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**Datasheet for the decision  
of 15 June 2012**

**Case Number:** T 0794/08 - 3.4.01

**Application Number:** 99911299.8

**Publication Number:** 1061996

**IPC:** A61N 1/36

**Language of the proceedings:** EN

**Title of invention:**

Apparatus for preferential outer retinal stimulation

**Patentee:**

JOHNS HOPKINS UNIVERSITY

**Opponent:**

IMI Intelligent Medical Implants AG

**Headword:**

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**Relevant legal provisions:**

EPC Art. 100(b)

**Keyword:**

"Sufficiency of disclosure (no)"

**Decisions cited:**

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**Catchword:**

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Case Number: T 0794/08 - 3.4.01

**D E C I S I O N**  
of the Technical Board of Appeal 3.4.01  
of 15 June 2012

**Appellant:**  
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**Representative:** Graf von Stosch, Andreas  
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**Respondent:**  
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**Representative:** Paget, Hugh Charles Edward  
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**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office posted 3 March 2008  
rejecting the opposition filed against European  
patent No. 1061996 pursuant to Article 101(2)  
2nd sentence EPC.

**Composition of the Board:**

**Chairman:** H. Wolfrum  
**Members:** F. Neumann  
A. Pignatelli

## **Summary of Facts and Submissions**

- I. The appellant (opponent) lodged an appeal against the decision of the opposition division, dispatched on 3 March 2008, rejecting the opposition against European patent No. 1 061 996.
- II. Pursuant to Articles 100(a) and 100(b) EPC 1973 the opposition had been based on the grounds of lack of novelty and inventive step and insufficiency of disclosure. During the proceedings before the opposition division the opponent introduced the further ground of Article 100(c) EPC 1973. All three grounds were considered in the decision of the opposition division.
- III. The notice of appeal was received on 9 April 2008 and the prescribed fee was paid on the same day. On 3 July 2008 a statement setting out the grounds of appeal was filed.

In the statement setting out the grounds of appeal the opponent argued on the basis of Articles 100(a), (b) and (c) EPC. Lack of novelty was argued with regard to prior art documents D1, D3, D21, D2, D4 (together with D4'), D6, D19 and D20.

Only documents D1 to D18 had been relied upon during the proceedings before the opposition division. However, the opponent now referred to documents D19 and D20 which had been filed before the opposition division but had not been admitted into the proceedings. Document D21, which was mentioned in the specification

of the contested patent, was also referred to with regard to the lack of novelty objection.

- IV. With letter dated 20 November 2008, the respondent (proprietor) filed a response to the appeal.

The proprietor challenged the public availability of document D4 and held that documents D19 and D20 were filed so late that they should not be admitted into the proceedings. Counter-arguments were submitted to the objections under Article 100(c) and (b) EPC. The prior art documents referred to by the opponent were each analyzed by the proprietor in an attempt to demonstrate novelty with respect to these citations.

- V. In a letter dated 9 April 2009, the opponent addressed the issue of admissibility of documents D4, D19 and D20. Further arguments were presented concerning added subject-matter and insufficiency of disclosure. A further document (D22) was introduced to support the lack of inventive step objection.

- VI. On 1 August 2011 the Board summoned the parties to oral proceedings, initially scheduled to take place on 14 December 2011 but subsequently rescheduled for 15 June 2012.

In a communication dated 23 September 2011 the Board set out its preliminary opinion with regard to the contentious issues in preparation of oral proceedings.

- VII. In a letter dated 16 December 2011 the proprietor submitted arguments concerning all the points raised. Reference was made to a number of further documents

(D23 to D31), some pre-published, some post-published, in an attempt to substantiate what the skilled person would regard as common general knowledge. Furthermore, six sets of claims were filed forming the basis of six auxiliary requests.

VIII. In a letter dated 15 December 2012, the opponent made further remarks concerning the questions of insufficient disclosure, novelty and the admissibility of D4 and D4'. In further letters of 10 January 2012 and 18 January 2012 the opponent produced two new documents (D32 and D33) which he claimed were novelty-destroying for the subject-matter of claim 1 of the contested patent.

IX. Oral proceedings were held on 15 June 2012. During these proceedings, the proprietor introduced a further document (D34) to substantiate common general knowledge.

X. The following documents are referred to in this decision. Since the remaining documents referred to by the parties play no role in the decision, it is not necessary, for the purposes of this decision, to identify them.

D2: LIU W. et al.; "Dual Unit Visual Intraocular Prosthesis"; Proceedings of the 19th International Conference of the Engineering in Medicine and Biology Society 1997; Oct. 30 - Nov. 2 1997; pages 2303-2306; Chicago, IL, USA;

D3: DAGNELIE G. et al.; "The Physiological Connection: Stimulating the Human and Amphibian Retina"; IEEE International Conference on Neural Networks 1997;

9-12 June 1997; vol. 4; pages 2321-2326; Houston, TX, USA;

- D7: GRUMET A. E.; "Extracellular Electrical Stimulation of Retinal Ganglion Cells"; Masters Thesis; Massachusetts Institute of Technology; September 1994;
- D21: US-A-5 109 844;
- D23: JESINGER R. A. et al.; "Flexible Electrode Array for Retinal Stimulation"; Proceedings of the Annual International Conference of the Engineering in Medicine and Biology Society, Paris, Oct. 29 - Nov. 1 1992; vol. 6; page 2393; 29 October 1992;
- D24: SCHWARZ M. et al.; "Hardware Architecture of a Neural Net Based Retina Implant for Patients Suffering from Retinitis Pigmentosa"; 1996 IEEE International Conference on Neural Networks, Washington, June 3-6 1996; pages 653-658;
- D25: STIEGLITZ T. et al.; "Development of Flexible Stimulation Devices for a Retina Implant System"; Proceedings of the 19th International Conference of the Engineering in Medicine and Biology Society; Oct. 30 - Nov. 2 1997; pages 2307-2310; Chicago, IL, USA;
- D34: US-B1-6 400 989.

- XI. The appellant (opponent) requested that the decision under appeal be set aside and the European patent be revoked in its entirety.
- XII. The respondent (proprietor) requested that the appeal be dismissed and that the patent be maintained as granted (main request) or that the patent be maintained on the basis of the wording of claims 1-13 of the sole auxiliary request filed on 16 December 2011 as

auxiliary request 2. All other auxiliary requests were withdrawn.

XIII. Independent claim 1 of the patent as granted reads as follows:

*"A retinal prosthesis comprising:  
At least one electrode to be positioned in the vicinity of retinal tissue; and  
means for applying a long duration stimulation signal to the at least one electrode such that deeper intermediate retinal cells are preferentially stimulated over the retinal ganglion cells and proximal overlying surface axons, wherein the long duration stimulation signal is a biphasic signal having a negative and a positive phase pulse and wherein the duration of the long duration stimulation signal is greater than about 2 millisecond per phase pulse."*

Claims 2 to 14 are dependent claims.

XIV. In independent claim 1 of the auxiliary request, the following wording, which corresponds to the wording of dependent claim 13 of the main request, has been added to the end of the wording of claim 1 of the main request:

*"and wherein the long duration stimulation signal has a duration and a magnitude selected to preclude inadvertent stimulation of retinal ganglion cells."*

Claims 2 to 13 are dependent claims.

## Reasons for the Decision

1. The appeal is admissible.

Main request - sufficiency of disclosure

2. The contested patent concerns electrical stimulation of the retina and in particular the recognition that stimulation signals of short duration directly stimulate surface retinal ganglion cells whilst stimulation signals of longer duration (i.e. greater than about 2ms per phase pulse) target deeper retinal cells (e.g. bipolar cells) to the exclusion of the surface ganglion cells. Such preferential stimulation of deeper retinal cells is advantageous because the visual perception of the stimulation is a focussed phosphene. In contrast, short-pulse stimulation may excite not only the surface ganglion cells, but may also cause inadvertent stimulation of the axons which overlie the individual ganglion cell bodies. This inadvertent axon stimulation would cause entire groups of ganglion cells to be excited, the visual perception of which would be a wide-area wedge of light instead of the desired focussed spot.

Claim 1 is directed to a retinal prosthesis comprising at least one electrode and a means for applying a biphasic stimulation signal of a duration greater than about 2 milliseconds per phase pulse. The application of a stimulation signal with such duration will result in preferential stimulation of the deeper retinal cells as opposed to the surface ganglion cells and overlying axons.



3. It is established jurisprudence that the protection conferred by a patent should correspond to the technical contribution to the art made by the disclosure of the invention described therein. In other words, the terms of the claim should be commensurate with, or be justified by, the invention. This principle ensures that the patent monopoly is not extended to subject-matter which, after reading the patent specification, would still not be at the disposal of the skilled person (see Case Law of the Boards of Appeal of the European Patent Office, 6th Edition 2010, II.A.6.2) and is codified by the wording of Articles 83 and 100(b) EPC.
  
4. In the present case, the technical contribution to the art is represented by the recognition that a long-duration pulse (defined in claim 1 as being "greater than about 2ms per phase pulse") will preferentially stimulate deeper retinal cells and give rise to focussed phosphenes. Indeed, it is the characteristics of the stimulation signal and in particular the duration of the stimulating pulse which the proprietor referred to as the invention and it is this aspect which the patent specification concentrates on. Nevertheless, the subject-matter defined in claim 1 is not limited to the manner in which the stimulation signal is applied but, instead, is directed to a complete retinal prosthesis.
  
5. The ground of opposition of Article 100(b) EPC 1973 is interpreted as requiring that, in opposition proceedings, it must be examined whether the patent application disclosed the invention in a manner sufficiently clear and complete for it to be carried

out by the person skilled in the art on the filing date (see Singer, Stauder; Europäisches Patentübereinkommen Kommentar; 5. Auflage; Art. 100, Rn 6).

Thus, in order to carry out the invention as claimed, the skilled person has to be in a position, after reading the patent application as filed, to construct a retinal prosthesis comprising at least one electrode and a means for applying a biphasic stimulation signal of a duration greater than about 2 milliseconds per phase pulse.

6. The only structural elements of the retinal prosthesis mentioned in the patent application are the at least one electrode and a means for applying a long duration stimulation signal to the at least one electrode. No other structural features are mentioned.

The opponent held that the electrode and stimulating means of claim 1 could not be considered to constitute, on their own, a retinal prosthesis. In fact, a retinal prosthesis needed at least a photodetector for detecting a light signal, processing electronics for converting the light signal into an electrical stimulation signal, a retinal stimulator for applying the stimulation signal to the retina, a signal communication means for transmitting the stimulation signal from the processing electronics to the retinal stimulator and a power supply. Since these features were not discussed in the application documents, the opponent submitted that the invention, as claimed, was not sufficiently disclosed.

7. In the absence of any constructional details of the retinal prosthesis in the application documents, it has to be ascertained whether the gap in the teaching may be filled by the common general knowledge of the skilled person. It is established jurisprudence that common general knowledge is represented by basic handbooks and textbooks on the subject in question or articles in scientific periodicals (see Case Law of the Boards of Appeal of the European Patent Office, 6th Edition 2010, I.D.7.3). As an exception, common general knowledge can also be represented by the information contained in patent specifications or scientific publications, if the invention lies in a field of research which is so new that the relevant technical knowledge is not yet available from textbooks (see Case Law of the Boards of Appeal of the European Patent Office, 6th Edition 2010, I.C.1.5). In particular, numerous publications in the specialist press over a fairly short time reporting on meetings and research in a particularly active field of technology could also be seen to be indicative of common general knowledge in this field at that time (see Case Law of the Boards of Appeal of the European Patent Office, 6th Edition 2010, I.D.7.3).
  
8. During the appeal proceedings it became clear that the development of retinal prostheses indeed lies in a field of research which is so new that the relevant technical knowledge had not, at the priority date, made its way into standard textbooks. In fact, only three research groups worldwide were working on this subject and the only information available was that published by these groups.

9. The proprietor held that from the evidence provided, it was clear that the various research groups were agreed upon the specific building-blocks required to build a retinal prosthesis. In particular, from the academic papers D7, D23, D24 and D25 and the patent specifications D21 and D34, it could be seen that the basic structural elements, as listed in paragraph 6 above, were well established even at the priority date of the contested patent.

To this extent the Board is willing to accept that the general agreement in the field in this regard could be taken as an indicator that the necessary building-blocks were indeed well-known and, as such, could be considered to represent the common general knowledge of the skilled person.

10. However, it becomes clear either from these documents themselves or from a number of other documents (see below) that at the priority date of the patent a functioning retinal prosthesis had yet to be realised. The opponent explained that whilst the basic elements may have been more or less agreed upon, a number of engineering challenges still had to be overcome before the concept could be converted into an implementable device. For example, the designers faced problems concerning the biocompatibility of materials, miniaturisation of components, corrosion resistance and fixation means. As may be inferred from the teachings of the above-mentioned documents, not all of the problems associated with the design of a retinal prosthesis had been overcome at the priority date of the contested patent. The Board considers that, in drawing attention to these documents, the opponent has

discharged the burden of proving serious doubts that the invention is sufficiently disclosed.

In particular, documents D7, D21, D23 to D25 (which were referred to by the proprietor to prove that the structural components of a retinal prosthesis were well known and understood), all discuss the development of a retinal prosthesis but none discloses that an implementable retinal prosthesis has actually materialised from the various development programs.

Moreover, D2, which bears a date of April 1997, discusses relevant prior work (page 2303) and makes clear that, to that date, an operating implantable artificial retina had not been achieved. Even the work reported on in D2 had not produced a functional prosthesis: the two main components had been individually demonstrated to work, but they had yet to be combined (see section 6: Conclusion).

Similarly, D3, which bears a date of June 1997, states that "a functional retinal prosthesis may not be far off" (final sentence on page 2326). In other words, the concept had yet to be implemented.

Finally, D24, from 1996, points to the complexity of the task and indicates that "For this reason, only a proof of the concept feasibility can be expected within the current decade" (see page 658, Summary).

In summary, from these documents it may be seen that shortly before the priority date of the contested patent (in the case of D3, only 9 months before), a

functioning retinal prosthesis had not yet been implemented.

11. Article 100(b) EPC is based on the requirement that the invention must be disclosed in a manner clear and complete enough for the skilled person to reproduce it. Whilst this provision does not require that a functioning device be physically available before an application is filed, the Board holds that it has to be at least plausible that the invention can be put into practice. By "put into practice", the Board does not mean that, in the present case, the necessary clinical trials and health authority approval procedures must already have been completed, but rather that it must be plausibly possible to construct a functioning retinal prosthesis.

In view of the fact that there is neither any teaching in the application documents nor any common general knowledge for the skilled person to rely upon to allow him to construct a functioning retinal prosthesis, the Board must conclude that the skilled person would not be in a position to carry out the invention. No evidence was produced which would suggest the contrary. In fact, during the oral proceedings, the proprietor confirmed that at the priority date a retinal prosthesis had still not been built.

12. The proprietor strongly contested the standard being applied by the opponent. It was submitted that there was no requirement that a disclosed invention should actually be available as a working model before a patent application can be filed. Even less so did an improvement to one isolated aspect of a specific device

require that a working model of the whole device be available before a patent application can be filed for the improvement. It was argued that if this were the case, it would lead to a collapse of the world's patent systems. Nuclear fusion was cited as an example of speculative technology which, although functionality had not yet been demonstrated, was nevertheless the subject of numerous patent applications.

The proprietor further submitted that the actual **invention**, i.e. the specific pulse characteristics, had been sufficiently disclosed **with regard to the state of the art** available at that time.

It was argued that a retinal prosthesis was at least a known concept at the priority date of the application. This concept involved a specific set of components which were well-understood at that time by the skilled person as being necessary for the construction of a retinal prosthesis. The "invention" was concerned with just one of these components. The fact that the entire retinal prosthesis could not, at that time, be realised had no bearing on the question of whether the invention had been sufficiently disclosed because the retinal prosthesis itself was not the invention.

The state of the art was apparent from the various citations referred to above. These documents explained in detail which structural units were required to construct a retinal prosthesis. In particular, D21, which was cited in the contested patent, contained a claim to a retinal prosthesis listing the necessary components. These documents served to show that a retinal prosthesis belonged to the state of the art and

that the constructional details were indeed known. Since the actual invention only concerned the pulse characteristics, the other details of the retinal prosthesis were of no relevance and did not have to be disclosed. The proprietor drew a comparison to a new gearing system being provided for a bicycle: details of the bicycle were not required if the invention only lay in the details of the gearing system.

13. The Board agrees that the bicycle example is indeed instructive, but for different reasons. A bicycle is "notorious"; a retinal prosthesis is not. Notorious knowledge is a concept that is often cited in cases of computer-implemented inventions but applies equally to the bicycle example cited here. Something is understood as being notorious if, firstly, it is so well known that its existence at the date of priority cannot be reasonably disputed and, secondly, if the technical details of the generic features are not significant (T 1411/08, reasons 4.1 and 4.2).

The bicycle itself has been known for over a century; the generic mechanical elements of a bicycle as well as their mutual arrangement and interaction are also well known and understood. Thus the above criteria for notoriety apply to a bicycle. This is not so for a retinal prosthesis. As has been shown above, at least the first criterion for notoriety is not satisfied: the non-existence of a retinal prosthesis at the priority date has even been confirmed by the proprietor. Thus, a retinal prosthesis cannot be considered notorious and the analogy to the new gearing system of a bicycle fails.



14. The Board considers that if the invention lies in an improvement to one aspect of a device then a patent may be granted for this improvement, assuming of course that the improvement has been disclosed in a manner clear and complete enough for it to be put into practice. If, on the other hand, protection is sought for a device incorporating this improvement, a patent may only be granted for the device if the disclosure is such as to enable the improved device to be put into practice. A patent is granted as a reward for the effort invested by an inventor in enriching the technology at the filing date and not as a reward for an non-implementable teaching which may only be put into practice once a third party has invested some effort of his own (see Schulte, Patentgesetz mit EPÜ, Kommentar, 8. Auflage 2008, §21, Rn 32).

In the present case, the invention lies in the solution of just one of the many problems associated with a retinal prosthesis. Other, perhaps more fundamental, problems were encountered in the design challenges referred to by the opponent (see section 10 above). The fact that a retinal prosthesis, by the proprietor's own admission, did not exist at the priority date implies that solutions to these problems had still to be found. Even if the basic elements of a retinal prosthesis could be considered to be agreed upon, a number of hurdles still had to be overcome before these elements could be combined into a functioning device. In such a case, it is only justified to seek protection for the one solution which has been presented in the application documents. A claim which is drafted in such general terms as to extend protection to the unknown (and, at that time, unsolved) solutions of all of the

engineering challenges involved in constructing a retinal prosthesis is not justified by the disclosure.

15. In this regard, the proprietor remarked during the oral proceedings that it would have been impossible for the inventor to solve all of the problems associated with the retinal prosthesis and to present them all in a single patent application.

The Board believes this observation exposes the fatal flaw in the contested patent. Reiterating what was said in paragraph 3 above, the protection conferred by a patent should correspond to the technical contribution to the art made by the disclosure of the invention described therein. If the technical contribution to the art lies only in the solution to one problem associated with a retinal prosthesis, then protection may only be sought for this one aspect.

16. The Board therefore concludes that the contested patent does not disclose the invention, as claimed in the main request, in a manner sufficiently clear and complete for it to be carried out by a skilled person.

#### Auxiliary Request

17. The independent claim of the auxiliary request is distinguished from the independent claim of the main request only in that the duration and magnitude of the stimulation signal are defined as being such as to preclude inadvertent stimulation of retinal ganglion cells. In other words, the independent claim of the auxiliary request is still directed to a retinal prosthesis and the arguments presented above with

regard to the main request apply with equal force to the auxiliary request.

For this reason, the Board concludes that, even taking into consideration the amendments proposed in the auxiliary request, the invention, as claimed in this request, is not disclosed in a manner sufficiently clear and complete for it to be carried out by a skilled person.

18. Since the requirements of Article 83 EPC are not fulfilled by the pending requests, the patent has to be revoked.
  
19. In view of this outcome, the arguments of the parties concerning the other patentability requirements of the EPC are not relevant and for this reason have not been discussed.

**Order**

**For these reasons it is decided that:**

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:

R. Schumacher

H. Wolfrum