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Datasheet for the decision of 28 September 2022

Case Number: T 0732/21 - 3.4.01

16189856.4 Application Number:

Publication Number: 3138605

IPC: A61N1/36, A61N1/372

Language of the proceedings: EN

Title of invention:

MRI-SAFE DISK MAGNET FOR IMPLANTS

Patent Proprietor:

MED-EL Elektromedizinische Geräte GmbH

Opponent:

Advanced Bionics AG

Headword:

MRI-Safe Implantable Disk Magnet/MED-EL

Relevant legal provisions:

EPC Art. 100(a), 100(b), 100(c), 84, 123(2), 76(1), 52(1), 56 EPC R. 80 RPBA 2020 Art. 13(2), 13(1), 12(4)

Keyword:

Amendment after summons - exceptional circumstances (yes)
Amendments - allowable (yes)
Claims - clarity (yes)
Inventive step - (yes)

Decisions cited:

T 0172/17, T 1535/17, T 2920/18, T 0339/19, T 2295/19



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Case Number: T 0732/21 - 3.4.01

DECISION
of Technical Board of Appeal 3.4.01
of 28 September 2022

Appellant: Advanced Bionics AG
(Opponent) Laubisruetistrasse 28
8712 Staefa (CH)

Representative: Schwan Schorer & Partner mbB

Patentanwälte Bauerstraße 22 80796 München (DE)

Respondent: MED-EL Elektromedizinische Geräte GmbH

(Patent Proprietor) Fürstenweg 77a 6020 Innsbruck (AT)

Representative: Lucke, Andreas

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Decision under appeal: Interlocutory decision of the Opposition

Division of the European Patent Office posted on

11 May 2021 concerning maintenance of the European Patent No. 3138605 in amended form.

Composition of the Board:

Chair D. Rogers

Members: A. Medeiros Gaspar

P. Fontenay

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Summary of Facts and Submissions

- I. The opponent appealed the Opposition Division's interlocutory decision, that European patent EP 3 138 605 as amended according to the proprietor's main request met the requirements of the EPC. The corresponding European patent application had been filed as a divisional application.
- II. The opponent requests that the contested decision be set aside and the patent revoked.
- III. According to the statement of grounds of appeal:
 - (a) the set of claims maintained included amendments extending the subject-matter defined beyond the content of the original application, as well as beyond the content of the parent application;
 - (b) the invention as defined in the amended patent was not disclosed in a manner sufficiently clear and complete for it to be carried out by the skilled person; and
 - (c) the invention lacked an inventive step in view of different combinations of the teachings of

D1: WO-A-WO03/081976,

D2: US-B-7 266 208 and

D9: US-A-2009/005836

all submitted with the notice of opposition. Other documents, on which the opponent relied in their submissions before the Opposition Division, were not relied upon on appeal.

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- IV. In response, the proprietor requested that the appeal be dismissed, i.e. that the patent be maintained in the amended form found allowable by the Opposition Division (main request), or on the basis of one of eleven auxiliary requests numbered 1, 2, 2a, 2b, 3, 4, 4a, 5, 5a, 6 and 7, in that order. Auxiliary requests 2a, 2b, 4a and 5a were filed for the first time on appeal; the other requests were filed before the Opposition Division.
- V. In a further submission the opponent objected to the consideration of the auxiliary requests 2a, 2b, 4a and 5a and argued that the remaining auxiliary requests suffered from at least some of the issues identified with regard to the main request.
- VI. After notification of the summons, the opponent submitted further substantive arguments in support of their case, as did subsequently the proprietor (on 3 August 2022) along with nine revised auxiliary requests, numbered 1 to 9 and accompanied by detailed explanations as to why, in their opinion, they should be admitted into the proceedings. In a yet further submission the opponent objected to the consideration of also these revised auxiliary requests.
- VII. At the beginning of the oral proceedings before the Board, the proprietor clarified their requests to be that the appeal be dismissed (main request), or that the decision be set aside and the patent be maintained on the basis of one of the revised auxiliary requests 1

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to 9 submitted after notification of the summons to oral proceedings. However, during the course of the oral proceedings, the proprietor withdrew all their requests with the exception of auxiliary request 3.

VIII. At the end of oral proceedings before the Board,

- the opponent confirmed their final requests to be that auxiliary request 3 not be admitted into the proceedings and that the decision be set aside and the patent revoked;
- the proprietor confirmed their final requests to be that the decision be set aside and the patent maintained upon the basis of auxiliary request 3 submitted on 3 August 2022.

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

a planar implant coil housing 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 within the plane of the implant coil housing,

a planar external transmitter coil housing for placement on the skin of the patient over said implant coil housing, said external transmitter - 4 - T 0732/21

coil housing comprising a second attachment magnet within the plane of the external transmitter coil housing;

characterized in that said first attachment magnet is rotatable in said plane of the implant coil housing, and the first and second attachment magnets have a magnetic dipole parallel to the respective plane of the implant coil housing or external transmitter coil housing for transcutaneous magnetic interaction with each other 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 and said magnetic dipole of said second attachment magnet is parallel to said plane of said external transmitter coil housing,

wherein said first attachment magnet has a planar disc shape or a cut away disc shape.

Reasons for the Decision

Auxiliary request 3 - Admission

1. The auxiliary request 3 was submitted after notification of the summons for oral proceedings before the Board. Its admission is at the discretion of the Board pursuant to Article 13(2) RPBA 2020.

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- 2. Article 13(2) RPBA 2020 requires, for admission, that exceptional circumstances be present and that these be justified by cogent reasons by the party concerned.
- 3. The Board notes first and foremost that, upon submitting this request, the proprietor complied with their obligations of identification and justification of their amendments in view of the particular circumstances of the appeal case.
- 4. The opponent argued that the auxiliary request 3 should not be admitted into the appeal proceedings because no exceptional circumstances prompted such a late amendment to the proprietor's case and because the requirement of prima facie allowability was not met.
- 5. The Board notes that the wording of Article 13(2) RPBA 2020 does not require that the amendment be triggered by exceptional circumstances, but rather that the circumstances themselves, maybe as a result of the submission, be considered exceptional (cf. T 2920/18, item 3.13, T 2295/19, item 3.4.12).
- 6. As correctly argued by the proprietor by reference to T°172/17 item 5.4 and T°1535/17 item 1.6, the explanatory remarks on Article 13(2) RPBA 2020 presented in document CA 3/19 (EPO OJ Suppl. 1/2020) state that, when exercising its discretion under Article 13(2) RPBA, the Board may also rely on criteria set out on Article 13(1) RPBA 2020, which itself refers to Article 12(4) to (6) RPBA 2020.
- 7. In the present case, the Board notes that the amendments introduced with the present request are straightforward and *prima facie* overcome all of the opponent's objections that the Board endorsed in its

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preliminary opinion, as well as a few other on which the Board expressed some doubts or which the Board did not even endorse. In fact, the amendments introduce several of the limitations that were argued by the opponent to be missing in the context the objections under Article 100(b) EPC. The limitations to the shape of the implantable magnet additionally overcome the objections under Article 100(c) EPC, as well as some of those under Article 100 (a) EPC.

- 8. It is also noted that the limitations to the shape of the implantable magnet were among those defined in claim 3 of the granted patent, against which objections under Article 100(a) EPC were raised already in the notice of opposition. Those objections were also elaborated upon during these appeal proceedings, after the reply to the statement of grounds of appeal, and considered by the Board in its preliminary opinion, even if seen as non-persuasive.
- 9. Hence, consideration of this request is neither detrimental to procedural economy, nor does it place an undue additional burden on either the Opponent or the Board.
- 10. The opponent argued that this request raises new issues under Articles 84, as well as 76(1) and 123(2) EPC, and should, for that reason, not be considered. Concretely, claim 1 did not define the transmitter coil housing as containing a transmitter coil. Additionally, the definition of the first and second attachment magnets as having a magnetic dipole parallel to the respective plane of the implant coil housing or external transmitter coil housing did not render clear which plane of which housing which magnet would the dipole of each magnet need to be parallel to.

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- 11. However, these objections, did not concern new issues, in the sense that they were or could at least have already been raised before with regards to previous requests. They were furthermore promptly refuted in substance by the proprietor and regarded by the Board as prima facie not convincing.
- 12. The opponent also argued that the arbitrary deletion of the dependent claims was evidently not reactive to a ground of opposition and that this would contravene the requirements of Rule 80 EPC.
- 13. However, as noted by the proprietor, the deletion of the dependent claims can be seen as preventing new objections under Article 123(2) EPC from being raised. The amendments are therefore occasioned by a ground of opposition. Whether or not the opponent raised the ground themselves is irrelevant, as established in the jurisprudence. Rule 80 EPC is, hence, complied with.
- 14. At last, the board notes that the purpose of the rules of procedure before the Boards is not, in itself, the refusal to consider late requests, but rather the defence of the parties rights to a fair hearing within a reasonable time, and that, in view of the above, in the present case, consideration of this particular request does not impair these basic rights of either party (cf. T 339/19, items 1.3.4 and 1.5; T 2920/18 item 3.14; T 2295/19, item 3.4.13).
- 15. All these aspects having been considered, the circumstances described above are regarded as exceptional and as weighing in favour of the admission of auxiliary request 3 (Article 13(2) RPBA 2020).

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16. Therefore, auxiliary request 3, as well as the objections raised against it, are admitted into these appeal proceedings.

Auxiliary request 3 - The Invention as described in the patent

- 17. The invention relates to implant systems (for example, cochlear implantable hearing devices), having implantable and external parts capable of communicating with one another and comprising respective attachment magnets to enable the external part to be held in place over the implantable part. It is concerned with improving compatibility of such devices with MRI imaging (patent, paragraphs [0001] to [0004]).
- According to the invention magnets with magnetization parallel to the plane defined by the planar internal and external coil housings of the device are employed (patent, figure 4), in contrast to the conventional magnets with magnetization perpendicular to the planar coil housings (patent, Figure 1). The magnet of the implantable part can furthermore rotate in the plane, i.e. around its axis (patent, paragraphs [0014] and [0015]).
- 19. This means that, where a person wearing the implant undergoes an MRI, the magnetic dipole of the implanted magnet rotates to approach alignment with the static field of the MR scanner, which renders the implant magnet less susceptible to demagnetization and the implantable part less susceptible to torque forces and displacement (patent, figures 5, 6 and 7 paragraphs [0016], [0017]).

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20. A slim profile avoids the need to drill a recess in the bone during implantation (patent, paragraph [0028]).

Auxiliary request 3 - Articles 76(1), 123(2) and 84 EPC

- 21. Paragraphs [0001] to [0045] of the description as filed are identical to paragraphs [0001] to [0045] of the parent application, whereas the published application numbers the paragraphs differently. The figures are also identical, as are the claims, with the exception that the features defined in claims 15 to 17 of the parent application are defined as alternatives in original claim 15 of the present application. For simplicity, the Board uses the common paragraph numbering of the original and parent applications.
- 22. Claim 1 of the Auxiliary Request 3 is based on the combination of the features originally defined in claims 1, 3, 6, 9 and 13. Original claim 1 defined an implantable system comprising a planar coil housing containing a signal coil for transcutaneous communication of an implant communication signal and a first attachment magnet rotatable within its plane and having a magnetic dipole parallel to the plane of the housing for transcutaneous magnetic interaction with a corresponding second attachment magnet. Original claims 9 and 13 defined the planar coil housing defined in original claim 1 as being either an implant coil housing for implantation under the skin of the patient and comprising a receiver coil or an external coil housing for placement on the skin of the patient and comprising a transmitter coil. Claims 3 and 6 defined at least one of the attachment magnets as being either disc-shaped or cut away disc shaped.

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- 23. Support for the combination of the different dependent claims is found in paragraphs [0027] [0029] and figures 3(B) and 4 of the original and parent applications.
- 24. The opponent argued that some of the limitations pertaining to the external coil housing, originally defined in either claim 1 or claim 13, were omitted, thereby extending the subject-matter defined beyond the content of the original and parent applications.

 Concretely, claim 1 of the present request no longer defines:
 - (a) a transmitter coil contained in the planar external transmitter coil housing; or
 - (b) that the second attachment magnet is rotatable in the plane of said external housing.
- 25. Concerning feature (a), the Board considers, irrespectively of the fact that paragraph [0029] of the original and parent applications omits the explicit definition the opponent refers to, that the definition of the external housing as a transmitter coil housing already implies that a transmitter coil is contained in said housing. Consequently, an extension beyond the content of the original disclosure cannot be recognised.
- As for feature (b), original paragraphs [0033] and [0034] support the omission of the definition of the external attachment magnet as rotatable within the plane of the external planar housing. In fact, paragraph [0033] explicitly discloses that "in some embodiments, the attachment magnet may be fixed within the external housing", whereas paragraph [0034] discloses that "alternatively, the attachment magnet may be encapsulated within the external component so

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that it can rotate on its axis like the attachment magnet in the implant".

- 27. Therefore the rotatability of the external magnet is disclosed as optional and not as an essential feature of the invention.
- At the oral proceedings the opponent argued that paragraphs [0033] and [0034] of the original application only disclose two alternatives, namely, that the external magnet is fixed or that it rotates on its axis like the attachment magnet of the implant, whereas claim 1, by not including a reference to either one or the other alternative encompasses more alternatives, which are not disclosed in the original application.
- 29. However, the skilled person would understand from the disclosure of the application that the rotatability of the second attachment magnet in the plane of said external housing not being an essential feature, he could implement the external magnet fixed or not in whatever way he would find appropriate as long as the other features defined as essential to the invention would be preserved.
- 30. Therefore the removal of feature (b), defining the rotatability of the external magnet, is not seen to contravene Article 123(2) EPC or Article 76 EPC.
- 31. In the grounds of appeal, the opponent also argued, with regards to another request, that there is no basis in the original application for implantable magnets that are not disc-shaped, since the implantable magnets disclosed in paragraphs [0027] to [0029] and, in fact, all implantable magnets disclosed are disc-shaped.

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- 32. Irrespective of whether or not the opponent meant to object also to a cut away disc shaped magnet, original claim 6 provides basis for employing such an attachment magnet, either on the implantable housing or on the external housing. Additionally, original paragraph [0029] renders it clear that, while the orientation of the magnetization direction parallel to the plane of the coil housing and the ability of the implantable magnet to rotate in that plane are essential, the disc shape is merely optional. Hence, also this objection is not persuasive.
- 33. The opponent also argued that the definition of the first and second attachment magnets as having a magnetic dipole parallel to the respective plane of the implant coil housing or external transmitter coil housing is unclear because the skilled person would not understand to which plane of which housing the dipole of each magnet would need to be parallel to. This would create an issue under Article 84 EPC, as well as under Articles 76(1) and 123(2), since the original and parent applications only disclosed embodiments in which the dipole of the magnet of the implant is parallel to the plane of the implantable housing and the dipole of the external housing is parallel to the plane of the external housing.
- 34. However, the skilled person would understand from the previous definition in the claim that the first magnet is contained in the planar implant coil housing and the second magnet is contained in the planar external transmitter coil housing, which one is the respective housing for each of them, said housing being indeed either the implant coil housing <u>or</u> the external coil housing. Therefore, having regard to the wording of the

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entire claim, there is no room for misinterpreting the particular passage of the claim argued by the opponent to be vague. Consequently, the subject-matter claimed also does not extend beyond the content of the original and parent applications.

35. Therefore this request complies with the requirements of Article 84 EPC, as well as Articles 76(1) and 123(2) EPC.

Auxiliary request 3 - Inventive Step

- 36. With the statement of grounds of appeal, the opponent argued that the subject-matter of claim 1 of the patent as maintained by the Opposition Division lacked inventive step in view of different combinations of the disclosure of documents D1, D2 and D9, all disclosing cochlear implant systems comprising, as in the patent, implantable and external parts with magnets so as to enable the external part to be held over the implantable part.
- D1 is, as the patent, concerned with the MRI compatibility of these systems. In its background art section, it describes prior art disc implants as being susceptible to torque forces and displacement when subject to the static magnetic fields generated during MRI imaging in the same way as the present patent (D1, figures 1 and 2, page 1 lines 9 to 24). It suggests, as a solution to this problem, that the implanted magnet be allowed to turn, possibly with some restrictions, into the external magnetic field lines (D1, page 7, lines 20 to 29, figure 3) and proposes concrete solutions employing, for instance, one or more magnets of a spherical shape (D1, figures 4 and 12).

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- D2 and D9 are not concerned with the MRI compatibility of these systems, but disclose, as does the patent, the implantable magnet as having a flat profile (D2, Figure 2; D9, Figure 10). D2 discloses the magnets employed as having their magnetic dipoles either oriented parallel or perpendicular to their surfaces (D2, Figures 4 and 6). D9 discloses the implantable magnet as being disc shaped (D9, figure 4).
- 39. The subject-matter of claim 1 of the present request differs from the disclosure of each of these documents, at least in that:
 - (a) the implantable magnet is disc shaped or cut-away
 disc shaped (D1, D2);
 - (b) the magnets of the implantable and external parts have a magnetic dipole parallel to the plane defined by the respective planar housings (D1, D9); and
 - (c) the implantable magnet is rotatable within the plane of its housing, i.e. around its axis (D1, D2, D9).
- 40. Irrespective of the starting point, the opponent argues that these differences are not linked and can, hence, be assessed in isolation. According to the opponent, while difference (a) merely implements a slim implant rendering the implantation of the implantable part of the system less invasive and difference (b) merely implements the magnetic coupling between the implantable and external parts, difference (c) is the difference that contributes to the compatibility of the system with MRI.
- 41. The Board considers these features to be linked. For an implanted magnet of a disc or cut-away disc shape, such

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as those defined in present claim 1, it is the combination of a magnetic dipole oriented parallel to its surface with the rotatability around its axis that contributes to an improved compatibility of the implant with MRI, as disclosed in the patent (figures 5 and 6 and paragraph [0017]). In fact, the rotatability of such a magnet around its axis alone would not impact on MRI compatibility of a magnet with a magnetic dipole oriented perpendicular to the planar surface of the disc, instead of parallel to it. Therefore the Board sees features (b) and (c), when combined with feature (a), as is the case for claim 1 of the present request, as linked and contributing in combination to the compatibility of the system defined with MRI.

- 42. The opponent argued that claim 1 of the present request lacks an inventive step over document D1, whether starting from the general teaching on page 7 lines 21-29, or from the disclosure of the embodiment comprising a single spherical implantable magnet (D1, Figure 12).
- 43. Concretely, with regards to the former, the opponent argues that D1 teaches a general solution to the problem of increasing MRI compatibility in that the implanted housing "allows the implanted magnet of whatever shape to turn, possibly with some restrictions, into the external magnetic field lines" (D1, page 7, lines 27 to 29, figure 3).
- 44. According to the opponent, making use of this general teaching and employing common general knowledge, the skilled person would implement an implantable device according to claim 1 of the present request, without requiring inventive skills for that.

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- 45. The Board disagrees. The only information this teaching provides is that the shape of the magnet is not important, as long as the implanted magnet can turn so as to align its dipole with the external magnetic field.
- 46. The skilled person willing to implement a magnet according to this teaching would seek in D1 itself for further information on how this could possibly be done and would find in D1 concrete solutions in the form of the different embodiments disclosed therein, none of which corresponding to the embodiments covered by claim 1 of the present request.
- The skilled person would also understand that making the disc shaped magnet described in the prior art section of D1 rotatable in the plane of the housing, i.e. around its axis, would not solve the MRI incompatibility problems described with regards to these magnets, given the orientation of its magnetic dipole and would, hence, understand D1 to teach him away from employing disc shaped magnets.
- 48. In the absence of any hint pointing towards it in D1, the skilled person would not consider changing the direction of the magnetic dipole from perpendicular to parallel to the surface of the disc, instead of changing the shape of the magnet, as taught in D1.
- 49. Therefore, the skilled person willing to implement an implantable system according to the teaching of page 7 lines 22-29 of D1, would not arrive in an obvious manner at an implantable system according to claim 1 of the patent.

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- The opponent also argued that claim 1 of the present request lacks an inventive step when starting from the embodiment of D1 disclosing an implantable system comprising a single spherical implant magnet (D1, Figures 12a,b).
- 51. According to the opponent, the skilled person starting from this disclosure could consider flattening the spherical magnet into a disc magnet for the purpose of rendering the implant less invasive. In doing so, he would carry out the necessary adaptations to retain, at least in part, the magnets compatibility with MRI and so he would arrive at the present invention in an obvious manner.
- 52. The Board does not agree. Even if the skilled person would consider a disc magnet, for the purpose of rendering the implantable magnet less invasive, this solution would be disregarded for implying a return to the starting point of D1 in terms of MRI compatibility, thereby conflicting with its fundamental teaching.
- Instead, the skilled person would take the solution to that problem taught in D1 itself, and would simply replace the single sphere of the embodiment of figures 12a,b by the three freely rotating spheres of smaller diameter of the embodiment of figures 4a,b of D1, with the result that the implantable part would be less invasive than in the embodiment of figures 12a,b, while keeping the ability to fully align with an external magnetic field of any orientation.
- 54. Therefore claim 1 of the present request entails an inventive step in view of the disclosure of D1.

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- In its preliminary opinion the Board took the view that the disclosures of D1 and D2 would not be combined, because each document teaches away from the fundamental teaching of the other. D1 teaches, for the purpose of increasing the MRI compatibility, the use of spherical magnets capable of freely rotating in all directions, whereas D2 teaches, for the purpose of reproducible placement of the external part of the device with regards to the anatomy of the patient, the use of a fixed implantable magnet with regards to which the external component can be oriented.
- Starting from the disclosure of D2, the skilled person, seeking to improve its MRI compatibility would consider the disclosure of D1, which deals with such a problem; but would disregard the solution it provides, since it would lead to a loss of information on the orientation of the external device with regards to the patient's anatomy, which is the main purpose of the disclosure of D2. For the same reason, it would also appear that the skilled person would either not consider, or disregard, the idea of making the magnet of D2 rotatable.
- 57. The opponent did not challenge this and instead only further objected to inventive step of claim 1 of the present request starting from D9.
- 58. After due reconsideration, the Board is still of the same opinion, which applies also to the present request. Therefore the subject-matter of claim 1 of the present request also entails an inventive step in view of D2, or of a combination of D2 with D1.
- 59. Starting from the disclosure of D9 (figure 4, paragraphs [0042] to [0045]), the opponent argued that claim 1 of the present request lacks an inventive step

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when further considering the general disclosure of D1, page 7 lines 22-29, and the common general knowledge of the skilled person.

- According to the opponent, the skilled person willing to improve the MRI compatibility of the implanted part of D9, would consult D1, directed at solving this problem, and would find in it the general teaching to allow an "implanted magnet of whatever shape to turn, possibly with some restrictions, into the external magnetic field lines" (page 7 lines 22 to 29) and would hence, implement the rotatability of the disc magnet of D9 as defined in the claim without the exercise of inventive skill.
- 61. The Board agrees with the opponent in that the skilled person seeking to render the implant of the system of D9 MRI compatible would find in D1 a solution to that problem that he would implement. The Board does not agree however with the opponent in that, in doing so, the skilled person would arrive at an implantable system as defined in claim 1.
- As already explained, the starting point of the disclosure of D1 is an implantable system comprising a disc shaped magnet, as in D9, which D1 presents as disadvantageous in terms of MRI compatibility and from which it teaches the skilled person to deviate so as to render the implants MRI compatible.
- 63. Hence, starting from D9, the skilled person, seeking to obtain an implant that is more MRI compatible, would follow the teaching of D1 and would replace the disc shaped magnet of D9 by one of the rotatable magnets disclosed in D1. In the absence of any hint in D1, the skilled person would not consider instead changing the

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- direction of the magnetic dipole from perpendicular to parallel to the surface of the disc.
- 64. Therefore the subject-matter of the present claim 1 involves an inventive step having regards to the state of the art, as reflected in documents D1, D2 and D9.

Final Conclusion

65. For the reasons presented above none of the objections brought forward by the opponent prejudice the maintenance of the patent on the basis of auxiliary request 3, which is found to meet the requirements of the EPC.

Order

For these reasons it is decided that:

- 1. The decision under appeal is set aside.
- 2. The case is remitted to the opposition division with the order to maintain the patent on the basis of auxiliary request 3 filed on 3 August 2022 and a description and drawings to be adapted thereto.

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The Registrar:

The Chair:



D. Meyfarth D. Rogers

Decision electronically authenticated