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# Datasheet for the decision of 25 January 2011

**Case Number:** T 0783/09 - 3.3.04

**Application Number:** 01909661.9

**Publication Number:** 1248604

**IPC:** A61K 45/00

**Language of the proceedings:** EN

**Title of invention:**
Combinations comprising dipeptidylpeptidase-IV inhibitors and antidiabetic agents

**Patentees:**
Novartis AG; Novartis Pharma GmbH

**Opponent:**
-

**Headword:**
Antidiabetic combinations/NOVARTIS

**Relevant legal provisions:**
EPC Art. 111(1), 123(2)

**Keyword:**
"Main request: claim 1 - added matter by selection from lists (no)"

**Decisions cited:**
T 0012/81, T 0010/97

**Catchword:**
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Beschwerdekammern | Boards of Appeal | Chambres de recours

**Case Number:** T 0783/09 - 3.3.04

# D E C I S I O N
**of the Technical Board of Appeal 3.3.04**
**of 25 January 2011**

**Appellants**: (Patent Proprietors)
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**Decision under appeal:** **Decision of the Opposition Division of the European Patent Office posted 29 January 2009 revoking European patent No. 1248604 pursuant to Article 101(3)(b) EPC.**

**Composition of the Board:**

**Chairman:** C. Rennie-Smith
**Members:** G. Alt
B. Claes

## Summary of facts and submissions

I. This is an appeal by the joint patent proprietors (hereinafter "appellant") against the decision of the opposition division to revoke the European Patent no. 1 238 604. The patent has the title "Combinations comprising dipeptidylpeptidase-IV inhibitors and antidiabetic agents".

II. The opposition held the patent invalid because none of the three requests before it complied with the requirements of Article 123(2) EPC.

III. In particular, with regard to the first auxiliary request the opposition division reasoned as follows:

IV. "IV. [...] to choose LAF237 must be considered as a selection from a list. Regarding the three selected thiazolidinediones, namely pioglitazone, rosiglitazone and troglitazone the following is noted: [...]. However, even though the application as originally filed mentions pioglitazone, rosiglitazone and troglitazone (cf. p. 15, 2nd paragraph) as a preferred group within the antidiabetic thiazolidinediones of Formula VIII, the application discloses many compounds as the "preferred" or "most preferred" "further antidiabetic compound". Reference is made for example to [...]. It is therefore considered that the skilled man reading the description as filed would find a long list of "further antidiabetic compounds" as well as a shorter (virtual) list of preferred or most preferred "further antidiabetic compounds" comprising pioglitazone, rosiglitazone and troglitazone together with [...]. Reference is also made to p. 21, 5th paragraph.

In view of this the list comprising pioglitazone, rosiglitazone and troglitazone cannot be considered in isolation, since no hint exists in the application as filed that these three compounds would be more preferred than the other preferred "further antidiabetic compounds". [...] Consequently, also the subject-matter of claim 1 of the first auxiliary request must be considered as a selection from two lists and therefore contravening Article 123(2) EPC."

V. With the statement of the grounds for appeal the appellant filed a main and two auxiliary request which were the same as the requests considered by the opposition division.

VI. The respondent and opponent withdrew its opposition in a letter dated 17 August 2010.

VII. Oral proceedings before the board took place on 25 January 2011.

The appellant filed new main and first auxiliary requests which were identical to the previously filed first and second auxiliary requests.

Claim 1 of the main request read:

"1. Combination comprising a dipeptidylpeptidase-IV inhibitor (DPP-IV) inhibitor which is (S)-1-[(3-hydroxy-1-adamantyl)acetyl-2-cyano-pyrrolidine, in free form or in acid addition salt form, and at least one further antidiabetic compound which is pioglitazone,

rosiglitazone or troglitazone or the pharmaceutically acceptable salt of such a compound."

Of the further claims of the main request, claims 2 to 6 and 9 were dependent on claim 1. Claim 7 related to any of the combinations of claims 1 to 6 for use as a medicament. Claim 8 related to the use of any of the combinations of claims 1 to 6 for the preparation of a medicament for treatment.

The appellant submitted that claim 1 complied with requirements of Article 123(2) EPC because the application as filed disclosed the combination of (S)-1-[(3-hydroxy-1-adamantyl)acetyl-2-cyano-pyrrolidine ("LAF237") with either of pioglitazone, rosiglitazone or troglitazone in an individualised manner. It did not matter that other individual combinations were also disclosed as "preferred".

The appellant requested that the decision under appeal be set aside and that the case be remitted to the first instance for further prosecution on the basis of the new main request.

At the end of the oral proceedings the board announced its decision.

## Reasons for the decision

Main request

1. The claims of the main request are the same as those of the first auxiliary request considered by the

opposition division. The first auxiliary request was refused because its claim 1 was considered not to comply with the requirements of Article 123(2) EPC.

From the reasons given for the refusal in the written decision (recited in section IV above) it is not clear to the board whether the opposition division considered that the combinations recited in claim 1 (i) were not disclosed per se in the application as filed (see the statement that the subject-matter must be considered as "a selection from two lists") or that (ii) they were not disclosed as a group (see the observation that the three combinations are part of a list and that no hint exists that these three compounds would be more preferred than the others). In the following decision the board deals with both aspects.

2. 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.

3. In accordance with established jurisprudence the relevant question to be decided in assessing whether or not an amendment adds subject-matter extending beyond the content of the application as filed is whether the skilled person would derive the proposed amendment directly and unambiguously from the application as filed.

4. Amended claim 1 relates to a combination comprising (S)-1-[(3-hydroxy-1-adamantyl)acetyl-2-cyano-pyrrolidine (also denoted as "LAF237"), in free form or in acid addition salt form, and at least one further

compound selected from the group of pioglitazone, rosiglitazone or troglitazone or the pharmaceutically acceptable salt of such a compound.

5. A first issue in the present case is whether or not the skilled person would derive directly and unambiguously each of the three "basic" combinations to which claim 1 pertains, i.e. LAF237 combined with either of pioglitazone, rosiglitazone or troglitazone from the application as filed.

5.1 As to the relevant content in the application as filed, there is a general disclosure of the invention - it relates to a combination of a DPP-IV inhibitor with at least one further antidiabetic compound - from page 1 to page 2, line 16 . This is succeeded by the description of numerous groups, subgroups and individual compounds of DPP-IV inhibitors from page 3, line 1 to page 10, line 11 and the description of numerous groups, subgroups and individual compounds of further antidiabetic compounds on page 2, last paragraph as well as from page 10, line 12 to page 21, fourth paragraph.

5.2 The subsequent fifth paragraph on page 21 - a passage also referred to in the decision under appeal (see point IV above) - reads:

"In a very preferred embodiment of the invention, the DPP-IV inhibitor is selected from (S)-1[(3-hydroxy-1-adamantyl) amino] acetyl-2-cyano-pyrrolidine (note by the board: also denoted as "LAF237") and (S)-1- {2-[5-cyanopyridin-2-yl) amino] ethyl-aminoacetyl}-2-cyano-pyrrolidine (note by the board: also denoted as

"DPP728"), and the further antidiabetic compound is selected from the group consisting of nateglinide, repaglinide, metformin, rosiglitazone, pioglitazone, troglitazone, glisoxepid, glyburide, glibenclamide, acetohexamide, chloropropamide, glibornuride, tolbutamide, tolazamide, glipizide, carbutamide, gliquidone, glyhexamide, phenbutamide, tolcyclamide, glimepiride and gliclazide, or the pharmaceutically acceptable salt of such a compound."

5.3 Thus, the fifth paragraph on page 21 indicates two individual DPP-IV inhibitors, among them the one according to claim 1, namely LAF237, and twenty-two individual antidiabetic compounds, among them the three according to claim 1, namely pioglitazone, rosiglitazone and troglitazone.

5.4 The skilled person would derive from this paragraph that "very preferred" combinations of the invention are

(i) those having the compound "LAF237" as DPP-IV inhibitor in combination with any one of the disclosed twenty-two compounds as the further antidiabetic compound and

(ii) those having the compound "DPP728" as DPP-IV inhibitor in combination with any one of the disclosed twenty-two compounds as the further antidiabetic compound.

Thus, the skilled person would directly and unambiguously recognize forty-four individual combinations, among them the three "basic" combinations referred to in claim 1.

5.5 Since it was stated in decision T 12/81 of 9 February 1982 (see Reasons, point 13) that if "two classes of starting substances are required to prepare end products and examples of individual entities in each class are given in two lists of some length, then a substance resulting from the reaction of a specific pair from the two lists can nevertheless be regarded for patent purposes as a selection and hence as new", the boards have denied in many cases a direct and unambiguous disclosure for an individualised subject-matter that was only derivable from a document by combining elements from lists.

5.6 However, given the term "can" in the citation from decision T 12/81, the absence of a direct and unambiguous disclosure for individualised subject-matter is not a mandatory consequence of its presentation as elements of lists. Thus, the "disclosure status" of subject-matter individualised from lists has to be determined according to the circumstances of each specific case by ultimately answering the question whether or not the skilled person would clearly and unambiguously derive the subject-matter at issue from the document as a whole (see point 3 above).

5.7 As noted above in point 5.4, in the present case this evaluation results in the finding that all combinations resulting from the combination of the elements of the two lists according to the passage on page 21 are directly and unambiguously disclosed in that passage.

5.8 The further alternative features of the combinations according to claim 1, i.e. that LAF237 is in free or in acid addition salt form and that the further antidiabetic compound is in the form of a pharmaceutically acceptable salt, are derivable from claim 6 and the fifth paragraph on page 21, respectively.

5.9 Thus, each of the combinations according to claim 1 is disclosed in an individualised manner in the application as filed and therefore there is no breach of Article 123(2) EPC in this respect.

6. A further issue in the present case is whether or not the claiming of only three of the forty-four combinations disclosed en bloc in the passage on page 21 extends the content of the application as filed in an unallowable way (see point 1 above).

6.1 The above-cited passage from page 21 of the application as filed advertises the forty-four combinations as "very preferred embodiments". By this statement the skilled person is taught that each of the forty-four combinations has the same quality, i.e. they are all very preferred combinations in the context of the invention. Nothing else is derivable from the remainder of the application, i.e. a particular quality, for example a particular technical effect, is neither attributed to the three combinations of claim 1 nor to the remaining forty-one.

6.2 Hence, the group of combinations in claim 1 cannot be considered as the result of a selection of three qualitatively equal elements from a list of forty-four

qualitatively non-equal elements - for which selection there would be no hint in the application as filed and the claiming of which group therefore would have to be considered as adding matter. Rather the group of claim 1 is to be considered as the result of the deletion of forty-one elements from a list of forty-four qualitatively equal elements.

6.3 In the board's judgement, under these circumstances, claim 1 is not directed to subject-matter extending beyond the content of the application as filed.

6.4 The present board's view is supported by case law, for example decision T 10/97 of 7 October 1999. It is stated in point 2 of the Reasons:

"It is true that not all the compounds listed in original claim 46 and Table 1 have been included in amended claim 1. However, [...] the claimed group of compounds is not obtained by restricting an originally disclosed generic definition of a substituent in a generic formula to a specific one selected from worked examples, but by deleting some members from a list of individualised equally useful compounds in order to improve the chances of patentability over the available prior art. In the Board's view, such deletions must be considered admissible in accordance with the case law of the boards of appeal (see decision T 393/91, not published in OJ EPO; point 2.2 of the reasons). For the remaining compounds, a particular technical effect has neither been disclosed nor alleged."

6.5 The board concludes that the claiming of only three of the forty-four combinations disclosed en bloc in the

passage on page 21 does not extend the content of the application as filed in an unallowable way.

7. Hence, in summary, the subject-matter of claim 1 complies with the requirements of Article 123(2) EPC.

8. This finding has the consequence that the decision under appeal is to be set aside.

9. The appellant requested remittal of the case to the first instance for further prosecution. According to Article 111(1) EPC the decision to remit a case or not is at the board's discretion.

In the present case, the board considers that, on the one hand, any remittal has of course the inevitable consequence of the prolongation of the procedure resulting in an extended period of uncertainty about the scope of the patent. On the other hand, the decision under appeal dealt only with the requirements of Article 123(2) EPC in relation to claim 1. It is the essential function of appeal proceedings to consider whether the decision which has been issued by the first instance department is correct. Furthermore, although this is not an absolute right, the parties should preferably be given the opportunity to have their case heard by two instances, if necessary. Moreover, in the present case, the opponent who is no longer a party to the proceedings would not be affected by the remittal.

On balancing the above considerations, the board comes to the conclusion that remittal is appropriate in the present case.

## 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 on the basis of the new main request filed during the oral proceedings.

The Registrar: The Chairman:

P. Cremona C. Rennie-Smith