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Datasheet for the decision of 11 January 2012

Case Number: T 0197/08 - 3.3.02

Application Number: 94305752.1

Publication Number: 639563

IPC: C07C 405/00, A61K 31/557, A61P 27/06

Language of the proceedings: EN

Title of invention:
Use of fluprostenol isopropyl ester for the manufacture of a medicament for the treatment of glaucoma and ocular hypertension

Patentee:
ALCON LABORATORIES, INC.

Opponent:
Pohlman, Sandra M.

Headword:
Fluprostenol isopropyl ester/ALCON LABORATORIES, INC.

Relevant legal provisions:
EPC Art. 123(2), 111

Relevant legal provisions (EPC 1973):
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Keyword:
"Main request - allowability of amendments (yes)"
"Remittal (yes): undecided issues"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0197/08 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 11 January 2012

Appellant: (Patent Proprietor)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 7 November 2007 revoking European patent No. 639563 pursuant to Article 102(1) EPC 1973.

Composition of the Board:

Chairman: U. Oswald
Members: A. Lindner
R. Cramer

Summary of Facts and Submissions

I. European patent No. 0 639 563 based on application No. 94 305 752.1 was granted on the basis of 5 claims. The independent claims read as follows:

"1. A topical ophthalmic composition for use in the treatment of glaucoma and ocular hypertension comprising, as the sole active ingredient, a therapeutically effective amount of fluprostenol isopropyl ester.

5. Use of fluprostenol isopropyl ester as the sole active ingredient for the manufacture of a medicament for topical application for the treatment of glaucoma and ocular hypertension."

II. An opposition was filed against the patent. The patent was opposed under Article 100(a) EPC for lack of inventive step, under Article 100(b) EPC for insufficiency of disclosure and under Article 100(c) EPC on the ground that the claims as granted contained subject-matter extending beyond the content of the application as originally filed. In the course of the opposition proceedings, the opponent additionally sought to introduce lack of novelty (Article 100(a) in conjunction with Article 54 EPC) as new ground for opposition.

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

(1) EP-A-0 603 800.

IV. In the decision pronounced on 15 October 2007 and posted on 7 November 2007, the opposition division revoked the patent pursuant to Article 102(1) EPC 1973.

V. In said decision, the opposition division came to the conclusion that the subject-matter of the main request in the form of the claims as granted extended beyond the content of the application as filed as no basis could be found for the limitation introduced into claim 1 by the term "sole active agent". Moreover, this term did not constitute an undisclosed disclaimer vis-à-vis the post-published document (1).

As regards the auxiliary request, the opposition division decided that the deletion of "sole active agent" and subsequent introduction of the term "consisting of a therapeutically effective amount of fluprostenol isopropyl ester and a suitable ophthalmic vehicle" resulted in a broadening of the scope. As a consequence, the requirements of Article 123(3) EPC were not met.

VI. The appellant (patentee) lodged an appeal against that decision.

VII. In a letter dated 16 December 2011, the respondent requested that, in case the board did not confirm the decision of the opposition division with respect to Articles 123(2) and 123(3) EPC, the case not be remitted to the department of first instance.

VIII. At the oral proceedings held before the board on 11 January 2012 the appellant filed a new main request and auxiliary request 1. The sole claim of the main

request is identical to claim 5 as granted. At the oral proceedings the respondent withdrew its request submitted with the letter dated 16 December 2011 and requested now that the case be remitted to the department of first instance if the board did not confirm the decision of the opposition division with respect to Articles 123(2) and 123(3) EPC.

IX. The appellant essentially argued as follows:

The filing of the new main request and of auxiliary request 1 was a reaction to objections raised for the first time at the oral proceedings before the board. Regarding the main request, the sole claim was identical to claim 5 as granted so that the respondent could not be taken by surprise.

In connection with the basis for the feature "fluprostenol isopropyl ester as the sole active ingredient" in the original application, it was argued that the word "sole" simply implied that only one active ingredient was present. The term "active ingredient", however, did not encompass every ingredient having any activity but meant any ingredient having the pharmacological activity indicated in the claims, i.e. any ingredient effective for the topical treatment of glaucoma and ocular hypertension. The original application clearly provided a basis therefor: firstly, combination products were not mentioned therein, secondly, the original application made an unambiguous distinction between active ingredients, which were discussed in the passage on page 5, line 15, to page 7, line 26, in which on page 7, line 5, fluprostenol isopropyl ester (FIE) was mentioned as a

preferred compound, and other ingredients, which were described in a separate passage starting on page 7, line 28. These other ingredients included among others antimicrobial preservatives, co-solvents and viscosity agents. Furthermore, examples 5 to 8 concerned tests in which a single active ingredient was used and each of the eight compositions according to example 9 comprised a sole active ingredient.

X. The respondent essentially argued as follows:

The new requests were filed at a very late stage of the appeal proceedings and therefore not admissible. The appellant should have been aware that a claim relating to a first medical use was different in scope from a Swiss-type claim so that different problems might arise under Article 123(2) EPC. As a consequence, the new requests should have been filed earlier. It was emphasised that in other appeal proceedings in which the respondent of the present proceedings was patentee, new requests had been found inadmissible under similar circumstances. As a consequence, the new requests in these proceedings should, in the interest of equal treatment, not be admitted either.

In connection with the basis of the feature "fluprostenol isopropyl ester as the sole active ingredient" in the original application, the respondent essentially argued that the term "as the sole active ingredient", which was absolute and exclusive, was not expressly mentioned in the original application. Nor did the original application contain a definition for it. Said term excluded any compound that had activity. Such formulations were, however, not disclosed in the

original application. Examples 5 to 8 did not refer to formulations at all but concerned the testing of compounds. These examples could therefore not serve as a basis for said feature. In addition, examples 5 to 6 preferred cloprostenol isopropyl ester over FIE and therefore even taught away from the use of FIE. As regards example 9, only one (formulation 4) out of eight formulations contained FIE. It followed therefrom that the introduction of "as the sole active ingredient" was *per se* not allowable under Article 123(2) EPC. In addition, its combination with FIE, which was selected from a group of compounds in which it was not its most preferred active ingredient, constituted an unallowable selection from two lists.

XI. The appellant requested that the decision under appeal be set aside and the case be remitted to the department of first instance for further prosecution on the basis of the main request or auxiliary request 1, all filed at the oral proceedings on 11 January 2012, or on the basis of auxiliary request 2, filed with the statement of the grounds of appeal dated 17 March 2008.

The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. Admissibility of the main request

This request was filed at a late stage of the oral proceedings before the board. Its admissibility is

therefore at the board's discretion and depends upon the overall circumstances of the case under consideration (see Article 13 RPBA). As the amendments were a reaction by the appellant to objections raised by the board for the first time at the oral proceedings in connection with claim 1 of the previous main request and as the respondent could not have been taken by surprise by the amendments in view of the fact that the sole claim of the new main request is identical to claim 5 of the previous main request, the board decided to admit the new main request into the proceedings (Article 13 RPBA).

3. Main request - Article 123(2) EPC

Article 123(2) EPC stipulates that the European patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed. According to the established jurisprudence of the boards of appeal, this content encompasses what can be directly and unambiguously deduced from the explicit and implicit disclosure of the application as filed in its entirety.

3.1 As a first step, the meaning of the expression "active ingredient" has to be clarified. According to the respondent, it comprises every compound having any activity. Such a definition does not appear to be suitable in view of the fact that virtually every compound interacts with its environment somehow and therefore shows some sort of activity. Such a meaning of active ingredient would restrict claim 1 to the use of IEP as such, i.e. to the use of IEP in the absence of any additional compounds including excipients or

preservatives, and this is clearly not how the skilled person would read the sole claim of the main request.

Taking into consideration that the skilled person makes a distinction between active ingredient on the one hand and excipients on the other hand, it might be argued that active ingredient encompasses every compound having any **pharmacological** activity including pharmacological activities not related to those defined in the claim. However, such an interpretation amounts more or less to the same restriction of the claim as the former definition. The appellant cited water, which may be used for treating dehydration, or sodium chloride, which is suitable for treating sodium deficiency, as examples of compounds having a pharmacological activity. The skilled person would not associate the exclusion of these compounds with the feature "as the sole active ingredient". As a consequence, this definition is not correct either.

The board concludes that "active" in the feature "as the sole active ingredient" implies an activity in relation to the treatment defined in the Swiss-type claim. As a consequence, the feature "as the sole active ingredient" excludes further compounds characterised by a pharmacological activity which mitigates or otherwise influences the symptoms of glaucoma and ocular hypertension. It does not, however, exclude further compounds such as preservatives, co-solvents and viscosity building agents. In this context, it is noted that some ocular preservatives such as boric acid may also be used as active ingredients for the treatment of inflammations, which in combination with conjunctival hyperemia and edema

are known side effects of prostaglandins used in the treatment of ocular hypertension including FIE (see page 2, lines 13-15, and page 32, lines 1-12, of the original application). However, the fact that such preservatives may be able to lessen some side effects possibly caused by FIE does not make them active ingredients in the sense of the claim. These preservatives are not excluded from the claim of the present main request in view of the fact they do not have any activity in connection with glaucoma and ocular hypertension.

The board therefore concludes that the Swiss-type claim according to the main request relates to a medicament for topical application which, apart from FIE, does not comprise additional compounds which are able to treat glaucoma and ocular hypertension. Further compounds such as e.g. the preservatives, co-solvents and viscosity building agents mentioned above are not excluded.

3.2 The board notes that the feature "fluprostenol isopropyl ester as the sole active ingredient" is not as such mentioned in the original application. The original application cites FIE as one of the preferred, albeit not the most preferred, active ingredients (see page 4, lines 14-17, and page 7, lines 4-8), but does not specify *expressis verbis* that it should be used as the sole active ingredient. In fact, the general description does not explicitly disclose monotherapy for any of the active agents therein; it merely says that certain cloprostenol and fluprostenol analogues as well as compounds according to general formula (IV) are useful in treating glaucoma and ocular hypertension

(see page 4, lines 22-26, and page 7, lines 10-11). Original claim 16 concerns the "use of a compound of formula (IV) … for the manufacture of a medicament for topical application for the treatment of glaucoma and ocular hypertension". These passages encompass both monotherapy and combination therapy and therefore cannot serve as a basis for the feature "fluprostenol isopropyl ester as the sole active ingredient".

However, the evaluation of the overall content of a patent application also requires an analysis of the examples disclosed therein. The original application comprises nine examples.

Examples 1 to 4 concern the synthesis of some active ingredients and are therefore irrelevant in this context. Examples 5 and 6 deal with pharmacological assays of some active ingredients including FIE (compound B) in which the intraocular pressure lowering effect (example 6) and development of hyperemia as an unwanted side effect (example 5) were examined on the basis of animal models. Examples 7 and 8 also describe animal models in which the intraocular pressure lowering effect of some active ingredients not including FIE are studied. Although not relating to pharmaceutical formulations, as was correctly pointed out by the respondent, these examples nevertheless reveal that the active ingredients disclosed in the original application are suitable for monotherapy.

Example 9 discloses eight pharmaceutical formulations for topical use for lowering the intraocular pressure. Although different active ingredients are used (various cloposterol derivatives in formulations 1-3, 5 and 7-8;

FIE in formulation 4; and 13,14-dihydrofluprostenol in formulation 6), these formulations have one thing in common, namely that a sole active ingredient in the sense as defined above was used.

3.3 To summarise: the general part of the description does not explicitly refer to the use of a sole active ingredient but includes both monotherapy and combination therapy. All the formulations of example 9 comprise a sole active ingredient, there is not a single formulation exemplifying combination therapy. The concept of monotherapy is confirmed by examples 5 to 8, in which the suitability of the active ingredients as sole active agents in terms of pharmacological effects and side effects is shown.

The board concludes therefrom that monotherapy, i.e. the use of a sole active ingredient, constitutes the preferred form of administration in the original application. This preference is not restricted to FIE but concerns all the active ingredients disclosed in the original application and therefore has general character. FIE was selected from a list of compounds, and in particular from a list of six particularly preferred active ingredients (see page 7, lines 4-8) and combined monotherapy (as the sole active ingredient), which constitutes *de facto* the only administration form envisaged in the original application. Under these circumstances, the board concludes that the feature "fluprostenol isopropyl ester as the sole active ingredient" is not the result of two selections from different lists, as basically only one selection, i.e. the selection of FIE from a list of six preferred active ingredients, has to be

made in order to arrive at the feature mentioned above. As a consequence, the requirements of Article 123(2) EPC are met.

4. Remittal to the first instance:

Although Article 111(1) EPC does not guarantee an absolute right to have all the issues in the case considered by two instances, it is well recognised that any party should where appropriate be given the opportunity to have two readings of the important elements of the case. Hence, a case is normally referred back if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

In view of the fact that the opposition division only decided on the ground of opposition according to Article 100(c) EPC, leaving aside the further grounds of opposition cited in the notice of opposition, the board has reached the conclusion that, in the circumstances of the present case, the case should be remitted to the department of first instance for further prosecution, all the more so, as remittal was requested by both parties.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution.

The Registrar: The Chairman:

N. Maslin U. Oswald