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**Datasheet for the decision  
of 17 July 2014**

**Case Number:** T 1703/10 - 3.3.08

**Application Number:** 01998193.5

**Publication Number:** 1338651

**IPC:** C12N15/09, C12N15/12

**Language of the proceedings:** EN

**Title of invention:**

Method of screening remedy for diabetes

**Patent Proprietor:**

Astellas Pharma Inc.

**Opponents:**

iNovacia AB  
Krauss, Jan  
Strawman Limited

**Headword:**

Screening remedy/ASTELLAS

**Relevant legal provisions:**

EPC Art. 54(3), 84, 123(2), 123(3)

**Keyword:**

Admissibility of appeal - (yes)  
Admissibility of auxiliary requests II to IV - (no)  
Admissibility of auxiliary request V - (yes)  
Main request and auxiliary request I - novelty (no)  
Auxiliary request V - broadening of claim (no)  
Auxiliary request V - added subject-matter (no)  
Auxiliary request V - clarity (yes)  
Auxiliary request V - novelty (yes)

**Decisions cited:**

G 0009/91, T 1091/00, T 0015/01, T 0501/09

**Catchword:**



**Beschwerdekammern  
Boards of Appeal  
Chambres de recours**

European Patent Office  
D-80298 MUNICH  
GERMANY  
Tel. +49 (0) 89 2399-0  
Fax +49 (0) 89 2399-4465

Case Number: T 1703/10 - 3.3.08

**D E C I S I O N  
of Technical Board of Appeal 3.3.08  
of 17 July 2014**

**Appellant:** Astellas Pharma Inc.  
(Patent Proprietor) 3-11, Nihonbashi-Honcho 2-chome,  
Chuo-ku  
Tokyo 103-8411 (JP)

**Representative:** Engelhard, Elisabeth  
Hoffmann Eitle  
Patent- und Rechtsanwälte  
Arabellastrasse 4  
81925 München (DE)

**Respondent I:** iNovacia AB  
(Opponent 1) Lindhagensgatan 133  
112 51 Stockholm (SE)

**Respondent II:** Krauss, Jan  
(Opponent 2) Boehmert & Boehmert  
Pettenkoferstrasse 20-22  
80336 München (DE)

**Representative:** Krauss, Jan  
Boehmert & Boehmert  
Pettenkoferstrasse 20-22  
80336 München (DE)

**Respondent III:** Strawman Limited  
(Opponent 3) 34 Lovedon Lane  
Winchester,  
Hampshire, SO23 7NU (GB)

**Representative:** Tollervey, Rebecca Marie  
Mewburn Ellis LLP  
33 Gutter Lane  
London  
EC2V 8AS (GB)

**Decision under appeal:**            **Decision of the Opposition Division of the  
European Patent Office posted on 11 June 2010  
revoking European patent No. 1338651 pursuant to  
Article 101(3) (b) EPC.**

**Composition of the Board:**

**Chairman**                    M. Wieser  
**Members:**                    T. J. H. Mennessier  
                                      D. Rogers

## **Summary of Facts and Submissions**

- I. The patent proprietor (appellant) lodged an appeal against the decision of the opposition division dated 11 June 2010, whereby European patent No. 1 338 651 which had been granted on European application No 01998193.5 (published as the international application WO 02/44362 - filed with the application number PCT/JP2001/010472) was revoked. Basis for the revocation was the main request filed on 22 December 2008 and the first auxiliary request filed at the oral proceedings held before the opposition division.
- II. Reason for the revocation was lack of novelty of the main and the first auxiliary request over the disclosure of document D2.
- III. The patent had been opposed by four parties (respondents I to IV). Respondent IV (opponent 04) withdrew its opposition.
- IV. Appellant's statement of grounds was accompanied by a main and ten auxiliary requests. The main request and the first auxiliary request corresponded, respectively, to the main request and the first auxiliary request on which the decision under appeal was based. Auxiliary requests II to X were new in the procedure.
- V. Respondents II and III (opponents 02 and 03, respectively) replied to the statement of grounds. The appellant reacted by filing further submissions.
- VI. The board issued a communication pursuant to Article 15(1) of the Rules of Procedure of the Boards of Appeal

(RPBA) expressing its preliminary and non-binding views and summoned the parties for oral proceedings.

VII. In reply to the board's communication, respondent III filed further submissions. Finally, the appellant requested that the issue of inventive step be discussed at the oral proceedings. Respondent III disagreed with this request.

VIII. Oral proceedings took place as scheduled on 17 July 2014. Respondents I and II did not attend.

IX. Claim 1 of the main request and of auxiliary request I read:

Main request:

- "1. Use of a polypeptide selected from the group consisting of
- (1) a polypeptide consisting of an amino acid sequence of SEQ ID NO: 2 or 16,
  - (2) a polypeptide comprising an amino acid sequence of SEQ ID NO: 2 or 16, and exhibiting (a) an activity of promoting insulin secretion from pancreatic  $\beta$  cells by activation under a high glucose concentration and/or (b) an activity of increasing an amount of intracellular cAMP in the cells by activation,
  - (3) a polypeptide comprising an amino acid sequence in which 1 to 10 amino acids are deleted, substituted, and/or added in an amino acid sequence of SEQ ID NO: 2 or 16, and exhibiting (a) an activity of promoting insulin secretion from pancreatic  $\beta$  cells by activation under a high glucose concentration and/or (b) an activity of increasing

an amount of intracellular cAMP in the cells by activation, and

- (4) a polypeptide comprising an amino acid sequence having a 90% or more homology with an amino acid sequence of SEQ ID NO: 2 or 16, and exhibiting (a) an activity of promoting insulin secretion from pancreatic  $\beta$  cells by activation under a high glucose concentration and/or (b) an activity of increasing an amount of intracellular cAMP in the cells by activation

as a screening tool for an agent for treating diabetes."

Auxiliary request I:

- "1. A method for screening an agent for treating diabetes, comprising the steps of:  
bringing a cell which is transformed with an expression vector comprising a polynucleotide encoding a polypeptide selected from the group consisting of
- (1) a polypeptide consisting of an amino acid sequence of SEQ ID NO: 2 or 16,
  - (2) a polypeptide comprising an amino acid sequence of SEQ ID NO: 2 or 16, and exhibiting (a) an activity of promoting insulin secretion from pancreatic  $\beta$  cells by activation under a high glucose concentration and/or (b) an activity of increasing an amount of intracellular cAMP in the cells by activation,
  - (3) a polypeptide comprising an amino acid sequence in which 1 to 10 amino acids are deleted, substituted, and/or added in an amino acid sequence of SEQ ID NO: 2 or 16, and exhibiting (a) an activity of promoting insulin secretion from pancreatic  $\beta$  cells by activation under a high glucose concentration and/or (b) an activity of increasing

an amount of intracellular cAMP in the cells by activation, and

- (4) a polypeptide comprising an amino acid sequence having a 90% or more homology with an amino acid sequence of SEQ ID NO: 2 or 16, and exhibiting (a) an activity of promoting insulin secretion from pancreatic  $\beta$  cells by activation under a high glucose concentration and/or (b) an activity of increasing an amount of intracellular cAMP in the cells by activation and is expressing the polypeptide

or a cell membrane thereof into contact with a compound to be tested; and

analyzing whether or not a polypeptide as described above is activated."

- X. Claim 1 of auxiliary request II differed from claim 1 of auxiliary request I in that the following feature was added at its very end:

"and confirming that the selected agent exhibits an activity of promoting insulin secretion and/or an activity of increasing an amount of intracellular cAMP."

Claim 1 of auxiliary request III differed from claim 1 of auxiliary request II in that the following feature was added at its very end:

"wherein the confirmation step of promoting insulin secretion is carried out under a high glucose concentration."

Claim 1 of auxiliary request IV differed from claim 1 of auxiliary request I in that the following feature was added at its very end:



"and confirming that the selected agent exhibits an activity of promoting insulin secretion."

XI. Auxiliary request V consisted of two claims, which read:

- "1. A method for screening an agent for treating diabetes, comprising the steps of:  
bringing a cell which is transformed with an expression vector comprising a polynucleotide encoding a polypeptide selected from the group consisting of
- (1) a polypeptide consisting of an amino acid sequence of SEQ ID NO: 2 or 16,
  - (2) a polypeptide comprising an amino acid sequence of SEQ ID NO: 2 or 16, and exhibiting (a) an activity of promoting insulin secretion from pancreatic  $\beta$  cells by activation under a high glucose concentration and/or (b) an activity of increasing an amount of intracellular cAMP in the cells by activation,
  - (3) a polypeptide comprising an amino acid sequence in which 1 to 10 amino acids are deleted, substituted, and/or added in an amino acid sequence of SEQ ID NO: 2 or 16, and exhibiting (a) an activity of promoting insulin secretion from pancreatic  $\beta$  cells by activation under a high glucose concentration and/or (b) an activity of increasing an amount of intracellular cAMP in the cells by activation, and
  - (4) a polypeptide comprising an amino acid sequence having a 90% or more homology with an amino acid sequence of SEQ ID NO: 2 or 16, and exhibiting (a) an activity of promoting insulin secretion from pancreatic  $\beta$  cells by activation under a high glucose concentration and/or (b) an activity of

increasing an amount of intracellular cAMP in the cells by activation and is expressing the polypeptide or a cell membrane thereof into contact with a compound to be tested; and analyzing whether or not a polypeptide as described above is activated **and confirming that the selected agent exhibits an activity of promoting insulin secretion, wherein the confirmation step of promoting insulin secretion is carried out under a high glucose concentration.**"

(emphasis added by the board to show the difference with claim 1 of auxiliary request I)

"2. The screening method according to claim 1, wherein the agent for treating diabetes is an agent for promoting insulin secretion."

XII. The following documents are referred to in the present decision:

- (D1) WO 00/50562 (published on 31 August 2000)
- (D2) US patent application with serial number 60/141,448 (a priority document of WO 00/31258 which was published on 2 June 2000)
- (D7) EP 1 092 727 A2 (priority date: 30 September 1999; filed on 26 September 2000; published on 18 April 2001)
- (D29) English translation of the international application as originally filed (PCT/JP2001/010472), as submitted with the request for entry into the European phase

XIII. The submissions made by the appellant, insofar as they are relevant to the present decision, can be summarised as follows:

#### Admissibility of the appeal

Respondent III's request that the appeal be deemed inadmissible was made for the first time at the oral proceedings and was an abuse of the procedure.

Novelty of the main request and of auxiliary request I over the disclosure in documents D1, D2 and D7:

The disclosure in document D1 was highly speculative. In particular the function of the newly identified molecule (SNORF25) was unclear. The hypothesis that all-trans-retinoic acid (ATRA) was the ligand of SNORF25 was proved to be wrong. A precise use of SNORF25 as a tool for designing a drug for treating diabetes was not disclosed. Diabetes was indeed cited within a number of various pathophysiological conditions (see page 32, line 30 to page 33, line 14 and page 49, line 29 to page 50, line 37).

The passage pointed to by the respondents at page 15, lines 15 to 17 of document D2 was nothing else but a very suggestive and hypothetical statement which was neither shown nor confirmed by any data. Document D2 did not provide an enabling disclosure.

The disclosure in document D7 was entirely hypothetical and unsupported. The document provided a variety of diseases which could be treated by use of substances modulating the polypeptide having the deduced amino acid sequence translated from the nucleotide sequence

in SEQ ID NO: 1 - which was the polypeptide of SEQ ID NO: 2 referred to in claim 1 of the main request and of auxiliary request I. Claim 52 of document D7 was directed to a method for treating diabetes which consisted of administering a substance modulating said polypeptide. However, document D7 failed to show that an agonist of the polypeptide was actually effective in the treatment of diabetes. Furthermore, document D7 did not show that the activation of the polypeptide promoted insulin secretion or that the polypeptide had an activity of promoting insulin secretion from pancreatic  $\beta$  cells under a high glucose concentration.

#### Admissibility of auxiliary requests II to V

Auxiliary requests II to V were filed with the statement of grounds in reply to the decision which relied on an erroneous interpretation of document D2. They could not have been filed earlier. They differed from the requests on which the decision was based only in that a confirmation step had been added. Different ways of carrying out the confirmation step were disclosed in the application as filed (see page 32 of document D29). The claimed subject-matter had a basis in the application as filed and was clear, concise and supported by the description.

#### Auxiliary request V

The language of claim 1 was clear and allowed a skilled person to perform the method for screening. No essential feature was lacking. The test for measuring insulin secretion was so well-known that the skilled person knew what to do. There was in particular no need to mention in the claim any specific islet  $\beta$  cells. Therefore, the requirements of Articles 84 and 123(2)

EPC were met. Furthermore, the claimed method was sufficiently disclosed and new.

Remittal

The case had been fully presented during the written submission phase. Therefore, auxiliary request V could be assessed for inventive step. There was no need for a remittal.

- XIV. The submissions made in writing by respondent II, insofar as they are relevant to the present decision, can be summarised as follows:

The claims as granted did not encompass a step of confirming that a screened substance was effective in the treatment of diabetes. Therefore, auxiliary request V violated Articles 123(3) EPC and should not be admitted into the procedure.

The main request as well as auxiliary requests I and V lacked novelty over the disclosure in document D2 and did not involve an inventive step.

- XV. The submissions made by respondent III, insofar as they are relevant to the present decision, can be summarised as follows:

Admissibility of the appeal

The statement of grounds failed to provide reasoned grounds for overturning the first instance decision. Much of the appellant's submissions regarding document D2 repeated word-for-word the arguments presented in the letter of 5 June 2008, with the consequence that

the appellant's case in appeal was not substantiated (see decision T 501/09 of 25 June 2013, points 2 to 8).

Novelty of the main request and of auxiliary request I over the disclosure in documents D1, D2 and D7:

Document D1 described a method of treating an abnormality in a subject by increasing the activity of the SNORF25 receptor by administering an agonist. A list of possible abnormalities to be treated was given, which included diabetes (see page 49, line 29 to page 50, line 13). Document D1 stated that the finding that human SNORF25 was expressed predominantly in the pancreas as well as the detection of SNORF25 mRNA in liver "indicat[ed] a possible role in the regulation of glucose levels and possibly diabetes" (see page 84, lines 15 to 17 and Table 1 on page 87). Furthermore, document D1 described various screening methods for identifying modulators of a mammalian SNORF25 receptor, and pharmaceutical compositions comprising said modulators (see page 13, lines 5 to 31). The embodiment described at page 67, line 36 to page 68, line 22 made use of isolated cell membranes from cells expressing the receptor. Therefore, document D1 disclosed the subject-matter of claim 1 of the main request and of auxiliary request I.

The natural reading of the passage at page 15, lines 15 to 17 of document D2 showed that the candidate compounds identified by using a constitutively activated form of RUP3 could be useful: i) for understanding the role of RUP3 in diabetes, and/or ii) as therapeutics for diabetes. The teaching certainly was not vague as diabetes was the only disease state mentioned in the entire document. Accordingly, this very specific disclosure was detrimental to the novelty

of claim 1 of the main request and of auxiliary request I.

Claim 48 of document D7 was dependent on claim 26 and related to the use of an agonist of a polypeptide having the sequence of SEQ ID NO: 2 of the patent at issue, in the manufacture of a medicament for the treatment of diabetes. It was evident from the disclosure in document D7 as a whole that the agonist referred to in this claim was to be obtained by screening against the receptor. Paragraph [0040] in document D7 singled out diabetes as the preferred disease to be treated by a compound as "described above", i.e. a compound identified by screening against the receptor (see [0030]). The fact that a list of diseases was given on page 4, lines 35 to 40 did not detract from the explicit teaching in paragraph [0040] and in claim 48. Document D7 related to one identified sequence, termed the PFI-007 receptor which had the sequence of SEQ ID NO: 2 of the patent at issue and singled out one preferred disease state, diabetes. Thus the identified sequence was explicitly connected to diabetes.

Furthermore, page 4, lines 25 to 30 of the application as filed (see document D29) stated, that the receptor used for the purposes of screening could be expressed in a cell. Similarly, at page 22, line 57 to page 23, line 3, document D7 disclosed the use of a cell line that expressed the receptor to screen for agents modulating the receptor activity in order to identify therapeutic agents. Furthermore, page 17, lines 3 to 5 of document D17 disclosed that the cells used in the screening method could be genetically engineered host cells. Therefore, document D7 provided a direct and unambiguous disclosure of the method for screening an

agent for treating diabetes according to claim 1 of auxiliary request I.

Admissibility of auxiliary requests II to V

Auxiliary requests II to V could have been presented during the opposition proceedings before the opposition division.

There was no support in the application as filed for a confirmation step after the agent for treating diabetes had been screened. Thus, claim 1 of each of auxiliary requests II to V contained added subject-matter (Article 123(2) EPC).

The feature of "*confirming that the selected agent exhibits an activity of increasing an amount of intracellular cAMP*" in claim 1 of each of auxiliary requests II and III not only added matter (Article 123(2) EPC) but was also ambiguous (Article 84 EPC). It was not clear what was involved in this further step or if and how it differed from the method of analysing activation as set out in paragraphs [0082] to [0087] of the patent specification.

Consequently, auxiliary requests II to V should not be admitted into the procedure.

Auxiliary request V

Performing the method of claim 1 required technical features which were not present in claim 1. The screened compound had to be taken out of the system and had to be used in a second screening method. Furthermore, claim 1 failed to mention which specific islet  $\beta$  cell was to be used to measure insulin



secretion. Therefore, the requirements of Articles 84 and 123(2) were not met.

Remittal

The main purpose of the appeal proceeding was to give the losing party the opportunity to challenge the decision of the opposition division, and not for the board to consider and decide on questions for the first time. Therefore, the case should be remitted to the department of first instance for further prosecution (i.e. assessment of inventive step) of auxiliary request V.

- XVI. 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 main request, or alternatively on the basis of the claims of one of auxiliary requests I to X, all filed under cover of a letter dated 21 October 2010.
- XVII. Respondent II requested in writing that the appeal be dismissed.
- XVIII. Respondent III requested that the appeal be deemed inadmissible and, as an auxiliary request, that the appeal be dismissed. It also requested that auxiliary requests II to X not be admitted into the proceedings.

## **Reasons for the Decision**

Admissibility of the appeal

1. The admissibility of the appeal was called into question by respondent III at the onset of the oral

proceedings. It argued that the appellant in its statement setting out the grounds of appeal had failed to clearly identify where the opposition division erred in its reasoning, but had rather simply re-iterated points already considered and rejected by the opposition division.

2. According to the established case law of the Boards of Appeal, the admissibility of an appeal may be assessed *ex officio* at every stage of the appeal proceedings, i.e. including during oral proceedings (cf. decision T 15/01, OJ EPO 2006, 153; Reasons, point 1).
3. In the present case, the admissibility of the appeal depends solely on the issue whether the statement setting out the grounds of appeal complies with Article 108 EPC, third sentence, and Rule 99(2) EPC.
4. Article 108 EPC, third sentence, in conjunction with Rule 99(2) EPC, stipulates that in the statement of grounds the appellant shall indicate the reasons for setting aside the decision impugned, or the extent to which it is to be amended, and the facts and evidence on which the appeal is based.
5. Document D2 is the key document in the decision under appeal. Both requests that were on file before the opposition division were considered to lack novelty over the disclosure in that document. In the statement of grounds, the appellant explained in detail why it considered document D2 not to be detrimental to the novelty of claim 1 of each of the main request and auxiliary request I (see pages 13 to 14 and 17). The appellant cannot not be blamed for having repeated - even word-for-word (see pages 14 to 15 of appellant's letter of 5 June 2008) - the arguments previously

developed before the first instance. The repetition merely indicates that, regarding its assessment of document D2, the appellant's position has not varied. Furthermore, together with its statement of grounds the appellant has filed new auxiliary requests aiming to overcome the novelty objection raised in the decision under appeal and has argued why it considers these requests to be novel over the disclosure in document D2.

6. The appellant's statement of grounds has put the board in a position to immediately understand why the impugned decision was found to be incorrect, and on which facts the appellant relied in this respect, without the need to start further investigations of its own. The board sees no reason to assume that the same was not possible for the respondents. Decision T 501/09 of 25 June 2013 to which respondent III has referred relates to a case where the statement of grounds relied on documents which were not in the procedure. This has clearly nothing to do with the present situation. Therefore, this decision is not relevant.
7. In view of the above, the board decides that the appeal is admissible.

Main request

Novelty (Article 54 EPC)

8. The opposition division decided that claim 1 lacked novelty over document D2, and that the disclosures in documents D1 and D7 did not anticipate the claimed subject-matter. While in the decision under appeal the focus is on document D2, respondent III also relied on documents D1 and D7. The three documents have been

considered by the board which has found document D7 to be highly relevant (see points 11 to 15, *infra*).

9. Document D1 relates to a polypeptide/receptor, designated as "SNORF25", which is the polypeptide having the amino acid sequence of SEQ ID NO: 2 of the patent at issue. Assays to screen for SNORF25 receptor agonists or antagonists are disclosed which may be used for a variety of therapeutic purposes, including diabetes, which is mentioned within a long list of disorders (see page 32, line 30 to page 33, line 14 and page 49, line 29 to page 50, line 37). Document D1 does, however, not contain a clear and unambiguous disclosure of a use according to present claim 1, wherein the polypeptide is used in a screening process to obtain an agent (agonist or antagonist) to be specifically used in the treatment of diabetes. Therefore, document D1 is not considered to be novelty destroying for the subject-matter of claim 1 referring to the use of a polypeptide as a screening tool for an agent for treating diabetes.
  
10. Document D2 is a priority document of the international application WO 00/31258 which was published on 2 June 2000, six months before the earliest priority claimed for the patent at issue. It generally relates to the same polypeptide/receptor - designated therein as "RUP3" - as the one with the amino acid sequence of SEQ ID NO: 2 in the patent at issue. The document describes that "*RUP3 is expressed within the human pancreas, **suggesting** that RUP3 **may** play a role in insulin regulation and/or glucocan regulation*" and that "[A]ccordingly, candidate compounds identified using a constitutively activated form of RUP3 **may be useful** for understanding the role of RUP3 in diabetes **and/or** as therapeutics for diabetes" (see page 15, lines 13 to

17; emphasis added by the board). Such a disclosure which is highly speculative does not amount to a direct and unambiguous disclosure of the use of a polypeptide as a screening tool for an agent for treating diabetes according to claim 1 of the main request. Document D2, therefore is not considered to anticipate the novelty of the main request.

11. Document D7 is a European patent application whose contents are considered as being comprised in the state of the art pursuant to Article 54(3) EPC.
12. Paragraph [0023] of document D7 refers to a polypeptide having the deduced amino acid sequence translated from the nucleotide sequence in SEQ ID NO: 1. This corresponds to the polypeptide having the amino acid sequence of SEQ ID NO: 2 referred to in claim 1 of the main request.
13. Paragraph [0027] of document D7 discloses a method for identifying a compound which binds to and modulates the "polypeptide described above" (i.e. the polypeptide of SEQ ID NO: 2 of the patent at issue). The method comprises contacting said polypeptide with a candidate compound and determining whether modulation occurs. This is consistent with the use of the polypeptide as a screening tool as described in claim 1 of the main request.
14. The compound of paragraph [0027] is in turn referred to in paragraph [0040] (see the phrase "the compound described above") where its use in the manufacture of a medicament **for the treatment of diabetes** is disclosed.
15. The disclosure in paragraphs [0023], [0027] and [0040] of document D7 describes the use of a polypeptide

having the amino acid sequence of SEQ ID NO: 2 of the patent at issue as a screening tool for an agent for treating diabetes. Therefore, the subject-matter of claim 1 lacks novelty over the disclosure in document D7. The main request does not meet the requirements of Article 54 EPC.

Auxiliary request I

Novelty (Article 54 EPC)

16. The opposition division decided that claim 1 of this request lacked novelty over document D2. As the board has found that the main request is novel over documents D1 and D2, it also finds that claim 1 of auxiliary request I is novel over these two documents. Thus it is necessary to decide if the claims of auxiliary request I are novel over the disclosure in document D7.
17. Claim 1 of auxiliary request I is directed to a method for screening an agent for treating diabetes. The method comprises two steps, namely a step of bringing a cell or a cell membrane thereof into contact with a compound to be tested and a step of analyzing. The cell is transformed with an expression vector comprising a polynucleotide encoding a polypeptide and is expressing said polypeptide. The polypeptide is defined as in claim 1 of the main request. According to one embodiment, it consists of an amino acid sequence of SEQ ID NO: 2. The step of analysing consists of determining whether or not the polypeptide is activated.
18. In addition to paragraphs [0023], [0027] and [0040] of document D7 account has to be taken of its paragraphs [0025] and [0028]. Paragraph [0025] provides a

definition of what is meant by the term 'modulation' as used in paragraph [0027]: "*Preferably the compound antagonises or selectively antagonises the polypeptide. Alternatively, the compound agonises the polypeptide.*" Paragraph [0027] makes a clear distinction between a compound which binds to the polypeptide and a compound which modulates the polypeptide. Therefore, the argument that "modulation" may be equated with "binding" is not tenable. Paragraph [0028] refers to the use of cells expressing the polypeptide on their cell surface. Such use in a screening method is confirmed in paragraph [0194].

19. The paragraphs of document D7, cited above, disclose a method for screening an agent for treating diabetes comprising all working steps of the method of claim 1. Therefore, the subject-matter of this claim lacks novelty (Article 54 EPC) over the disclosure in document D7.

#### Admissibility of auxiliary requests II to V

20. Auxiliary requests II to V were filed with the statement of grounds. They differ from auxiliary request I in that claim 1 of each request has been amended to include an additional feature with the aim to overcome an objection of lack of novelty in the light of the disclosure in document D2. The board considers the filing of auxiliary requests II to V, which were filed at the earliest possible stage of the appeal proceedings, to be a legitimate and normal reaction to the decision to revoke the patent.
21. Nevertheless, in order to be admissible these auxiliary requests must not be directed to subject-matter which *prima facie* is not allowable.

22. Claim 1 of each of auxiliary requests II and III requires a step of confirming that the selected agent exhibits an activity of increasing an amount of intracellular cAMP (see Section X, *supra*). The patent, in paragraphs [0082] to [0087] sets out various ways of determining activation of the polypeptide but there is no basis for a further step of confirming an activity of increasing intracellular cAMP. The passage on page 14, first paragraph of the application as filed (see document D29), referred to by the appellant, does not relate to testing of the selected agent but rather to confirming whether the polypeptide/receptor exhibits the desired activity. It is not clear what is involved in this further confirmation step or if and how it differs from the disclosure in paragraphs [0082] to [0087]. Therefore, auxiliary requests II and III *prima facie* contain added subject-matter (Article 123(2) EPC) and lack clarity (Article 84 EPC).
23. The appellant has referred to page 32, lines 11 to 24 of the disclosure of the application as filed (see document D29) as providing support for claim 1 of auxiliary request IV. However, this passage discloses that a selected agent is useful as an active ingredient if it exhibits an activity of promoting insulin secretion under a high glucose concentration. This means that the confirmation step has to be carried out **under a high glucose concentration**. Claim 1 fails to contain this particular feature. Therefore, the skilled person reading claim 1 of auxiliary request IV is confronted with information which is not directly and unambiguously derivable from the the application as filed, contrary to the requirements of Article 123(2) EPC.



24. Claim 1 of auxiliary request V differs from claim 1 of auxiliary request I in that a confirmation step has been added, wherein a screened agent is examined for its ability to exhibit an activity of promoting insulin secretion **under a high glucose concentration**. Page 32, lines 11 to 24 of the application as filed (see document D29) discloses that the screened agent is tested for its ability to activate the polypeptide in question. If this activation of the polypeptide results in a promotion of insulin secretion under a high glucose concentration, this is a confirmation that the selected agent exhibits the desired activity. Therefore, this passage provides a direct and unambiguous disclosure for the amendment introduced into claim 1 of auxiliary request V.
25. Compared to claim 1 of auxiliary requests II and III, the confirmation step of claim 1 of auxiliary request V no longer requires that the selected agent exhibits an activity of increasing an amount of intracellular cAMP (see Section X, *supra*). Therefore, the amendment introduced into claim 1 of auxiliary request V is clear and meets the requirements of Article 84 EPC.
26. The objection raised by respondent II against, *inter alia*, auxiliary request V with respect to the requirements of Article 123(3) EPC is unfounded. The addition of a further working step to a claim referring to a method, i.e. at the very end of a claim - as is the case with the confirmation step in claim 1, - can indeed only have a limiting effect. Therefore, the amendment does not result in an extension of the protection conferred by the patent.
27. The board decides not to admit requests II to IV into the procedure as they violate *prima facie* Article 84

EPC (see auxiliary requests II and III) and/or Article 123(2) EPC (see auxiliary request II, III and IV). However, the board decides to admit auxiliary request V into the procedure.

#### Auxiliary request V

28. Claim 1 differs from claim 1 of auxiliary request I only in the addition of a confirmation step at the end of the claim. The added confirmation step defines that it has to be confirmed that the selected agent exhibits an activity of promoting insulin secretion, wherein this step is carried out under a high glucose concentration (see Section XI, *supra*).
29. The passage in the application as filed (see document D29) from page 32, lines 31 to page 33, line 21 provides information supporting the two-step method of claim 1, including the confirmation step. The addition of a confirmation step does not result in an extension of the protection conferred by the patent. A skilled person willing to perform the claimed method finds all the necessary information in the claim. He/she certainly knows how to measure insulin secretion. Therefore, auxiliary request V meets the requirements of Articles 84, 123(2) and 123(3) EPC (see also points 24 to 26, *supra*).
30. With regard to the requirements of Article 83 EPC none of the Respondents has raised an objection relating to auxiliary request V. The board sees no reason to raise an objection of its own.
31. In the light of the board's decision with regard to the main request and auxiliary request I, (which means that auxiliary request V is novel over documents D1 and D2),

the only issue to be decided in the context of Article 54 EPC, is whether the claims of auxiliary request V are novel over the disclosure in document D7. Respondent III does not object to the novelty of auxiliary request V. Respondent II did not comment in this respect. The board is satisfied that, owing to the amendments carried out, auxiliary request V complies with the requirements of Article 54 EPC.

Remittal(Article 111(1) EPC)

32. In the last submission in preparation for the oral proceedings the appellant requested that, at the oral proceedings, an inventive step assessment should be made. On the contrary, respondent III requested that, in the event that any request is found to meet the requirements of novelty, the case be remitted to the department of first instance for further prosecution including an assessment of inventive step (see Section VII, *supra*).
33. At the oral proceedings, the appellant and respondent III, in this respect, referred to their written submissions.
34. According to Article 111(1) EPC the Board of Appeal may either exercise any power within the competence of the department which was responsible for the decision appealed or remit the case to the department for further prosecution. Remittal to the department of first instance is at the discretion of the board (cf. decision T 1091/00 of 2 July 2002, point 4 ).
35. 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 preferably be given the opportunity to have the important elements of the case heard before two instances. The essential function of appeal proceedings is to consider whether the decision which has been issued by the first instance department is correct. Hence, a case is normally remitted, if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

36. In particular, remittal is taken into consideration by the boards in cases where a first instance department issues a decision solely upon one particular issue (here novelty) which is decisive for the case against a party and leaves other essential issues (here inventive step) 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 the undecided issues.
37. The Opposition Division in the decision under appeal has only dealt with the question of novelty in relation to document D2, without comprehensively touching any other substantial requirements of the EPC. Thus, the fundamental requirement under Article 56 EPC has not yet been examined by the department of first instance. Consequently, the first instance decision was not such as to put the Board in a position such that it can decide whether or not all of the substantial requirements of the EPC are met by the present patent.
38. Therefore, although being aware that this could lead to a considerable delay of the procedure, the board considers it to be justified and appropriate to allow the set of claims of auxiliary request V to be examined by two instances, and decides therefore, exercising its

discretion under Article 111(1) EPC, 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 upon the basis of the claims of auxiliary request V, filed under cover of a letter dated 21 October 2010.

The Registrar:

The Chairman:



A. Wolinski

M. Wieser

Decision electronically authenticated