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**Datasheet for the decision  
of 21 October 2014**

**Case Number:** T 1043/10 - 3.3.04

**Application Number:** 07100818.9

**Publication Number:** 1790353

**IPC:** A61K38/26, A61K31/35

**Language of the proceedings:** EN

**Title of invention:**

Combined use of a GLP-1 compound and a modulator of diabetic late complications

**Applicant:**

Novo Nordisk A/S

**Headword:**

Diabetic late complications/NOVO NORDISK

**Relevant legal provisions:**

EPC Art. 56

**Keyword:**

Inventive step of all requests - (no)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern  
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Case Number: T 1043/10 - 3.3.04

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.04**  
**of 21 October 2014**

**Appellant:** Novo Nordisk A/S  
(Applicant) Novo Allé  
2880 Bagsværd (DK)

**Representative:** Potter Clarkson LLP  
The Belgrave Centre  
Talbot Street  
Nottingham, NG1 5GG (GB)

**Decision under appeal:** **Decision of the Examining Division of the European Patent Office posted on 28 December 2009 refusing European patent application No. 07100818.9 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairwoman** G. Alt  
**Members:** M. Montrone  
K. Garnett

## Summary of Facts and Submissions

- I. This appeal was lodged by the applicant (hereinafter "appellant") against the decision of the examining division to refuse European patent application No. 07100818.9, published as EP 1 790 353. The title of the application is "*Combined use of a GLP-1 compound and a modulator of diabetic late complications*". The application is a divisional application of European patent application No. 02787467.6.
- II. The examining division held that the subject-matter of the claims of the sole request before it did not meet the requirements of Article 56 EPC in view of document D1 taken as closest prior art in combination with the teaching of document D6 (the respective documents are identified in section III, below).
- III. The following documents are cited in this decision:
- D1: EP 1 088 824
- D3: WO 01/66135
- D5: Toft-Nielsen et. al., August 2001, J. Clin. Endocrin. Metabolism; vol. 86, pg. 3853-3860
- D6: Merck Manual, 17th edition, 1999, pages 168, 169, 728 to 731, 1872 to 1875;
- D8: Experimental data filed as Appendix 1 with the statement of grounds of appeal concerning unpublished observations from a meta-analysis comparing an anti-diabetic medication alone with a combined treatment of anti-diabetic and anti-hypertensive medications.

IV. The appellant submitted with its statement of grounds of appeal a main request corresponding to the request dealt with in the decision under appeal, and nine auxiliary requests. It argued that the subject-matter of claim 1 involved an inventive step, relying *inter alia* on D8.

Claim 1 of the main request reads:

"1. Use of a of a GLP-1 compound and a modulator of a diabetic late complication for the preparation of one or more medicaments for the treatment of a diabetic late complication, wherein the modulator of a diabetic late complication is an antihypertensive agent selected from the group consisting of an ACE inhibitor and an angiotensin II receptor antagonist, and wherein said diabetic late complication is selected from the group consisting of nephropathy, hypertension, neuropathy and retinopathy, in a patient in need thereof."

V. The appellant was summoned to oral proceedings scheduled for 21 October 2014.

VI. In its letter dated 15 August 2014 the appellant announced that it would not attend the oral proceedings. Further, it submitted (i) amended auxiliary requests 1, 6, 7, 8 and 9 which replaced the respective requests filed with the statement of grounds of appeal, (ii) new auxiliary requests 10 to 13, (iii) adapted pages of the description for all requests and (iv) a request that a decision according to the state of the file be issued.

In the following recitation of the claims, emphasis is added by the board to indicate the differences with regard to claim 1 of the main request.

Claim 1 of auxiliary request 1 reads:

"1. Use of a GLP-1 compound and a modulator of a late diabetic complication for the preparation of one or more medicaments for the treatment of a diabetic late complication, wherein said modulator of a late diabetic complication is an antihypertensive agent selected from the group consisting of an ACE inhibitor and an angiotensin II receptor antagonist, and wherein said ACE inhibitor is selected from the group consisting of alatriopril, captopril, enalapril, fosinopril, lisinopril, quinapril, ramipril, spirapril, benazepril, imidapril, trandolapril, and perindopril erbumine; and said angiotensin II receptor antagonist is selected from the group consisting of losartan, valsartan, irbesartan or a salt thereof; and wherein said diabetic late complication is selected from the group consisting of nephropathy, hypertension, neuropathy and retinopathy, in a patient in need thereof."

Claim 1 of auxiliary request 2 reads:

"1. Use of a of a GLP-1 compound and a modulator of a diabetic late complication for the preparation of one or more medicaments for the treatment of a diabetic late complication, wherein the modulator of a diabetic late complication is an antihypertensive agent selected from the group consisting of an ACE inhibitor and an angiotensin II receptor antagonist, and wherein said diabetic late complication is selected from the group consisting of nephropathy, hypertension and retinopathy, in a patient in need thereof."

Claim 1 of auxiliary request 3 reads:

"1. Use of a of a GLP-1 compound and a modulator of a diabetic late complication for the preparation of one or more medicaments for the treatment of a diabetic late complication, wherein the modulator of a diabetic late complication is an antihypertensive agent selected from the group consisting of an ACE inhibitor and an angiotensin II receptor antagonist, and wherein said diabetic late complication is selected from the group consisting of nephropathy and hypertension in a patient in need thereof."

Claim 1 of auxiliary request 4 reads:

"1. Use of a of a GLP-1 compound and a modulator of a diabetic late complication for the preparation of one or more medicaments for the treatment of a diabetic late complication, wherein the modulator of a diabetic late complication is an antihypertensive agent selected from the group consisting of an ACE inhibitor and an angiotensin II receptor antagonist, and wherein said diabetic late complication is hypertension, in a patient in need thereof."

Claim 1 of auxiliary request 5 reads:

"1. Use of a GLP-1 compound selected from Arg34, Lys26(Nε-(γ-Glu(Nα-hexadecanoyl)))-GLP-1(7-37) and exendin-4 or an analog or derivative thereof, and a modulator of a late diabetic complication for the preparation of one or more medicaments for the treatment of a diabetic late complication, wherein said modulator of a late diabetic complication is an antihypertensive agent selected from the group

consisting of an ACE inhibitor and an angiotensin II receptor antagonist, and wherein said diabetic late complication is selected from the group consisting of nephropathy, hypertension, neuropathy and retinopathy, in a patient in need thereof."

Claim 1 of auxiliary request 6 reads:

"1. Use of a GLP-1 compound selected from Arg34, Lys26(Nε-(γ-Glu(Nα-hexadecanoyl)))-GLP-1(7-37) and exendin-4 or an analog or derivative thereof, and a modulator of a late diabetic complication for the preparation of one or more medicaments for the treatment of a diabetic late complication, wherein said modulator of a late diabetic complication is an antihypertensive agent selected from the group consisting of an ACE inhibitor and an angiotensin II receptor antagonist, and wherein said ACE inhibitor is selected from the group consisting of alatriopril, captopril, enalapril, fosinopril, lisinopril, quinapril, ramipril, spirapril, benazepril, imidapril,trandolapril, and perindopril erbumine; and said angiotensin II receptor antagonist is selected from the group consisting of losartan, valsartan, irbesartan or a salt thereof; and wherein said diabetic late complication is selected from the group consisting of nephropathy, hypertension, neuropathy and retinopathy, in a patient in need thereof."

Claim 1 of auxiliary request 7 reads:

"1. Use of a GLP-1 compound selected from Arg34, Lys26(Nε-(γ-Glu(Nα-hexadecanoyl)))-GLP-1(7-37) and exendin-4 or an analog or derivative thereof, and a modulator of a late diabetic complication for the preparation of one or more medicaments for the

treatment of a diabetic late complication, wherein said modulator of a late diabetic complication is an antihypertensive agent selected from the group consisting of an ACE inhibitor and an angiotensin II receptor antagonist, and wherein said ACE inhibitor is selected from the group consisting of alatriopril, captopril, enalapril, fosinopril, lisinopril, quinapril, ramipril, spirapril, benazepril, imidapril,trandolapril, and perindopril erbumine; and said angiotensin II receptor antagonist is selected from the group consisting of losartan, valsartan, irbesartan or a salt thereof; and wherein said diabetic late complication is selected from the group consisting of nephropathy, hypertension and retinopathy, in a patient in need thereof."

Claim 1 of auxiliary request 8 reads:

"1. Use of a GLP-1 compound selected from Arg34, Lys26(Nε-(γ-Glu(Nα-hexadecanoyl)))-GLP-1(7-37) and exendin-4 or an analog or derivative thereof, and a modulator of a late diabetic complication for the preparation of one or more medicaments for the treatment of a diabetic late complication, wherein said modulator of a late diabetic complication is an antihypertensive agent selected from the group consisting of an ACE inhibitor and an angiotensin II receptor antagonist, and wherein said ACE inhibitor is selected from the group consisting of alatriopril, captopril, enalapril, fosinopril, lisinopril, quinapril, ramipril, spirapril, benazepril, imidapril,trandolapril, and perindopril erbumine; and said angiotensin II receptor antagonist is selected from the group consisting of losartan, valsartan, irbesartan or a salt thereof; and wherein said diabetic late complication is selected from the group consisting of



nephropathy and hypertension, in a patient in need thereof."

Claim 1 of auxiliary request 9 reads:

"1. Use of a GLP-1 compound selected from Arg34, Lys26(Nε-(γ-Glu(Nα-hexadecanoyl)))-GLP-1(7-37) and exendin-4 or an analog or derivative thereof, and a modulator of a late diabetic complication for the preparation of one or more medicaments for the treatment of a diabetic late complication, wherein said modulator of a late diabetic complication is an antihypertensive agent selected from the group consisting of an ACE inhibitor and an angiotensin II receptor antagonist, and wherein said ACE inhibitor is selected from the group consisting of alatriopril, captopril, enalapril, fosinopril, lisinopril, quinapril, ramipril, spirapril, benazepril, imidapril,trandolapril, and perindopril erbumine; and said angiotensin II receptor antagonist is selected from the group consisting of losartan, valsartan, irbesartan or a salt thereof; and wherein said diabetic late complication is hypertension, in a patient in need thereof."

Claim 1 of auxiliary request 10 reads:

"1. Use of the GLP-1 compound Arg34, Lys26(Nε-(γ-Glu(Nα-hexadecanoyl)))-GLP-1(7-37) and a modulator of a late diabetic complication for the preparation of one or more medicaments for the treatment of a diabetic late complication, wherein said modulator of a late diabetic complication is an antihypertensive agent selected from the group consisting of an ACE inhibitor and an angiotensin II receptor antagonist, and wherein said ACE inhibitor is selected from the group

consisting of alatriopril, captopril, enalapril, fosinopril, lisinopril, quinapril, ramipril, spirapril, benazepril, imidapril, trandolapril, and perindopril erbumine; and said angiotensin II receptor antagonist is selected from the group consisting of losartan, valsartan, irbesartan or a salt thereof; and wherein said diabetic late complication is selected from the group consisting of nephropathy, hypertension, neuropathy and retinopathy, in a patient in need thereof."

Claim 1 of auxiliary request 11 reads:

"1. Use of the GLP-1 compound Arg34, Lys26(Nε-(γ-Glu(Nα-hexadecanoyl)))-GLP-1(7-37) and a modulator of a late diabetic complication for the preparation of one or more medicaments for the treatment of a diabetic late complication, wherein said modulator of a late diabetic complication is an antihypertensive agent selected from the group consisting of an ACE inhibitor and an angiotensin II receptor antagonist, and wherein said ACE inhibitor is selected from the group consisting of alatriopril, captopril, enalapril, fosinopril, lisinopril, quinapril, ramipril, spirapril, benazepril, imidapril, trandolapril, and perindopril erbumine; and said angiotensin II receptor antagonist is selected from the group consisting of losartan, valsartan, irbesartan or a salt thereof; and wherein said diabetic late complication is selected from the group consisting of nephropathy, hypertension and retinopathy, in a patient in need thereof."

Claim 1 of auxiliary request 12 reads:

"1. Use of the GLP-1 compound Arg34, Lys26(Nε-(γ-Glu(Nα-hexadecanoyl)))-GLP-1(7-37) and a modulator of a

late diabetic complication for the preparation of one or more medicaments for the treatment of a diabetic late complication, wherein said modulator of a late diabetic complication is an antihypertensive agent selected from the group consisting of an ACE inhibitor and an angiotensin II receptor antagonist, and wherein said ACE inhibitor is selected from the group consisting of alatriopril, captopril, enalapril, fosinopril, lisinopril, quinapril, ramipril, spirapril, benazepril, imidapril, trandolapril, and perindopril erbumine; and said angiotensin II receptor antagonist is selected from the group consisting of losartan, valsartan, irbesartan or a salt thereof; and wherein said diabetic late complication is selected from the group consisting of nephropathy and hypertension, in a patient in need thereof."

Claim 1 of auxiliary request 13 reads:

"1. Use of the GLP-1 compound Arg34, Lys26(N $\epsilon$ -( $\gamma$ -Glu(N $\alpha$ -hexadecanoyl)))-GLP-1(7-37) and a modulator of a late diabetic complication for the preparation of one or more medicaments for the treatment of a diabetic late complication, wherein said modulator of a late diabetic complication is an antihypertensive agent selected from the group consisting of an ACE inhibitor and an angiotensin II receptor antagonist, and wherein said ACE inhibitor is selected from the group consisting of alatriopril, captopril, enalapril, fosinopril, lisinopril, quinapril, ramipril, spirapril, benazepril, imidapril, trandolapril, and perindopril erbumine; and said angiotensin II receptor antagonist is selected from the group consisting of losartan, valsartan, irbesartan or a salt thereof; and wherein said diabetic late complication is hypertension, in a patient in need thereof."

In summary, claim 1 of the thirteen auxiliary requests differ from that of the main request in that:

- The ACE inhibitors and angiotensin II receptor antagonists are specifically defined (see auxiliary requests 1 and 6 to 13);
- The list of diseases to be treated is reduced to nephropathy, hypertension and retinopathy (see auxiliary requests 2, 7 and 11); nephropathy and hypertension (see auxiliary requests 3, 8 and 12); or hypertension (see auxiliary requests 4, 9 and 13);
- The GLP-1 compounds are specifically defined (see auxiliary requests 5 to 13).

VII. In a communication pursuant to Article 15(1) RPBA the board indicated its preliminary view with regard to the main request that the data of document D8 did not support the presence of an advantageous effect for the compounds used in the claimed treatment because the data neither disclosed the type of anti-hypertensive agent claimed nor disclosed the treatment of one of the four claimed late-diabetic complications. Moreover, the board noted that the subject-matter of claim 1 appeared to be obvious in the light of the teaching of document D3.

VIII. Oral proceedings before the board took place on 21 October 2014 in the absence of the appellant.

IX. The appellant's arguments, as far as they are relevant for the present decision, may be summarized as follows:

*Main Request*

*Inventive step (Article 56 EPC)*

Depending on the diabetic late complication to be treated, either document D1 (for neuropathy and hypertension) or document D6 (for nephropathy or retinopathy) represented the closest prior art.

Document D1 disclosed the treatment of retinopathy, nephropathy, hypertension or neuropathy primarily by administering a glycogen phosphorylase inhibitor. Although it was disclosed that this inhibitor could be combined with a second compound, such as GLP-1, for the treatment of the claimed diseases, the specific combination could only be arrived at by a selection from two different lists, one comprising more than 20 compounds and the other 25 different diseases. In the absence of any teaching in document D1 to use the glycogen phosphorylase inhibitor together with GLP-1 for the treatment of the four diseases claimed, there was no specific disclosure of this particular combination in document D1. Anti-hypertensive drugs were not disclosed at all.

Document D6 disclosed the treatment of diabetic nephropathy and retinopathy by the use of anti-hypertensive drugs but it did not disclose either the use of GLP-1 as an anti-diabetic drug or hypertension as a late diabetic complication.

The technical problem to be solved was the provision of an improved treatment for each of the four diabetic

late complications claimed, i.e. neuropathy, hypertension, nephropathy and retinopathy.

The problem was solved by the subject-matter of claim 1, as evidenced by the experimental data disclosed in document D8 concerning patients treated concomitantly by anti-diabetic and anti-hypertensive medication which treatment resulted in relevant improvements in blood pressure control.

Neither the problem nor the solution to it was suggested in any of the documents D1 to D6 nor was there any motivation for the skilled person to combine the teaching of these documents. Document D5 in particular, although relating to the effectiveness of GLP-1 in the treatment of type 2 diabetes, neither disclosed the use of anti-hypertensive agents or their combination with GLP-1 nor was it related to the treatment of any of the four diabetic late complications referred to in claim 1. The subject-matter of claim 1 thus involved an inventive step.

- X. The appellant requested in writing that the decision under appeal be set aside and that a patent be granted on the basis of either the main request filed with the statement of grounds of appeal, or the first auxiliary request referred to in its letter dated 15 August 2014, or one of the second to fifth auxiliary requests as filed with the statement of grounds of appeal, or one of the sixth to thirteenth auxiliary requests as referred to in its letter dated 15 August 2014.

## **Reasons for the Decision**

*Main request*

*Inventive step (Article 56 EPC)*

*Closest prior art*

1. In assessing whether or not a claimed invention meets the requirements of Article 56 EPC, the Boards of Appeal of the EPO generally apply the "problem and solution approach", which requires as a first step the identification of the closest prior art.

The closest prior art is generally a document disclosing subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention and having the most technical features in common, i.e. requiring the minimum of structural modifications (see Case Law of the Boards of Appeal, 7th edition 2013, I.D.3.1).

2. Claim 1 is drafted in the form of a second or further therapeutic use in the so called "Swiss-type" format. It relates to the combined use of a Glucagon-like peptide-1 (GLP-1) with an anti-hypertensive agent selected from an angiotensin-converting-enzyme (ACE) inhibitor or an angiotensin II receptor antagonist for the treatment of diabetic late complications selected from nephropathy, hypertension, neuropathy and retinopathy.
3. In the following the board needs only to assess inventive step with regard to one embodiment of

- claim 1, i.e. the treatment of hypertension as a diabetic late complication by a combination of GLP-1 and an ACE inhibitor.
4. The examining division considered document D1 as representing the closest prior art for the subject-matter of claim 1. The appellant on the other hand started from either document D1 or document D6.
  5. However, neither of these two documents concerns the treatment of hypertension as a late diabetic complication. Document D1 discloses the treatment of hypertension, but not as a diabetic late complication (see paragraphs 44, 49, 82). Document D6 only discloses the treatment of nephropathy, neuropathy and retinopathy as diabetic late complications (see page 168, column 2, second and third paragraph).
  6. It was known at the priority date of the present application that hypertension is a common diabetic late complication, in particular in patients suffering from type 2 diabetes. This is explicitly acknowledged in the background art part of the application both in paragraph [0003], which reads: *"Diabetics often tend to acquire a series of complications. Some of these complications exhibit fast onset once diabetes develops, whereas other types of complications are common only after years of diabetes. The latter complications are therefore often termed "diabetic late complications", and they typically comprise nephropathy, retinopathy, neuropathy and hypertension"*, and in paragraph [0007], which reads: *"Hypertension is also a very common diabetic late complication, since it affects 40-60% of type 2 diabetics between the ages of 40-75.[...] The drugs used for treatment of hypertension are mainly angiotensin converting enzyme*



*inhibitors, angiotensin II receptor antagonist and  $\beta$ -blockers".*

The application further discloses that diabetes is characterised by increased glucose plasma levels (hyperglycemia) (see paragraph [0002]). In fact, at the priority date of the application diabetes was known to be a chronic disease requiring a permanent anti-hyperglycemic therapy.

7. It can therefore be taken from the introductory part of the application that at the priority date the standard therapy for patients suffering from hypertension as a diabetic late complication was the administration of two separate medications, i.e. one being one of the known anti-hyperglycemic drugs and the other being one of the known anti-hypertensive drugs.
8. In view of the criteria established by the case law (see point 1, above), the board therefore considers that this standard combination therapy represents the closest prior art for the embodiment of claim 1 assessed (see point 3, above).

*Problem to be solved and solution*

9. The technical problem to be solved is to be formulated in the light of the technical effects achieved by those features distinguishing the claimed invention from the closest prior art (see Case Law of the Boards of Appeal, 7th edition 2013, I.D.4.3.1, second paragraph).
10. The relevant embodiment of the subject-matter of claim 1 (see point 3, above) differs from the standard combination therapy which is considered as the closest

prior art by the selection of GLP-1 as the specific anti-hyperglycemic drug.

11. The appellant has asserted that this difference results in an improved treatment of hypertension as a diabetic late complication and submitted document D8 as evidence for this (see section IV, above). Document D8 discloses experimental data from *"an unpublished observation from a meta-analysis of more than 3000 patients treated with anti-diabetic medication alone or concomitantly with anti-diabetic medication and anti-hypertensive medication"*. It has not been suggested that the compiled data of document D8 were available at the priority date of the application.
  
12. According to the established jurisprudence of the Boards of Appeal experimental data not contained in the application as filed or being prior art but submitted later cannot be used when it is the only evidence that a desired technical effect has been achieved, since the assessment of inventive step is to be made at the effective date of the application on the basis of the information derivable from the application together with common general knowledge then available to the skilled person. Only if it is credible that the desired technical effect is achieved by the claimed subject-matter either in view of the data presented in the application or in the light of the available prior art, can then later filed evidence be used as a back-up (see Case Law of the Boards of Appeal, 7th edition 2013, I.D.4.6).
  
13. The board notes that neither the application as filed nor any of the available prior art documents disclose that the combination of GLP-1 with an ACE inhibitor is superior to any other combination known from the

closest prior art for the treatment of hypertension as diabetic late complication. The application refers in this context only to an experimental set-up for a future clinical study (see paragraphs [0068] to [0079]).

Hence, there is no evidence from the application or the prior art available at the priority date rendering it plausible that the technical effect of the embodiment considered here (see point 3, above) is an improvement of the treatment of hypertension as a diabetic late complication when compared to the standard treatment known at the priority date.

Thus, in view of the case law referred to in point 12 above, the evidence of document D8, which was not available at the priority date, cannot be taken into account.

Consequently, an improvement based on the use of GLP-1 is not a technical effect that can be considered for the formulation of the technical problem.

14. The board notes that even if the evidence of document D8 were taken into account, it appears that it does not support an improved treatment of the hypertension since it neither identifies the use of an ACE inhibitor as the anti-hypertensive agent (it merely refers to "*anti-hypertensive medication*" or "*anti-hypertensive treatment*") nor discloses whether the patients treated in fact suffered from hypertension as a diabetic late complication or whether they had suffered from hypertension before the onset of diabetes.
15. Accordingly, there is no relevant technical effect other than the anti-hyperglycemic activity associated

with the use of GLP-1. Consequently, the technical problem to be solved is to be formulated as the provision of a treatment for hypertension as a diabetic late complication by a combination therapy using an alternative anti-hyperglycemic drug and an ACE inhibitor as the anti-hypertensive drug.

16. The board is satisfied that this technical problem is plausibly solved by the subject-matter of claim 1 for the considered embodiment (see point 3, above) because the anti-hypertensive effect of ACE inhibitors is well known in the art (see paragraph [0007] of the application).

*Obviousness*

17. The question to be assessed is then whether or not the skilled person when starting from the closest prior and faced with the problem defined in point 15 above would be motivated to use GLP-1 for glyceimic control in combination with an ACE inhibitor.
18. At the priority date of the present application it was known from the prior art that GLP-1 is a drug that effectively lowers blood glucose levels in diabetic patients (see for example document D5, abstract). This is also acknowledged in the introductory part of the application where it is disclosed that "*GLP-1 is an important gut hormone with regulatory function in glucose metabolism and gastrointestinal secretion and metabolism*" and that exendin as a GLP-1 analog is "*a potent GLP-1 receptor agonist which has been shown to stimulate insulin release and ensuing lowering of the blood glucose level when injected into dogs.*" (see paragraphs [0009] and [0010]).

19. There are also no indications in the prior art that would have deterred the skilled person from considering the claimed combination therapy in the treatment of hypertension as a diabetic late complication. To the contrary, document D3 discloses, although not in the context of the treatment of hypertension as a late diabetic complication, a combined use of GLP-1 and ACE inhibitors as anti-hypertensive agents (see page 11, line 34 to page 12, line 1).
  
20. Therefore, in the board's view, the use of GLP-1 as a drug for glycemetic control in combination with an ACE inhibitor as an anti-hypertensive agent for the treatment of hypertension as a diabetic late complication would have been obvious for the person skilled in the art. Consequently, at least one embodiment of claim 1 of the main request - and hence claim 1 as a whole - cannot be considered to involve an inventive step.
  
21. The main request therefore does not fulfill the requirements of Article 56 EPC.

*Auxiliary requests 1 to 13*

22. The treatment of hypertension as a diabetic late complication is an embodiment of claim 1 of all thirteen auxiliary requests. The subject-matter of claim 1 of all of the auxiliary requests differs from the subject-matter of claim 1 of the main request only by further definitions of GLP-1, the ACE inhibitors and angiotensin II receptor antagonists used (see section VI above).

23. The specific GLP-1 compounds referred to in claim 1 of all auxiliary requests were known at the priority date (see the application, paragraph [0010]) including their use in combination with ACE inhibitors (see document D3, the paragraph bridging pages 11 and 12).
24. Hence, the board arrives at the same conclusion as with regard to the subject-matter claim 1 of the main request, i.e. that the embodiment concerning the treatment of hypertension as a diabetic late complication with a combination of GLP-1 derivatives and the specific ACE inhibitors referred to in the thirteen auxiliary requests would have been obvious. Consequently, none of the thirteen auxiliary requests fulfils the requirements of Article 56 EPC.

## Order

### **For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairwoman:



P. Cremona

G. Alt

Decision electronically authenticated