to reduce torque in an external magnetic field such as an MRI. All the taught orientations (other than spheres where it appears to depend) have the axis of rotation perpendicular to the skin. I note that Professor Suaning believes the thrust of Zimmerling is to provide a solution that gives a perfect alignment with an MRI field. This does not change the fact that it also discloses the compromise of a partial alignment.

Obviousness over Zimmerling

216. In *Actavis v ICOS Corp* [2019] UKSC 15 at [63] Lord Hodge repeated the reference in *Conor Medsystems Inc v Angiotech Pharmaceuticals Inc* [2008] UKHL 49 to the non-exhaustive list of factors set out by Kitchin J (as he was) to assist with the multi-factorial question for the Court in assessing obviousness in *Generics (UK) Ltd v H Lundbeck A/S* [2007] RPC 32 [72]:

> "6*3. In Conor Medsystems Inc v Angiotech Pharmaceuticals Inc [2008] UKHL 49; [2008] RPC 28; [2008] 4 All ER 621, at para 42 Lord Hoffmann endorsed the fact-specific approach which Kitchin J set out in Generics (UK) Ltd v H Lundbeck [2007] RPC 32, para 72 where he stated: "The question of obviousness must be considered on the facts of each case. The court must consider the weight to be attached to any particular factor in the light of all the relevant circumstances. These may include such matters as the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research, the effort involved in pursuing them and the expectation of success." Kitchin J's list of factors is illustrative and not exhaustive."*

217. Applying *Pozzoli* I have dealt with the Skilled Team and the CGK above. I note this model is intended to provide a structure for the Court to assist it in arriving at the conclusory statutory question. It is not intended to create an 'over mechanistic' approach.

218. The approach to identifying the inventive concept in <u>*Pozzoli*</u> is at [17]-[18]:

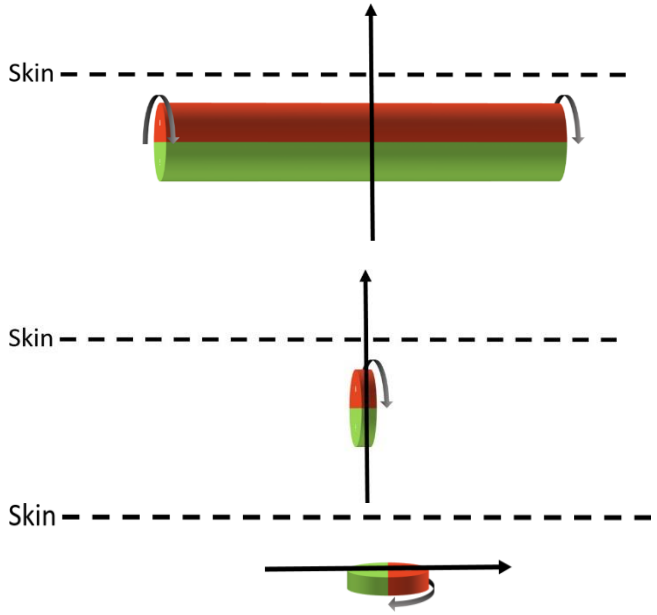
> "*What now becomes stage (2), identifying the inventive concept, also needs some elaboration. As I pointed out in Unilever v Chefaro [1994] RPC 567 at page 580:*
>
> > *17. It is the inventive concept of the claim in question which must be considered, not some generalised concept to be derived from the specification as a whole. Different claims can, and generally will, have different inventive concepts. The first stage of identification of the concept is likely to be a question of construction: what does the claim mean? It might be thought there is no second stage – the concept is what the claim covers and that is that. But that is too wooden and not what courts, applying Windsurfing stage one, have done. It is too wooden because if one merely construes the claim one does not distinguish between portions which matter and portions which, although limitations on the ambit of the claim, do not. One is trying to identify the essence of the claim in this exercise.*
> >
> > *18. So what one is seeking to do is to strip out unnecessary verbiage, to do what Mummery LJ described as make a précis."*

219. I have construed the claims in issue above.

Differences over Zimmerling

220. The teaching does not describe the use of a rotatable diametric implant magnet in the plane of the implant coil housing with a magnetic dipole parallel to the plane of the implant coil housing/skin. It also does not teach the use of a diametric magnet as the external magnet in the headpiece.

221. A key difference for Professor Suaning seems to be one of geometry. I have set out below some diagrams provided by AB to explain. These show a representation of the Zimmerling cylinder magnet. It then shows a representation of what a disk magnet would look like (this is to demonstrate the geometry point – it is not an acceptance that the Skilled Person would think of shortening the cylinder as shown). Although this disk magnet has its magnetic dipole across its axis of rotation the geometry is such that it is perpendicular to the skin. The final diagram shows the Patent's solution. This is a disk magnet with its magnetic dipole across its axis of rotation. The geometry is now that the plane of rotation is parallel to the skin. Disk magnets were what was used in the cochlear implants at the Priority Date and were CGK. There is no serious dispute that if you wanted to make/buy a relevant disk magnet which was magnetized across its axis of rotation (diametric) this would not be available at the Priority Date. The evidence supports this position. It is not suggested this needed any invention.



222. The parties accept (for different reasons which I deal with below) that Zimmerling's use of rotatable implant magnets would be of interest as an approach to overcoming the problem with MRI compatibility.

223. Before turning to the fourth head of Pozzoli it is necessary to deal with a criticism of Professor Parker raised by Med-El. I have already dealt with Med-El's criticisms of Professor Parker's evidence relating to his instructions and approach to his role and also to the information he had in relation to his approach to assisting on infringement. This further criticism relates to the earlier one where it was alleged Professor Parker was either not instructed properly or was not following those instructions. Their arguments are dealt with over 7 pages of Med-El's closing. Effectively what is said is that Professor Parker only came to his views on obviousness because he is an inventive person, steeped in knowledge about the relevant field and has failed to follow the rigorous approach required to qualify his thought process to give his evidence from the perspective of the relevant uninventive skilled person at the Priority Date, without hindsight.

224. I have assessed earlier and held that Professor Parker was properly instructed as set out in his report and that it has not been demonstrated he has failed in any material way to follow those instructions. Med-El argue that he did not follow his role 'without hindsight'.

225. In this context it is worth considering the helpful comments of Mr Justice Arnold (as he was) in *Medimmune v Novartis* [2011] EWHC 1669 [99] - [114] and in *FibroGen v Akebia* [2011] EWHC 1669 [10-13], [36]:

> *"36. This submission illustrates why it can be advantageous to try to instruct expert witnesses in sequence, first asking them about the common general knowledge, then showing them the prior art and asking them questions such as what steps would be obvious in the light of it and only then showing them the patent in suit. This is a procedure known as "sequential unmasking" in the psychological literature (see generally on this subject C.T. Robertson and A.S. Kesselheim (eds), Blinding as a Solution to Bias, Academic Press, 2016). The point of it is to try to avoid, or at least reduce, hindsight. In my opinion, it is desirable to try to minimise hindsight on the part of expert witnesses where possible. There is no rule or principle that experts must be instructed sequentially, however. Moreover, there are often real practical problems in doing so. To take just one obvious example, any discussion about the common*

general knowledge must start by identifying the skilled person or team. How is this to be done if the expert cannot be shown the patent? One way is to ask the expert to make an assumption, which they can check later when they see the patent; but that is not necessarily a perfect solution. Other problems can be caused by the pre-existing knowledge of the expert and by amendments to the parties' cases (such as the introduction of new prior art after the expert has read the patent). Still further, instructing experts in this way can make their task even more burdensome, particularly when it comes to cross-examination, because they may find it difficult to recall what they knew when unless it is clearly documented. (It should be borne in mind, however, that some cross-examination as to the way in which the expert has been instructed is often justified in any event.)"

226. In this case 'sequential unmasking' of the documents was followed. AB explained to Professor Parker that as part of his role when considering the CGK in sequence he should do so from the perspective of "*... a skilled medical device engineer working in the cochlear implant space as at April 2010.*". A likely necessary prompt in the circumstances and envisioned by Arnold LJ in the above noted case. Med-El had the same discussion with Professor Suaning in sequence. Initially he did this from his understanding and the perspective of a developer of cochlear implants. Both experts have prepared their reports having had sight of the Patent, have given their views on the skilled person and presumably making any adjustments to their initial views on the CGK as a consequence. The same point goes for the expert views when initially reviewing the prior art. The point is that, in my view, both parties and their experts have been diligent in the discipline of the process employed to try to minimise any hindsight.

227. The main criticisms of Professor Parker here relate to disclosures during cross-examination which Med-El allege reveals that Professor Parker knew of the invention. They say this hindsight, combined with their argument that he did not follow his instructions properly, means his evidence is of no probative value. I have already explained my finding that Professor Parker was properly instructed and appears to have followed those instructions in providing his evidence. In many ways the criticism should end at that point. On this basis, any information Professor Parker had on the state of the art or the invention (I note as a comparison that Professor Suaning had knowledge of the relevant post Priority Date Med-El product (the Synchrony) on the market and, rightly, no criticism is made by AB) would be dealt with by the discipline of the approach to the issues in his instructions.

228. For completeness, however, I will review the specific concerns. During cross examination there was a disclosure from Professor Parker which Med-El rely on:

> 9. Q I am grateful. Putting oneself back, forgetting things that
> 10 you know and being uninventive can all be very difficult
> 11 things to do. How did you ensure that you did it?
> 12 A. Putting myself back to 2010? For me I do not think that was
> 13 very difficult. I remember having a conversation with
> 14 Kirkland at the start, questioning whether or not my knowledge
> 15 at 2010 would be relevant, because I had already been out of
> 16 the cochlear implant field for, you know, two or three years
> 17 and I did not or had not kept up-to-date with what products
> 18 were there or not there. I did ----
> 19 Q. Save from conversations with your colleagues and the like?
> 20 A. Yes, save for dinner gossip, if you like. They assured me
> 21 that that was a reasonable situation and so on, so I did not
> 22 feel I had to do anything specifically, other than not try and
> 23 research what had happened in the interim between 2010 and
> 24 today, which I did not do preparing these reports.

229. There is a further exchange relied on by Med-El on this point:

> 7 Q. No. When you sat to give your evidence about what the skilled
> 8 team would do with Zimmerling ----
> 9 A. Yes.

10 Q. ---- were you already aware of what the Cochlear products, the
11 AB products and the MED-EL products that were on the market as
12 at 2020?
13 A. **As at 2020, vaguely**. **I knew what Cochlear had on the market**,
14 but I had not paid much attention to changes that had happened
15 from AB and from MED-EL.
16 Q. As I understand it, you were contacted at some point by
17 Kirkland & Ellis and asked to consider giving evidence about
18 cochlear implants.
19 A. Yes, that is correct.
20 Q. Surely, you did a bit of a look around, at least on the
21 internet, at the three major players, Cochlear, AB and MED-EL,
22 to bring yourself up to speed a bit before talking to Kirkland
23 & Ellis?
24 A. Frankly, I did not, no. Maybe I should have, I do not know
25 whether that was the right thing to do or not. **But I do**

2 actually have colleagues of mine or former colleagues from
3 Cochlear and we have dinner occasionally and there are sort of
4 snippets from the industry. But, no, I really had no idea.
5 The Synchrony and those sorts of devices were brand new to me.
6 I discovered them through these proceedings.

230. Professor Parker's cross-examination revealed he has 'dinner gossip' with old colleagues from Cochlear. The exchange does not get close to the level of concern Med-El try to give it. If they had wanted to know specifically what the dinner gossip referred to they could have asked. As it was, Professor Parker gave the context which does not raise any serious concerns.

231. Another related point raised by Med-El was Professor Parker's response to a direct question from Med-El's counsel on whether he did not know about the invention before deciding how to apply the teaching in Zimmerling he explained: "*Yes, there was a conversation that we had early on in the discussion. I knew that it involved rotation in some way, but other than that, I was not aware of the patent or any of the details.*". His response therefore started with the clarification that he did not know about the invention prior to deciding how to apply Zimmerling. His statement appears to be referring to a discussion with AB's representatives. On the face of this and on his express statement, which I have no reason to doubt, he confirmed this was not really about his knowledge of the invention but rather some relevant related information. From what he says, it does not appear to go further than what is in Zimmerling. Ideally this would have been disclosed. I do not know why this was not done by AB's representatives. Much would depend on the context and detail. We do not have sufficient information available on either.

232. As noted above, Professor Parker came across as an open and fair witness doing his best to assist the court. In assessing the evidence and submissions on this I do not believe there is anything which justifies me looking beyond the express statement provided by Professor Parker on the topic. Despite this, I have considered the points raised and come to the conclusion they do not support the criticisms. In the circumstances, I do not believe this diminishes Professor Parker's evidence in any material way. In the end, once I have assessed that the instructions have been properly made and followed it is as Jacob LJ said in *Technip* below – about the reasons. In reaching my decision I will, of course, consider all these points carefully as part of my exercise in weighing the various issues.

233. The level of, on my findings, unfair criticisms levied at Professor Parker gives the impression there may be an effort being undertaken to try to avoid dealing directly with the evidence of Professor Parker. As noted above,

Professor Parker came to the almost immediate view - before seeing the Patent - upon being shown Zimmerling about what the Skilled Person would do:

> "*It immediately struck me that there were other straightforward shapes which could be used to take advantage of the rotatable design disclosed by Zimmerling, In particular, the first suggestion I made was the use of a flat disk-shaped magnet instead of the bulkier magnets shown in Zimmerling. The reason I thought of this is because flat, disk shaped magnets were the most commonly used type in the common general knowledge … and so the easiest way to implement Zimmerling would be to use the designs and components already being used.".*

234. In coming to a view on these issues I am conscious in particular of needing to be careful in considering inventions which can look simple in hindsight. In this case Professor Suaning puts the decision to choose a disk-shaped magnet and then 'flip the dipole' as a eureka moment. Whereas Professor Parker says in response to a long list of reasons from Med-El of what needs to be considered by the Skilled Team prior to coming to this view: "*Because it is completely obvious. I do not know how else to answer that*….".

235. I refer to *Siddell v Vickers & Sons Ltd* (1890) 7 RPC 292 and Lord Reid in *Technograph Printed Circuits Ltd v Mills & Rockley (Electronics) Ltd* [1972] RPC 346 [355] in this regard. The skilled person is a notional construct who will not have all of the attributes of any of the experts in this case. In the context of the above discussions and indeed the criticisms I refer to Jacob LJ in *Technip France SA's Patent* [2004] RPC 32 [14] explaining what is of most relevance when considering expert evidence:

> *"14. But just because the opinion is admissible, it by no means follows that the court must follow it. On its own (unless contested) it would be 'a mere bit of empty rhetoric' Wigmore, Evidence (Chadbourn rev) para.1920. What really matters in most cases is eh reasons given for the opinion. As a practical matter a well-constructed expert's report containing opinion evidence sets out the opinion and the reasons for it. If the reasons stand up the opinion does, if not, not. A rule of evidence which excludes this opinion serves no practical purpose. What happens if the evidence is regarded as inadmissible is that experts' reports simply try to creep up to the opinion without openly giving it. They insinuate rather than explicate" (Minories at p.188)."*

236. In the context of obvious routes to try I refer to *Brugger v Medicaid No.2* [1996] RPC 635 noting that there can be a number of obvious routes to try from a piece of prior art. Also, *MedImmune v Novartis* [2012] EWCA Civ 1234 [90]-[93] where Kitchin LJ (as he was) explained that whether something is obvious to try depends on all the circumstances. Also as noted by Laddie J in *Inhale v Quadrant* [2002] RPC 21 [47] "*A document directed at solving the particular problem at issue will be seized upon by the skilled addressee.*".

Pozzoli – the fourth head

237. In approaching this step I do so without any reference to the Patent.

238. It is common ground that the Skilled Team would be interested in improving their cochlear implant products in terms of better MRI compatibility, in particular to reduce torque effects. Although the evidence varies by degree all parties accept, and where they do not my finding on the evidence is that, there would have to be a significant clinical benefit to revert to an implant shape that required bone drilling – it would be avoided if possible.

239. There are a number of issues to consider in this multi-factorial approach to obviousness. I have considered all the evidence and arguments but do not refer to every point. In summary, the main differences are that Professor Suaning's Skilled Engineer would focus on the embodiments of Zimmerling and really only Figure 4A and the related embodiment as a possible design of interest. Professor Parker's Skilled Engineer would be more interested in the general teaching of Zimmerling and start with the design of the CGK products on the market – those with internal axially magnetised implant magnets.

240. Professor Parker's approach to the issues in this case taking on the mantle of the Skilled Team is set out in his Second Report that "*In reaching my conclusion that a disk-shaped magnet would be an obvious choice of magnet shape to use at the Priority Date when presented with Zimmerling, I relied only on what would have been known to the skilled medical device engineer at the Priority Date. If a skilled medical device engineer decided to implement Zimmerling, they would be highly motivated to do so within the existing coil assembly form factor, in particular if possible using the shapes of the magnets and the housings, due to a combination of the regulatory factors described in my first report and the non-negotiable requirement to design a coil assembly that could be implanted without the need for bone excavation. It is clear that the existing shape and housing used at the Priority Date meets the clinical requirements."* AB's case is it is an obvious thing to do – to use Zimmerling's teaching

on existing products to address the MRI issue. Professor Parker explains the reasons he arrives at the geometry point that appears to be the dispute with Professor Suaning.

241. Professor Suaning sets out at paragraph 18 of his Second Report four actions he says would need to be done and three further matters which would need to be considered before the Skilled Engineer would consider using a flat, disk-shaped magnet.

242. Turning to the noted points raised by Professor Suaning which the Skilled Person would need to consider before selecting a flat disk-shaped magnet. I summarise these and set out counter-points raised and reasons:

(a) Ignore the specific magnets taught in Zimmerling. Both experts accept Zimmerling teaches the internal magnet can align at least partially with an MRI field. That is not ignored. The other embodiments are considered. There can be more than one obvious route.

(b) Choose a magnet that does not provide all the advantages disclosed in Zimmerling (i.e. full torque reduction). The teaching of Zimmerling is not so specific. It discusses the compromise of partial alignment, thinness and need for magnetic volume to attract to the external magnet.

(c) Implement a diametrically magnetized disk shaped magnet. Professor Suaning's view is that there is no motivation to try with the existing CGK disk-shaped magnet used in cochlear implants. He says, it would be a eureka moment to come across it and then say "Ah, you flip it" (the dipole). His view is that no-one was thinking about anything other than axial (implant magnets) previously as no-one was thinking about rotating. However, he accepted this type of rotation was taught by Zimmerling. The CGK or Zimmerling taught that it was known – but not that it had been so used in the context of a flat disk-shaped implant magnet. Regulatory considerations may point to considering existing shape magnet.

(d) Implement a mechanism to allow the diametric magnet to operate reliably over its lifetime to align. Zimmerling teaches about how to work with a rotating implant magnet (lubricants, gaps). The experts agree, these types of steps are all within the reasonable workmanlike skill of the Skilled Person.

(e) Appreciate that the diametrically magnetized, rotatable disk-shaped magnet will work with open and closed bore MRI. The geometry of this compromise is taught in Zimmerling. It is not explained there is anything in the shape of a disk-magnet that would make it difficult for the Skilled Person to follow the existing teaching. The evidence of Professor Parker confirms this. It is dealt with further below.

(f) Appreciate that such a magnetic configuration (partial alignment) would be useful in most clinical scenarios. Professor Suaning felt this calculation did not require invention - it was within the Skilled Person's toolkit. Professor Parker's evidence is similar.

(g) Consider using a diametrically magnetized external magnet, and appreciate that the rotating design of the internal magnet would overcome the issue raised in Professor Parker's First Report. Professor Suaning accepted in cross examination the choice of diametric implant magnet means the Skilled Person would choose a diametric external magnet without invention. This obvious 'knock-on' impact was confirmed by Professor Parker. The rotation of the implant magnet means the attachability point raised by Professor Parker in his First Report does not arise. Professor Parker confirmed the point in cross examination.

243. Professor Suaning carefully considers the specific embodiments in Zimmerling and dismisses or de-prioritises most for various reasons and decides to prioritise Figure 4A and its embodiment as worth investigating. This is due to its providing the 'ideal' solution to the MRI problem as spheres can provide perfect alignment with an external magnetic field and by having multiple spheres the housing can remain thinner than with one larger sphere (but balancing that there needs to be a sufficient magnetic volume for sufficient attraction to the external magnet). Professor Suaning did not think the Skilled Person would look at trying to implement the teaching of Zimmerling more generally and would not have thought of doing so using the CGK disk-shaped implant magnet. In his view the Skilled Engineer would seek to optimise the Fig. 4 design. In doing that he thought they would consider using different numbers of spherical magnets.

244. In the context of giving his evidence on this point I found some of Professor Suaning's evidence somewhat inconsistent. For example, he did not feel the skilled person would consider using a disk-shaped magnet but he viewed the fact the magnet housing used in Figure 4A was a disk-shape would be 'attractive' and 'an advantage'. Another example was that after lengthy cross-examination on what the Skilled Person would know about basic rules of magnets and their rotation in external fields Professor Suaning noted he believed the Skilled Engineer would only have a few days of lectures on magnetism in their academic courses. In the end, with later concessions, this was not really material. However, when discussing how to implement Fig 4A Professor Suaning noted that a move from the 3 sphere arrangement to a 6 sphere arrangement for the internal magnets may be better and would be obvious to the Skilled Engineer. The reason being to maximise magnetic volume and this would be a CGK arrangement of the magnets using the hexagonal geometric efficiency of packing spheres in a plane which he

referred to as Kepler conjecture. Professor Suaning accepted this would all require work to assess the competing issues of magnetic volume and interaction between the different spheres.

245. AB's case is summarized effectively as set out by Professor Parker in paragraphs 233 and 240. Professor Parker accepts Figure 4A and its embodiment would be worth trying but that it would not be his top priority. His concerns with this approach are the complexity and increased likelihood of failure in an implant. Something reflected in the evidence from the clinical experts. A clinical improvement would likely be necessary although that is less of an issue if the regulators approved the design. It is a balancing act. However, standing at the start of that process it would likely be an additional risk to the expectation of success. There were also concerns about the magnetic volume of the spheres for attachment purposes and interaction between the spheres.

246. At its core, the critical dispute is whether it is obvious at the Priority Date for the uninventive skilled person to think of using the CGK cochlear product's implant disk-magnet shape and then to 'flip the dipole' from axial to diametric. Even this second aspect – to flip the dipole from axial to diametric –is argued to be obvious in the light of the teaching in Zimmerling once you have the idea of using the CGK disk-implant magnet. This is partly because it is argued using the CGK magnet brings with it the orientation parallel to the coil housing and then the question is – how do I make that rotate? The geometry then dictates that the magnet must be magnetised across its axis of rotation in order to rotate. This is both CGK and taught in Zimmerling. Professor Suaning accepted much of this analysis but not this critical point.

247. Under cross examination Professor Parker was challenged that his assessment here does not reflect the appropriate level of consideration that the Skilled Person would give to the matter. I have set out most of these points above. There are other points – such as the interaction of a rotating disk-magnet with the existing CGK implant coil system. This and other points appeared to be dismissed in my view and fall away.

248. Professor Parker's position remained as noted giving the following reasoning:

> A: "*I understand what you are saying, but I do not think that there are steps in that. You have a magnet and axially polarised magnets have been used forever. So you know for a fact that they have sufficient attractive force to hold a headset on to the skin. Now you flip the dipole of the field, so that it is aligned again parallel with the coil or parallel with the skin. You know. You do not have to do much work to know that that will provide enough attractive force to hold the magnet on to the skin as one step. All the other steps of including Teflon as a lubricant or allowing it to spin. The magnet itself, the fact that diametrically magnetised disk-shaped magnets are available and used industrially in other applications, all of that I do not think requires very much thought at all, in fact."*

249. In the light of the way the arguments are put by Med-El on the 'eureka' step which is critical to AB's obviousness case I refer to *British Westinghouse Electric and Manufacturing Company Ltd v Braulik* (1910) 27 RPC 209 [230] as a reminder of the need for rigour in our analysis to minimise the risk of hindsight creeping in which could lead a court to treat as obvious a relatively simple step which gives rise to benefits. This is despite that step not having been obvious to the skilled person at the relevant time.

> 230. "*... I view with suspicion arguments to the effect that a new combination, bringing with it new and important consequences in the shape of practical machines, is not an invention, because, when it has once been established, it is easy to show how it might be arrived at by starting from something known, and taking a series of apparently easy steps. This ex post facto analysis of invention is unfair to the inventors, and, in my opinion, it is not countenanced by English patent law.*"

Long-felt want/ secondary considerations

250. Med-El pleads in support of its case that there is a 'long felt want' due to the CGK problem with MRI compatibility of cochlear implants.

251. In this context there are a number of relevant cases to consider including *Halliburton Energy Services Inc v Smith International (North Sea) Ltd* [2005] EWHC 1623 (Pat):

> *"In the final assessment of a finely balanced argument on obviousness, it is possible that the balance will be tilted in favour of the patent if it is established that many were trying and failing: but this sort of consideration is secondary, and will draw attention away from the main question, which is what is obvious to the skilled person in the light of each cited document, taken separately and interpreted through the eyes of the skilled person. In the usual case, I think, the fact that some investigators tried and failed to solve the problem allegedly solved by the patent is irrelevant to the question with which I am confronted, unless it can be shown that those who failed were aware of the publication under consideration, and the fact of failure will therefore have the strongest effect when the common general knowledge alone is relied on, although even then it must be shown that those who tried and failed were possessed of the common general knowledge and were not the victims of idiosyncratic prejudice or ignorance."*

252. And *Brugger v Medic-Aid Ltd* [1996] RPC 635 [654]:

> *"No doubt a manufacturer with existing tooling is likely to follow a line of modification which is least likely to result in him having to retool completely or significantly. This may act as a commercial constraint which will reduce his willingness to embark on certain lines of development. Indeed the cost of retooling may be such that he will not consider the rewards which would flow from the improved product would justify the change. These purely commercial considerations are likely to affect the direction, if any, in which the established manufacturer may go. However, they give a distorted picture of what, from a technical and patent point of view, is obvious. As I have said, a new entrant into the trade may well have different commercial constraints. The court has to be alert to the difference between commercial attractiveness and technical obviousness. They are not always the same. Failure to modify a piece of prior art, even if that delay extends over a long period, may be due to commercial factors rather than perceived technical obstacles"*

253. Mr Justice Meade recently reviewed the law in *Optis v Apple* [2021] EWHC 3121 (Pat) [184]-[187] and [216] which in turn referred to Laddie J in *Pfizer's Patent.*:

> *"184. This use of secondary evidence requires caution, as the authorities indicate. Laddie J in Pfizer's Patent [2001] FSR 16 at [63] said the following in the relation to secondary evidence when there is more than one route to a desired goal:*
>
> > *"63. Of particular importance in this case, in view of the way that the issue has been developed by the parties, is the difference between the plodding unerring perceptiveness of all things obvious to the notional skilled man and the personal characteristics of real workers in the field. As noted above, the notional skilled man never misses the obvious nor sees the inventive. In this respect he is quite unlike most real people. The difference has a direct impact on the assessment of the evidence put before the court. If a genius in a field misses a particular development over a piece of prior art, it could be because he missed the obvious, as clever people sometimes do, or because it was inventive. Similarly credible evidence from him that he saw or would have seen the development may be attributable to the fact that it is obvious or that it was inventive and he is clever enough to have seen it. So evidence from him does not prove that the development is obvious or not. It may be valuable in that it will help the court to understand the technology and how it could or might lead to the development. Similarly evidence from an uninspiring worker in the field that he did think of a particular development does not prove obviousness either. He may just have had a rare moment of perceptiveness. This difference between the legal creation and the real worker in the field is particularly marked where there is more than one route to a desired goal. The hypothetical worker will see them all. A particular real individual at the time might not. Furthermore, a real worker in the field might, as a result of personal training, experience or taste, favour one route more than another. Furthermore, evidence from people in the art as to what they would or would not have done or thought if a particular piece of prior art had, contrary to the fact, been drawn to their attention at the priority date is, necessarily, more suspect. Caution must also be exercised where the evidence is being given by a worker who was not in the relevant field at the priority date but has tried to imagine what his reaction would have been had he been so.*
>
> *216. As to the secondary evidence, it is not very helpful and certainly nowhere near enough to displace the above clear consistency in the primary evidence that the Ericsson function would be identified by the skilled person as being deficient. Some of those that commented noticed the C=16 problem; Qualcomm and LGE noticed the lockstep problem (albeit of course that LGE's input was from the inventor). NTT drew a diagram for C=16 but somehow did not spot that problem and I conclude based on Prof Lozano's evidence that they made a mistake that the ordinary skilled person would not have. Likewise Prof Lozano said Nokia's submission was wrong (in a different respect).*
>
> *217. The picture is just far too patchy and inconsistent to draw any conclusion from these real people's experience as to how the notional addressee would have behaved. Not only were the workers operating under pressure of time with, no doubt, other tasks to perform, but they also had their own interests to serve, for example with Qualcomm advocating "Gold" codes in which the company had a proprietary position."*

254. The evidence from Med-El on this point is fairly light touch. One point I need to deal with first is the 'absence' of Zimmerling as a witness. AB assert that in the circumstances, a *Wisniewski v Central Manchester Health Authority* [1998] LI Rep Med 223 inference arises. In assessing fact evidence there is a principle of natural justice that it is unjust for a party to defend itself against calculated silence. Zimmerling – an inventor of both the Prior Art and the Patent - is an employee of Med-El. I am told he has given evidence on a related case in the USA. He was not called to give evidence in this case.

255. To warrant the application of the court's discretion regarding any adverse inference it is necessary to show that Med-El adduced some evidence on the issue where the witness might have been expected to have material evidence. Med-El have some evidence on this point and Zimmerling may be able to provide some relevant input. However, that is the highest the position reaches. This is not an issue where the Court needs Zimmerling to assist it in resolving the question. Zimmerling may have some useful information but so do many others – he is not central to the case. In the circumstances, I do not accept AB's contention that the court should make an adverse inference due to Med-El's choice not to call Zimmerling.

256. By the early 2000s the relevant industry (the evidence is there are three main players –AB, Med-El and Cochlear) knew a better solution was needed to compatibility of cochlear implants with MRIs – particularly as the use and prevalence of MRI machines was continuing to increase. This is all in the CGK. The main solutions to the issue available before the Priority Date are also set out in the Agreed CGK at Annex 2 paragraph 39.

257. Med-El argue that Zimmerling was known to the three main cochlear implant companies. The only evidence of fact on this comes from Professor Parker. Zimmerling was published 7 years before the Priority Date. Professor Parker was the Chief Technology Officer at Cochlear until 2007 when he left. Professor Suaning left Cochlear in 1997 although he did maintain connection with the industry. After cross examination little more was known than the fact Zimmerling had been picked up by Cochlear in around 2003 in a patent watch and had not been considered in any substance by Professor Parker. He did not know, although helpfully assumed it may be the case, that the other competitors would keep a close eye on documents like this. That is not enough to support the contention the document was well known to all the relevant parties in the industry. At that point, following the guidance in *Halliburton* the contention on long felt want is looking difficult.

258. The timelines to launch of the various commercial products including (it is argued) rotating diametric implant magnets by the three main companies is 2014, 2018 and 2019. The first in time being Med-El. We have no detail on the specifics. What was debated was the influence of the regulatory period for approval of such medical devices – Professor Suaning 5-10 years and Professor Parker 3 months to 5 years for a complete re-build. I felt Professor Parker had much better experience and understanding of the regulatory framework than Professor Suaning. This was based on his role and work over the relevant period. In my view, the shorter timeline for regulatory approval could show – if anything – that there was no rush to get this new product to market. However, I take very little of use in this context from this information. There appear to be other factors at play here, for example; there were other solutions for implants to the MRI issue that were regulated and/or being used, the main companies in this field were selling implants with removable magnets before and after the Priority Date (Professor Parker's evidence was that was the focus for Cochlear before the Priority Date -although Cohclear knew they needed to get around to resolving this over the next 10 years) and as noted in the CGK there were other important 'battles' that had been going on (this is a hearing implant and MRI compatibility is a secondary issue). It does seem there was a concern that there was no satisfactory solution for the perceived increased use of 3T MRI machines at the Priority Date. The evidence shows this is an ongoing issue of concern with the nature of an increasing gradient rather than a binary issue.

259. I have considered all the relevant evidence and submissions but have only dealt with what I assess to be the main issues in what is already an extensive Judgment. In my view the remaining points have no material impact.

260. In the circumstances, weighing the limited evidence, my decision is that either there is not enough evidence to show what the industry knew and how it was reacting or the evidence demonstrates a set of multi-factorial reasons for the situation which do not provide sufficient support for the arguments to displace the primary case on obviousness. There is simply not enough relevant information to give rise to finding of a 'long felt want'. Had this secondary evidence relating to obviousness been found to support a 'long felt want' in this case that would have increased its relevance to the overall obviousness assessment. However, as has been explained in the authorities considering this issue, it is secondary evidence and therefore must be kept in its place. The question would be how would that evidence (had it been made out) have assisted the court in understanding the view of the uninventive skilled person. Based on my conclusions on the approach to the problem here by the skilled person it would not have been enough to change my final assessment on obviousness. I also note militating against the relevancy of this secondary evidence is the fact that various solutions available before the Priority Date (for example removable implant magnets) continue to be used after the Priority date – including in later commercialised Med-El products.

Conclusion on obviousness

261. I have considered whether this obviousness case of AB's is tainted by hindsight as asserted by Med-El. For the reasons given I do not believe there is any relevant hindsight impacting the obviousness analysis. As noted above the secondary evidence does not alter my overall conclusion. I have considered the allegations raised that the AB case is an illusion of simplicity and ignores multiple hurdles a skilled person would consider. I have found that

these are standard uninventive and workmanlike steps and are not using hindsight. I have also looked at the availability of other alternative routes and decided this does not displace my view. My assessment of much of the case put forward by Med-El is it asserts additional complexity where there is none or on the evidence certainly much less or less important than is suggested.

262. Zimmerling contains relevant teaching responding to the MRI compatibility problem for cochlear implants. It provides information on rotating implant magnets which have their dipoles across their axis of rotation to minimise the issue of the interaction with the external fields. The problem here is not to focus on a solution to create a system that can align perfectly. That ideal needs to be looked at in the practical context. The problem is to solve a real world issue for patients. That means a solution that works at clinically relevant angles i.e. works for the patient.

263. In essence I accept AB's case on obviousness and evidence and reasoning from Professor Parker. It is obvious to choose the existing CGK disk-shaped magnet implant as one obvious option of a shape of implant magnet to progress in the light of Zimmerling's teaching. My reasons for this include the following factors; (1) this is a known entity – the shape of the magnet is known to the Skilled Person– 'it is lying around on the desk', (2) it is known to have the required magnetic volume to attach to the external magnet – no or minimal extra work is needed, (3) the choice of using the same shape as existing products would be motivated in part by the expectation the regulatory issues may be more straightforward than a new shape (or shapes like spheres), (4) using the existing 'thin' shape should avoid the needs for any additional risk of bone drilling which may be required if a bulkier magnet was used, (5) the orientation of the existing assembly housing can be used along with pre-existing system components. Once chosen, the teaching in Zimmerling or the CGK dictates (it is obvious) that the magnetization for the disk-magnet should be changed to being across the axis of rotation to provide for rotation. The Skilled Person would have been able to appreciate the choice of magnet shape and orientation would provide sufficient alignment with an external magnetic field. Based on the teaching in Zimmerling and the views of the experts, once the decision to have the disk-shaped diametrically magnetised magnet is reached the rest of the implementation is obvious and workmanlike and would be expected to succeed. As part of this final consideration my finding is that the choice of a matching external diametric magnet is also obvious for the reasons discussed above. It is a 'knock-on' requirement from the earlier decision. In coming to these views I have considered this multi-factorial analysis in the round. I have considered the counterarguments and on the balance of probabilities have decided they do not prevail. No one factor has been critical.

264. In conclusion, weighing the evidence and submissions carefully and being conscious to avoid hindsight, I conclude that claims 1, 10 and 14 as amended of the Patent are obvious over Zimmerling.

SUMMARY OF MAIN CONCLUSIONS

265. I have considered whether this obviousness case of AB is tainted by hindsight as asserted by Med-El. For the reasons given I do not believe there is any relevant hindsight impacting the obviousness analysis.

266. For the reasons stated above, my conclusions are:

(i) All the claims in issue are obvious over Zimmerling.

(ii) The sufficiency attack fails.

(iii) Had the Patent been valid, claims 1, 10 and 14 as amended would have been infringed under s.60(1) but not s.60(2).

(iv) The Amendment Application is allowed but does not save the Patent from being invalid.

267. In the usual way, this Judgment will be handed down remotely. I will adjourn further consideration to a form of order hearing on a date to be fixed and in the meantime, I will direct that time for filing any Appellant's Notice will not run until that further hearing.

Annex A

1. An implant system for a recipient patient, said implant system comprising:

   a planar implant coil housing (402) for implanting under the skin of said patient containing a receiver coil for transcutaneous communication of an implant communication signal, and containing a first attachment magnet (401) within the plane of the implant coil housing (402),

   an external coil housing (405) for placement on the skin of the patient over said implant coil housing (402), said external coil housing (405) comprising a second attachment magnet (404); characterized in that said first attachment magnet (401) is rotatable in said plane of the implant coil housing (402), and has a magnetic dipole parallel to the plane of the implant coil housing (402) for transcutaneous magnetic interaction with said second attachment magnet (404) allowing to form a magnetic attraction connection between them in which the magnetic dipole of said first attachment magnet (401) is parallel to said plane of the implant coil housing (402).

2. An implant system according to claim 1, further comprising:

   at least one magnetic focus director (801) within the implant coil housing (402) adjacent to the first attachment magnet (401) and transcutaneously directing the magnetic field to increase magnetic attraction force between the first and second attachment magnets (401, 404).

3. An implant system according to claim 1, wherein at least one of the attachment magnets (401, 404) has a planar disc shape, a rectangular beam shape, a cylindrical beam shape or a cut away disc shape.

4. An implant system according to claim 1, wherein said second attachment magnet (404) comprises a pair of complementary cylindrical attachment magnets (1101, 1102).

5. An implant system according to claim 4, further comprising:

   a magnetic flux guide (1301) connecting the pair of complementary cylindrical attachment magnets (1101,1102).

6. An implant system according to claim 1, wherein the first attachment magnet (401) is adapted to rotate within the implant coil housing (402) in response to an external magnetic field.

7. An implant system according to claim 6, further comprising:

   a lubrication coating (802) covering at least a portion of the first attachment magnet (401) and reducing friction between the first attachment magnet (401) and the implant coil housing (402) to promote the rotation of the first attachment magnet (401).

8. An implant system according to claim 1, wherein the implant system is a cochlear implant system, or a middle ear implant system, or

   a vestibular implant system, or

   a laryngeal pacemaker implant system.

9. An implant system according to claim 1, wherein said implant system is configured to have said plane of said implant coil housing (402) parallel to the skin when said implant coil housing (402) is implanted under the skin of the patient.

10. An implant system according to claim 1, wherein said implant system is configured to have said second attachment magnet (404) being magnetised parallel to the skin when the external coil housing (405) is placed on the skin of the patient over said implant coil housing (402).

11. An implant system according to one of the preceding claims, wherein the first or second attachment magnet (401, 404) is disc-shaped and has its magnetic dipole oriented across a diameter of the corresponding attachment magnet (401, 404).

12. An implant system according to one of the preceding claims, wherein said implant system is configured such that when the external coil housing (405) is placed onto the patient's skin over the implant coil housing (402), said first attachment magnet (401) may turn around on its axis such that the north and south poles of said first attachment magnet (401) is positioned adjacent to south and north poles respectively of the second attachment magnet (404).

~~13. An implant system according to claim 4 or 5, wherein the second attachment magnet (404) is configured to be oriented over the first attachment magnet (401) with its magnetic axis vertical to the implant coil housing (402).~~

~~14~~13. An implant system according to claim 1, wherein the first attachment magnet (401) is a single cylindrical magnet and the second attachment magnet (404) is a pair of complementary cylindrical attachment magnets (1101, 1102) with opposite magnetic polarities which interact with the first attachment magnet allowing the first attachment

magnet to freely rotate in the plane of the implant coil housing (402) to orient itself to magnetically interact with the external attachment magnets (1101, 1102).

~~15~~14. An implant system according to one of the preceding claims, wherein said first attachment magnet (401) is non-spherical and said implant coil housing (402) has a flat bottom so that there is no need to drill a recess into the bone during implantation, wherein said implant system is in particular suited for implantation in young children.

ANNEX B

IN THE HIGH COURT OF JUSTICE Claim No. HP-2021-000028 BUSINESS AND PROPERTY COURTS

INTELLECTUAL PROPERTY LIST (ChD) PATENTS COURT

SHORTER TRIALS SCHEME BETWEEN:

ADVANCED BIONICS AG

(a company incorporated under the laws of Switzerland)

ADVANCED BIONICS UK LIMITED

Claimants

- and -

MED-EL ELEKTROMEDIZINISCHE GERÄTE GMBH

(a company incorporated under the laws of Austria)

Defendant

AGREED COMMON GENERAL KNOWLEDGE

The below statement sets out the matters agreed by the parties to be within the common general knowledge of the skilled team at the Priority Date. This statement is provided for the purpose of these proceedings only, and is based on the English legal concepts of the notional "skilled person" (or "skilled team") and the "common general knowledge".

This statement is designed to set out for the Court the matters which the parties agree were CGK in 2010. This is without prejudice to the right of each party to allege (and to dispute) that additional matters were CGK.

Hearing loss and the auditory system (Crane 1 §§46-52)

Hearing loss is the most common sensory deficit to affect humans.

The degree of hearing loss varies on a spectrum from mild hearing loss, through moderate and severe hearing loss, to profound hearing loss. At the mildest level, a patient can usually hear most speech, but certain sounds (such as whispers, or parts of words such as consonants on the end of words) may be hard to hear. At the other

extreme, a patient with profound hearing loss may not hear any speech at all, and may only hear very loud sounds.

Hearing loss can affect just one or both ears; and can be the result of problems in different parts of the hearing system. Typically hearing loss is divided into 'conductive hearing loss' (where the movement of sound through the external or middle ear is blocked) and 'sensorineural hearing loss' (which is a problem with the cochlea or auditory nerve pathway of the inner ear). Cochlear implants are typically used for sensorineural hearing loss patients that cannot get adequate benefit from hearing aids. There are many different causes of sensory hearing loss. The treatment will vary depending on the degree and cause of the hearing loss; and includes use of hearing aids and implants such as cochlear implants.

The structure of the human ear is shown below.

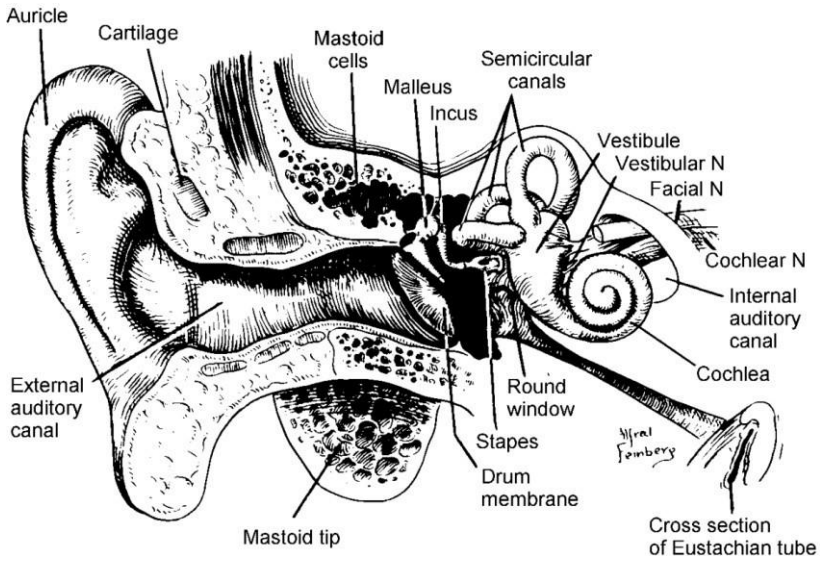


Figure ACGK1 Anatomy of the Human Ear[1]

The human ear consists of the outer, middle and inner ear and operates broadly as follows:

Sound is a pressure wave that is conducted to our ears by vibrations in the air molecules that surround us. Sound waves are directed by the pinna into the

[1] Image taken from Alberti, P.W. The Anatomy and Physiology of the Ear and Hearing. 2006. Available online at https://www.who.int/occupational_health/publications/noise2.pdf, citing Hallowell, Davis and S. Richard Silverman

(Ed.), (1970). Hearing and Deafness, 3rd ed., Holt, Rinehart and Winston.

external auditory canal and vibrate the ear drum (also known as the tympanic membrane).

The ear drum transmits energy to the ossicles, which are three small bones in the middle ear, so that sound is conducted to the oval window of the inner ear. The malleus (or "hammer") contacts the eardrum, the incus (or "anvil") serves as an intermediary, and the stapes (or "stirrup") inserts into the oval window.

The cochlea is the part of the inner ear responsible for converting sound vibrations into electrical nerve impulses. The healthy human cochlea is a fluid- filled spiral structure that resembles a snail's shell. It contains two and three- quarter turns and is lined along its entire length with thousands of specialized sensory cells known as 'hair cells'. These hair cells detect sound vibrations and send sound information as nerve signals to the brain along the auditory nerve. Hair cells located at the base of the cochlea detect high frequency sounds, whereas hair cells at apex of the cochlea detect low frequency sounds. As the vibrations move though the fluid in the cochlea, these pressure waves in the cochlea are converted to electrical signals by the hair cells, which are then passed along the auditory nerve to the auditory centers of the brain. When the electrical nerve impulses reach the brain they are perceived as sound.

Hearing loss can result from problems with the outer, middle or inner ear or the auditory nerve and central pathways:

problems in the outer or middle ear conducting sound to the inner ear are known as 'conductive hearing loss'. Many causes of conductive hearing loss can be treated with surgery (middle ear effusion, tympanic membrane perforation, ossicular fixation, otosclerosis, cholesteatoma, etc.). Medical treatment can be effective in some causes of conductive hearing loss such as middle ear effusion. Hearing aids, bone conduction devices, or middle ear implants may be useful.

If the hair cells of the cochlear are missing or damaged, 'sensorineural hearing loss' results. With some kinds of recent onset sensory hearing loss (e.g. idiopathic sudden sensorineural hearing loss) medical treatment such as steroids may be helpful. However, in humans there is currently no way to repair damaged hair cells or the auditory pathways once damage becomes established. The degree of missing or damaged hair cells will affect the degree

of hearing loss. For mild to moderate hearing loss, a conventional hearing aid or other method of amplification may be the best solution. For severe-to- profound sensorineural hearing loss amplification may no longer be adequate, and a cochlear implant may be the best solution.

'Mixed hearing loss' is a combination of both sensorineural and conductive hearing loss. Treatment options include those for each component of the hearing loss.

Cochlear implants

A cochlear implant is a small, electronic device that lets a person who is profoundly deaf or hard of hearing perceive sound. One portion – the external component – is placed on the skin behind a person's ear, while another portion – the internal component – is surgically inserted under the skin. The implant works by directly stimulating the neural tissue within the cochlea with electrical pulses, thus bypassing damaged portions of the inner ear. The implant's signals are sent to the brain, which recognizes the signals as sounds. (Rubinstein 1, §31; Crane 1 §53)

Patients are very involved in selecting a device. (Rubinstein 1, §39 & §46, Crane 2, §8).

The internal component

The internal component of a cochlear implant device is surgically implanted under the patient's skin with the electrode array sitting inside the cochlea and may be implanted from a few months of age to adulthood. Cochlear implants may be placed in one ear (unilateral) or both ears (bilateral). (Rubinstein 1, §33 & 37; Crane 1 §§53-55)

The internal component contains: (i) an RF Receiver coil; (ii) a processor; (iii) a flexible electrode array; (iv) optionally a ground electrode and (v) an attachment magnet. The RF receiver coil receives the transmitted power and data signal. This signal is decoded by the processor. The processor uses the decoded signal to generate electrical signals based on this information, to be sent in each frequency band to a different electrode in the electrode array. (Crane 1 §61-62)

The electrode array, which is inserted in the cochlea, is used to transmit the decoded signals to specific parts of the cochlea. The arrangement of electrodes within the array

mimics the frequency selectivity of the cochlea, in that specific locations of the cochlea are responsible for detecting specific pitches of sound. In this way, the natural hearing process is closely mirrored. (Crane 1 §63)

The surgery to implant the internal component typically takes less than two hours. The operation is usually performed under general anesthesia. To summarize the process very briefly, a small incision is made behind the ear. It is then necessary to perform a mastoidectomy (open the hollow, air-filled spaces in the skull behind the ear) to gain access to the facial recess from which the stapes and round window niche are usually visible. The cochlea is usually accessed through the round window, although other approaches to inserting the electrode can be used such as the oval window, or making a cochleostomy anterior to the round window. The processor component is placed posteriorly through the skin incision, so it lies over the skull behind the mastoid bone. A pocket may be drilled in the skull to recess some of the device and the lead that goes to the electrode. In some cases, a larger recessed area can be made in the bone that includes the posterior aspect of the implant including the receiver coil, of the internal component to sit in. This larger recessed area requires more exposure and often a bigger incision. However, devices being implanted at the Priority Date were generally thinner than the earlier devices (such as those with ceramic housings), and did not generally require bone drilling for the posterior aspect of the implant including the receiver coil and the magnet (Crane 1 §64, Parker 2 §7). This is illustrated below[2]:

[2] Figure BC3 from Professor Crane's first report

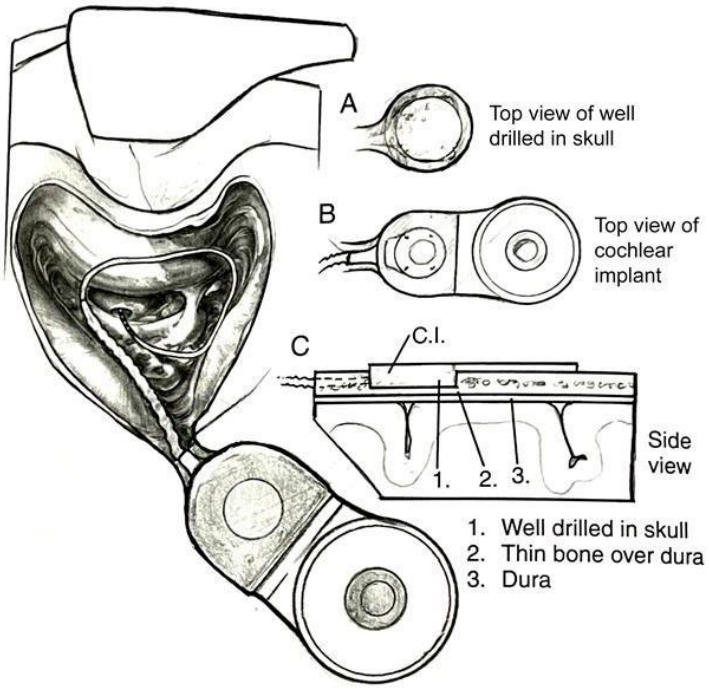


Figure ACGK2 Internal component of a cochlear implant system following implantation

As illustrated, the housing for the electronics was optionally recessed using bone drilling (Parker 2, §7). However, there was a technique for implantation without any bone drilling at all, the 'sub-periosteal pocket technique', which in 2010 was used on some, but not all, patients. (Rubinstein 1, §53; Crane 2 §16)

The internal component is intended to last for the lifetime of the patient whereas the external component can be upgraded if it is damaged or when more advanced products become available. (Crane 1 §57)

The external components

The external (visible) part of a cochlear implant system will comprise microphones, speech processing electronics, batteries and an RF coil to transmit sound and power to the implanted device. In 2010, these components were typically contained in two parts: a part that sat behind the ear and a puck-shaped component containing the RF coil that would sit on the skin over the corresponding RF coil of the implanted device. The puck-shaped component was typically held in place via magnets, one inside the internal device and one inside the external device. (Rubinstein 1, §57)

The external components are easily removable, but the wearer will lose hearing in that ear for the duration that they are removed as the internal component does not have a microphone or independent power supply. (Crane 1 §58)

The puck-shaped external component of the cochlear implant is held in place via a magnetic attraction between a magnet that sits in the middle of the RF coil in the internal component and a magnet that sits in the middle of the RF coil in the puck-shaped external component. The magnets also ensure appropriate alignment of the internal and external RF coils. In 2010, the internal magnet was typically disk shaped (Rubinstein 1, §36). The magnets of the internal and external components were axially magnetised and their magnetic dipole was perpendicular to the skin (Parker 1, §52).

It was typical that manufacturers would make the magnet in the external component interchangeable, so that the appropriate strength of the magnet and hence the attractive force between the magnets could be chosen. A magnet that would be too strong would be avoided, as this risks damaging the skin between the magnets during periods of prolonged usage. At the same time, however, it would be important to select a magnet of sufficient strength to keep the headpiece in place. (Rubinstein 1, §58)

Cochlear implant devices at the Priority Date

The three major companies producing cochlear implants at the Priority Date were Cochlear, Advanced Bionics and MED-EL. (Parker 1, §42, Crane 1 §66)

Cochlear launched the Nucleus CI22M system in 1986. The Nucleus 24 was Cochlear's first mainstream commercialized device, and was launched in 1997. It was followed by the Nucleus 24R and Nucleus 24RE implantable devices, in 2000 and 2005, respectively. At the Priority Date, Cochlear's most recently launched product was the Nucleus 5 implant, launched in 2009. (Parker 1, §43, Crane 1 §70)

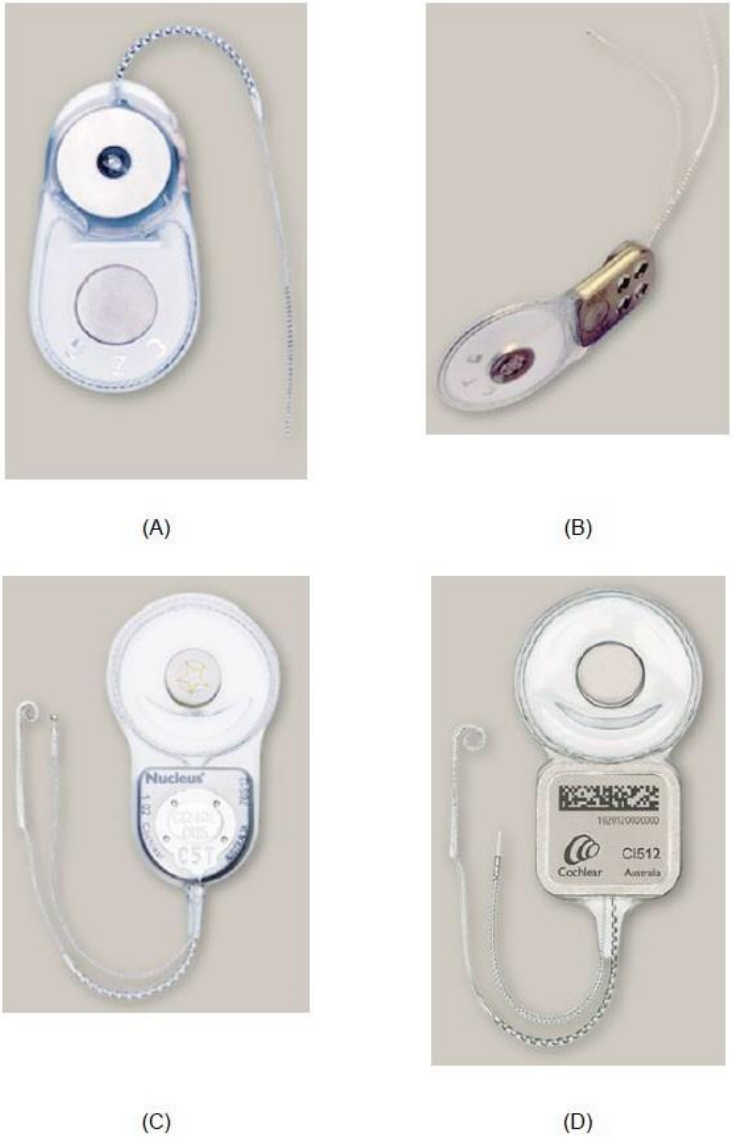


Figure ACGK3 Cochlear's Nucleus CI22M, CI24M, CI24RE and CI512 implants

For the design of the Nucleus 5 implantable component, Cochlear adopted a titanium (i.e. non-ferromagnetic) casing which encapsulates the electronics, coil, and attachment magnets. The electronics are housed within the square element of the implantable device, underneath the portion bearing the branding and bar code. The circular element contains a coil for power and data transfer, at the centre of which is the attachment magnet with a thin disk shape. As shown in Figure ACGK3 above, the earlier Nucleus 24RE adopted a similar design, as did its predecessors, the Nucleus 24 and Nucleus 24R (Parker 1, §44). In the Cochlear Nucleus 24, and all Cochlear devices thereafter available at the Priority Date, the magnet was removable. (Crane 1,

§70)

Advanced Bionics launched its Clarion cochlear implant in 1996, its Clarion CII in 2001 and its HiRes 90K cochlear implant in 2003.[12] The Clarion and Clarion CII had a ceramic case, which contained the attachment magnet, electronics and coil, whereas the HiRes 90K had a titanium casing for the electronics and a circular element in a silicone case containing the coil with a replaceable magnet at the centre. Unlike the earlier Clarion and Clarion CII models, the internal magnet of the HiRes 90K could be removed for MRI scans. (Crane 1 §73, Parker 1, §46, §48)

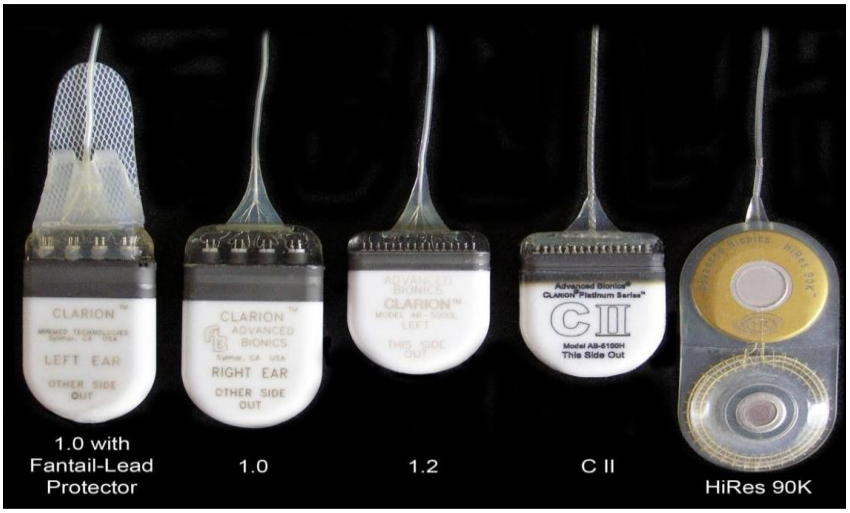


Figure ACGK4 AB Clarion, Clarion CII and Hi-Res 90K devices[3]

MED-EL launched the Comfort cochlear implant in 1989, the COMBI 40 in 1994, the COMBI 40+ (C40+) cochlear implant in 1996, the PULSAR cochlear implant in 2004 and the SONATA cochlear implant in 2006. The PULSAR device had a ceramic casing, whereas the SONATA device had a titanium housing (Parker 1, §47-48; Crane 1 §71). MED-EL did not use removable magnets before the Priority Date (Crane 1 §72).

[3] Figure BC6 from Crane 1

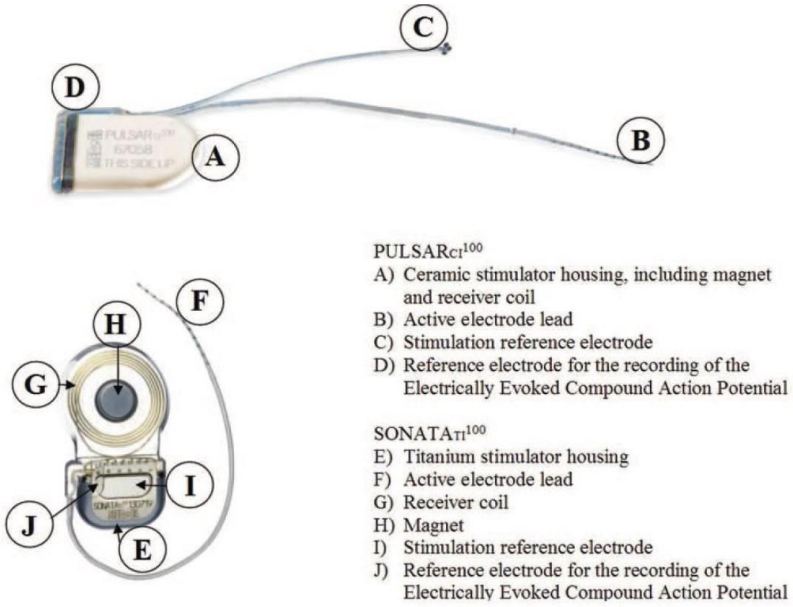


Figure ACGK5 PULSAR and SONATA MED-EL devices

By the Priority Date, the three most recently launched devices had a titanium case for electronic components with an external coil in the centre of which contained a titanium encased disk-shaped rare earth permanent magnet. There was a slim housing containing the receiver coil, the implanted magnet and a silicon chip for processing sound; and an electrode array for insertion into the cochlea. (Parker 1, §51; Suaning 2, §11)

The coil housing in these devices was essentially flat and planar. Likewise, the portion of the implant which houses the electronics was flat. While the two halves of the implant were each flat, they were angled relative to each other in order to conform better to the natural curve of the skull. (Parker 1, §51, Crane 2, §10)

The implant magnet in each of these devices was disk-shaped and its magnet dipole was oriented along its central axis (i.e., perpendicular to the skin). (Parker 1 §52)

As well as the need for a low-profile, other design considerations at the Priority Date included: reliability, regulatory compliance, suitable attachment magnet strength, and compatibility with external devices such as MRI scanners. (Rubinstein 1, §49-54; Parker 1, §53-56; Suaning 1, §61; Crane 1, §74-83)

Magnetic resonance imaging

Magnetic resonance imaging ("**MRI**") is a non-invasive technique in which magnetic fields are implemented to scan and image soft tissues for clinical use. The MRI scanner features a cylindrical construct with a central bore as shown in the diagram below. The cylinder houses an electrical coil formed of superconductive material which is maintained at a very low temperature by continuous cooling with liquid helium. In its superconducting state, the coil can sustain a large electrical current and so generate a very strong magnetic field. The MRI machine is therefore a large electromagnet which can produce a very significant field. (Parker 1, §28).

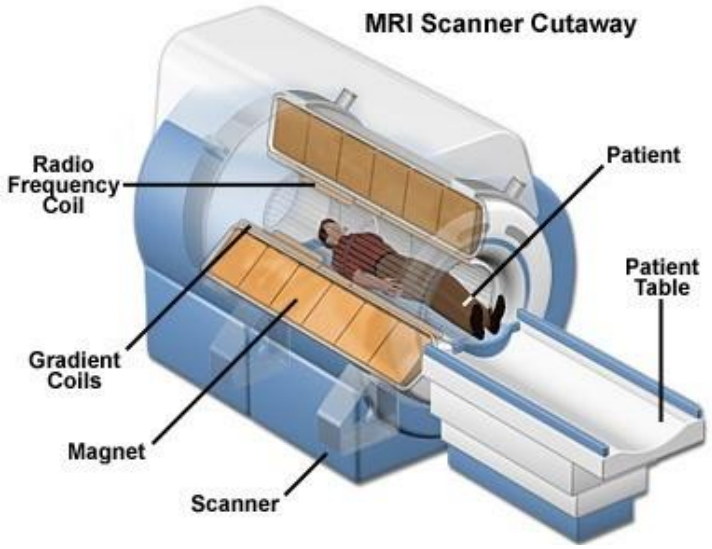


Figure ACGK7 example of closed bore MRI machine

The number of MRI machines in use had risen between 2000 and the Priority Date; there was an increase in the popularity of MRI as a diagnostic tool in the period up to 2010. (Rubinstein 1, §§60-62)

MRI systems are classified by the strength of the static magnetic field measured in tesla (T). At the Priority Date, the most common MRI machine in clinical use was 1.5T but 3T machines were becoming more common. (Parker 1, §31-32; Crane 1 §74)

There are two major types of MRI machines in clinical use: closed bore machines and open systems.

Closed bore machines employ a donut shaped magnet system and the patient is passed through the centre of the donut. When the patient is placed into the bore, the static magnetic field lines are aligned from their head to toe – i.e. along the length of the patient. (Parker 1, §33)

Open systems are open on three to four sides depending on manufacturer and model. The magnet strength in these machines is lower than closed bore machines (typically 0.35T to 1.2T) which results in reduced image quality which takes longer for imaging (typically 1.5 times longer) when compared to closed bore MRI.

Figure ACGK8 example of Open Bore MRI Machines

MRI machines and cochlear implants

A number of problems and potential hazards arise when ferromagnetic or magnetic material is placed in a strong magnetic field, such as the introduction of the implanted component of a cochlear implant into an MRI machine. At the Priority Date four known potential interactions for cochlear implants were[4]:

Torque: the strength of the main magnetic field is so great that when the magnetic dipole of the implanted magnet is not aligned with it, the implanted magnet experiences a torque. This can cause the implanted magnet to be dislocated, causing improper function to the device, and pain and potentially tissue damage to the patient.

[4] Parker 1, §36; Rubinstein 1, §64; Suaning 1 §78 - 82; Crane 1 §78 - 83; Crane 2 §18

Demagnetization: where a permanent magnet is held in misalignment with an external magnetic field, it can lose magnetization and its magnetic dipole can become weaker.

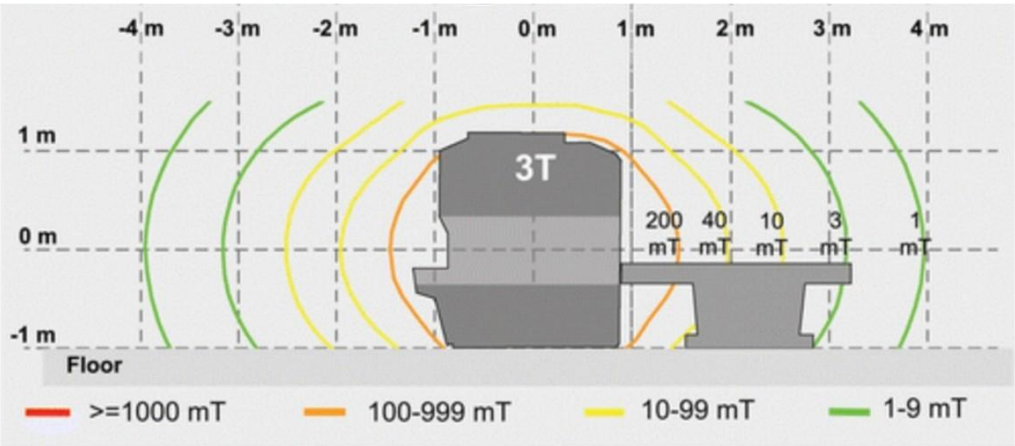
RF heating: The oscillating frequency field can induce a current in electrical conductors. The current arises as an eddy current, circling within the wires of the implant rather than flowing around a complete electrical circuit. The resistive heating caused by the eddy current causes the wire to become hot, which can damage components. Temperature rises from this effect could also result in burning tissue.

Artifacts: the presence of metal components will produce artifacts on the MRI image in the location of the metal component. The quality of the image depends on the homogeneity of the magnetic field gradient. The presence of a metal changes the uniformity of the magnetic field gradient and results in distortion of the image in the location of the metal component.

RF heating and artifacts problems arise only when the MRI machine is scanning and imaging a patient (with artifact problems only arising when the area being imaged is near to the implanted portion). Torque can be experienced by the magnet when the patient enters the room and becomes worse as the patient approaches the MRI machine. This is because the magnetic field of the MRI scanner extends outside the bore (but is stronger closer to the bore). Cochlear implant users remove the external headpiece of their device before entering the room with an MRI machine. (Parker 1,

§37 & §38)

The following figure shows the strength of the magnetic field extending from the bore of a 3T machine. (Parker 1, Figure 6)



By 2010, clinicians would be aware of three options for cochlear implant users:

Avoid MRI scans.

Have the user undergo two surgical procedures to remove and subsequently replace the implant or the magnet before and after the scan.

Wrap the user's head with a supportive bandage and sometimes secure a support over the implant site.

(Rubinstein §68; Crane 1 §86, 90 - 95)

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