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Datasheet for the decision of 10 September 2014

Case Number: T 1797/10 - 3.3.01

Application Number: 08009893.2

Publication Number: 1997484

IPC: A61K31/00, A61K31/401, A61K31/4196, A61P3/10, A61K31/415, A61P3/00, G01N33/58, G01N33/566, C12N15/12

Language of the proceedings: EN

Title of invention:
Method of identifying GLP-1 secretagogues

Applicant:
Arena Pharmaceuticals, Inc.

Headword:
GLP-1 secretagogues/ARENA

Relevant legal provisions:
EPC Art. 84, 111(1), 113(1)

Keyword:
Claims - clarity after amendment (yes)
Remittal to the department of first instance - (yes)

Decisions cited:
T 1063/06

Catchword:

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Case Number: T 1797/10 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 10 September 2014

Appellant: (Applicant)	Arena Pharmaceuticals, Inc. 6154 Nancy Ridge Drive San Diego, CA 92121 (US)
Representative:	Cripps, Joanna Elizabeth Mewburn Ellis LLP 33 Gutter Lane London EC2V 8AS (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 15 March 2010 refusing European patent application No. 08009893.2 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	A. Lindner
Members:	C. M. Radke
	L. Bühler

Summary of Facts and Submissions

I. European patent application No. 08 009 893.2 was published as EP-A-1 997 484. The examining division decided to refuse the application. The applicant's appeal is directed against this decision.

II. The examining division decided that claim 1 of the main request and of each of the three auxiliary requests were not clear, in that they could be interpreted as relating to

- a process for making a product (and thus covering said product according to Article 64(2) EPC),
- a hidden screening method, or
- a hidden second medical use,
- or anything between these options

(see page 5 of the decision, first paragraph under point 2).

III. In its communication dated 11 June 2014 the board gave its reasoned preliminary opinion that the subject-matter of the claims then on file did not meet the requirements of Articles 76(1), 123(2), 53(c), 83 and 84 as well as Rule 43(2) EPC (inadvertently referred to as Rule 42(2) EPC in the communication).

IV. In its reply, the appellant presented counter-arguments and filed amended claims according to a main request and five auxiliary requests. During the oral proceedings before the board, the appellant submitted amended claims forming the basis of a new main request.

V. The claims on file are
claims 1 to 35 of the main request, submitted during the oral proceedings of 10 September 2014;
claims 1 to 25 of the first auxiliary request,

claims 1 to 25 of the second auxiliary request,
claims 1 to 13 of the third auxiliary request,
claims 1 to 13 of the fourth auxiliary request,
claims 1 to 13 of the fifth auxiliary request,
all the claims of the auxiliary requests being those filed under cover of the letter dated 8 August 2014.

The independent claims of the main request are claims 1, 2, 13, 14, 27 and 28, which read as follows:

"1. A method of preparing a composition comprising a GPR119 agonist having the effect of GLP-1 secretagogues useful for treating or preventing a condition ameliorated by increasing a blood GLP-1 level, said method comprising

(a) contacting a GPR119 agonist in vitro with a mammalian enteroendocrine cell; and

(b) determining whether the GPR119 agonist stimulates GLP-1 secretion from the mammalian enteroendocrine cell wherein the ability of the GPR119 agonist to stimulate GLP-1 secretion from the mammalian enteroendocrine cell is indicative of the agonist being a GLP-1 secretagogue useful for treating or preventing a condition ameliorated by increasing a blood GPL-1 level; and

(c) admixing said GPR119 agonist with a pharmaceutically acceptable carrier."

"2. A method of preparing a composition comprising a GPR119 agonist having the effect of GLP-1 secretagogue useful for treating or preventing a condition ameliorated by increasing a blood GLP-1 level, said method comprising

(a) determining a blood GLP-1 level in a biological sample obtained from a mammal, said mammal having been administered with a GPR119 agonist; wherein

the ability of the GPR119 agonist to increase a blood GLP-1 level in the mammal is indicative of the agonist being a GLP-1 secretagogue useful for treating or preventing a condition ameliorated by increasing a blood GPL-1 level; and

(b) admixing said GPR119 agonist with a pharmaceutically acceptable carrier."

"13. A method of preparing a pharmaceutical composition comprising a GPR119 agonist having the effect of GLP-1 secretagogue; said GPR119 agonist having been contacted in vitro with a mammalian enteroendocrine cell, and determined to stimulate GLP-1 secretion from the mammalian enteroendocrine cell wherein the ability of the GPR119 agonist to stimulate GLP-1 secretion from the mammalian enteroendocrine cell is indicative of the agonist being a GLP-1 secretagogue useful for treating or preventing a condition ameliorated by increasing a blood GPL-1 level; said method comprising admixing the GPR119 agonist with a pharmaceutically acceptable carrier."

"14. A method of preparing a pharmaceutical composition comprising a GPR119 agonist having the effect of GLP-1 secretagogue useful for treating or preventing a condition ameliorated by increasing a blood GPL-1 level; said GPR119 agonist having been administered to a mammal to determine whether the GPR119 agonist increased a blood GLP-1 level in the mammal being indicative of the agonist being a GLP-1 secretagogue useful for treating or preventing a condition ameliorated by increasing a blood GPL-1 level; said method comprising admixing the GPR119 agonist with a pharmaceutically acceptable carrier."

"27. A method of preparing a dosage form of a

pharmaceutical composition comprising a GPR119 agonist having the effect of GLP-1 secretagogue useful for treating or preventing a condition ameliorated by increasing a blood GLP-1 level, said method comprising

(a) contacting a GPR119 agonist in vitro with a mammalian enteroendocrine cell; and

(b) determining whether the GPR119 agonist stimulates GLP-1 secretion from the mammalian enteroendocrine cell wherein said the ability of the GPR119 agonist to stimulate GLP-1 secretion from the mammalian enteroendocrine cell is indicative of the agonist being a GLP-1 secretagogue useful for treating or preventing a condition ameliorated by increasing a blood GPL-1 level; and

(c) preparing a dosage form of a pharmaceutical composition comprising said GPR119 agonist having the effect of GLP-1 secretagogue useful for treating or preventing a condition ameliorated by increasing a blood GPL-1 level and a pharmaceutically acceptable carrier."

"28. A method of preparing a dosage form of a pharmaceutical composition comprising a GPR119 agonist having the effect of GLP-1 secretagogue useful for treating or preventing a condition ameliorated by increasing a blood GLP-1 level, said method comprising

(a) determining a blood GLP-1 level in a biological sample obtained from a mammal, said mammal having been administered with a GPR119 agonist; wherein the ability of the GPR119 agonist to increase a blood GLP-1 level in the mammal is indicative of the agonist being a GLP-1 secretagogue useful for treating or preventing a condition ameliorated by increasing a blood GPL-1 level; and

(b) preparing a dosage form of a pharmaceutical composition comprising said GPR119 agonist having

the effect of GLP-1 secretagogue useful for treating or preventing a condition ameliorated by increasing a blood GPL-1 level and a pharmaceutically acceptable carrier."

VI. The appellant requested that the decision under appeal be set aside and that the case be remitted to the department of first instance for further prosecution or the proceedings continued in writing if the claims of the main request filed during the oral proceedings were considered to meet the requirements of Article 84 EPC.

VII. The arguments of the appellant, as far as relevant for this decision, may be summarised as follows:

Article 84 EPC

In view of the fact that the claims relating to a "small molecule" had been deleted the present claims were clear.

Remittal

The primary purpose of the appeal was to review the reasons on which the decision under appeal was based. The refusal of the application was based only on a finding of lack of clarity. The appellant did not have sufficient time to deal with all the new issues raised in the communication of the board within the time limited given therein. This was all the more so as it needed to take into account that some objections might affect pending applications and granted patents containing similar claims. Remittal would ensure that the applicant was given a fair opportunity to be heard on all requirements of patentability.

VIII. At the end of the oral proceedings the chairman announced the decision of the board.

Reasons for the Decision

1. The appeal is admissible.

2. Article 84 EPC / main request

2.1 The examining division held that claim 1 of the main request and of the auxiliary requests then on file related to a so-called "reach through"-claim drafted as a "two step process claim". It deemed that the scope and the category of this claim was unclear as it could be interpreted to relate to

- a process ending in a product,
- a hidden screening method,
- a hidden second medical use

or to anything in between (see point 2 on page 5 and point 7 on page 8 of the Reasons for the decision under appeal).

2.2 Present claim 1 differs from the one on which the decision under appeal was based in that the step

"(c) preparing a composition comprising said GPR119 agonist having the effect of GLP-1 secretagogues useful for treating or preventing a condition ameliorated by increasing a blood GLP-1 level"

has been replaced by

"(c) admixing said GPR119 agonist with a pharmaceutically acceptable carrier."

A corresponding amendment was made in claim 2 (see point V above).

2.3 Consequently, independent claims 1 and 2 are now directed to a "method of preparing a composition comprising a GPR119 agonist" where the method comprises the step of "admixing said GPR119 agonist with a pharmaceutically acceptable carrier".

Independent claims 13 and 14 are directed to a "method of preparing a pharmaceutical composition comprising a GPR119 ... said method comprising admixing the GPR119 agonist with a pharmaceutically acceptable carrier."

Independent claims 27 and 28 are directed to a "method of preparing a dosage form of a pharmaceutical composition comprising a GPR119 agonist ... and a pharmaceutically acceptable carrier."

Hence, all the independent claims now clearly relate to a method of preparing a composition containing a GPR119 agonist and a pharmaceutically acceptable carrier.

Therefore, the present claims overcome the objection as to lack of clarity which led to the refusal of the present application.

2.4 The examining division emphasised in its reasoning on clarity that claim 1 of the main request and of the auxiliary requests then on file was a "reach through" claim (see point 2 on page 5 and point 7 on page 8 of the Reasons for the decision under appeal). For the avoidance of doubt, it is to be noted that the board, in accordance with the jurisprudence of the boards of appeal, subsumes such an objection under Article 83 EPC rather than under Article 84 EPC (see T 1063/06, OJ EPO 11/2009, 516, in particular point 5 of the Reasons; see the respective chapter II.C.5.5 in the 7th edition of

Case Law of the Boards of Appeal of the EPO, page 312 of the English edition).

2.5 The board has not found any other reason to raise an objection under Article 84 EPC to the claims of the main request. Therefore, these claims meet the requirements of this Article.

3. Request to remit the case to the department of first instance or to continue the proceedings in writing

3.1 The appellant argued that it did not have sufficient time to deal with all the new issues raised in the communication of the board within the time limit given therein, in particular as it had to take into account that some objections might affect pending applications and granted patents containing similar claims (see point VII above).

The appellant was informed of these new objections in the communication of the board posted on 11 June 2014, which the appellant received on 16 June 2014. This communication indicated that the final date to make a written submission was one month before the date of the oral proceedings. The oral proceedings took place on 10 September 2010. Hence, the appellant had less than two months time to respond to the various objections which had not been considered by the department of first instance in the contested decision. The board accepts the appellant's argument that the need to take into account possible effects on closely related pending applications and granted patents made it more difficult for the appellant to respond in an appropriate and timely manner to the board's objections.

Consequently, a decision during the oral proceedings on all the objections raised in the communication of the board would have deprived the appellant of an adequate opportunity to address these objections.

In order to give the appellant sufficient time to respond to all these objections, the board had the option either to remit the case or to continue the appeal proceedings in writing.

3.2 It is the established jurisprudence of the boards of appeal that an appellant has no absolute right to have each individual issue considered by two instances, Article 111(1) EPC 1973 leaving it to the discretion of the board whether to exercise any power within the competence of the department of first instance or to remit the case to that department. When exercising its discretion under Article 111(1) EPC 1973 either to decide or to remit the case, the board should take particular circumstances into account.

The decision now under appeal is based solely on the finding that the claims then on file did not meet the requirements of Article 84 EPC. The board would thus have had to examine for the first time numerous issues not yet considered by the department of first instance. This is, however, not the main function of the boards of appeal. Accordingly, and in order not to deprive the appellant of the possibility of having its case considered by two instances, the board, in the exercise of its power under Article 111(1) EPC 1973, considered it appropriate in the circumstances to remit the case to the department of first instance 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 department of first instance for further prosecution.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated