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**Datasheet for the decision
of 16 February 2011**

Case Number: T 0025/10 - 3.3.02

Application Number: 07007054.5

Publication Number: 1842542

IPC: A61K 31/41

Language of the proceedings: EN

Title of invention:

Novel PPAR ligands that do not cause fluid retention, edema or congestive heart failure

Applicant:

Bethesda Pharmaceuticals, Inc.

Opponent:

-

Headword:

PPAR Ligands for insulin resistant hypertension/BETHESDA

Relevant legal provisions:

EPC Art. 76(1), 53(c)

Relevant legal provisions (EPC 1973):

-

Keyword:

"Main request, auxiliary requests 5: subject-matter of divisional extents earlier application; not directly and unambiguously derivable"
"Auxiliary requests 1 to 4, 6 and 7; 'Therapy consisting of pharmaceutical substances for use in treatment' not allowable under Art. 53(c) EPC."

Decisions cited:

T 0873/94, T 1170/02, T 0330/05, T 0150/07, T 0288/92

Catchword:

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Case Number: T 0025/10 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 16 February 2011

Appellant: Bethesda Pharmaceuticals, Inc.
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Representative: Smith, Stephen Edward
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 20 August 2009
refusing European application No. 07007054.5
pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: U. Oswald
Members: H. Kellner
L. Bühler

Summary of Facts and Submissions

- I. European patent application No. 07 007 054.5, filed as a divisional application in respect of the earlier (parent) application No. 03 785 060.9, the latter based on PCT/US2003/024881 and published as WO 2004/014308, was refused by a decision of the examining division on the basis of Article 97(2) EPC. The decision was taken *inter alia* on the ground that the subject-matter of the divisional application extended beyond the content of the earlier application as filed (Article 76(1) EPC 1973).

The wording of claim 1 of the set of claims of the main request before the examining division reads (amendments with respect to claim 1 as filed in the divisional application in suit in bold):

"Use of a therapeutically effective amount of **a**
~~compound sufficient to~~
~~(a) at least partially activate peroxisome proliferator~~
~~activated receptors (PPARs) and~~
~~(b) at least partially inhibit, antagonize or block an~~
~~activity of angiotensin II type 1 receptors~~
an angiotensin II type 1 receptor blocker
which also increases the activity of peroxisome
proliferator activated receptor gamma
for the preparation of a medicament for the treatment
of hypertension **in insulin-resistant patients**, wherein
the compound is for use in combination with a
diuretic."

- II. The examining division considered that in this claim the combination of the three features of (i) compounds

with a particular activity, (ii) a diuretic and (iii) the treatment of hypertension in insulin-resistant patients had introduced a new specific teaching to the skilled man with respect to the parent application.

The same argumentation applied to auxiliary requests 1 to 4.

In addition, "it was thought that the auxiliary requests were unacceptable under Article 53(c) EPC as the term "therapy" may include method steps".

III. The appellant lodged an appeal against the decision of the examining division and filed grounds of appeal.

Claim 1 of the main request differs from claim 1 as decided on by the examining division in the added word "compound" after the wording "angiotensin II type 1 receptor blocker".

The text of claims 1 of auxiliary requests 1 and 2 is (added text with respect to the main request in bold):

"A combination therapy consisting of a therapeutically effective amount of an angiotensin II type 1 receptor blocker compound which also increases the activity of peroxisome proliferator activated receptor gamma **and a diuretic as its constituent pharmacological agents, for use in** the treatment of hypertension in insulin-resistant patients."

Claim 1 of auxiliary request 3 differs from these two claims in that the word "compound" after "angiotensin II type 1 receptor blocker" is missing.

The wording of claim 1 of auxiliary request 4 is (amended text with respect to claim 1 of auxiliary request 1 in bold):

"A combination therapy consisting of a therapeutically effective amount of an angiotensin II type 1 receptor blocker compound which also increases the activity of peroxisome proliferator activated receptor gamma and a diuretic as its constituent pharmacological agents, for use in the treatment of hypertension in ~~insulin-resistant~~ patients **with type II diabetes mellitus.**"

Claim 1 of auxiliary request 5 reads (amended text with respect to claim 1 of auxiliary request 1 in bold):

"A combination therapy **product** consisting of a therapeutically effective amount of an angiotensin II type 1 receptor blocker compound which also increases the activity of peroxisome proliferator activated receptor gamma and a diuretic as its constituent pharmacological agents, for use in the treatment of hypertension in insulin-resistant patients."

Claim 1 of auxiliary request 6 differs from claim 1 of auxiliary request 3 in the wording
", wherein angiotensin II type 1 receptor blocker is telmisartan" added at the end of the claim.

In claim 1 of auxiliary request 7 the wording added at the end is

", wherein the diuretic is chlorthalidone".

IV. Oral proceedings took place on 16 February 2011 in the absence of the appellant's representative, as indicated in its letter of 26 January 2011.

V. The appellant's arguments in the written procedure may be summarised as follows:

Since the examining division had implicitly performed a novelty test, it had not arrived at the correct conclusion with respect to the provisions of Article 76(1) EPC 1973.

The skilled person was explicitly taught in the application that the invention encompassed the use of combination therapies comprising a diuretic and that the therapies of the invention may be used inter alia to treat insulin-resistant hypertension. It was not necessary for the application to disclose specifically the features of claim 1 in combination, in order for the skilled person to understand that such a combination was contemplated by the passages of the application as cited to indicate original disclosure. The whole contents of the parent application, including the disclosures of the cited passages, would be taken at face value by the skilled person. In so doing he/she would readily appreciate that the applicant intended the invention to encompass the use of combination therapies comprising a diuretic in the treatment of insulin-resistant hypertension.

Thus, the application as filed provided a direct and unambiguous basis for the claimed subject-matter "*prima facie*".

In the event that the board was not inclined to follow the reasoning laid out in decisions T 873/94 (OJ EPO 1997, 456), T 1170/02 of 1 March 2006 (not published in the OJ), T 330/05 of 30 August 2005 (not published in the OJ), T 150/07 of 27 October 2009 (not published in the OJ) and/or T 288/92 of 18 November 1993 (not published in the OJ), referral to the Enlarged Board of Appeal was requested for clarification on the correct legal test to be applied for the assessment of the allowability of "amendments pursuant to Article 123(2) EPC".

- VI. The appellant (applicant) requested in writing that the decision under appeal be set aside and that a patent be granted on the basis of the main request or any of the auxiliary requests 1 to 7 filed with the statement of grounds on 17 December 2009.

Reasons for the Decision

1. The appeal is admissible.
2. *Main request; Article 76(1) EPC 1973*
 - 2.1 The subject-matter of claim 1 of the main request relates to
the use of a therapeutically effective amount of

- an angiotensin II type 1 receptor
 - blocker compound
 - which also increases the activity of
 - peroxisome proliferator activated receptor
 - gamma
- for the preparation of a medicament
- for the treatment of hypertension
 - in insulin-resistant patients
 - wherein the compound is for use in combination with a diuretic.

2.2 In paragraph [0020] of the description as originally filed for the parent application (earlier application; references relate to WO 2004/014308), it is set out that the "invention" relates to the administration of compounds

- sufficient to partially or fully inhibit, antagonize or **block** the activity of
- **angiotensin II type 1 receptors** and
- sufficient to partially or fully **activate**
- **peroxisome proliferator activated receptors**
- (PPARs)
- without causing, promoting, or aggravating fluid retention, peripheral edema, pulmonary edema, or congestive heart failure

(the parts of the text finding a counterpart in the claim are in bold).

Each of the next three paragraphs in the description of the parent application starts with the same wording "In one embodiment", leaving the skilled person free to optionally select one of them in finding the relevant subject-matter of the divisional application.

Particular reference to paragraph [0023], the third of these paragraphs, discloses that a compound such as described in paragraph [0020] is administered in a therapeutically effective amount sufficient to

- prophylactically prevent, slow, delay or **treat** a metabolic disorder or disease

selected from the group consisting of

- insulin resistance, glucose intolerance, impaired glucose tolerance, impaired fasting serum glucose, impaired fasting blood glucose, hyperinsulinemia, pre-diabetes, type 1 diabetes, type 2 diabetes mellitus,

- **insulin-resistant**

- **hypertension,**

the metabolic syndrome, the metabolic hypertensive syndrome, (metabolic) syndrome X, the dysmetabolic syndrome, obesity, visceral obesity, hypertriglyceridemia, elevated serum concentrations of free fatty acids, elevated serum concentrations of C-reactive protein, elevated serum concentrations of lipoprotein(a), elevated serum concentrations of homocysteine, elevated serum concentrations of small, dense low-density lipoprotein (LDL)-cholesterol, elevated serum concentrations of lipoprotein-associated phospholipase (A2), reduced serum concentrations of high density lipoprotein (HDL)-cholesterol, reduced serum concentrations of HDL(2b)-cholesterol, and reduced serum concentrations of adiponectin

(the parts of the text finding a counterpart in the claim are in bold).

Finally, 38 pages later in the parent application as originally filed (paragraph [0100] on page 48), a further option which the skilled person is free to use or not is set out:

"A compound according to the present invention" in combination with

- "a diabetes mellitus-treating agent, a diabetic complication-treating agent, an antihyperlipemic agent, a hypotensive or antihypertensive agent, an anti-obesity agent, a **diuretic**, a chemotherapeutic agent, an immunotherapeutic agent, and immunosuppressive agent, and the like (hereinafter referred to as a concomitant agent)"

(the parts of the text finding a counterpart in the claim are in bold).

2.3 From the comparison of the features in claim 1 of the main request (point 2.1 above) and the features as originally disclosed (point 2.2 above), it follows that considerable portions of relevant text representing features that are compulsorily linked to the teaching of the application (for instance "without causing...") have to be left out and highly sophisticated selections have to be made from the passages cited, in order to arrive at the subject-matter of claim 1 (the passages being the same, the appellant refers to as source of original disclosure in its grounds of appeal; see pages 5 and 6, points 4.11 to 4.14).

Consequently, the question whether the subject-matter of the claim may be derived directly and unambiguously from the original disclosure of the parent application clearly has to be answered in the negative.

The result is the same when assessing whether the teaching of claim 1 of the main request may be derived directly and unambiguously from the claims as originally disclosed in the parent application.

- 2.4 The examining division in its decision considered the claims and the relevant parts of the description, including the examples of the earlier application as filed. It drew the conclusion that claim 1 of the main request extended beyond the earlier application as filed by way of introduction of "a new specific teaching to the skilled man".

As a consequence of the board's considerations as set out, it confirms the examining division's finding that the subject-matter of claim 1 of the main request extends beyond the content of the earlier application as filed and thereby fails to meet the requirements of Article 76(1) EPC 1973.

3. *Auxiliary requests 1 to 4, 6 and 7; Article 53(c) EPC*

These auxiliary requests relate to "combination therapies" as compared with "combination therapy products" in auxiliary request 5. Since the basic definition of a "therapy" is nothing else than "a treatment by therapy" which includes method steps, auxiliary requests 1 to 4, 6 and 7 are in breach of the provisions of Article 53(c) EPC, because "European patents shall not be granted in respect of: (c) methods for treatment of the human or animal body by surgery or therapy ... practised on the human or animal body; ...".

As indicated in point II of this decision, such objection was already well known to the appellant from the decision of the examining division (page 1, point 4, lines 3 and 4 from the bottom).

4. *Auxiliary request 5; Article 76(1) EPC 1973*

4.1 The subject-matter of claim 1 of auxiliary request 5 in principle relates to a medicinal product, consisting of a therapeutically effective amount of

- an angiotensin II type 1 receptor
 - blocker compound
 - which also increases the activity of
 - peroxisome proliferator activated receptor
 - gamma
 - and a diuretic
- as its constituent pharmacological agents,
- for use in the treatment of hypertension
 - in insulin-resistant patients.

As can be seen by comparison with the text of point 2.1 of this decision, the same features are involved as in claim 1 of the main request.

Therefore, *mutatis mutandis* the same arguments as to claim 1 of the main request apply to claim 1 of auxiliary request 5. Consequently, auxiliary request 5 is also not allowable under Article 76(1) EPC 1973.

5. The appellant cited a variety of decisions of the boards to make clear that, when assessing whether a divisional application meets the provisions of

Article 76(1) EPC 1973, it was not allowed to perform an exercise resembling a novelty test.

Only the question of deriving the subject-matter of the divisional application directly and unambiguously from the parent application was to be answered.

Since the present decision does not depend on whether a novelty test is appropriate or not when assessing Article 76(1) EPC 1973, the cited decisions are not relevant for this case.

6. In addition, the question of a divisional application having been filed only in respect of subject-matter which does not extend beyond the content of the earlier application as filed or not is to be decided on a case by case basis depending on the substantive subject-matter as disclosed.

Therefore, and since the cited decisions of the boards of appeal are not pertinent in this decision, there is no need and no basis to refer questions to the Enlarged Board of Appeal as the appellant has requested.

7. In these circumstances the appeal must be dismissed because the subject-matter of the divisional application in the form of the main request and auxiliary request 5 extends beyond the content of the earlier application as filed and thereby fails to meet the requirements of Article 76(1) EPC 1973, while auxiliary requests 1 to 4, 6 and 7 are in breach of Article 53(c) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

N. Maslin

U. Oswald