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Datasheet for the decision of 6 December 2019

Case Number: T 1267/16 - 3.3.04

Application Number: 11773314.7

Publication Number: 2595658

IPC: A61K41/00, C07K16/28, C07K16/40

Language of the proceedings: EN

Title of invention:
A combination pharmaceutical composition and methods of treating diabetes and metabolic disorders

Applicant:
Epshtein, Oleg Iliich

Headword:
diabetes/EPSHTEIN

Relevant legal provisions:
EPC Art. 84, 112a(2), 113(1), 123(2)
EPC R. 106
RPBA Art. 15(1)

Keyword:
All claim requests - clarity (no)
Postponement of oral proceedings (no)
Right to be heard - violation (no)

Decisions cited:

G 0010/93

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Case Number: T 1267/16 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 6 December 2019

Appellant: (Applicant)	Epshtein, Oleg Iliich 4 Samotyochny Per. D. 3, kv. 72 Moscow 127473 (RU)
Representative:	Leonard, Thomas Charles Kilburn & Strode LLP Lacon London 84 Theobalds Road London WC1X 8NL (GB)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 23 December 2015 refusing European patent application No. 11773314.7 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair	G. Alt
Members:	B. Claes
	L. Bühler

Summary of Facts and Submissions

I. The appeal by the applicant (hereafter "appellant") lies from the decision of the examining division to refuse European patent application No. 11773314.7, published as international patent application WO 2012/010966, with the title "*A combination pharmaceutical composition and methods of treating diabetes and metabolic disorders*".

II. In the decision under appeal the examining division held that: claims 1 to 15 of the main request lacked clarity (Article 84 EPC); the subject-matter of claims 1 to 5 lacked novelty (Article 54 EPC); and the application did not sufficiently disclose the invention defined in claims 6 to 15 (Article 83 EPC); auxiliary requests 1 to 5 did not remedy the deficiencies of the main request relating to clarity, sufficiency of disclosure and novelty; the 6th and 7th auxiliary requests did not remedy the deficiencies of the main request relating to clarity and sufficiency of disclosure; and the subject-matter of the sole claim of auxiliary request 8 did not involve an inventive step (Article 56 EPC).

Claim 1 of the **main request** read:

"1. A pharmaceutical composition comprising a) an activated-potentiated form of an antibody to human insulin receptor, and b) an activated-potentiated form of an antibody to endothelial NO synthase." (emphasis added by the board)

Claim 1 of **auxiliary request 1** read:

"1. A pharmaceutical composition comprising a) a mixture of activated-potentiated forms of an antibody to a C-terminal fragment of the beta subunit of human insulin receptor, and b) a mixture of activated-potentiated forms of an antibody to endothelial NO synthase, wherein the pharmaceutical composition is obtained by uniform decreases in molecular concentration of the initial molecular form of the antibodies." (emphasis added by the board)

Claim 1 of **auxiliary request 2** read:

"1. A pharmaceutical composition comprising a) a mixture of activated-potentiated forms of an antibody to a C-terminal fragment of the beta subunit of human insulin receptor, and b) a mixture of activated-potentiated forms of an antibody to endothelial NO synthase, wherein each of said mixtures of activated-potentiated forms of the antibodies is in the form of a mixture of C12, C30 and C200 dilutions." (emphasis added by the board)

Claim 1 of **auxiliary request 3** read:

"1. A pharmaceutical composition comprising a) a mixture of C12, C30 and C200 dilutions of an antibody to a C-terminal fragment of the beta subunit of human insulin receptor, and b) a mixture of C12, C30 and C200 dilutions an antibody to endothelial NO synthase." (emphasis added by the board)

Claim 1 of **auxiliary request 4** read:

"1. A pharmaceutical composition comprising a) a mixture of C12, C30 and C200 activated-potentiated forms of an antibody to a C-terminal fragment of the beta subunit of human insulin receptor, and b) a mixture of C12, C30 and C200 activated-potentiated forms of an antibody to endothelial NO synthase, wherein the pharmaceutical composition is obtained by uniform decreases in molecular concentration of the initial molecular form of the antibodies." (emphasis added by the board)

Claim 1 of **auxiliary request 5** read:

"1. A pharmaceutical composition comprising a) a mixture of C12, C30 and C200 dilutions of an antibody to a C-terminal fragment of the beta subunit of human insulin receptor, and b) a mixture of C12, C30 and C200 dilutions an antibody to endothelial NO synthase, wherein the pharmaceutical composition is obtained by uniform decreases in molecular concentration of the initial molecular form of the antibodies." (emphasis added by the board)

Claim 1 of the **6th auxiliary request** read:

"1. A pharmaceutical composition comprising a) a mixture of C12, C30 and C200 dilutions of an antibody to a C-terminal fragment of the beta subunit of human insulin receptor, and b) a mixture of C12, C30 and C200 dilutions an antibody to endothelial NO synthase, wherein the pharmaceutical composition is for use in the treatment of diabetes." (emphasis added by the board)

Claim 1 of the **7th auxiliary request** read:

"1. A pharmaceutical composition comprising a) a mixture of C12, C30 and C200 dilutions of an antibody to a C-terminal fragment of the beta subunit of human insulin receptor, and b) a mixture of C12, C30 and C200 dilutions an antibody to endothelial NO synthase, wherein the pharmaceutical composition is for use in a method of treatment of diabetes." (emphasis added by the board)

The sole claim of the **8th auxiliary request** was for a method of making a pharmaceutical composition of the invention and read:

"1. A method of making a pharmaceutical composition comprising a) a mixture of C12, C30 and C200 dilutions of an antibody to a C-terminal fragment of the beta subunit of human insulin receptor and b) a mixture of C12, C30 and C200 dilutions of an antibody to endothelial NO-synthase, the method comprising preparing the centesimal dilutions of the antibodies and multiple shaking of each obtained solution in accordance with homeopathic technology, and then either combining the potentiated solutions by mixing them, or, alternatively, impregnating a carrier mass with said combined solution or with the solutions separately." (emphasis added by the board)

III. The appellant based its appeal on the same requests as the decision under appeal had dealt with. In the statement of grounds of appeal the appellant submitted arguments in favour of the claim requests in relation to sufficiency of disclosure, clarity and novelty.

IV. In a communication, which served in preparation of oral proceedings, the board expressed its preliminary opinion on the appeal.

The term "activated-potentiated" in the feature "activated-potentiated form of an antibody" in claim 1 of the main request did not define the compounds a) and b) in terms of the structure of the form of the antibody, but related to a process for the manufacture of that form of the antibody. Although the claim thus characterised the compounds comprised in the claimed pharmaceutical composition by the process "activated-potentiated" for the method of their preparation, it did not define, *inter alia*, the starting material or particular process steps for obtaining the "activated-potentiated forms" of the antibodies, nor did the feature itself convey what the process was like. The board therefore concluded that no identifiable characteristics were conferred on the composition as claimed by the process feature "activated-potentiated" that unambiguously characterised the claimed composition. The claim thus lacked clarity.

The board further noted that the term "activated-potentiated" did not have a commonly accepted, unambiguous meaning for the skilled person - be it as a feature describing the "form" of the antibodies or as a feature describing their manufacture.

It was also noted that the description of the application failed to unambiguously disclose the process necessary for preparing the claimed "activated-potentiated forms" of particular antibodies. Indeed, as concerns the relevant process steps, the board was unable to discern from the description of the application any particular set of measures for

obtaining the "activated-potentiated" antibodies of the invention that went beyond being defined as that which was "accepted" in the "homeopathic art".

In response to the appellant's argument that knowing whether or not a product prepared by the disclosed process fell within the ambit of the claim depended on whether or not it displayed the biological effects of the disclosed claimed compositions as were evidenced by the data presented in the examples of the application and in the post-published documents D26 and D27, the board noted that the specific process, required to inevitably obtain the claimed product, needed to be defined in the claim for a product-by-process claim to be considered clear. Indeed, any argument relying on compositions made according to a process disclosed in the application (as opposed to the claim) or on post-filed data could not persuasively explain that the product claim was clear.

The two final points of the communication read:

"*Auxiliary requests 1 to 7 - clarity (Article 84 EPC)*

21. The considerations in relation to the claims of the main request apply *mutatis mutandis* to the claims of auxiliary requests 1 to 7.

Auxiliary request 8 - inventive step (Article 56 EPC)

22. The board at present concurs with the examining division that the subject-matter of the sole claim of auxiliary request 8 lacks an inventive step for the reasons given in the decision under appeal."

V. In response to the board's communication the appellant submitted (new) auxiliary requests 8 and 9; the former 8th auxiliary request (see section II) was renumbered as auxiliary request 10. The new requests were stated to be filed in response to clarity objections formulated by the board.

Claim 1 of (new) **auxiliary request 8** read:

"1. A pharmaceutical composition comprising a) a mixture of C12, C30 and C200 dilutions of a polyclonal antibody to a C-terminal fragment of the beta subunit of human insulin receptor, and b) a mixture of C12, C30 and C200 dilutions of a polyclonal antibody to endothelial NO synthase, wherein the activated-potentiated form of a polyclonal antibody is:
i) a product of a homeopathic process;
ii) biologically active and wherein the biological activity of the pharmaceutical composition is not attributable to the molecular form of the polyclonal antibodies; and
iii) wherein the biological activity of the activated-potentiated form can be determined experimentally using pharmacological models of activity." (emphasis added by the board)

Claim 1 of **auxiliary request 9** read:

"1. A pharmaceutical composition comprising, in a 1:1 ratio, a) a mixture of activated-potentiated forms of a polyclonal antibody to a C-terminal fragment of the beta subunit of human insulin receptor, and b) a mixture of activated-potentiated forms of a polyclonal antibody to endothelial NO synthase, wherein:

each of said mixtures of activated-potentiated forms of the antibodies is in the form of a mixture of C12, C30 and C200 dilutions in a 1:1:1 ratio;

said C-terminal fragment of the beta subunit of human insulin receptor has a sequence selected from the group consisting of SEQ ID No: 9, SEQ ID No: 10, SEQ ID No: 11, SEQ ID No: 12, SEQ ID No: 13 and SEQ ID No: 14;

said endothelial NO synthase has sequence selected from the group consisting of SEQ. ID No. 15 and SEQ ID No: 16, or a fragment thereof having a sequence selected from the group consisting of SEQ ID No: 17, SEQ ID No: 18, SEQ ID No: 19, SEQ ID No: 20, SEQ ID No: 21 and SEQ ID No: 22; and

the pharmaceutical composition is obtained by preparing the centesimal dilutions of the antibodies in accordance with homeopathic technology, and then either combining the potentiated solutions by mixing them, or, alternatively, impregnating a carrier mass with a combined solution or with the solutions separately." (emphasis added by the board)

VI. The following documents are referred to in this decision:

D26: Nicoll *et. al* (2013), International Journal of Endocrinology, Vol. 2013, Article ID 925874.

D27: "*In vitro experimental study of OOO "NFP "MATERIA MEDICA HOLDING" samples on human subcutaneous adipocyte adiponectin secretion*", Final Report number: MED111011-1.

VII. In the course of the oral proceedings the appellant submitted sets of claims in six further auxiliary requests (designated auxiliary requests 11 to 16).

After the board had heard the appellant on all seventeen claim requests and expressed opinions on them, the appellant requested postponement of the oral proceedings. They further informed the board that they intended to raise an objection under Rule 106 EPC in conjunction with Article 112a(2) EPC and to withdraw auxiliary requests 10 to 16 should the board refuse the request for postponement of the oral proceedings. After the appellant had been heard on their request for postponement, they submitted a document comprising the corresponding request for postponement of the oral proceedings, the (conditional) objection under Rule 106 EPC in conjunction with Article 112a(2) EPC and a statement on the (conditional) withdrawal of certain auxiliary requests.

- The written request for postponement of the oral proceedings read:

"*I submit the Board of Appeal has raised two, separate, new objections during oral proceedings for the first time, as follows:*

1. A clarity (Article 84 EPC) objection has been raised against Auxiliary Request 10 (AR10).

- *This is the first time a clarity objection has been raised against this claim request.*
- *The Examining Division considered this claim request to meet the requirements of Article 84 EPC (cf the Decision to Refuse, 23 Dec 2015, para 29 with respect to Auxiliary Request 8, which was the number of the request at that time).*
- *In the communication of 8 November 2019, the Board of Appeal raised clarity (Article 84 EPC) objections against all claim request except what*

is now numbered AR10. Instead, the Board of Appeal considered that request to lack inventive step under Article 56 EPC "for the reasons given in the decision under appeal".

2. The inventive step (Article 56 EPC) objection against AR10 is based on entirely new reasoning.

- *The Examining Division considered AR10 to lack inventive step because "no technical effect appears to be associated with this distinguishing feature" and "the ED remains unconvinced of the reproducibility of this effect for the reasons explained above (Sufficiency of Disclosure) (cf the Decision to Refuse, 23 Dec 2015, para 30 with respect to Auxiliary Request 8, which was the number of the request at that time)*
- *In contrast, the Board of Appeal considers AR10 to lack inventive step for the reason the technical effect of the composition made by the claimed method cannot be relied upon when arguing in favour of inventive step of a claim tothe* [sic] *method of production o the composition.*

Pursuant to, for example, T849/03, a decision should not catch the parties unawares. In the examination procedure the right to be heard is therefore violated not only in the event of failure to inform the applicant beforehand of the reasons forming the basis of a rejection but also if, at the time the decision is issued, the applicant had no reason to expect such a decision (cf Case Law book, 9th Edition, III.B.2.5.1). In particular with respect to new objection 1. above, the applicant had no reason to expect the Board of Appeal would decide that AR10 would fail to meet the requirements of Article 84 EPC, this objection having been raised for the first time during oral proceedings.

Accordingly, the Applicant's right under Article 113 EPC will be violated unless the oral proceedings are postponed because the Applicant and the Representative have not been provided sufficient time to respond. Postponement of the oral proceedings will allow the Representative to properly consider the new objections, to seek instructions from the Applicant, and/or to fully consider how best to respond to the new objections.

I therefore request the postponement of the oral proceedings. Specifically, I request the opportunity to reply to the new objections in writing and for a new date of oral proceedings to be set.

Such a postponement is justified and indeed required for the reasons already stated, namely to allow the Representative to properly consider the new objections, to seek instructions from the Applicant, and/or to fully consider how best to respond to the new objections.

Although there has already been a reaction to the new objections with the filing of Auxiliary Requests 12 to 16 during the oral proceedings, it is submitted it is not possible for the Representative to "to properly consider the new objections, to seek instructions from the Applicant, and/or to fully consider how best to respond to the new objections" during the course of a single day of oral proceedings. As such, the Applicant's right to be heard pursuant to Article 113 EPC cannot be respected in the absence of a postponement of the oral proceedings."

- The (conditional) objection under Rule 106 EPC in conjunction with Article 112a(2) EPC read:

"*Should the Board of Appeal not be willing to grant a postponement of the oral proceedings, I raise an objection under Rule 106 EPC in conjunction with Article 112a(2)(c). More specifically, in the absence of a postponement of the oral proceedings, the Applicant's right to be heard pursuant to Article 113 EPC would be violated, and this amounts to a fundamental violation giving rise to grounds for filing a Petition to Review pursuant to Article 112a(2)(c) EPC.*"

- The statement on the (conditional) withdrawal of certain auxiliary requests read:

"*Should the Board of Appeal not be willing to grant a postponement of the oral proceedings, I withdraw Auxiliary Requests 10 to 16 from consideration. The Main Request and Auxiliary Requests 1 to 9 remain on file.*"

The board decided to refuse the request for postponement of the oral proceedings and, assuming that the appellant's conditional request under Rule 106 EPC was thus confirmed, decided to dismiss this request.

At the end of the oral proceedings the Chair announced the decision of the board.

VIII. The appellant's final requests were that the decision under appeal be set aside and that a patent be granted according to the set of claims of the main request filed by letter of 5 October 2015 or, alternatively, according to one of the following sets of claims:

- auxiliary requests 1 to 5 filed by letter of 5 October 2015;
- the 6th or 7th auxiliary request filed during the oral proceedings on 4 November 2015; or
- auxiliary requests 8 and 9 filed by letter of 22 November 2019.

Reasons for the Decision

1. The appeal is admissible.

Main request - claim 1 - clarity (Article 84 EP)

2. Article 84 EPC lays down the principles governing the content and wording of claims and provides *inter alia* that they shall define the matter for which protection is sought and must be clear. Claims must be clear for the sake of legal certainty, as their purpose is to enable the protection conferred by a patent to be determined (see Case Law of the Boards of Appeal of the EPO, 9th Edition, 2019, II.A.1.1). Accepted principles developed in the case law of the Boards of Appeal in this context are that in order to be clear an independent claim should explicitly specify all of the essential features needed to define the invention and that, generally, the meaning of the essential features of a claim should be clear for the person skilled in the art from the wording of the claim alone (see decision G 1/04, OJ EPO 2006, 334, point 6.2 of the Reasons).

3. Here, the claim at issue is for a pharmaceutical composition comprising a so-called "activated-potentiated form of an antibody". A first antibody is an antibody to a human insulin receptor in compound a)

and a second antibody is an antibody to endothelial nitric oxide (NO) synthase in compound b) (see section II).

4. The term "activated-potentiated" in the feature "activated-potentiated form of an antibody" does not define compounds a) and b) in terms of the structure of the resulting form of antibody, but instead relates to a process for the manufacture of that form of the antibody. Hence, in claim 1 a product, here an antibody, is defined by the process by which it is prepared, which process thus constitutes an essential feature of the claimed invention which should be clear for the person skilled in the art from the wording of the claim alone.

5. The board has not seen evidence on file that, for a person skilled in the technical field of applied medical immunology, an "activated-potentiated form of an antibody" constituted a common, conventional and unambiguous notion with a precise technical meaning for defining antibodies.

6. The appellant has argued, with reference to a particular passage in the description of the application (recited in point 10 below, see the last paragraph), that whether or not a given antibody form was an "activated-potentiated form" and was prepared by the disclosed process depended on whether it displayed the biological effects of the compositions disclosed, as were evidenced by the data presented in the examples in the application and in the post-published documents D26 and D27.

7. In the case in hand, however, it is the very definition of the process recited in the claim that must be clear

so as to unambiguously define the claimed product. Therefore, any argument relying on compositions made according to a process disclosed in the application (as opposed to the claim) or on post-filed data cannot persuasively explain that the product claim, here a composition claim, is clear.

8. The board therefore concludes that the process feature in claim 1 "activated-potentiated" lacks clarity and therefore fails to unambiguously characterise the product defined by it, i.e. the specific form of an antibody to human insulin receptor and the specific form of an antibody to endothelial NO. Hence, ultimately, the claimed product, i.e. a pharmaceutical composition comprising these antibodies, is not clearly defined.

9. As noted above in point 2, the meaning of a claim should be clear from its wording alone, i.e. without reference to the description. However, even if the description of the application were to be taken into account in this case, it also fails to unambiguously disclose the particulars of the process leading to the "activated-potentiated forms" of antibodies mentioned in the claim as it discloses numerous, non-individualised alternatives of measures on how to prepare the activated-potentiated forms of antibodies of the invention. Reference is made in particular to the paragraphs in the description of the application on page 7, lines 15, to page 8, line 16, in respect of the notion "activated-potentiated form of an antibody" (emphasis added by the board):

"*The term "activated-potentiated form" [...] with respect to antibodies recited herein is used to denote a product of homeopathic potentization of any initial*

solution of antibodies. "Homeopathic potentization" denotes the use of methods of homeopathy to impart homeopathic potency to an initial solution of relevant substance. Although not so limited, "homeopathic potentization" may involve, for example, repeated consecutive dilutions combined with external treatment, particularly (mechanical) shaking. In other words, an initial solution of antibody is subjected to consecutive repeated dilution and multiple vertical shaking of each obtained solution in accordance with homeopathic technology. The preferred concentration of the initial solution of antibody in the solvent, preferably water or a water-ethyl alcohol mixture, ranges from about 0.5 to about 5.0 mg/ml. The preferred procedure for preparing each component, i.e. antibody solution, is the use of the mixture of three aqueous or aqueous-alcohol dilutions of the primary matrix solution (mother tincture) of antibodies diluted 100^{12}, 100^{30} and 100^{200} times, respectively, which is equivalent to centesimal homeopathic dilutions (C12, C30, and C200) or the use of the mixture of three aqueous or aqueous-alcohol dilutions of the primary matrix solution of antibodies diluted 100^{12}, 100^{30} and 100^{50} times, respectively, which is equivalent to centesimal homeopathic dilutions (C12, C30 and C50). Examples of homeopathic potentization are described in U.S. Patent. Nos. 7,572,441 and 7,582,294, which are incorporated herein by reference in their entirety and for the purpose stated. While the term "activated-potentiated form" is used in the claims, the term "ultra-low doses" is used in the examples. The term "ultra-low doses" became a term of art in the field of art created by study and use of homeopathically diluted and potentized form of substance. The term "ultra-low dose" or "ultra-low doses" is meant as fully supportive

and primarily synonymous with the term "activated-potentiated" form used in the claims.

In other words, an antibody is in the "activated-potentiated" form when three factors are present. First, the "activated-potentiated" form of the antibody is a product of a preparation process well accepted in the homeopathic art. Second, the "activated-potentiated" form of antibody must have biological activity determined by methods well accepted in modern pharmacology. And third, the biological activity exhibited by the "activated potentiated" form of the antibody cannot be explained by the presence of the molecular form of the antibody in the final product of the homeopathic process."

10. In view of the above considerations the board decides that claim 1 fails to comply with the requirements of Article 84 EPC.

Auxiliary request 1 - claim 1 - clarity (Article 84 EPC)

11. This claim, in the same way as claim 1 of the main request, refers to "activated-potentiated" forms of antibodies, with it now being in the form of "a mixture" of forms of an antibody. The claim furthermore stipulates that the "*pharmaceutical composition is obtained by uniform decreases in molecular concentration of the initial molecular form of the antibodies*".

12. Thus, claim 1 recites the process-feature "activated-potentiated", which same feature was held to be unclear in relation to claim 1 of the main request, as a definition of the antibody. Moreover, the board is unable to see that the further features added to the

claim contribute to the clarity of the feature "activated-potentiated" as they do not relate to it. Consequently, the board is not satisfied that the amendments to the wording of this claim are suitable for overcoming the concerns of the board as to the clarity of claim 1 of the main request.

13. The appellant has not submitted specific arguments for this claim in the context of clarity.

14. Accordingly, claim 1 of auxiliary request 1 does not fulfil the requirements of Article 84 EPC either.

Auxiliary request 2 - claim 1 - clarity (Article 84 EPC)

15. This claim specifies that the mixtures of "activated-potentiated" forms of antibodies are in the form of "a mixture of C12, C30 and C200 dilutions".

16. This claim, in the same way as claim 1 of the main request and auxiliary request 1, refers to "activated-potentiated" forms of antibodies - a definition which is held to be unclear. Furthermore, for this claim too, the board does not consider the additional wording to overcome the concerns of the board as to the clarity of the feature "activated-potentiated", but rather the contrary. Indeed, the board judges that the definition of the pharmaceutical composition as comprising mixtures of dilutions of "C12, C30 and C200 dilutions" in fact aggravates the lack of clarity in that it introduces a further one. The reference to the dilution of a starting material that has not been clearly defined, namely "activated-potentiated forms of an antibody", and, even if it were clearly defined, the absence of an indication of the concentration of the starting material that is diluted is a definition that

does not indicate what the concentration of the activated-potentiated form of the antibody is.

17. Thus, claim 1 of auxiliary request 2 does not fulfil the requirements of Article 84 EPC either.

Auxiliary request 3 - claim 1 - clarity (Article 84 EPC)

18. Although a reference to activated-potentiated forms of antibodies is absent from this claim, it refers to "C12, C30 and C200 dilutions" of antibodies. As the board has judged in point 17 above, this feature lacks clarity.

19. Thus, claim 1 of auxiliary request 3 does not fulfil the requirements of Article 84 EPC.

Auxiliary requests 4, 5 and 8 and the 6th and 7th auxiliary requests - clarity (Article 84 EPC)

20. Claim 1 of auxiliary request 4 and the 8th auxiliary request lack clarity for the same reasons as claim 1 of auxiliary request 2.

21. Claim 1 of auxiliary request 5 and the 6th and 7th auxiliary requests lack clarity for the same reasons as claim 1 of auxiliary request 3.

Auxiliary request 9 - claim 1 - clarity (Article 84 EPC) and added subject-matter (Article 123(2) EPC)

22. During the oral proceedings, the board expressed the opinion that the amendment of adding the feature "a mixture of C12, C30 and C200 dilutions in a 1:1:1 ratio" to the wording of the claim adds subject-matter

extending beyond the application as filed and that this is contrary to the requirements of Article 123(2) EPC.

23. Since the claim lacks clarity for the same reasons as claim 1 of auxiliary request 2, the board sees no need to justify its opinion on added subject-matter.

Request for postponement of the oral proceedings - right to be heard (Article 113(1) EPC)

24. The appellant requested postponement of the oral proceedings in order to safeguard their right to be heard after the board had announced the opinion during the oral proceedings that the sole claim of auxiliary request 10 also lacked clarity, after the board had expressed concerns that claims of auxiliary requests 12, 13, 15 and 16 failed to meet the requirements of Article 84 and/or Article 123(2) EPC, and after the appellant had been heard on the issue of inventive step with respect to the subject-matter of the sole claim of auxiliary request 14.

25. The appellant submitted that the board had raised two new objections for the first time during the oral proceedings, i.e. a clarity objection against the sole claim of auxiliary request 10 and an inventive-step objection against its subject-matter based on a new reasoning (see section VII).

26. In an appeal relating to a decision to refuse the application the board has the power to examine whether the application or the invention to which it relates meets the requirements of the EPC. This power also applies to requirements which the examining division did not take into consideration or which it regarded as having been met. If it believes that such a requirement

has not been met, the board shall include this ground in the appeal proceedings (see decision G 10/93, OJ EPO 1995, 172, point 4 of the Reasons). The board considers this principle to also apply to new objections by the board during the appeal proceedings regarding requirements considered earlier in the proceedings. The board further notes that it is not a requirement to provide an appellant in advance with all foreseeable arguments in favour of or against a request (Case Law of the Boards of Appeal of the EPO, 2019, V.B.4.3.5).

27. In the communication pursuant to Article 15(1) RPBA (see section IV), after having expressed its preliminary opinion that claims of the main request and auxiliary requests 1 to 7 lacked clarity, the board stated in relation to auxiliary request 8 (what was meant was the 8th auxiliary request which, in response to said communication, was renumbered auxiliary request 10) that the claimed subject-matter lacked an inventive step for the reasons given in the decision under appeal.

28. As for the alleged new objection pursuant to Article 84 EPC the board notes that its communication in preparation for the oral proceedings addressed the findings in the decision under appeal. The board neither acknowledged the clarity of the claims of the 8th auxiliary request nor agreed with the examining division's reasoning with respect to Article 84 EPC. Rather, the board maintained the initial objection and provided detailed reasons.

29. In view of the board's indication that "*the claim* [1 of the main request] *neither defines, for example, the starting material or particular process steps for obtaining the "activated-potentiated forms" of those*

antibodies mentioned nor does the feature itself convey what the process is like" (see point 12 of the communication), when they received the communication the appellant was aware of the gist of the board's objection on lack of clarity and, in fact, addressed it by submitting six auxiliary requests.

30. The appellant thus could not legitimately expect that inventive step would be the only point of discussion with respect to the 8th auxiliary request during oral proceedings.

31. Thus, the board's announcement during the oral proceedings that the sole claim of auxiliary request 10 lacked clarity followed the extensive discussion with the appellant on the issue of clarity in relation to claims of all higher-ranking requests and was plainly consistent with and consequential to the board's opinions expressed thereon and in its communication. In substance, no new matter was raised that could have come as an (objective) surprise to the appellant.

32. In relation to the allegedly new reasoning expressed by the board during the oral proceedings for confirming its statement in the communication that the claimed subject-matter of auxiliary request 10 lacked an inventive step, the board holds that the appellant must expect new arguments to arise on the part of the board in the discussion at the oral proceedings (see point 27 above). The appellant did not explain why proper consideration of these arguments required postponement of the oral proceedings or why it was necessary in this situation to seek instructions from the applicant.

33. In view of the above considerations the board did not see a reason for holding that continuing with the oral

proceedings would violate the appellant's right to be heard pursuant to Article 113(1) EPC and therefore decided to refuse the appellant's request for postponement of the oral proceedings.

Objection under Rule 106 EPC in conjunction with Article 112a(2) EPC

34. The objection under Rule 106 EPC in conjunction with Article 112a(2) EPC was raised as a direct consequence of the board refusing to postpone the oral proceedings as the appellant considered their right to be heard pursuant to Article 113 EPC to be violated, which they argued amounted to a fundamental violation giving rise to grounds for filing a petition to review pursuant to Article 112a(2)(c) EPC.

35. For the same reasons as those for refusing the request for postponement of the oral proceedings the board dismissed this objection. In particular, it is reiterated that, according to established case law, a board of appeal is not required to provide the parties in advance with all foreseeable arguments in favour of or against a request (see point 26 above). In this case, the appellant was made aware of the grounds on which the decision was based and had adequate opportunity to present its point of view to the board before a decision was made. The board does not deny that not every detail of its reasons for the present decision was set forth in its communication, but only emerged during the hearing in the discussion with the appellant. This is, however, not a breach of the appellant's right to be heard but rather the consequence of hearing the appellant, considering the arguments presented by them, and informing the

appellant of the board's arguments in order to provide an opportunity to respond.

Order

For these reasons it is decided that:

1. The objection under Rule 106 EPC is dismissed.

2. The appeal is dismissed.

The Registrar: The Chair:

I. Aperribay G. Alt

Decision electronically authenticated