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Datasheet for the decision of 8 September 2023

Case Number: T 2742/18 - 3.4.01

Application Number: 08782410.8

Publication Number: 2185236

IPC: A61N1/36, A61N1/05, A61N1/375

Language of the proceedings: EN

Title of invention:
IMPLANTABLE DEVICE FOR THE BRAIN

Patent Proprietor:
Cortigent, Inc.

Opponent:
Pixium Vision SA

Headword:
Brain stimulator / Cortigent

Relevant legal provisions:
EPC Art. 100(c), 100(b), 53(c), 52(1), 54, 56, 83, 123(2)
RPBA 2020 Art. 12(4)

Keyword:
Exceptions to patentability - method for treatment by surgery (no)
Sufficiency of disclosure - all requests (yes)
Amendments - main request, first auxiliary request - allowable (no) - seventh auxiliary request - allowable (yes)
Novelty - second auxiliary request (no)
Inventive step - third auxiliary request (no) - seventh auxiliary request (yes)
Amendment to case - seventh auxiliary request - amendment admitted (yes)

Decisions cited:
T 0960/15

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Case Number: T 2742/18 - 3.4.01

D E C I S I O N
of Technical Board of Appeal 3.4.01
of 8 September 2023

Appellant: (Opponent)	Pixium Vision SA 74 rue du Faubourg Saint Antoine 75012 Paris (FR)
Representative:	Graf von Stosch, Andreas Graf von Stosch Patentanwaltsgesellschaft mbH Prinzregentenstraße 22 80538 München (DE)
Respondent: (Patent Proprietor)	Cortigent, Inc. 13170 Telfair Avenue Sylmar, CA 91342 (US)
Representative:	Mewburn Ellis LLP Aurora Building Counterslip Bristol BS1 6BX (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 2 October 2018 rejecting the opposition filed against European patent No. 2185236 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chair	P. Scriven
Members:	T. Petelski
	C. Almberg

Summary of Facts and Submissions

I. An opposition was filed to the patent in its entirety. It relied on the grounds of Articles 100(a), 100(b), and 100(c) EPC.

II. The Opposition Division's decision to reject the opposition was based on the following documents:

E1: *Penn Researchers Calculate How Much the Eye Tells the Brain,* Penn Medicine News, 26 July 2006, pages 1-2
E2: US 2003/0233133 A1
E4: US 2007/0005112 A1
E5: WO 2006/118679 A2
E6: US 5 215 088 A
E7: US 2006/0247754 A1
E18: US 7 212 851 B2
E21: *Design for a phosphene visual prosthesis,* Marg et al., Brain Research, volume 19 issue 3, 4 May 1970, pages 502-510
E22: *Implantable microscale neural interfaces,* Cheung, Biomed Microdevices, volume 9, 25 January 2007, pages 923-938
E23: *Demonstration of artificial visual percepts generated through thalamic microstimulation,* Pezaris and Reid, Proceedings of the National Academy of Sciences, volume 104 no. 18, 23 April 2007, pages 7670-7675
E24: *Electrical stimulation of the brain and the development of cortical visual*

prostheses: An historical perspective,
Lewis and Rosenfeld, Brain Research 1630,
available online since 5 September 2015,
pages 208-224

The references to E21 to E24 are those used in the impugned decision and in the written submissions with which they were submitted; they are not those printed on the submitted copies of the documents.

III. The opponent appealed the decision.

IV. With their reply, the proprietor submitted eight sets of claims, constituting a main request and seven auxiliary requests. The main request and the fifth and sixth auxiliary requests had already been submitted before the Opposition Division, the latter two as fourth and fifth auxiliary requests, respectively.

V. The proprietor argued that the Opposition Division should not have admitted E21 - E24.

VI. In written proceedings, the opponent requested that the appealed decision be set aside and that the patent be revoked.

VII. The opponent argued, seemingly, that all the auxiliary requests should be disregarded.

VIII. During oral proceedings, held in absence of the opponent (as previously announced), the proprietor withdrew their fourth to sixth auxiliary requests, so that their final requests were that the appeal be dismissed, i.e., that the patent be maintained as granted, or based on one of the first to third and seventh auxiliary requests.

IX. Claim 1 of the proprietor's main request and first auxiliary request are identical and read (reference signs removed):

A neural stimulator adapted to electrically stimulate the brain, said stimulator comprising:

a hermetic package enclosing electronics;

an electrode array electrically coupled to said electronics suitable for brain stimulation; and a thin film lead attached to and proceeding from said package, wherein said thin film lead has a first end and

a second end, said first end containing exposed electrode sites constituting said electrode array, said second end containing bond pads for electrical connection to the package; whereby said electrode array is a thin film electrode array with greater than 30 electrodes, and wherein said hermetic package and said thin film electrode array are suitable to be implanted within a head.

X. Claim 1 of the second auxiliary request differs from that of the main and first auxiliary requests in that the "thin film lead" has become a "flexible circuit thin film lead".

XI. Claim 1 of the third auxiliary request reads as follows (reference signs removed, additions with respect to claim 1 of the main request underlined):

A neural stimulator adapted to electrically stimulate the brain, said stimulator comprising:

a hermetic package enclosing electronics an inductive coil coupled to the electronics;

an electrode array electrically coupled to said electronics suitable for brain stimulation; and a flexible circuit thin film lead attached to and proceeding from said package, wherein said flexible circuit thin film lead has a first end and

a second end, said first end containing exposed electrode sites constituting said electrode array, said second end containing bond pads for electrical connection to the package via flip-chip bumping with an epoxy underfilling;

whereby said electrode array is a thin film electrode array with greater than 30 electrodes,

wherein the flexible circuit thin film lead includes platinum conductors insulated from each other and the external environment by a biocompatible dielectric polymer;

wherein a junction of the thin film lead, inductive coil, and electronic package is encapsulated by a silicone overmold to connect them together mechanically and

wherein said hermetic package and said thin film electrode array are suitable to be implanted within a head.

XII. Claim 1 of the seventh auxiliary request adds, to the end of claim 1 of the third auxiliary request, a last feature:

[*... implanted within a head*]*; and*

wherein the hermetic package includes a ceramic substrate brazed to a biocompatible metal case wall which is enclosed by a laser welded biocompatible metal lid; the metal lid being electrically coupled to the electronics to provide an electrical return to the brain.

XIII. The dependent claims 2 - 11 of the seventh auxiliary request are, apart from numbering, identical to claims 2 - 5, 6 - 8, and 12 - 14 of the patent, in that order.

Reasons for the Decision

Introduction and analysis of claim 1

1. The invention is about a neural stimulator for stimulating the brain. A hermetic package, foreseen for implantation in the head, encloses control electronics that are coupled to the stimulator's electrode array by a thin film lead. The electrode array comprises "exposed" electrodes, which, in contrast to "penetrating" electrodes, do not protrude.

2. The sole independent claim defines the neural stimulator as "adapted to electrically stimulate the brain". This formulation was added to the claim during examination proceedings. In order to review whether this amendment adds new information to the application as filed, its meaning and its implications for the neural stimulator have to be established.

3. Since much of the prior art on file is about neural stimulators for the retina, the implications of an adaptation to stimulate the brain will also have consequences for novelty and inventive step.

4. According to the proprietor, the skilled person would have understood that an adaptation to brain stimulation implied four restrictions.

   (a) The stimulator, and in particular the package, had to be adapted for attachment within the head.

   (b) The materials, dimensions and size of the stimulator had to be such that it could be implanted within the head.

(c) The electrodes had to have a suitable shape and size to interface with brain tissue. A more detailed definition of the electrodes in the claim would not be justified, because a broad protection was necessary in view of the possible shapes and sizes required for distinct parts of the brain. Paragraph [0087] of the patent gave multiple examples of areas of the brain in which the stimulator could be used.

(d) The electronics, including the electrodes, had to be suitable for providing the required charge densities. Paragraph [0063] of the patent disclosed a lower limit of 0.1 mC/cm^2. The brain required higher charge densities than those used to stimulate the more sensitive retina. A more specific definition of the charge densities in the claim would make no sense, because every person was different and finding a suitable charge density was a process of trial and error.

5. The Board agrees with the proprietor that the skilled person would associate the suitability for stimulating the brain with restrictions to biocompatible materials, a small size compared to the head, a suitable shape for implantation and attachment within the head, and electrode shapes suitable for interfacing with some part of the brain (above points (a) to (c)). Also, the charge densities provided must be such that brain neurons can be stimulated (parts of point (d)).

6. However, the proprietor was not able convincingly to show that the charge densities suitable for stimulating neurons in the brain are different from those used to stimulate neurons in other parts of the body, for

example the retina. Hence, that assertion is not accepted.

Main request - added subject-matter

7. Claim 1 differs from claim 1 as filed in that:

(a) The neural stimulator is defined as

... adapted to electrically stimulate the brain ....

(b) The neural stimulator comprises

... a thin film lead attached to and proceeding from said package, wherein said thin film lead has a first end and a second end, said first end containing exposed electrode sites constituting said electrode array, said second end containing bond pads for electrical connection to the package; whereby said electrode array is a thin film electrode array ....

(c) The neural stimulator is further defined in that

... said hermetic package and said thin film electrode array are suitable to be implanted within a head.

8. Re (a) and (c): the application, with the title "implantable device for the brain", discloses, on page 2, lines 22 - 24, that the invention (an "implantable device"), or components thereof, is or are

... intended to be installed in the head, or on or in the cranium or on the dura, or on or in the brain.

9. In addition, it discloses, on page 3, lines 5 - 8:

The present invention includes an improved hermetic package, connected to a thin film array, for implantation in the human body, and particularly in the human head for the purposes of stimulating the brain on the surface or at some depth.

10. Still further, several figures consistently show the implantation of a neural stimulator with the components defined by claim 1 (hermetic package and electrode array), for example Figures 2A and 2B (see page 3, lines 19 - 22).

11. Naturally, the implanted device for stimulating the brain is "suitable to be implanted" within the head and "adapted to stimulate the brain", which is why the application as a whole provides a basis for the features (a) and (c).

12. Re (b): the closest disclosures to this feature, in the application as filed, are the passages relating to Figures 1, 7, 17, and 28:

(a) Page 9, lines 1 - 3:

Attached to and proceeding from the package 14 is a thin film lead 10 to be routed to the tissue to be stimulated or recorded from.

(b) Page 11, lines 26 - 31:

Referring to FIG. 7, the flexible circuit thin film lead 10, includes platinum conductors 94 insulated from each other and the external environment by a biocompatible dielectric polymer 96, preferably polyimide. One end of the array contains exposed electrode sites that are placed in close proximity to the surface to be stimulated or recorded from 333. The other end contains bond pads 92 that permit electrical connection to the electronics package.

(c) Page 22, lines 27 - 29:

The cable, bond pad region, and array is a single integrated unit that forms the flexible thin film lead 10 shown in FIG. 17 with bond pads 335 at the proximal end and electrodes 333 at the distal end.

(d) Page 35, lines 1 - 5:

Fig. 28 shows the flexible circuit electrode array prior to folding and attaching the array to the electronics package. At one end of the flexible circuit cable 10 is an interconnection pad 52 for connection to the electronics package. At the other end of the flexible circuit cable 10 is the flexible circuit electrode array 333.

13. These passages disclose that two ends of the thin film lead contain exposed electrode sites and bond pads. However, the passages on pages 11, 22, and 35 refer to

the lead with reference sign 10 only as "flexible thin film lead 10" or "flexible circuit cable 10", whereas claim 1 defines the "thin film lead" without the attribute "flexible".

14. The flexibility appears to be an important aspect of the lead for routing the stimulation signals to the tissue to be stimulated (page 9, lines 1 - 3), and to be one of the reasons for using thin-film technique. The reference to a "thin film lead" without the word "flexible", in the passage on page 9, does not change this understanding. Figures 1 - 7 are used to illustrate various aspects, and options thereof, of the same basic neural stimulator. The passage on page 9 is part of the general description of the basic components of the neural stimulator shown in Figure 1. The lead is then described in more detail in the passage on page 11, by reference to Figure 7. Hence, the "thin film lead" mentioned on page 9 is actually a "flexible thin film lead". The same holds for mentions of "thin film leads" without the word "flexible" on pages 23 and 24. These passages refer to the lead previously described as flexible, in the passage on page 22. There is no disclosure of a thin film lead that is not flexible, in the application as filed.

15. The Board does not agree to the proprietor's view that the thin film lead was flexible just by virtue of the fact that it was a thin film lead. "Thin" does not unambiguously imply "flexible", and "thin film lead" does not unambiguously imply that the whole lead is a thin film. A thin film lead may well consist of an inflexible substrate carrying (flexible or inflexible) thin film conductors. Such leads are within the scope of claim 1, but are not of the original disclosure.

16. Therefore, the generalisation from "flexible thin film lead" to "thin film lead" in feature (b) introduces subject-matter that extends beyond the application as filed.

17. The passages on pages 9, 11, 22, and 35, cited above, stand in the context of larger parts of the description directed to the respective Figures 1, 7, 17, and 28, that not only disclose the structure of the thin film lead but also describe additional features, which are not defined in claim 1, such as, for example, an induction coil, a molded body, or material information.

18. The opponents regarded the omissions of such features from the claim as unallowable intermediate generalisations of the thin film lead.

19. However, the situation here is different from the situation with flexibility. The skilled person understands that the additional elements of the implant serve different purposes and are neither inextricably linked to the thin-film lead, nor are in other ways essential for the claimed neural stimulator.

20. The (flexible) thin-film lead serves the purpose of routing the stimulation signal from the hermetic package to the brain tissue to be stimulated (page 9, lines 1 - 3). The features that are essential for this purpose are the bond pads at one end of the thin-film lead, the exposed electrode sites at the other end, the thin-film nature of the lead, its flexibility, and its suitability for implantation. With the exception of the flexibility (see above), claim 1 defines all these features.

21. None of the other features mentioned in the passages in question is essential for signal routing. For example, the inductive coil has the purpose of communicating with an external apparatus (page 26, lines 19 - 20), and the molding has the purpose of reducing irritation and holding the parts together (page 9, lines 10 - 12 and 22 - 24). Also, the particular choice of (biocompatible) materials for the different components of the stimulator have no influence on the routing of the stimulation signals by the thin film lead.

22. Therefore, the Board is persuaded that the features defining the thin-film lead, which are included in claim 1, can be generalized from the other features of the embodiments.

23. The opponent also argued that the individual addressability of the electrodes should have been included in claim 1. The Board, however, considers that this feature is implicit. In the field of neural stimulators, individual addressability must be assumed unless the opposite is explicitly mentioned.

24. Consequently, the Main Request is not allowable because the subject-matter of claim 1 extends beyond the application as filed for the sole reason that it does not define the thin film lead as flexible (Article 100(c) EPC).

All requests - sufficiency

25. The opponent's sufficiency objection is strongly related to the issue of what exactly makes a neural stimulator "adapted to electrically stimulate the brain", as defined in claim 1 of each request. In the

opponent's view, two different understandings were possible:

(a) Adaptation to stimulate the brain required the selection of certain parameter values regarding the dimensions and geometry of the stimulator, and of the charge density provided by it. The patent, however, did not teach the skilled person any such parameters that would elevate a neural stimulator to a brain stimulator. Therefore, the patent lacked an enabling disclosure.

(b) The adaptation to stimulate the brain had no implications whatsoever. In that case the feature was meaningless. Although sufficiency might not be an issue, the Board should consider in its assessment of inventive step that every neural stimulator (in particular those disclosed by E2, E5, and E7) were adapted to stimulate the brain.

26. The Board's view of the skilled person's understanding of "adapted to electrically stimulate the brain" is set out above (paragraphs 5. and 6.). It implies certain restrictions as to the materials used (biocompatibility), the dimensions and geometry of the electrodes (they should be suitable for making contact with neurons in the brain) and the charge density (sufficient to stimulate brain neurons). The proprietor failed persuasively to show that the charge densities suitable for stimulating cortical neurons are different from the charge densities suitable for stimulating other, for example retinal, neurons. Hence, in the context of the present invention, every neural stimulator that possesses a size and shape that allows it to contact parts of the brain with electrodes is adapted to stimulate the brain, even if it was designed

for stimulation of other body parts. Whether this is the case for the retinal stimulators of E2, E5, or E7, is not a question of sufficiency but of patentability, and will be discussed below.

27. The skilled person is aware of the dimensions and the structure of the brain, as well as of electrical brain stimulators in general. Therefore, based on the disclosure of the patent, it is an easy task to realize a stimulator adapted to stimulate the brain within the broad meaning of this expression established by the Board.

28. Hence, the invention as defined by claims 1 of the main and the auxiliary requests is sufficiently disclosed (Articles 100(b) and 83 EPC, respectively).

All claim requests - exception from patentability

29. The opponent raised an objection to the patentability of the claims under Article 53(c) EPC.

30. The claims of all requests concern a neural stimulator, that is, a device, whereas the exclusion provisions of Article 53(c) EPC refer to methods for treatment of the human or animal body by surgery and therapy. Article 53(c) EPC thus constitutes no obstacle to the maintenance of a patent directed to such a device.

First auxiliary request - added subject-matter

31. Claim 1 is identical to claim 1 of the main request.

32. Hence, irrespective of its admission, the first auxiliary request is not allowable for added subject-matter for the same reasons as the main request (Article 123(2) EPC).

Second auxiliary request - novelty over E2

33. Claim 1 overcomes the added-matter objection to claim 1 of the main request by defining the lead as a "flexible circuit thin film lead".

34. According to the proprietor, the retinal stimulator disclosed by E2 was not adapted to stimulate the brain for the following reasons:

(a) The shape of the coil 28 shown in Figure 1 of E2 was matched to the eyeball and would not fit into an implantation site within the head.

(b) The electrodes pierced through the sclera of the eye, and were attached to the retina. This arrangement would not work in the brain, not least because the lead was shorter than necessary to contact the brain, and because the retina required a smaller electrode array with a different shape.

(c) The charge densities used with the delicate retina were lower than those used in the brain.

35. Re (a): the Board notes that claim 1 defines a neural stimulator comprising a hermetic package with electronics and a thin film lead attached to it, but not the entire implantable device together with the communication coil. E2 also comprises a combination of a hermetic package 20 with electronics and lead 18

attached to it, as shown in Figure 5. This combination is suitable for implantation within a head and for stimulating brain neurons. It is irrelevant that this combination might be connected to something else, like coil 28, that is not suitable for use with brain stimulation.

36. Re (b): considering the typical dimensions of an eyeball, Figure 1 of E2 allows the skilled reader to draw the conclusion that the length of the flexible circuit 18 (the lead) will be of the order of one centimetre. This is sufficient for the electrode array 10 to contact outer regions of the brain when the hermetic package 20 of E2 is attached to the dura, cranium, or scalp of a patient. In addition, the dimensions and shape of an electrode array designed for the retina (see Figure 4 of E2) will also be capable of stimulating certain regions of the brain. As evidence for this, E7 discloses a retinal stimulator similar to the one in E2. In E7, Figures 3A-E, 4, 6A-B, and 7 - 12 illustrate shapes of electrode arrays and leads adapted to stimulate the retina. These Figures are identical to Figures 15A-E, 26, and 28 - 35 (in this order), of the patent in suit, which illustrate arrays and leads adapted to stimulate the brain. Hence, the size (approximately and relative to a human eye) and shape of the neural stimulator of E2 do not make it unsuitable to stimulate the brain.

37. Re (c): the proprietor did not substantiate their assertion that the charge densities suitable for stimulating retinal neurons were different from those suitable to stimulate cortical or other brain neurons. In view of the bioelectric similarity of neuronal cells, and in the absence of a concrete indication to the contrary, the Board must assume that the charge

densities suitable for stimulating retinal neurons are also suitable for stimulating at least some neurons of the brain, in particular, when considering the proprietor's statement that the required charge density for brain stimulation varies from person to person (and depending on the brain region). Therefore, without further specification, the feature "adapted to electrically stimulate the brain" in claim 1 cannot distinguish the subject-matter of claim 1 from E2 by implication of specific charge densities.

38. Further, according to the proprietor, E2 also failed to disclose a thin film electrode array with greater than 30 electrodes.

39. In paragraphs [0003] to [0012], E2 describes the background of the invention. Paragraph [0005] mentions the shortcomings of using discrete wires to fabricate an electrode array. Paragraph [0006] goes on to present a solution to these shortcomings using a "lithographically fabricated thin film flex circuit ... accommodating about 60 electrodes". The flex circuit "is essentially a passive conductor ribbon". The subsequent paragraphs describe the difficulties of attaching the bond pads of this thin film circuit to the hermetically sealed electronics package in a way that makes the combination suitable for implantation in living tissue. The main goal of the invention, in E2, is to solve this problem by providing a retinal stimulator with a suitable attachment. It follows directly and unambiguously from the passages mentioned, and in particular from paragraph [0012], that the invention is meant to build on the prior art in that it provides a new way of bonding the same flexible circuits used in its prior art to the respective electronics packages. Hence, whenever E2 mentions the

"flexible circuit ribbon", as in paragraph [0034], the thin film flex circuit with about 60 electrodes as described in paragraph [0006] is encompassed.

40. Hence, E2 discloses a thin film electrode array with greater than 30 electrodes.

41. It already follows from the above that, irrespective of its admission, the second auxiliary request is not allowable, because the subject-matter of claim 1 lacks novelty over E2 (Articles 52(1) and 54(1), (2) EPC).

Consideration of documents E21 - E24

42. Documents E21 - E24 are relevant to auxiliary requests 3 and 7. The proprietor argued that these documents, which were filed late, should not have been admitted into proceedings. This is an argument that they should not be considered in the appeal.

43. The Opposition Division admitted E21 into the opposition proceedings because it found, prima facie, that it provided a more promising starting point for an inventive step attack than the other available items of prior art. E22, E23, and E24 were admitted because they provided ancillary information to E21 (appealed decision, point 18.2).

44. The Board holds that the Opposition Division applied (only) the right principles when deciding on the admission of documents E21 - E24, and applied these principles in a reasonable manner. The Board fails to see any reason as to why the appealed decision should be reversed in this respect (cf. T 960/15, Reasons 1 to 9).

45. Hence, E21 - E24 remain in the proceedings.

Third auxiliary request - inventive step in view of E2

46. Claim 1 differs from claim 1 of the second auxiliary request in that

(a) an inductive coil is coupled to the electronics;

(b) the electrical connection of the bond pads to the package is realized via flip-chip bumping with an epoxy underfilling;

(c) the flexible circuit thin film lead includes platinum conductors insulated from each other and from the external environment by a biocompatible dielectric polymer; and

(d) a junction of the thin film lead, inductive coil, and electronic package is encapsulated by a silicone overmold to connect them together mechanically.

47. The proprietor was of the opinion that the coil in E2 was incompatible with implantation within the head. Hence, feature (a) had the effect that E2 could no longer be considered as being adapted for stimulating the brain. Further, E2 disclosed none of the features (b) - (d). Instead of flip-chip bumping, E2 used the thick film pads 23 for attaching the bond pads to the package, and there was no overmold and no polymer insulation in E2.

48. The Board agrees with the proprietor in that E2 neither discloses a stimulator, which, together with the coil,

is adapted to stimulate the brain (feature (a)), nor an overmold (feature (d)). On the other hand, E2 does disclose flip-chip bumping and platinum wires with a polymer insulation (features (b) and (c)), as will be shown.

49. The thick film pads 23 in E2 are only used for a welded connection with cable 30 (and coil 28). The flexible circuit 18, in contrast, is bonded to the package using flip-chip bumping with epoxy underfilling, as explained in paragraphs [0040] to [0043], in relation with Figures 6a-c. These figures are identical to Figures 16A-C of the patent.

50. Further, paragraph [0062] of E2 discloses that the conductors (or "traces") 34, which are shown in Figure 4, can be made of platinum. Although paragraph [0062] relates to Figure 10, it is apparent that this information applies to all other embodiments, which are silent on the material of the conductors. There is no reason to think that the same conductors 34 in other embodiments should not be made of platinum, which is the preferred material for all conductors in E2 due to its conductivity, its good biocompatibility, and its patternable properties (see, for example, paragraphs [0035], [0042], [0060], and [0062]). The conductors 34 are embedded in an insulating substrate 38 (also 238), which comprises the polymer polyimide ([0037], [0042]). This material is also biocompatible ([0063]).

51. Hence, E2 comprises the above cited features (b) and (c).

52. It follows that the subject-matter of claim 1 differs from E2 in that:

(a) the neural stimulator comprising the inductive coil is suitable for an implantation that allows stimulation of the brain, and

(b) a junction of the thin film lead, inductive coil, and hermetic package is encapsulated by a silicon overmold to connect said parts mechanically.

53. Re (a): the adaptation for implantation, which allows stimulation of the brain, has the technical effect, with regard to E2, that the stimulator can be used to stimulate the brain. The Board sees the corresponding problem in finding another application for the stimulator.

54. Re (b): the provision of an overmold has the technical effect of providing mechanical strength to the junction of the three parts. The Board sees the corresponding problem in finding a way to hold the parts together.

55. Hence, the two features have different effects and solve different problems, which is why there is no synergy between them. Therefore, they need to be considered separately.

56. The skilled person, looking for further applications of the stimulator of E2 (problem (a)) knew that, apart from stimulating retinal neurons, the cortical neurons in the visual cortex could also be stimulated to restore sight. Contrary to the proprietor's view, a person skilled in retinal stimulation would also have known about, and considered, cortical stimulation. This is confirmed by the section on the background of the invention in E2, which cites arrays of cortical electrodes and arrays of retinal electrodes ([0003] and [0004]), and also by the abstract of E2, which

describes the invention as an electronics package that is

> *... suitable for implantation in living tissue, such as for a retinal or cortical electrode array to enable restoration of sight ....*

57. The closeness of retinal and cortical stimulation would also have been obvious from E23, page 7670, which covers the stimulation of retinal neurons and the stimulation of visual cortical neurons for sight restoration in one paper, and from E22, last passage of point 6 on page 936, which states:

> *An implantable visual prosthesis may in the future restore vision by providing stimulation at different locations along the visual pathway including the retina, optic nerve, and visual cortex.*

58. In view of this, the skilled person would readily have considered the idea of adapting the stimulator of E2 for brain stimulation. The stimulator was already adapted for implantation into the head (the eye). The only necessary and apparent adaptation, which would have followed naturally from the skilled person's initial consideration, concerned the coil. Instead of a coil fitted to the eyeball, the skilled person would have chosen one shaped to fit to the skull. By carrying out this simple adaptation, the skilled person would have adapted the retinal stimulator for stimulation of the brain.

59. The proprietor's argument that the coil in E2 was not biocompatible is not persuasive, as the coil is in direct contact with the eyeball within the head.

60. When looking for a way to provide mechanical strength to the stimulator assembly (problem (b)), the skilled person would first have had to understand the disclosure of E2 in this regard. With reference to Figures 3 and 5, E2 discloses that the flexible circuit 18 is bonded to output contacts 22, and that the cable 30 of coil 28 is welded to thick film pad 23. Such electrical connections provide little mechanical strength and no electrical insulation from body fluids, at least as far as the welded contact is concerned. In order to provide the necessary insulation and keep all components nicely together, the skilled person would have chosen to apply a silicon overmold to cover the junction of all three parts as one of several obvious options. The skilled person might additionally have been inspired to provide an overmold for insulation and mechanical strength by the cable-socket like elements visible in Figure 1 at the junction between the coil-cable 30, the flexible circuit 18, and the hermetic package 20.

61. Hence, it would have been obvious for the skilled person to arrive at the subject-matter of claim 1, starting from E2.

62. The proprietor presented the argument that there was a prejudice in the art against using exposed electrodes for brain stimulation by pointing to various prior art documents, most notably to a teaching in point 5.3 in E24. This teaching was evidence that there was a bias towards spiked electrodes for brain stimulation, at the time of filing of the patent. Thus, even assuming that

the skilled person starting from E2 might have considered adaptation to brain stimulation, the prejudice would have prevented her from pursuing it.

63. The cited passage in point 5.3 of E24 describes the problem that a "single large-array method of electrode implantation was no longer feasible", because the penetrating electrodes, which were advantageous for microstimulation, were

> *... embedded in a rigid material, which could not conform to the brain surface over a wide area. Thus, the wireless receiving circuitry and stimulating electronics could no longer be combined with the electrode arrays into a single package.*

64. This problem is not related to E2, because the flexible electrode array in E2 is separated from the electronics package and is positioned at the desired position on the retina, or, when adapted for brain stimulation, in the brain, through a flexible circuit.

65. Hence, even if it were assumed that spiked electrodes were more commonly used for brain stimulation at the time in question, the Board is not persuaded of any prejudice against exposed electrodes. The proprietor could not persuasively demonstrate why the skilled person would have rejected the idea of stimulating cortical neurons using the exposed electrodes of E2, which are suited for stimulating retinal neurons. Consequently, applicant's argument that there was a prejudice is not pertinent.

66. It follows that, irrespective of its admission, the third auxiliary request is not allowable, because the

subject-matter of claim 1 lacks an inventive step over E2 (Articles 52(1) and 56 EPC).

Seventh auxiliary request - admission

67. The seventh auxiliary request was first filed with the proprietor's reply to the opponent's appeal, in due time, in 2019. Its admission is subject to the Board's discretion (Article 12(4) RPBA 2007, applicable under Article 25(2) RPBA 2020).

68. The Board took auxiliary request 7 into account, in line with the presumption under the applicable legal basis; and because it, *prima facie*, appeared to be allowable; and also because, in the absence of the withdrawn fourth to sixth auxiliary requests, it was a convergent development of the preceding first, second and third auxiliary requests. The Board also considered the lack of complexity, in that this request is identical to the version filed during opposition, except for the deletion of dependent claim 9.

Seventh auxiliary request - added subject-matter

69. The opponent raised objections of added subject-matter that apply to all features that were not in claim 1 of the main request, and also to the features of dependent claims 2 to 5. The opponent did not contest that there were literal bases for these features in the application as filed, with the exception of the metal lid coupled to the electronics. Rather, the opponent firstly objected to an arbitrary extraction of features from their context, which resulted in unallowable intermediate generalisations; and secondly to the

mosaic-like combination of those features in the claims, which resulted in originally undisclosed subject-matter.

70. Firstly, concerning the objection of new combinations, the Board does not see any added matter. The reasons are as follows.

71. The description of the application as filed is structured in a particular way. First, with reference to Figure 1 and 2, a general set-up of the implant is described. Then, elements and aspects of this general set-up, and variations of it, are described with reference to the further figures. For example, Figures 2A and 2B show possible implant locations; Figures 3 to 6 the hermetic package; Figures 9 to 10B the ceramic substrate therein, etc.

72. From this, the skilled person understands that variants of one aspect are meant to be combined with variants of a different aspect, unless the combination is not technically feasible. The patent neither encourages the combination of only certain variants of the different aspects, nor does it advise against any.

73. In claim 1, the different aspects of the stimulator that are combined concern the choice of material for the conductors and their insulation (platinum insulated by a polymer), the process of attaching the thin-film lead to the hermetic package (flip-chip bumping with epoxy underfilling), the mechanical stabilization of the components (silicone overmold), the design of the hermetic package (ceramic substrate brazed to a metal case wall, enclosed by laser-welded metal lid), and the choice of the return electrode (the metal lid). There is nothing that speaks against a combination of these

particular variants of the different aspects of the stimulator. The same holds for the number of electrodes or the presence of a second hermetic package as defined by dependent claims 2 to 5.

74. Hence, the Board considers that the combinations of features in the claims that were introduced by the amendments are directly and unambiguously derivable from the application as filed.

75. Secondly, concerning the issue of intermediate generalisations, the Board, for the following reasons, finds the generalisations allowable.

76. The features objected to all relate to different aspects of one implant, namely communication (inductive coil), connection to electrodes (flexible lead), fabrication of the contacts (flip-chip bonding), materials of the lead (platinum conductors, polymer insulation), mechanical reinforcement (overmold), construction of the package (ceramic substrate, metal wall and lid), the necessary electrical return (via the metal lid), the number of electrodes (more than 50, 100, and 200 in claims 2 - 4), and the presence of a second hermetic package (for second electronics).

77. The skilled person understands that these features are meant to be combined, despite their mention in relation to different figures. The different purposes of the features in question is, if not explicit, immediately apparent to the skilled person. Knowing the purpose aids in establishing whether a feature can be separated from others. The opponent merely pointed to other features appearing in the same context, but did not demonstrate an interrelation of the features in question with these other features that would not allow

their separation. The Board does not see this problem with any of the features at issue.

78. Hence, the Board considers the extraction of the features in question unproblematic.

79. Lastly, the Board turns to the alleged lack of a basis for the coupling of the metal lid to the electronics.

80. Page 26 of the application as filed discloses the option of using the lid of the electronics package as a return electrode. It is implicit that the return electrode is coupled to the same electronics that supplies the electrode array with the simulation signal, or else there would be a charge accumulation within the head. The coupling of the lid to the electronics is also explicitly disclosed by original claims 14 and 15.

81. Hence, the application as filed provides a valid basis for this coupling. Again, the Board sees no problem in combining this aspect of the stimulator with other aspects of the same stimulator.

82. Consequently, the Board considers that Article 123(2) EPC does not prohibit the amendment.

Seventh auxiliary request - novelty and inventive step

83. Claim 1 differs from claim 1 of the third auxiliary request in that it further defines that

> *... the hermetic package includes a ceramic substrate brazed to a biocompatible metal*

case wall which is enclosed by a laser welded biocompatible metal lid;

the metal lid being electrically coupled to the electronics to provide an electrical return to the brain.

84. None of the documents on file discloses a metal lid that is electrically coupled to the electronics to provide an electrical return to the brain.

85. Typically, a return electrode is placed in the vicinity of the electrodes (see, for example, E24, point 3.5, and Figure 9), as this is the most convenient way of assembling the stimulator electrically. Such an arrangement also provides control over the paths of the charges through the tissue. E21 confirms that such an arrangement is the most convenient. However, E21 deviates from this arrangement and proposes implanting a strip of platinum foil in the scalp as return electrode, in order to keep the generated electrolytic products out of the brain (last paragraph on page 510). E2, E4, E5, and E7 are silent as to the position of the return electrode.

86. The problem related to the return electrode, which had to be solved starting from any of documents E2, E4, E5, or E7 (ignoring the further differences and problems to be solved), is to find a convenient place for the return electrode. Starting from E21, it is to find an alternative placement for it.

87. Starting from E2, E4, E5, or E7, the skilled person would most probably have placed the return electrode conveniently near the stimulation electrodes, perhaps on the opposite side of the retina. The Board cannot

see why the skilled person would have chosen a metal lid of the electronics package as a return electrode, even when adapting to brain stimulation, and neither did the opponent provide a persuasive argument for this configuration.

88. Starting from E21, the situation is different. Here, the electrode is implanted in the skull. The skilled person might have chosen the alternative placement at the back of the electrode array, which has the advantage of being more convenient, at the cost of having the electrolyte products in the brain. The skilled person would, however, not have considered using the lid of the electronic package as return electrode, because this would seriously have disturbed the communication between the secondary coils in the electronic package and the primary coils on the outside of the skull.

89. The other documents on file do not provide any relevant disclosure related to the return signal.

90. Hence, at least the feature defining the metal lid as a return electrode renders the subject-matter of claim 1 inventive in view of any of the documents E2, E4, E5, E7, and E21, which were used by the opponent as starting points for their attacks on patentability.

91. Therefore, Articles 54 and 56 EPC do not stand against the allowability of the seventh auxiliary request.

Conclusions

92. The main and first auxiliary requests are not allowable, because the subject-matter of their respective claim 1 extends beyond the application as filed.

93. The second auxiliary request is not allowable, because the subject-matter of claim 1 lacks novelty over E2.

94. The third auxiliary request is not allowable, because the subject-matter of claim 1 lacks an inventive step over E2.

95. The seventh auxiliary request is admitted into the proceedings. Since none of the grounds raised by the opponent against it stands, and since the Board does not see any other issues, the seventh auxiliary request is allowable.

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

   - the claims of the seventh auxiliary request, filed with reply to the appeal;

- the drawings as in the patent;

and to adapt the description as necessary.

The Registrar: The Chair:

D. Meyfarth P. Scriven

Decision electronically authenticated