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# Datasheet for the decision of 11 October 2021

**Case Number:** T 1996/17 - 3.3.04

**Application Number:** 06801867.0

**Publication Number:** 1971362

**IPC:** A61K38/26, A61K9/00, A61P3/10, A61P3/04

**Language of the proceedings:** EN

**Title of invention:**
Exendin for treating diabetes and reducing body weight

**Patent Proprietor:**
Amylin Pharmaceuticals, LLC
AstraZeneca Pharmaceuticals LP

**Opponents:**
PHARMATHEN S.A.
Glaxo Group Limited
PENTAFARMA, Sociedade Técnico-Medicinal, SA
COOLEY LLP
Generics [UK] Ltd (trading as Mylan)
Teva Pharmaceutical Industries Ltd.

**Headword:**
Exendins for treating type II diabetes/AMYLIN

**Relevant legal provisions:**
EPC Art. 123(3)
RPBA 2020 Art. 13(2)

**Keyword:**
Amendments - broadening of claim (yes)
Amendment after summons - exceptional circumstances (no) - cogent reasons (no)

**Decisions cited:**

**Catchword:**

Europäisches Patentamt
European Patent Office
Office européen des brevets

**Beschwerdekammern**

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**Case Number: T 1996/17 - 3.3.04**

# D E C I S I O N
# of Technical Board of Appeal 3.3.04
# of 11 October 2021

| | |
|---|---|
| **Appellant:** (Patent Proprietor 1) | Amylin Pharmaceuticals, LLC<br>9360 Towne Centre Drive<br>San Diego, CA 92121 (US) |
| **Appellant:** (Patent Proprietor 2) | AstraZeneca Pharmaceuticals LP<br>1800 Concord Pike<br>Wilmington, DE (US) |
| **Representative:** | Hoffmann Eitle<br>Patent- und Rechtsanwälte PartmbB<br>Arabellastraße 30<br>81925 München (DE) |
| **Respondent:** (Opponent 1) | PHARMATHEN S.A.<br>6, Dervenakion Str.<br>153 51 Pallini Attikis (GR) |
| **Representative:** | Appleyard Lees IP LLP<br>15 Clare Road<br>Halifax HX1 2HY (GB) |
| **Respondent:** (Opponent 2) | Glaxo Group Limited<br>980 Great West Road<br>Brentford Middlesex TW8 9GS (GB) |
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| **Respondent:** (Opponent 3) | PENTAFARMA, Sociedade Técnico-Medicinal, SA<br>Rua da Tapada Grande, n° 2<br>Abrunheira<br>2710-089 Sintra (PT) |

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| **Representative:** | Weist, Stefan<br>Kraus & Weisert<br>Patentanwälte PartGmbB<br>Thomas-Wimmer-Ring 15<br>80539 München (DE) |
| **Respondent:**<br>(Opponent 4) | COOLEY LLP<br>3175 Hanover Street<br>Palo Alto, CA 94304-1130 (US) |
| **Representative:** | Mewburn Ellis LLP<br>Aurora Building<br>Counterslip<br>Bristol BS1 6BX (GB) |
| **Respondent:**<br>(Opponent 5) | Generics [UK] Ltd (trading as Mylan)<br>Albany Gate<br>Darkes Lane<br>Potters Bar<br>Hertfordshire EN6 1 AG (GB) |
| **Representative:** | Elkington and Fife LLP<br>Prospect House<br>8 Pembroke Road<br>Sevenoaks, Kent TN13 1XR (GB) |
| **Respondent:**<br>(Opponent 6) | Teva Pharmaceutical Industries Ltd.<br>5 Basel Street<br>Petach Tikva 49131 (IL) |
| **Representative:** | Lederer & Keller Patentanwälte<br>Partnerschaft mbB<br>Unsöldstraße 2<br>80538 München (DE) |

**Decision under appeal:** **Decision of the Opposition Division of the European Patent Office posted on 7 July 2017 revoking European patent No. 1971362 pursuant to Article 101(3)(b) EPC.**

**Composition of the Board:**

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| **Chair** | B. Claes |
| **Members:** | O. Lechner |
| | R. Romandini |

## Summary of Facts and Submissions

I. The patent proprietors ("appellants") filed an appeal against the decision of the opposition division to revoke European patent No. 1 971 362 ("patent"), which has the title "*Exendin for treating diabetes and reducing body weight*".

Claims 1 and 4 of the patent read:

"1. A formulation comprising an exendin or exendin analog agonist, a biocompatible polymer and a sugar for use in a method of treating diabetes in a human, wherein said method comprises:
(a) administering the formulation to the human once weekly; and
(b) administering the formulation sufficient to maintain a sustained minimum plasma concentration of the exendin or exendin analog agonist of about 170 pg/ml to about 600 pg/ml for at least 1 month.

4. A formulation for use according to any one of claims 1 to 3, wherein the exendin or exendin analog agonist is exendin-4."

II. The patent was opposed by six parties, and the opposition proceedings were based on the grounds in Article 100(a) EPC (here in conjunction with Articles 54 and 56 EPC) and Article 100(b) and (c) EPC.

III. The opposition division decided, *inter alia*, that the patent with the set of claims of auxiliary request 6 failed to disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 83 EPC).

Auxiliary request 10 related to subject-matter which extended beyond the content of the application as filed (Article 123(2) EPC).

IV. With their statement of grounds of appeal, the appellants re-submitted the set of claims of auxiliary request 6 as the new main request and submitted sets of claims of new auxiliary requests 1 to 3 (each corresponding in essence to auxiliary request 10 dealt with in the decision under appeal).

Claims 1 of auxiliary requests 1 and 2 read:

Auxiliary request 1

"1. A formulation comprising exendin-4, a biocompatible polymer and a sugar for use in a method of treating type II diabetes in a human, wherein said method comprises:

(a) administering the formulation to the human once weekly by subcutaneous injection; and

(b) administering the formulation sufficient to maintain a sustained minimum plasma concentration of exendin-4 of about 170 pg/ ml to about 350 pg/ml for at least 1 month."

Auxiliary request 2

"1. A formulation exendin-4, a comprising microparticles containing poly(lactide-co-glycolide) polymer and sucrose for use in a method of treating type II diabetes in a human, wherein said method comprises:

(a) administering the formulation to the human once weekly by subcutaneous injection; and

(b) administering the formulation sufficient to maintain a sustained minimum plasma concentration of exendin-4 of about 170 pg/ ml to about 350 pg/ml for at least 1 month."

V. Opponents 1, 5 and 6 (respondents I, V and VI, respectively) replied to the appeal. They submitted, *inter alia*, that the main request and auxiliary requests 1 to 3 did not comply with the requirements in Articles 54, 56, 83, 84, 87, 123(2) and/or (3) EPC and Rule 80 EPC.

VI. The appellants reacted to the replies of the respondents and submitted a new "*corrected*" auxiliary request 3.

VII. Respondents I and V replied to the appellants' submissions.

VIII. After the board summoned the parties to oral proceedings, the appellants filed a new auxiliary request 3 with a letter dated 21 July 2020.

IX. In a communication under Article 15(1) RPBA 2020, the board provided a preliminary appreciation of the appeal. The board held, *inter alia*, that claim 1 of the main request and auxiliary requests 1 to 3 infringed the requirements of Article 123(3) EPC.

X. By letter dated 27 October 2020, the appellants submitted arguments addressing issues under Article 123(3) EPC. They re-submitted the former auxiliary requests 1 and 2 (see section IV.) as the new

main request and auxiliary request 1, respectively, and six further new auxiliary requests 2 to 7.

XI. Respondent I submitted that the new auxiliary requests 2 to 7 should not be admitted into the proceedings.

XII. During the oral proceedings, at which opponents 2, 3 and 4 were not present, the appellants renumbered the former auxiliary requests 4 to 7 as new auxiliary requests 2 to 5. Former auxiliary requests 2 and 3 were renumbered as auxiliary requests 6 and 7, respectively. At the end of the oral proceedings, the Chair announced the board's decision.

XIII. The arguments of the appellants may be summarised as follows.

*Main request and auxiliary request 1 - Claim 1*

*Extension of protection (Article 123(3) EPC)*

The amendment in part b) replacing the phrase "the exendin or exendin analog" with "exendin-4" did not extend the scope of protection.

Claim 1 of the patent referred "*to a formulation comprising **an** exendin **or** exendin analog agonist, wherein the sustained minimum plasma concentration of **the** exendin or exendin analog agonist is further defined*". In the context of the sustained minimum plasma concentration, the word "exendin" in claim 1 was exclusively used in the singular. This was corroborated by the wording of claim 4 as granted, stating that "***the** exendin or exendin analog agonist **is** exendin-4*". Thus, the wording of claims 1 and 4 as granted, which used the singular, did not leave any doubt that the

formulation according to claim 1 comprised only a single type of exendin. The indefinite article "a" or "an" did not imply "one or more".

Accordingly, claim 4 of the patent provided that only exendin-4 was administered and that the minimum plasma concentration of the exendin or exendin analogue agonist measured in step (b) of claim 1 was only the result of the administration of this specific exendin-4 (see also paragraphs [0026] to [0032] of the patent).

None of exendin-3 or the other exendin analogue agonists listed in paragraph [0037] of the patent as "additional embodiments" was claimed. This became evident, *inter alia*, by the use of the singular form when referring to the sustained minimum plasma concentration of the exendin or exendin analogue agonist. Moreover, the general definition in this paragraph could not serve as a basis for a different interpretation of claim 1, which in itself was clear (see Case Law of the Boards of Appeal 9th edition, 2019, II.A.6.3.1, page 310).

*Auxiliary requests 2 to 7*

*Admittance (Article 13(2) RPBA 2020)*

The amendment replacing "exendin-4" with "exendins or exendin analog agonists" in feature (b) of claim 1 of auxiliary requests 2 to 5 addressed an objection under Article 123(3) EPC, raised for the first time by the respondents in the appeal proceedings.

The deletion of "mean plasma concentration of exendin-4 of 170 pg/ml to 290 pg/ml" from feature (b) of claim 1 of auxiliary requests 5 and 7 (see section XVI) was

made in view of the preliminary opinion of the board raising objections under Article 84 EPC.

The amendment from "amount of 2.0 mg" to "dose of 2.0 mg" in claim 1 of auxiliary requests 4 to 7 concerned a correction in line with the disclosure on page 12, line 4 and the examples of the application as filed.

The filing of new requests in response to new objections qualified as exceptional circumstances under Article 13(2) RPBA. These requests should therefore be admitted.

XIV. The arguments of the respondents may be summarised as follows.

*Main request and auxiliary request 1 - Claim 1*

*Extension of protection (Article 123(3) EPC)*

The claims were not the result of a true combination of claim 1 and claim 4 of the patent. The replacement of the phrase "the exendin or exendin analog" with "exendin-4" broadened the scope of protection provided by the patent.

The claimed formulation comprised exendin-4. The claims failed, however, to limit the exendin concentration other than exendin-4 and did thus not exclude the presence of a further exendin analogue agonist in the formulation. This was supported, for example, by paragraphs [0026] to [0032] of the patent according to which the formulation comprised "at least one exendin or exendin analog agonist".

Paragraph [0037] of the patent provided that the phrase "the exendin or exendin analog" had to be read to encompass "*one or more of exendin-3, exendin-4 or an exendin analog agonist*". Thus, "the" exendin had to be read as "one or more".

The claims covered a formulation comprising, e.g. exendin-3 and exendin-4, a biocompatible polymer, and a sugar for use in a method of treating type II diabetes in a human which comprised (a) administering the formulation to the human once weekly by subcutaneous injection and (b) administering the formulation sufficient to maintain a sustained minimum plasma concentration of exendin-4 of 350 pg/ml for at least one month. Assuming that the administration was further sufficient to maintain a sustained minimum plasma concentration of exendin-3 of 350 pg/ml for at least one month, the sustained minimum plasma concentration of both exendin-3 and exendin-4 together would be 700 pg/ml for at least one month. However, this embodiment did not fall within the scope of protection of the granted patent.

*Auxiliary requests 2 to 7*

*Admittance (Article 13(2) RPBA)*

Any late-filed claim request addressing the board's preliminary opinion under Articles 84 and 123(3) EPC should not be considered in the appeal proceedings.

Each of auxiliary requests 2 to 7 included major substantive changes to the claims compared to those of the auxiliary requests 1 to 3 filed with the appellants' statement of grounds of appeal, and their admittance was governed by Article 13(2) RPBA.

Auxiliary requests 2 to 5 did not address the objection under Article 123(3) EPC against the amendment from "sustained minimum plasma concentration of exendin-4" to "sustained minimum plasma concentration of exendins or exendin analog agonists". The objection had been raised in reply to the statement of grounds of appeal.

The appellants failed to put forward exceptional circumstances, justified with cogent reasons, for the striking out of the mean plasma concentration range from auxiliary requests 5 and 7. A lack of clarity objection under Article 84 EPC had also been raised in reply to the statement of grounds of appeal in the context of the same amendment in claim 1 of auxiliary request 3 as filed with the statement of grounds of appeal.

Thus, auxiliary requests 2 and 7 should not be admitted into the proceedings in accordance with Article 13(2) RPBA 2020.

XV. The appellants (patent proprietors) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the set of claims of the main request or one of auxiliary requests 1 to 7, all filed with the letter dated 27 October 2020. They further requested that auxiliary requests 2 to 7 be admitted into the proceedings and that the case be remitted to the opposition division for further prosecution on novelty and inventive step.

XVI. Respondents I, V and VI (opponents 1, 5, and 6) requested that the appeal be dismissed and that auxiliary requests 2 to 7, filed with the letter dated 27 October 2020, not be admitted into the proceedings.

Respondents I and V additionally requested that the case not be remitted to the opposition division.

## Reasons for the Decision

*Parties not represented at oral proceedings*

1. Opponents 2, 3 and 4 were not represented at the oral proceedings as announced previously. The board decided, in accordance with Rule 115(2) EPC and Article 15(3) RPBA 2020, to continue the proceedings in their absence.

*Main request and auxiliary request 1 - Claim 1*

*Extension of scope of protection - Article 123(3) EPC*

2. Claim 1 of the patent as granted referred to "[*a*] formulation comprising an exendin or exendin analog agonist […] (b) administering the formulation sufficient to maintain a sustained minimum plasma concentration of the exendin or exendin analog agonist of about 170 pg/ml to about 600 pg/ml for at least 1 month" (underling added by the board).

   Dependent claim 4 limited the exendin or exendin analogue agonist to exendin 4.

3. Claim 1 of the main request refers to "[a] formulation comprising ~~an exendin **or** exendin analog agonist~~ exendin-4 […] (b) administering the formulation sufficient to maintain a sustained minimum plasma concentration of ~~the exendin or exendin analog agonist~~ exendin-4 of about 170 pg/ml to about ~~600~~350 pg/ml for

at least 1 month" (amendments highlighted by the board).

Claim 1 of the auxiliary request 1 refers to "[a] formulation comprising microparticles containing ~~an exendin **or** exendin analog agonist~~ exendin-4 […] (b) administering the formulation sufficient to maintain a sustained minimum plasma concentration of ~~the exendin **or** exendin analog agonist~~ exendin-4 of about 170 pg/ml to about ~~600~~350 pg/ml for at least 1 month" (amendments highlighted by the board).

4. The board notes that the articles "an" and "the" used in claims 1 and 4 of the patent as granted are no longer part of the claim wording (compare points 2. and 3. above). Moreover, the expression "comprising" used in claim 1 of the patent as granted to define the claimed formulation *comprising* an exendin or exendin analogue agonist, a biocompatible polymer and a sugar allows additional exendins to be co-administered as part of the formulation.

5. The amendment of part (b) in claim 1 of the main request and auxiliary request 1 now "only" requires the sustained minimum plasma concentration of exendin-4 to be within the range of about 170 pg/ml to about 350 pg/ml. Thus, the amended claim defines only the range of the sustained minimum plasma concentration of exendin-4 alone, not that of all exendins comprised in the administered formulation.
Accordingly, the claims now entail embodiments which were not within the scope of protection conferred by claim 1 or any other claim of the granted patent.

6. The appellants argued that due to the use of "an" and "the" exendin analogue agonist in claim 1 of the patent

as granted, the word "exendin" was exclusively used in the singular. The formulation thus comprised only a single type of exendin. Hence, the minimum plasma concentration of the exendin or exendin analogue agonist measured in step (b) could only be the result of the administration of this specific exendin-4 when taking into consideration claim 4 of the patent as granted. None of exendin-3 or exendin analogue agonists, which were listed in paragraph [0037] of the patent as "additional embodiments", was claimed.

7. As observed by the appellants and in line with established case law (see Case Law of the Boards of Appeal 9th edition, 2019 (CLBA), II.A.6.3.4, paragraph 3), a discrepancy between the claims and the description is not a valid reason for ignoring the literal content of a claim and interpreting it differently. The description cannot be used to give a different and narrower meaning to a claim which in itself imparted a clear, credible, technical teaching.

8. However, the term "exendin analog agonist" is not a scientific term directly known to the skilled person. To assess its correct meaning, the skilled person had to consult the description (see CLBA II.A.6.3.1.).

9. The appellant referred to paragraphs in the description, such as [0016], [0023], [0026] to [0032], [0039] and [0040], which mention that "preferably" or "in one embodiment" the exendin or exendin analogue agonist is exendin-4. This is in line with the subject-matter of claim 4 of the patent as granted, which is also restricted to exendin 4.

10. However, paragraph [0037] mentions that "[a]*dditional embodiments provide that the exendin or exendin analog*

*agonist is one or more of exendin-3, exendin-4 or an exendin analog agonist. In some embodiments, the exendin or exendin analog agonist is not exendin-3 or exendin-4".*

Thus, when reading the "comprising"-language of claim 1, the skilled person would indeed also consider the presence of multiple exendins in the formulation. This implies that the total amount of all exendins or exendin analogue agonists, and not just the amount of exendin-4, administered with the formulation should result in the stated sustained minimum plasma concentration of about 170 pg/ml to about 350 pg/ml (see part b) of claim 1 of the main request and auxiliary request 1).

11. The board therefore concludes that the amendments to claim 1 of the main request extend the scope of protection conferred by the patent and are not allowable under Article 123(3) EPC.

12. This applies *mutatis mutandis* to claim 1 of auxiliary request 1, which also refers to exendin-4.

*Auxiliary requests 2 to 7 - Admittance into the proceedings (Article 13(2) RPBA 2020)*

13. Auxiliary requests 2 to 7 were filed by the appellants in response to the board's preliminary opinion (see section VIII.) provided in the communication under Article 15(1) RPBA. The requests constitute an amendment to the appellants' case to which Article 13(2) RPBA 2020 applies.

14. The circumstance of two amendments in the sets of claims of these requests are of relevance for the admittance of these auxiliary requests.

15. First, the board agrees with the respondents that the objection under Article 123(3) EPC concerning the replacement of the wording "exendin-4" with "exendins or exendin analog agonists" in feature (b) of claim 1 of auxiliary requests 2 to 5 (compared to the sets of claims as filed with the statement of grounds of appeal, see sections IV. and XII.) had been raised by respondents I and VI in their respective replies to the statement of grounds of appeal (see section V.) when addressing the main request and auxiliary requests 1 to 3 (versions as filed with the statement of grounds of appeal; see section IV.).

16. Second, the board equally concurs with the respondents that arguments as to the lack of clarity of the feature "mean plasma level within the range of 170 to 290 pg/ml" as now featuring in part (b) of claim 1 of auxiliary requests 6 and 7 had been submitted by respondents I and VI in their respective replies to the appeal (see section V.) when addressing claim 1 of auxiliary request 3 filed with the statement of grounds of appeal (see section IV.).

17. An important aim of Articles 12 and 13 RPBA 2020 is that the parties' submissions are concentrated at the earliest possible stage of the proceedings so that the case is as complete as possible when the examination starts. Therefore, amendments to a party's case are to be filed at the earliest possible moment in the appeal proceedings. Article 13(2) RPBA 2020 applies to amendments to a party's appeal case made after notification of a summons to oral proceedings: such

amendments "*shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.*"

17.1 This provision has two implications. It requires the party to a) explain what the "exceptional circumstances" are and b) provide cogent reasons both for the content and the timing of the amendment, i.e. why the amendment represents a justified response to the circumstances and why it was not possible to file the amendment earlier.

17.2 Auxiliary requests 2 to 7 were filed on 27 October 2020 (see section X.) after the parties had been summoned to oral proceedings (see section VIII.) and after the board had provided its preliminary opinion in a communication under Article 15(1) RPBA (see section IX.).
The appellants argued that the amendments in each of these auxiliary requests addressed issues under Articles 84 and 123(3) EPC which had been newly raised in the respondents' replies to the statement of grounds of appeal.
However, neither in their letter of 27 October 2020 nor later in the appeal proceedings have the appellants identified exceptional circumstances justifying why these requests were filed only after the board's preliminary opinion was issued.

18. For this reason, the board decided to not admit auxiliary requests 2 to 7 into the proceedings (Article 13(2) RPBA 2020).

**Order**

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

The appeal is dismissed.

The Registrar: The Chair:

I. Aperribay B. Claes

Decision electronically authenticated