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Datasheet for the decision of 2 March 2021

Case Number: T 2645/18 - 3.3.04

Application Number: 11757190.1

Publication Number: 2601210

IPC: C07K14/435, A61K38/24

Language of the proceedings: EN

Title of invention:
Improved recombinant human follicle-stimulating hormone

Patent Proprietor:
Glycotope GmbH

Opponent:
Rösler Patentanwaltskanzlei

Headword:
Recombinant human FSH/GLYCOTOPE

Relevant legal provisions:
EPC Art. 123(2), 112(1)
RPBA 2020 Art. 13(2)

Keyword:

Amendments - added subject-matter (yes)
Referral to the Enlarged Board of Appeal (no)
Late-filed request - justification for late filing (no)

Decisions cited:

G 0002/10, G 0001/12, T 1241/03, T 1621/16, T 2368/13, T 1482/17, T 0640/17

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Case Number: T 2645/18 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 2 March 2021

Appellant: (Opponent)	Rösler Patentanwaltskanzlei Landsberger Strasse 480a 81241 München (DE)
Representative:	Pochart, François August Debouzy 6-8, avenue de Messine 75008 Paris (FR)
Respondent: (Patent Proprietor)	Glycotope GmbH Robert-Rössle-Strasse 10 13125 Berlin (DE)
Representative:	Hemsath, Lars König-Szynka-Tilmann-von Renesse Patentanwälte Partnerschaft mbB Mönchenwerther Straße 11 40545 Düsseldorf (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 20 August 2018 concerning maintenance of the European Patent No. 2601210 in amended form**

Composition of the Board:

Chair	B. Claes
Members:	A. Schmitt
	L. Bühler

Summary of Facts and Submissions

I. The appeal lodged by the sole opponent (appellant) lies from the opposition division's interlocutory decision that European patent No. 2 601 210 as amended in the form of the Main Request submitted on 12 April 2018 and the invention to which it relates meet the requirements of the EPC.

Claim 1 of the Main Request reads as follows:

"1. A recombinant FSH preparation, wherein the recombinant FSH in the preparation has a glycosylation pattern comprising the following characteristics:
(i) a relative amount of glycans carrying bisecting N-acetylglucosamine (bisGlcNAc) of at least 20 % of the total amount of glycans attached to FSH in the preparation; and
(ii) a relative amount of 2,6-coupled sialic acid of at least 40% of the total amount of sialic acids; and
(iii) a relative amount of glycans carrying a sulfate group of at least 2.5% of the total amount of glycans attached to FSH in the preparation."

II. The patent, entitled "*Improved recombinant human follicle-stimulating hormone*", was granted from European patent application No. 11 757 190.1, which had been filed as an international patent application with the number PCT/EP2011/063492 ("application"), published as WO 2012/017058.

Claims 1 and 2 of the application read as follows:

"1. A recombinant FSH preparation, wherein the recombinant FSH in the preparation has a glycosylation

pattern comprising one or more of the following characteristics:
(i) a relative amount of glycans carrying bisecting N-acetylglucosamine (bisGlcNAc) of at least 20 %; and/or
(ii) a relative amount of glycans carrying fucose of at least 30%; and/or
(iii) a relative amount of 2,6-coupled sialic acid of at least 30%; and/or
(iv) it is a diverse glycosylation pattern.

2. The recombinant FSH preparation according to claim 1, wherein the glycosylation pattern comprises at least two of the features (i), (ii) and (iii), and preferably all of the features (i), (ii) and (iii)."

Claims 1 and 4 of the patent as granted read as follows:

"1. A recombinant FSH preparation, wherein the recombinant FSH in the preparation has a glycosylation pattern comprising the following characteristics:
(i) a relative amount of glycans carrying bisecting N-acetylglucosamine (bisGlcNAc) of at least 20 % of the total amount of glycans attached to FSH in the preparation; and
(ii) a relative amount of 2,6-coupled sialic acid of at least 40% of the total amount of sialic acids.

4. The recombinant FSH preparation according to any one of claims 1 to 3, wherein the recombinant FSH in the preparation has a glycosylation pattern comprising the following characteristics:
(i) a relative amount of glycans carrying bisecting N-acetylglucosamine (bisGlcNAc) of at least 25 %, preferably at least 30 %, of the total amount of glycans attached to FSH in the preparation; and

(ii) a relative amount of 2,6-coupled sialic acid of at least 50%, preferably at least 53%, of the total amount of sialic acids."

III. The opposition proceedings were based on the grounds of opposition in Article 100(a) EPC, in this case lack of inventive step (Article 56 EPC), and in Article 100(b) and (c) EPC.

IV. In the statement of grounds of appeal, the appellant contested, *inter alia*, the opposition division's decision that the subject-matter of claim 1 of the Main Request had a basis in the application.

V. With their reply to the appeal, the patent proprietor (respondent) submitted arguments, *inter alia*, to the effect that the claims of the Main Request and Auxiliary Requests I to III, all submitted during the opposition proceedings by letter dated 12 April 2018, met the requirements of Article 123(2) EPC.

Claim 1 of Auxiliary Request I is identical to claim 1 of the Main Request (see section I.).

Claim 1 of each of Auxiliary Requests II and III are identical and differ from claim 1 of the Main Request (see section I.) in that the glycosylation pattern of the recombinant FSH further comprises a relative amount of glycans carrying fucose of at least 30% of the total amount of glycans attached to FSH in the preparation.

VI. The board issued a summons to oral proceedings in view of the parties' requests and a communication pursuant to Article 15(1) RPBA 2020, in which it, *inter alia*, expressed concerns regarding the admissibility of the appeal and expressed the preliminary opinion that the

subject-matter of claim 1 of the Main Request and of each of Auxiliary Requests I to III extended beyond the content of the application.

VII. In response to the board's communication the appellant requested that the appellant's name be corrected in the notice of appeal to "RÖSLER Patentanwaltskanzlei", pursuant to Rule 139 EPC.

VIII. By letter dated 19 November 2020, the respondent submitted a set of claims of Auxiliary Request IV and filed arguments based on decision T 1241/03 of the boards of appeal to the effect that the combination of the specific relative amounts of the glycosylation characteristics as recited in claim 1 of the Main Request did not add subject-matter.

Claim 1 of Auxiliary Request IV differs from claim 1 of the Main Request (see section I) in that the relative amount of glycans carrying bisGlcNAc is at least 25% of the total amount of glycans attached to FSH in the preparation.

IX. In a further letter dated 17 February 2021, the respondent provided more arguments as regards added subject-matter and referred to decisions T 1621/16 of 14 October 2019, T 2368/16 of 7 February 2020, T 1482/17 of 18 September 2020 and T 640/17 of 30 September 2020. They requested that "*if the Board intends to deviate in its assessment of Art. 123(2) EPC from the considerations and criteria introduced in T1621/16*", a question be referred to the Enlarged Board of Appeal (see section XIII.).

X. Oral proceedings were held by videoconference with the consent of both parties. At the end of the oral proceedings, the chair announced the board's decision.

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

Admissibility of the appeal

The notice of appeal had mistakenly been filed in the name of "Uwe Rösler" as an individual. The true intention of the appellant was to file it in the name of the opponent, "RÖSLER Patentanwaltskanzlei". It was therefore requested that the name of the opponent be corrected in the notice of appeal to "RÖSLER Patentanwaltskanzlei", pursuant to Rule 139 EPC.

Main Request and Auxiliary Request I - claim 1

Amendments (Article 123(2) EPC)

The application did not directly and unambiguously disclose the combination of the FSH glycosylation characteristics (i), (ii) and (iii) recited in the claim. At least four arbitrary selections from several lists were required to arrive at such a combination of characteristics. In particular, characteristic (iii) (glycans carrying a sulfate group) was arbitrarily selected from a list of five different glycosylation characteristics presented as equal alternatives, its concentration value (at least 2.5%) was selected from a further list, and the concentration value of characteristic (ii) (at least 40% of 2,6-coupled sialic acid) was selected from yet another list of equal alternatives.

The application did not disclose a pointer to the combination of the three FSH glycosylation characteristics.

The sentence on page 13, lines 12 to 14 of the application related to a speculation ("*may be responsible*") and listed the three glycosylation characteristics only as alternatives linked by "*and/or*". Moreover, the following sentence described other glycosylation characteristics of the FSH preparation which could also be responsible for the observed effect (see page 13, lines 15 to 18 of the application). Furthermore, the glycosylation pattern of the FSH preparation recited in the subsequent passage lacked sulfated glycans and comprised two glycosylation characteristics that were not recited in the claim (see page 13, lines 24 to 31 of the application).

Accordingly, combinations of glycosylation characteristics other than those recited in the claim were also considered relevant. Consequently, the sentence on page 13, lines 12 to 14 of the application did not constitute a pointer to the claimed invention.

Furthermore, the glycoprofiling carried out in Example 4 of the application did not emphasise a specific relevance of glycans carrying bisGlcNAc, 2,6-coupled sialic acid and sulfated glycans for the activity of the analysed FSH preparation, either. This was evident from the fact that other differences in the glycosylation pattern of the analysed FSH preparation were detected and considered to be responsible for the increased activity (see Tables 3 and 5 and page 31, lines 5 to 12 of the application).

Finally, the preferred embodiments listed in Table 1 of the application also failed to point to the FSH preparation as claimed. Only Embodiment 1 consisted of at least 20% of glycans carrying bisGlcNAc, at least 2.5% of glycans carrying a sulfate group and 2,6-coupled sialic acid; however, in this embodiment, the relative amount of the 2,6-coupled sialic acid was at least 53%, and therefore this embodiment was not a pointer to a relative amount of 2,6-coupled sialic acid of at least 40%.

Decision T 1621/16 was not relevant for the case at hand because the lists of relative amounts for 2,6-coupled sialic acid and glycans carrying a sulfate group in the application were not lists of converging alternatives, wherein each of the narrower elements was "*fully encompassed by all the preceding less preferred and broader options*" (see decision T 1621/16, point 1.7.2 of the Reasons). Instead, equally preferred alternatives linked by "or" were listed, including ranges, such that not every element was "*fully encompassed*" by all the preceding elements. Therefore, the situation was instead comparable to that in the cases underlying decisions T 375/15 and T 1413/16, in which the board held that the requirements of Article 123(2) EPC were not fulfilled.

The claim thus related to subject-matter which extended beyond the content of the application.

Admittance of a request for referral of questions to the Enlarged Board of Appeal (Article 13(2) RPBA 2020)

The respondent's request to refer questions to the Enlarged Board of Appeal was submitted two weeks prior to the oral proceedings (in February 2021), although

decision T 1621/16 had already been published online a year earlier, in February 2020. The respondent had made submissions in November 2020 with respect to added subject-matter in which it made reference to a different decision (here decision T 1241/03), i.e. it had not deemed decision T 1621/16 to be relevant for the decision under appeal at that point in time.

Furthermore, the questions put forward by the respondent had already been answered in decision T 1621/16 (point 1.6.3 of the Reasons), and there was no diverging case law as required for a referral to the Enlarged Board of Appeal under Article 112(1)(a) EPC. Moreover, since the application did not contain lists of converging alternatives, decision T 1621/16 was not relevant for the decision under appeal.

Therefore, the request to refer questions to the Enlarged Board of Appeal should not be admitted into the appeal proceedings.

Auxiliary Requests II and III - claim 1

Amendments (Article 123(2) EPC)

The recombinant FSH in the claimed FSH preparation in each of Auxiliary Requests II and III comprised a combination of the glycosylation characteristics "a relative amount of 2,6-coupled sialic acid of at least 40%" and "a relative amount of glycans carrying a sulfate group of at least 2.5%". The combination of these two features was not disclosed in the application for the same reasons as for claim 1 of the Main Request. Consequently, the subject-matter of claim 1 of each of Auxiliary Requests II and III comprised

subject-matter extending beyond the content of the application.

Auxiliary Request IV

Admittance into the proceedings (Article 13(2) RPBA 2020)

Auxiliary Request IV should not be admitted into the appeal proceedings pursuant to Article 13(2) RPBA 2020 since there were no exceptional circumstances justifying admittance. Auxiliary Request IV was not submitted in response to objections put forward by the board for the first time in its preliminary opinion, but could and thus should have been submitted earlier. Furthermore, the respondent had not explained why it was submitted so late.

XII. The respondent's arguments, where relevant to the present decision, are summarised as follows.

Main Request and Auxiliary Request I - claim 1

Amendments (Article 123(2) EPC)

According to a first line of argument, the application disclosed pointers to the specific combination of the three glycosylation characteristics (i), (ii) and (iii) of the recombinant FSH of the claimed FSH preparation in the respective relative amounts as recited in the claim.

Firstly, the disclosure on page 13, lines 10 to 14 of the application constituted a direct pointer to a combination of the three glycosylation characteristics since it attributed the higher specific therapeutic

activity of the FSH preparation of the invention than known FSH preparations to these characteristics.

Secondly, as shown in Example 4 and as was evident from Tables 3 and 8 (bisGlcNAc), Table 4 (2,6-coupled sialic acid) and Table 10 (sulfated glycans), the three glycosylation characteristics were different from those of the known FSH preparations. This fact equally constituted a pointer to the claimed FSH preparation.

Finally, each of the 20 embodiments listed in Table 1 on pages 16 to 17 comprised glucans carrying bisGlcNAc, 2,6-coupled sialic acid and sulfated glycans and nine of these only contained these three glycosylation characteristics, which constituted yet another pointer to FSH preparations comprising these three glycosylation characteristics.

Furthermore, the combination of the relative amounts of these three glycosylation characteristics in the claim was a clear and unambiguous consequence of what was explicitly mentioned in the application, and therefore it was implicitly disclosed, according to established case law (see e.g. decision T 375/15, point 13 of the Reasons). Moreover, as confirmed in decision T 1511/07 (point 2.2 of the Reasons), the combination of especially preferred ranges of parameters satisfied the requirements of Article 123(2) EPC.

In particular, the relative amount of the glycans carrying bisGlcNAc (at least 20%) was disclosed e.g. in claim 1, on page 3, lines 4 to 16, and page 13, lines 24 to 31, and was also supported by Tables 3 and 8 of the application.

Furthermore, the relative amount of 2,6-coupled sialic acid (at least 40%) was disclosed in the last line on page 14. The fact that the relative amount of 2,6-coupled sialic acid in the FSH preparation analysed in Example 4 was higher than 50% (see Table 4) also supported an increased relative amount of this glycosylation characteristic as compared with the amount recited in claim 1 of the application (at least 30%).

Finally, the relative amount of sulfated glycans (at least 2.5%) was the preferred amount from only two values disclosed on page 14, lines 15 to 16 ("at least 1%, preferably at least 2.5%"). The 20 embodiments listed in Table 1 also emphasised 2.5% as the lower threshold for the relative amount of sulfated glycans. Moreover, no unwarranted advantage was associated with this value as the relative amount of sulfated glycans did not matter for inventive step.

Therefore, the relative amounts of the three glycosylation characteristics bisGlcNAc, 2,6-coupled sialic acids and glycans carrying a sulfate group were not arbitrarily selected. Furthermore, according to established case law of the boards of appeal, the concentrations of each component of a composition could be taken from different parts of the application, including lists of different concentrations, without contravening the requirements of Article 123(2) EPC (see e.g. decision T 1241/03, point 7 of the Reasons). Consequently, the relative amounts of the three glycosylation characteristics could be combined.

According to a second line of argument, the claimed subject-matter had a basis in the application following a selection from a single list. Table 1 listed

20 preferred embodiments, 12 of which comprised the three glycosylation characteristics in the relative amounts as recited in the claim, except for the relative amount of 2,6-coupled sialic acid. Therefore, in order to arrive at the claimed FSH preparation, only the amount "at least 40%" for 2,6-coupled sialic acid had to be selected from a single list disclosed on page 14, last line to page 15, line 3 of the application. According to established case law of the boards of appeal, the selection from a single list complied with the requirements of Article 123(2) EPC.

According to a third line of argument, the claimed subject-matter also met the requirements of Article 123(2) EPC following the reasoning in decision T 1621/16, which was endorsed in later decisions T 2368/18, T 1482/17 and T 640/17. The concentration values as recited in claim 1 were "fall-back positions" disclosed in lists of converging alternatives and the application disclosed clear pointers to the combination of the three characteristics (i), (ii) and (iii).

Consequently, the claimed subject-matter met the requirements of Article 123(2) EPC.

Admittance of a request for referral of questions to the Enlarged Board of Appeal (Article 13(2) RPBA 2020)

The request to refer questions to the Enlarged Board of Appeal should be admitted into the appeal proceedings because decision T 1621/16 had opened a new line of argument regarding multiple selections from lists of converging alternatives that was applicable to the case at hand. Since the board held that claim 1 of the main request did not meet the requirements of Article 123(2) EPC, it deviated from the new line of

argument established in T 1621/16. Consequently, the law was not being applied consistently.

It was therefore necessary for the Enlarged Board of Appeal to answer the formulated questions, in particular whether the selection of an element from a list of converging alternatives was a new feature or merely a restricted version of the same feature.

The request for referral could not have been submitted earlier as each of the decisions T 2368/16, T 1482/17 and T 640/17, which cited T 1621/16, had developed it further and had only been published in May, October and November 2020, respectively. The questions to be referred to the Enlarged Board of Appeal could only have been formulated after all four related decisions had been published.

Auxiliary Requests II and III – claim 1

Amendments (Article 123(2) EPC)

The additional glycosylation characteristic of the recombinant FSH preparation recited in the claim as compared with claim 1 of the Main Request ("a relative amount of glycans carrying fucose of at least 30% of the total amount of glycans attached to FSH in the preparation") had a basis in claim 1 of the application. Furthermore, claim 2 of the application provided a basis for a recombinant FSH preparation comprising the FSH glycosylation characteristics (i), (ii) and (iii) recited in claim 1 of Auxiliary Requests II and III, except for the relative amount "at least 40%" of 2,6-coupled sialic acid (characteristic (iii)).

Moreover, a relative amount of glycans carrying a sulfate group of at least 2.5% (characteristic (iv) recited in the claim) was disclosed as the preferred amount on page 14, lines 15 to 16, and was repeated on page 15, line 16 and disclosed in 12 of the 20 embodiments in Table 1. Furthermore, there was a clear pointer to this feature in Example 4 (Table 10).

The amendments to claim 1 of each of Auxiliary Requests II and III thus amounted to a selection from a single list, namely the relative amount of 2,6-coupled sialic acid of "at least 40%" selected from the list disclosed on page 14, last line, to page 15, line 3, which met the requirements of Article 123(2) EPC.

Auxiliary Request IV

Admittance into the proceedings
(Article 13(2) RPBA 2020)

This request should be admitted into the appeal proceedings under Article 13(2) RPBA 2020 because it did not add complexity and could not surprise the appellant or the board. The subject-matter of claim 1 of Auxiliary Request IV only differed from the subject-matter of claim 1 of Auxiliary Requests II and III in that the relative amount of bisGlcNAc was at least 25% instead of at least 20%. This feature had already been present in claim 4 as granted (item (i)).

This amendment addressed the objections raised under Article 123(2) EPC to claim 1 of the Main Request. The relative amounts of all components of the FSH preparation as claimed in claim 1 of Auxiliary Request IV had the same level of preference. Their combination was thus allowable under Article 123(2) EPC

in accordance with established case law (Case Law of the Boards of Appeal, 9th edition, 2019, II.E.1.6.2 on pages 462 and 463).

XIII. The appellant requested that the decision under appeal be set aside and that the European patent No. 2601210 be revoked. They further requested that the Auxiliary Request IV not be admitted into the appeal proceedings and that no questions be referred to the Enlarged Board of Appeal.

The respondent requested that the appeal be dismissed (Main Request). Alternatively, they requested that the following questions be referred to the Enlarged Board of Appeal:

> "*1. Should the selection of elements from lists of converging alternatives of a feature be treated in the same way as the selection of elements from lists of non converging alternatives?*
> *2. If no, is the selection of an element from a list of converging alternatives a restriction of said feature?*
> *3. Which conditions must be met for amendments based on multiple such selections (i.e. selections from lists of converging alternatives) to meet the requirements of Article 123(2) EPC?*"

Alternatively, the respondent requested, that the decision under appeal be set aside and the patent be maintained on the basis of Auxiliary Requests I to III filed on 12 April 2018, or Auxiliary Request IV filed on 19 November 2020.

Reasons for the Decision

Admissibility of the appeal

1. The opposition had been filed in the name of "RÖSLER Patentanwaltskanzlei", i.e. in the name of the representative's association. The notice of appeal was filed in the name of "Uwe Rösler, RÖSLER Patentanwaltskanzlei", who, as an individual, was not party to the opposition proceedings and was hence not entitled to appeal pursuant to Article 107 EPC.

2. The appellant requested that its name on the notice of appeal be corrected to the name of the opponent, "RÖSLER Patentanwaltskanzlei", pursuant to Rule 139 EPC, as had been its true intention.

3. According to decision G 1/12 of the Enlarged Board of Appeal (OJ EPO 2014, A114), an error in the appellant's name in the notice of appeal can be corrected under Rule 139 EPC, first sentence, under the conditions established by the case law of the boards of appeal.

4. The legal person which should have filed the notice of appeal is the legal person that filed the opposition, i.e. "RÖSLER Patentanwaltskanzlei". It was therefore immediately clear that the name of the appellant on the notice of appeal was erroneous and how it should be corrected.

5. The board has no reason to doubt that the appellant's true intention was to file the notice of appeal in the name of the opponent, "RÖSLER Patentanwaltskanzlei", in particular as the statement of grounds of appeal was filed in the opponent's correct name.

6. Consequently, the request for the name of the appellant in the notice of opposition to be corrected is allowed under Rule 139 EPC. This correction has retroactive effect.

7. Consequently, the appeal complies with Articles 106 to 108 and Rule 99 EPC and is admissible.

Main Request and Auxiliary Request I - claim 1

Amendments (Article 123(2) EPC)

8. Compliance with the requirements of Article 123(2) EPC is assessed according to the so-called "gold" standard as set out in decision G 2/10 of the Enlarged Board of Appeal (OJ EPO 2012, 376, point 4.3 of the Reasons). In relation to the combination of features pertaining to separate embodiments or lists, it is established by the boards of appeal that the content of an application must not be considered to be a reservoir from which features pertaining to separate embodiments of the application can be combined in order to artificially create a particular embodiment (see e.g. Case Law of the Boards of Appeal of the European Patent Office, 9th edition, 2019, II.E.1.6.1.). In particular, a combination of features singled out by selection from two lists is not considered to be disclosed in an application unless there is a clear pointer to such a combination (see e.g. Case Law of the Boards of Appeal of the European Patent Office, 9th edition, 2019, II.E. 1.6.2.).

9. In the case at hand, the application does not directly and unambiguously disclose a recombinant FSH preparation, wherein the recombinant FSH comprises, *inter alia*, the combination of the glycosylation

characteristics (ii) and (iii) as recited in the claim, i.e. a relative amount of 2,6-coupled sialic acid of at least 40% of the total amount of sialic acids and a relative amount of glycans carrying a sulfate group of at least 2.5% of the total amount of glycans attached to FSH in the preparation.

10. It has not been contested by the respondent that the application does not explicitly disclose a recombinant FSH preparation, wherein the glycosylation pattern of the FSH comprises 2,6-coupled sialic acid and glycans carrying a sulfate group in the relative amounts as recited in the claim; however, they argued that the application nonetheless provided a basis for the claimed subject-matter according to three lines of argument.

11. The board is not convinced by the first line of argument submitted in this context, according to which the application disclosed pointers to a combination of the relative amounts "at least 40%" for 2,6-coupled sialic acid and "at least 2.5%" for sulfated glycans.

12. The respondent referred to the sentence bridging pages 14 and 15, as well as Table 1 and Table 4 of Example 4 as a basis for the relative amount "at least 40%" of 2,6-coupled sialic acid; however, this amount is only disclosed in the sentence bridging pages 14 and 15 of the application as part of a list of alternative relative amounts for 2,6-coupled sialic acid: "*Preferably, the relative amount of 2,6-coupled sialic acid is at least 40%, at least 45%, at least 50%, at least 53%, at least 55%, at least 60% or at least 65%, in particular in the range of about 40 % to about 99%, preferably about 40% to about 80%, about 50% to about 60% or about 53 % to about 70 %*". In Table 1, only

relative amounts of 53% or more are disclosed for 2,6-coupled sialic acid, and in Table 4, only a single relative amount of 57% is disclosed.

13. Accordingly, the board fails to see how the data disclosed in Tables 1 and 4 could be considered by the skilled person to specifically single out a relative amount of 2,6-coupled sialic acid of at least 40%. Consequently, the inclusion of a relative amount of 2,6-coupled sialic acid of at least 40% in the glycosylation pattern recited in the claim required a selection from a list of equal alternatives from the list disclosed in the sentence bridging pages 14 and 15 of the application.

14. As regards the relative amount of sulfated glycans, the respondent referred to page 14, lines 15 to 16, as well as Table 1 and Table 10 of Example 4; however, first of all, on page 14, the glycosylation characteristic "glycans carrying a sulfate" is disclosed only within a list of five additional glycosylation characteristics of the recombinant FSH (see page 14, lines 10 to 16). Consequently, in this passage, it has to be selected from a number of equal alternatives.

15. Moreover, the application discloses two lists of preferred relative amounts for glycans carrying a sulfate group. The first list is disclosed on page 14 (see point 14.). The second list is disclosed on page 15, lines 12 to 15 and reads as follows: "*Preferably, the relative amount of glycans carrying a sulfate group (sulfated glycans) is at least 1 %, at least 1.5%, at least 2%, at least 2.5%, at least 3% or at least 5%, more preferably at least 15 %, at least 10% or at least 12%*".

16. Therefore, in these passages of the application, the relative amount "at least 2.5%" is not specifically singled out since other relative amounts are also indicated as "preferred" or even "more preferred" amounts.

17. The respondent also referred to Table 1 and Table 10 of Example 4 as a basis for the relative amount of sulfated glycans as recited in the claim; however, Table 1 discloses 20 preferred embodiments, in which the recombinant FSH preparation has one of 20 specific glycosylation patterns. Ten of these specific glycosylation patterns have a relative amount of glycans carrying a sulfate group of at least 2.5%. This feature is, however, disclosed in this table only in the context of specific embodiments precisely defining all glycosylation parameters for each of the embodiments, i.e. this feature is disclosed only in combination with other precisely defined glycosylation parameters. The board thus holds that these embodiments do not provide a basis for the inclusion of the glycosylation feature "a relative amount of glycans carrying a sulfate group of at least 2.5%" in any other FSH glycosylation patterns unrelated to those disclosed in Table 1. Table 10 on the other hand discloses a relative amount of glycans carrying a sulfate group of 15% and therefore cannot constitute a basis for a FSH preparation in which the FSH comprises a relative amount of glycans carrying a sulfate group of at least 2.5%.

18. Consequently, the application does not contain any disclosure which the skilled person would understand as specifically singling out glycans carrying a sulfate group in the relative amount of at least 2.5% other than in the context of specifically defined

embodiments. The inclusion of the glycosylation characteristic "a relative amount of glycans carrying a sulfate group of at least 2.5% of the total amount of glycans attached to FSH in the preparation" in the FSH glycosylation pattern as recited in the claim thus required the selection from at least a first list of several equal alternatives disclosed on page 14, lines 10 to 16 of the application as filed.

19. Consequently, the board holds that, in order to arrive at an FSH preparation in which the recombinant FSH in the preparation comprises, *inter alia*, a relative amount of 2,6-coupled sialic acid of at least 40% of the total amount of sialic acids and a relative amount of glycans carrying a sulfate group of at least 2.5% of the total amount of glycans attached to the FSH, as recited in the claim, at least two selections from two different lists of equal alternatives were required; however, a combination of features singled out by selection from two lists is not considered to be disclosed in the application as filed unless there is a pointer to such a combination (see point 8. above).

20. The respondent referred to the disclosure on page 13, lines 10 to 14 and in Table 1 and Tables 4 and 10 of Example 4 as constituting pointers to the combination of these glycosylation characteristics. On page 13, lines 10 to 14, however, the glycosylation characteristics are recited without any relative amounts, and therefore this disclosure does not point to the combination of glycosylation characteristics recited in the claim. Furthermore, none of the 20 specific embodiments disclosed in Table 1 on pages 16 to 17 comprises a relative amount of 2,6-coupled sialic acid of less than 53%, and therefore the embodiments in Table 1 do not point to any lower relative amount of

this glycosylation characteristic either. Finally, the relative amounts for each of the glycosylation characteristics disclosed in Tables 4 and 10 of Example 4 are much higher than those recited in the claim (57% for 2,6-coupled sialic acids in Table 4 and 15% for glycans carrying a sulfate group in Table 10). The board thus holds that Example 4 does not point to the combination of glycosylation characteristics as recited in the claim either.

21. Consequently, the board considers that the application as filed does not disclose a pointer to the combination of the two features "a relative amount of 2,6-coupled sialic acid of at least 40% of the total amount of sialic acids" and "a relative amount of glycans carrying a sulfate group of at least 2.5% of the total amount of glycans attached to the FSH".

22. The board is also not convinced by the respondent's argument that the case at hand is comparable to that underlying decision T 1241/03. In that particular case a combination of specific ranges for the concentration of a compound and the pH of a buffer of a formulation disclosed in different sections of the application was held by the board not to add subject-matter (see point 7 of the Reasons). The selected ranges were, however, both singled out in the application as the preferred range (see point 6 of the Reasons).

23. This is different from the case at hand, wherein the two concentration values were selected from two lists of equal alternatives without any pointer to the combination of these two features (see points 20. and 21.). According to established case law of the boards of appeal, in the absence of a clear pointer, such a combination cannot be considered as being disclosed in

the application as filed (see e.g. Case Law of the Boards of Appeal of the European Patent Office, 9th edition, 2019, II.E.1.6.2.).

24. Consequently, the respondent's first line of argument fails to convince the board that the claimed subject-matter is disclosed in the application as filed.

25. The respondent's second line of argument also fails to convince the board because, for each of the 20 specific embodiments listed in Table 1, all the glycosylation parameters are precisely defined, as is evident from the sentence preceding the table: "*In certain preferred embodiments, the recombinant FSH preparation according to the invention has one of the glycosylation patterns listed in the following Table 1*" (page 16, lines 18 to 19). Table 1 thus cannot serve as a basis for embodiments in which one or more of the parameters defined in Table 1 have been altered, except for such alterations as explicitly disclosed in the paragraph following the table (see page 17, lines 4 to 10). These alterations, however, are likewise precisely defined and only relate to a further increase in the relative amount of 2,6-coupled sialic acid ("*the relative amount of 2,6-coupled sialic acids preferably is at least 55%, more preferably at least 60%, instead of at least 53%*"). Therefore, replacing the relative amount of 2,6-coupled sialic acids in any of the embodiments of Table 1 with the lower relevant amount "at least 40%" results in subject-matter which extends beyond the disclosure of the application as filed.

26. Finally, the board is not convinced by the respondent's third line of argument either, according to which the selected concentration values were "fall-back positions" disclosed in lists of converging

alternatives according to the reasoning in decision T 1621/16. In accordance with the established case law of the boards of appeal, it is concluded in decision T 1621/16 that a combination of features, even if disclosed in lists of converging alternatives, "*should be supported by a pointer in the application as filed*" (point 1.7.3 of the Reasons).

27. In the case at hand, the board concluded that the application did not contain disclosure which the skilled person would consider to point to the combination of the glycosylation characteristics as recited in the claim (see points 20. to 21.). For this reason alone, the rationale in decision T 1621/16 does not support the respondent's third line of argument, irrespective of whether or not the relative amounts disclosed for 2,6-coupled sialic acid on page 14, line 37 to page 15, line 3 could be regarded as a list of converging alternatives.

28. In view of the above considerations, the board holds that the claimed subject-matter relates to added subject-matter. Claim 1 of the Main Request and Auxiliary Request I thus does not comply with the requirements of Article 123(2) EPC.

Admittance of a request for referral of questions to the Enlarged Board of Appeal (Article 13(2) RPBA 2020)

29. With a letter dated 17 February 2021, the respondent requested that "*[i]f the Board intend[ed] to deviate in its assessment of Art. 123(2) EPC from the considerations and criteria introduced in T1621/16*", this point of law be referred to the Enlarged Board of Appeal (see sections IX. and XIII.).

30. Decision T 1621/16 was published on 11 February 2020. The board had issued a communication pursuant to Article 15 RPBA 2020 setting out its preliminary opinion, *inter alia*, as regards added subject-matter on 16 July 2020 (see section VI.). In response, on 19 November 2020 (see section VIII.), the respondent had provided further arguments as to why it considered that claim 1 of the Main Request met the requirements of Article 123(2) EPC. In its arguments, the respondent referred to decision T 1241/03 of the boards of appeal but did not mention decision T 1621/16. Therefore, in November 2020, nine months after its publication, the respondent had not considered decision T 1621/16 to be sufficiently relevant for the case at hand to be mentioned in its reply.

31. The respondent argued that the request for the referral to the Enlarged Board of Appeal could not have been put forward earlier because decisions T 2368/13, T 1482/17 and T 640/17, which cited T 1621/16 and developed it further, had only been published in May, October and November 2020, respectively. The request for the referral could only have been put forward after all these related decisions had been published.

32. The board is not convinced by this argument. A decision does not become relevant for a case only after it has been cited by other decisions. Decision T 1621/16 had already been published in February 2020 and thus could and should have been mentioned at least in the respondent's letter of November 2020 if the respondent considered it to be relevant for the case at hand. Moreover, the questions formulated by the respondent for the referral concerned selections from lists of converging alternatives, an issue which had already been dealt with in various other decisions of the

boards of appeal prior to decision T 1621/16 (see e.g. decision T 1621/16, point 1.6.3 of the Reasons, summarising the case law as regards such selections; see also Case Law of the Boards of Appeal of the European Patent Office, 9th edition, 2019, II.E.1.6.2.); however, despite this existing case law of the boards of appeal, the respondent had not argued that selections from lists of converging alternatives were relevant in the case at hand prior to its letter dated 19 February 2021.

33. The board thus holds that two of the decisions citing T 1621/16 only being published in October and November 2020 does not present a cogent reason justifying the fact that the request to refer the questions to the Enlarged Board of Appeal was put forward only in February 2021. Hence, the respondent had not provided any convincing justification as to why the request to refer the questions to the Enlarged Board of Appeal was put forward so late.

34. Consequently, the board decided not to admit the respondent's request to refer questions to the Enlarged Board of Appeal into the appeal proceedings under Article 13(2) RPBA 2020.

Auxiliary Requests II and III - claim 1

Amendments (Article 123(2) EPC)

35. The subject-matter of claim 1 of each of Auxiliary Requests II and III relates to a recombinant FSH composition, wherein the recombinant FSH in the preparation comprises, *inter alia*, a relative amount of 2,6-coupled sialic acid of at least 40% of the total amount of sialic acids and a relative amount of glycans

carrying a sulfate group of at least 2.5% of the total amount of glycans attached to FSH in the preparation (see section V.).

36. In addition to the arguments put forward in support of claim 1 of the Main Request, the respondent referred to claim 2 of the application (see section II.), and argued that the amendments to claim 1 of each of Auxiliary Requests II and III amounted to a selection from a single list, namely the relative amount "at least 40%" selected from the list disclosed on page 14, last line to page 15, line 3.

37. However, the recombinant FSH in the FSH preparation as defined in claim 2 of the application does not comprise glycans carrying a sulfate group or a relative amount of 2,6-coupled sialic acid of at least 40%. The disclosure in claim 2 of the application thus has no bearing on the board's conclusion, drawn in the context of the Main Request, that the combination of the two glycosylation characteristics "a relative amount of 2,6,-coupled sialic acid of at least 40% of the total amount of sialic acids" and "a relative amount of glycans carrying a sulfate group of at least 2,5% of the total amount of glycans" is not disclosed in the application as filed (see points 8. to 28.).

38. Consequently, claim 1 of each of Auxiliary Requests II and III does not fulfil the requirements of Article 123(2) EPC.

Auxiliary Request IV

Admittance into the proceedings (Article 13(2) RPBA 2020)

39. Auxiliary Request IV was submitted with a letter dated 19 November 2020 and thus constitutes an amendment to the respondent's case made after notification of a summons to oral proceedings. Pursuant to Article 13(2) RPBA 2020, it thus should not be taken into account unless there are exceptional circumstances, justified with cogent reasons.

40. The respondent submitted that Auxiliary Request IV did not add complexity to the case and could not surprise the board and the appellant because the amended feature in claim 1 of Auxiliary Request IV had already been present in claim 4 as granted. Furthermore, the amendment addressed the appellant's objections raised under Article 123(2) EPC to claim 1 of the Main Request.

41. However, the objections under Article 123(2) EPC to claim 1 of the Main Request had already been raised by the appellant in its statement of grounds of appeal and corresponded to those raised during the opposition proceedings. Therefore, a request aimed at overcoming these objections, as argued by the appellant, could and should have been filed earlier.

42. Consequently, the board held that there were no exceptional circumstances which justified admitting Auxiliary Request IV into the appeal proceedings.

43. Accordingly, the board decided not to admit Auxiliary Request IV into the appeal proceedings pursuant to Article 13(2) RPBA 2020.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chair:

I. Aperribay B. Claes

Decision electronically authenticated