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Datasheet for the decision of 17 May 2010

Case Number: T 0566/07 - 3.3.02

Application Number: 99921290.5

Publication Number: 1075284

IPC: A61K 49/00

Language of the proceedings: EN

Title of invention:
The use of a vital dye for facilitating surgical procedures for vitreo-retinal surgery

Patentee:
Melles, Gerrit Reinold Jacob

Opponent:
Industria Terapeutica Splendore Alfa Intes
FLUORON GmbH

Headword:
Vital dyes for vitreo-retinal surgery/MELLES

Relevant legal provisions:
EPC Art. 53(c)

Relevant legal provisions (EPC 1973):
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Keyword:
"All requests: allowability under Art. 53(c) EPC - no: Claim 1 comprises two separate methods, i.e. a diagnostic method defined by a Swiss-type claim followed by a separate method of surgery"

Decisions cited:
G 0005/83, G 0002/08, T 1020/03

Catchword:
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Case Number: T 0566/07 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 17 May 2010

Appellant: (Opponent II)	FLUORON GmbH Biberkopfweg 1 D-89231 Ulm (DE)
Representative:	Leissler-Gerstl, Gabriele Hoefer & Partner Patentanwälte Pilgersheimer Strasse 20 D-81543 München (DE)
Respondent: (Patent Proprietor)	Melles, Gerrit Reinold Jacob 's Landswerf 69 NL-3063 GC Rotterdam (NL)
Representative:	Bijvank, Koen Mattijs Lodewiek Vereenigde P.O. Box 87930 NL-2508 DH Den Haag (NL)
Party as of right: (Opponent I)	Industria Terapeutica Splendore Alfa Intes Via Fratelli Bandiera, 26 I-80026 CASORIA NA (IT)
Representative:	Prato, Robert STUDIO TORTA Via Viotti, 9 I-10121 Torino (IT)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted 1 February 2007 rejecting the opposition filed against European patent No. 1075284 pursuant to Article 102(2) EPC 1973.**

Composition of the Board:

Chairman: U. Oswald
Members: A. Lindner
T. Karamanli

Summary of Facts and Submissions

I. European patent No. 1 075 284 based on application No. 99 921 290.5 was granted on the basis of a set of 11 claims. The mention of the grant of the patent was published on 12 February 2003.

The sole independent claim reads as follows:

"1. Use of at least one vital dye for the manufacture of a composition for staining a retinal membrane in an eye."

II. Two oppositions were filed against the granted patent. The patent was opposed under Article 100(a) EPC 1973 for lack of novelty, lack of inventive step, and exclusion from patentability under Article 52(4) EPC 1973, as well as under Article 100(b) 1973 EPC for insufficiency of disclosure.

III. The documents cited during the opposition and appeal proceedings included the following:

(4) J. Fr. Ophthalmol., 20(3), 1997, 189-194
(17) Albrecht v. Graefes Arch. klin. exp. Ophthal., 178, 1969, 72-87

IV. In the decision announced on 13 December 2006, the opposition division rejected the opposition. Its principal findings in the reasons for the decision posted on 1 February 2007 were as follows: in connection with the ground for opposition according to Article 100(b) EPC 1973, it was held that the examples showed how the invention could be carried out with

trypan blue and it was up to the opponents to prove that other vital dyes did not work, which they had failed to do. Moreover, the use as claimed was not excluded from patentability by Article 52(4) EPC 1973. The claimed subject-matter was novel, as document (4) concerned staining of idiopathic subretinal neovascular membranes, which were different from retinal membranes, and document (17) related to the staining of gliose structures, which belonged to the retina and not to the retinal membrane. Moreover, starting from document (17) as closest prior art, the claimed subject-matter involved an inventive step, as it was not obvious that dyes which were suitable for staining the retina itself would also stain pathological retinal membranes.

V. Opponent II (appellant) lodged an appeal against that decision.

VI. With a letter of 27 November 2009, the appellant submitted new documents in connection with objections concerning novelty, inventive step and insufficiency.

VII. With an official communication of 8 December 2009, the parties were summoned to oral proceedings appointed for 17 May 2010.

VIII. With a letter of 9 March 2010, the respondent (patentee) filed a main request and two auxiliary requests.

IX. In a letter of 16 April 2010, the appellant raised objections under Article 84 EPC 1973 and Article 123(2) and (3) EPC. The objections raised in connection with Article 100(a) and (b) EPC 1973 were maintained.

X. With a letter of 19 April 2010, opponent I (party as of right) declared that he would not attend the oral proceedings.

XI. With a letter of 20 April 2010, the respondent filed a new main request.

XII. The sole independent claims 1 of the requests on file read as follows:

(i) main request:

"1. Use of at least one vital dye for the manufacture of a composition for staining a retinal membrane in an eye to visually distinguish the retinal membrane from the underlying retina in a method for performing retinal membrane removal."

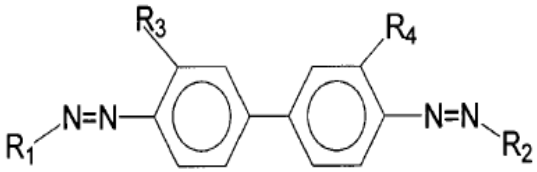
(ii) auxiliary request 1:

"1. Use of at least one vital dye for the manufacture of a composition for staining a retinal membrane in an eye to visually distinguish the retinal membrane from the underlying retina in a method for performing retinal membrane removal, wherein the retinal membrane is stained by applying the dye onto the membrane."

(iii) auxiliary request 2:

"1. Use of at least one vital dye for the manufacture of a composition for staining a retinal membrane to visually distinguish the retinal membrane from the underlying retina in an eye in a method for performing retinal membrane removal, wherein the retinal membrane

is a proliferative vitreo-retinal membrane or an epitretinal membrane, wherein the retinal membrane is stained by applying the dye onto the membrane, and wherein the dye is chosen from the group of azafloxin, basic blue (nil blue sulphate), bismarck brown, basic red (rhodamine 6G), bengal red, brilliant crysyl blue, eosin, fluorescein, gentian violet, indocyanine green, janus green, methylene green, methylene blue, neutral red, trypan blue, trypan red, and dyes having the formula (I)



(I)

wherein R_1 and R_2 are the same or different aryl groups, and wherein R_3 and R_4 are independently chosen from hydrogen, methyl, ethyl, methoxy, amino, hydroxyl and sulfonate, and combinations thereof."

XIII. Oral proceedings took place on 17 May 2010.

XIV. The appellant's arguments can be summarised as follows:

Claim 1 of the main request concerned a Swiss-type claim directed to the staining of retinal membranes, which was followed by the surgical step of removing said retinal membrane. The staining procedure concerned a diagnostic procedure for which a Swiss-type claim was applicable. However, there was no interrelationship

between the staining procedure and the subsequent membrane removal, as the vital dye did not make any contribution to said removal. As a consequence, claim 1 related to two procedures, i.e. a diagnostic procedure, which was defined by a Swiss-type claim and therefore not exempted from patentability by Article 53(c) EPC, followed by a separate method of surgery, which was exempted from patentability by Article 53(c) EPC.

XV. The respondent's arguments can be summarised as follows:

Claim 1 of the present main request was construed in the Swiss-type format for which decision G 0005/83 (OJ EPO 1985, 64) was applicable and which was directed to a single surgical procedure comprising staining the retinal membrane in order to visually distinguish it from the underlying retina so that it could then be removed more easily. According to decision T 1020/03 (OJ EPO 2007, 204), there was a seamless fit: either a method did not relate to a therapeutic treatment and therefore fell outside the provision of Article 53(c) EPC or it did concern a method as defined by Article 53(c) EPC 1973, in which case a claim in the Swiss-type format was patentable subject to compliance with the other provisions of the EPC (see point 36 of T 1020/03). Such was the case here: the surgical method as such was not allowable under the corresponding Article 53(c) EPC, so that a Swiss-type claim was the appropriate format. Furthermore, it was clearly stated in decision G 0002/08 of 19 February 2010 that the term "any specific use" must not be interpreted narrowly. For these reasons alone, claim 1 was allowable under Article 53(c) EPC.

Moreover, the appellant's argument that claim 1 related *de facto* to two different methods involving first a diagnostic method followed by a surgical method was not based on a reasonable interpretation of the technical content of the contested patent.

XVI. The appellant requested that the decision under appeal be set aside and that the patent be revoked.

The respondent requested that the decision under appeal be set aside and the patent be maintained in amended form on the basis of the claims according to the main request, filed with a letter of 20 April 2010 or according to the first and second auxiliary requests, filed with a letter dated 9 March 2010.

Reasons for the Decision

1. The appeal is admissible.

2. Admissibility of the main request and auxiliary requests 1 and 2:

With a letter of 9 March 2010, i.e. at a late stage of the appeal proceedings, the respondent filed a new main and two auxiliary requests. However, the amendments made were a reaction to objections and to new documents submitted by the appellant with a letter dated 27 November 2009. Then, with a letter of 20 April 2010, the respondent filed a new main request. The only modification as compared to the main request filed with letter dated 27 November 2009 concerned a change of the back reference in dependent claim 7, which had been

objected to by the appellant in its letter dated 16 April 2010. The appellant did not raise any objections against the admission of these requests. Since the present requests were filed in reaction to the appellant's submissions and do not raise complex subject-matter, the board decided to admit these requests into the proceedings (Article 13 RPBA).

3. Main request - Article 53(c) EPC:

3.1 Applicable law:

The present decision was taken after the revised European Patent Convention entered into force on 13 December 2007. Since the European patent in suit was granted before that date, Article 53(c) EPC applies and Article 54(5) EPC does not apply to it, in accordance with Article 7(1), second sentence, of the Act revising the EPC of 29 November 2000 and Article 1 Nos. 1 and 3 of the Decision of the Administrative Council of 28 June 2001 on the transitional provisions under Article 7 of the Act revising the European Patent Convention of 29 November 2000 (Special edition No. 1, OJ EPO 2007, 197).

3.2 According to decision G 0005/83, a European patent may be granted with so-called Swiss-type 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 point 2 of the order). This approach was a "special approach to the derivation of novelty" (see point 21 of G 0005/83) and therefore constituted a narrow exception to the principles governing the novelty requirements which was

not intended to be applied in other fields of technology (see G 0002/08, point 7.1.1 of the Reasons). Since the intention of the legislator was clearly not to exclude second therapeutic indications of a known medicament from the field of patentability the so-called Swiss-type claim constituted the adequate but exceptional solution (see G 0002/08, point 7.1.1 of the Reasons). In view of these considerations, the board takes the view that this exception to the general novelty requirement is only justified if a claim is indeed drafted in a clear Swiss-type format.

The abolition of Swiss-type claims as decided by the Enlarged Board of Appeal in its decision G 0002/08 has no retroactive effect (see G 0002/08, point 7 and in particular point 7.1.4 of the Reasons) and does therefore not apply in the present case. Moreover, the board notes that Article 54(5) EPC does not apply to the present patent (see point 3.1 above).

Claim 1 of the main request is drafted as a Swiss-type claim (see point XI(i) above), but differs from the Swiss-type format adopted by the Enlarged Board of Appeal in its decision G 0005/83 in that it comprises several applications: the composition manufactured by using at least one vital dye is to be used

(a) for staining a retinal membrane in an eye

(b) for distinguishing the retinal membrane from the underlying retina

(c) in a method for performing retinal membrane removal.

It therefore has to be evaluated how the various applications are related to each other and to the composition manufactured from the vital dye.

3.3 The board is of the opinion that there is a causal link between features (a) and (b) in that feature (b) further specifies the staining of the retinal membrane. The combination of features (a) and (b) defines a single staining method, in which the retinal membrane is stained but the retina or the adjacent tissue in general is either not stained or stained with a different intensity and/or a different hue. Identical staining of the retinal membrane and the adjacent tissue, which would inhibit differentiation, is thereby excluded.

3.4 As regards the interrelationship of features (a)/(b) on the one hand and feature (c) on the other hand, the respondent argued that claims had to be read in a reasonable way taking into account the technical teaching of the patent and the general knowledge of the skilled person. The technical teaching of the contested patent excluded the concept of two separate methods, i.e. a diagnostic method followed by a separate method of surgery, for the following reasons:

3.4.1 *The staining of the retinal membrane could not be carried out for purely diagnostic purposes, as the diagnosis, i.e. the verification of the presence of a retinal membrane, had already been made before.*

The board wants to point out that fact that the presence of the retinal membrane had already been established does not exclude a second diagnostic step

by means of staining. According to the patent (see column 3, lines 2-8) the vital dye to be applied provides sufficient staining for a useful colouring to be visible, which means that the staining step allows a better view of the retinal membrane and thus a better identification of its form and structure, which constitutes a method of diagnosis.

3.4.2 *The vital dyes used in the present invention were not suitable for purely diagnostic purposes, as a visual distinction could only be made during retinal membrane peeling.*

The board notes that this argument of the respondent is not in line with the technical teaching of the contested patent. Again, reference is made to the passage in column 3, lines 2-8 ("…the minimum amount of dye which is necessary to provide sufficient staining **for a useful coloring to be visible** should be so low…" [emphasis by the board]). The board therefore concludes that the staining may be performed in order to increase visibility of the retinal membrane.

The respondent further explained that *in view of its position between the vitreous and the retina, the retinal membrane covered and therefore hid the retina and that was the reason why a differentiation between the stained retinal membrane and the unstained or differently stained retina was possible only during retinal membrane peeling.*

This argument is not convincing, as, firstly, there are retinal membranes which do not completely cover the retina and, secondly, even if they do, the staining

nevertheless improves their visibility, even if the underlying retina is not discernible in this case.

3.4.3 *The respondent further reasoned that the staining step is technically not separable from the membrane removal step, as the dye is in a preferred embodiment directly applied onto the retinal membrane after removal of the vitreous.*

It is correct that example 2 of the contested patent describes such a staining technique, which is, however, as correctly pointed out by the respondent, a preferred embodiment of the invention. The subject-matter of claim 1 is not restricted to a specific method of applying the vital dye. As a consequence, other methods conventionally used such as intravenous or intravitreal injection, which allow a separation between staining of the retinal membrane and its removal, are included.

Finally, reference is made to column 4, lines 53-56 of the contested patent, which indicates that retinal membrane staining is **preferably** [emphasis by the board] employed as part of a vitreo-retinal surgical procedure, which means that separate staining, e.g. for diagnostic purposes, is envisaged as a less preferred embodiment.

3.5 As a consequence, the board concludes that it is reasonable, both technically and in view of the teaching of the contested patent, to regard the staining procedure as a first activity, which is then followed by a second surgical method.

3.6 Moreover, the concept of two separate subsequent methods is not excluded by the wording of claim 1. In this context, the term "in a method…", which forms the link between staining and membrane removal but does not precisely define the nature of said link, is of particular interest. In the board's view, the term "in a method…" may imply that the staining procedure is embedded in the membrane removal procedure, but it also has the meaning that the staining of the retinal membrane is simply carried out in the larger context of membrane removal surgery. Thus, the wording of claim 1 includes the situation that a retinal membrane, whose presence has already been diagnosed, is stained in order to improve its visibility so that more details can be recognised, which is a further diagnostic step. Then, in the light of these results, the ophthalmologist can decide whether or not to remove it. In view of the fact that the dye can be applied intraveneously or intravitreously, there is no obligation to perform the membrane removal right after the staining procedure.

3.7 To summarise:

3.7.1 In the light of the teaching of the contested patent two options are technically reasonable. The present invention may relate to

(a) a single method comprising both staining of the retinal membrane and its removal; or

(b) a first method of staining the retinal membrane followed by a separate method of its removal.

3.7.2 In connection with the wording of present claim 1, it was concluded in point 3.6 above that the link between staining and membrane removal ("in a method…") also includes both options (a) and (b).

3.8 For determining whether the skilled person would read present claim 1 as a single method or as a sequence of two independent activities, the purpose defined in the Swiss-type wording is of critical importance: claim 1 is directed to the "use of at least one vital dye for the manufacture of a composition **for staining a retinal membrane**…" [emphasis by the board]. The indication of the purpose "for staining a retinal membrane" defines the activities encompassed by the Swiss-type format: all steps relating to the staining are comprised. The removal of the retinal membrane is not part of the staining procedure. It would therefore not be reasonable to include the important step of retinal membrane removal in a method defined as "use of at least one vital dye for the manufacture of a composition for staining a retinal membrane…". The inclusion of this step would even be contradictory to the purpose mentioned above.

3.9 The board therefore had to conclude that present claim 1 has to be read as a sequence of two separate activities: a use of at least one vital dye for the manufacture of a composition for staining a retinal membrane, drafted in the Swiss-type format and therefore not in conflict with Article 53(c) EPC, followed by a separate surgical method of removing the retinal membrane, which is not drafted in the Swiss-type format and is therefore excluded from patentability pursuant to Article 53(c) EPC.

3.10 Cited decisions:

3.10.1 The respondent cited decision T 1020/03 in support of the allowability of present claim 1 under Article 53(c) EPC. In said decision (see point 79 of the Reasons) the case was remitted to the first instance "for further consideration of novelty and inventive step, depending on whether the intended method of therapy was itself novel and inventive, taking into account **all the features of the use in the claim**…" [emphasis by the board].

The board is of the opinion that decision T 1020/03 is not relevant for the subject-matter as claimed in claim 1 of the present main request, as the claim which was the subject of said decision was a Swiss-type claim defining a single method of therapy which apart from the therapeutic indication comprised the dosage regimen as an additional feature. The same applied in decision G 0002/08, also cited by the respondent in this context. However, neither of these two decisions concerned a claim including two separate sequential activities, one of which is excluded from patentability pursuant to Article 53(c) EPC.

3.10.2 A further decision cited by the respondent in this context was decision G 0001/07 of 15 February 2010. However, this decision is not relevant for the present case for the same reasons as outlined above in point 3.10.1. It does not relate to a situation, where a claim refers to two separate sequential activities, one of which is excluded from patentability pursuant to Article 53(c) EPC.

3.11 As claim 1 includes a separate method of surgery, the claim as a whole is excluded from patentability pursuant to Article 53(c) EPC.

3.12 In view of the board's finding as regards claim 1, an evaluation of the dependent claims is not necessary.

4. First auxiliary request - Article 53(c) EPC:

Claim 1 of the first auxiliary request differs from claim 1 of the main request by the additional feature that the underlying membrane is stained by applying the dye onto the membrane. It is noted that this feature does not restrict the staining procedure to a method as described in example 2 of the contested patent, wherein the dye is directly applied onto the retinal membrane by means of a brush or a canula after removal of the vitreous. All that this feature implies is that the staining effect is obtained by the incorporation of the vital dye into the retinal membrane, thereby excluding negative staining, i.e. where the surrounding tissue but not the retinal membrane itself is stained. As a consequence, this additional feature does not alter the fact that claim 1 of the first auxiliary request is not allowable under Article 53(c) EPC, as it comprises two separate activities, the second of which concerns a surgical procedure (see point 3 above).

5. Second auxiliary request - Article 53(c) EPC:

Claim 1 of the second auxiliary request differs from claim 1 of the first auxiliary request in that both the retinal membrane and the vital dye are more

specifically defined. But these further definitions likewise do not alter the fact that claim 1 of the second auxiliary request is not allowable under Article 53(c) EPC, as it comprises two separate activities, the second of which concerns a surgical procedure (see points 3 and 4 above).

6. In view of the fact that none of the requests on file are allowable under Article 53(c) EPC, an evaluation of the formal objections raised by the appellant in connection with the amendments made in the course of the appeal proceedings and of the other grounds of opposition is not necessary.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The European patent is revoked.

The Registrar: The Chairman:

N. Maslin U. Oswald