UPC CFI, Central Division Paris, 26 December 2024, Advanced Bionics v MED-EL

mri-safe disk magnet for implants

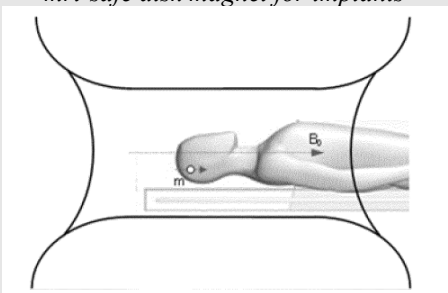


Fig. 5

PATENT LAW – PROCEDURAL LAW

Revocation rejected, maintained as amended by auxiliary request (Article 65 UPCA)

Parties are to submit copies of documents relied on (the patent in dispute, in the version issued by the EPO, and the original application) into the proceedings (Article 76 UPCA)

- **within the regulatory system of 'UPC', each party must prove the facts alleged and the Court cannot, in general, acquire evidence ex officio, nor base its decision on evidence or documents not formally acquired in the proceedings.**

133. The Court has decided, exceptionally, to derogate from the aforementioned general principle in light of the absence of a consolidated case law on the matter, the ease of acquiring these documents and the parties' implicit consent to this procedure. It further highlights that a different and more rigorous interpretation of the relevant rules would not have had significantly more favourable effects for the defendant - the party that would have benefited from an orthodox application of the burden of proof that would have rested on the claimant - given the outcome of the proceedings

Admissible later filed documents (R. 44 RoP, R. 263 RoP)

- **the documents introduced by the Claimants in the Reply to defence to revocation (Exhibits KAP D06, KAP D16 – D26) and the documents introduced by the Defendant in the Rejoinder to the Reply to defence to revocation (Exhibits BB16 – BB27) are admissible, given that they contain arguments regarding the common general knowledge and the claim interpretation which were advanced in their respective initial written pleadings and are intended to contrast and react to the arguments raised by the opposing party.**

Admissibility of subsequent request to amend the patent (R 30(2) RoP)

- **in deference to the need for expeditious judgments and efficient proceedings, the Court may decide the case even by overturning the priority order of the issues to be decided where a determination can be made on the basis of a more easily resolvable reason - albeit logically subordinate - without examining those that are antecedent.**
- **for the reasons that will be explained below, there is no need to examine the auxiliary requests contained in the subsequent request to amend the patent, in addition to those timely filed, since the examination of the latter allows the Court to consider the attacks on the validity of the patent to be overcome and renders such later auxiliary requests devoid of any concrete relevance.**

Inventor not allowed as expert (R. 181(2) RoP)

- **as inventor of the patent at issue he may have a direct interest in the outcome of the case and therefore does not meet the requirements of Rule 181 (1) (a) and (b) 'Rop' for impartiality, objectivity and independence.**

Skilled person (Article 56 EPC)

- **Court considers that the person skilled in the art must be identified in a mechanical engineer with either a Bachelor's degree or a Master's degree in mechanical engineering and several years of experience in the technical field of medical devices and specifically in the field of cochlear implants**

Common General Knowledge

- **The '*CGK*', in general, is information which has been commonly known to the skilled person from written sources or from practical experience in the relevant technical field.** The '*CGK*' includes knowledge which is directly available from familiar sources of information relating to the specific technical field at the prior date but is not to be confused with publicly available knowledge, which may not be general and common. A familiar source of information typically is a source to which a skilled person regularly turns for guidance on standard design solutions that are generally applicable, such as standard textbooks, encyclopaedias, manuals, handbooks, dictionaries and databases which the skilled person knows and can use as a suitable and reliable source for the respective information in the respective technical field. A familiar source of information should not be confused, however, with all publicly available prior art documents.

53. In any case, the '*CGK*' is subject of evidence. Pursuant to **Article 54 'UPCA'**, the burden of proving the existence of the '*CGK*' lies with the party invoking it. Without bearing the burden of proof, the opposing party may present evidence to establish the '*CGK*', including evidence to the contrary.

No insufficient disclosure (Article 83 EPC, Article 138(1)(b) EPC)

- **embodiment construed by the Claimants is not part of the subject-matter of the patent. On that basis, the Claimants objections with regard to insufficiency of disclosure are moot.**
- **The skilled person is deemed to possess the relevant '*CGK*' and use it by reading the patent and implementing the embodiments. Therefore, this teaching should be clear to the skilled person and enable him/her to produce embodiments with a disc-shaped magnet rotatable in the plane of the coil housing parallel to the patient's skin (and to the magnetic field of the MRI machine). Hence, the patent fulfils the sufficiency requirements under Article 83 EPC**

Added matter – impermissible generalization (Article 123(2) EPC)

- **There is no indication in para. [0010] or in the application as a whole that indicates that the implantable system could be any other type of implant system as those specifically mentioned, and in the view of the panel this is not directly and unambiguously derivable for the person skilled in the art from the content of the application as filed using common general knowledge.**
- **The omission of the exhaustive list of para. [0010] of the application resulted therefore in an impermissible generalization of the claimed invention.** Thus, the patent as granted contains added subject matter and does not fulfil the requirements of **Art. 123(2) 'EPC'**.

79. The Claimants further argue as well that the term *'implant system'* itself is broader than the term '*implantable system'* taking arguments from para. [0003] of the originally application which describes implant systems *'[employing] attachment magnets in the implantable part and an external part to hold the external part magnetically in place over the implant'*.

80. The panel shares the opinion that the term '*implantable system'* refers to the internal part only, while *"implant system*" includes necessarily an internal part but may also include an external part. The proper understanding of the term '*implant system'* depends on the scope of the disclosed technical features.

81. As a further precautionary measure, the Defendant indicated in the Defence to revocation its willingness to delete the respective one(s) or all of the dependent claims in order to overcome the extension beyond the content of the patent application

Inventive step (article 56 EPC)

- **necessary to determine whether, given the state of the art, a person skilled in the art would have arrived at the technical solution claimed by the patent using its technical knowledge and carrying out simple operations. Inventive step is assessed in terms of the specific problem encountered by the person skilled in the art (see Paris LD, decision issued on 3 July 2024, UPC_CFI_230/2023).**
- **In order to assess whether or not a claimed invention is obvious to a person skilled in the art, it is first necessary to determine one or more teachings in the prior art that would have been of interest to a person skilled in the art who, at the priority date of the patent in suit, was seeking to develop an invention or process similar to that disclosed in the prior art. Then, it must be assessed whether it would have been obvious for the skilled person to arrive at the claimed solution of the underlying technical problem on the basis of a realistic disclosure of the selected prior art documents (see, Munich CD, decision issued on 17 October 2024, UPC_CFI_252/2023; Dusseldorf LD, decision issued on 10 October 2024, UPC_CFI_363/2023).**
- The problem-solution approach is one possible way for assessment of the inventive step.
- **More detailed teaching of '*Zimmerling*' is a more suitable starting point for the skilled person**

The teaching of '*Zimmerling'* is more detailed in this regard and therefore a more suitable starting point for the skilled person.

- **teaching in '*Zimmerling*' leads the skilled person to another solution for the above-mentioned problem and, thus, away from the solution in claim 1 of Auxiliary Request 0a.**
- **Not obvious in light of 'CKG' in combination with 'Zimmerling'**

Source: **Unified Patent Court**

UPC Court of First Instance,
Central Division Paris, 26 December 2024
(Catallozzi, Zhilova, Roselinger)
DECISION
of the Court of First Instance of the Unified Patent Court
Central division - Paris seat
issued on 26 December 2024
in revocation action No. ACT_ 576555/2023
UPC_CFI_338 /2023
and in the counterclaim for revocation No. CC_15513/2024
UPC_CFI_410/2023
HEADNOTES:
1. In deference to the need for expeditious judgments and efficient proceedings, the Court may decide the case even by overturning the priority order of the issues to be decided where a determination can be made on the basis of a more easily resolvable reason - albeit logically subordinate - without examining those that are antecedent.
2. Although not a party to the proceedings, the inventor of the patent at suit cannot be examined as a witness or expert because he/she may have a direct interest in the outcome of the case and does not meet the requirements of **Rule 181 (1) (a) and (b) 'RoP'** for impartiality, objectivity and independence.
KEYWORDS: insufficiency of the disclosure, added matter, lack of inventive step
PARTIES:
Claimant in the revocation action
Advanced Bionics AG
Laubisrütisstraße 28 8712 Stäfa, Switzerland

Claimants in the counterclaim for revocation action
1) Advanced Bionics GmbH
Max-Eyth Strasse 20 70736, Fellbach-Oeffingen, Germany
2) Advanced Bionics Sarl
9 rue Maryse Bastié, CS 90606 – 69675, Bron Cedex, France All Claimants are represented by Attorneys-at-law Ms. Miriam Kiefer, Mr. Carsten Plaga and Dr. Benedikt Walesch, Kather Augenstein Rechtsanwälte PartGmbB, and co-represented by European Patent attorneys Ms. Laura Ramsay, Dehns, and Dr. Bernhard Thum, assisted by Mr. Jonas Weickert, Thum & Partner;
Defendant
MED-EL Elektromedizinische Geräte GmbH
Fürstenwall 77a 6020 Innsbruck, Austria
represented by Dr. Michael Rüberg, Attorney-at-Law, and by European Patent attorneys Dr. Andreas Lucke and Dr. Michael Lohse, Boehmert & Boehmert
PATENT AT ISSUE EP4074373 MRI-SAFE DISK MAGNET FOR IMPLANTS
COMPOSITION OF PANEL
Paolo Catallozzi Presiding judge
Tatyana Zhilova Legally qualified judge and judge-rapporteur
Kerstin Roselinger Technically qualified judge
SUMMARY OF FACTS AND PARTIES' REQUESTS
I. The patent at suit
1. The patent at suit was filed on 21 April 2011 with application number 22177545.5 and claims priority of the US 32715810 P of 23 April 2010 (IPC A61N 1/36, A61N 1/37 and A61N 1/372). The European Patent Office (EPO) published the grant of the patent in English on 27 September 2023. The Claimants also initiated opposition proceedings before the EPO on the day of filing the claim before the UPC.
2. The invention relates to implantable medical devices, and specifically, to magnetic elements in such devices that allow for magnetic resonance imaging [0001].
3. The patent comprises only one independent claim (claim 1), regarding an implant system for a recipient patient, said implant system comprising a magnetic arrangement.
4. Further the patent comprises nine subordinate claims. Claims 2 to 9 concern the external part of the medical device that is outside of the patient's body or the interaction of the internal part with an external part, respectively. Claim 10 is subordinate to all preceding claims and specifies that the implant system is one of a cochlear implant system, a middle ear implant system, a vestibular implant system, and a laryngeal pacemaker implant system.
II. The revocation action
5. On 27 September 2023 Advanced Bionics AG (AB) filed a revocation action against MED-EL Elektromedizinische Geräte GmbH *('MED-EL')* concerning the patent at issue (EP '373) before this Central Division, registered as No. ACT_ 576555/2023, UPC_CFI_338 /2023. The Defendant is the registered proprietor of the patent at issue.
6. The parties are competitors in the market for hearing technologies and are active in the development, production and distribution of cochlear implant systems *("Cl-systems"*). The Claimants are part of the Advanced Bionics group.
7. According to the Claimants and undisputed by the Defendant, at the time of filing the statement of claim EP '373 was in effect in the following Contracting Member States of the Agreement on the Unified Patent Court ('UPCA'): Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Portugal, Slovenia, Sweden. No opt-out from the exclusive jurisdiction of the Unified Patent Court had been declared.
8. The Claimant challenges the validity of the patent on the grounds of added subject matter and lack of inventive step. The Defendant contests the alleged grounds for revocation. In the alternative, the Defendant submits auxiliary requests to amend the patent.
9. The written procedure was closed on 13 June 2024 and the interim conference was held on 15 July 2024.
III. The counterclaims for revocation
10. On 22 March 2024 Advanced Bionics GmbH and Advanced Bionics Sarl filed a counterclaim for revocation of the patent at issue in the infringement action brought against them by '*MED-EL'* before the Mannheim Local Division (ACT_585052/2023, UPC_CFI_410/2023), registered as No. CC_15513/2024.
11. The Counterclaimants raised grounds for invalidity corresponding to those on which the revocation action filed by the Claimant was based. In addition, the counterclaim was based on insufficiency of disclosure.
12. By **order issued on 10 July 2024 the Mannheim Local Division** decided to refer the counterclaim for revocation to this Central Division for decision pursuant to **Article 33 (3) (b) 'UPCA'** and **37 (2) 'Rop'**.
IV. The consolidation of the proceedings
13. After the counterclaim was assigned to this panel, the judge-rapporteur held the interim conference on 25 October 2024 and then ordered, pursuant to **Rule 302 'Rop'**, the consolidation of these counterclaims for revocation with the revocation action.
14. Therefore, a single oral hearing for both the revocation action and the counterclaim for revocation was held on 29 October 2024.
V. Parties' requests and value of the proceedings
15. The Claimants request the following decision in merit:
(1) European patent **EP 4 074 373** to be revoked entirely with effect for the territories of Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Portugal, Slovenia, Sweden.
(2) The Defendant's alternative requests to maintain the patent based on any of Defendant's proposed amendments of the claims to be dismissed.
(3) The Defendant to be ordered to bear the legal costs of the proceedings.

16. The Defendant requests the following decision in merit.
(1) The revocation action and the counterclaim for revocation be dismissed;
(2) The Patent be maintained:
a) as granted; or in the alternative
b) in amended form on the basis of one of Auxiliary Requests 0a, 0a*, 0b, 0c, 1, 1a, 2, 2a, 3, 3a, 3a*, 4, 4a, 5, 5a, 6 and 6a, in this order.
(3) The Claimant to be ordered to bear the costs of the proceedings.
17. By order of the judge-rapporteur, issued on 29 July 2024, the value of the proceedings was set to EUR 5.000.000,00.

GROUNDS FOR THE DECISION

A. Procedural issues

I. Late-filed facts and evidence

18. In the second round of pleadings' exchange (Reply and Rejoinder) both parties submitted newly filed documents and made procedural requests, that the Court admits these exhibits into the proceedings.
19. As a rule, the parties are obliged to present their complete case as early as possible (**Preamble to the 'Rop'**, para. 7, last sentence).
20. **Rule 44 'Rop'** states that the statement for revocation shall contain *"... (e) one or more grounds for revocation, which shall as far as possible be supported by arguments of law, and where appropriate an explanation of the claimant's proposed claim construction; (f) an indication of the facts relied on; (g) the evidence relied on, where available, and an indication of any further evidence which will be offered in support ...*".
21. Consequently, the claimant cannot introduce new grounds of invalidity of the attacked patent or introduce new documents considered novelty destroying or affecting inventive step in subsequent written acts. This would result in a broadening or, in any case, a modification of the subject matter of the dispute, constituting an amendment of the case and falling within the scope of **Rule 263 'Rop'**, which may only be permitted by the Court upon specific request and after it has been shown that the requirements of that Rule have been met.
22. However, it should be noted that in certain situations, following the defence raised by the defendant, the claimant may need to allege new facts, insofar as they are considered capable of supporting the main facts already timely alleged and disputed by the defendant. In this case, the need to respond to the defendant's defence, the terms of which cannot be foreseen ex ante by the claimant, justifies the introduction of such new facts in the reply to defence to revocation.
23. This is consistent with the principles set by the Court of Appeal (**Decision issued on 21 November 2024, UPC CoA 456/2024**) according to which while the parties are required to set out their case as early as possible in the proceedings nevertheless specific new arguments may be admitted into the proceedings in consideration of specific circumstances of the case.
24. Applying these principles to the present case, it must be concluded that the documents introduced by the Claimants in the Reply to defence to revocation (Exhibits KAP D06, KAP D16 – D26) and the documents introduced by the Defendant in the Rejoinder to the Reply to defence to revocation (Exhibits BB16 – BB27) are admissible, given that they contain arguments regarding the common general knowledge and the claim interpretation which were advanced in their respective initial written pleadings and are intended to contrast and react to the arguments raised by the opposing party.

II. Admissibility of subsequent requests to amend the patent

25. With the Defence to revocation the Defendant filed Auxiliary requests 0a, 0b, 0c, 1, 1a, 2, 2a, 3, 3a, 4, 4a, 5, 5a, 6 and 6a, to be considered if the Court does not intend to maintain the patent as granted.
26. At the interim conference regarding the counterclaim for revocation the Defendant requested the permission to subsequent amend the patent according also to 0a* and 3a*, which would consist of, respectively, deleting some dependent claims in the Auxiliary request 0a and in the Auxiliary request 3a already on file. The Defendant stated that this will further narrow the patent and simplify the request to amend the patent and is therefore in the interest of both parties. The subsequent request to amend the patent was also filed in the CMS on the same day and registered as Application No. App_58456/2024.
27. The Claimants objected to the subsequent requests to amend the patent, arguing that this motion is inadmissible as it was filed two working days before the oral hearing. They further argue that deleting dependent claims (in particular, claim 4) has a material and repercussive influence on claim interpretation of claim 1 even though the latter was not amended compared to the earlier filed requests.
28. The judge-rapporteur allowed the Defendant to file the subsequent requests to amend the patent pursuant **Rule 30 (2) 'Rop'** by the end of the working day of 25 October 2024 and addressed the question of their admissibility and permission to the panel giving the opportunity to the Claimants to comment on the subsequent requests during the oral hearing.
29. Auxiliary request 0a* builds on Auxiliary request 0a. The amendment consists in deleting all dependent claims 2 to 9. There is no change in independent claim 1 as set forth in Auxiliary request 0a.
30. Auxiliary request 3a* builds on Auxiliary request 3a. The amendment consists in deleting dependent claim 4, subordinate to dependent claim 2, and dependent claim 5, subordinate to dependent claim 4. There is no change in independent claim 1 as set forth in Auxiliary request 3a.
31. During the oral hearing both parties were granted extra time to comment on the subsequent requests to amend the patent filed. The parties confirmed their statements. The Claimants argued that the subsequent amendments influence the interpretation of independent claim 1 and would have impact on the infringement proceedings pending before the Mannheim Local Division.

32. This Court notes that **Rule 30 (2) 'Rop'** is a strict rule of preclusion which only admits subsequent requests to amend the patent with the permission of the Court. When assessing whether a new amendment is permitted, the Court has to take into account, on one hand, the fact that a subsequent amendment of a patent may lead to more efficient proceedings , narrowing the subject matter and simplifying the procedural activities, and to a proper safeguard of the interest of the patent proprietor in controlling the scope of protection of its exclusive rights; on the other hand, the admission of subsequent requests to amend the patent may affect the purpose of delivering an expeditious decision, forcing an extension of the time of the written procedure in relation to the right of the other parties to arrange the consequent defence, and may undermine the right of defence of these latter parties (**see CD Paris, order issued on 27 February 2024, UPC_CFI_255/2023**). In this regard, it is important to consider whether the new amendment would have been necessary at an earlier point in time in response to the invalidity plaintiff's arguments and whether the late request for amendment causes delays in the proceedings (**Mannheim LD, order issued on 27 June 2024, UPC_CFI_210/2023**).

33. The issue concerning the controversial admissibility of subsequent request to amend the patent, consisting of the filing of new auxiliary requests in addition to those already timely filed with the application to amend the patent, should in theory be decided preliminarily to the examination of the merits of the dispute, as it pertains to the delimitation of the subject matter of the dispute, which is a logically and legally prior question.

34. However, in deference to the need for expeditious judgments and efficient proceedings, the Court may decide the case even by overturning the priority order of the issues to be decided where a determination can be made on the basis of a more easily resolvable reason - albeit logically subordinate - without examining those that are antecedent.

35. This situation arises in the present case where, for the reasons that will be explained below, there is no need to examine the auxiliary requests contained in the subsequent request to amend the patent, in addition to those timely filed, since the examination of the latter allows the Court to consider the attacks on the validity of the patent to be overcome and renders such later auxiliary requests devoid of any concrete relevance.

III. Hearing of parties' experts

36. To prove the common general knowledge both parties have submitted written expert evidence that they consider necessary. The Claimants submitted the expert statements of […] The Defendant submitted the expert statements of […] and written witness statements ("*Affidavit*") of the inventor of the patent at suit […]. Both parties have requested that the experts be heard in person by the Court at the oral hearing.

37. Pursuant to **Rule 177 (1) (b) 'Rop'**, applicable mutatis mutandi in conjunction with **Rule 181 (1) 'Rop'**, the Court may order an expert to be heard in person if his or her opinion is challenged by the opposing party and if this is deemed to be useful.

38. Having taken into account that the Claimants are challenging the opinion of […] against that of […] the Court considered appropriate to summon both pursuant to **Rule 177(1) (b) 'Rop'** by order issued on 25 September 2024.

39. […] was not allowed to be heard in person as expert or as witness. The Court considers that as inventor of the patent at issue he may have a direct interest in the outcome of the case and therefore does not meet the requirements of **Rule 181 (1) (a) and (b) 'Rop'** for impartiality, objectivity and independence.

40. […] and […] were heard in person at the oral hearing and were asked questions by the parties and the panel limited to the facts establishing the common general knowledge at the priority date.

B. Issues on merit

I. Legal framework

41. Pursuant to **Art. 65 (1) (2) 'UPCA'** the Court shall decide on the validity of a patent on the basis of an action for revocation or a counterclaim for revocation only on the grounds referred to in **Articles 138 (1)** and **139 (2) 'EPC'**.

42. The Court of Appeal has laid down the following legal framework for the interpretation of patent claims (order dated **26 February 2024, UPC_CoA_335/2023**, p. 26-27 of the original German language version, also see order issued on **13 May 2024, UPC_CoA_1/2024**).

43. In accordance with **Art. 69 EPC** and **the Protocol on its interpretation**, a patent claim is not only the starting point, but the decisive basis for determining the scope of protection of a European patent. The interpretation of a patent claim does not depend solely on the strict, literal meaning of the wording used. Rather, the description and the drawings must always be used as explanatory aids for the interpretation of the patent claim and not only to resolve any ambiguities in the patent claim. However, this does not mean that the patent claim merely serves as a guideline and that its subject-matter also extends to what, after examination of the description and drawings, appears to be the subject-matter for which the patent proprietor seeks protection. (**see Court of Appeal, order issued on 26 February 2024, UPC_CoA_335/2023**).

44. A feature in a patent claim is always to be interpreted in the light of the claim as a whole (**see Court of Appeal, order issued on 13 May 2024, UPC_CoA_1/2024, point 29**). From the function of the individual features in the context of the patent claim as a whole, it must be deduced which technical function these features actually have individually and as a whole. The description and the drawings may show that the patent specification defines terms independently and, in this respect, may represent a patent´s own lexicon. Even if terms used in the patent deviate from general usage, it may therefore be that ultimately the meaning of the terms resulting from the patent specification is authoritative. In applying these principles, the aim is to combine adequate protection for the patent proprietor with sufficient legal certainty for third parties.

45. The relevant point in time for interpreting a patent claim for the assessment of validity is the filing (or priority) date of the application that led to the Patent.
46. The patent claim is to be interpreted and all alleged grounds for revocation are to be assessed from the point of view of a person skilled in the art at the relevant date of the application.
47. According to **Article 76 (2) 'UPCA'** the Court bases its decision on the merits only on grounds, facts and evidence which were submitted by parties and on which the opposing party had the opportunity to comment.

II. The concept of person skilled in the art and the common general knowledge

48. The identification of the person skilled in the art and the common general knowledge ('*CGK*') can conveniently be done in one go.
49. The person skilled in the art is a legal fiction which, in the interests of legal certainty, forms a standardized basis for the assessment of the legal concepts of '*prior art*', '*novelty*, '*inventive step*' and '*enablement*'. The skilled person stands for the average expert who is typically active in the technical field of the invention, has had the usual prior training and has acquired average knowledge, skills and practical experience for routine work, but does not have inventive imagination, thinking and skills. When interpreting a patent claim, the person skilled in the art does not apply a philological understanding but determines the technical meaning of the terms used with the aid of the description and the drawings.
50. Parties seem to agree on the qualification of the skilled person which should be a skilled medical device engineer working in the technical field of cochlear implants.
51. The Court considers that the person skilled in the art must be identified in a mechanical engineer with either a Bachelor's degree or a Master's degree in mechanical engineering and several years of experience in the technical field of medical devices and specifically in the field of cochlear implants.
52. The '*CGK*', in general, is information which has been commonly known to the skilled person from written sources or from practical experience in the relevant technical field. The '*CGK*' includes knowledge which is directly available from familiar sources of information relating to the specific technical field at the prior date but is not to be confused with publicly available knowledge, which may not be general and common. A familiar source of information typically is a source to which a skilled person regularly turns for guidance on standard design solutions that are generally applicable, such as standard textbooks, encyclopaedias, manuals, handbooks, dictionaries and databases which the skilled person knows and can use as a suitable and reliable source for the respective information in the respective technical field. A familiar source of information should not be confused, however, with all publicly available prior art documents.
53. In any case, the '*CGK*' is subject of evidence. Pursuant to **Article 54 'UPCA'**, the burden of proving the existence of the '*CGK*' lies with the party invoking it. Without bearing the burden of proof, the opposing party may present evidence to establish the '*CGK*', including evidence to the contrary.

III. Technical field and prior art discussed in the patent at suit

54. The patent relates to implantable medical devices. According to para. [0001] of EP '373, the invention relates specifically to magnetic elements in such a device that allow for magnetic resonance imaging.
55. Para. [0002] of EP '373 describes the state of the art at the priority date. The description refers to hearing implants, such as Middle Ear Implants (MEIs) and Cochlear Implants (CIs), which typically include: 1) an external transmitter housing, worn on the outside of the head; and 2) a corresponding receiver system, surgically implanted under the patient's skin (between the skin and the skull bone, behind the ear). Both the external and the internal part have attachment magnets to hold the external part magnetically in place over the implant. The attachment magnets have a conventional coin-shape and a north-south magnetic dipole that is perpendicular to the skin of the patient. Fig. 1 and Fig. 3A of the patent illustrate the background art.

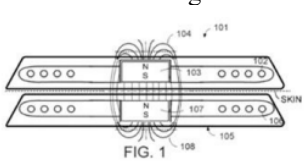
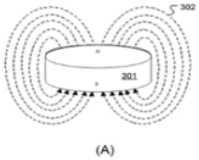


FIG. 1



(A)

56. One problem arises when the patient undergoes magnetic resonance imaging (MRI) examination as described in para. [0003]. While the external part of the implants is easily removable from the patient's body and therefore is not affected by the magnetic field of the MRI scanner, the internal part of conventional implants interacts with the external magnetic field applied for the MRI which may lead to negative consequences. The external magnetic field may create a torque on the internal magnet, which may displace the internal magnet or the entire implant housing and thereby also damage adjacent tissue in the patient. Further, the external magnetic field from the MRI may reduce or remove the magnetization of the implant magnet so that the internal magnet is no longer strong enough to hold the external transmitter housing in its proper position. The implant magnet may also cause artifacts in the MRI image, and there may be induced voltages in the receiving coil and hearing artifacts due to the interaction of the external magnetic field of the MRI with the implanted device. Thisis especially an issue with MRI field strengths exceeding 1.5 Tesla.
57. Various known solutions of this problem are described in para. [0004]: either not to permit MRI or to limit the strength of the applied magnetic field. One alternative solution is the surgical removal of the internal magnet: at the oral hearing the use of removable magnets was defined by […] as '*gold standard*' in the cochlear implantology to prevent artifacts in the MRI image caused by the internal magnet and to avoid patient trauma because the torque problem arises as soon as the patient enters the room (see as well Exhibit KAP D6, paras. 53 and 54). Othersolutions suggest the use

ofspherical magnets which are free to rotate and, thus, capable of aligning with the external magnetic field. The disadvantage of this arrangement, however, is that spherical magnets need to have a greater thickness than the other components of the implant and therefore require drilling a recess into the underlying bone. This additional step is very challenging and might be impossible for young children. The patent refers in this context to the prior art document WO 03/081976 A2 (which is as well referred to by the Claimants as Exhibit KAP D1 '*Zimmerling'* and defined as closest prior art).

IV. The invention

58. Given this background, the problem to be solved by the invention, is how to design an implant system that allows the patient to safely undergo MRI examination without surgical removal of the attachment magnet in the implant and without the need to drill a recess into the skull bone during implantation.

59. According to the invention, this problem is solved by an implant system with a planar discshaped magnet having a magnetic dipole parallel to the plane of the coil housing and capable to align its magnetic dipole with an external magnetic field of an MRI machine through rotation in the plane of the coil housing.

60. The invention is defined by claim 1 of EP '373, the only independent claim having the following features:

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

1.1 a planar coil housing (402)

1.1.1. containing a signal coil for transcutaneous communication of an implant communication signal;

1.2. a first attachment magnet (401) within the plane of the coil housing (402)

1.2.1. rotatable therein and

1.2.2. having a magnetic dipole parallel to the plane of the coil housing (402) for transcutaneous magnetic interaction with a corresponding second attachment magnet (404),

1.3. wherein the coil housing (402) is an implant coil housing for implantation under the skin of the patient

1.4. wherein the signal coil is a receiver coil and

1.5. wherein the said first attachment magnet (401) has a planer disc shape or a cut away disc shape.

61. Several features need to be carefully examined asthe parties debated about their interpretation and, in any case, they relate to relevant aspects of the claimed invention.

62. Firstly, features (1.3.) and (1.4.), specifying that the coil housing (402) is an implant coil housing for implantation under the skin of the patient and that the signal coil is a receiver coil, are to be read in conjunction with features (1.1.) and (1.1.1.).

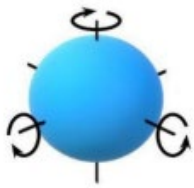
63. Feature (1.5.), specifying that the first attachment magnet has a planar disc shape or a cut away disc shape, is to be read in conjunction with feature (1.2.) and 1.2.1, i.e., that the first attachment magnet is located within the plane of the coil housing and rotatable therein.

64. The parties agree that the term '*therein'* included in feature (1.2.1.) is to be understood as '*rotatable in the plane of the coil housing'*. The examined experts […] and […] also share this understanding in line with the common general knowledge.

V. Insufficient disclosure

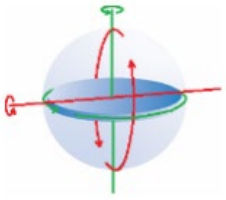
65. The Claimants argue that the teaching of the patent in suit does not enable the skilled person to carry out the whole subject-matter defined in claim 1 without undue burden.

66. The patent describes in para. [0004] that spherical magnets belong to the state of the art for MRI-compliant implants and provide a safe solution even for external magnetic fields with high field strength. Spherical attachment magnets as described in para. [0004] can rotate freely around several axes of rotation and, hence, in a variety of different planes and are therefore capable to align with an external magnetic field. Three orthogonal axes of rotation are shown in the picture below provided by the Claimants in the Counterclaim for revocation. Spherical magnets have, however, the disadvantage that the spherical bump of the magnet housing requires preparing a recess in the underlying bone.



67. According to the patent in suit, the coil housing has a flat bottom so that there is no need to drill a recessinto the bone during implantation. The Claimantsstate that the disclosure of the patent in suit is summarised in para. [0025]: *'Non-spherical shaped magnets with a magnetic field oriented in the plane of the coil housing (i.e., parallel to the skin) [offer] 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.*** *[...]'* (emphasis added by the Claimants)

68. The claimants argue that disc-shape magnets (illustrated in dark blue in the figure below) also can rotate in several planes (one of which is the plane of the coil housing) about different axes of rotation (red and green), whereby the volume of rotation is a sphere (light blue), as shown in the picture provided by the Claimants in the Counterclaim for revocation.



69. However, the claim 1 of the patent requiresthe coil housing to be a planar coil housing (feature 1.1) and the rotation of the disc-shaped magnet should be '*therein'* (feature 1.2.1). The Claimants argue that it is not certain whether rotation of the first attachment magnet is limited to being rotatable only in the plane of the coil housing or

if the first attachment magnet is rotatable in several planes, one of them being the plane of the coil housing. If a planar discshaped magnet is rotatable around all three orthogonal axes as illustrated above, the rotational volume would be a sphere, in similarity to a spherical magnet and the above-mentioned disadvantages that such an arrangement entails.

70. The Court considers that feature 1.2.1 '*rotatable therein'*, interpreted as '*rotatable in the plane of the coil housing'* as previously stated, is to be read in conjunction with feature 1.2.2 '*having a magnetic dipole parallel to the plane of the coil housing'*. The magnetic dipole of the first attachment magnet can only remain parallel to the plane of the coil housing during rotation if rotation is limited to rotation within the plane of the coil housing, i.e., around an axis perpendicular to the plane of the coil housing. This view is confirmed by the patent in para. [0025] where it is explicitly stated that *'the disk-shaped attachment magnet design described above allows for rotation of the magnet in only one plane*' (emphasize added by the panel), para. [0029] which states that *'the torque exerted to the implant can remain relatively high when the implant magnet which has only one degree of freedom cannot align well enough with the external magnetic field'* (emphasize added by the panel) and is supported by […] in his expert report, […] The Court therefore concludes that the above-mentioned embodiment construed by the Claimants is not part of the subject-matter of the patent. On that basis, the Claimants objections with regard to insufficiency of disclosure are moot.

71. Pursuant **Article 138 (1) (b) 'EPC'** in conjunction with **Article 83 'EPC'**, applicable according to **Article 65 (2) 'UPCA'**, the patent shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

72. The disclosure shall be in the patent itself encompassing the claims, description and drawings.

73. Several paragraphs provide teaching on the position and rotation of the attachment magnet (see paras. [0014], [0015], [0016], [0019]). Para [0016] discloses that in situations where the rotational axis of the attachment magnet (i.e. its axis of symmetry) is exactly perpendicular to the static magnetic field of the MR system, the attachment magnet can turn around and align its magnetic dipole exactly with the static magnetic field without torque or demagnetization. This is, however, an ideal theoretical case. But also when the attachment magnet cannot completely align with the static magnetic field of the MR scanner, but remains at an angle up to about 20 degrees between the magnetic momentum of the implant magnet and the static magnetic field of the MR scanner, the attachment magnet will turn around its axis and try to align its magnetic dipole with the surrounding magnetic field as best possible, the torque is still reduced significantly and there is virtually no risk for weakening the attachment magnet. This also confirms the above-mentioned interpretation of the features of claim 1.

74. The skilled person is deemed to possess the relevant '*CGK'* and use it by reading the patent and implementing the embodiments. Therefore, this teaching should be clear to the skilled person and enable him/her to produce embodiments with a disc-shaped magnet rotatable in the plane of the coil housing parallel to the patient's skin (and to the magnetic field of the MRI machine). Hence, the patent fulfils the sufficiency requirements under **Article 83 'EPC'**.

VI. Extension beyond the content of the patent application as filed

75. It is not disputed between the parties that the European patent application EP 22 177 545.5, on which the patent at suit is based, is a 3rd generation divisional application based on European Patent Application 11 717 431.8, published as WO 2011/133747 A1 (hereinafter referred to as the "*original application*"). The latter represents "*the earlier application as filed"* with regard to **Article 100(c) 'EPC'** to which the parties refer in their written submissions and during the oral hearing. In para. [0010] of the original application it is stated that '*the implantable system may be a cochlear implant system, a middle ear implant system, a vestibular implant system, or a laryngeal pacemaker implant system'*. Further, all the claims in the application as filed relate to an '*implantable system'*.

76. In the claims of the patent as granted the term '*implantable system'* has been replaced by the term *'implant system'*. The list of para. [0010] is, however, not present in the independent claim 1, but only in subordinate claim 10.

77. The Claimants argue that this replacement broadened the subject-matter of the claim beyond that of the earlier application as filed by replacing the four specific implant systems described therein with the more general class of "*implant systems*" as a whole. The Defendant counterargues that the skilled person can clearly and unambiguously derive from the earlier application that the teaching contained therein is applicable to implant systems in general and not limited to any particular kind of implant system.

78. The Claimants are right. There is no indication in para. [0010] or in the application as a whole that indicates that the implantable system could be any other type of implant system as those specifically mentioned, and in the view of the panel this is not directly and unambiguously derivable for the person skilled in the art from the content of the application as filed using common general knowledge. The omission of the exhaustive list of para. [0010] of the application resulted therefore in an impermissible generalization of the claimed invention. Thus, the patent as granted contains added subject matter and does not fulfil the requirements of **Art. 123(2) 'EPC'**.

79. The Claimants further argue as well that the term *'implant system'* itself is broader than the term '*implantable system'* taking arguments from para. [0003] of the originally application which describes implant systems *'[employing] attachment magnets in the implantable part and an external part to hold the external part magnetically in place over the implant'*.

80. The panel shares the opinion that the term '*implantable system'* refers to the internal part only,

while *"implant system"* includes necessarily an internal part but may also include an external part. The proper understanding of the term '*implant system'* depends on the scope of the disclosed technical features.

81. As a further precautionary measure, the Defendant indicated in the Defence to revocation its willingness to delete the respective one(s) or all of the dependent claims in order to overcome the extension beyond the content of the patent application.

Auxiliary Request 0a

82. The proposed amendment according to Auxiliary Request 0a combines claims 1 and 10 as granted to a new claim 1, namely that '*implant system'* is one of a cochlear implant system, a middle ear implant system, a vestibular implant system, and a laryngeal pacemaker implant system and, therefore, overcomes the objection of added subject-matter for claim 1.

83. There are no amendments in all other subordinate claims 2 to 9. With regard to claim 2 the Claimants argued that the omission of the *"external part"* being *"an external transmitter coil housing"* from the subject-matter of claim 2 of the divisional application represents an unallowable intermediate generalisation of the content of the earlier application as filed. In response, the Defendant has stated that the original disclosure makes it clear that the implantable and the external part are separate entities and that the earlier application provides clear and unambiguous disclosure for the claimed implant system in combination with an external part comprising a second attachment magnet without said external part necessarily being a transmitter coil housing and refers in this regard, as an example to paras. [0003], [0030] and figure 4, 8-11 of the application. Further, the Claimants argue that there is only basis in the earlier application as filed for a second attachment magnet having a "*magnetic dipole parallel to the plane of its coil housing*". The Defendant responds that example 1, original claim 1 and claim 1 as granted only impose a single limitation on the second attachment magnet, namely, to be a corresponding second attachment magnet for transcutaneous magnetic interaction with a first attachment magnet. The Defendant further states that the skilled person clearly and unambiguously derives from the applications as filed that there are no further limitations as to the magnetization of the second attachment magnet, and that the features in question are obviously not inextricably linked or related. Claimants' objections with regard to claims 3-9 are based on their dependency on claim 2. The Claimants further argue that the feature of claim 6 referring to the attachment magnets each having two poles and attractive forces on both poles was not recited by the claims of the earlier application as filed but only described in para. [0043] of the description, and only in the context of a single second attachment magnet (in contrast to the embodiments of Figs. 11-13) and therefore constitutes an intermediate generalization. The Defendant rebuts that this feature finds basis in the description, e.g. in para. [0043]. Further, the feature of claim 6 is also disclosed for embodiments having a second attachment magnet comprising a pair of complementary cylindrical attachment magnets asin claims 4, 5 and Fig. 11- 13.

84. The panel agrees with the Defendant that the subject-matter of claim 2, claim 6 and the other dependent claims does not extend beyond the application as originally filed but is directly and unambiguously derivable from the content of the application as filed when account is taken of matter which is implicit to a person skilled in the art using common general knowledge. Therefore, Auxiliary request 0a does satisfy the requirements of **Article 123(2) EPC**.

VII. The Inventive step attack

85. The assessment of the inventive step must be carried out in accordance with **Article 56 'EPC'**, which states that *'[an] invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obviousto a person skilled in the art'*. Hence, it is necessary to determine whether, given the state of the art, a person skilled in the art would have arrived at the technical solution claimed by the patent using its technical knowledge and carrying out simple operations. Inventive step is assessed in terms of the specific problem encountered by the person skilled in the art (**see Paris LD, decision issued on 3 July 2024, UPC CFI 230/2023**).

86. In order to assess whether or not a claimed invention is obvious to a person skilled in the art, it is first necessary to determine one or more teachings in the prior art that would have been of interest to a person skilled in the art who, at the priority date of the patent in suit, was seeking to develop an invention or process similar to that disclosed in the prior art. Then, it must be assessed whether it would have been obvious for the skilled person to arrive at the claimed solution of the underlying technical problem on the basis of a realistic disclosure of the selected prior art documents (**see, Munich CD, decision issued on 17 October 2024, UPC CFI 252/2023**; **Dusseldorf LD, decision issued on 10 October 2024, UPC CFI 363/2023**). The problem-solution approach is one possible way for assessment of the inventive step.

87. The prior art document WO 03/081976 A2 (Exhibit KAP D 01 '*Zimmerling'*) relates to the problems that occur when the wearer of a cochlear implant has to undergo MRI examination: the implanted magnet may experience a torque that can twist the magnet and the implant out of position and injuring the wearer; the implanted magnet can become partly demagnetized and not be able to hold the external part in place; the radio frequency (RF) pulses of the MRI unit may induce voltage in the implant coil, implant circuit or electrode circuit, this might lead to unwanted stimulation or destroy implant electronics; artifacts in the MRI image may be caused by the local magnetic field of the implant magnet.

88. '*Zimmerling'* is in the same technical area as the patented invention, is trying to solve the same problem and has some features in common with the patented solution. '*Zimmerling'* is therefore a suitable starting point for a skilled person.

89. The prior art document US 7266208 B2 (KAP D 02 '*Charvin'*) relates to an acoustic auditory aid for the rehabilitation of partial neurosensory hearing loss. '*Charvin'* does not relate to and does not even mention the MRI-compatibility of CI's, and is concerned with the solution of rather remote problems, (column 1, line 42): *"these devices present the disadvantage of being painful to wear, and of posing a threat of falling consequent to certain movements of the head ... they are relatively visible and lack esthetics ...disagreeable sensation of blocked up ear, perception of parasitical sounds during chewing ... problems of hygiene and potentially of infections*". Therefore, 'Charvin' cannot be considered as a suitable starting point for the skilled person to arrive at the subject-matter of claim 1 of the patent.

90. The prior art document 'Dissertation of Christian Teissl - Cochlear Implants and Magnetic Resonance Imaging: Compatibility and Safety Aspects', October 1998 (KAP D 03 '*Teissl 1*') presents a collection of independent research articles describing CI´s and MRI. '*Teissl 1*' describes tests on a cochlear implant MedEl Combi 40/40+ and mentions that a small internal magnet is used to hold the external transmitter in place (p. 9 section 1.3.2 and further, p. 72): "*Small internal magnets (rare-earth permanent magnets of cylindrical shape, magnetized in the main axis of symmetry, which is normal to the skin…) are used to guarantee a sufficient transmission quality between the external transmitter and the internal receiver by holding the external transmitter in place*". '*Teissl 1*' suggests a number of different design changes to make CI´s MRI-safe, among these alternatives the removal of the internal magnet, torque reduction due to a compensation effect, weight reduction of the external transmitter and self-aligning internal magnets (p. 127 section 1.5), however, without presenting any details on how the selfalignment is accomplished (p. 127 section 1.5): "*another possibility of reducing the torque effectively ... would be an internal magnet which aligns itself within an external magnetic field.*" This is just one of many proposed alternatives (sections 1.1 to 1.8 in chapter IV, page 127) the skilled person can choose among, and no details are provided on how this alignment is achieved. '*Teissl 1*' neither mentions to align an internal magnet with an external magnetic field through rotation nor to change the magnetization of an internal magnet in an implant but rather underlines the need for axial magnetization of the internal magnet in order to keep the external transmitter in place. Therefore, '*Teissl 1*' is a less suitable starting point for the skilled person to arrive at the subject-matter of claim 1 of the patent than '*Zimmerling'*.

91. The prior art document US 6348070 B1 (KAP D 04 '*Teissl 2*') refers to cochlear implants and their interference with magnetic fields appearing during MRI and, thus, to the same technical filed as the patented invention. '*Teissl 2*' states that these magnetic fields can exert a strong torque on implanted magnets, especially if the magnetic moment of the implanted magnet is perpendicular to the longitudinal main magnetic field of the scanner. In order to solve this problem, *'Teissl 2'* proposes to provide the implantable prosthesis with at least two magnets, the magnets having antiparallel magnetic moments of identical magnitude. The exerted torques on the two magnets that are identical in terms of their magnetic moments in a homogenous magnetic field are equal and will therefore compensate each other, thereby substantially reducing the total torque and, thus, improving MRI-safety. '*Teissl 2*' very shortly mentions that it has been contemplated that in a further embodiment the total torque on a magnet of the implant may be reduced to residual values and partial demagnetization may be prevented by enabling the magnet to align with an external magnetic field, but does not provide any details of such an embodiment. '*Teissl 2'* has less features in common with the patented invention as '*Zimmerling'* and solves the above-mentioned problem *in* a different manner, which would lead the skilled person away from the patented solution.

92. The prior art document WO 2008/109800 A1 (KAP D 05 '*Hochmair'*) relates to the field of CI´s and MRI examination and tries to solve the same problems as the patent in suit. '*Hochmair'*, therefore, belongs to the same technical field as the present invention. The teaching in '*Hochmair'* focusses on a magnet holding structure adapted for allowing removal and subsequent reinsertion of the internal magnet in order to avoid imaging artifacts due to the internal holding magnet and, thus, on a different aspect as the invention of the patent in suit. '*Hochmair'* refers the teaching of '*Zimmerling'* in the background section and mentions, in similarity with '*Zimmerling'*, that the internal holding magnet is spherical or cylindrical and reorientable in responsive alignment to a direction of an external magnetic field during MRIexamination but in thisregard does not provide any information that goes beyond what is known from '*Zimmerling'* concerning the shape or the rotation axis of the implant attachment magnet. The teaching of '*Zimmerling'* is more detailed in this regard and therefore a more suitable starting point for the skilled person.

93. For these reasons the assessment of the inventive step will be made on the basis of '*Zimmerling'* combined with the 'CGK' as requested by the Claimants.

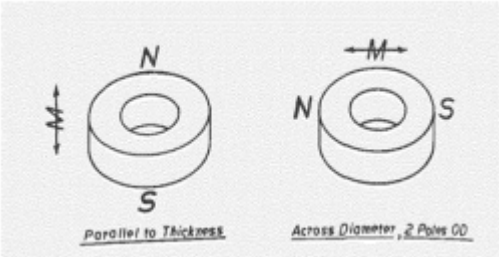
94. Considering that the other prior art documents are a less suitable starting point for the assessment of the inventive step, the Court deems it appropriate to discuss the possible combination between them and '*Zimmerling'*.

'*CGK*' at the priority date of the patent

95. The parties seem to agree that disc-shaped magnets were generally used in CI´s at the priority date of the patent. In his expert statement [ ] states [ ] that, at the priority date of the patent, "*disc-shaped implant magnets were the preferred choice for the implant magnet, because choosing a disc-shaped magnet maximizes the total magnetic volume of the implant magnet within the available space*." He also specified, [ ] that "*the implant magnet occupied a volume having a diameter no greater than 10 to 12 mm and had a thickness no greater than 4 mm* " which would result in a diameter/height ration of about 3:1 or 2,5:1. See also *'Teissl 1'* (page 80, figure 2) where the internal magnet is of cylindrical shape with a

diameter/height ratio of about 4:1. The use of disc-shaped magnets in CI´s at the priority date of the patent is also confirmed by in his expert statement Those statements were confirmed by the experts as well during the oral hearing.

96. The parties seem also to agree that both axial and diametrical magnetization was known to the skilled person (picture Exhibit KAP D 15, Permanent Magnet Design and Application, Handbook, Moskovitz).

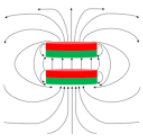


97. The patent also illustrates in Fig. 3A the axial magnetization as the magnetic dipole arrangement typically used in existing implant attachment magnets.

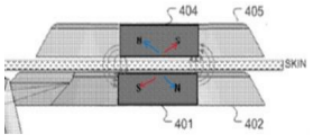
98. From the expert statements it can be concluded that axially magnetized disc-shaped magnets in CI´s were state of the art at this point in time. In his expert statement […] states […] that "*all devices on the market had adopted essentially the same design for the implantable component: namely, a titanium case for electronic components with an external coil in the centre of which contained a titanium encased disk-shaped rare earth permanent magnet*." Further, about the magnetization, […] states: "*The implant magnet in each of these devices is disk-shaped and its magnet dipole is oriented along its central axis (i.e. perpendicular to the skin)".*

99. In his expert statement […] confirms the same state of art at the priority date: *"cochlear implants at the priority date utilized flat, disk-shaped magnets,such magnets were all axially magnetized. Diametrically magnetized disk-shaped magnets were not used at all in cochlear implants."* Further […] states […] : "*I do not consider that the Skilled Biomedical Engineer would have contemplated any arrangement for the magnet in a cochlear implant other that the standard, axially magnetized magnet."*

100. Further, in his statement […] and at the oral hearing […] states that by the axial arrangements the opposite poles of the internal and the external magnet provide for a strong attractive force, enabling a high degree of attraction and alignment between the internal and external components. By the axial arrangements of both magnets no repulsive forces arise in the centre of the magnets, in contrast to the diametrical magnetization. This was explained by […] at the oral hearing and illustrated by a drawing which the panel reproduces below.



axial arrangement
Exhibit BB21, p.12



diametrical arrangement
Fig.4 of the patent at suit (colours added by the panel according to [redacted] explanation at the oral hearing)

Disclosure of WO 03/081976 A2 (D 01 '*Zimmerling*')

101. The solution provided by '*Zimmerling'* is a magnet that is free to rotate such that is capable of aligning at least partially with an external magnetic field.

102. '*Zimmerling'* suggests that the magnet may be spherical or cylindrical (p. 5, line 1-2). Using spherical magnets has the advantage that the spherical magnet can align entirely with an external magnetic field without any limitations. However, the spherical magnets need to have a greater thickness than the other components of the implant and therefore require drilling a recess into the underlying bone (see para. 57 above). '*Zimmerling'* also mentions the advantages of a magnet of cylindrical shape, namely that the aspect ratio, i.e., the diameter vs. length, can be chosen such that for a given volume, which is necessary to generate an adequate holding force, the thickness of the magnet is smaller than that of a spherically shaped magnet.

103. '*Zimmerling'* states, see page 8, line 8 ff., that the cylindrical magnet carries a magnetization being normal to its axis whereby the axis is arranged horizontally parallel to the skin in the plane of the implanted coil, see also Fig. 9 showing a permanent magnet 901 with a cylindrical shape rotatable around its rotational axis and with a diametric N-S dipole in similarity with the present invention. '*Zimmerling'* states that the magnet may turn its magnetic moment such as to align with a magnetic field generated by a high field MRI scanner whose field lines in a typical examination position run along the patient's axis. For MRI scanners which use vertical magnetic fields, '*Zimmerling'* suggests mounting the axis of the cylinder still in the plane of the implanted coil, but at approximately up to 45 degrees off the horizontal plane to be able to partially adjust to (lower field) MRI-machines which use vertical magnetic fields.

104. The present invention differs from the cylindrical magnet embodiment, described in '*Zimmerling'* and shown in Fig. 9, in feature 1.1 *"a planar coil housing*", feature 1.2.1 "*rotatable within the plane of the coil housing",* feature 1.2.2 "*having a magnetic dipole parallel to the plane of the coil housing*" as well as feature 1.5 "*said first attachment magnet has a planar disc shape or a cut away disc shape*". These distinguishing features achieve the effect of providing an implant of flat shape (i.e. that can be implanted without requiring drilling a recess into the underlying bone) while improving MRI-compatibility of the implant for MRI scanners using a vertical field. This technical effect is also described in the patent in suit, see para. [0015] (underlined by the panel) '*As the implant user is brought into the MR scanner, the attachment magnet may have a component of its magnetization which is perpendicular*

to the external magnetic field of the MR scanner. This will result in the attachment magnet turning around on its axis to align the magnetization direction of the magnetic dipole with the static field of the MR scanner. This occurs in both conventional closed MR scanners characterized by a bore with a horizontal static magnetic field as shown in Figure 5 running parallel to the axis from head to toe on the patient, as well as in so-called open MR scanners as shown in Figure 6 characterized by a vertical static magnetic field running perpendicular to the body axis through the body of the patient from front to back."

105. Starting from Zimmerling's teaching on cylindrical magnets the objective technical problem to be solved can be considered as how to design an implant with an improved MRI-compatibility that avoids unnecessary bone excavation.

106. The skilled person, faced with the problem of designing an implant of flat shape with improved MRI-compatibility, receives some guidance from '*Zimmerling'*, e.g., page 8, line 20 ff, that '*the implant may include severalsmaller magnetsinstead of one magnet, allowing a thinner design of the implant'*, see also figure 4 (a) and 4 (b). The proposed implant 401 includes three spherically shaped magnets 402 – 404, which will enable full alignment of the internal magnets with an external magnetic field applied both by open MR scanners and closed MR scanners. By this teaching, the skilled person is lead towards a solution to use several smaller spherical internal magnets and thus away from the solution presented in the patent.

107. Claimants argue that "*it can be seen from figure 9 that the rotatable cylindrical magnet 901 taught by 'Zimmerling' is suitable for presenting its N-S magnetic dipole parallel to the plane of the coil housing*". This argument is not convincing.

108. Figure 9 in '*Zimmerling'* shows a magnet with a diametric N-S dipole similar to the present invention. The coil housing and the coil are not shown in Figure 9. Leaning towards Figures 12A and 12B in search for further information, the skilled person does not receive any guidance to place the magnetic dipole parallel to the plane of the coil housing. In one particular position the dipole might temporarily be parallel to the coil housing, but during rotation of the magnet the parallel placement is not upheld, in contrast to the present invention, where the dipole is always parallel to the coil housing.

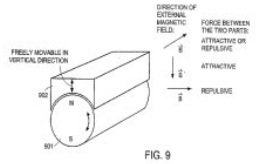


FIG. 9

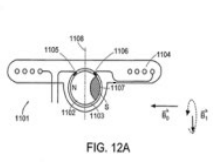


FIG. 12A

109. In '*Zimmerling'*, the axis of rotation of the magnet is parallel to the plane of the coil housing (see e.g., figures 12A and 12B). In contrast, in the present invention, the axis of rotation is perpendicular to the plane of the coil housing (which corresponds to feature 1.2.1 in the claim "*the first attachment magnet is rotatable within the plane of the coil housing").* This has a significant benefit for the patient as it allows the implant to be made much thinner and, thus, to prevent bone excavation while at the same time enabling the internal magnet to align with the external magnetic field of both closed and open MRI scanners.

110. Taking into account the above considerations it can be concluded that starting from the cylindrical magnet of figure 9 the skilled person would not arrive at the disc-shaped magnet with diametric magnetization rotatable around axis perpendicular to the coil housing (features 1.2.1, 1.2.2 and 1.5 of the claimed invention).

111. '*Zimmerling'* also describes embodiments with attachment magnets of spherical shape, see fig. 10 and 12-15, e.g., spherical magnet 1001. These embodiments enable complete alignment of the internal magnet with an external magnetic field, both for closed MR scanners and open MR scanners. The present invention as defined in claim 1 in AR0 differs from this embodiment shown in '*Zimmerling'* by feature 1.1 "*a planar coil housing",* feature 1.2 "*a first attachment magnet within the plane of the coil housing*", feature 1.2.1 *"rotatable in the plane of the coil housing"*, feature 1.2.2 "*having a magnetic dipole parallel to the plane of the coil housing*" and feature 1.5 *"the first attachment magnet has a planar disc shape or a cut away disc shape*". In this context, the panel notes that figure 15A-C refer to the same embodiment, and figure 15C shows a top view of the implant presented in figure 15A and 15B. The effect of these distinguishing features is that the need for bone excavation is obviated. The person skilled in the art, with the background of the above-mentioned embodiment presented in […] therefore faces the problem to design a more compact implant with a slim profile to avoid the need to drill a recess into the bone during implantation.

112. There is no indication in '*Zimmerling'* that would lead the skilled person to the solution defined in claim 1 of Auxiliary Request 0a. Instead, the skilled person, facing the above-mentioned problem, finds another solution to this problem in Fig. 4A and 4B of '*Zimmerling'* where the same problem is addressed. '*Zimmerling'* proposes to include several smaller magnets instead of one magnet, thus allowing for a thinner design of the implant, see page 8, line 20 ff. This teaching in '*Zimmerling'*, however, leads the skilled person to another solution for the above-mentioned problem and, thus, away from the solution in claim 1 of Auxiliary Request 0a.

113. The panel therefore concludes that the subject-matter of claim 1 in the amended form according to Auxiliary request 0a is inventive over '*Zimmerling'*.

'*Zimmerling'* combined with '*CGK'*

114. As discussed above, at the time of the patent, disc-shaped magnets with axial magnetization were generally used in CI´s. It was also common general knowledge that magnets could be magnetized parallel to their thickness, i.e. axially, or across their diameter, i.e. diametrically. Even '*Zimmerling'* discloses in the embodiment in Fig. 9 an internal magnet with diametrical magnetization, however, with a magnetic dipole perpendicular to the skin. Diametrical magnetization with a magnetic dipole parallel to the skin has significant disadvantages since

the attraction force between the internal magnet and an external part of an implant device is significantly lower than when axially magnetized magnets are used (see para. 100 above). This has also been confirmed by both […] and […]

115. Therefore, the decision of the skilled person to choose an internal magnet with a diametrical magnetization and a magnetic dipole arranged parallel to the skin of the wearer of an implant despite being well aware of the disadvantages of such an arrangement could not be considered as being obvious in light of '*CGK'* in combination with '*Zimmerling'*.

116. In his expert statement […] states, that the combination of the teaching of '*Zimmerling'* with the 'CGK' directly and unambiguously leads to the solution provided by the claimed invention: '*When I was first shown Zimmerling and asked what the skilled person would do, and before I had seen the EP'605 Patent, it immediately struck me that there were otherstraightforward 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 used to my knowledge) and so the easiest way to implement Zimmerling would be to use the designs and components already being used.'*

117. This statement should not be taken into account. Firstly, obviousness is not a question of fact but a question of law, hence, it could not be proven by expert and witness evidence. Secondly, […] being an inventor of over 100 patents for medical devices which cover a variety of aspects of cochlear implants […] does not meet the profile of the hypothetical skilled person for an inventive step assessment who has no inventive imagination and skills, no ability for creative thinking and is a captive of established prejudices in the relevant field. For these reasons, the panel deviates from the reasoning and reaches a different conclusion than the High Court of England and Wales in its Judgment of the High Court of England & Wales, [2022] EWHC 1345 (Pat), (Exhibit KAP D8) which attached great significance to the expert statement of […]

118. Taking into account the above considerations it can be concluded that, starting from the teaching of '*Zimmerling'*, the skilled would not arrive at the disc-shaped magnet with diametric magnetization rotatable around axis perpendicular to the coil housing (features 1.2.1,1.2.2 and 1.5 of the claimed invention).

119. For these reasons, claim 1 of the patent in the amended form of Auxiliary Request 0a is not obvious in view of '*Zimmerling'* combined with 'CGK'.

'*Zimmerling'* combined with '*Charvin'*

120. The skilled person, with the background of '*Zimmerling'* and faced with the problem of designing an implant of flat shape with improved MRI-compatibility, would not consider '*Charvin'* and expect to find a solution to this problem since '*Charvin'* does not relate to or even mention MRI-compatibility. '*Charvin'* shows the use of a diametrically magnetized magnet with the axis of magnetization parallel to a patient's skin (Fig. 4). However, the purpose of this solution is not MRI-compatibility, but to support the external casing 1 in a certain orientation. That directly leads the skilled person away from any consideration to make the internal magnet 21 rotatable, as this would be contraindicative to the purpose of the diametrical magnetization, namely to support the outer casing in a certain orientation.

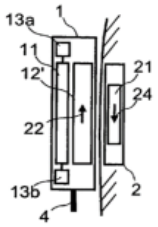


Fig. 4

121. Further, the teaching of '*Charvin'* is incompatible with a magnet being rotatable within the plane of the implant casing 2 and with the teaching of '*Zimmerling'*. The support of the outer casing 1 in a certain orientation would be impossible if the magnet would rotate in the casing 2. Turning to '*Zimmerling'* in combination with '*Charvin'* is a step taking in hindsight by the Claimants.

122. For these reasons claim 1 of the patent in the amended form of Auxiliary Request 0a is not obvious in view of '*Zimmerling'* combined with '*Charvin'*.

'*Zimmerling'* combined with '*Teissl* 1'

123. '*Teissl 1'* does not teach that the internal attachment magnet is rotatable within the plane of the coil housing and has a magnetic dipole parallel to the plane of the coil housing. It states that the magnet is cylindrical, and the internal magnetshown in Figure 2 on page 80 has a planar disc-shape. It mentions that it is a shortcoming if the magnetic moment of the internal magnet of a cochlear implant is perpendicular to the main magnetic field of the imager and suggests, as a solution, to turn the patient on the side (emphases added by panel), so that the magnetic moment of the internal magnet of the cochlear implant is parallel to the main magnetic field of the imager(page 121, last paragraph), thereby leading the skilled person away from the solution of claim 1. '*Teissl 1'* neither mentions to align an internal magnet with an external magnetic field through rotation norto change the magnetization of an internal magnet in an implant but rather underlines the need for axial magnetization of the internal magnet in order to keep the external transmitter in place. To arrive from '*Zimmerling'* in combination with the disclosure of '*Teissl 1'* at the subject-matter of claim 1 requires a number of modifications, which cannot be considered obvious.

'*Zimmerling'* combined with '*Hochmair'*

124. '*Hochmair'* suggests an implanted device having a low-torque internal magnet arrangement which allows for typical MRI procedures that otherwise require

surgical removal and replacement of the magnet. The magnet holding structure is also adapted to allow for easy removal of the internal magnet for MRI procedures where the magnet might produce unacceptable imaging artifacts. In similarity with '*Zimmerling'*, the internal holding magnet is reorientable in responsive alignment to a direction of an external magnetic field, e.g., during an MRI examination (paras. [0010] and [0021]) but the teaching of '*Hochmair'* is not concerned with the design of the magnet itself. The embodiments in '*Hochmair'* do not disclose features 1.1 "*a planar coil housing*" (the embodiments of '*Hochmair'* have a spherical bump similar to the teaching of '*Zimmerling'*), feature 1.2.2 "*a first attachment magnet having a magnetic dipole parallel to the plane of the coil housing*" and feature 1.5 "*the first attachment magnet has a planar disc shape or a cut away disc shape*". A skilled person, facing the above-mentioned problem of designing an implant of flat shape to avoid bone excavation in view of '*Zimmerling'* does not find a solution in '*Hochmair'*, as this problem is not addressed or even mentioned in '*Hochmair'*.

125. However, '*Hochmair'* teaches away from the claimed invention suggesting a removable internal magnet holding case (paras. [0020], [0025], [0029]) and spherical or cylindrical magnets (para. [0024]).

126. Furthermore, '*Hochmair'* teaches that "*the internal magnet holding case may be centered within an opening in the center of the receiving coil and covered by nearby bone, securely holding it in place*" (para. [0029]). This is one of the problems from '*Zimmerling'* that the skilled person aims to solve (see para. 105 above) and therefore he/she would not search guidance in '*Hochmair'* which not only does not provide any solution, but treats the identified problem as a possible solution.

127. For these reasons claim 1 of the patent in the amended form of Auxiliary Request 0a is not obvious in view of '*Zimmerling'* combined with '*Hochmair'*.

'*Zimmerling'* combined with '*Teissl 2'*

128. '*Teissl 2'* very shortly mentions that *"it has been contemplated that in a further embodiment of the present invention, the total torque on a magnet of the implant may be reduced to residual values, and partial demagnetization may be prevented, by enabling the magnet to align with an external magnetic field*" (c. 7, line 28 - c. 8, line 3), without, however presenting any details of such an embodiment, in particular not that the internal magnet is rotatable in the coil housing. '*Teissl 2'* instead focusses on an alternative solution to reduce torque on internal magnets by proposing (c. 3 line 53 ff) "*a magnet system of an implantable prosthesis for reducing torque exerted by an external magnetic field and preventing demagnetization, the system comprising at least two magnets, the magnets having antiparallel magnetic moments of identical magnitude*" (emphases added by the panel). The teaching in *'Teissl 2'* realizes MRI-safety by use of a compensation effect, since the exerted torque on two magnets that are identical in terms of their magnetic moments in a homogenous magnetic field is equal and the total torque on an implant housing can therefore be significantly reduced. The magnets in this embodiment of '*Teissl 2'* are mounted in the housing and are not proposed to rotate or align otherwise.

129. Furthermore, the magnet according to '*Teissl 2*' is *"magnetized in the main axis of symmetry*" and not, as in the claimed invention, diametrically magnetized. Accordingly, a modification of '*Zimmerling'* in accordance with the teaching of *'Teissl 2'* does not lead the skilled person to the subject-matter of the claimed invention as defined in claim 1 of Auxiliary Request 0a.

130. For these reasons claim 1 of the patent in the amended form of Auxiliary Request 0a is not obvious in view of '*Zimmerling'* combined with *'Teissl 2'*.

Final remark

131. The Court notes that the parties have based their arguments on both the patent in dispute, in the version issued by the EPO, and the original application (WO 2011/133747 A1), but neither party has submitted these documents into the proceedings, limiting themselves only to mentioning them in their written and oral pleadings and, the claimant, to producing only the intended for grant version (KAP 02).

132. Nonetheless, the Court has conducted its examination by independently retrieving these documents without any request for acquisition from the parties, even though it considers that, within the regulatory system of 'UPC', each party must prove the facts alleged and the Court cannot, in general, acquire evidence ex officio, nor base its decision on evidence or documents not formally acquired in the proceedings.

133. The Court has decided, exceptionally, to derogate from the aforementioned general principle in light of the absence of a consolidated case law on the matter, the ease of acquiring these documents and the parties' implicit consent to this procedure. It further highlights that a different and more rigorous interpretation of the relevant rules would not have had significantly more favourable effects for the defendant - the party that would have benefited from an orthodox application of the burden of proof that would have rested on the claimant - given the outcome of the proceedings.

Conclusions

134. The alleged insufficiency of the disclosure is not proven.

135. The extension of the patent as granted beyond the content of the patent application is overcome by Auxiliary Request 0a.

136. The alleged lack of inventive step of claim 1, as amended by Auxiliary Request 0a, is not proven.

137. The revocation action should be dismissed, and the patent should be maintained in the amended version (Auxiliary Request 0a) which reads as follows:

"1. An implant system for a recipient patient, said implant system comprising a magnetic arrangement, the arrangement comprising: a planar coil housing (402) containing a signal coil for transcutaneous communication of an implant communication signal; a first attachment magnet (401) within the plane of the coil housing (402), rotatable therein, and having a magnetic dipole parallel to the plane of the coil housing (402) for transcutaneous magnetic interaction with a corresponding second attachment magnet (404),

wherein the coil housing (402) is an implant coil housing for implantation under the skin of the patient and wherein the signal coil is a receiver coil, and wherein said first attachment magnet (401) has a planar disc shape or a cut away disc shape, wherein the implant system is one of a cochlear implant system, a middle ear implant system, a vestibular implant system, and a laryngeal pacemaker implant system.
2. An implant system according to claim 1, further comprising an external part comprising said second attachment magnet (404).
3. An implant system according to claim 2, wherein the second attachment magnet (404) has a planar disc shape, or a rectangular beam shape, or a cylindrical beam shape, or a cut away disc shape.
4. An implant system according to claim 2, wherein said second attachment magnet comprises a pair of complementary cylindrical attachment magnets (1101, 1102).
5. An implant system according to claim 4, wherein said arrangement further comprises: a magnetic flux guide (1301) connecting the pair of complementary cylindrical attachment magnets (1101, 1102).
6. An implant system of one of claims 2 to 5, wherein said first and second attachment magnets (401, 404) each have two poles, and said transcutaneous magnetic interaction of said first attachment magnet (401) with said second attachment magnet (404) involves attractive forces on both poles, so that an attraction is caused by two forces which apply at the two poles of each magnet.
7. An implant system of claim 6, wherein by said attractive forces applying on the two poles of each magnet (401, 404), a magnetic attachment of the external part can be achieved.
8. An implant system of one of claims 2 to 7, wherein said external part comprises an ex-ternal transmitter coil housing (405).
9. An implant system according to claim 8, wherein said external transmitter coil housing (405) is planar."

138. Any arguments of the parties which have not been specifically addressed must be deemed absorbed.

C. Costs

139. As the revocation action is dismissed not only because the Defendant submitted a limitation of the patent during the proceedings but also because the other grounds for invalidity are not proven, the panel deems it appropriate that the costs of the Court and of the parties shall be borne by the Claimant and by the Counterclaimants, jointly, in the amount of 70%, and by the Defendant in the amount of 30%.

140. As previously noted, the value of the revocation action for the purpose of applying the scale of ceilings for recoverable costs has been set at 5,000,000 euros. The same valuation has been applied to the counterclaims for revocation, collectively considered.

DECISION

Based on the foregoing, the Paris Central Division of the UPC, rules as follows:

1. The revocation action filed by Advanced Bionics AG and the counterclaims for revocation filed by Advanced Bionics GmbH and Advanced Bionics Sarl concerning the European Patent EP 4 074 373 B1 are rejected.
2. EP 4 074 373 B1 is maintained as amended by Auxiliary Request 0a.
3. The Registry shall send a copy of this decision to the European Patent Office and to the national patent office of any Contracting Member States concerned, after the deadline for appeal has passed.
4. The costs of the proceedings shall be borne by the Claimant and the Counterclaimants, jointly, in the amount of 70%, and by the Defendant for the remaining fraction.
