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Datasheet for the decision of 20 March 2008

Case Number: T 1568/06 - 3.4.01

Application Number: 02780956.5

Publication Number: 1409073

IPC: A61N 1/08

Language of the proceedings: EN

Title of invention:
Methods for improving damaged retinal cell function

Applicant:
Optobionics Corporation

Opponent:
-

Headword:
-

Relevant legal provisions:
-

Relevant legal provisions (EPC 1973):
EPC Art. 54(1),(2), 84, 112(1)(a), 111(1)

Keyword:
"Novelty - main request (no)"
"Clarity - auxiliary request (no)"
"Referral to Enlarged Board of Appeal (no)"
"Remittal to examining division (no)"

Decisions cited:
-

Catchword:
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Case Number: T 1568/06 - 3.4.01

D E C I S I O N
of the Technical Board of Appeal 3.4.01
of 20 March 2008

Appellant: Optobionics Corporation
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Representative: Grünecker, Kinkeldey,
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 4 May 2006 refusing European application No. 02780956.5 pursuant to Article 97(1) EPC 1973.**

Composition of the Board:

Chairman: B. Schachenmann
Members: G. Assi
F. Neumann

Summary of Facts and Submissions

I. The appellant (applicant) lodged an appeal, received on 14 July 2006, against the decision of the examining division, dispatched on 4 May 2006, refusing the European patent application No. 02780956.5 (publication number 1 409 073). The fee for the appeal was paid on 14 July 2006. The statement setting out the grounds of appeal was received on 14 September 2006.

The reasons for the decision under appeal were given by way of reference to a communication dated 18 October 2005 in which the subject-matter of claim 1 then on file was considered to lack novelty (Article 54, paragraphs 1 and 2, EPC 1973) in view of document US-B1-6,230,057 (D1).

II. On 12 October 2007 the appellant was summoned to oral proceedings scheduled to take place on 29 February 2008.

III. On 6 November 2007 the Board sent a communication intended to assist the appellant in preparing for oral proceedings. In addition to D1, the following documents were cited in the communication:
(D5) US-A-5,556,423;
(D6) US-A-5,895,415;
(D7) US-A-5,944,747.

IV. Oral proceedings took place on 29 February 2008.

V. In the oral proceedings the appellant requested that the decision under appeal be set aside.

The appellant also requested that it be decided that the subject-matter of claim 1 according to a main request, filed in the oral proceedings, or to auxiliary requests 1 to 4, filed by a letter of 28 January 2008, or to an auxiliary request 5, filed in the oral proceedings, be novel and, in particular, that in the respective claim 1, having the structure "*Use of a source ... for producing an implant for improving the visual function of a damaged retina in a human eye by applying electrical stimulation to the eye ...*", the novel therapeutic application or therapeutic use of the implant be sufficient to establish novelty, even though the source, the implant and the method for producing the implant are known in the art.

Should the Board be unable to grant the above request concerning novelty, the appellant requested that the following question be referred to the Enlarged Board of Appeal:
"*Is the subject-matter of a claim having the form "Use of a device X for producing a medical device Y for therapeutic used Z" novel over a prior art according to which the device X, the medical device Y, and the method for producing the medical device Y are known in the art, but the therapeutic use Z with the medical device Y is novel over the prior art?*"

Moreover, the appellant requested that the case be remitted to the department of first instance for further prosecution.

VI. The wording of claim 1 of the main request reads as follows:

"*Use of a source of electrical stimulation for producing an implant for improving the visual function of a damaged retina in a human eye by applying electrical stimulation to the eye, wherein applying electrical stimulation improves visual function of at least one structure of the retina which is not in contact with the source of electrical stimulation.*"

The wording of claim 1 of the auxiliary request 1 reads as follows:

"*Use of a source of electrical stimulation for producing an implant for improving the visual function of a damaged retina in a human eye by applying chronic electrical stimulation to the eye, wherein applying electrical stimulation improves visual function of at least one structure of the retina which is not in contact with the source of electrical stimulation.*"

The wording of claim 1 of the auxiliary request 2 reads as follows:

"*Use of a source of electrical stimulation for producing an implant for improving the general inherent visual function of damaged retinal cells of a damaged retina in a human eye by applying electrical stimulation to the eye, the retina or both, wherein applying electrical stimulation improves visual function of at least a portion [of] the damaged retina which is not in contact with the source of electrical stimulation.*"

The wording of claim 1 of the auxiliary request 3 reads as follows:

"*Use of a source of electrical stimulation for producing an implant for improving the visual function of a damaged retina in a human eye by applying electrical stimulation comprising a predetermined pattern to the eye, wherein applying electrical stimulation improves visual function of at least one structure of the retina which is not in contact with the source of electrical stimulation.*"

The wording of claim 1 of the auxiliary request 4 reads as follows:

"*Use of a source of electrical stimulation for producing an implant for improving the visual function of a damaged retina in a human eye by applying electrical stimulation comprising a predetermined pattern being temporal, and being monophasic, biphasic or being complex combinations of monophasic or biphasic wavefroms [waveforms] with varying ramps of increasing and decreasing current and voltage to the eye, wherein applying electrical stimulation improves visual function of at least one structure of the retina which is not in contact with the source of electrical stimulation.*"

The wording of claim 1 of the auxiliary request 5 reads as follows:

"*Use of a source of electrical stimulation for producing an implant for improving the visual function of a damaged retina in a human eye by stimulating production and release of growth factors by applying electrical stimulation to the eye, wherein applying electrical stimulation improves visual function of at*

least one structure of the retina which is not in contact with the source of electrical stimulation."

Reasons for the Decision

1. The appeal is admissible.

2. The revised version of the European Patent Convention or EPC 2000 entered into force on 13 December 2007. At that time, the present application was still pending. Pursuant to Article 7(1) of the Act, dated 29 November 2000, revising the European Patent Convention of 5 October 1973 (Special Edition No. 1 OJ EPO, 196), the revised version of the Convention shall not apply to European patent applications pending on 13 December 2007, unless otherwise decided by the Administrative Council of the European Patent Organisation. With a decision of 28 June 2001 (Special Edition No. 1 OJ EPO 2007, 197), the Administrative Council decided on the transitional provisions under Article 7 of the said Act of 29 November 2000. With a further decision of 7 December 2006 (Special Edition No. 1 OJ EPO 2007, 89), the Administrative Council decided on the Implementing Regulations to the EPC 2000.

Therefore, in the present decision, reference will be made to "*EPC 1973*" or "*EPC*" for EPC 2000 (EPC, Citation practice, pages 4-6) depending on the version to be applied according to the Revision Act and the decisions of the Administrative Council mentioned above.

3. *Claim 1 of the main request*

3.1 Claim 1 of the main request corresponds to the claim which was rejected by the examining division for lack of novelty with regard to document D1.

3.2 Document D1 discloses a medical product comprising a plurality of multiphasic microphotodiode retinal implants (MMRIs) to be implanted in the subretinal space, whereby the MMRIs convert light into small electrical currents to stimulate the retina (see column 2, line 40 to column 3, line 8). This product can be used to correct vision loss or even complete blindness caused by certain retinal diseases (see column 1, lines 11-25).

Using the terminology of claim 1 of the main request, document D1 thus discloses an implant (the MMRI) comprising a source of electrical stimulation (the photodiodes in the MMRI), the implant improving the visual function of a damaged retina in a human eye by applying electrical stimulation to the eye, in particular to the retina. The disclosure of D1, in the Board's view, necessarily implies the use of the source of electrical stimulation as a component of the implant for its production.

3.3 For assessing novelty, the issue still remains to be considered concerning the claimed effect of the electrical stimulation on the retina, in particular the fact that the electrical stimulation improves visual function of at least one structure of the retina "*which is not in contact with the source of electrical stimulation*".

In agreement with the examining division's opinion, the claimed effect may be regarded to be inherently related to the use of any implant generating electrical stimulation and thus of the implant known from D1. Namely, it is likely that the stimulated retinal area is larger (even though to a small extent) than the surface of contact of the source of stimulation with the retina. A reason consists in that the electric currents originating from at least the peripheral regions of the source will also extend into retinal areas that surround the source and thus are not in direct contact with the source itself. Support for this understanding is provided by the disclosures of documents D5 (see column 1, line 65 to column 2, line 5), D6 (see column 1, line 67 to column 2, line 4) and D7 (see column 4, line 59 to column 5, line 21).

3.4 The appellant held that the known retina implant according to D1 produced prosthetic artificial vision based on electrical stimulation of the neuroretina in contact with, or in close proximity to, the source of electrical stimulation. The known implant thus simply performed the function of the missing or damaged retina cells. The retina implant according to the present invention, however, improved the inherent visual function of retina cells which were not only in contact with, or in close proximity to, but also distant from the source of electrical stimulation. This surprising effect might be explained by the fact that the electrical stimulation led to the production of endogenous neurotrophic growth factors which promoted visual function of large retinal areas and also protected the retina from degeneration. This essential

difference had the result that if the retina implant were to be removed, the visual function of the damaged retina would be improved according to the present invention but would still be degraded according to D1.

In the light of the foregoing, the appellant submitted that the wording of claim 1 of the main request should properly be understood as follows:

(a) The wording "*improving the visual function of a damaged retina in a human eye*" did not mean that prosthetic artificial vision was produced, as according to D1;

(b) The wording "*electrical stimulation*" implied an active step which involved stimulation with a predetermined pattern different from the stimulation obtained under normal viewing conditions;

(c) The wording "*not in contact with*" also covered locations of the retina distant from the retina implant.

In the appellant's view, a skilled person would read claim 1 of the main request in this way and would thus come to the conclusion that the subject-matter of claim 1 of the main request was novel.

3.5 The Board does not agree. It is a commonly accepted principle that a claim should be read giving the words the meaning and scope which they normally have in the relevant art, unless in particular cases the description gives the words a special meaning, by explicit definition or otherwise. In examination procedure, if such a special meaning applies, it should,

so far as possible, be clear from the wording of the claim alone.

3.6 In the present case, the Board notes that claim 1 of the main request relies on a terminology which is commonly used in the technical field of retina implants and has a well-defined meaning.

In particular, the wording "*improving the visual function of a damaged retina in a human eye*" normally means that vision loss (of a damaged retina) is corrected, as achieved by the retina implant according to D1 (see column 1, lines 11-13). Thus, the wording in question does not exclude that prosthetic artificial vision is obtained, as taught by D1.

The wording "*electrical stimulation*" normally indicates that light causes an electrical potential to develop on a photosensitive layer causing charges to be produced which migrate into the retina causing stimulation. In its normal meaning, the wording does not necessarily imply an active step which involves stimulation with a predetermined pattern as opposed to stimulation under normal viewing conditions.

Moreover, the wording "*not in contact with*" does not exclude retinal locations in close proximity to the source of stimulation. Thus, it does not necessarily refer to distant locations only.

For these reasons, the appellant's understanding of claim 1 of the main request appears to be unduly restrictive. If, as the appellant submitted, the present invention would consist in the use of a known

retina implant not only for providing prosthetic artificial vision but also for simultaneously achieving a regeneration of the retina by the release of endogenous neurotrophic growth factors caused by the application of a predetermined stimulation pattern in addition to daylight stimulation, this invention is not, in the Board's view, claimed in clear and explicit terms.

3.7 In conclusion, the subject-matter of claim 1 of the main request lacks novelty (Article 54, paragraphs 1 and 2, EPC 1973) with regard to the disclosure of document D1 as understood by a skilled person.

3.8 Hence, the main request is not allowable.

4. *Claim 1 of the auxiliary request 1*

4.1 Claim 1 of the auxiliary request 1 differs from claim 1 of the main request in that "*chronic*" electrical stimulation is applied to the eye.

4.2 The usual meaning of the word "*chronic*" is "*long-lasting*" or "*persisting for a long time*". This meaning appears to be supported by the description (see page 30, line 19), according to which electrical stimulation may be provided "*continuously*".

4.3 However, there is an inconsistency with the further possibility mentioned on page 30, line 19 of the description, according to which electrical stimulation may also be provided "*intermittently*". Such an inconsistency between the description and the claim renders claim 1 of the auxiliary request 1 unsupported

by the description (Article 84, second sentence, EPC 1973).

4.4 Hence, the auxiliary request 1 is not allowable.

5. *Claim 1 of the auxiliary request 2*

5.1 Claim 1 of the auxiliary request 2 differs from claim 1 of the main request in that the "*general inherent*" visual function "*of damaged retinal cells*" of a damaged retina is improved, in that electrical stimulation is applied to the eye, "*the retina or both*" and in that electrical stimulation improves visual function of at least "*a portion [of] the damaged retina*" which is not in contact with the source of electrical stimulation.

5.2 The word "*general*" referring to the inherent visual function of damaged retinal cells renders the scope of the claim unclear (Article 84, first sentence, EPC 1973) because it is not clear how it should further qualify the inherent visual function.

5.3 Similarly, the feature of applying electrical stimulation to the eye, "*the retina or both*" is unclear because the retina is part of the eye.

5.4 Hence, the auxiliary request 2 is not allowable.

6. *Claim 1 of the auxiliary request 3*

6.1 Claim 1 of the auxiliary request 3 differs from claim 1 of the main request in that the electrical stimulation comprises "*a predetermined pattern*".

6.2 According to the appellant's presentation of the invention, the provision of an electrical stimulation comprising a predetermined pattern represents an essential feature for achieving a regeneration of the retina by the release of endogenous neurotrophic growth factors. However, the claim only recites that the pattern is predetermined, which fact would imply that the pattern is distinguished from the ambient light image normally seen by the eye. Such a lack of information concerning the nature of the pattern to be applied renders the claim unduly general, speculative and unclear (Article 84 EPC 1973). For the presumption that any conceivable pattern would indeed permit to achieve the desired effect there is no evidence or support by the description.

6.3 Hence, the auxiliary request 3 is not allowable.

7. *Claim 1 of the auxiliary request 4*

7.1 Claim 1 of the auxiliary request 4 differs from claim 1 of the main request in that the electrical stimulation comprises "*a predetermined pattern being temporal, and being monophasic, biphasic or being complex combinations of monophasic or biphasic wavefroms [waveforms] with varying ramps of increasing and decreasing current and voltage*".

7.2 Claim 1 of the auxiliary request 4 thus represents an attempt to define the nature of the predetermined pattern. This attempt, however, is without success because the terms used to define the pattern are themselves unspecified. As an example, the wording "*complex combinations*" is particularly unclear. Thus,

also claim 1 of the auxiliary request 4 is unduly general, speculative and unclear (Article 84 EPC 1973).

7.3 Hence, the auxiliary request 4 is not allowable.

8. *Claim 1 of the auxiliary request 5*

8.1 Claim 1 of the auxiliary request 5 differs from claim 1 of the main request in that the wording "*by stimulating production and release of growth factors*" has been added. This claim was filed in the oral proceedings.

8.2 Pursuant to Article 13, paragraph 3, RPBA (OJ EPO 2007, 536), amendments sought to be made after oral proceedings have been arranged shall not be admitted if they raise issues which the Board or the other party or parties cannot reasonably be expected to deal with without adjournment of the oral proceedings. It is noted that this provision, owing to the wording "*shall not*", does not grant a discretionary power to the Board.

8.3 In the present case, the appellant agreed that the added feature is not subject-matter of any of the originally filed claims. Rather, it derives from the description of the published application (see page 11, lines 10-31; page 29, lines 18-21). This means that the amendment constitutes unsearched subject-matter and as such raises issues which the Board cannot be expected to deal with without adjournment of the oral proceedings.

8.4 Hence, the auxiliary request 5 is not admitted.

9. *Referral of a question to the Enlarged Board of Appeal*

9.1 Pursuant to Article 112, paragraph 1(a), EPC 1973, in order to ensure uniform application of the law, or if a point of law of fundamental importance arises, a Board of Appeal shall, during proceedings on a case and either of its own motion or following a request from a party to the appeal, refer any question to the Enlarged Board of Appeal if it considers that a decision is required for the above purposes.

9.2 In the present case, an issue dealt with during the appeal procedure concerned the question addressed by the Enlarged Board of Appeal in G 1/83, G 5/83 and G 6/83 (OJ EPO 1985, 060) whether and in what way a known medicament for the treatment of a specific illness could be protected for the treatment of other illnesses (second and further medical indications). The Enlarged Board held that "*A European patent may be granted with claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application*" (see Order, point 2). On this basis, the appellant took the view that the Enlarged Board's approach inevitably lead to the conclusion that "*a further and novel therapeutic application of a medical device, as in the present case, must be protectable by a claim directed to the use of this device for the manufacture of a medical product for a specified novel (and inventive) application, even if the medical device, and the process of manufacturing the medical product are known in the art*" (see grounds of appeal, page 9, third paragraph). The Board thus considered the issue whether the claim wording adopted by the Enlarged Board might

be used by analogy in a case as the present one by simply replacing "*substance or composition*" and "*medicament*" with "*source of stimulation*" and "*implant*", respectively. The question underlying the appellant's request for referral to the Enlarged Board should be seen in this context.

9.3 However, in the light of the foregoing, the point of law raised by the appellant may be left open because it is not relevant for deciding the present case. In fact, the question submitted by the appellant is not relevant in relation either to claim 1 of the main request, the subject-matter of which does not meet the requirements of Article 54, paragraphs 1 and 2, EPC 1973, or to any of claims 1 of the auxiliary requests 1 to 4, which do not meet the provisions of Article 84 EPC 1973.

9.4 Hence, the request for referral of a question to the Enlarged Board of Appeal is refused.

10. *Remittal of the case to the examining division*

10.1 Neither the main request nor the auxiliary requests 1 to 4 filed by the appellant are allowable. Under these circumstances, the request for remittal of the case to the examining division for further prosecution (Article 111, paragraph 1, EPC 1973) is refused.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar The Chairman:

T. Buschek B. Schachenmann