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Datasheet for the decision of 16 November 2023

Case Number: T 0314/20 - 3.3.04

Application Number: 08787264.4

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Language of the proceedings: EN

Title of invention:

PHARMACEUTICAL COMPOSITION COMPRISING A GLUCOPYRANOSYL-SUBSTITUTED BENZENE DERIVATIVE

Patent Proprietor:

Boehringer Ingelheim International GmbH

Opponents:

Generics (U.K.) Limited
STADA Arzneimittel AG
Hexal AG
ZAKLADY FARMACEUTYCZNE POLPHARMA S.A.

Relevant legal provisions:

EPC Art. 56, 112(1)(a)

Keyword:
Inventive step - technical effect derivable from the application as originally filed in the sense of G 2/21, point 2 of the order (no) - obvious solution
Referral to the Enlarged Board of Appeal - (no)

Decisions cited:
G 0002/21, G 0002/10, G 0001/03, T 1525/19, T 0116/18

Catchword:
On the interpretation of decision G 2/21 (see points 6.12 to 6.13.11 of the Reasons)

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Case Number: T 0314/20 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 16 November 2023

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Respondent: (Patent Proprietor)	Boehringer Ingelheim International GmbH Binger Strasse 173 55216 Ingelheim am Rhein (DE)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 10 December 2019 rejecting the opposition filed against European patent No. 2187879 pursuant to Article 101(2) EPC**

Composition of the Board:

Chair	M. Pregetter
Members:	S. Albrecht
	R. Romandini

Summary of Facts and Submissions

I. European patent 2 187 879 ("patent") was granted on European patent application 08 787 264.4 ("application"). This application had been filed as an international application under the PCT published as WO 2009/022007.

Claim 1 as granted reads as follows:

"1. A pharmaceutical composition comprising the glucopyranosyl-substituted benzene derivative 1-chloro-4-(β-D-glucopyranos-1-yl)-2-[4-(*(S)*-tetrahydrofuran-3-yloxy)-benzyl]-benzene in combination with the DPP IV inhibitor 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-*(R)*-amino-piperidin-1-yl)-xanthine or a pharmaceutically acceptable salt thereof."

In the following, the claimed glucopyranosyl-substituted benzene derivative is referred to by its international non-proprietary name "empagliflozin", and the claimed DPP IV inhibitor is referred to by its international non-proprietary name "linagliptin".

II. The patent was opposed by four opponents. The grounds for opposition were Article 100(a) (lack of novelty and inventive step), Article 100(b) (sufficiency of disclosure) and Article 100(c) (added subject-matter) EPC.

III. The opposition division decided to reject the oppositions. In its decision, it considered document D2 a suitable starting point for the assessment of inventive step of the subject-matter of claim 1 as

granted. Starting from this document and having regard to the experimental data disclosed in the patent and in documents D55 and D56, the objective technical problem was identified as providing improved blood glucose control in comparison to the use of a glucopyranosyl-substituted benzene derivative alone as well as prolonged increased GLP-1 levels and thus an improved diabetes treatment. The solution proposed by the patent was deemed not obvious in light of the prior art on file.

IV. All four opponents ("appellant I", "appellant II", "appellant III", and "appellant IV", respectively) appealed the decision of the opposition division. They requested that it be set aside and that the patent be revoked in its entirety. With its reply to the statements of grounds of appeal, the patent proprietor ("respondent") requested that the appeals be dismissed (i.e. that the patent be maintained as granted).

V. In a communication pursuant to Article 15(1) RPBA issued on 6 October 2023, the Board drew the parties' attention to the points to be discussed during the oral proceedings, which had been scheduled in view of corresponding requests of the parties, and addressed, *inter alia*, inventive step for claim 1 as granted.

VI. In its letter dated 3 November 2023, appellant IV withdrew its request for oral proceedings and informed the Board that it would not be attending the oral proceedings.

VII. Oral proceedings were held on 16 November 2023 by videoconference in the presence of appellants I, II and III and the respondent. During the oral proceedings, the respondent filed a request for two questions to be

referred to the Enlarged Board of Appeal (see point X. below). At the end of the oral proceedings, the Chair announced the Board's decision.

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

D2 WO 2005/092877 A1

D3 WO 2004/018468 A2

D3a CA 2 496 249 A1

D13 G. Schernthaner *et al.*, "How attractive is the combination of a sodium glucose co-transporter 2 inhibitor with a dipeptidyl peptidase 4 inhibitor in the treatment of type 2 diabetes?", Diabetes, Obesity and Metabolism 17, 2015, 613-15

D38 A.E. Weber, "Dipeptidyl Peptidase IV Inhibitors for the Treatment of Diabetes", J Med. Chem 47, 2004, 4135-41

D46 A.L. Handlon, "Sodium glucose co-transporter 2 (SGLT2) inhibitors as potential antidiabetic agents", Expert Opin. Ther. Patents 15(11), published online 28 October 2005, 1531-40

D55 Experimental report by Boehringer Ingelheim with the title "Effect of Linagliptin and an SGLT2 inhibitor and its combination on active GLP-1 in diabetic ZDF rats", filed by the patent proprietor by letter dated 8 May 2019

D56 Experimental report having the title "COMPARISON OF TREATMENTS WITH EMPAGLIFLOZIN", filed by the patent proprietor by letter dated 8 May 2019

D61 J.Rosenstock *et al.*, "Dual Add-on Therapy in Type 2 Diabetes Poorly Controlled With Metformin Monotherapy: A Randomized Double-Blind Trial of Saxagliptin Plus Dapagliflozin Addition Versus Single Addition of Saxagliptin or Dapagliflozin to Metformin", Diabetes Care 38, March 2015, 376-83

D66 Copy of the minutes of the oral proceedings in appeal case T 1525/19-3.3.07

IX. The appellants' submissions relevant to this decision can be summarised as follows.

Inventive step - claim 1 as granted

Document D2 constituted a suitable starting point for the assessment of inventive step of the claimed subject-matter. This document disclosed combinations of SGLT2 inhibitors, in particular empagliflozin, with DPP IV inhibitors such as vildagliptin and sitagliptin for use in the treatment of diabetic conditions.

The subject-matter of claim 1 differed from this disclosure in terms of the DPP IV inhibitor, i.e. linagliptin. No technical effect could be assigned to this difference. The two technical effects identified by the respondent in this regard, i.e. an improvement in HbA1c and an increase in GLP-1 levels, should be disregarded when formulating the objective technical problem because:

(a) the evidence relied on by the respondent for the alleged improvement in HbA1c (i.e. experimental data disclosed in Table 1 of document D13) lacked comparison with the closest prior art

(b) the purported increase in GLP-1 levels allegedly shown in post-published documents D55 and D56 was not derivable for the skilled person from the technical teaching of the application documents as required by decision G 2/21

The objective technical problem was thus to provide an alternative combination of the SGLT2 inhibitor empagliflozin with a DPP IV inhibitor.

The solution proposed in claim 1 would have been obvious having regard to document D3 which disclosed linagliptin as a suitable combination partner for SGLT2 inhibitors. Contrary to the respondent's position, document D3 did not need to provide a pointer to linagliptin that rendered the claimed solution obvious. In the absence of any technical effect linked to the distinguishing feature, the claimed solution merely represented one of a number of obvious alternative combinations at the skilled person's disposal. Choosing between such alternatives did not involve an inventive step.

Request for referral to the Enlarged Board of Appeal

The respondent's request for a referral to the Enlarged Board of Appeal (see point X. below) should be refused. Contrary to the respondent's position, the factual situation in the current case and in appeal case T 1525/19 (case T 1525/19) were not the same. In case T 1525/19, which had been decided at oral proceedings before Board 3.3.07 on 1 September 2023, the patent application as originally filed had a later priority date than in the current case, and its disclosure had been limited considerably compared to that of the patent application as originally filed of the current case. Examples of such a limitation were the restriction of the subject-matter of claim 1 as originally filed to linagliptin and the absence of Examples 2 and 3 of the application as originally filed of the current case.

Moreover, neither the Board in the current case nor the competent Board in case T 1525/19 had issued a reasoned decision yet. Absent any such reasoned decisions, it could not be assessed whether the two Boards did indeed interpret point 2 of the order of decision G 2/21 differently.

X. The respondent's submissions relevant to this decision can be summarised as follows.

Inventive step - claim 1 as granted

The subject-matter of claim 1 differed from the closest prior art, i.e. document D2's generic disclosure of a combination of a glucopyranosyl-substituted benzene derivative of formula I acting as an SGLT2 inhibitor with a DPP IV inhibitor, in that the glucopyranosyl-substituted benzene derivative was empagliflozin and in that the DPP IV inhibitor was linagliptin.

The technical effects linked to these differences were an improvement in HBA1c and an increase in GLP-1 levels, as shown in post-published documents D13, D55 and D56. With regard to the increase in GLP-1 levels, the criteria set out in point 2 of the order of decision G 2/21 were met.

Accordingly, the objective technical problem was to provide an improvement in HbA1c and an increase in GLP-1 levels.

The solution proposed in claim 1 would not have been obvious having regard to the state of the art.

Even if the objective technical problem formulated by the appellants were accepted, the skilled person would

not have combined the closest prior art with document D3 in the first place. Had the skilled person nonetheless considered such a combination, they would not have arrived at the claimed solution because documents D2 and D3 lacked any pointer towards empagliflozin as an SGLT2 inhibitor and linagliptin as a DPP IV inhibitor, respectively.

Request for referral to the Enlarged Board of Appeal

The underlying fact pattern of the current case was the same as that of case T 1525/19. The limitation to certain dosages in the claim under consideration in case T 1525/19 did not come into play. Moreover, both the current case and case T 1525/19 revolved around inventive step over the same document (i.e. document D2, referred to as document D3 in case T 1525/19) in light of the same post-published experimental data (i.e. the data disclosed in documents D55 and D56, referred to as documents D62 and D64, respectively, in case T 1525/19). The admissibility of these data in light of decision G 2/21 was also at issue. Yet, as shown in document D66 (see paragraph bridging pages 4 and 5), the Board in case T 1525/19 came to a different conclusion than the Board in the current case. In light of these diverging views taken by the two Boards on the interpretation of Headnote 2 of decision G 2/21 and the fundamental importance of this point, the following questions ("questions 1 and 2") should be put to the Enlarged Board of Appeal:

"1. What are the criteria for assessing whether or not a technical effect is encompassed by a technical teaching and what requirements need to be met.

2. What are the criteria for assessing whether a technical effect is embodied by the same originally disclosed invention and what requirements need to be met."

XI. The parties' final requests relevant for the present decision were as follows.

The appellants requested that the decision under appeal be set aside and that the patent be revoked in its entirety.

The respondent requested that the appeals be dismissed. The respondent further requested that two questions be put to the Enlarged Board of Appeal under Article 112(1)(a) EPC (see point X. above).

Reasons for the Decision

1. The appeals are admissible.

Inventive step (Article 100(a) in conjunction with Article 56 EPC) - claim 1 as granted

The closest prior art

2. As held by the opposition division and in agreement with the parties, the Board considers document D2 to be a suitable starting point for the assessment of inventive step of the subject-matter of claim 1.

Starting point in document D2 (the closest prior art)

3. It is common ground that this document discloses, *inter alia*, combinations of glucopyranosyl-substituted benzene derivates of formula I and DPP IV inhibitors in

general terms (see page 43, line 29 to page 44, line 3, in conjunction with claim 1).

Distinguishing features over the closest prior art

4. As confirmed by the respondent during the oral proceedings, the subject-matter of claim 1 differs from the closest prior art in that:

(a) the glucopyranosyl-substituted benzene derivative of formula I is empagliflozin

(b) the DPP IV inhibitor is linagliptin or a pharmaceutically acceptable salt of it

Technical effects linked to the distinguishing features and formulation of the objective technical problem

5. At the oral proceedings, the respondent formulated the objective technical problem to be solved by the claimed invention over the closest prior art as *"an improvement in HbA1c and an increase in GLP-1"*.

6. The Board does not agree.

Alleged improvement in HbA1c

6.1 To support the purported improvement in HbA1c, the respondent relied on post-published document D13, in particular the changes in HbA1c reported in the first and ninth lines of Table 1.

6.1.1 The first line of Table 1 of document D13 reports HbA1c changes observed in a clinical study by Rosenstock *et al.*, which is disclosed in detail in post-published document D61. In this study, diabetic patients having a

mean baseline HbA1c of 8.9% and treated with the SGLT2 inhibitor dapagliflozin (10 mg) and the DPP IV inhibitor saxagliptin (25 mg) in addition to metformin had their baseline HbA1c reduced by 1.47% (see document D13, page 614, first line of Table 1 in conjunction with page 613, left-hand column, third to seventh lines from the bottom and document D61, page 376, third paragraph).

6.1.2 The ninth line of Table 1 of document D13, in turn, reports HbA1c changes observed in a clinical study by DeFronzo *et al.* In this study, the addition of empagliflozin (25 mg) and linagliptin (5 mg) to metformin in a patient subgroup with a baseline HbA1c ≥ 8.5% resulted in an even more pronounced HbA1c reduction of 1.84% (see document D13, page 614, ninth line of Table 1 in conjunction with page 613, right-hand column, lines 9 to 17).

6.2 However, the higher HbA1c reduction over the one observed in the study by Rosenstock *et al.* is not suitable to show the alleged HbA1c improvement over the closest prior art. As explained in points in 6.1.1 and 6.1.2 above, the aforementioned HbA1c reductions of 1.84% and 1.47% stem from clinical studies involving the combined use of an SGLT2 inhibitor, a DPP IV inhibitor and metformin as the third antidiabetic agent in patients with elevated baseline HbA1c levels (≥ 8.5%). By contrast, the closest prior art does not disclose any combinations of an SGLT2 inhibitor, a DPP IV inhibitor and metformin, let alone the use of such combinations in diabetic patients with baseline HbA1c levels of ≥ 8.5%. At the oral proceedings, the respondent conceded that document D13 had no teaching in terms of a straight comparison to the closest prior art.

6.3 As a consequence, the alleged HBA1c improvement cannot be taken into account for formulating the objective technical problem.

Alleged "increase in GLP-1"

6.4 It is undisputed that the term "*increase in GLP-1*" means an increase in the plasma levels of active GLP-1 (see paragraphs [0071] and [126] of the patent).

6.5 In support of the alleged "increase in GLP-1", the respondent referred to post-published documents D55 and D56.

6.6 Document D55 reports the effects of the SGLT2 inhibitor empagliflozin alone, the DPP IV inhibitor linagliptin alone and the combination of both on active GLP-1 concentration in diabetic ZDF rats. As evidenced by Tables 1:1 and 1:2 of this document, the combination of empagliflozin with linagliptin significantly increases active GLP-1 concentrations over control. Linagliptin likewise increases active GLP-1 concentrations over control, albeit to a significantly lesser extent. Empagliflozin alone, in turn, has practically no effect on GLP-1 levels.

6.7 At the oral proceedings, there was no dispute that the aforementioned findings in document D55 on linagliptin as the sole active agent and empagliflozin as the sole active agent form part of the skilled person's common general knowledge at the filing date of the patent. It was furthermore undisputed that document D55 does not include any experimental data providing a comparison with the closest prior art (see point 3. above).

6.8 Turning to document D56, this document discloses the results of a study in diabetic rats dosed "*q.d. daily*" from day 0 to day 5 with either linagliptin, empagliflozin, empagliflozin and linagliptin, empagliflozin and the DPP IV inhibitor sitagliptin, empagliflozin and the DPP IV inhibitor vildagliptin or vehicle.

6.9 Relying on the experimental data depicted in Figures 1 to 3 and Table 1 of document D56, the respondent submitted that the claimed combination of empagliflozin and linagliptin increased the plasma level of active GLP-1 in patients with diabetic diseases in a stronger and more prolonged manner than the other two combinations tested in this document, i.e. combinations of empagliflozin with sitagliptin and vildagliptin, respectively.

6.10 The appellants objected to the experimental data disclosed in document D56 as not being suitable to demonstrate this alleged GLP-1 increase.

6.11 It is, however, not necessary for the Board to deal with these objections. As explained below, the technical effect relied on by the respondent for inventive step (see point 6.9 above) and possibly shown by document D56 cannot be taken into account for formulating the objective technical problem in light of decision G 2/21 of the Enlarged Board of Appeal (OJ 2023, A85).

General principles set out in decision G 2/21

6.12 Introduction

6.12.1 According to decision G 2/21 (see point 2 of the order) a patent applicant or proprietor may rely upon a technical effect for inventive step if the skilled person, having the common general knowledge in mind, and based on the application as originally filed, would derive said effect as "being encompassed by the technical teaching" and "embodied by the same originally disclosed invention".

6.12.2 Point 93 of the Reasons of this decision provides some further guidance on the interpretation of this order. This point reads as follows:

"The relevant standard for the reliance on a purported technical effect when assessing whether or not the claimed subject-matter involves an inventive step concerns the question of what the skilled person, with the common general knowledge in mind, would understand at the filing date from the application as originally filed as the technical teaching of the claimed invention. The technical effect relied upon, even at a later stage, needs to be encompassed by that technical teaching and to embody the same invention, because such an effect does not change the nature of the claimed invention."

6.12.3 Hence, to assess whether a purported technical effect can be relied upon for acknowledgement of inventive step of the claimed subject-matter, the following requirements must be met. The skilled person, having the common general knowledge in mind, and based on the application as originally filed, must be able to derive

said effect as (i) being encompassed by the technical teaching and (ii) being embodied by the same originally disclosed invention.

6.12.4 The Enlarged Board introduced these two requirements in response to questions 2 and 3 formulated in the interlocutory decision T 116/18 of 11 October 2021 (OJ EPO 2022, 76, henceforth: "the referral decision" or "the referral"). In these two questions, the referring Board had asked whether an "*ab initio* plausibility" standard (question 2) or an "*ab initio* implausibility" standard (question 3) were to be applied when assessing whether post-published evidence could be taken into consideration for acknowledgement of inventive step. The Enlarged Board decided not to reorder or rephrase the referred questions (see decision G 2/21, point 7 of the Reasons). Hence, their wording remains relevant for interpreting the meaning of the Enlarged Board's answer in point 2 of the order of decision G 2/21. It is apparent that questions 2 and 3 only had to be directly addressed if one of the two "plausibility" standards were to be applied (see point 14 of the referral decision T 116/18: "*[t]he three referral questions made in the order of the present decision relate to the three lines of case law discussed above, namely whether any plausibility standard can be applied at all (first referral question) and, if so, whether an ab initio plausibility standard (second referral question) or an ab initio implausibility standard (third referral question) is to be applied*"; see decision G 2/21, points 2 and 5 of the Reasons).

6.12.5 In view of this background, the current Board identifies three challenges in interpreting point 2 of the order of decision G 2/21.

First, the requirements "encompassed by the technical teaching" and "embodied by the same originally disclosed invention" were not used in the plausibility case law underlying questions 2 or 3 of the referral. Therefore, their relation to this case law remains to be defined, particularly in terms of whether, and to what extent, they replace, align with, or modify it.

Second, the Enlarged Board did not expressly define these requirements. It could be argued that the dependent clause "because such an effect does not change the nature of the claimed invention" in point 93 of decision G 2/21 (see point 6.12.2 above) serves as their definition. However, if this were the case, it would be unclear why the Enlarged Board did not simply state that a patent applicant or proprietor can only rely on a technical effect if such an effect does not change the nature of the claimed invention, instead of introducing two distinct requirements. It seems more likely that the above clause describes a consequence that arises when both requirements (i) and (ii) are met. Thus, the second sentence in point 93 of decision G 2/21 could be interpreted to mean that "if the skilled person, having the common general knowledge in mind, and based on the application as originally filed, would derive [the] technical effect as being encompassed by the technical teaching and embodied by the same originally disclosed invention" (see point 2 of the order of decision G 2/21), such an effect would not change the nature of the claimed invention.

Finally, the Enlarged Board did not expressly state the purpose of these requirements.

Nevertheless, in dealing with these questions, the current Board can start from the considerations in decision T 116/18.

6.13 Decision T 116/18 of 23 July 2023

6.13.1 In decision T 116/18, the competent Board reached a number of conclusions on the relationship, the purpose and the content of the two requirements outlined in point 2 of the order of decision G 2/21.

Relationship

6.13.2 Concerning their relationship, the Board concluded that they are cumulative and separate requirements (point 11.4 of decision T 116/18). This followed from the conjunction "and" linking them; a conclusion with which this Board agrees.

Purpose

6.13.3 Concerning the purpose of these two requirements, the Board in case T 116/18 concluded that point 2 of the order of decision G 2/21 aimed to prevent speculative inventions (point 11.8 of decision T 116/18), namely the filing of applications directed to speculative (armchair) inventions made only after the filing date (point 11.1 of decision T 116/18). This purpose is not expressly stated in the Reasons of G 2/21. Nevertheless, this Board considers it reasonable to conclude that preventing an applicant or patent proprietor from relying on a technical effect that does not fulfil the requirements set out in point 2 of the order of G 2/21 - and which would therefore change the nature of the claimed invention - is intended as a safeguard to ensure that only inventions already made

and disclosed at the filing date are granted patent protection. This appears also to be consistent with point 2.5.3 of decision G 1/03, according to which, when an application for a patent is filed, the process of making the invention has to be completed. Hence, the current Board agrees also with this interpretation of G 2/21 provided in T 116/18.

Content

6.13.4 Regarding the content of these two requirements, the analysis in decision T 116/18 is extensive. The following parts of T 116/18 are directly relevant to the current Board's assessment:

"*11.5 Requirements (i) and (ii) use the terms 'technical teaching' and 'invention'. The EPC does not contain the concept of technical teaching, while a tautological definition of the term 'invention' is considered to be formulated at Rule 42(1)(c) EPC, namely as a solution to a technical problem.*

11.6 In the case law the term 'invention' has been defined by the Enlarged Board only indirectly by adopting the reasoning in the 'Rote Taube' decision by the German Federal Court of Justice (BGH 27.3.1069, X ZB 15/67: 'Lehre zum planmäßigen Handeln unter Einsatz beherrschbarer Naturkräfte zur Erreichung eines kausal übersehbaren Erfolges'; translation given in G 1/19 (point 75 of the Reasons): 'a teaching to methodically utilize controllable natural forces to achieve a causal, perceivable result'). According to G 2/07 and G 1/19, the 'Rote Taube' decision stated that the term 'invention' required (G 2/07, point 6.4.2.1 of the Reasons) or implied (G 1/19, point 75 of the decision) a technical teaching. In the present board's view, this

definition of the term 'invention' does not reveal any difference from the term 'technical teaching' which would justify the assumption that the two terms have a different meaning.

11.7 In fact, according to established case law, a technical teaching is defined in terms very similar to the way in which an invention is defined in the 'Rote Taube' decision, namely as 'an instruction addressed to a skilled person as to how to solve a particular technical problem using particular technical means' (G 1/19, point 24 of the decision; CLBA I.D.9.2.4).

11.8 As set out above, in the board's view G 2/21 seeks to prevent speculative inventions. In turn, the broader the application as filed, the more likely it is that the invention defined in it was speculative from the outset. Hence, in order to fulfil this purpose of G 2/21, the assessment as regards requirements (i) and (ii) of order no. 2 has to be made based on the broadest technical teaching of the application as filed contained in it with regard to the claimed subject-matter.

11.9 Against this background, the term 'technical teaching' in requirement (i) has the same meaning as the term 'same originally disclosed invention' in requirement (ii), namely the broadest technical teaching of the application as filed contained in it with regard to the claimed subject-matter.

11.10 In the light of this, for requirement (i) of order no. 2 to be met, the purported technical effect together with the claimed subject-matter need only be conceptually comprised by the broadest technical teaching of the application as filed. This in turn

means that said effect need not be literally disclosed in it by way of a positive verbal statement (see also point 11.13.1 below). Instead, for example, it may also be sufficient that the skilled person, having the common general knowledge in mind, and based on the application as filed, recognises that said effect is necessarily relevant to the claimed subject-matter.

11.11 As regards the second requirement (ii) formulated in order no. 2, namely that the effect must be derivable as being embodied by the same originally disclosed invention, in the board's view, the following question is to be asked: would the skilled person, having the common general knowledge on the filing date in mind, and based on the application as filed, have legitimate reason to doubt that the technical teaching at issue, i.e. the purported technical effect together with the claimed subject-matter, is an embodiment of the originally disclosed invention, i.e. the broadest technical teaching of the application as filed?

In other words again, the question to be asked can also be formulated as it was by the respondent: would the skilled person, having the common general knowledge on the filing date in mind, and based on the application as filed, have legitimate reason to doubt that the purported technical effect can be achieved with the claimed subject-matter?
Requirement (ii) is met unless the above question is to be answered in the affirmative.

(...)

11.13 Contrary to the appellant's argument, the board takes the view that it is also not necessarily a precondition for requirement (ii) to be fulfilled that

the application as filed contains a positive verbal statement about the purported technical effect.

11.13.1 More specifically, the board considers it of little use to focus on selected wording of the application as filed. The question of whether requirement (ii) is met can only be answered against the background of the entirety of the application as filed. In addition to this, as conceded by the appellant itself at the oral proceedings, understanding requirement (ii) to mean that a positive verbal statement about the effect must be present in the application as filed would correspond to, or at least come very close to, the very strict gold standard of a direct and unambiguous disclosure developed by the Enlarged Board for assessing the requirements of, for example, Article 123(2) EPC (see the Enlarged Board's decision G 2/10). The board is convinced that such an understanding cannot have been the Enlarged Board's intention in its decision G 2/21. The Enlarged Board can be safely assumed to have taken its decision carefully and thoroughly considered which words to use; however, neither order no. 2 nor e.g. point 72 of the Reasons uses the words associated with the gold standard, but, on the contrary, they apply less strict words. They speak of 'derivable'/'derive' but not of e.g. 'directly and unambiguously derivable'" (...).

6.13.5 This Board faces two issues with the interpretation of decision G 2/21 given in the passages quoted from decision T 116/18 in point 6.13.4 above.

6.13.6 First, there is an inconsistency in the reasoning supporting it. On the one hand, the relevant Board stated (see point 11.3.2 of decision T 116/18) that in decision G 2/21 the Enlarged Board did not refer to any

"plausibility" standards identified by the Board in its referring decision but instead adopted new requirements. The relevant Board continued by stating that the actual reason why the Enlarged Board formulated order No. 2 as it did may be left unanswered. What mattered was that when deciding whether a patent applicant or proprietor may rely on a purported technical effect for inventive step, it was the requirement(s) defined by the Enlarged Board in point 2 of the order that had to be applied, rather than simply using any rationale developed in the previous plausibility case law.

6.13.7 On the other hand, however, when defining how to meet requirement (ii) of point 2 of the order of decision G 2/21, this same Board stated that requirement (ii) of the order was met unless the skilled person, having the common general knowledge on the filing date in mind, and based on the application as filed, would have legitimate reason to doubt that the purported technical effect can be achieved with the claimed subject-matter (T 116/18, points 11.11 and 11.14).

6.13.8 In doing so, the Board effectively adopted what it defined in the referral T 116/18 as the "*ab initio* implausibility" standard. Indeed, the latter is defined as follows in the referral:

"*In accordance with a second line of case law, post-published evidence can only be disregarded if the skilled person would have had legitimate reasons to doubt that the purported technical effect would have been achieved on the filing date of the patent in suit. Such doubts may arise, for example, from the fact that either the application as filed or the common general knowledge on the filing date of the patent in suit give*

an indication that the purported technical effect can in fact not be achieved" (point 13.5 of the referral decision).

6.13.9 Second, and related point, some of the inferences drawn in the passages quoted above from decision T 116/18 are not supported by the text of decision G 2/21. Two of these are relevant in this regard.

(a) As explained under point 6.13.8 above, the relevant Board concluded that the test to be applied in assessing whether the requirement (ii) of point 2 of the order of decision G 2/21 was met was the "*ab initio* implausibility" test. However, nowhere in decision G 2/21 did the Enlarged Board state that requirement (ii) of point 2 of the order was met unless the person skilled in the art would have had legitimate reasons to doubt that the purported technical effect would have been achieved on the filing date.

(b) The relevant Board concluded that a positive verbal statement of the technical effect relied upon by the patent applicant or proprietor in the patent application as originally filed was not necessary for requirements (i) and (ii) of point 2 of the order of decision G 2/21 to be met (see points 11.10 and 11.13.1 of decision T 116/18). However, such a statement is also not to be found in decision G 2/21.

6.13.10 Admittedly, the Board in decision T 116/18 gave two main reasons for the conclusion under point 6.13.9(b) above:

(i) the Enlarged Board did not state that the effect must be "directly and unambiguously derivable" but used less strict words ("derivable"/"derive"); (T 116/18, point 11.13.1);

(ii) the terms "invention" and "technical teaching" meant the same in decision G 2/21, and both were to be understood as "*the broadest technical teaching of the application as filed contained in it with regard to the claimed subject-matter*" (T 116/18, point 11.10).

6.13.11 The first reason relates specifically to requirement (ii) and the second reason to requirement (i) of point 2 of the order of G 2/21. However, neither is conclusive.

Concerning the first reason, namely the use of the terminology "derive/derivable" in decision G 2/21, the order and the Reasons of decision G 2/21 use these words in a different context. The order does not state that a patent applicant or proprietor may rely upon a technical effect for inventive step if the skilled person would derive such effect from the application as originally filed. Instead, it states that a patent applicant or proprietor may rely upon a technical effect if the skilled person, having the common general knowledge in mind, and based on the application as originally filed, would derive said effect as being encompassed by the technical teaching and embodied by the same originally disclosed invention. Therefore, it is not possible to infer from the verb "derive" in point 2 of the order of decision G 2/21 any specific

meaning for the terms "embodied" or "encompassed". This is so because the verb "derive" simply introduces the two requirements rather than defining them.

The same holds true for point 72 of the Reasons of decision G 2/21. There, the Enlarged Board summarises the case law and does not define the requirements of point 2 of the order of that decision. In summarising the case law it speaks, *inter alia*, of a technical effect which "was derivable for the person skilled in the art from the technical teaching of the application documents".

Concerning the second reason, namely the Board's contention that the term "technical teaching" in requirement (i) has the same meaning as the term "same originally disclosed invention" in requirement (ii) and that both mean the "broadest technical teaching of the application as filed contained in it with regard to the claimed subject-matter" (T 116/18, point 11.9 of the Reasons), the current Board has the following observations: it is not immediately clear how it can be concluded from this semantic equivalence and related definition that for requirement (i) to be met the purported technical effect together with the claimed subject-matter need only be "conceptually encompassed" by the broadest technical teaching and that this in turn means that "said effect need not be literally disclosed in it by way of a positive verbal statement" (T 116/18, point 11.10 of the Reasons).

Therefore, this Board considers that the passages of decision G 2/21 referred to by decision T 116/18 do not lead to the conclusion that the standard of disclosure that applies to Article 87 EPC (referring to the concept of "same invention"), Article 123(2) EPC or

Article 54(1) EPC (see decision G 1/03, point 2.2.2 of the Reasons; decision G 2/10, point 4.6 of the Reasons) is excluded when assessing whether the technical effect on which the patent applicant or proprietor relies is (i) encompassed by the technical teaching that the skilled person, with the common general knowledge in mind, would understand at the filing date from the application as originally filed "as the technical teaching of the claimed invention", and (ii) embodied by the same originally disclosed invention. While this may be a valid approach, it does not follow from the text of decision G 2/21.

6.14 The Board's approach in the case at hand

In the present case, the current Board does not need to give a definitive answer as to whether it can endorse all the conclusions of decision T 116/18 regarding the two requirements set out in point 2 of the order of decision G 2/21. The Board considers that the purpose of these requirements is to prevent patents from being granted for inventions that are not complete at the filing date. Such speculative applications arise where either the existence of the claimed technical effect or its generalisation is speculative. This may occur because relevant data have not yet been generated or, if available to the patent applicant, have not been disclosed in the patent application. If the Board’s understanding of the purpose of the two requirements - which aligns with the view in T 116/18 - is correct, the respondent cannot rely on the technical effect in this case. This is because a skilled person would not expect the technical effect in question - an increase in active GLP-1 levels from the combination of empagliflozin and linagliptin compared to increases in active GLP-1 levels achieved with combinations of

emplagliflozin with sitagliptin and vildagliptin, respectively - on the basis of the original disclosure of the application itself. This effect is not only unsupported and not made credible by the application as originally filed; it even contradicts its technical teaching. Therefore, whatever the meaning of the two requirements in G 2/21, they cannot be met in the present case if patenting for inventions not made at the filing date is to be excluded.

Application of decision G 2/21 to the case at issue

6.15 In the following sections 6.16 to 6.23, unless stated otherwise, the referenced text passages are to the application as originally filed.

6.16 It is common ground that the invention disclosed in the application as originally filed relates in its broadest terms ("originally disclosed invention") to combinations of SGLT2 inhibitors with DPP IV inhibitors for metabolic disorders and related diseases, in particular diabetic diseases (see page 10, lines 2 to 4; page 11, line 5 to page 13, line 3; page 28; first row of Table 1). The SGLT2 inhibitor is a glucopyranosyl-substituted benzene derivative of formula (I) as defined on page 11, lines 6 to 11, and the DPP IV inhibitor is as specified on page 11, line 13 to page 13, line 3.

6.17 In terms of the technical effects attributed by the application as originally filed to the combinations according to the originally disclosed invention, it is furthermore undisputed that one of these effects is an increase in active GLP-1 levels. This effect is mentioned in two instances in the application as

originally filed, namely on page 34, lines 30 to 35 and page 48, lines 12 to 18.

6.17.1 Specifically, page 34, lines 30 to 35 explains that the DPP IV inhibitor in the combination is able - via the increases in active GLP-1 levels - to reduce glucagon secretion in a patient and to give rise to beneficial effects on beta-cell regeneration and neogenesis, thus rendering a combination with a glucopyranosyl-substituted benzene derivative quite useful and therapeutically relevant.

6.17.2 Page 48, lines 12 to 18, in turn, states:

"The increase in active GLP-1 levels by treatment according to this invention after single or multiple dosing can be determined by measuring those levels in the plasma of animal models described hereinbefore in either the fasting or postprandial state. Likewise, a reduction in glucagon levels in plasma can be measured under the same conditions. The glucopyranosyl-substituted benzene derivative in combination with the DPP IV inhibitor will exhibit higher active GLP-1 concentrations and lower glucagon concentrations than the glucopyranosyl-substituted benzene derivative alone."

6.18 At the oral proceedings, the respondent confirmed that these two disclosures of the application as originally filed applied to all combinations according to the originally disclosed invention.

6.19 The respondent emphasised, however, that the application as originally filed disclosed the currently claimed combination as the most preferred embodiment. In support of its contention, the respondent referred

to page 24, line 24 to page 27, line 16 and to page 28, lines 5 to 6 of the application as originally filed.

6.20 The Board does not agree.

6.20.1 On page 24, line 24 to page 27, line 14, the application as originally filed describes linagliptin as one of twelve preferred DPP IV inhibitors according to a first embodiment (embodiment "A"). In the following two paragraphs (see page 27, line 15 to page 28, line 6), the application as originally filed states:

"These DPP IV inhibitors are distinguished from structurally comparable DPP IV inhibitors, as they combine exceptional potency and a long-lasting effect with favourable pharmacological properties, receptor selectivity and a favourable side-effect profile or bring about unexpected therapeutic advantages or improvements when combined with other pharmaceutical active substances. Their preparation is disclosed in the publications mentioned.

Regarding the second embodiment (embodiment B), preferred DPP IV inhibitors are selected from the group consisting of sitagliptin, vildagliptin, saxagliptin and alogliptin."

6.20.2 As correctly argued by the appellants at the oral proceedings, the first of these two paragraphs does not single out the currently claimed combination of empagliflozin and linagliptin. Rather, it refers to combinations of the aforementioned twelve DPP IV inhibitors with other, not further defined pharmaceutically active substances.

6.20.3 Moreover, the Board has not been made aware of any text passage in the application as originally filed on the basis of which the skilled person would understand the term "structurally comparable DPP IV inhibitors" referred to in this first paragraph to include the DPP IV inhibitors sitagliptin, vildagliptin, saxagliptin and alogliptin, respectively.

6.20.4 On the contrary, as observed by the appellants at the oral proceedings, the application as originally filed presents combinations of empagliflozin with linagliptin, sitagliptin, vildagliptin, saxagliptin or alogliptin at an equal level of preference. This is apparent from the paragraph directly below Table 1 (see page 33, lines 2 to 5). This paragraph explains that among the 176 combinations exemplified in Table 1, the combinations numbered "97", "165", "166", "167" and "168" are most preferred. Combination 97 pertains to the currently claimed combinations, i.e. combinations of empagliflozin and linagliptin or a pharmaceutically acceptable salt of it (see Table 1, row "97" in conjunction with page 23, compound "(9)" and page 24, lines 24 to 27). Combinations 165 to 168 relate to combinations of empagliflozin with sitagliptin, vildagliptin, saxagliptin and alogliptin, respectively (see Table 1, rows "165" to "168" in conjunction with page 23, compound "(9)").

6.21 To further support its position that the application as originally filed discloses the currently claimed combination as the most preferred embodiment, the respondent referred to page 41, lines 25 to 28 and the first of the three pharmacological examples of the application as originally filed.

6.22 Undisputedly, page 41, lines 25 to 28 singles out empagliflozin and linagliptin for discussion of the dose but, as submitted by the appellants at the oral proceedings, the application as originally filed does the same for combinations of empagliflozin with sitagliptin, vildagliptin, alogliptin and saxagliptin in the following four paragraphs (see page 41, line 30 to page 42, line 8).

6.23 As regards the three pharmacological examples of the application as originally filed (see page 66, line 3 to page 68, line 3), the first of these examples shows the beneficial effect on glycaemic control of combination 97 (empagliflozin with linagliptin) as compared to the respective monotherapies. However, such beneficial effects are likewise shown for combinations 167 (empagliflozin with saxagliptin) and 165 (empagliflozin with sitagliptin) in the second and third of these examples, respectively.

6.24 Summarising the above, the Board concludes that the technical teaching of the claimed invention that the skilled person, with the common general knowledge in mind, understands at the filing date from the application as originally filed, encompasses the following.

(a) Combination 97 (i.e. the currently claimed combinations) gives rise, *inter alia*, to an increase in plasma levels of active GLP-1 in patients with metabolic disorders and related diseases.

(b) Combinations 165 to 168 (i.e. combinations of empagliflozin with sitagliptin, vildagliptin, alogliptin and saxagliptin, respectively), having

the same level of preference, achieve the same increase in plasma levels of active GLP-1 in patients with metabolic disorders and related diseases as combination 97.

6.25 By contrast, the purported technical effect relied upon by the respondent for inventive step is an increase in plasma levels of active GLP-1 which is stronger and more prolonged in time than the one achieved by combinations 165 and 166, i.e. combinations of empagliflozin with sitagliptin and vildagliptin, respectively (see point 6.9 above).

6.26 It follows from the analysis made in points 6.20 to 6.24 above that the skilled person, having the common general knowledge in mind, and based on the application as originally filed, would not derive the increase in plasma levels of active GLP-1 relied on by the respondent (see point 6.25 above) as being encompassed by the technical teaching of the claimed invention and embodied by the same originally disclosed invention.

6.27 In the respondent's view, point 2 of the order of decision G 2/21 solely required that the technical effect relied on for inventive step itself was encompassed by the technical teaching of the application as originally filed. In the case at hand, this effect was an increase in plasma levels of active GLP-1. How strong or prolonged this increase was compared to increases in plasma levels of active GLP-1 achieved with comparative combinations of SGLT2 inhibitors with DPP IV inhibitors or other such combinations that might be construed from the closest prior art was not the subject-matter of decision G 2/21 but rather a matter of a downstream assessment of inventive step.

6.28 The Board does not concur. Irrespective of how the term "technical effect" in point 2 of the order of decision G 2/21 is to be interpreted, it remains that the technical effect relied upon by the respondent for acknowledgement of inventive step rests on experimental data (i.e. document D56, Figures 1 to 3 and Table 1) which does not confirm the technical teaching conveyed by the application as originally filed (i.e. the same increase in active plasma levels of active GLP-1 for combinations 97, 165 and 166). Rather, these experimental data teach against it. As a matter of fact, the respondent itself submitted (see reply to the statements of grounds of appeal, page 16, third paragraph) that:

"the combination of empagliflozin and linagliptin has a strong and sustained effect on the GLP-1 level. The observed effect cannot be associated with empagliflozin and DPP IV inhibitors in general as it is not observed with empagliflozin in combination with sitagliptin or vildagliptin. The observed effect is thus unique to the claimed combination."

Hence, the increase in active GLP-1 levels relied on by the respondent for acknowledgement of inventive step of the claimed subject-matter forms the basis of an invention which has not been made or disclosed at the filing date of the application. Consequently, this technical effect cannot be taken into account for formulating the objective technical problem (see point 6.14 above).

6.29 As regards the respondent's argument that the technical effect relied on did not change the nature of the claimed invention since the claimed combination was

disclosed in the application as originally filed and no additions or changes to this combination were required to arrive at this effect, the Board notes that this is not sufficient for the requirements stated in point 2 of the order of G 2/21 to be met. More precisely, it is not enough that the claimed invention is disclosed in the application as originally filed in terms of its technical features and that these same features (possibly) achieve this effect without requiring any modification. Rather, it is the purported technical effect relied on for inventive step that must be derivable by the skilled person, having the common general knowledge in mind, and based on the application as originally filed, as being encompassed by the technical teaching and embodied by the same originally disclosed invention. These requirements are not met in the case at issue. For the reasons set out above, the technical effect "increase in GLP-1" associated specifically with the combination claimed would be unexpected to the skilled person in view of the application as originally filed. As a consequence, the alleged "increase in GLP-1" relied upon by the respondent for acknowledgement of inventive step cannot be taken into account for the formulation of the objective technical problem.

7. From the above it follows that the objective technical problem is to provide a specific combination of a glucopyranosyl-substituted benzene derivative of formula I as shown in document D2 with a DPP IV inhibitor in the context of diabetic diseases.

8. As a solution to this problem, the claimed invention proposes the pharmaceutical composition recited in claim 1.

Assessment of obviousness of the proposed solution

9. In the board's judgement, the proposed solution would have been obvious having regard to the state of the art. The reasons are as follows.

9.1 Document D2's disclosure generally relates to glucopyranosyl-substituted benzene derivatives of formula I with SGLT2 inhibitory activity and uses of the same for the treatment of medical conditions, in particular diabetes (see page 43, lines 7 to 10 in conjunction with page 2, line 22 to page 6, line 26).

9.2 Page 26 of this document lists 17 particularly preferred glucopyranosyl-substituted benzene derivatives of formula I, including empagliflozin (see page 26, compound (3)). Further, on page 43, line 29 to page 44, line 3, document D2 states in general terms that glucopyranosyl-substituted benzene derivatives of formula I may be used in combination with, *inter alia*, DPP IV inhibitors for the treatment of diabetic diseases.

9.3 In light of these disclosures, the skilled person would have considered empagliflozin as a suitable glucopyranosyl-substituted benzene derivative of formula I for use in combination with DPP IV inhibitors for the treatment of diabetic diseases.

9.4 In their search for a specific DPP IV inhibitor as a combination partner for empagliflozin for the treatment of diabetic diseases, the skilled person would have consulted document D3 because this document refers to DPP IV inhibitors in the treatment of diabetes (see page 1, first paragraph) and suggests combining these

with other pharmaceutically active agents such as SGLT2 inhibitors (see page 38, lines 17 to 25).

9.5 In reading document D3, the skilled person would have found on page 25, line 22 to page 28, line 20 a list of 30 particularly preferred DPP IV inhibitors, including linagliptin (see page 26, compound (13)).

9.6 As a consequence, the skilled person would have considered linagliptin a suitable combination partner for empagliflozin in document D2 and would thus have arrived at the claimed subject-matter in an obvious manner.

10. The respondent's arguments to the contrary do not persuade the Board.

10.1 In a first line of argument, the respondent pointed to the experimental data of document D13 discussed under point 6.1 above as demonstrating the improved HbA1c profile of the claimed combination versus that of other combinations of SGLT2 inhibitors and DPP IV inhibitors. Since document D2 lacked any pointer to empagliflozin among the glucopyranosyl-substituted benzene derivatives of formula I listed on page 26, the skilled person would not have arrived at the claimed subject-matter without exercising inventive skill.

10.2 However, for the reasons explained in points 6.1 to 6.2 above, the alleged HBA1c improvement cannot be taken into account for formulating the objective technical problem. Therefore, the respondent's argument must fail for this reason alone.

10.3 In a further line of argument, the respondent pointed to the fact that not only did document D2 not provide

any pointer to select empagliflozin over the other glucopyranosyl-substituted benzene derivatives of formula I listed on page 26, but it also gave concrete examples of DPP IV inhibitors other than linagliptin (see page 44, line 3 citing "LAF237" and "MK-431", i.e. vildagliptin and sitagliptin, respectively). Furthermore, a whole host of different DPP IV inhibitors were available to the skilled person, as evidenced by document D38. Accordingly, the skilled person would not have had any incentive to consult document D3 when confronted with the technical problem posed. Even if the skilled person had nonetheless looked at document D3, they would have noticed that the only SGLT2 inhibitor exemplified in this document (i.e. "T-1095", see page 38, line 25) was a C-glycoside (see document D46, Figure 1, compound 2), while the glucopyranosyl-substituted benzene derivatives of formula I described in document D2 were O-glycosides. As a consequence, the skilled person would not have combined the teaching of document D3 with that of document D2.

10.4 The Board does not concur.

10.4.1 As explained in point 7. above, the objective technical problem to be solved by the claimed invention merely involves providing a specific combination of a glucopyranosyl-substituted benzene derivative of formula I as shown in document D2 with a DPP IV inhibitor in the context of diabetic diseases. The selection of empagliflozin from among the 17 glucopyranosyl-substituted benzene derivatives of formula I disclosed on page 26 of document D2 has not been shown to be connected to any particular effect and therefore constitutes an arbitrary choice from the compounds listed on this page.

10.4.2 The same holds true for the selection of linagliptin from among the 30 DPP IV inhibitors disclosed on page 25, line 22 to page 28, line 20 of document D3.

10.4.3 In such cases of arbitrary selections, the prior art does not need to contain a pointer towards the compounds claimed, i.e. empagliflozin and linagliptin.

10.4.4 Instead, all possible solutions have to be regarded as being equally suitable and obvious candidates for solving the objective technical problem as defined above (see Case Law of the Board of Appeal, 10th edn. 2022, section I.D.9.21.9 a)). Such candidates include combinations of glucopyranosyl-substituted benzene derivatives of formula I disclosed on page 26 of document D2 (e.g. empagliflozin), not only with any of the two DPP IV inhibitors exemplified in document D2 but also with any of the DPP IV inhibitors disclosed on page 25, line 22 to page 28, line 20 of document D3 (e.g. linagliptin) as well as any of the DPP IV inhibitors discussed in document D38. All these candidates have to be considered to be suggested to the skilled person.

10.4.5 Concerning the respondent's argument in relation to T-1095 being an O-glycoside (see point 10.3 above), the Board has not been presented with any substantiated arguments why the skilled person would have interpreted the disclosure "*SGLT2-Inhibitoren wie T-1095*" on page 38, line 25 of document D3 (i.e. *"SGLT2 inhibitors such as T-1095"*; see page 37, first full paragraph of document D3a) as requiring that the SGLT2 inhibitor must be an O-glycoside. Rather, as convincingly argued by the appellants, document D3 focuses on the functional nature of the combination partners proposed

in this document (see paragraph bridging pages 38 and 39 of this document). Therefore, the Board agrees with the appellants' position that the skilled person would have understood the disclosure *"wie T-1095"* merely as an exemplification of the functional class of SGLT2 inhibitors. In coming to this conclusion, the Board did not overlook the respondent's submission that the aforementioned paragraph bridging pages 38 and 39 of document D3 uses the word *"wie"* in front of the term "T-1095", while examples of other functionally defined combination partners listed in this paragraph are preceded by the words *"z.B." or "wie etwa" or "wie zum Beispiel"*. However, these differences in wording alone do not allow concluding that document D3 teaches away from using SGLT2 inhibitors other than O-glycosides as combination partners for the DPP IV inhibitors disclosed in this document.

10.5 As a final point, the Board observes that the respondent is correct in arguing that the DPP IV inhibitors disclosed on page 44, line 3 of document D2 as well as the SGLT2 inhibitors disclosed on page 38, line 25 of document D3 are only one of many combination partners proposed in these documents. However, this argument is not relevant when considering the objective technical problem to be solved (see point 7. above).

Overall conclusion on inventive step of claim 1 as granted

11. In light of the above considerations, the Board comes to the conclusion that claim 1 as granted does not meet the requirements of Article 56 EPC.

Referral to the Enlarged Board of Appeal

12. Article 112(1)(a) EPC stipulates that the Board of Appeal shall, during proceedings on a case and either of its own motion or following a request from a party to the appeal, refer any question to the Enlarged Board of Appeal if it considers that a decision is required in order to ensure uniform application of the law or if a point of law of fundamental importance arises.

13. In the case at hand, after hearing the Board's conclusion on the formulation of the objective technical problem at the oral proceedings, the respondent requested the referral of two questions to the Enlarged Board of Appeal (see point X. above). In support of its request, the respondent argued that the terms "encompassed by the technical teaching" and "embodied by the same originally disclosed invention" referred to in point 2 of the order of decision G 2/21 did not have any basis in the EPC. It was unclear what exactly these terms meant and what the requirements were that had to be met. Furthermore, as the divergent outcomes in the current proceedings and in case T 1525/19 showed, these terms had already been interpreted differently by the Boards, despite the underlying fact pattern of the current case being the same as that of case T 1525/19, despite both cases revolving around inventive step over the same document in light of the same post-published experimental data, and despite this inventive step discussion including the consideration whether these data can be taken into account in light of decision G 2/21.

14. The Board does not concur. It instead agrees with the appellants' position that the factual situation in the current case and in appeal case T 1525/19 are not the

same (see point IX. above). Furthermore, the Board does not consider it necessary or appropriate to refer any of the questions formulated by the appellant for the following reasons.

15. First, the mere fact that the outcomes in case T 1525/19 and this case are different does not mean that the two Boards applied different interpretations of the EPC or decision G 2/21. Diverging outcomes may result from a different assessment of the facts, the disclosure of the patent or the prior art. They can originate from a different understanding of the relevant common general knowledge or abilities of the skilled person in the art. For instance, two departments may follow the same interpretation of Article 56 EPC and apply the problem-solution approach to the same facts and, nevertheless, reach different conclusions. To establish a true divergence, the interpretations of point 2 of the order of decision G 2/21 adopted by each Board would have to be known, and whether these interpretations depart from each other would have to be verified.

16. Second, even if there were a divergence, this would not make a referral mandatory. A referral is required only if a Board intends to depart from an interpretation of the EPC given by the Enlarged Board of Appeal (see Article 21 RPBA). It is not necessary if a Board intends to depart from the interpretation of an Enlarged Board's decision or an EPC provision given by another Board (see Article 20 RPBA).

17. Third, and related to this, the Enlarged Board of Appeal deliberately chose not to define the requirements set out in decision G 2/21. Nor did it argue that the case law underlying questions 2 and 3 of

the referral in T 116/18 had been rejected. Against this background, it is at least uncertain whether the Enlarged Board of Appeal would introduce further definitions if asked for additional guidance.

18. Fourth, a referral would only be appropriate if two or more conflicting lines of interpretation existed, which would lead, in the current case, to diverging outcomes. Currently, no such divergent lines of case law are apparent.

19. Finally, in the case at hand, the Board also believes that any tenable interpretation of the requirements introduced in decision G 2/21 would lead to the conclusion that the respondent cannot rely on the alleged "increase in GLP-1" of the claimed combination (see points 6.14 to 6.29 above).

20. For all these reasons, the Board refused the request for a referral.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The request for referral of questions to the Enlarged Board of Appeal is refused.

3. The patent is revoked.

The Registrar: The Chair:

N. Schneider M. Pregetter

Decision electronically authenticated