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Datasheet for the decision of 17 March 2022

Case Number: T 2598/18 - 3.3.01

Application Number: 12851708.3

Publication Number: 2782586

IPC: A61K31/733, A61K31/64, A61P3/10, A61K45/06, A61K31/635

Language of the proceedings: EN

Title of invention:
IMPROVED SYNERGISTIC ANTI-DIABETIC COMPOSITIONS

Applicant:
Ozstar Therapeutics Pty Ltd

Headword:
Synergistic composition of inulin and sulfonylurea for treating diabetes/OZSTAR

Relevant legal provisions:
EPC Art. 54(3), 123(2)

Keyword:
Novelty - main request (no) - auxiliary request 1 (no)
Amendments - auxiliary requests 2 and 3 - allowable (no)

Decisions cited:
T 1859/09

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Case Number: T 2598/18 - 3.3.01

D E C I S I O N
of Technical Board of Appeal 3.3.01
of 17 March 2022

Appellant: (Applicant)	Ozstar Therapeutics Pty Ltd 10/2 Waverton Avenue Waverton NSW 2060 (AU)
Representative:	Forresters IP LLP Skygarden Erika-Mann-Straße 11 80636 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 11 May 2018 refusing European patent application No. 12851708.3 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	A. Lindner
Members:	M. Pregetter
	P. de Heij

Summary of Facts and Submissions

I. The examining division refused European patent application no. 12851708.3. The main request and auxiliary request 1, both filed on 8 March 2018, were found to lack novelty (Article 54(3) EPC).

Claim 1 of the main request reads as follows.

"1. Inulin having a Degree of Polymerization (DP) below about 25 for use in a method of treating diabetes or hyperglycaemia or for delaying the onset of diabetes wherein said inulin is administered with a sulfonylurea and/or a sulfonamide."

II. The following document is pertinent to the decision.

(1) WO2011/146981

III. The applicant (appellant) appealed the decision of the examining division. With the statement setting out the grounds of appeal, the appellant resubmitted the main request and auxiliary request 1 and submitted auxiliary request 2.

IV. The board issued a communication pursuant to Rule 100(2) EPC.

V. With a letter dated 21 October 2020 in reply to the board's communication, the appellant submitted auxiliary requests 1 to 3. The board understands that these auxiliary requests replace the auxiliary requests submitted with the grounds of appeal.

Claim 1 of auxiliary request 1 reads as follows.

"1. Inulin having a Degree of Polymerization (DP) in the range of from 2 to 10 or 3 to 10 for use in a method of treating type 2 diabetes or hyperglycaemia or for delaying the onset of diabetes wherein said inulin is administered with a sulfonylurea and/or a sulfonamide."

Claim 1 of auxiliary request 2 reads as follows.

"1. Inulin having a Degree of Polymerization (DP) in the range of from 2 to 10 or 3 to 10 for use in a method of treating type 2 diabetes or hyperglycaemia or for delaying the onset of type 2 diabetes wherein said inulin is administered with glimepiride or glipizide".

Claim 1 of auxiliary request 3 is identical to claim 1 of auxiliary request 2. Auxiliary request 3 differs from auxiliary request 2 in the wording of claim 5.

VI. The board issued a summons to oral proceedings.

VII. With a letter dated 15 February 2022, the appellant informed the board that it would not attend oral proceedings. It maintained its requests of 21 October 2020.

VIII. The appellant's arguments, in so far as they are relevant to the decision, may be summarised as follows.

Novelty

The subject-matter of the claims of auxiliary request 1 was novel in view of the disclosure of document (1). The therapeutic effect of claim 1 was to be considered

a technical feature of the claim which had to be taken into account. In accordance with T 1859/08, it had to be directly and unambiguously derivable from the prior art that the therapeutic effect, i.e. regulating or normalising blood glucose concentration, was obtained by a treatment comprising administration of inulin having a degree of polymerisation (DP) in the range from 2 to 10 or 3 to 10 and a sulphonylurea and/or sulphonamide. Inulin preparations were heterogenous and varied significantly with respect to the DP. Inulin having the claimed range(s) of DP were distinct from inulin comprising higher DP ranges. Document (1) disclosed a clinical benefit with regard to two inulin treatments. The first, "JLS", had a heterogeneous DP ranging from 3 to 60, the second, "Orafti", had a DP in the range of 8 to 60. There were no experiments showing a clinical benefit due to the administration of inulin having a DP in the range from 2 to 10 or 3 to 10 in combination with a sulphonylurea and/or sulphonamide. The disclosure of Table 1 of document (1) was not pertinent as it could not even be seen as relating to inulins that were "currently being explored" (see situation in T 1859/08). Thus, document (1), which did not directly and unambiguously disclose that the therapeutic effect had been obtained by the claimed combination, was not novelty-destroying.

Concerning the subject-matter of the main request, reference was made to the submissions of 8 March 2018 (made in preparation for the oral proceedings before the examining division). In addition to the arguments of the preceding paragraph, it was brought forward that only inulin "JLS" (Just Like Sugar®) in document (1) showed synergistic effects with sulphonylurea (glibenclamide) and that it was not clear whether inulin or the remaining 4% of "JLS" was responsible for

the synergistic effect. Document (1) did not disclose that only the DP fraction of below 25 was responsible for the observed activity. Therefore, document (1) contained merely a generic disclosure for inulin which could not take away the novelty of inulin having low DPs. The range recited in claim 1 of the main request represented a purposeful selection over the disclosure of document D1.

Amendments

Basis for the amendments effected in claim 1 of auxiliary request 2 (the claims of auxiliary request 3 were the same as the claims of auxiliary request 2 save for the deletion of the second part of claim 5) could be found in paragraphs [0009], [0034] and [0035]. These paragraphs referred to improved synergistic compositions having inulin with DP ranges 2 to 10 and 3 to 10 and the sulphonylurea glimepiride or glipizide. The synergistic compositions inherently covered the use of the compositions in a method of treating diabetes as detailed in the examples and elsewhere in the specification. Examples 3 and 4 related to the treatment of type 2 diabetes using a combination of glimepiride and inulin (CI) and glipizide and inulin (CI), respectively. Support for prophylactic or therapeutic treatment of diabetes could be found in paragraphs [0016] to [0019] and for delaying the onset of diabetes and hyperglycemia in paragraph [0038].

IX. The appellant requests that the decision under appeal be set aside and that a patent be granted based on the main request, submitted with the statement of grounds of appeal, or, alternatively, that a patent be granted based on any of auxiliary requests 1 to 3, submitted with the letter dated 21 October 2020. If any of the

claim requests is found allowable (the board understands: is considered novel), the appellant requests that the application be remitted to the examining division for further prosecution.

Reasons for the Decision

1. The appeal is admissible.

2. *Novelty - main request and auxiliary request 1*

2.1 Claim 1 of the main request is worded in accordance with Article 54(5) EPC. It defines a compound for use in a method of treatment. The compound is inulin having a DP below "about" 25. The method of treatment is presented as the treatment of diabetes or hyperglycaemia or for delaying the onset of diabetes. Claim 1 of auxiliary request 1 restricts the DP to 2 to 10 or 3 to 10 and diabetes to type 2 diabetes. Furthermore, claim 1 of the main request and auxiliary request 1 requires that the inulin is administered with a sulphonylurea and/or a sulphonamide. Claim 1 neither defines any dose of inulin nor quantifies the contribution of the inulin to the overall treatment. A synergistic effect is not defined.

Claims worded in accordance with Article 54(5) EPC require that the claimed treatment be causally linked to the administration of the compound(s) claimed. This has to be taken into account when examining novelty.

2.2 Document (1) concerns "a method of treating diabetes comprising the administration to a subject requiring such treatment of a composition comprising inulin, or a source thereof, and a sulphonylurea, in the amount and for a time sufficient to reduce, regulate or normalize

blood glucose concentration" (page 6, lines 4 to 7). It further discloses that the administration of inulin is intended to improve the efficacy of the sulphonylurea treatment; that the diabetes is type-2 diabetes; and that treatment of hyperglycemia, also as a pre-diabetic state, is envisaged (page 6, lines 8 to 25 and claims 1 to 5).

On page 6, lines 26 to 28, inulin sources for use in the treatment are described, including onion and leek. Table 1 shows that these sources include inulin having a degree of polymerisation below 25. Some of these inulin sources have only inulin of a DP below 25 (onion, leek and wheat). Onion is explicitly identified as having inulin of a DP of 2 to 12 with an average of 5.

Document (1) provides experimental evidence for the treatment of diabetes by inulin administered on top of sulphonylureas in Example 1. The inulin is derived from chicory root (CR). It was "obtained in the form of a product named Just Like Sugar® (Just Like Sugar, Inc., P.O. Box 96083, Las Vegas, Nevada 89193, USA; Product Code: AR160GR-2) which contains, inter alia, about 96% inulin and was used as a suitable source of inulin for the present studies. This source of inulin will be referred to where appropriate as inulin (JLS). Typically, inulin extracted from CR has a heterogeneous DP, ranging from about 3 to about 60, with average DP of about 25 (19; 22)." (page 15, last paragraph). A further inulin used in the examples is obtained from Orafti Inc. and has a DP in the range of 8 to 60 with an average of about 25 (page 16, lines 1 to 3). It also is effective, albeit at higher doses (Example 3, page 18, lines 20 and 21). There is thus clear disclosure that a preparation comprising inulin having a broad

range of DPs and including low DPs is effective in treating type 2 diabetes. Document (1) at no point indicates that a further ingredient of the commercially available inulin preparations might be responsible for the activity. Therefore, document (1) discloses that inulin as such has activity. For actual use, inulin derived from chicory or other plant-based sources, such as onion, is taught.

The board agrees with the appellant that document (1) does not contain experimental data for an inulin source consisting of inulin having a degree of polymerisation below 25 (or below 10). However, in view of the broad range of DPs of the inulin used in Examples 1 and 3 and the list of inulin sources falling within various parts of this broad range, the disclosure of document (1) has to be read as pertaining to the treatment of diabetes in various forms by any inulin, i.e. by a chemical compound having the carbohydrate units and bonds specific for inulin in the form of a chain-terminating glucosyl moiety, fucosyl moieties and β(1-2) bonds, and in particular by the inulins derived from the plant-based sources explicitly listed. This disclosure includes treatment by inulin from onions which contain inulin having a DP of 2, within the range as specified in the main request and auxiliary request 1.

The appellant has not pointed to any passage in document (1), or to any other evidence, that could alter this reading.

2.3 Decision T 1859/08 presents considerations concerning a prior-art document which does not include any experimental evidence but describes merely that a therapy was being explored in the absence of any data on efficacy. The situation at hand differs

fundamentally from the situation of T 1859/08 in that current document (1) discloses efficacy experimentally for inulins of varying DPs.

2.4 Consequently, the disclosure of document (1) is novelty-destroying for the subject-matter of claim 1 of the main request and auxiliary request 1 (Article 54(3) EPC).

3. *Amendments - auxiliary requests 2 and 3*

The technical features of claim 1 of auxiliary requests 2 and 3 can be separately found in the application as filed.

Paragraphs [0016],[0017], [0018] and [0038] relate to a method of prophylactic or therapeutic treatment of diabetes, hyperglycaemia and type 2 diabetes and delaying the onset of diabetes, respectively. These paragraphs concern the use of any sulphonylurea/ sulphonamide and inulin having a DP below about 25.

In paragraphs [0009] and [0034], the ranges for the degrees of polymerisation of 2 to 10 or 3 to 10 are disclosed. However, these ranges do not represent the most preferred ranges. A selection from these two ranges is thus necessary.

Paragraph [0035], in the context of type 2 diabetes, describes that inulin synergises with sulphonylureas such as glimepiride and glipizide. Furthermore, the combination of glimepiride and inulin (CI) and glipizide and inulin (CI) for the treatment of type 2 diabetes is disclosed in Examples 3 and 4, respectively. The two sulphonylureas are thus singled out in the context of treatment of type 2 diabetes. The

situation differs for the treatment of hyperglycaemia, which is also defined in claim 1. Here, glimepiride and glipizide have to be selected, for example, from the list of paragraph [0010]. Glimepiride or glipizide are thus not the most preferred sulphonylureas for the treatment of all indications listed in claim 1.

The subject-matter of claim 1 of auxiliary requests 2 and 3 is the result of the selection of several technical features not disclosed in combination in the application as filed and thus is not directly and unambiguously derivable.

Consequently, the subject-matter of claim 1 of auxiliary requests 2 and 3 extends beyond the content of the application as filed (Article 123(2) EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

M. Schalow A. Lindner

Decision electronically authenticated