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Datasheet for the decision of 16 September 2008

Case Number: T 1357/06 - 3.3.02

Application Number: 98200252.9

Publication Number: 0861666

IPC: A61K 31/4439

Language of the proceedings: EN

Title of invention:
Pharmaceutical composition for use in treatment of diabetes

Patentee:
Takeda Pharmaceutical Company Limited

Opponent:
Teva Pharmaceutical Industries Ltd.

Headword:
Treatment of diabetes/TAKEDA PHARMACEUTICAL CO. LTD.

Relevant legal provisions:
EPC Art. 123(2)

Relevant legal provisions (EPC 1973):
EPC Art. 76, 111

Keyword:
"Main request: claim 1 allowable under Article 76 and 123(2) EPC (yes)"
"Remittal - (yes): undecided issues"

Decisions cited:
-

Catchword:
-

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Case Number: T 1357/06 **-** 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 16 September 2008

Appellant: (Patent Proprietor)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 3 July 2006 revoking European patent No. 0861666 pursuant to Article 102(1) EPC 1973.

Composition of the Board:

Chairman: H. Kellner
Members: A. Lindner
J. Van Moer

Summary of Facts and Submissions

I. European patent No. 0 861 666 based on application No. 98 200 252.9 was granted on the basis of a set of 23 claims.

Independent claim 1 reads as follows:

"1. Pharmaceutical composition which comprises an insulin sensitivity enhancer selected from pioglitazone, 5-[[4-[2-(methyl-2-pyridylamino)ethoxy]phenyl]methyl]-2, 4-thiazolidinedione or a pharmacologically acceptable salt thereof in combination with metformin."

II. The patent was opposed under Article 100(a) EPC for lack of inventive step and under Article 100(c) EPC for amendments that contain subject-matter extending beyond the content of the earlier application as filed.

III. In the decision pronounced on 1 June 2006, the patent in suit was revoked by the opposition division, as the ground of opposition mentioned in Article 100(c) EPC prejudiced the maintenance of the European patent in its unamended and amended form.

In connection with the main request in the form of the claims as granted, the opposition division came to the conclusion that, starting from the earlier application as filed, the following three selections must be made in order to arrive at the subject-matter of claim 1: firstly, pioglitazone or rosiglitazone must be chosen from the group of the insulin sensitivity enhancers; secondly, a biguanide must be selected from a list comprising at least an α-glucosidase inhibitor, an

aldose reductase inhibitor, a biguanide, a statin compound, a squalene synthesis inhibitor, a fibrate compound, a LDL catabolism enhancer and an angiotensin converting enzyme inhibitor; thirdly, metformin must be chosen from a list of three biguanides.

As for claim 1 of the auxiliary request, which related to the combination of pioglitazone plus meformin, the opposition division held that for the same reasons as outlined above, this claim also introduced added subject-matter to the earlier application as filed.

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

V. With his letter dated 1 August 2008, the appellant filed a first, a second and a third auxiliary request.

VI. Oral proceedings before the board took place on 16 September 2008. During the oral proceedings, the appellant withdrew his main request.

Claim 1 of the first auxiliary request, which is now the main request, reads as follows:

"1. Pharmaceutical composition which comprises the insulin sensitivity enhancer, pioglitazone, or a pharmacologically acceptable salt thereof, in combination with metformin."

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

The combination of claims 1, 2 and 10 of the earlier application disclosed a composition comprising

pioglitazone in combination with a second active agent. As a consequence, only one selection, i.e. the selection of metformin from a group of three biguanides had to be made.

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

In order to arrive at the subject-matter of claim 1 of the new main request, three selections had to be made: firstly, pioglitazone had to be selected from the group of insulin sensitivity enhancers. Secondly, the biguanides had to be chosen from a list of eight generic groups of compounds, or even ten if the insulin secretion enhancers and insulin preparations according to page 5, lines 1-2 of the earlier application as filed were included. In this context, it was emphasised that the biguanides were by no means preferred. Thirdly, the metformin had to be selected from a group of three biguanides, which yielded a huge number of possible combinations. Alternatively, it was argued that two selections had to be made in that, having chosen the pioglitazone from the group of the insulin sensitivity enhancers, it was possible to directly select the second active agent from the compounds listed in the passage from page 20, line 3 to page 22, line 24, which resulted in an even larger number of possible combinations. Both alternatives led to the result that claim 1 of the main request contained subject-matter that extended beyond the content of the earlier application as filed.

IX. The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the claims of the first auxiliary request filed with letter of 1 August 2008 as a new main request or,

alternatively, on the basis of the second or third auxiliary request filed also with letter of 1 August 2008 now first or second auxiliary requests.

The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. Main request:

The subject-matter of present claim 1 is now restricted to a pharmaceutical composition comprising pioglitazone or a pharmacologically acceptable salt thereof in combination with metformin as the second antidiabetic agent.

2.1. Basis of present claim 1 in the earlier application as filed (Article 76 EPC):

Claim 10 of the earlier application as filed refers back to claim 2 which in its turn has a back reference to claim 1. The subject-matter defined by these claims concerns a pharmaceutical composition comprising pioglitazone or a pharmacologically acceptable salt thereof in combination with at least one member of the group consisting of an α-glucosidase inhibitor, an aldose reductase inhibitor, a biguanide, a statin compound, a squalene synthesis inhibitor, a fibrate compound, a LDL catabolism enhancer and an angiotensin converting enzyme inhibitor.

Starting from this disclosure, a single selection has to be made in order to arrive at the subject-matter of present claim 1: metformin has to be chosen as the second antidiabetic agent. This selection is made from the list of specific compounds to be found in the passage from page 20, line 3 to page 22, line 24 of the earlier application as filed. Despite the fact that this list comprises a considerable number of compounds, the combination of pioglitazone with each individual compound of this list is considered to be specifically disclosed in view of the fact that only one selection has to be made. In this context, it is emphasised that it is not necessary to firstly select the biguanides, before in a further selection the metformin can be chosen from the biguanides, as metformin can be directly taken from the compounds listed on page 20, line 3 to page 22, line 24. Therefore, the subject-matter of claim 1 meets the requirements of Article 76 EPC.

2.2. Basis of present claim 1 in the divisional application as filed (Article 123(2) EPC):

Claims 1, 2 and 10 of the divisional application as originally filed are identical with the corresponding claims of the earlier application as filed except for the deletion of the α-glucosidase inhibitors from claim 1. As a consequence, the subject-matter defined by these claims concerns a pharmaceutical composition comprising pioglitazone or a pharmacologically acceptable salt thereof in combination with at least one member of the group consisting of an aldose reductase inhibitor, a biguanide, a statin compound, a squalene synthesis inhibitor, a fibrate compound, a LDL catabolism enhancer and an angiotensin converting enzyme

inhibitor. As was already outlined in paragraph 2.1 above, a single selection has to be made in order to arrive at the subject-matter of present claim 1: metformin has to be chosen from the compounds listed in the passage from page 20, line 10 to page 22, line 24 of the divisional application as filed. As a consequence, the subject-matter of claim 1 meets the requirements of Article 123(2) EPC.

3. Remittal to the first instance

3.1. Although Article 111(1) EPC does not guarantee the parties an absolute right to have all the issues in the case considered at two levels, it is recognised that any party should, if possible, be given the opportunity to two hearings on the important elements of the case. The essential function of an appeal in inter partes proceedings is to consider whether the decision which has been issued by the first instance department is correct. 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 particular, remittal is considered appropriate by the boards in cases where a first instance department issues a decision solely upon one particular issue which is decisive for the case against a party and leaves other issues outstanding. If, following appeal proceedings, the appeal on the particular issue is allowed, the case is normally remitted to the first instance department for consideration of essential undecided issues.

3.2. The observations and comments made above apply fully to the present case. The Opposition Division decided that

claim 1 was not patentable because the ground of opposition mentioned in Article 100(c) EPC prejudiced the maintenance of the European patent in its unamended and amended form, but left outstanding the evaluation of the remaining claims as well as the remaining issues, in particular that of inventive step (Articles 52(1) and 56 EPC), which had been cited as ground for opposition in the notice of opposition.

3.3 Thus, in view of the above considerations the Board has reached the conclusion that, in the circumstances of the present case, it is necessary to remit the case to the Opposition Division for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance for further prosecution on the basis of claim 1 of the main request.

The Registrar: The Chairman:

M. Kiehl H. Kellner