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D E C I S I O N
of 5 June 2003

Case Number: T 0045/01 - 3.4.3

Application Number: 90308575.1

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Language of the proceedings: EN

Title of invention:
Artificial retina device

Patentee:
Chow, Alan Y.

Opponent:
Eberhard-Karls-Universität Tübingen

Headword:
-

Relevant legal provisions:
EPC Art. 56, 100(a), 100(b), 115(1)(e), 114(2)

Keyword:
"Inventive step (yes) could-would approach"
"Late-filed evidence alleging inoperability - admitted"
"Appointment of neutral expert (no)"

Decisions cited:
T 0375/00

Catchword:
-



Case Number: T 0045/01 - 3.4.3

D E C I S I O N
of the Technical Board of Appeal 3.4.3
of 5 June 2003

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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 17 November 2000
rejecting the opposition filed against European
patent No. 0460320 pursuant to Article 102(2)
EPC.

Composition of the Board:

Chairman: R. K. Shukla
Members: G. L. Eliasson
J. H. Van Moer

Summary of Facts and Submissions

- I. This appeal lies from the decision of the opposition division dated 17 November 2000 rejecting the opposition against European patent No. 0 460 320 pursuant to Article 102(2) EPC.

Claim 1 as granted has the following wording:

- "1. An artificial retina device to be implanted between the inner retinal layer and the outer retinal layer of an eye, comprising:

a plurality of discrete photovoltaic cells having electrical outputs that correspond to the amplitude of light incident on said device, said photovoltaic cells being disposed on one surface of a substrate, each photovoltaic cell comprising an active electrode layer overlying a photosensitive layer and being connected to an electrical ground, each active electrode layer being arranged to contact individual cells or small groups of cells in the inner retinal layer of the eye such that, in operation, the output of the device comprises a plurality of amplitude modulated signals for stimulating individual cells or small groups of cells in the inner retinal layer of the eye."

- II. An opposition was filed by the appellant (opponent) on the grounds *inter alia* of lack of inventive step (Article 100(a) EPC) and insufficient disclosure (Article 100(b) EPC). In the opposition proceedings, the following documents, among others, were cited:

D1: US-A-4 628 933;

D2: US-A-2 760 483;

D4: S. M. Sze, "Physics of Semiconductor Devices, Second Edition" (J. Wiley & Sons, New York 1981), pages ix to xii, 32, 78, 415, 433, 749, 754 to 760, 790, 791, and 799 to 801; and

D8: Bergmann-Schaefer, "Lehrbuch der Experimentalphysik" (Walter de Gruyter, Berlin 1971), pages 512 to 513.

III. In the decision under appeal, the opposition division reasoned essentially as follows:

(a) The opponent's contention that on the basis of calculations and experiments carried out by him, the light incident on the retina is not sufficient to operate the device as claimed, is not convincing, since other experiments may lead to other results and there is apparently no technical or physical reason why the claimed device should not work.

(b) Regarding inventive step, document D1 is considered the closest prior art, since it has most common features with the device according to claim 1. Contrary to the opponent's submissions, document D2 does not disclose discrete photovoltaic cells, since the statement suggesting that individual selenium crystal size may act as discrete photovoltaic cells is in contradiction

with the statement that the whole surface of the supporting base is covered with a thin layer of photosensitive material (cf. D2, paragraph bridging columns 1 and 2).

The claimed device differs in particular from that of document D1 in that it has active electrode layers overlying the photosensitive layer so that, when implanted, the cells of the inner retina layer is stimulated by amplitude modulated signals.

(c) A combination of document D1 with document D2 would be based on hindsight since there is no incentive to combine these documents. But even if the skilled person would combine the teaching of documents D1 and D2 he would not arrive at the claimed device, since none of the two documents discloses an electrode layer capable of transferring amplitude modulated signals to the inner retina layer.

IV. The appellant (opponent) lodged an appeal on 8 January 2001, paying the appeal fee the same day. A statement of the grounds of appeal was filed on 5 March 2001. In the statement of the grounds, the opponent cited new documents to support his submissions.

V. In response to a communication of the Board accompanying summons to oral proceedings, the patent proprietor filed with the letter dated 5 May 2003 new main claims forming first and second auxiliary requests. The opponent filed observations with the letters dated 27 May and 3 June 2003.

VI. At the oral proceedings held on 5 June 2003, the parties made the following requests:

The appellant (opponent) requested that the decision under appeal be set aside and that the European patent No. 0 460 320 be revoked. Auxiliary he requested to appoint an expert under Article 117(1) EPC.

The respondent (patent proprietor) requested that the appeal be dismissed and that the patent be maintained as granted or on the basis of the auxiliary request 1 or 2 filed with letter of 5 May 2003.

VII. The opponent (appellant) made essentially the following arguments in support of his requests:

(a) A detailed theoretical analysis shows that a discrete photovoltaic cell having a size of 20 x 20 μm , as disclosed in the patent in suit, can only produce a peak current of 160 nA. This current, which is only obtainable at very high light intensities, is nevertheless substantially below the stimulation threshold value of 1 μA required for evoking an appropriate neuronal response. Therefore, given the light intensity inside the eye, the induced photovoltage is too small to excite the nerve cells, and therefore, the device of the patent in suit would not work for its intended purpose as an artificial retina device. This is also evidenced by the fact that the patent proprietor has not published any results on the clinical trials which were announced to start in June 2000.

In case the Board has doubts about the validity of the above-mentioned calculations, and the patent proprietor contests the above findings on inoperability, it is requested to appoint a neutral expert under Article 117(1)(e) EPC.

(b) Document D2 should be considered the closest prior art, since it discloses a *subretinal* artificial retina device, whereas the device of document D1 is an *epiretinal* device. Furthermore, the document D2 discloses an array of discrete photovoltaic cells, since the passage in column 2, lines 1 to 5 can only be interpreted as meaning that the device of document D2 comprises a thin polycrystalline selenium layer so that each crystal grain acts as a discrete photovoltaic cell. If a thick uniform layer of selenium were to be applied, it would be impossible to achieve the desired high degree of resolution. Furthermore, the device of document D2 generates amplitude-modulated signals, in contrast to the device of document D1 which generates frequency-modulated signals.

(c) Thus, the claimed device differs from that of document D2 only in that each photovoltaic cell comprises an active electrode layer which overlies a photosensitive layer.

The problem to be solved therefore relates to producing an improved version of the device of document D2 which does not contain toxic compounds, such as selenium.

- (d) The claimed novel features are nothing more than a simple description of a photovoltaic cell, as has been generally known several years prior to the priority date of the patent in suit and as described in basic text-books, such as documents D4 and D8.

In 1989, the priority year of the opposed patent, the skilled person would not have considered selenium which was the only generally available photovoltaic material at the time of document D2, but would have considered other available photovoltaic materials such as Si. There was, hence, no inventive activity involved to select a technology that was readily available and which reflected the up-to-date state of the art.

VIII. The patent proprietor (respondent) provided essentially the following arguments in support of his requests:

- (a) The calculations provided by the opponent do not prove inoperability, since the calculations show that a photovoltaic cell having the dimensions 100 x 100 μm would produce a current of 4 μA which is well above the alleged threshold value of 1 μA . Therefore, by choosing sufficiently large photovoltaic cells, the opponent's calculation shows that a signal above the alleged threshold value is possible.

The patent proprietor has studied the article of Zrenner et al. quoted by the opponent as source for the threshold current of 1 μA . This value is obtained from *in vitro* experiments, and is

therefore not relevant for an artificial retina device implanted in an eye of a human.

Furthermore, it is known in the art that visual sensation is obtained also for signals below the measured threshold value. Therefore, the calculation furnished by the opponent fails to prove inoperability.

- (b) Since document D2 contains numerous contradictions, the skilled person would not consider it to be an enabling disclosure. Although document D2 reports of one successful implant, it is highly questionable that this single device was ever operable, taking in particular into account that the device of document D2 is coated with selenium which is known to be highly toxic.

The statement on column 1, line 70 to column 2, line 5 of document D2 suggesting that individual selenium crystal grains may act as discrete photovoltaic cells, is merely speculative, since in order for such an arrangement to work, the electrical resistance between individual crystal grains of selenium must be much higher than the resistance between the selenium crystal grains and the fluids in the adjacent cell structure in the eye. Since selenium is known from document D8, page 512, second paragraph, to be a good conductor, the resistance between individual crystal grains of selenium has to be low.

Finally, document D2 discloses that the artificial retina device is to be implanted between the retina and the choroid or between the choroid and

the sclera (cf. column 1, lines 37 to 42). In either case the incoming light has to pass through the retinal pigment epithelium (RPE) before reaching the artificial retina device. Since the RPE is a pigmented opaque layer, there would be little or no prospect of obtaining visual sensation, let alone an image with appreciable resolution, using the device of document D2.

Therefore, in view of the above considerations, the patent proprietor considers document D1 to represent the closest prior art, as held in the decision under appeal.

- (c) At the priority date of the patent in suit, there was a prejudice in the art against introducing an implant in the sub-retinal space, i.e. between the inner and outer retinal layers. The only locations in the eye which were considered in the prior art to be suitable for positioning an artificial retina device were either epiretinal, as disclosed in document D1, sub-choroidal, or sub-scleral, the latter both disclosed in document D2. The patent proprietor was the first to suggest an implant in the sub-retinal space.

Therefore, the skilled person would only consider the device of document D2 to be suitable for a sub-choroidal or sub-scleral implant. Since, as mentioned above, an artificial retina device implanted in a sub-choroidal or sub-scleral location would have no prospect of producing a high-resolution image, the skilled person would not consider improving the device of document D2,

and would rather concentrate his efforts on improving the device of document D1. This device, however, has an entirely different design from that of the claimed device, since it is an epiretinal device which produces a frequency-modulated signal.

Reasons for the Decision

1. The appeal meets the requirements of Articles 106 to 108 and Rule 64 EPC and is therefore admissible.
2. The new documents cited by the opponent with the statement of the grounds of appeal are not more relevant than the documents mentioned under item II above, and they were also not relied upon by the opponent in the oral proceedings before the Board. These documents are therefore disregarded under Article 114(2) EPC.
3. *Alleged Inoperability of the claimed device*
 - 3.1 In the opposition procedure, the opponent raised an objection under Article 100(b) EPC for the reason that the device as disclosed in the patent in suit could not operate as an artificial retina device. In this respect, the opponent referred to "extensive calculations and experiments" which, according to the opponent, showed that normal daylight or artificial light incident on a retina in an eye was insufficient in intensity to generate artificial vision by stimulation after having been converted in a photovoltaic cell into electrical stimulation signals. The opponent, however, did not

furnish the calculations and any details of the experiments.

3.2 With the statement of the grounds of appeal, the opponent provided for the first time a detailed calculation showing the alleged inoperability of the claimed device. In the calculation, references are made to numerous scientific publications, none of which however were filed with the statement of the grounds of appeal (cf. item VII(a) above).

3.3 Although the calculation furnished with the statement of the grounds of appeal was filed outside of the opposition period under Article 99(1) EPC, the Board exceptionally exercises its discretion under Article 114(2) EPC to admit the calculation into the appeal proceedings for the following reasons:

Firstly, the calculation and the arguments based on the calculation are technically straight-forward, so that they are not likely to cause any procedural delay or complication, if admitted into the appeal proceedings. Secondly, and especially, the patent proprietor declared at the oral proceedings that he was in a position to respond to this objection (cf. item VIII(a) above).

3.4 For the reasons which follow, however, the Board does not find the opponent's objection of lack of operability based on his calculation convincing:

Firstly, as the patent proprietor pointed out, even if the computed current values are accepted as correct and as representing the values under optimum conditions,

the calculation shows that the theoretical current induced from each photovoltaic cell is proportional to its area (cf. item VIII(a) above). Therefore, according to the calculation, a current above the alleged threshold voltage of 1 μ A is in principle attainable by using sufficiently large photovoltaic cells.

Secondly, the opponent has not provided any evidence to show that the stated threshold value of 1 μ A for simulation is relevant for an artificial retina device which is implanted in a human eye, since, as argued by the patent proprietor, this value related to *in vitro* experiments (cf. item VIII(a) above). The opponent not only failed to furnish the article by Zrenner et al. from which the threshold value was quoted, but was also not in a position to make any clarifying comments on this issue at the oral proceedings before the Board.

Therefore, the Board finds that the above objection raised under Article 100(b) EPC does not prejudice maintenance of the patent in suit.

4. *Request for the appointment of a neutral expert under Article 117(1)(e) EPC*

The opponent requested the appointment of a neutral expert under Article 117(1)(e) EPC in case the patent proprietor contested the findings of the opponent regarding inoperability of the claimed device and was not in a position to submit facts evidencing the operability and if the Board would have doubts relating to the calculations of the opponent furnished with the statement of the grounds of appeal.

In the present case, the only point of contention between the parties was the value of the threshold current of 1 μ A for stimulation. Since, as already discussed above, the computed values of current furnished by the opponent show that it is possible in principle to achieve current above 1 μ A in relatively large area photovoltaic cells, this issue, i.e. the exact value of the threshold current, is not relevant to the issue of the inoperability of the artificial retinal device as claimed. The Board therefore does not consider it necessary to appoint a neutral expert.

The request for appointing a neutral expert under Article 117(1)(e) EPC is therefore rejected.

5. *Inventive step - Main Request*

- 5.1 The patent in suit concerns an artificial retina device comprising an array of photovoltaic cells where each photovoltaic cell is disposed on one surface of a substrate. Each photovoltaic cell comprises an active electrode overlying a photosensitive layer. The output signal through each active electrode depends on the intensity of the incoming light, i.e. the output signal is amplitude modulated.

Claim 1 specifies that the device is "to be implanted between the inner and outer retina layers" (cf. layers 56 and 62, respectively, in Figure 4 of the patent in suit). In the following, an implant in this location will be referred to as a "subretinal implant".

Following the established practice of the EPO relating to the interpretation of functional features in device claims, this feature is in the following construed as

merely meaning that the device has to be *suitable* for being implanted between the inner and outer retina layers.

In its intended use inserted in an eye, incoming light produces an amplitude modulated signal in each photovoltaic cell which is transferred through the corresponding active electrode stimulating the adjacent cells in the inner retina layer.

5.2 Document D1 was considered the closest prior art in the decision under appeal. It discloses an artificial retina which comprises an array of photodiodes on one side of a substrate and electrodes on the other side of the substrate to be connected to the retina (cf. abstract). It is an epiretinal implant, i.e. it is to be placed on the inner retina layer such that the electrodes stimulate the nerve fiber layer (cf. column 3, lines 28 to 42). In order to mimic the signals the nerve fiber layer would receive in response to light received in a normal, functioning retina, it is required to provide additional circuitry requiring an external power source in order to transform the amplitude modulated signals from the photodiodes to frequency-modulated signals (cf. Figure 6; column 4, lines 27 to 53).

5.2.1 The device as defined in claim 1 according to the main request differs from the device of document D1 in that it has active electrode layers overlying the photosensitive layer so that, when implanted, the cells of the inner retina layer are stimulated by amplitude modulated signals. In the device of document D1, on the other hand, the active electrodes are formed on the

surface of the substrate which is opposite from that where the photodiodes are formed. This difference is also reflected in the feature that the claimed device has to be suitable for implantation between the inner and outer retina layers. Furthermore, document D1 discloses an array of photodiodes or a charged coupled devices (CCD) and does not disclose any photovoltaic devices.

- 5.3 Document D2 discloses an artificial retina device comprising a substrate with a photosensitive layer, such as selenium, deposited on the substrate (cf. Figures 1 and 2; column 1, line 62 to column 2, line 5). Alternatively, it is possible to omit the substrate if the photosensitive layer has sufficient mechanical strength (cf. column 2, lines 6 to 12). The device of document D2 is intended to be inserted between the retina and the choroid or between the choroid and the sclera (cf. column 1, lines 37 to 42). The device operates according to the so-called Becquerel effect which means that in use, the artificial retina device and the fluids in the adjacent cell structure act together as a photovoltaic element (cf. D2, column 2, lines 34 to 37). As a consequence, the output signal is amplitude modulated. It is furthermore stated that "the selenium crystal size must be as small as possible, so that the individual crystal potential developed under the action of the light image will have as high a degree of resolution as possible" (column 2, lines 1 to 5).

From the structural attributes of the device of document D2, it appears that it would be suitable for being implanted between the inner and the outer retinal layers, although this is not disclosed in document D2.

5.3.1 The claimed device thus differs from that of document D2, in that (a) it comprises a plurality of discrete photovoltaic cells, whereas the device of document D2 discloses a (polycrystalline) selenium layer; and (b) each photovoltaic cell comprises an active electrode layer, whereas in the device of document D2, no electrode layer is formed on the selenium layer.

5.3.2 Regarding feature (a) (plurality of discrete photovoltaic cells), the opponent referring to the above-mentioned passage in column 2, lines 1 to 5, argued that document D2 discloses a plurality of discrete photovoltaic cells, since when the photosensitive selenium layer is made thin enough, each individual selenium crystal would function as an individual photovoltaic cell (cf. item VIII(b) above).

As convincingly argued by the patentee, however, the above-mentioned passage in document D2 is firstly in contradiction with the teaching of covering the whole surface of the supporting base with a thin layer of photosensitive material, and the statement that it would be possible to dispense with the supporting base altogether if the photosensitive layer has sufficient mechanical strength (cf. item VIII(b) above).

Secondly, if the selenium layer were to be thin enough to consist of a monolayer of individual crystal grains, then, as submitted by the patent proprietor, such an arrangement would only be able to function as an array

of individual photovoltaic cells if the contact resistance between adjacent selenium grains was much larger than the resistance between a selenium grain and the fluid of the adjacent eye cells. Since polycrystalline selenium is known to be a good conductor, the contact resistance between adjacent grains cannot be very large, and consequently, the arrangement does not consist of individual, electrically isolated photovoltaic cells. Therefore, the statement in document D2 suggesting that individual selenium grains might function as individual photovoltaic cells must be regarded as speculative.

5.4 Nevertheless, the Board follows the opponent that document D2 should be considered the closest prior art, since it has the common features with the claimed device that it relates to an artificial retina device which is suitable for a *subretinal* implant. It furthermore operates according to photovoltaic effect and produces an amplitude modulated signal. In contrast, the device of document D1 is only suitable for an epiretinal implant and produces a frequency modulated signal. Furthermore, document D1 does not disclose any photovoltaic elements.

5.5 According to the opponent, the technical problem starting from the device of document D2 relates to providing an improved semiconductor device which does not contain toxic compounds, such as selenium (cf. item VII(c) above).

The opponent argued that a skilled person faced with the above problem would arrive at the claimed device in a routine manner merely by replacing the outdated

selenium-based technology with an array of photovoltaic devices made of silicon, as commonly known in the art, and as exemplified in document D4. Since this modification would be considered as a normal step of upgrading the device of document D2 to the state of the art at the priority date of the patent in suit, such a replacement would be considered as a natural technological development without any inventive merit (cf. item VII(d) above).

5.6 The Board finds that the above argument against inventive step is based on hindsight, since it fails to interpret the disclosure of document D2 in the manner in which it would have been understood by the skilled person at the priority date of the patent in suit. Although the Board does not doubt that a skilled person *could* modify the device of document D2 to arrive at the claimed device given the task of modifying the device of document D2, the Board finds, for the reasons which follow, that the skilled person at the priority date of the patent in suit *would not* contemplate such a modification at all.

5.6.1 It was not contested that the patent proprietor was indeed the first one to suggest, contrary to the prevalent practice and prejudice, that a retinal device could be inserted between the inner and the outer retina layers. At the priority date of the patent in suit, the known artificial retina devices were designed to be implanted only in the locations as disclosed in documents D1 and D2 (cf. item VIII(c) above).

5.6.2 Document D2 consistently discloses that the device described therein is to be implanted behind the retina layer either between the retina and the choroid or between the choroid and sclera (cf. column 1, lines 37 to 52). Both these locations, however, have the severe drawback that the incoming light has to pass through the retinal pigment epithelium (RPE) (cf. layer 58 in Figure 4 of the patent in suit), which is an opaque, pigmented layer of cells. Thus, only a limited amount of light will be able to pass through the RPE to reach the artificial retina device. Furthermore, since the RPE is opaque, it could only be expected that the image obtained from light transmitted through the RPE could, at best, have only very poor resolution.

5.6.3 Thus, the skilled person would not at the priority date of the patent in suit consider any modification of the device of document D2 which is to be implanted between the retina layer and the choroid or between the sclera and the choroid, since an implant in both of these positions would receive only a limited amount of light passing through the RPE layer, so that the skilled person would not regard any modifications of the device of document D2 to be useful for improving the vision. It is thus only with the knowledge furnished by the patent proprietor of the possibility of implanting an artificial retina device between the inner and outer retina layers that the issue of upgrading the device of document D2 would have any practical significance.

5.7 Also a skilled person starting from document D1, as in the decision under appeal, would fail to arrive at the claimed subject matter for similar reasons. The skilled person would only regard the device of document D2 to

be suitable for an implant behind the RPE layer with its substantial drawbacks, as mentioned above. Therefore, the skilled person would not consider combining the teaching of document D1 with that of document D2.

5.8 Therefore, in the Board's judgement, the patent in suit meets the requirements of inventive step within the meaning of Article 56 EPC.

6. For the above reasons, none of the grounds for opposition raised by the opponent (appellant) prejudice the maintenance of the patent in suit as granted, and therefore, the appeal has to be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

U. Bultmann

R. K. Shukla