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Datasheet for the decision of 5 December 2023

Case Number: T 1777/21 - 3.3.04

Application Number: 14721834.1

Publication Number: 2991671

IPC: A61K38/26, A61P3/10

Language of the proceedings: EN

Title of invention:
Oral dosing of GLP-1 compounds

Patent Proprietor:
Novo Nordisk A/S

Opponents:
Teva Pharmaceutical Industries Ltd.
Sanofi
Hexal AG
Galenicum Health S.L.U.
Lederer & Keller Patentanwälte Partnerschaft mbB
Generics (U.K.) Limited

Headword:
GLP-1 peptide dosing/NOVO NORDISK

Relevant legal provisions:
EPC Art. 56

Keyword:
Inventive step - (no)

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Beschwerdekammern

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Case Number: T 1777/21 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 5 December 2023

Appellant: (Patent Proprietor)	Novo Nordisk A/S Novo Allé 2880 Bagsværd (DK)
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Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 6 August 2021 revoking European patent No. 2991671 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairwoman	M. Pregetter
Members:	O. Lechner
	L. Bühler

Summary of Facts and Submissions

I. The patent proprietor (appellant) filed an appeal against the decision of the opposition division revoking European patent No. 2991671.

II. The patent is based on European patent application No. 14721834.1, which had been filed as an international application and published as WO 2014/177683 A1 (the "application as filed"), claiming priority from European patent application No. 13166205.8, which had been filed on 2 May 2013.

III. In its decision, the opposition division held that the set of claims of auxiliary request 3 was novel but not entitled to the claimed priority date, and that it lacked inventive step. None of the sets of claims of the other requests was found to satisfy the requirements of the EPC.

IV. With the statement of grounds of appeal, the appellant maintained the main request (patent as granted) and resubmitted some of the auxiliary requests discussed in the decision under appeal, including auxiliary request 3, and submitted further auxiliary requests and new documents D63 to D65.

V. Opponents 1 and 3 to 6 (respondents 1 and 3 to 6) replied to the statement of grounds of appeal. Respondent 3 also filed new document D66. Opponent 2 did not take an active part in the appeal proceedings.

VI. With a letter dated 20 September 2023, the appellant submitted document D67.

VII. Respondent 4 (see letter dated 26 July 2023), respondent 5 (see letter dated 22 November 2023) and respondent 2 (see letter dated 30 November 2023) announced that they would not attend the oral proceedings.

VIII. During the oral proceedings before the board, which took place by videoconference on 5 December 2023, the appellant withdrew all the requests except for auxiliary request 3.
At the end of the oral proceedings, the chairwoman announced the board's decision.

IX. Claim 1 of auxiliary request 3 reads as follows.

"A solid composition comprising a GLP-1 peptide and an enhancer which is sodium *N*-(8-(2-hydroxybenzoyl)amino) caprylate (SNAC) for use in the treatment or prevention of type 2 diabetes by oral administration, wherein
a) said peptide has plasma half-life in humans of at least 60 hours;
b) said composition is administered at least 3 times; and
c) said composition is administered such that the ratio between the plasma half-life in days in humans of said peptide and the dosing interval in days of said composition is more than 2:1."

X. Reference is made to the following documents.

D4: Study NCT01686945; April 15, 2013; Clinical Trials.gov archive; U.S. National Library of Medicine; 8 pages

D5: WO 2012/080471 Al

D7: Aungst B. J.; The AAPS Journal (2012); Vol. 14(1): 10-18

D9: Nauck M. A. et al.; Diabetologia (2012); Vol. 55, [Suppl 1]:S7

D10: WO 2013/139694 Al

D19: Edmonds D. J. et al.; Annual Reports in Medicinal Chemistry (2013); Vol. 48:119-130

D21: EU Clinical Trials Register EudraCT Number: 2012-004994-16; https://www.clinicaltrialsregister.eu/ctr-search/trial/2012-004994-16/DE; 2013-07-30; 7 pages

D22: Study NCT01923181; version 1, published August 15, 2013; Clinical Trials.gov archive; U.S. National Library of Medicine; 14 pages

D26: González Brao M.; Meeting Report; Drugs of the Future (2012); Vol. 37(12):871-874

D47: Steinert R. E. et al.; Am J Clin Nutr (2010); Vol. 92:810-817.

D48: Study NCT02014259; version 1, published December 12, 2013; Clinical Trials.gov archive; U.S. National Library of Medicine; 5 pages

D50: Tyagi P. et al.; J Control Release (2018); Vol. 287:167–176

D51: Dahlgren D. et al.; Eur J Pharm Biopharm (2019); Vol. 142:411-420

D52: Figures presenting plasma concentration; submitted by the appellant with its reply to the notice of opposition; 1 page

D53: FDA News release; "FDA approves first oral GLP-1 treatment for type 2 diabetes"; September 20, 2019; https://www.fda.gov/news-events/press-announcements/fda-approves-first-oral-glp-1-treatment-type-2-diabetes; 3 pages

D54: Helfand C.; "Novo Nordisk wins FDA green light for 'holy grail' diabetes drug Rybelsus"; 20 September 2019; https://www.fiercepharma.com/pharma/novo-nordisk-wins-fda-green-light-for-holy-grail-oral-semaglutide; 4 pages

D58: Declaration of Flemming S. Nielsen; 22 April 2021; 4 pages

XI. The appellant's arguments, where relevant to the decision, can be summarised as follows.

Inventive step - Article 56 EPC - claim 1

(a) Closest prior art

Document D4 or document D22 was more appropriate as the closest prior art than document D10, because they contained clinical trial protocols of investigations into once-daily dosing of oral GLP-1 compositions in patients with type 2 diabetes. In contrast, document D10 did not disclose any dosage regimen in a therapeutic context, but merely used daily dosing in a

bioavailability study. Document D10 was nevertheless also suitable as a starting point for analysing inventive step.

Document D10 demonstrated that GLP-1 could be bioavailable when delivered orally to dogs in a daily dose, but did not provide any information on the resulting GLP-1 plasma levels, their variability or any therapeutic effect. Moreover, while dogs were suitable for testing bioavailability in general, they were not appropriate as the basis for an assumption on the possible therapeutic effects of GLP-1 peptides. The similarity between the protocol used for the bioavailability testing in Assay (II) of document D10 (see page 38 ff.) and the claimed dosage regime was a mere coincidence, as effects in dogs could not be correlated with those in a human patient. The half-life for GLP-1 peptides such as semaglutide differed greatly between dogs and humans. In humans it was around 160 hours (see document D9, first sentence), whilst in dogs it was around 60 hours. However, the half-life of a therapeutic agent was relevant when designing or testing a dosage regimen. The skilled person would not have considered the protocol used in dogs in document D10 to be relevant to the success of the treatment as claimed. The treatment protocol provided in document D10 was a research tool to determine bioavailability, not a therapeutic dosage regimen. The administration of a daily dose of GLP-1 peptide for five consecutive days was designed to increase the statistical relevance of the study while keeping the number of experimental animals low. In addition, there was no evidence of elevated blood glucose levels in the dogs tested.

(b) Difference, its technical effect, and objective technical problem

The data in the patent addressed a key obstacle in the development of a dosage regimen for oral delivery of GLP-1 peptides, i.e. plasma variability. It demonstrated that this variability was significantly reduced using the claimed dosage regimen, which was suitable for providing consistent plasma levels of GLP-1 and thus made a therapeutic effect plausible. The data in the patent compared the variability provided by the claimed regimen to the variability provided by a single dose. It was not necessary for the data in the patent to compare the claimed regimen with an alternative multidose regimen to support an inventive step, for example because the skilled person would not have had a reasonable expectation of success with a particular oral dosage regimen.

The claimed subject-matter differed from the disclosure in document D10 in that it provided i) a therapeutic oral dosage regimen and ii) an effective treatment of type 2 diabetes.

The objective technical problem was to provide an effective dosage regimen that could be used in a large patient population without the need for titration to arrive at the effective dose.

(c) Obviousness

The skilled person would not have had a reasonable expectation of success in achieving a therapeutic effect for the claimed oral administration regimen of a GLP-1 peptide. At the time of filing, it was well established that the oral administration of peptides, including GLP-1, was associated with significant difficulties, in particular as a result of low

bioavailability and high plasma variability. Documents D19, D50 and D51 all described the issue of interpatient variability and led the skilled person to conclude that there was no reasonable expectation of success for an oral GLP-1 peptide treatment regimen in providing a viable therapeutic treatment of general applicability. From document D7 (see page 10, left-hand column, page 15, left-hand column, paragraph 1) it was evident that drug absorption and variability in plasma bioavailability were also separate issues.

The problems were also apparent from Tables 3 to 5 and 7 to 10 of document D5, which showed that in many dogs the bioavailability (F) was zero, and that the standard deviation of bioavailability was greater than the mean.

It was established case law that clinical trial protocols such as those disclosed in document D4 or D22 did not provide any information regarding possible beneficial effects (see for example decisions T 158/96, T 385/07 and T 715/03). Such clinical trial protocols could perhaps give rise to a hope of success, but not to a reasonable expectation of it.

The skilled person could not have reasonably expected to achieve consistent GLP-1 plasma levels within a therapeutic window by oral administration, or that a frequent multidose oral administration method would successfully achieve a therapeutic effect.

Contrary to the opposition division's decision, document D9 could not provide a reasonable expectation of success for orally administered GLP-1 peptides either, since it related to the treatment of type 2 diabetes with subcutaneous injections of semaglutide administered once a week.

Moreover, more frequent dosing would not be expected to improve the clinical efficacy, but would be associated with a risk of lower compliance in a real-world clinical setting.

Diabetes was a chronic condition and required long-term therapy. The skilled person would have considered the variability shown in document D5 and the significant obstacles described in documents D19 and D50 to indicate likely failure for treatment or prevention of type 2 diabetes with the claimed oral dosage regimen.

XII. The respondents' arguments, where relevant to the decision, can be summarised as follows.

Inventive step - Article 56 EPC - claim 1

(a) Closest prior art

Document D10 disclosed a multiple-dose study with once-daily dosing of oral formulations containing the GLP-1 peptide semaglutide and SNAC for five consecutive days (see page 38, "*Assay (II): Dissolution testing*"). The results showed bioavailability of semaglutide at levels that had relevance for therapy. The compositions disclosed in document D10 were intended for use in medicine, such as the treatment of diabetes or obesity by means of oral administration (see claim 15).

(b) Difference, its technical effect, and objective technical problem

The subject-matter of claim 1 differed from the teaching in document D10 in the achievement of a

therapeutic effect against type 2 diabetes and the dosage regimen claimed.

The data in the patent did not allow any conclusion to be drawn as to the technical effect of these differences. The comparative study conducted in Examples 1 to 3 of the patent was not designed in a manner appropriate for showing that there was an effect on plasma variability caused by the claimed multidose regimen, as compared to other continuous administration regimens in the treatment of chronic diseases such as type 2 diabetes, as envisaged by document D10. The study in the patent failed to compare the claimed dosage regimen with an alternative multidose regimen administered less frequently. Moreover, as none of the parameters relevant to type 2 diabetes, such as blood glucose, had been measured, the data in the patent did not provide any evidence of a technical effect in the treatment of type 2 diabetes beyond that taught in document D10.

The appellant had clearly acknowledged in the statement of grounds of appeal (see paragraph 4.37) that an effect of reduced interpatient variability had only been shown for an oral administration of 70 doses, far more than the 3 doses specified in claim 1.

A subject who received only one administration of the claimed composition was closer to a patient who received three administrations as specified in item b) of claim 1 than a patient who received 70 doses.

The same applied to a subject who received five consecutive administrations, as disclosed in document D10 (see page 38, lines 28 to 30), which was not only encompassed by the claim under consideration but was

also closer to the (at least) three administrations specified in claim 1 than the examples in the patent. Therefore, the alleged effect on interpatient variability could not be taken into account.

If document D10 did not destroy novelty, the objective technical problem to be solved was to provide an effective therapeutic oral dosage regimen for GLP-1 peptides having a plasma half-life in humans of at least 60 hours, for the treatment of type 2 diabetes.

(c) Obviousness

With reference to documents D19 and D50, the appellant had argued that the skilled person would have had concerns regarding the oral administration of GLP-1 peptides, because of the high variability of plasma levels in humans.

However, document D50 was not part of the prior art and thus was not available to the skilled person at the date of filing.

The teaching of document D19 did not reduce the skilled person's expectation of success. Document D19 actually acknowledged on page 122, with reference to document D4 (reference 11 in document D19), that an oral formulation of semaglutide was undergoing multidose clinical trials.

In fact, a person skilled in the art would have understood from both document D19 and document D4 that, despite potential challenges, great progress had been made in the oral administration of peptide drugs - at least for the peptide drug known at the time as semaglutide. Moreover, document D47 disclosed

physiological effects after oral administration of GLP-1 formulated with SNAC (see abstract).

The clinical trials described in documents D4, D21, D22 and D48 were for the treatment of type 2 diabetes. The trial described in document D48 also included a combination of semaglutide and SNAC (see page 3, "Assigned Interventions").

In line with case law, the mere announcement of clinical trials on humans was sufficient to give a person skilled in the art an expectation of success. In the present case it was known that the GLP-1 peptide semaglutide was effective in the treatment of type 2 diabetes (see documents D9 and D26) and that oral administration resulted in plasma bioavailability (see documents D5, D10, D19 and D47).

The subject-matter of claim 1 did not involve an inventive step over the disclosure of document D10 alone or in combination with any one of documents D4, D21 and D22.

XIII. The parties' requests, where relevant to the decision, were as follows.

(a) The appellant (patent proprietor) requested that the decision under appeal be set aside, and that the patent be maintained in amended form on the basis of auxiliary request 3.

(b) Respondents 1 and 3 to 6 (opponents 1 and 3 to 6) requested that the appeal be dismissed, and that the patent be revoked.

(c) Respondent 2 (opponent 2) did not file any requests during the appeal.

Reasons for the Decision

1. Respondents 2, 4 and 5 did not attend the oral proceedings, which were continued in their absence. Respondents 4 and 5 were treated as relying on their written case, in line with Rule 115(2) EPC and Article 15(3) RPBA.

Inventive step - Article 56 EPC - claim 1

2. The opposition division decided that the claimed priority of 2 May 2013 was not valid for the claims of auxiliary request 3, and that documents D8, D10, D19, D21, D22, D48 and D49 were part of the prior art under Article 54(2) EPC. This part of the opposition division's decision was not contested during the appeal proceedings.

Closest prior art

3. All the parties accepted document D10 as a suitable starting point for assessing inventive step.

4. Document D10 describes the use of a composition comprising a GLP-1 peptide and SNAC for use in medicine, such as for treatment of (preferably type 2) diabetes or obesity, wherein said composition is administered orally (see page 2, lines 25 to 29; page 26, line 12; claim 15). GLP-1 peptides are described as having insulinotropic activity (see page 13, last paragraph).

Claim 15 of document D10 depends on claim 8, which specifies that the GLP-1 peptide may be N-ε26-[2-(2-{2-[2-(2-{2-[(S)-4-carboxy-4-(17-carboxyheptadecanoyl-amino) butyrylamino]ethoxy}ethoxy)acetylamino]ethoxy} ethoxy)acetyl][Aib8,Arg34]GLP-1(7-37), which is semaglutide.

SNAC is reported to function as a delivery agent which has previously been shown to improve the bioavailability of orally administered peptides (see page 1, paragraph 2).

Document D10 also discloses bioavailability studies (see page 38, Assay (II); Example 7, Table 9; and Example 10, Table 12) in which a tablet comprising 300 mg of SNAC and 10 mg of one of the GLP-1 peptides semaglutide or compound A (see Example 1, Tables 2 and 3) was given orally to dogs (which were not described as suffering from a disease or condition), either in a single dose or once a day for five days (multiple dosing).

Document D10 does not mention the plasma half-life of semaglutide in humans, but a plasma half-life of 160 hours, i.e. a half-life of at least 60 hours, for semaglutide was generally known in the field, as evidenced by document D19 (see page 122, last paragraph of chapter 2) or D9.

5. The board agrees with the appellant that Assay (II) in document D10 (see page 38) does not intend to disclose a therapeutic treatment, but rather a protocol to assess the bioavailability of two GLP-1 peptides (one of which is semaglutide) in dogs with no reported diseases. The therapeutic methods as described on pages 24 to 26 or claim 15 of document D10 do not mention any

therapeutic dosage regimen. Moreover, document D10 does not provide any evidence of a therapeutic or preventive effect in relation to (type 2) diabetes, as no parameters indicating such an effect (such as serum glucose levels or HbA1c levels) were determined.

Difference and its technical effect

6. Thus, the subject-matter of claim 1 differs from the teaching in document D10 in respect of
i) the effective treatment of type 2 diabetes and
ii) the dosage regimen.
Claim 1 is not restricted to the treatment of human patients.

7. The appellant argued that the effect of the differences was that the claimed dosage regimen resulted in reduced interpatient variability [note added by the board: this is the range of fluctuation in GLP-1 peptide concentration in the blood of different patients over a given period during which the dose of GLP-1 peptide applied remains unchanged], enabling consistent daily drug exposure with orally administered GLP-1 peptides. This eliminated the need to determine for each individual patient the oral dose that was needed to obtain therapeutic plasma concentrations.

8. The patent shows in Example 1 that daily oral delivery of semaglutide in a formulation comprising 300 mg SNAC for 70 days to healthy (10, 20 or 40 mg semaglutide/day) and type 2 diabetic (40 mg/day) human test subjects results in decreased variability (measured as percent confidence value (%CV)) for both AUC and C_{max} when compared to a single oral dose of 10 mg semaglutide in a formulation with 300 mg SNAC (see Table 1).

9. It was known that a single oral dose of 20 mg semaglutide and 300 mg SNAC results in considerable variability in drug exposure (see document D19, page 122, paragraph 2). On the other hand, as submitted by the respondents, current therapies for chronic diseases such as type 2 diabetes generally rely on repeated long-term administration.

Given the recognised need for repeated long-term treatment of type 2 diabetes, it is not appropriate to compare the variability of semaglutide serum levels achieved after 70 days of daily treatment with that of a single dose of semaglutide, which is known to be associated with high variability in drug exposure. The patent fails to compare the claimed dosage regimen with a multidose regimen of semaglutide (with SNAC) suitable for treating the chronic condition of type 2 diabetes, such as one of those known in the prior art and already undergoing clinical trials (see for example documents D4, D19, D21 or D22).

10. Moreover, given the known issue with interpatient variability in bioavailability associated with a single dose, the board also notes a gap in evidence between an effect observed after 70 daily doses and the claimed dosage regimen, which includes only 3 administrations. The reduced variability of bioavailability has not been shown for the lower range of the defined minimum number of administrations. Consequently, the effect has not been credibly shown over the entire scope of claim 1.

11. The appellant has not provided any further data to substantiate the effect for the claimed subject-matter in the light of the prior art.

12. Thus, the technical effect of the differences identified in point 6. above is that the claimed dosage regimen allows the effective treatment of type 2 diabetes.

Objective technical problem

13. The objective technical problem is the provision of an effective oral treatment (or prevention) of type 2 diabetes with a GLP-1 peptide having a long plasma half-life.

The problem has been solved.

Obviousness

14. From the bioavailability studies provided in document D10, which has been identified as a suitable starting point, the skilled person knows that daily administration for five consecutive days will result in a certain plasma level of semaglutide.
It was known in the art that semaglutide is bioavailable when administered orally together with SNAC (see documents D10; D19, page 122, penultimate paragraph; or D47, abstract) and that GLP-1 peptides, when present in plasma, have pharmacological effects suitable for the treatment of type 2 diabetes (see documents D9; D10, page 13, last paragraph; D19, page 120; or D26, page 871, right-hand column).

15. The skilled person would have been cautious, in view of the prior art relating to the oral administration of semaglutide. Document D19, a review article, reports that formulating GLP-1 peptides for oral administration to deliver reasonable bioavailability with low interpatient variability is a challenge (see page 121).

However, document D19 goes on to discuss some strategies for addressing this issue, including the use of GLP-1 peptides with a longer half-life, and permeability enhancers such as SNAC. Document D19 reports on page 122, paragraph 2 that oral administration of semaglutide with SNAC resulted in a (low) mean 1.4% bioavailability with considerable variability in exposure. Referring to document D4 (see reference 11 in document D19), this paragraph also mentions that an oral formulation of semaglutide is currently undergoing multidose clinical trials in Europe, albeit at doses considerably higher (up to 60 mg) than those used for the subcutaneous route.

Thus, the skilled person would have been aware of ongoing clinical studies, and would have taken into account clinical studies describing oral treatment with semaglutide, such as the study described in document D4, and those in documents D21, D22 and D48.

15.1 Document D4 describes the phase I clinical trial NCT01686945 investigating the safety, tolerability, pharmacokinetics and pharmacodynamics of daily doses of oral semaglutide, with a delivery agent, given for at least 69 days to healthy male subjects and male subjects with type 2 diabetes.

15.2 Document D21 describes the multidose clinical phase II trial EudraCT: 2012-004994-16, which compares the efficacy on glycaemic control of 2.5, 5, 10, 20 or 40 mg of orally administered semaglutide in a SNAC formulation in subjects with type 2 diabetes. Three dose-escalation schemes using a single end-dose level for 26 weeks of oral administration are compared (see points A.3, E.1.1, E.2.1 and E.2.2).

15.3 Document D22 describes the multiple-dose clinical phase II trial NCT01923181 examining dosage range, escalation, and efficacy for oral semaglutide in subjects with type 2 diabetes (see title). The regimen comprises once-daily oral administration of different amounts of semaglutide in tablet form for 26 weeks (see table starting on page 4).

15.4 Document D48 describes the phase I multiple-dose clinical trial NCT02014259, in which healthy subjects and subjects with type 2 diabetes are given a daily oral dose of semaglutide formulated with SNAC, with a dose escalation consisting of 5 days on 5 mg semaglutide followed by 5 days on 10 mg (see page 3).

16. Documents D9, D19 and D26 report successful treatment of type 2 diabetes with subcutaneously administered GLP-1 peptides. In addition, it was known from documents D10 and D19 that oral administration of GLP-1 peptides with low clearance together with SNAC resulted in (plasma) bioavailability of the drug. The step to clinical trials, see D4, D21, D22 and D48, shows that the skilled person would have seriously contemplated the teaching of documents D10, D19 and D26 and would have taken the step to application in patients.

17. The appellant also argued that the data in document D5 disclosed that in many dogs the bioavailability (F) was zero and the standard deviation of bioavailability was greater than the mean. Document D5 shows that, following a single oral dose to dogs, tablets comprising 15 or 20 mg semaglutide and 300 mg SNAC resulted in better bioavailability (see Example 1; Tables 9 and 10) than tablets comprising lower (150 mg) or higher (600 mg) amounts of SNAC (see Tables 3 and 5), for which a higher percentage of individuals with

zero bioavailability could be observed. However, these data are based on a single administration of the drug, and it can be expected that repeated administration, as required for a chronic disease such as type 2 diabetes, would produce even more favourable results.

18. In view of this, the board considers that the skilled person had not just a hope, but a reasonable expectation of success. Despite being cautious about the low bioavailability associated with high interpatient variability in exposure, as reported in document D19, the skilled person would have expected benefits for the prevention and treatment of type 2 diabetes, and would have administered semaglutide in combination with SNAC with the dosage regimen leading to bioavailability as described in document D10, i.e. administration on a daily basis.

Other documents cited

19. Document D7 is considered to be less relevant than the teaching in document D19, since it deals with absorption enhancers in general and not specifically with GLP-1 peptides. In the context of GLP-1 peptides, document D19 is more relevant. Furthermore, it is noted that oral bioavailability was already disclosed in document D10, which is the starting point for the assessment of inventive step.

20. Referring to documents D53 and D54, the appellant argued that the successful oral administration of GLP-1 peptides in the treatment of type 2 diabetes had been considered something of a holy grail, i.e. a huge challenge. However, as discussed above, it was already known at the relevant date that orally administered semaglutide in combination with SNAC was bioavailable

(see documents D10; D19, page 122, penultimate paragraph; or D47, abstract).

21. The results of document D52 are irrelevant in view of the lack of data on a once-daily administration on three consecutive days (see also point 10. above).

Case law cited regarding the expectation of success in the context of clinical trial protocols

22. The decisions cited by the appellant in support of its argument that a clinical trial protocol did not give rise to an expectation of success have as their common element that they deal in detail with the specific facts relating to the case in question, i.e. that they are case-specific.

23. In the present case, the closest prior art is not a clinical study but a patent document which discloses oral bioavailability after as few as five daily doses. The file does not contain any submission that this teaching of document D10 is incorrect.

The clinical studies referred to in the present case merely reinforce the skilled person's expectation that the oral bioavailability of semaglutide results in therapeutic treatment.

Conclusion on inventive step

24. For the reasons set out above, the board decided that the subject-matter of claim 1 lacks an inventive step within the meaning of Article 56 EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

I. Aperribay M. Pregetter

Decision electronically authenticated