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**Datasheet for the decision
of 29 November 2024**

Case Number: T 1870/22 - 3.3.07

Application Number: 17204363.0

Publication Number: 3326620

IPC: A61K9/20, A61K38/26,
A61K31/195, A61P3/04, A61P3/10

Language of the proceedings: EN

Title of invention:

SOLID COMPOSITIONS COMPRISING A GLP-1 AGONIST AND A SALT OF N-(8-(2-HYDROXYBENZOYL)AMINO)CAPRYLIC ACID

Patent Proprietor:

Novo Nordisk A/S

Opponents:

Teva Pharmaceutical Industries Ltd
Hexal AG
Galenicum Health S.L.U.
Generics (U.K.) Limited

Headword:

SOLID COMPOSITIONS COMPRISING A GLP-1 AGONIST AND A SALT OF N-(8-(2-HYDROXYBENZOYL)AMINO)CAPRYLIC ACID/Novo Nordisk A/S

Relevant legal provisions:

EPC R. 80

EPC Art. 76(1)

Keyword:

Amendment occasioned by ground for opposition - (yes)

Divisional application - extension beyond the content of the
earlier application as filed (no)

Decisions cited:

G 0002/10, G 0001/05

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0

Case Number: T 1870/22 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 29 November 2024

Appellant: Novo Nordisk A/S
(Patent Proprietor) Novo Allé
2880 Bagsværd (DK)

Representative: Ford, Hazel
Mathys & Squire
The Shard
32 London Bridge Street
London SE1 9SG (GB)

Respondent: Teva Pharmaceutical Industries Ltd
(Opponent 1) 124 Dvora HaNevi'a St.
6944020 Tel Aviv (IL)

Representative: von Kauffmann, Carl
Global IP Group - Teva
Graf-Arco-Straße 3
89079 Ulm (DE)

Respondent: Hexal AG
(Opponent 2) Industriestrasse 25
83607 Holzkirchen (DE)

Representative: Maiwald GmbH
Elisenhof
Elisenstraße 3
80335 München (DE)

Respondent: Galenicum Health S.L.U.
(Opponent 3) CL Sant Gabriel n°50
08950 Esplugues de Llobregat (ES)

Representative: Galenicum Health S.L.U.
CL Sant Gabriel n°50
08950 Esplugues de Llobregat (ES)

Respondent: Generics (U.K.) Limited
(Opponent 4) Building 4, Trident Place
Mosquito Way
Hatfield
Hertfordshire AL10 9UL (GB)

Representative: Ter Meer Steinmeister & Partner
Patentanwälte mbB
Nymphenburger Straße 4
80335 München (DE)

Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 13 June 2022
revoking European patent No. 3326620 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman A. Usuelli
Members: D. Boulois
S. Ruhwinkel

Summary of Facts and Submissions

I. European patent No. 3 326 620 B1 was granted on the basis of a set of 25 claims. The patent has the application number 17 204 363.0 and is a divisional application of EP 11 805 824.7 with the publication number EP 2 651 398. The parent patent is the subject of the decision T 1404/21.

Independent claim 1 as granted read as follows:

"1. A solid composition for oral administration comprising semaglutide and a salt of N-(8-(2-hydroxybenzoyl)amino)caprylic acid, wherein said composition comprises at least 60%(w/w) of said salt of N-(8-(2-hydroxybenzoyl)amino)caprylic acid."

II. The patent was opposed under Article 100 (a), (b) and (c) EPC on the grounds that its subject-matter lacked inventive step, was not sufficiently disclosed and extended beyond the content of the application as filed.

III. The appeal lies from the decision of the opposition division to revoke the patent. The decision was based on the main request and auxiliary requests 1-3 and 7 filed on 30 April 2021 and auxiliary requests 4-6, 8 and 9 filed on 29 April 2022.

IV. The document cited during the opposition proceedings included the following:

D20: WO 2012/080471 (parent application)

- V. According to the decision under appeal, a decision on the admissibility of the main request under Rule 80 EPC was not required in view of the final decision on Article 76(1) EPC.

The main request did not comply with the requirements of Article 76(1) EPC in view of the claimed amount percentage of the salt of N-(8-(2-hydroxybenzoyl)amino) caprylic acid in claim 1.

The opposition division considered that there was no indication in the parent application that an amount of at least 60% (w/w) of the salt of N-(8-(2-hydroxybenzoyl)amino) caprylic acid could be used instead of at least 0.6 mmol and that the patent as a whole required such minimum amount of 0.6 mmol of the salt of N-(8-(2-hydroxybenzoyl)amino) caprylic acid (also abbreviated as NAC).

The same conclusion applied to all auxiliary requests.

- VI. The proprietor (hereinafter the appellant) filed an appeal against said decision. With the statement setting out the grounds of appeal the appellant filed a main request and auxiliary requests 1-9.

Claim 1 of the main request was identical to claim 1 as granted. Dependent claim 3 was deleted in comparison to the claims as granted.

- VII. Opponent 02 (hereinafter respondent 02) and opponent 04 (hereinafter respondent 04), responded to the statement of grounds of appeal.

- VIII. Opponent 01 withdrew its opposition with its letter of 9 January 2024.

- IX. Opponent 03 (hereinafter respondent 03) and respondent 02 informed the Board and the parties that they will not attend the oral proceedings.
- X. A communication from the Board, dated 30 August 2024, was sent to the parties.
- XI. Oral proceedings took place on 29 November 2024.
- XII. The arguments of the appellant may be summarised as follows:

Main request - Rule 80 EPC

In its original statement of opposition, respondent 02 raised an objection of lack of sufficient disclosure under Article 83 EPC that was specifically directed against granted claim 3. The amendment made in the main request was in direct response to the attack under Article 83 EPC made by respondent 02 in its statement of opposition and was therefore justified under Rule 80 EPC.

In contrast the respondent's 02 objection to claim 4 of the main request related to a lack of clarity caused by one of the multiple dependencies of claim 4 and this objection could not be compared with the objection against claim 3.

Main request - Article 76(1) EPC

The subject-matter of claim 1 of the main request had a basis in the parent application. It was apparent that the parent application as filed related generally to solid compositions, for oral administration, comprising

a GLP-1 agonist and a salt of N-(8-(2-hydroxybenzoyl)amino)caprylic acid without specification of any amount (cf. page 1 or page 12 of D20). The parent application as filed disclosed furthermore explicitly compositions that comprise at least 60% (w/w) of the salt of NAC (cf. page 13 of D20).

The claimed subject-matter did not result from multiple selections:

- as stated by the opposition division, semaglutide was specifically disclosed as a GLP-1 agonist, was used in all the compositions of the examples, and was clearly the preferred option;
- the feature "for oral administration" was specifically disclosed (see, e.g., page 1 lines 34-35, page 12 lines 5-6), was consistent with the oral dosing used in the examples, and was clearly also the preferred option.
- the only selection from a list that is required to reach claim 1 of the main request was the selection of at least 60% (w/w) of the salt of NAC. That feature was presented as the broadest of a list of three convergent options at page 13.

Moreover, "at least 0.6 mmol" of a salt of NAC was not an essential feature of the parent application, since none of the passages relating to a minimum of 0.6 mmol salt of NAC disclosed that it was an essential feature. Some passages of D20 even did not specify that an amount of the salt of NAC was necessary. Hence, there was no deletion of an alleged essential feature.

It was also inappropriate for the opposition division to make a decision under Article 76(1) EPC that actually related to the inventive contribution of the

claimed compositions. This point was not relevant for the assessment of Article 76(1) EPC.

XIII. The arguments of the respondents may be summarised as follows:

Main request - Rule 80 EPC

According to respondent 02, the appellant argued that there was no insufficiency of disclosure of claim 3 and there was no incompatibility between the features of claim 4 being dependent on claim 3 of the main request. Therefore, it was understood that the contradictory numerical ranges stipulated in granted claim 3 depending on granted claim 1 led to a lack of clarity of the intended scope for the same reasons as submitted for claim 4 of the main request being dependent on claim 3 of the main request. Hence, the deletion of granted claim 3 in the new main request was not in response to a ground of opposition, but served the purpose of addressing clarity issues under Article 84 EPC. In conclusion, the main request was not admissible under Rule 80 EPC.

According to respondent 04, objections against granted claim 3 under Article 83 EPC were raised by respondent 02 in its notice of opposition and the patentee deleted granted claim 3 without providing any explanation. Respondent 02 raised similar objections to claims 3 and 4 of the new main request, corresponding to granted claims 4 and 5. The patentee argued that those were lack of clarity attacks and could not be raised as a ground of opposition; the claims were not further amended. Both objections had however to be considered as objections under Article 83 EPC or objections under Article 84 EPC. In case the objections were considered

as lack of clarity objections under Article 84 EPC, deletion of granted claim 3 should not be admissible under Rule 80 EPC.

Main request - Article 76(1) EPC

According to respondent 02, the feature of the composition comprising an amount of "at least 0.6 mmol" of NAC salt was an essential feature of D20, and its omission in claim 1 resulted in an undue extension and violation of the provisions of Article 76(1) EPC. The skilled person considering D20 as a whole would have found two alternatives of what was meant with the term "certain amount of NAC salt", namely at least 0.6 mmol or at least 175 mg. The subject-matter of claim 1 of the main request extended beyond what was directly and unambiguously disclosed in D20. Moreover, the subject-matter of claim 1 constituted a threefold selection from lists, from the active agent, the oral administration and the claimed amount of at "least 60% (w/w)".

Respondent 02 also was of the opinion that a remittal to the opposition division was not necessary.

According to respondent 04, the main request did not meet the requirements of Article 76(1) EPC, since the total absolute amount in mmol of the salt of NAC was described throughout the parent application to be essential, while it was omitted in claim 1 of the main request and replaced by a relative amount. The importance of the absolute amount of at least 0.6 mmol was demonstrated by the examples of D20 (cf. Table 1). From the results, the conclusion was drawn in the opposed patent that 300 mg of SNAC led to a better bioavailability than 150 mg (0.5 mmol) SNAC.

XIV. Requests

The appellant requested that the decision under appeal be set aside and the patent be maintained according to the set of claims filed as main request, or alternatively according to any of auxiliary requests 1-9 filed with the statement of grounds of appeal dated 21 October 2022. The appellant also requested that the case be remitted to the opposition division for further prosecution of the unexamined grounds of opposition.

Respondent 02 (in writing) and respondent 04 requested that the appeal be dismissed.

The respondents also requested that the main request and auxiliary requests 1-9 not be admitted under Rule 80 EPC.

Respondent 04 further requested that auxiliary requests 7 and 8 not be admitted for lack of convergence.

Respondent 04 also requested that the case be remitted to the opposition division in the event that a decision is to be taken on a ground of opposition not dealt with in the opposition division's decision.

Reasons for the Decision

1. Main request - Rule 80 EPC

1.1 The compliance of the main request with Rule 80 EPC has been contested by the respondents in view of the deletion of claim 3 as granted.

Claim 3 as granted read:

"3. The composition according to any of the preceding claims, wherein the molar ratio between semaglutide and said salt of N-(8-(2-hydroxybenzoyl)amino)caprylic acid in the composition is less than 10, such as less than 5 or less than 1."

According to the respondents the patent proprietor deleted claim 3, in response to objections relating to Article 84 EPC and not in reply to the objections raised initially against claim 3 under Article 83 EPC. Since the respondents' objections are considered to be lack of clarity objections under Article 84 EPC, deletion of granted claim 3 should not be admissible under Rule 80 EPC.

- 1.2 The Board notes that the objections against claim 3 as granted were raised by the respondent 02 under Article 83 EPC in its notice of opposition. In response to this objection, the proprietor deleted dependent claim 3 in its main request. **Hence, this deletion is in direct response to the objections made by respondent 02 under Article 100(b) EPC and is justified under Rule 80 EPC.**

More specifically, the respondent 02 objected claim 3 under Article 83 EPC by arguing that the skilled person was not able to rework the invention over the entire molar ratio claimed. In view of the claimed percentage of "at least 60% (w/w) of said salt of N-(8-(2-hydroxybenzoyl)-amino) caprylic acid" in claim 1, the patent as defined in the preferred option of claim 3 was not re-workable for the range of from 0.05 to 1, and it could only be realized in the range of from 0.05 to (almost) 0. In other words, 95 % of the preferred range was not re-workable (see points 14 to 20 of the submissions of 3 December 2020).

The Board notes that the molar ratio reported in claim 3 as granted is also disclosed in the patent description (see par. [0030] of the specification). In the Board's view, if a claimed invention appears at first sight infeasible, due to technical incompatibilities with other parts of the claims or of the description, **this may result simultaneously to a lack of clarity and insufficiency of disclosure which justifies the deletion of the claim under Rule 80 EPC.**

2. Main request - Article 76(1) EPC

2.1 Claim 1 of the main request reads:

"1. A solid composition for oral administration comprising semaglutide and a salt of N-(8-(2-hydroxybenzoyl)amino)caprylic acid, wherein said composition comprises at least 60% (w/w) of said salt of N-(8-(2-hydroxybenzoyl)-amino) caprylic acid."

The subject-matter of claim 1 has been objected under Article 76(1) EPC under two points:

a) the claimed amount of "at least 60% (w/w) of said salt of N-(8-(2-hydroxybenzoyl)-amino) caprylic acid" has replaced the originally claimed amounts of the salt of N-(8-(2-hydroxybenzoyl)-amino) caprylic acid (NAC) of "at least 0.6, or at least 0.8 mmol", and there was no indication in the parent application that an amount of "at least 60% (w/w)" could be used instead of "at least 0.6 mmol". The opposition division concluded in its decision that an amendment replacing or removing a feature presented as essential contravened the requirements of Article 76(1) EPC.

b) respondent 02 also considers that the subject-matter of claim 1 constitutes a selection from a threefold selection from lists, with regard to the claimed amount, semaglutide and the oral administration.

2.2 The description of the parent application specifies that the "salt of N-(8-(2-hydroxybenzoyl)-amino) caprylic acid" is used as delivery agent (see page 10, lines 24-28).

With regard to the claimed amount of the delivery agent (see point a) above), several parts of the parent application D20 mention it:

- page 13, lines 1 and 4;
- page 21, line 4;
- page 23, line 23.

2.2.1 The disclosure on the first paragraph of page 13, line 1, relates to the claimed composition and discloses that "in some embodiments the composition comprises at least 60% (w/w) delivery agent, less than 10% (w/w) binder, 5-40% (w/w) filler, and less than 10% (w/w) lubricant or glidant". In this first passage, the amount of "at least 60% (w/w)" is linked with amounts of other components of the composition, namely the amounts of binder, filler, lubricant or glidant. Therefore, the amount "at least 60% (w/w)" cannot be extracted in isolation of the other features.

In the second paragraph of the same page on line 4, the parent application further discloses that "**in some embodiments** the composition comprises **at least 60% (w/w), such as at least 70% (w/w) or at least 75% (w/w), delivery agent**". This disclosure appears to be independent from the previous paragraph of the same

page given the way it is introduced by the terms "in some embodiments". Said paragraph relating to the delivery agent is furthermore followed by three distinct paragraphs relating to the presence and amounts, "in some embodiments", of respectively a binder, a filler, and a lubricant and/or a glidant. The inconsistency in the last paragraph between the disclosed amount of lubricant and/or glidant, namely "0.1-10% (w/w)", and the amount of "less than 10% (w/w) lubricant or glidant" in the first paragraph suggests that each paragraph of page 13 must be seen as separate embodiments.

Consequently, the amount of the delivery agent in the second paragraph of page 13 is disclosed in isolation and represents a separate embodiment. Accordingly, it constitutes a valid basis for the feature "at least 60% (w/w) of said salt of N-(8-(2-hydroxybenzoyl)-amino) caprylic acid" of claim 1 of the main request.

2.2.2 The further disclosure on page 21, embodiment 15 relating to "15. A composition according to any one of the preceding embodiments, wherein said composition comprises at least 60% (w/w), such as at least 70% (w/ or at least 75% (w/w), of said salt of N-(8-(2-hydroxybenzoyl)amino)caprylic acid", cannot serve as basis for the feature of "at least 60% (w/w) of said salt of N-(8-(2-hydroxybenzoyl)-amino) caprylic acid" of claim 1, since it is clearly linked to compositions comprising the delivery agent in a minimal amount of at least 0.6 mmol (cf. embodiment 1 on page 19) or in the range of 0.6-2.1 mmol (cf. embodiment 11 on page 20).

The same conclusion applies with regard to the disclosure of page 23, i.e. "44. A composition according to any one of the preceding embodiments,

wherein said composition comprises at least 60% (w/w) delivery agent, less than 10% (w/w) binder, 5-40% (w/w) filler, and less than 10% (w/w) lubricant and/or glidant.", since the disclosed amount of "at least 60% (w/w)" is linked with other amounts of the composition, namely the amounts of binder, filler, lubricant or glidant.

- 2.2.3 The Board could not follow the line of argumentation developed by the respondents and by the opposition division in its decision regarding the feature "at least 60% (w/w) of said salt of N-(8-(2-hydroxybenzoyl)-amino) caprylic acid" in claim 1 for the following reasons.

The respondents argued that the amounts of 0.6 mmol or 175 mg of the delivery agent are **essential features** of the disclosure of the parent application, especially in light of the technical problem to be solved, and that it is not possible to consider single statements in the application in isolation, said statements involving the presence of less than said 0.6 mmol or 175 mg of the delivery agent; the deletion of such essential features contravened Article 76(1). This argumentation was followed by the opposition division in its decision.

In more detail, the respondents consider that the replacement of the absolute amounts of 0.6 mmol or 175 mg of the delivery agent by the relative amount of 60% (w/w) is not possible, because the skilled person is taught by the parent application that **a specific and minimal absolute amount of NAC is required to ensure bioavailability of the GLP-1 agonist**, as demonstrated by the results of Table 1 of the patent, wherein 300 mg of SNAC (compositions B, D, E, F) led to a better bioavailability than 150 mg of SNAC (composition A),

while bioavailability was not affected by the relative amounts which was over 60% (w/w) in all examples.

In the same context, the opposition division considers in its decision that the skilled person recognises that the only difference between the background art cited in the description of the contested patent and the proposed solution is the absolute amount of the salt of NAC, indicating that this feature represents **the contribution to the state of the art.**

In the Board's view, **the only and fundamental test for determining whether the subject-matter of claim 1 meets the requirements of Article 76(1) EPC is the same adopted for assessing the requirement of Article 123(2) EPC, namely the "gold standard" disclosure test** (see G 1/05 of 28 June 2007, point 5.1 of the reasons, and G 2/10, point 4.3 of the reasons). This standard requires that the subject-matter of a claim of a divisional application or patent remains within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of the earlier application as filed. Moreover, the skilled person may not be presented with new technical information (see G 2/10, point 4.5.1 of the reasons).

While the points raised by the respondents or by the opposition division might be founded, these considerations or approaches are irrelevant to the assessment of added matter under Articles 76(1) or 123(2) EPC, and relate rather to the assessment of sufficiency of disclosure or inventive step. Under Articles 76(1) or 123(2) EPC, it is sufficient that a feature be derivable directly and unambiguously from

the parent of patent application, which is the case here as shown above.

Moreover, there is no indication in the parent application that the minimum amount of 0.6 mmol of a NAC salt is essential. D20 states in several parts that "certain amounts" of a salt of NAC are necessary (e.g. page 1, line 33). Other parts of the description do not mention any minimum amount at all (e.g., page 1, lines 5-6).

The examples illustrate furthermore a composition that contains at least 60% (w/w) of a salt of NAC (SNAC), but contains less than 0.6 mmol of said salt of NAC, which is effective at delivering semaglutide to the blood stream by oral route, even if it is less effective than compositions comprising more than 0.6 mmol of SNAC (see composition A of Table 1).

Thus, the arguments of the respondents are not convincing.

- 2.3 With regard to point b), respondent 02 considers that the subject-matter of claim 1 constitutes a selection from a threefold selection from lists, with regard to the claimed amount, semaglutide and the oral administration.

The Board concurs with the decision of the opposition on this point (see points 2.5-2.7 of the decision) and considers also that this objection is not founded.

The feature "oral administration" does not involve any selection. This route of administration was already part of original claim 1. Moreover, it is stated on

page 12 (lines 5-6) that the composition is administered by the oral route.

Semaglutide is the preferred GLP-1 agonist as disclosed in original claim 11 and on page 4 (line 13). Moreover, all the examples relate to semaglutide.

The association between a GLP-1 agonist and "certain amounts of a salt of N-(8-(2-hydroxybenzoyl)-amino) caprylic acid" is disclosed directly and unambiguously in the parent application, such as on page 1, lines 31-35. **The amount of the delivery agent has to be seen as a selection among several possibilities**, namely the absolute values of at least 0.6 mmol or 175 mg, and the relative amount disclosed in the parent application on page 13, line 4, i.e. "in some embodiments the composition comprises **at least 60% (w/w), such as at least 70% (w/w) or at least 75% (w/w), delivery agent**".

Consequently, the Board agrees with the opposition division that only a single selection is necessary to arrive at the subject-matter of claim 1.

2.4 Consequently, the subject-matter of claim 1 is derivable directly and unambiguously from the parent application and the main request meets the requirements of Article 76(1) EPC.

3. Remittal to the opposition division

As mentioned above, the subject-matter of the main request meets the requirements of Article 76(1) EPC. However, the main request has not yet been examined with regard to other grounds of opposition, such as *inter alia* inventive step or sufficiency of disclosure or even Article 123(2) EPC.

Under Article 111(1) EPC, the Board may in the present case either proceed further with the examination of the other grounds of opposition, or remit the case to the opposition division for further prosecution.

Article 11 RPBA provides that the Board shall not remit a case to the department whose decision was appealed for further prosecution, unless special reasons present themselves for doing so. The Board holds that such special reasons are apparent in the present case.

The provision of Article 11 RPBA has indeed to be read in conjunction with Article 12(2) RPBA, which provides that it is the primary object of the appeal proceedings to review the decision under appeal in a judicial manner (see also T 1966/16, point 2.2 of the reasons, T 0547/14 points 7.1 and 7.2, and T 0275/15 point 4.). This principle would not be respected if the Board were to conduct a complete examination of the opposition grounds.

As discussed above, in the present case the opposition division decided only on the question of Article 76(1) EPC and did not consider the further grounds of opposition. Under these circumstances, the Board considers it appropriate to exercise its discretion under Article 111(1) EPC and to remit the case to the department of first instance for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the Opposition Division for further prosecution.

The Registrar:

The Chairman:



A. Vottner

A. Uselli

Decision electronically authenticated