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Datasheet for the decision of 3 May 2024

Case Number: T 0170/22 - 3.3.04

Application Number: 10735109.0

Publication Number: 2451482

IPC: A61K45/06, A61K31/155, A61K31/7034, A61P3/04, A61P3/10, A61K31/4436, A61K31/381, A61K47/38, A61K31/7042

Language of the proceedings: EN

Title of invention:
COMBINATION THERAPY FOR THE TREATMENT OF DIABETES

Patent Proprietor:
Janssen Pharmaceutica NV

Opponents:
Teva Pharmaceutical Industries Ltd.
Generics [UK] Limited

Headword:
Antidiabetic combinations/JANSSEN

Relevant legal provisions:
EPC Art. 56, 84, 123(2), 123(3)
EPC R. 80
RPBA 2020 Art. 12(3), 12(4), 12(5), 12(6), 13(2)

Keyword:
Main request, auxiliary request 24 - inventive step - reasonable expectation of success (no)
Main request - clarity after amendment (no)
Auxiliary request 1 - amendment to case - admitted (no)
Auxiliary requests 2 to 4 - amendment after notification of A. 15(1) RPBA communication - exceptional circumstances (no)
Auxiliary request 24 - substantiation of clarity objection (no)
Auxiliary request 24 - amendments occasioned by ground for opposition (yes), added subject-matter (no), extension of the scope of protection (no)

Decisions cited:
G 0002/21, G 0003/14, G 0002/10, T 0664/20, T 0266/15, T 0514/14, T 0287/11, T 2017/07, T 0596/96, T 0079/96

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Case Number: T 0170/22 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 3 May 2024

Appellant: (Patent Proprietor)	Janssen Pharmaceutica NV Turnhoutseweg 30 2340 Beerse (BE)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Respondent: (Opponent 1)	Teva Pharmaceutical Industries Ltd. 124 Dvora HaNevi'a St. 6944020 Tel Aviv (IL)
Representative:	D Young & Co LLP 3 Noble Street London EC2V 7BQ (GB)
Respondent: (Opponent 2)	Generics [UK] Limited Station Close Potters Bar Hertfordshire EN6 1TL (GB)
Representative:	Elkington and Fife LLP Prospect House 8 Pembroke Road Sevenoaks, Kent TN13 1XR (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 9 November 2021 revoking European patent No. 2451482 pursuant to Article 101(3)(b) EPC**

Composition of the Board:

Chairwoman	M. Pregetter
Members:	S. Albrecht
	A. Bacchin

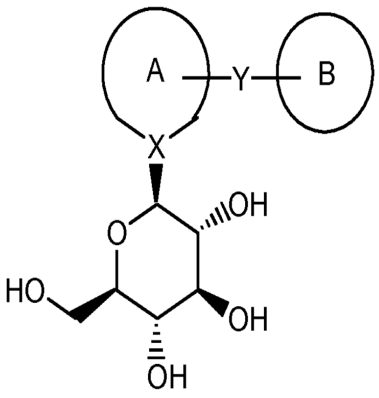
Summary of Facts and Submissions

I. European patent 2 451 482 ("the patent") is based on European patent application No. 10735109.0 ("the application"). The patent was granted with fifteen claims.

Claim 1 as granted reads:

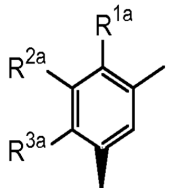
"1. Metformin or a pharmaceutically acceptable salt thereof for use in a method for treating a glucose related disorder, said method comprising administering to a subject in need thereof a pharmaceutical composition comprising

(a) metformin or a pharmaceutically acceptable salt thereof;
(b) a compound of formula (I)

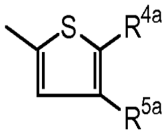


(I)

wherein Ring A is



wherein R^{1a} is a halogen atom, a lower alkyl group, or a lower alkoxy group, and R^{2a} and R^{3a} are hydrogen atoms;
and Ring B is



wherein R^{4a} is a phenyl group optionally substituted by a substituent selected from the group consisting of a halogen atom, a cyano group, a lower alkyl group, a halo-lower alkyl group, a lower alkoxy group, a halo-lower alkoxy group, a mono- or di-lower alkylamino group, a carbamoyl group, and a mono-or di-lower alkylcarbamoyl group; or a heterocyclyl group optionally substituted by a halogen atom, a cyano group, a lower alkyl group, a lower alkoxy group, a carbamoyl group, or a mono- or di-lower alkylcarbamoyl group, and R^{5a} is a hydrogen atom; and
Y is $-CH_2-$;
or a pharmaceutically acceptable salt thereof;

(c) between 5% and 50% by weight of diluent selected from the list comprising lactose, microcrystalline cellulose, dicalcium phosphate and starch;
(d) between 1% and 10% by weight of binder; and

(e) between 1% and 10% by weight of disintegrant selected from the list comprising sodium starch glycolate, croscarmellose sodium and crospovidone; wherein the metformin or pharmaceutically acceptable salt thereof is in an amount in the range of from 500 mg to 2000 mg; and the compound of formula (I) is in an amount of from 10 mg to 300 mg."

Claim 2 as granted is identical to claim 1 except that the preamble reads: "*A compound of formula (I) for use [...]*".

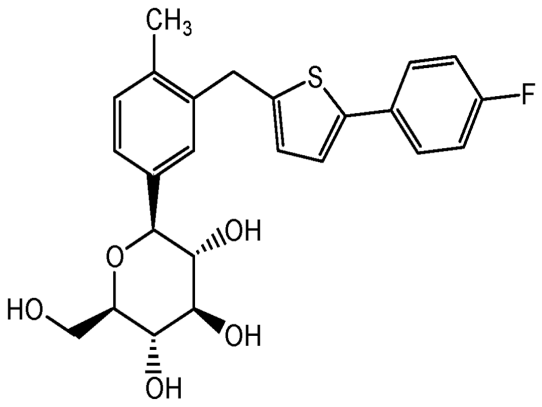
II. Opposition proceedings were based on the grounds for opposition under Article 100(a) EPC in conjunction with Articles 54 and 56 EPC for lack of novelty and lack of inventive step and under Article 100(b) and (c) EPC.

III. The opposition division's decision to revoke the patent was based on a main request and 27 auxiliary requests, labelled as auxiliary requests 1, 2, 6, 7, 10, 10b, 10c, 11 to 18, 18a, 18b, 18c, and 19 to 27. The main request was the set of claims filed as auxiliary request 10a on 11 June 2021. The sets of claims of auxiliary requests 1, 2, 6, and 7 were filed with the reply to the notices of opposition. The sets of claims of auxiliary requests 10, 11 to 18, and 19 to 27 were filed on 21 April 2021. The sets of claims of auxiliary requests 10b, 10c, 18a, 18b, and 18c were filed on 11 June 2021.

Claim 1 of the main request reads:

"1. Metformin hydrochloride for use in a method for treating a glucose related disorder, said method comprising administering to a subject in need thereof a pharmaceutical composition comprising

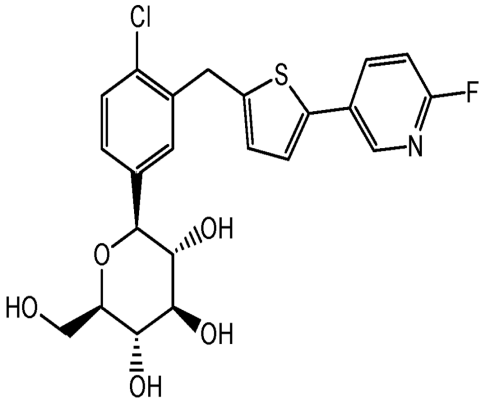
(a) metformin hydrochloride;
(b) a compound of formula (I) selected from the group consisting of:
i) a compound of formula (I-X)



(I-X)

or a pharmaceutically acceptable salt thereof; and

ii) a compound of formula (I-Y)



(I-Y)

or a pharmaceutically acceptable salt thereof;
(c) between 5% and 50% by weight of diluent selected from the list comprising lactose, microcrystalline cellulose, dicalcium phosphate and starch;

(d) between 1% and 10% by weight of binder selected from the list comprising polyvinylpyrrolidone, methylcellulose, hydroxypropyl cellulose and hydroxypropyl methylcellulose;
(e) between 1% and 10% by weight of disintegrant selected from the list comprising sodium starch glycolate, croscarmellose sodium and crospovidone;
(f) between 0% and 5% by weight of wetting agent selected from the list comprising sodium lauryl stearate and polysorbate 20;
(g) between 0% and 3% by weight of lubricant selected from the list comprising magnesium stearate and sodium strearyl [sic] fumarate; and
(h) flow promoter or glidant selected from the list comprising colloidal silicon dioxide and talc

wherein the metformin hydrochloride is in an amount in the range of from 500 mg to 2000 mg; and the compound of formula (I) is in an amount of from 15 mg to 300 mg."

Claim 2 of the main request is identical to claim 1 except that the preamble reads: "*A compound of formula (I) for use [...]*".

IV. In the decision under appeal, the opposition division found, *inter alia*, that the claimed subject-matter of the main request and all 27 auxiliary requests lacked inventive step over document D9 as the closest prior art when combined with document D5.

V. The patent proprietor ("appellant") lodged an appeal against the opposition division's decision.

VI. In the statement of grounds of appeal, the appellant requested as its main request that the decision under

appeal be set aside and that the patent be maintained on the basis of the main request underlying the impugned decision ("main request"). Alternatively, the appellant requested that the patent be maintained in amended form on the basis of one of the sets of claims of the following auxiliary requests:

- auxiliary requests 1 to 49
- "M" versions of the main request and those auxiliary requests among the 49 auxiliary requests that comprise independent claims not mentioning metformin as the first drug in the preamble (see sections 4.14 to 4.15 of the statement of grounds of appeal; hereafter "M requests")

The sets of claims of auxiliary requests 1 to 27 were identical to auxiliary requests 1, 2, 6, 7, 10, 11 to 18, 19 to 27, 10b, 10c, 18a, 18b, and 18c, respectively, underlying the appealed decision (see table in section 4.1 of the statement of grounds of appeal).

The subject-matter of the sole claim (claim 1) of auxiliary request 24 differs from that of claim 1 of the main request in the definition of components (c) to (h) (see point 61. below).

The sets of claims of auxiliary requests 28 to 49 were filed with the statement of grounds of appeal.

In relation to the M requests, the appellant indicated in the statement of grounds of appeal that it would file copies of these requests at the Board's direction.

VII. With their replies to the statement of grounds of appeal, opponents 1 and 2 ("respondent I" and

"respondent II") requested that the appeal be dismissed.

VIII. With its letter dated 6 April 2023, the appellant filed 24 sets of claims, i.e.

- "M" version of the main request ("main request-M")
- "SA" versions of auxiliary requests 8 to 12, 14 to 22, 25, 36 to 40, 42 to 44 and 47

IX. Oral proceedings before the Board were arranged, as requested by the parties, and were scheduled for 2 May and 3 May 2024.

X. In a communication under Article 15(1) RPBA ("communication"), the Board drew the parties' attention to the points to be discussed during the oral proceedings.

XI. With its letter dated 24 April 2024, the appellant filed three further sets of claims, i.e. auxiliary requests 2 to 4, and withdrew the following claim requests:

- all M requests
- auxiliary requests 6, 7, 17 to 22, 34, and 35
- "SA" versions of auxiliary requests 17 to 22

In this same letter, the appellant indicated that auxiliary request 46 filed with the statement of grounds of appeal would become auxiliary request 1, and specified the order of its requests to be as follows:

main request followed by auxiliary requests 1 to 4, 28, 47, 49, "SA" version of auxiliary request 47 ("auxiliary request 47-SA"), auxiliary requests 24, 27,

37, 42, 9, 14, 25, 43, 40, 15, 12, 44, 16, 39, 11, "SA" versions of auxiliary requests 37, 42, 9, 14, 25, 43, 40, 15, 12, 44, 16, 39, 11, auxiliary requests 38, 36, 10, 8, "SA" versions of auxiliary requests 38, 36, 10 and 8 (see paragraph bridging pages 2 and 3 of the minutes of the oral proceedings before the Board)

XII. Oral proceedings took place before the Board on 2 May and 3 May 2024 in the presence of all parties. In the course of these proceedings, the appellant withdrew auxiliary requests 28, 47, 49 and 47-SA. At the end of the oral proceedings, the Chair announced the Board's decision.

XIII. The following documents are referred to in this decision.

D1: M.F. Albertoni Borghese *et al.*, "INHIBITORS OF SODIUM/GLUCOSE COTRANSPORT", Drugs of the Future 34(4), 2009, 297-305

D2: US 2005/0233988 A1

D3: WO 2008/069327 A1

D5: WO 2009/035969 A1

D9: I. Idris *et al.*, "Sodium-glucose co-transporter-2 inhibitors: an emerging new class of oral antidiabetic drug", Diabetes, Obesity and Metabolism 11, 2009, 79-88

D9a: Copy of document D9 showing publication date of 29 December 2008

D18: L. Lachman *et al.*, "The Theory and Practice of Industrial Pharmacy", 3rd edn., Bombay: Varghese Publishing House, 1987, 233-234

In the written and oral appeal proceedings, reference was made to further documents including documents D21, D29 to D34, D42 and D47. However, these documents are

not crucial to this decision, and therefore do not need further consideration.

XIV. The appellant's submissions relevant to this decision can be summarised as follows.

Main request, auxiliary request 24 - inventive step (Article 56 EPC)

The dapagliflozin phase II study disclosed in document D9 (see page 83, last paragraph to page 84, end of first full paragraph) could be considered the closest prior art. The claimed subject-matter differed from this disclosure, *inter alia*, in that the SGLT2 inhibitor was a compound of formula (I-X) or (I-Y) and in that this inhibitor was formulated with metformin hydrochloride into a single composition.

Based on the experimental data disclosed in examples 1 and 2 of the patent, the objective technical problem to be solved by the claimed invention was to provide a combination in a single composition which achieved improvement over each monotherapy for the improved treatment of glucose-related disorders.

The solution to this problem proposed in the claims would not have been obvious. The prior art relied on by the respondents did not provide any motivation (or justification) to combine metformin hydrochloride and a compound of formula (I-X) or (I-Y) into a single composition. Even if the skilled person had contemplated such combinations, there would not have been a reasonable expectation of successfully providing improvements over either monotherapy alone due to the considerable unpredictability and uncertainty surrounding the compounds of formulas (I-X) and (I-Y),

their mechanisms of action, and their pharmacological properties at the priority date.

Main request - clarity (Article 84 EPC)

The feature "*selected from the group comprising [..]*" introduced in the definition of binder component (d) of claim 1 was clear, concise and limiting. The respondents' diverging interpretations of this feature were not reasonable and would not be adopted by a mind willing to understand.

In any event, an objection under Article 84 EPC would be impermissible under decision G 3/14 (OJ EPO 2015, A102), since the feature "*selected from the list comprising*" already formed part of the definition of components (c) and (e) in the granted claims.

Auxiliary request 1 - admittance (Article 12(4) and (6) RPBA)

Claim 1 of auxiliary request 1 differed from claim 1 of the main request in two main aspects, i.e. the preamble of this claim and the definition of binder component (d).

The amendment to the preamble of claim 1 constituted a legitimate response to the decision under appeal, in particular the last paragraph of section 14.2 of this decision. In this paragraph, the opposition division had informed the parties for the first time of its definition of the objective technical problem starting from document D9.

The amendment to binder component (d) formed part of claim 1 of auxiliary request 10c, and hence had already been decided upon by the opposition division.

Auxiliary requests 2 to 4 - admittance (Article 13(2) RPBA)

The filing of auxiliary requests 2 to 4 did not amount to a change in the appellant's appeal case within the meaning of Article 13(2) RPBA. None of these claim requests raised any new issues. All of the features in each of these three requests were present in claim requests which were already on file.

In any event, the Board's objections in paragraphs 3.2, 4. and 6.2.2 of its communication were cogent reasons justifying exceptional circumstances within the meaning of Article 13(2) RPBA.

Auxiliary request 24 - admittance of the respondents' objection of lack of clarity (Article 12(3), (5) RPBA)

This objection lacked substantiation contrary to the requirements of Article 12(3) and (5) RPBA.

Auxiliary request 24 - amendments (Rule 80 EPC)

The newly added feature to binder component (d) (i.e. insertion of the feature "*and wherein binder in the composition is selected from polyvinylpyrrolidone, methylcellulose, hydroxypropyl cellulose and hydroxypropyl methylcellulose;*" after the term *"binder,"* in claim 1 as granted) constituted a serious attempt to overcome an objection under Article 100(c) EPC raised by the respondents in their notices of opposition (see section 43 of respondent I's notice of opposition and sections (07) to (15) of respondent II's notice of opposition). Consequently, no objection could be raised under Rule 80 EPC against the newly added feature to binder component (d).

Auxiliary request 24 - amendments (Article 123(3) EPC)

The newly added feature to binder component (d) of claim 1 did not infringe Article 123(3) EPC. The format of claim 1 was in line with "cascade form" claim drafting (see Case Law of the Boards of Appeal, 10th edn., 2022, hereafter "Case Law", II.E.2.4.13). This cascade form imposed two separate conditions on the binder in the claimed pharmaceutical composition, i.e. (i) it must be present in an amount of between 1% and 10% by weight and (ii) it must be one of polyvinylpyrrolidone, methylcellulose, hydroxypropyl cellulose and hydroxypropyl methylcellulose.

Auxiliary request 24 - amendments (Article 123(2) EPC)

The claimed pharmaceutical composition found direct and unambiguous basis on page 19, lines 4 to 20, in conjunction with page 13, lines 17 to 18, page 21, lines 4 to 23, and page 24, line 19 to page 25, line 10, of the application as filed.

XV. The respondents' submissions relevant to this decision can be summarised as follows.

Main request, auxiliary request 24 - inventive step (Article 56 EPC)

In the absence of any comparison between the claimed subject-matter and the combination of dapagliflozin and metformin disclosed in document D9, the technical effects invoked by the appellant could not be taken into consideration in formulating the objective technical problem. Instead, this problem was to be

worded as an alternative combination for the treatment of glucose-related disorders.

Based on the information on the compound of formula (I-X) disclosed in documents D2, D3 and D5, and the common general knowledge on SGLT2 inhibitors in the field of diabetes reflected in documents D9 and D1, it would have been obvious to replace one SGLT2 inhibitor (dapagliflozin) with another SGLT2 inhibitor (compound of formula (I-X)) with a reasonable expectation of solving the above-mentioned technical problem.

Main request - clarity (Article 84 EPC)

Binder component (d) of claim 1 lacked clarity due to different but equally valid interpretations of the newly added feature "*selected from the group comprising*". This lack of clarity was not present in the claims as granted and had therefore to be examined in relation to Article 84 EPC.

Auxiliary request 1 - admittance (Article 12(4) and (6) RPBA)

In order to determine whether auxiliary request 1 constituted an amendment of the appellant's appeal case, the entire request needed to be looked at rather than the individual amendments in this request. The issues allegedly addressed by this request already formed part of the opposition proceedings. Consequently, there were no reasons which could justify the filing of auxiliary request 1 with the statement of grounds of appeal.

Auxiliary requests 2 to 4 - admittance (Article 13(2) RPBA)

The filing of auxiliary requests 2 to 4 constituted an amendment of the appellant's appeal case within the meaning of Article 13(2) RPBA. Contrary to the appellant's view, these requests contained amendments to the claims of the contested patent that were not previously on file.

There were no exceptional reasons that justified the admittance of these auxiliary requests. The points summarised by the Board in paragraphs 3.2 and 4. of its communication had been previously raised by the respondents. As to the Board's concerns expressed in paragraph 6 of its communication, these were both appropriate and foreseeable given the undue complexity of the appellant's earlier-filed requests during appeal proceedings.

Auxiliary request 24 - admittance of the respondents' objection of lack of clarity (Article 12(3), (5) RPBA)

This objection had been properly substantiated, see sections (16) and (17) of respondent II's reply to the statement of grounds of appeal.

Auxiliary request 24 - amendments (Rule 80 EPC)

Based on an interpretation of the newly added feature to binder component (d) of claim 1 of auxiliary request 24 according to which the list of binders in this claim had no limiting effect, this newly added feature did not change the scope of protection afforded by the patent. As a consequence, this amendment was not occasioned by a ground for opposition, contrary to the requirements of Rule 80 EPC.

Auxiliary request 24 - amendments (Article 123(3) EPC)

The pharmaceutical composition recited in the claims as granted could not include more than 10% by weight of any binder. By contrast, in the claims of auxiliary request 24 the 10% weight restriction only applied to the four specific binders listed in these claims. Consequently, the newly added feature to binder component (d) in claim 1 of auxiliary request 24 resulted in a broader scope of protection than afforded by the patent as granted, contrary to Article 123(3) EPC.

Auxiliary request 24 - amendments (Article 123(2) EPC) - respondent II

The subject-matter of claim 1 did not find direct and unambiguous basis in the application as filed for two reasons.

Firstly, arriving at the subject-matter of claim 1 required a selection from multiple lists of numerical ranges taken from the application as filed and disclosed in various levels of preference.

Secondly, the application as filed lacked any basis for excluding the presence of binders other than those specified in claim 1.

XVI. The appellant's final requests relevant to the present decision were as follows.

The appellant requested that the decision under appeal be set aside and that the patent be maintained on the

basis of the main request underlying the impugned decision.

Alternatively, the appellant requested that the patent be maintained in amended form on the basis of one of the sets of claims of:

(a) auxiliary request 1, filed as auxiliary request 46 with the statement of grounds of appeal
(b) auxiliary requests 2 to 4, all filed on 23 April 2024
(c) auxiliary request 24, identical to the set of claims of auxiliary request 10c underlying the appealed decision

Reference is made to the minutes of the oral proceedings with regard to the requests concerning the remaining auxiliary requests, which are not relevant to the present decision.

XVII. The respondents' final requests relevant to the present decision were as follows.

Both respondents requested that the appeal be dismissed and the patent revoked in its entirety.

They further requested that auxiliary requests 1 to 4 not be admitted into the proceedings.

Respondent I further requested that the appellant's observations made in its letter dated 23 April 2024 concerning the assessment of Article 56 EPC not be admitted into the proceedings.

Reasons for the Decision

1. The appeal is admissible.

Main request
Background of the claimed invention

2. As can be seen from point III. above, the pharmaceutical composition recited in claims 1 and 2 of the main request comprises two pharmaceutically active agents, i.e. metformin hydrochloride and a compound of formula (I) selected from:

- a compound of formula (I-X) or a pharmaceutically acceptable salt thereof ("compound (I-X)") and

- a compound of formula (I-Y) or a pharmaceutically acceptable salt thereof ("compound (I-Y)")

3. Compounds (I-X) and (I-Y) exhibit an inhibitory activity against the type 2 sodium/glucose transporter found in the intestine and kidney of mammalian species (SGLT2 inhibitors), and further exhibit a blood glucose lowering effect (see paragraph [0028] of the patent).

Inventive step (Article 56 EPC)
The closest prior art

4. All the parties took document D9 as the basis for their analysis of inventive step.

4.1 Document D9 is a scientific review article published around 6 months before the first priority date claimed for the patent, i.e. on 29 December 2008 (see document

D9a). This document (see abstract, last sentence) outlines the biology, expression and pleiotropic activity of the SGLT system and the pharmacological profile of SGLT2 inhibitors. Moreover, this document provides a summary of preclinical and early clinical data available for characterising the efficacy, safety and potential clinical utility of SGLT2 inhibitors in the management of diabetes.

4.2 With regard to early clinical data, document D9 provides an overview of completed and ongoing clinical trials with the SGLT2 inhibitors dapagliflozin, sergliflozin and AVE2268 (see chapter "Early Clinical Development of SGLT Inhibitors" starting at page 83, right-hand column, third full paragraph, and page 85, table 1).

4.3 One such completed clinical trial with dapagliflozin is a placebo-controlled, phase II clinical study in patients with type 2 diabetes (see page 83, right-hand column, last paragraph, to page 84, left-hand column, end of first full paragraph).

4.3.1 This study included patients who were either drug-naive or on a stable dose of metformin for at least 4 weeks prior to randomisation (fasting glucose < 240 mg/dl and HbA1c 6-10%). The patients received daily doses of 5 mg, 25 mg or 100 mg dapagliflozin (or placebo), either alone or with metformin, for 14 days.

4.3.2 All drug treatments gave rise to a dose-dependent increase in urinary glucose excretion, a dose-dependent reduction in fasting plasma glucose concentrations and improvements in glucose tolerance.

4.4 The respondents identified the disclosure of the phase II study arm employing dapagliflozin and metformin as an appropriate starting point within document D9 for the assessment of inventive step ("closest prior art"). The Board does not see any reason to differ.

Distinguishing features vis-à-vis the closest prior art

5. It was common ground that the claimed subject-matter differs from the closest prior art, *inter alia*, on account of the following:

- the identity of the SGLT2 inhibitor, i.e. compound (I-X) or (I-Y) instead of dapagliflozin ("difference (1)")

- the combination of metformin hydrochloride and compound (I-X) or (I-Y) in a single composition ("difference (2)")

Objective technical problem(s) and proposed solution(s)

6. Formulating the objective technical problem effectively solved by the claimed subject-matter entails determining the technical effect(s) or result(s) achieved by and linked to the distinguishing feature(s).

6.1 The appellant submitted that the claimed combination of metformin hydrochloride with compound (I-X) or compound (I-Y) achieved a reduction in blood glucose levels which was significantly superior to each monotherapy (i.e. approximately additive). In support of its case, the appellant relied on the *in-vivo* data reported in tables 1 and 3 of the patent.

6.2 Example 1 of the patent reports a study in a mouse model for type 2 diabetes. This study investigates the effects of separate and combined administration of metformin (500 mg/kg body weight) and compound (I-Y) (1 mg/kg body weight and 10 mg/kg body weight) on the animals' fed and fasted blood glucose levels, as well as on the animals' blood glucose area under the curve (AUC) during an oral glucose tolerance test (OGTT).

6.3 The study disclosed in example 2 is similar to that underlying example 1, but uses a different SGLT2 inhibitor (compound (I-X)) and a different type of mouse model ("ob/ob" mouse, see paragraph [0192] of the patent).

6.4 As can be seen from the above, the comparators used in the studies of examples 1 and 2 are the respective monotherapies rather than the dapagliflozin/metformin combination representing the closest prior art.

6.5 Hence, as correctly observed by the respondents, the *in-vivo* data contained in examples 1 and 2 of the patent are not suitable for demonstrating any technical effect linked to the claimed SGLT2 inhibitors (i.e. difference (1), see point 5. above) over the closest prior art. Moreover, the Board shares the respondents' doubts as to whether these data credibly show the alleged additive effect of the claimed combinations over each monotherapy across the claimed scope.

6.6 What the *in-vivo* data contained in examples 1 and 2 of the patent do show, however, is that compounds (I-Y) and (I-X), taken alone and in combination with metformin, are effective in reducing all three blood parameters in the tested animals, i.e. fed and fasted

blood glucose levels, and blood glucose AUC during OGTT relative to vehicle (see tables 1 and 3 of the patent).

6.7 In view of the foregoing, the Board is satisfied that, like the combination of metformin with dapagliflozin representing the closest prior art, the claimed combination of metformin hydrochloride with compound (I-X) or (I-Y) is suitable for the treatment of glucose-related disorders. In other words, the claimed combinations constitute alternative means for treating glucose-related disorders. This was not contested by the respondents.

6.8 With regard to difference (2) (see point 5. above), it was not in dispute that formulating metformin hydrochloride and compound (I-X) or (I-Y)) in a single composition rather than in two separate compositions gives rise to added patient convenience and compliance.

6.9 However, the Board cannot recognise any causal link between the aforementioned beneficial effects and the active agents recited in the claims of the main request. Rather, these effects may be observed with any two or more active agents when formulated in a single composition rather than in two separate compositions. This has not been disputed by any of the parties.

7. Consequently, differences (1) and (2) are not functionally interdependent and therefore give rise to two partial objective technical problems (see Case Law of the Boards of Appeal, 10th edn., 2022, hereafter "Case Law", I.D.9.3.2), namely:

(a) that of providing alternative means to treat glucose-related disorders ("first technical problem")

(b) that of providing means to improve patient compliance and convenience ("second technical problem")

8. The respondents did not include the effects of improved patient compliance and convenience in the objective technical problem. Specifically, respondent II argued that as a matter of practicality, the only technical effects to be considered for formulating the objective technical problem were those that could credibly be held non-obvious.

9. The Board does not agree. Determining the objective technical problem requires an assessment of the technical results and effects achieved by the claimed invention as compared with the closest prior art (see decision G 2/21, OJ EPO 2023, A85, points 24 to 26 of the Reasons). The problem-solution approach does not require a technical effect to be credibly held non-obvious for it to be included in the objective technical problem. The assessment of whether a technical effect achieved by a distinguishing feature would have been obvious in the light of the prior art is to be made at a later stage of the problem-solution approach, i.e. when assessing the obviousness of the claimed solution.

10. The appellant defined the objective technical problem differently, i.e. as "*the provision of a combination in a single composition which achieved improvement over each monotherapy for the improved treatment of glucose-related disorders*". However, in view of the positive outcome of the assessment of inventive step for the appellant (see points 14. to 27. below), the

objective technical problem defined by the appellant need not be discussed.

11. The proposed solution to the first technical problem is to use metformin hydrochloride in combination with compound (I-X) or (I-Y).

12. The proposed solution to the second technical problem is to combine the two pharmaceutically active agents in a single composition.

Obviousness

13. In the case of two partial objective technical problems, obviousness must be assessed for each partial problem separately.

Obviousness of the proposed solution to the first objective technical problem (see point 7.(a) above)

14. The key question to be answered in this context is whether the prior art relied on by the respondents would have given the skilled person a reasonable expectation of successfully solving the problem of providing alternative means to treat glucose-related disorders with combinations of metformin hydrochloride and compound (I-X) or (I-Y).

15. On the basis of the facts and submissions before it, the Board concludes that this question must be answered in the negative.

16. In support of their case on obviousness, the respondents relied, *inter alia*, on the prior art knowledge on compounds (I-X) and (I-Y) contained in documents D2, D3 and D5.

16.1 Document D2, a US patent application, describes SGLT inhibitors of a specified formula for use in the treatment of glucose-related disorders including diabetes mellitus (see paragraphs [0009] to [0013]). One of these SGLT2 inhibitors is compound (I-X) (see page 46, compound 84). This compound exhibits an *in-vitro* SGLT2 half-maximal inhibitory concentration (IC50) of 2.2 (see ninth row of the table disclosed in paragraph [0800]).

16.2 Documents D3 and D5 are international patent applications published under the PCT.

16.2.1 Document D3 pertains to a crystalline form of compound (I-X) useful as an SGLT inhibitor. It describes methods for preparing and isolating this compound, pharmaceutical compositions comprising it and pharmaceutical methods of treatment (see page 1, lines 9 to 16).

16.2.2 Document D5 discloses processes for the preparation of compounds having inhibitory activity against SGLT being present in the intestine or kidney (see page 1, lines 11 to 13). These compounds include compound (I-X) (see page 5, lines 5 to 9) and I-Y (see page 9, lines 1 to 5). Document D5 further states that:

- the crystalline forms of compounds (I-X) and (I-Y) are SGLT2 inhibitors with excellent blood glucose lowering effect (see page 69, lines 25 to 28)

- the compounds described in this document are useful in the treatment of, *inter alia*, type 2 diabetes (see paragraph bridging pages 11 and 12) and may be

used with further antidiabetic agents such as biguanides (see page 54, lines 1 to 11)

17. As correctly observed by the appellant, the aforementioned prior art disclosures in documents D2, D3 and D5 do not contain any preclinical data for compounds (I-X) and (I-Y) except for the *in-vitro* data for compound (I-X) discussed in point 16.1 above. The glycaemic effects reported in document D5 (see point 16.2.2 above) are assertions devoid of evidential value.

18. In view of the foregoing, it follows that compounds (I-X) and (I-Y) were still in early stages of their pharmaceutical development at the effective date of the patent.

19. The Board acknowledges that the basis for proceeding with the pharmaceutical development of a compound is favourable preclinical data. However, the mere fact that the prior art contains such data (and lacks any prejudice or disincentive to proceed with the next stage of pharmaceutical development) does not constitute in itself a sufficient criterion to establish a reasonable expectation of success. Whether such expectation can indeed be acknowledged, is to be decided on a case-by-case basis having regard to all the relevant circumstances of a given case. One particularly relevant aspect to be considered in this assessment is the objective technical problem that the skilled person is tasked with, more importantly the requirement(s) specified in this problem that a potential solution to this problem must fulfil.

20. In the case at issue, as explained in point 7.(a) above, the first objective technical problem that the

claimed invention sets out to achieve in view of the closest prior art is that of providing alternative means to treat glucose-related disorders. Hence, like the dapagliflozin/metformin combination representing the closest prior art, a potential solution to this problem must be efficacious in the treatment of patients afflicted with glucose-related disorders. In other words, this solution must reach the threshold of therapeutic efficacy in these patients but it is not required to be as efficacious as the dapagliflozin/metformin combination representing the closest prior art.

21. As explained in point 17. above, the sole preclinical data on compounds (I-X) and (I-Y) publicly available at the effective date of the patent are the compounds' *in-vitro* IC50 values for SGLT2. There is no prior art on file disclosing any other preclinical data, let alone any clinical data in actual patients. Hence, a high level of uncertainty regarding the potential of compounds (I-X) and (I-Y) for successful therapy of patients with glucose-related disorders would have been involved.

22. In view of this uncertainty, the Board considers that the aforementioned *in vitro* data would, at best, have provided the skilled person with a hope of success but not a reasonable expectation that combinations of metformin hydrochloride with compound (I-X) or (I-Y) would be effective in the treatment of glucose-related disorders.

23. The respondents' arguments in support of a reasonable expectation of success (see point XV. above, under the heading "*Main request, auxiliary request 24 - inventive step (Article 56 EPC)*") are not convincing.

23.1 Document D9 indisputably states (see page 85, left-hand column, lines 6 to 9, in conjunction with figure 3) that SGLT2 inhibitors should be easy to combine with other oral and injectable treatments because they do not affect glucose metabolism. Document D9 further discloses (see conclusions on page 86) that:

"Significant interest has emerged in the therapeutic use of SGLT2 inhibitors for the treatment of type 2 diabetes and obesity. Preliminary evidence from early-phase II clinical trials, communicated mainly in abstract form, has provided proof of concept that SGLT2 inhibitors lower plasma glucose concentrations after single-dose administration and after short-term oral use either as monotherapy or in combination with metformin."

23.2 Document D1 is a further scientific review article published shortly before the first priority date claimed for the patent. Like document D9, document D1 explains (see page 300, right-hand column, second full paragraph) that SGLT2 inhibitors can be used in monotherapy or in combination with other oral agents such as metformin or insulin.

23.3 However, when reading the aforementioned passages of documents D9 and D1 in context, the skilled person would have understood the SGLT2 inhibitors referred to in these passages to be those compounds that had already entered early-phase clinical development (see document D9, page 83, right-hand column, penultimate paragraph; document D1, pages 301 to 302, under the heading "Selective inhibitors"), i.e. compounds that had already undergone extensive preclinical testing and

shown favourable results in these tests (e.g. dapagliflozin).

23.4 This not being so for compounds (I-X) and (I-Y) (see point 17. above), the aforementioned disclosures of documents D9 and D1 would not have given the skilled person a reasonable expectation that combinations of metformin hydrochloride with compound (I-X) or (I-Y) would be effective in the treatment of glucose-related disorders.

23.5 Likewise, the fact that, in relation to diabetes, combinations of active agents with different mechanisms of action were generally considered advantageous in the art cannot compensate for the absence of more advanced preclinical data in relation to compounds (I-X) and (I-Y) (e.g. the *in-vivo* preclinical data disclosed in examples 1 and 2 of the patent).

24. Against this background, the Board concludes that the proposed solution to the first objective technical problem would not have been obvious having regard to the prior art cited by the respondents.

Obviousness of the proposed solution to the second objective technical problem (see point 7.(b) above) and overall conclusion on inventive step of the main request

25. The Board agrees with the respondents that the proposed solution to the second technical problem would have been obvious having regard to the skilled person's common general knowledge reflected in document D18, page 234, left-hand column, first full paragraph.

26. However, according to the case law of the Boards of Appeal (see Case Law, I.D.9.3.2), it suffices for the

subject-matter of a claim based on a combination of features to be inventive, if the solution of at least one partial objective technical problem would not have been obvious having regard to the state of the art.

27. Since, for the reasons set out above, the proposed solution to the first objective technical problem would not have been obvious, it follows that the subject-matter of claim 1 involves an inventive step starting from the closest prior art.

28. With regard to claim 2 of the main request (see point III. above), the respondents did not present any arguments beyond those already submitted with respect to claim 1 of the main request.

29. As a consequence, the subject-matter of claim 2 of the main request involves an inventive step for the same reasons as the subject-matter of claim 1 of this request.

30. For the sake of completeness, the Board notes that its inventive step reasoning provided above is not based on any of the appellant's observations made in its letter dated 23 April 2024 concerning the assessment of Article 56 EPC. Consequently, there was no need for the Board to decide on respondent I's request for non-admittance of these observations.

Main request
Clarity - Article 84 EPC - claim 1

31. Compared to claim 1 as granted (see point I. above), claim 1 of the main request is amended to, *inter alia*, define binder component (d) of the pharmaceutical

composition as follows (changes indicated by the Board):

"(d) between 1 % and 10% by weight of binder **selected from the list comprising polyvinylpyrrolidone, methylcellulose, hydroxypropyl cellulose and hydroxypropyl methylcellulose**;"

32. The feature "*selected from the list comprising polyvinylpyrrolidone, methylcellulose, hydroxypropyl cellulose, and hydroxypropyl methylcellulose*" newly added to claim 1 of the main request will be referred to below as "amendment in dispute".

33. Decision G 3/14 (OJ EPO 2015, A102, Order) prescribes that, in considering whether, for the purposes of Article 101(3) EPC, a patent as amended meets the requirements of the EPC, the claims of the patent may be examined for compliance with the requirements of Article 84 EPC only when, and then only to the extent that, the amendment introduces non-compliance with Article 84 EPC.

34. In the case at hand, both of these conditions are fulfilled, i.e.:

(i) the amendment in dispute gives rise to a lack of clarity of the binder component (d) of claim 1, and

(ii) this lack of clarity was not already present in the claims as granted but introduced in claim 1 by way of the amendment in dispute.

Re point (i) - the amendment in dispute gives rise to a lack of clarity of the binder component (d) of claim 1

35. The amendment in dispute gives rise to at least two technically sensible but contradictory interpretations of the binder component (d).

35.1 One such technically sensible interpretation is the one put forward by the opposition division in the decision under appeal (see point 10 of the Reasons). According to this interpretation, the amendment in dispute is entirely non-limiting due to the presence of the open terminology "*comprising*" after the word "*list*".

35.2 Another technically sensible interpretation of the binder component (d) is the one adopted by the respondents. According to this interpretation, the term "*comprising*" after the word "*list*" has a closed meaning such that the list of the four specific binders in the binder component (d) is exhaustive.

36. The appellant proposed yet another interpretation of the binder component (d). The appellant agreed with the opposition division that the term "*comprising*" in the amendment in dispute was open terminology. However, this term did not qualify the list of binders but the binder itself, i.e. the binder must include at least some of polyvinylpyrrolidone, methylcellulose, hydroxypropyl cellulose and hydroxypropyl methylcellulose.

37. The Board does not concur with the appellant's interpretation of binder component (d).

37.1 Reading claim 1 according to the common rules of syntax, there is no doubt that the wording "*comprising*"

qualifies the feature "*list*" in the amendment in dispute.

37.2 As submitted by respondent II (see sections (08) to (10) of its reply to the statement of grounds of appeal), the term "*comprising*" generally implies an open definition when used in a claim preamble in the context of a claim defining a product.

37.3 However, in the current case, the term "comprising" does not define a single entity but a "list" of four alternative binders (polyvinylpyrrolidone, methylcellulose, hydroxypropyl cellulose, and hydroxypropyl methylcellulose). In this particular context, the term "comprising" can take two distinct, contradictory meanings, i.e.:

(i) the open meaning proposed by the opposition division, i.e. it can be understood as "*including but not limited to*"

(ii) the closed meaning proposed by the respondents, i.e. it can be understood as "*consisting of*"

37.4 The open meaning of the term "comprising" has the implication that the list of binders in binder component (d) is open-ended, i.e. the four binders of this list are merely exemplary and other binders may be present.

37.5 The closed meaning of the term "comprising" has the opposite implication, namely that the list of binders in binder component (d) is exhaustive. In other words, binder component (d) of claim 1 must be between 1% and 10% by weight of polyvinylpyrrolidone, methylcellulose,

hydroxypropyl cellulose, or hydroxypropyl methylcellulose.

38. This contradiction in meaning of the binder component (d) cannot be resolved by reference to the description of the patent. None of the passages of the patent cited by the appellant in this context (i.e. page 12, line 58 to page 13, line 2, page 13, lines 4 to 6, and page 13, lines 21 and 22) disclose the wording of the amendment in dispute.

39. Contrary to the appellant's position, this contradiction cannot be resolved by taking the broadest technically sensible meaning of binder component (d) (i.e. the one adopted by the opposition division) either.

39.1 In support of its case, the appellant cited section I.C.4.1 of the Case Law citing decisions T 79/96 and T 596/96.

39.2 However, the appellant did not point the Board to any passage in this case law stating that for the purpose of examining clarity under the EPC, a lack of clarity arising from a contradiction in meaning of a feature of a claim can be "cured" by selecting the broadest of the two or more technically sensible meanings of the feature in dispute. In the absence of any such passage, the appellant's argument is not convincing.

40. It follows from the above that the amendment in dispute gives rise to at least two technically sensible but contradictory interpretations of binder component (d) of claim 1, and therefore renders this component ambiguous and thus unclear.

Re point (ii) - the lack of clarity relating to binder component (d) is introduced in claim 1 by way of the amendment in dispute

41. The appellant contended that the respondents' objections of lack of clarity in relation to binder component (d) were in substance directed against the phrase "*selected from the list comprising*". This phrase was already present in granted claims 1 and 2, albeit in components (c) and (e) rather than component (d). Nevertheless, the exact location of this phrase in claims 1 and 2 as granted did not have any bearing on the substance of the respondents' objection against this phrase. Consequently, the respondent's objections were impermissible under decision G 3/14.

42. The appellant's arguments are not convincing.

42.1 Contrary to the appellant's view, the respondents' objection of lack of clarity is not against the phrase "*selected from the group comprising*" in isolation but rather against this phrase when considered in combination with the feature "*between 1% and 10% by weight of binder*" (see point 31. above).

42.2 This lack of clarity was not present in the claims as granted because the claims as granted only define binder component (d) as "*between 1% and 10% by weight of binder*". The fact that the definitions of components (c) and (e), in the claims as granted, contain the phrase "*selected from the group comprising*" does not alter this finding and is therefore not pertinent.

42.3 To further support its case, the appellant referred to decision T 266/15. However, the technical circumstances underlying that decision differ from those underlying

the current case to the extent that the findings and reasons developed in that decision are not transferable to the current case.

42.3.1 In decision T 266/15, the feature objected to as being unclear was a relative amount of antimicrobial metal in elemental form (i.e. from 10 mg/m^2 to 600 mg/m^2 of antimicrobial composite). The competent Board noted that claim 11 as granted already required a (different) specific amount of antimicrobial metal in elemental form (silver) per surface of composite. The Board concluded therefrom that any lack of clarity which could derive from that relative amount was already present in the claims as granted, and could not be examined in opposition appeal proceedings (see T 266/15, Reasons 5).

42.3.2 By contrast, in the case at hand, the lack of clarity derives from a definition of binder component (d) which was not already present in the claims as granted.

Overall conclusion on the respondents' objection of lack of clarity of claim 1

43. In view of the foregoing considerations, the Board concludes that the respondents' objection of lack of clarity against claim 1 of the main request is permissible under decision G 3/14.

44. The definition of binder component (d) introduced by way of amendment into claim 1 of the main request thus does not meet the requirements of Article 84 EPC. As a consequence, the main request is not allowable.

Auxiliary request 1
Admittance (Article 12(4) and (6) RPBA)

45. The appellant filed the set of claims of auxiliary request 1 as auxiliary request 46 with the statement of grounds of appeal.

46. Claim 1 of auxiliary request 1 differs from claim 1 of the main request (see point III. above), *inter alia*, in that:

- the preamble of claim 1 has been adjusted to confirm that both metformin and the SGLT2 inhibitor are for use in the claimed method of treatment ("amendment 1")

- the wording "*selected from the list comprising*" in binder component (d) has been replaced by the expression "*, and wherein binder in the composition is selected from*" ("amendment 2")

47. Article 12(2) RPBA specifies that, in view of the primary object of the appeal proceedings being to review the decision under appeal in a judicial manner, a party's appeal case shall be directed to the requests, facts, objections, arguments and evidence on which the decision under appeal was based.

48. Under Article 12(4), first and second sentences, RPBA, any part of a party's appeal case which does not meet the requirements in Article 12(2) RPBA is to be regarded as an amendment, unless the party demonstrates that this part was admissibly raised and maintained in the proceedings leading to the appealed decision, and such amendments may be admitted only at the discretion of the Board.

49. In the case at issue, it is true that amendment 2 already formed part of claim 1 of auxiliary request 10c underlying the appealed decision (i.e. current auxiliary request 7). However, amendment 1 did not. Consequently, auxiliary request 1 was not considered in the decision under appeal, and therefore constitutes an amendment within the meaning of Article 12(4) RPBA.

50. According to Article 12(6), second sentence, RPBA, the Board shall not admit requests, facts, objections or evidence which should have been submitted, or which were no longer maintained, in the proceedings leading to the decision under appeal, unless the circumstances of the appeal case justify their admittance.

51. The appellant submitted that amendment 1 addressed the opposition division's finding of lack of inventive step of claim 1 of the main request set out in the decision under appeal, in particular the opposition division's definition of the objective technical problem provided for the first time in point 14.2. of this decision. Amendment 2, in turn, addressed the respondents' objections under Articles 84 and 123(3) EPC.

52. The Board does not concur.

52.1 In point 14.2 of its decision (see last paragraph of this section), the opposition division stated the following:

"*In the absence of any comparison between the claimed compositions and those of D9, the single data point (in table 1) showing a more than additive effect for the combination metformin with compound I-Y is not enough to acknowledge any superior activity of the claimed*

composition. Taking into account that no unexpected effect over that of the closest prior combination has been demonstrated, the opposition division considers that starting from D9, the problem to be solved is to provide an alternative combination for the treatment of glucose related disorders."

52.2 However, in its communication annexed to the summons to oral proceedings dated 10 December 2020 (see paragraph 6.4.2), the opposition division had already expressed the preliminary view that an additive effect was not considered suitable for acknowledging inventive step of the subject-matter of claim 1 of the main request. The opposition division further observed that the data of the patent did not seem suitable for demonstrating a surprising effect, such as a supra-additive or synergistic effect for all compounds falling under formula (I). Thus, the objective technical problem as formulated in the opposition division's decision, rather than a surprising development, was a direct consequence of that preliminary assessment.

52.3 Moreover, in its submissions under Rule 116 EPC dated 21 April 2021 (see section (37)), respondent II had already taken document D9 as the closest prior art and defined the objective technical problem associated with the use of compound of formula (i) as the provision of an alternative combination. Moreover, in these same submissions (see sections (06) and (08)), respondent II had raised the objections under Article 84 and 123(3) EPC that auxiliary request 1 attempts to address.

52.4 In reply to these submissions, the appellant filed nine further auxiliary requests, labelled as auxiliary requests 4a, 4b, 4c, 10a, 10b, 10c, 18a, 18b and 18c,

respectively, with its letter dated 11 June 2021. However, none of these requests contained amendment 1 in order to address the lack of inventive step objection, whereas the appellant did address the respondents' objections under Articles 84 and 123(3) EPC with auxiliary requests containing amendment 2 (4b, 4c, 10b, 10c, 18b and 18c).

52.5 Consequently, the appellant could and should have filed auxiliary request 1 together with these nine requests.

52.6 In view of this conclusion, the Board did not need to decide whether the re-ordering of auxiliary request 46 as auxiliary request 1, as such, constituted an amendment of the appellant's appeal case.

53. The Board therefore decided not to admit auxiliary request 1 into the proceedings (Article 12(6), second sentence, RPBA).

Auxiliary requests 2 to 4
Admittance (Article 13(2) RPBA)

54. The appellant filed auxiliary requests 2 to 4 on 23 April 2024, i.e. after notification of the Board's communication under Article 15(1) RPBA.

55. Article 13(2) RPBA stipulates that "[a]ny amendment to a party's appeal case made after the expiry of a period specified by the Board in a communication under Rule 100, paragraph 2, EPC or, where such a communication is not issued, after notification of a communication under Article 15, paragraph 1, shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned."

56. Exceptional circumstances within the meaning of Article 13(2) RPBA generally concern new or unforeseen developments in the appeal proceedings themselves, such as new objections raised by the Board or another party, whereas the normal course of events does not justify late submissions (see Case Law, V.A.4.5.4.a)).

57. In the case at issue, the filing of auxiliary requests 2 to 4 amounts to a change in the appellant's appeal case within the meaning of Article 13(2) RPBA. Even if the individual changes in auxiliary requests 2 to 4 were present in other requests, it remains the case that auxiliary requests 2 to 4 were never part of the appeal proceedings until 23 April 2024, i.e. less than 2 weeks before the oral proceedings before the Board.

58. Furthermore, contrary to the appellant's view, the Board's objections set out in paragraphs 3.2, 4. and 6.2.2 of its communication do not constitute cogent reasons justifying exceptional circumstances within the meaning of Article 13(2) RPBA.

58.1 In paragraphs 3.2 and 4. of its communication, the Board commented on claim 1 of the main request in relation to Articles 84 and 123(3) EPC, respectively. As submitted by respondent II, these comments do not raise new questions but are essentially based on issues and arguments submitted by the respondents in their respective replies to the statement of grounds of appeal (see sections 7.1 and 7.4 to 7.9 of respondent I's reply to the statement of grounds of appeal; sections (10) to (12), (21), and (22) of respondent II's reply to the grounds of appeal).

58.2 Paragraph 6.2.2. of the Board's communication concerns the admittance of the then pending auxiliary requests. In this context the Board stated, *inter alia*, that in addition to issues of lack of substantiation, auxiliary requests 1 to 27 did not appear convergent. This information does not constitute an exceptional circumstance within the meaning of Article 13(2) RPBA because the examination of the admittance of requests is a normal course of events in appeal proceedings.

58.3 To support its case, the appellant relied on section V.A.4.5.5(a) of the Case Law. However, the appellant did not point the Board to any decision among those discussed in this section in which the competent Board recognised an objection of lack of convergence of claim requests raised by it for the first time in a communication under Article 15(1) RPBA as constituting an exceptional circumstance within the meaning of Article 13(2) RPBA.

59. Under these circumstances, the Board decided not to admit auxiliary requests 2 to 4 into the appeal proceedings in accordance with Article 13(2) RPBA.

Auxiliary request 24
The claimed subject-matter

60. In view of the withdrawal of auxiliary requests 28, 47, 49 and 47-SA, auxiliary request 24 became the next request to be considered after auxiliary request 4 (see points XI. and XII. above).

61. Claim 1 of auxiliary request 24 differs from claim 1 of the main request (see point III. above) in that components (c) to (h) are defined as follows (changes indicated by the Board):

"(c) between 5% and 50% by weight of diluent ~~selected from the list comprising~~, **and wherein diluent in the composition is selected from** lactose, microcrystalline cellulose, dicalcium phosphate and starch;
(d) between 1 % and 10% by weight of binder ~~selected from the list comprising~~, **and wherein binder in the composition is selected from** polyvinylpyrrolidone, methylcellulose, hydroxypropyl cellulose and hydroxypropyl methylcellulose;
(e) between 1 % and 10% by weight of disintegrant ~~selected from the list comprising~~, **and wherein disintegrant in the composition is selected from** sodium starch glycolate, croscarmellose sodium and crospovidone;
(f) between 0% and 5% by weight of wetting agent ~~selected from the list comprising~~, **and wherein wetting agent in the composition is selected from** sodium lauryl stearate and polysorbate 20;
(g) between 0% and 3% by weight of lubricant ~~selected from the list comprising~~, **and wherein lubricant in the composition is selected from** from magnesium stearate and sodium strearyl fumarate; and
(h) flow promoter or glidant ~~selected from the list comprising~~, **and wherein flow promoter or glidant in the composition is selected from** colloidal silicon dioxide and talc".

Amendments

62. The respondents' objections against claim 1 of auxiliary request 24 under Rule 80 and Articles 84, 123(2) and (3) EPC all relate to the insertion of the feature:

", *and wherein binder in the composition is selected from polyvinylpyrrolidone, methylcellulose, hydroxypropyl cellulose and hydroxypropyl methylcellulose;*"

after the term "*binder*" in binder component (d) of claim 1 as granted (see point I. above).

63. This amendment will be referred to below as "newly added feature to binder component (d)".

Amendments - admittance of the respondents' objection of lack of clarity (Article 12(3), (5) RPBA)

64. Under Article 12(3) RPBA, the statement of grounds of appeal and the reply must contain a party's complete appeal case. Accordingly, they must set out clearly and concisely the reasons why it is requested that the decision under appeal be reversed, amended or upheld, and should expressly specify all the requests, facts, objections, arguments and evidence relied on. Under Article 12(5) RPBA, the Boards have discretion not to admit any part of a submission by a party which does not meet the requirements of Article 12(3) RPBA.

65. The respondents submitted that the newly added feature to binder component (d) of claim 1 of auxiliary request 24 had the same meaning as the feature "*selected from the list comprising polyvinylpyrrolidone, methylcellulose, hydroxypropyl cellulose, and hydroxypropyl methylcellulose*" in binder component (d) of claim 1 of the main request. Consequently, claim 1 of auxiliary request 24 lacked clarity for the same reasons as claim 1 of the main request.

66. However, the respondents did not explain, either in writing or orally, why these two features were identical, despite being different in wording. Respondent I's statement made in section 9.2. of its reply to the statement of grounds of appeal does not provide any information as to the underlying reasoning for the alleged lack of clarity. The same holds true for respondent II's statements in sections (16), (17) and (24) of its reply to the statement of grounds of appeal.

67. In the absence of any such reasoning, the respondents' objection of lack of clarity lacks substantiation, contrary to the requirements of Article 12(3) RPBA.

68. The Board therefore decided, in the exercise of its discretion under Article 12(5) RPBA, not to admit the respondents' objection of lack of clarity into the proceedings.

Amendments - Rule 80 EPC

69. According to Rule 80 EPC, the description, claims and drawings of a European patent may be amended, provided that the amendments are occasioned by a ground for opposition under Article 100 EPC, even if that ground has not been invoked by the opponent.

70. As convincingly argued by the appellant (see point XIV. above, under the heading "*Auxiliary request 24 - amendments (Rule 80 EPC)*"), the newly added feature to binder component (d) is a serious attempt to overcome a ground for opposition (under Article 100(c) EPC) and thus occasioned by a ground for opposition, as required by Rule 80 EPC.

71. Respondent II's arguments to the contrary are not considered persuasive.

71.1 In the Board's understanding, respondent II's objection under Rule 80 EPC is subject to an interpretation of the newly added feature to binder component (d) according to which the list of binders in this component has no limiting effect.

71.2 However, Rule 80 EPC does not place any restriction as to the form of amendments a patent proprietor can make to address a ground for opposition. This rule merely requires an amendment to be occasioned by a ground for opposition, i.e. the amendment must be a serious attempt to overcome a ground for opposition. This rule sets out a requirement for admitting an amendment. It does not stipulate that the amendment must actually also overcome the ground for opposition, this being assessed on its own merits. The requirement of Rule 80 EPC is fulfilled in the case at issue (see point 70. above), irrespective of whether the newly added feature to binder component (d) is limiting on the claim scope or not.

Amendments - Article 123(3) EPC

72. Article 123(3) EPC stipulates that a European patent may not be amended in such a way as to extend the protection conferred. In order to conclude whether or not amendments made to a claim are allowable under Article 123(3) EPC, it is therefore necessary to compare the protection conferred by the claims as granted with that of the claims as amended.

73. A composition which is defined in a granted claim as "comprising" the components indicated therein is open

to the presence of any further components, unless otherwise specified. Furthermore, the use of the term "comprising" in connection with a numerical range defining the amount of a component implicitly means that the protection conferred by the claim does not extend to compositions containing that component in amounts outside the defined range (see e.g. decisions T 2017/07, Headnote, T 287/11, Reasons 2.3.1, and Case Law, II.E.2.4.13).

74. In a claim directed to such an openly defined composition, an amendment restricting the breadth of a component present therein may have the effect of broadening the scope of protection of that claim, and may thus extend the protection conferred by the granted patent (Article 123(3) EPC).

75. With regard to the scope of claim 1 as granted, it was common ground that by virtue of the term "*[..] pharmaceutical composition comprising [..]*", the pharmaceutical composition defined in this claim is open to the presence of further components in addition to components (a) to (e). It was likewise undisputed that this composition is subject to the implicit proviso excluding the presence of a binder in an amount outside of the claimed 1% to 10% weight range.

76. The pharmaceutical composition recited in claim 1 of auxiliary request 24 ("amended claim 1") differs from the pharmaceutical composition of claim 1 as granted, *inter alia*, in the definition of binder component (d). While claim 1 as granted requires this component to be "*between 1 % and 10% by weight of binder*", amended claim 1 additionally defines component (d) as follows:

"and wherein binder in the composition is selected from polyvinylpyrrolidone, methylcellulose, hydroxypropyl cellulose and hydroxypropyl methylcellulose;"

77. The parties adopted diverging interpretations of binder component (d) in amended claim 1 (see points XIV. and XV. above, under the heading "*Auxiliary request 24 - amendments (Article 123(3) EPC)*").

78. In the Board's judgement, amended claim 1 is drafted in cascade form (sequential drafting). The use of in-cascade-drafting in an open claim ("comprising"), namely retaining in an amended claim the broad definition of the claim as granted and adding, by means of the phrase "and wherein...", an additional restriction, avoids the situation where an amendment initially made with the intention of restricting a claim actually extends the protection conferred by it, in contravention of Article 123(3) EPC (see Case Law, II.E.2.4.13). As a consequence, the Board adheres to the appellant's interpretation of binder component (d) in amended claim 1 (see point XIV. above, under the heading "*Auxiliary request 24 - amendments (Article 123(3) EPC)*").

79. This interpretation is in line with the description of the patent.

79.1 Paragraphs [0057] and [0059] of the patent define suitable binders for the pharmaceutical composition, albeit in qualitative terms only. Polyvinylpyrrolidone, methylcellulose, hydroxypropyl cellulose, and hydroxypropyl methylcellulose are mentioned as examples of such binders.

79.2 Paragraph [0069] of the patent, in turn, defines the binder in the pharmaceutical composition in quantitative terms. This paragraph reads:

"In the invention, the pharmaceutical composition comprises between about 1% and about 10% by weight of binder (relative to the total weight of the composition or composition layer), preferably between about 3% and about 5% by weight binder, more preferably about 4% binder."

79.3 As can be seen from the above, paragraph [0069] refers to the term "binder" in the most general terms only. No reference is made to any particular binder, let alone to any of the binders listed in paragraphs [0057] and [0059] of the patent.

80. In view of the preceding considerations set out in points 78. to 79.3 above, the Board concludes that the claimed 1% to 10% weight range applies to any and all binder(s) present in the pharmaceutical composition. In other words, amended claim 1 is subject to the same implicit proviso as claim 1 as granted (see point 75. above), i.e. the newly added feature to binder component (d) does not broaden the scope of protection conferred by claim 1 as granted. Respondent II's argument according to which the appellant had failed to establish compliance with Article 123(3) EPC to a standard "beyond reasonable doubt" must therefore fail.

81. The respondents' arguments based on decisions T 2017/07, T 514/14 and T 664/20 are not convincing either.

81.1 In decisions T 2017/07 (see Reasons, points 2.1 to 2.10, in particular point 2.4) and T 664/20 (see

Reasons, points 11. to 13. in conjunction with point VI.), the competent Boards found a lack of compliance with Article 123(3) EPC in respect of claims language different from the one used for defining binder component (d) in the current case ("in cascade").

81.2 Likewise, in decision T 514/14 (see Reasons, point 4.3), the competent Board found the claim in question to lack clarity in respect of claims language different from the one used for defining binder component (d) in the current case.

81.3 Consequently, the findings in these three decisions do not apply here.

82. It follows that the newly added feature to binder component (d) (see points 62. and 63. above) does not broaden the scope of protection conferred by the patent.

Amendments - Article 123(2) EPC

83. The basic principle underlying Article 123(2) EPC and the ground for opposition under Article 100(c) EPC is that any amendment to a European patent relating to the disclosure (the description, claims and drawings) can only be made within the limits of what a skilled person would derive directly and unambiguously, explicitly or implicitly, using common general knowledge, and seen objectively and relative to the date of filing, from the application as filed. This definition has become the "gold" standard for assessing any amendment for its compliance with Article 123(2) EPC (see decision G 2/10, OJ EPO 2012, 376, point 4.3 of the Reasons).

84. In the case at issue, it was a matter of dispute between the appellant and respondent II whether the pharmaceutical composition defined in amended claim 1 finds direct and unambiguous basis in the application as filed. In support of its objection, respondent II presented two lines of argument (see point XV. above, under the heading "*Auxiliary request 24 - amendments (Article 123(2) EPC) - respondent II*").

85. Both lines of argument fail to convince the Board.

With regard to respondent II's first line of argument (multiple selections required to arrive at the claimed combination of numerical ranges)

85.1 On page 19, lines 4 to 20, the application as filed describes a pharmaceutical composition comprising two pharmaceutically active components, namely:

(a) metformin or a pharmaceutically acceptable salt thereof;

(b) a compound of formula (I) or a pharmaceutically acceptable salt thereof selected from compound (I-X) and (I-Y);

wherein the metformin or pharmaceutically acceptable salt thereof is present in an amount in the range of from about 100 mg to about 2000 mg, preferably from about 500 mg to about 1000 mg, or any amount or range therein;

and wherein the compound of formula (I) or pharmaceutically acceptable salt thereof is present in an amount in the range of from about 1 mg to about 1000 mg, or any amount or range therein (preferably in

an amount in the range of from about 1 mg to about 500 mg, or any amount or range therein, more preferably in an amount in the range of from about 10 mg to about 300 mg, or any amount or range therein).

85.2 As correctly observed by respondent II, the claimed numerical range for component (a) (500 mg to 2000 mg) emerges from the upper limit of the broader range (2000 mg) and the lower limit of the narrower range (500 mg) described on page 19, lines 4 to 20, of the application as filed. Hence, a selection must be made from this disclosure to arrive at the claimed numerical range for component (a).

85.3 However, the same does not hold true for the claimed numerical ranges for components (b) to (g).

85.3.1 The claimed numerical range for the pharmaceutically active component (b) (i.e. 10 mg to 300 mg) is the narrowest and most preferred range of the three numerical ranges mentioned on page 19, lines 4 to 20, of the application as filed (see point 85.1 above). Consequently, it does not constitute a selection from these three numerical ranges.

85.3.2 The claimed numerical ranges for the excipient components (c) to (g) are the broadest of the three numerical ranges described on page 24, line 19 to page 25, line 10, of the application as filed for each of these components. As convincingly argued by the appellant, the broadest numerical range among a list of ranges does not require any selection because it constitutes the most general quantitative disclosure of the component in question in the application as filed.

85.4 In view of the foregoing, the Board concludes that the claimed combination of numerical ranges for components (a) to (g) is directly and unambiguously derivable from the aforementioned disclosures on page 19, lines 4 to 20 and on page 24, line 19 to page 25, line 10, of the application as filed by making a single selection.

Respondent II's second line of argument (lack of basis in the application as filed for excluding the presence of binders other than those specified in claim 1)

85.5 At the oral proceedings, the appellant objected to the admittance of this objection as being an amendment to respondent II's appeal case. Nevertheless, the Board decided to admit this objection into the proceedings. In view of the outcome of the appeal proceedings, a detailed reasoning on the admittance of this objection is not necessary.

85.6 Turning to the substance of this objection, respondent II argued that the double limitation imposed by amended claim 1 on the binder (i.e. in terms of the amount and the nature of the binder) had no basis in the application as filed.

85.7 The Board does not agree.

85.7.1 It is not in dispute that the claimed quantitative limitation (i.e. between 1% and 10% by weight of binder) finds direct and unambiguous basis on page 24, lines 24 to 26, of the application as filed.

85.7.2 The claimed qualitative limitation (i.e. the binder must be one of polyvinylpyrrolidone, methylcellulose, hydroxypropyl cellulose, and hydroxypropyl methylcellulose) finds direct and unambiguous basis in

page 21, lines 15 to 16, of the application as filed, which reads:

"*(ii) binders such as polyvinylpyrrolidone (such as POVIDONE), methylcellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose (such as METHOCEL™ E-5), and the like;*"

As can be seen from this disclosure, the four binders explicitly mentioned on page 21, line 15, of the application as filed are exactly the same as those specified in amended claim 1.

85.7.3 The Board does not dispute that the list of binders in this passage is not exhaustive. It is also true that the application as filed does not explicitly disclose that binders other than the four binders listed in amended claim 1 may not be present in the claimed pharmaceutical composition.

85.7.4 However, the qualitative limitation of the binder in amended claim 1 (see point 85.7.2 above) inherently has the effect of excluding binders other than those listed in amended claim 1. Consequently, the relevant question for the purpose of Article 123(2) EPC is whether this limitation is directly and unambiguously derivable from the application as filed. For the reasons set out in point 85.7.2 above, this question is to be answered in the affirmative.

Overall conclusion on Article 123(2), (3) and Rule 80 EPC

86. With regard to claim 2 of auxiliary request 24, the respondents did not present any arguments beyond those already submitted with respect to claim 1 of this request.

87. The Board therefore concludes that the respondents' objections under Article 123(2) and (3) EPC and respondent II's objection under Rule 80 EPC do not prejudice the maintenance of the patent on the basis of the set of claims of auxiliary request 24.

88. Since the respondents did not raise any objections under Article 123(2), (3) EPC or Rule 80 EPC against any of the other amendments made to claims 1 and 2 of auxiliary request 24, the Board, not itself having any objections, concludes that auxiliary request 24 meets the requirements of Article 123(2), (3) and Rule 80 EPC.

Article 56 EPC

89. In the Board's view, the inventive-step reasoning set out in points 4. to 29. above in relation to the main request is equally applicable to auxiliary request 24.

90. The respondents did not present any arguments beyond those already submitted with respect to the main request.

91. Under these circumstances, the Board concludes that auxiliary request 24 involves an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent on the basis of claims 1 and 2 of auxiliary request 24 filed with the statement of grounds of appeal and a description to be adapted, as needed.

The Registrar: The Chairwoman:

S. Lichtenvort M. Pregetter

Decision electronically authenticated