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**Datasheet for the decision
of 19 June 2019**

Case Number: T 1317/15 - 3.3.04
Application Number: 09782080.7
Publication Number: 2331569
IPC: C07K14/755, C07K14/745,
A61K38/00
Language of the proceedings: EN

Title of invention:

Recombinantly produced human factor VIII and IX

Applicant:

Octapharma AG

Headword:

Recombinantly produced human factor VIII/OCTAPHARMA

Relevant legal provisions:

EPC Art. 54
EPC R. 115(2)
RPBA Art. 12(4), 15(3)

Keyword:

Main request: novelty (no);
Auxiliary requests 1 to 7: could have been filed in first
instance proceedings (yes), admitted (no)

Decisions cited:

G 0002/88, G 0001/92, T 0210/93, T 0910/98, T 0684/02,
T 2215/08, T 1039/09, T 1822/12

Catchword:



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Case Number: T 1317/15 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 19 June 2019

Appellant: Octapharma AG
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Representative: Patent- und Rechtsanwälte Ullrich & Naumann
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 26 January 2015
refusing European patent application No.
09782080.7 pursuant to Article 97(2) EPC**

Composition of the Board:

Chair G. Alt
Members: R. Morawetz
M. Blasi

Summary of Facts and Submissions

- I. The appeal lies against the decision of the examining division refusing European patent application No. 09 782 080.7 entitled "*Recombinantly produced human factor VIII and IX*".
- II. During the proceedings before the examining division, the examining division issued a communication pursuant to Article 94(3) EPC maintaining, *inter alia*, an objection as regards lack of novelty of the subject-matter of claim 1 vis-à-vis the disclosure of document D1 (WO 2007/003582, published 11 January 2007) in relation to the claim request filed with the entry into the regional phase before the EPO.

The applicant replaced this claim request with a new set of claims, with claim 1 being identical to previous claim 1.

The examining division summoned the applicant to oral proceedings and, *inter alia*, explained in an accompanying communication in detail why the subject-matter of claims 1 to 7 of the sole request before it lacked novelty vis-à-vis the disclosure of document D1.

The applicant withdrew its request for oral proceedings and did not react in substance to the issues raised in the communication accompanying the summons to oral proceedings.

The examining division cancelled the summons to attend oral proceedings and continued the proceedings in writing by issuing the decision to refuse the application, one of the reasons being that the subject-

matter of claims 1 to 7 lacked novelty. The reasoning given by the examining division for that finding was the same as that set out in the communication accompanying the summons to the oral proceedings.

III. With the statement of grounds of appeal, the applicant (appellant) submitted the set of claims underlying the decision under appeal as the main request and sets of claims of new auxiliary requests 1 to 7. Oral proceedings were requested for the event that none of the sets of claims were considered allowable.

Claim 1 of the main request reads as follows (emphases below added by the board for ease of reading and understanding):

"1. Use of a human embryonic cell line (HEK) selected from the group consisting of HEK 293 (ATCC CRL-1573; DSM ACC 305; ECACC ref: 85120602) and 293F (Invitrogen R79007) for obtaining a recombinant human factor VIII or IX protein **having a human-like glycosylation pattern but the protein is devoid of N-glycolylneuraminic acid and/or the carbohydrate group Gal α -3Gal.**"

Claim 1 of auxiliary request 1 reads as follows:

"1. A recombinant human factor VIII or IX protein having a human-like glycosylation pattern but the protein is devoid of N-glycolylneuraminic acid and/or the carbohydrate group Gal α -3Gal obtainable from a human cell line selected from the group consisting [sic] HEK 293 (ATCC CRL-1573; DSM ACC 305; ECACC ref: 85120602) and 293F (Invitrogen R79007)."

Claim 1 of auxiliary request 2 reads as follows:

"1. A recombinant human factor VIII protein **having a human-like glycosylation pattern but the protein is devoid of N-glycolylneuraminic acid and/or the carbohydrate group Gal α -3Gal** and the recombinant human factor VIII is obtainable by producing the protein in a human embryonic cell line (HEK) selected from the group consisting of HEK 293 (ATCC CRL-1573; DSM ACC 305; ECACC ref: 85120602) and 293F (Invitrogen R79007) wherein the recombinant human factor VIII has an affinity to the von Willebrand factor that is higher than that of recombinant factor VIII produced in murine cells."

Claim 1 of auxiliary request 3 reads as follows:

"1. A recombinant human factor VIII or IX protein **having a human-like glycosylation pattern but the protein is devoid of N-glycolylneuraminic acid and/or the carbohydrate group Gal α -3Gal** for use in the treatment of a factor VIII- and/or a factor IX-associated disorder wherein the recombinant human factor VIII or IX protein is obtainable by producing the protein in a human embryonic cell line (HEK) selected from the group consisting of HEK 293 (ATCC CRL-1573; DSM ACC 305; ECACC ref: 85120602) and 293F (Invitrogen R79007)."

Claim 1 of auxiliary request 4 is identical to claim 1 of auxiliary request 3.

Claim 1 of auxiliary request 5 reads as follows:

"1. A recombinant human factor VIII protein **having a human-like glycosylation pattern but the protein is**

devoid of N-glycolylneuraminic acid and/or the carbohydrate group Gal α -3Gal for use in the treatment of a factor VIII associated disorder wherein the recombinant human factor VIII has an affinity to the von Willebrand factor that is higher than that of recombinant factor VIII produced in murine cells and is obtainable by producing the protein in a human embryonic cell line (HEK) selected from the group consisting of HEK 293 (ATCC CRL-1573; DSM ACC 305; ECACC ref: 85120602) and 293F (Invitrogen R79007)."

Claim 1 of auxiliary request 6 reads as follows:

"1. A complex of recombinant factor VIII protein and the von Willebrand factor wherein the recombinant human factor VIII protein **having a human-like glycosylation pattern but the recombinant factor VIII protein is devoid of N glycolylneuraminic acid and/or the carbohydrate group Gal α -3Gal.**"

Claim 1 of auxiliary request 7 reads as follows:

"1. A complex of recombinant factor VIII protein and the von Willebrand factor wherein the recombinant human factor VIII protein **having a human-like glycosylation pattern but the recombinant factor VIII protein is devoid of N glycolylneuraminic acid and/or the carbohydrate group Gal α -3Gal** and has an affinity to the von Willebrand factor that is higher than that of recombinant factor VIII produced in murine cells."

IV. The board summoned the appellant to oral proceedings and informed them of its preliminary opinion in a communication pursuant to Article 15(1) RPBA.

In points 6.1 to 6.3 of this communication, the board indicated that it considered that the examining division's finding of lack of novelty of the subject-matter of claim 1 of the main request appeared to be correct.

In points 7.1 to 7.4 of this communication, the board observed that the skilled person would have had no reason to assume that the rhFVIII expressed in HEK 293F cells according to the method disclosed in document D1 comprised N-glycolyl-neuraminic acid and/or the carbohydrate group Gal α -3Gal.

In points 10 to 22 of this communication, the board observed that it considered the admittance of auxiliary requests 1 to 7 to be an issue and further that these requests appeared not to be allowable because they all suffered from a deficiency under Article 84 EPC and because the subject-matter of some of them was not novel or lacked an inventive step.

- V. The appellant informed the board in writing that they would not be represented and would not attend the oral proceedings. The appellant did not react in substance to the board's communication.

- VI. Oral proceedings before the board took place on 19 June 2019, in the absence of the appellant. At the end of the oral proceedings, the Chair announced the board's decision.

VII. The appellant's arguments may be summarised as follows:

Main request

Novelty (Article 54 EPC) - claim 1

The examining division had ignored a decisive feature of claim 1, i.e. "*devoid of N-glycolylneuraminic acid and/or the carbohydrate group Gal α -3Gal*".

Document D1 did not disclose this feature, not even inherently.

It did not matter whether it might have been possible to analyse the lack of the *N-glycolyl-neuraminic acid and/or the carbohydrate group Gal α -3Gal* in FVIII because prior "*to the invention it was clear to the skilled person that the molecule expressed in HEK 293 comprises those carbohydrate moieties*".

"Only in knowledge of the teaching of the present invention, it has now become clear that the recombinant FVIII and FIX of the present invention differs from that one which has been disclosed by D1."

Auxiliary requests 1 to 7

Admittance into the appeal proceedings

Since the wording of the set of claims examined by the examining division had not been found allowable, it seemed that "*a reset of the subject-matter for which protection is thought [sic] is appropriate*".

VIII. The appellant requested in writing that the decision under appeal be set aside and that a patent be granted on the basis of the set of claims of the main request or, alternatively, one of the set of claims of auxiliary requests 1 to 7, all filed with the statement of grounds of appeal.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 99 EPC and is therefore admissible.
2. The duly summoned appellant was neither present nor represented at the oral proceedings. The board decided to continue the proceedings without the appellant in accordance with Rule 115(2) EPC and treated them as relying on their written case in accordance with Article 15(3) RPBA.

Main request

Novelty (Article 54(2) EPC) - claim 1

3. Document D1 relates to the serum-free, recombinant production of human proteins in immortalised human cell lines (see page 1, lines 3 to 7). It discloses a process for the production of recombinant human factor VIII (rhFVIII), one of the proteins referred to in claim 1, in the human embryonic kidney (HEK) 293F cell line, one of the cell lines referred to in claim 1 (see Examples 1B, 4B and Figure 8 of document D1).

While document D1 discloses that human recombinant proteins produced in human cell lines carry a "*human glycosylation pattern*" (see page 7, lines 15 to 16), it

does not further characterise the glycosylation pattern of the rhFVIII protein produced in HEK 293F cells.

4. Claim 1 of the main request relates to the use of a HEK cell line "*selected from the group consisting of HEK 293 [...] and 293F [...] for obtaining a recombinant human factor VIII [rhFVIII] or IX [rhIX] protein having a human-like glycosylation pattern but the protein is devoid of N-glycolylneuraminic acid and/or the carbohydrate group Gal α -3Gal*".
5. In the board's view, despite the wording chosen, claim 1 is, in fact, a claim to a process of producing a product (see also decision G 2/88, OJ EPO 1990, 93, Reasons, point 2.2). It results in the production of a product, e.g. a rhFVIII protein having a certain glycosylation pattern, the process step according to the claim being the use of the HEK cells.
6. Thus, - and this is undisputed - the process of claim 1 and the process disclosed in document D1 are the same except that the characterisation of the product produced according to the process of claim 1 as "*having a human-like glycosylation pattern but the protein is devoid of N-glycolylneuraminic acid and/or the carbohydrate group Gal α -3Gal*" is not explicitly disclosed in that document.
7. However, the process of document D1 is used in the present application for the preparation of rhFVIII. Thus, Example 1 states that rhFVIII "*was produced in the human cell line HEK293F according to the process described in EP-A-1 739 179*" (see application as filed, page 12, lines 21 to 24).

EP-A-1 739 179 is the publication of the European patent application from which document D1 claims priority. The process disclosed in document D1 (see Examples 1B, 4B and Figure 8) is identical to that disclosed in EP-A-1 739 179 (see paragraphs [0046], [0064], [0073] and Figure 9). According to the present application, the claimed glycosylation pattern is the consequence of using this process (see page 8, lines 5 to 8).

8. The appellant submits, firstly, that the examining division did not consider the feature "*devoid of N-glycolylneuraminic acid and/or the carbohydrate group Gal α -3Gal*" of claim 1 and, secondly, that the claimed subject-matter is novel over the disclosure in document D1 because this feature of claim 1 is not disclosed in that document, not even inherently.
9. As to the appellant's first argument, contrary to the appellant's submission, the examining division did not in fact ignore this feature but gave reasons why this feature could not confer novelty on the claimed subject-matter (see decision under appeal, points 3.4, 3.6 and 3.7).
10. As to the appellant's second argument, the Enlarged Board of Appeal (EBA) has dealt in opinion G 1/92 (OJ EPO 1993, 277) with points of law concerning the interpretation of the requirement "made available to the public" in relation to the prior use of a product (see Reasons, point 1.1). The EBA held (see Order, point 1) that the chemical composition of a product is state of the art when the product as such is available to the public and can be analysed and reproduced by the skilled person, irrespective of whether particular reasons can be identified for analysing the

composition. This ruling has been constantly applied in the jurisprudence of the boards of appeal when the product was the result of a process of producing a product (see decisions T 210/93, Reasons, points 3.2.4.2 to 3.2.5; T 910/98, Reasons, point 2.2.2 and T 1822/12, Reasons, point 3.2.3).

11. The appellant does not dispute that the rhFVIII protein produced in HEK 293F cells is available from document D1 and that it can be reproduced according to the process described in that document and that its glycosylation pattern can be analysed.

Thus, applying the reasoning of the EBA in opinion G 1/92 to the present situation leads to the conclusion that the teaching of document D1 made the chemical composition of rhFVIII produced by the process disclosed in document D1, including its glycosylation pattern achieved after production in HEK 293F cells, available to the public. Therefore, the feature at issue cannot establish the novelty of the subject-matter of claim 1 vis-à-vis document D1.

This view is in line with established jurisprudence of the boards of appeal holding that a claim directed to the use of a known process for a particular purpose, the purpose being the preparation of a product naturally resulting from such process, is in fact nothing but a claim to that very same process (see Case Law of the Boards of Appeal, 8th edition 2016, section I.C.8.1.3 d) and the decisions cited therein: T 210/93, Reasons, points 3.2.2 to 3.2.5; T 684/02, Reasons, point 5.5; T 2215/08, Reasons, point 2.4.1 and T 1039/09, Reasons, points 2 to 20).

12. The appellant's third argument, that prior to the invention "*it was clear to the skilled person that the molecule expressed in HEK 293 comprises those carbohydrate moieties*" which the FVIII according to claim 1 is said to be devoid of, cannot succeed either. What is decisive is what had been made available to the public by the disclosure in document D1 as a matter of fact (see points 10 and 11 above) and not what the skilled person might - or might not - have thought had been made available. The board had drawn the appellant's attention to the fact that there was no evidence supporting their submission and that there was rather evidence to the contrary (see section IV above).
13. The appellant's last argument, that "*only in knowledge of the teaching of the present invention, it has now become clear that the recombinant FVIII and FIX of the present invention differs from that one which has been disclosed by D1*" likewise fails because, as established above (see point 11), the glycosylation pattern of the rhFVIII protein produced in HEK 293F cells had already been made available to the public by the teaching of document D1.
14. Therefore, the subject-matter of claim 1 of the main request is anticipated by the disclosure of document D1 with the consequence that the main request does not meet the requirements of Article 54 EPC.

Admittance of auxiliary requests 1 to 7 (Article 12(4) RPBA)

15. These sets of claims were submitted with the statement of grounds of appeal.
16. They differ from the set of claims of the sole request underlying the decision under appeal in that the claims

were amended and are now directed, *inter alia*, to rhFVIII and rhFIX proteins defined in terms of their production process, *i.e.* by product-by-process features.

17. Article 12(4) RPBA provides that, without prejudice to the power of the board to hold inadmissible facts, evidence or requests which could have been presented in the first-instance proceedings, everything presented by the parties pursuant to Article 12(1) RPBA (*i.e.* in *ex parte* proceedings, the notice of appeal and the statement of grounds of appeal in particular) has to be taken into account by the board if and to the extent it relates to the case under appeal and meets the requirements in Article 12(2) RPBA.

The board, in line with the established case law (see Case Law of the Boards of Appeal of the EPO, 8th edition 2016, IV.E.4.3.3b)), concludes that it has discretion over whether to hold inadmissible claim requests which, although they could have been, were not presented by an applicant in the proceedings before the examining division.

18. In the board's opinion, the appellant could indeed have been expected in the circumstances of the present case to present the sets of claims of auxiliary requests 1 to 7 filed with the statement of grounds of appeal already in the proceedings before the examining division for the following reasons.

- 18.1 The examining division had issued a communication pursuant to Article 94(3) EPC maintaining, *inter alia*, an objection as regards lack of novelty of the subject-

matter of claim 1 vis-à-vis the disclosure of document D1 in relation to the claim request filed with entry into the regional phase before the EPO.

The appellant had a first opportunity to file observations or amendments in reply to this communication, which they used by replacing the then pending claim request with a new claim set with claim 1 being identical to previous claim 1.

- 18.2 When summoning the appellant to oral proceedings, the examining division had given, in the annex to the summons, detailed reasons why it maintained the objection that the subject-matter of claims 1 to 7 of the single set of claims then on file lacked novelty vis-à-vis the disclosure of document D1.
- 18.3 The appellant neither commented on the substance of the communication nor submitted amended claims and so made no further effort to obtain a favourable decision. Instead, they withdrew their request for oral proceedings and announced their absence from the oral proceedings.
- 18.4 The reasons given by the examining division for the refusal are the same as set out in the communication accompanying the summons to the oral proceedings, and the claim request underlying the decision under appeal is the same as the one underlying the summons to oral proceedings.
- 18.5 Therefore, the factual situation as regards the substantive objections was the same when the appellant was summoned for oral proceedings and when it filed its statement of grounds of appeal. The situation was in fact the same as upon entry into the regional phase

before the EPO since claim 1 had remained identical since then.

- 18.6 In the board's view, it is thus apparent that the appellant could - and should - have filed the auxiliary claim requests which were filed with the statement of grounds of appeal and on the basis of which the appellant is asking the board to set aside the decision of the examining division, during the first-instance proceedings, namely, appropriately in response to the communication pursuant to Article 94(3) EPC or in reply to summons to oral proceedings by the examining division at the latest.
19. The board has seen no explanation either in the notice of appeal or the statement of grounds of appeal as to why the auxiliary requests had not been submitted to the examining division.
20. Rather, the appellant submitted in the statement of grounds of appeal that since the wording of the set of claims examined by the examining division had not been found allowable, it seemed that "*a reset of the subject-matter for which protection is thought [sic] is appropriate*". It appears to the board that by re-introducing product-by-process claims, that were present in the claims of the application as filed (see claim 12) but deleted in the claim request filed with entry into the regional phase before the EPO, the claimed subject-matter has indeed been "*reset*".
21. However, appeal proceedings are neither a continuation of the examination proceedings nor a second procedure for the substantive examination of European patent applications.

22. The appellant, having received the board's communication in which the board had indicated that it considered the admittance of the auxiliary claim requests into the proceedings to be an issue, made no submissions in this respect.
23. In addition, in the board's opinion, the sets of claims of auxiliary requests 1 to 7 presented with the statement of grounds of appeal do also not clearly overcome the pending objections and moreover give rise to further objections, as was set out in the board's communication in preparation for the oral proceedings. The appellant has not submitted any arguments aimed at dissuading the board in this respect and, hence, the board has not been given any reason to deviate from this opinion.
24. In view of the above considerations, the board, exercising its discretion pursuant to Article 12(4) RPBA, decided not to admit the set of claims of auxiliary requests 1 to 7 into the appeal proceedings.

Conclusion

25. The subject-matter of claim 1 of the main request is not novel, and the main request is thus not allowable. The sets of claims of auxiliary requests 1 to 7 are not admitted into the appeal proceedings. Therefore, the decision under appeal cannot be set aside and the appeal must be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chair:



S. Lichtenvort

G. Alt

Decision electronically authenticated