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**Datasheet for the decision
of 8 October 2018**

Case Number: T 0329/12 - 3.3.08

Application Number: 05017434.1

Publication Number: 1609853

IPC: C12N5/00

Language of the proceedings: EN

Title of invention:

Process for controlling sialylation of proteins produced by mammalian cell culture

Patent Proprietor:

F. Hoffmann-La Roche AG
Genentech, Inc.

Opponents:

Franke, Andreas
Maiwald Patent- und Rechtsanwalts-gesellschaft mbH

Headword:

Sialylation control/HOFFMANN-LA ROCHE

Relevant legal provisions:

EPC Art. 54, 56, 83, 123(2)
RPBA Art. 12(4)

Keyword:

Continuation of appeal proceedings after lapse of the patent
(yes)

Auxiliary request 2 - added matter (no)

Sufficiency of disclosure (yes)

Novelty (yes)

Inventive step (yes)

Decisions cited:

Catchword:



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Case Number: T 0329/12 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 8 October 2018

Appellants I:
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Decision under appeal: Interlocutory decision of the Opposition
Division of the European Patent Office posted on
15 December 2011 concerning maintenance of the
European Patent No. 1609853 in amended form.

Composition of the Board:

Chairman B. Stolz
Members: M. R. Vega Laso
D. Rogers

Summary of Facts and Submissions

- I. European patent No. 1 609 853 with the title "Process for controlling sialylation of proteins produced by mammalian cell culture" was granted on application No. 05017434.1 which is a divisional application of the European patent application No. 96918251.8 filed under the Patent Cooperation Treaty and published as WO 96/39488.

- II. Two oppositions to the grant of the patent were filed. The oppositions were based on the grounds for opposition under Article 100(a) in conjunction with Articles 54 and 56; Article 100(b) and Article 100(c) EPC in conjunction with Articles 123(2) and 76(1) EPC.

- III. In an interlocutory decision posted on 15 December 2011, an opposition division found that, account being taken of the amendments introduced into claims 1 to 20 according to the auxiliary request 4 filed at the oral proceedings, the patent and the invention to which it relates met the requirements of the EPC. Accordingly, the patent could be maintained on the basis of the amended claims and the description of the patent as granted.

- IV. Claim 1 of the auxiliary request 4 read as follows:

"1. A process for controlling the amount of sialic acid present on an oligosaccharide side chain of a glycoprotein produced in the production phase of culture in a mammalian host cell, which process comprises selecting, engaging, and maintaining cell culture parameters for the production phase for the desired sialic acid content of the mature glycoprotein,

wherein said cell culture parameters affect cell specific productivity and are selected according to the criterion that the sialic acid content varies inversely with the cell specific productivity during the production phase."

Dependent claims 2 to 20 specify further features of the claimed process.

- V. The patent proprietors and opponents 1 and 2 each filed an appeal against the interlocutory decision and submitted a statement setting out the grounds of appeal. Since opponent 1 withdrew his appeal later in the appeal proceedings (see section IX below), in the following he will be referred to as "the party as of right". The patent proprietors and opponent 2 are, respectively, appellants I and appellant II.
- VI. Together with their statement of grounds of appeal, appellants I submitted four sets of claims as main request and auxiliary requests 1 to 3. Except for the correction of a typographical error, the claims according to the auxiliary request 2 were essentially identical to those of the auxiliary request 4 underlying the decision under appeal (see section IV above).
- VII. Each party replied to the statement of grounds of the other parties. Together with their reply, appellants I filed two sets of claims as auxiliary requests 4 and 5, as well as further evidence. Appellant II and the party as of right submitted comments and additional evidence. Each party requested oral proceedings.
- VIII. The parties were summoned to oral proceedings. In a communication sent in preparation of the oral

proceedings, the board remarked that, unless special circumstances applied, the term of the patent at issue had expired in June 2016 (Article 63(1) EPC). The parties were requested to inform the board whether they wished the appeal proceedings to be continued. Additionally, the board provided observations on procedural issues and expressed a provisional opinion on some issues concerning Articles 123(2), 83, 54 and 56 EPC.

IX. In reply to the board's communication, appellant II informed the board that it would not attend the oral proceedings and the party as of right (opponent 1) withdrew his appeal. Appellants I confirmed their attendance.

X. Oral proceedings were held on 8 October 2018 in the absence of appellant II and the party as of right. At the outset of the oral proceedings, appellants I withdrew their main request and auxiliary request 1.

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

(8): W. Chotigeat et al., *Cytotechnology*, 1994, Vol. 15, pages 217 to 221;

(15): S.K.W. Oh et al., *Biotechnology and Bioengineering*, 1993, Vol. 42, pages 601 to 610;

(16): WO 89/04867, published on 1 June 1989;

(20): R. Kimura and W.M. Miller, *Biotechnol. Prog.*, 1997, Vol. 13, pages 311 to 317;

- (21): D. Lamotte et al., *Cytotechnology*, 1999, Vol. 29, pages 55 to 64;
- (22): Y. Mimura et al., *Journal of Immunological Methods*, 2001, Vol. 247, pages 205 to 216;
- (23): R. Kimura and W.M. Miller, *Biotechnology and Bioengineering*, 1996, Vol. 52, pages 152 to 160;
- (24): Dictionary excerpts for the terms "control" and "maintain" from www.thefreedictionary.com, downloaded on 11 April 2012; and
- (25): Y.H. Sung et al., *Journal of Biotechnology*, 2004, pages 323 to 335.

XII. The submissions made by appellants I concerning issues relevant to this decision, were essentially as follows:

Articles 123(2) and 76(1) EPC

The objection that the subject-matter of claim 1 extends beyond the content of the application as filed because the claim did not recite a growth phase and a transition phase, was without merit. In the passage on page 7, lines 28 to 30 of the application as filed, "transition phase" was defined as the period of time during which culture conditions for the production phase are engaged. Claim 1 required the steps of selecting and engaging cell culture parameters to obtain a mature glycoprotein with the desired sialic acid content; hence, it was immaterial that the wording "transition phase" was not used in the claim. Since claim 1 specified that the cell culture parameters were maintained in the production phase, they had necessarily to be engaged before the start of the

production phase, as disclosed on page 3, lines 38 to 40 of the application as filed.

As regarded the growth phase, it was apparent from page 1, lines 3 and 4 of the application as filed that the invention was concerned with controlling the amount of sialic acid present on an oligosaccharide chain of a glycoprotein produced in a mammalian host cell - in the production phase of culture -, not about the provision of the cells themselves. The skilled person was not presented with any new, technically relevant, information beyond the disclosure in the application as filed and the parent application. Hence, Articles 123(2) and 76(1) EPC were not contravened.

Article 83 EPC

The invention as claimed was disclosed in the application as filed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. The evidence submitted to support the objection of lack of sufficient disclosure did not cast any serious doubts.

Article 54 EPC

Claim 1 required a purposive selection of the cell culture parameters based on the recited criteria to achieve the desired degree of sialylation. This step was a technical feature of the claimed process, as it achieved the purpose of controlling the sialic acid content of the mature glycoprotein, which was a technical result. Document (8) did not teach the skilled person to select cell culture parameters according to the criterion recited in the claim.

Consequently, document (8) did not destroy the novelty of the subject-matter of claim 1.

Article 56 EPC

Starting from document (8) as the closest state of the art, the skilled person would not have selected cell culture parameters on the basis of the criterion specified in claim 1, because document (8) taught the opposite, namely that there was a direct relationship between the sialic acid content and the cell specific productivity. In other words, document (8) taught away from the claimed invention. Thus, an inventive step had to be acknowledged.

- XIII. The submissions by appellant II, insofar as they are relevant to the present decision, may be summarised as follows:

Articles 123(2) and 76(1) EPC

The opposition division was wrong when referring to granted claim 1 to support its view that the requirement that the "*cell culture parameters are selected, engaged and maintained for the production phase*" implied that the parameters were selected before or at the onset of the production phase. This requirement was not present in the original claims and the description as filed only referred to this term either in the context of a specific glycoprotein (i.e. TNFR1-IgG1) or the selection step in the transition phase. However, claim 1 neither required the presence of a transition phase nor was it limited to the production of a specific glycoprotein. The same applied to the requirement "*produced in the production*

phase of culture" which was not present in the original claims and had no basis in the application as filed.

The passage on page 11, lines 4 to 9 of the application as filed to which the opposition division referred, did not provide a basis for the claimed process, in particular as regards the feature that the selected cell culture parameters are maintained in the production phase. As apparent from document (24), the term "maintained" in claim 1 was not synonymous to the term "controlled" used in the passage in question, because the latter comprised the step of regulating, i.e. engaging suitable parameters.

As acknowledged by the opposition division, claim 1 encompassed two alternative embodiments: a single-step culture and a multi-stage culture. While the first embodiment had a basis in the application as filed, a multi-stage culture without defining a growth phase and a transition phase was not directly and unambiguously disclosed. As apparent from the passage on page 7, lines 18 to 34 of the application as filed, the transition phase was technically distinct from both the growth phase and the production phase. As a transition phase was not recited in claim 1, the claimed subject-matter extended beyond the content of the application as filed.

Article 83 EPC

The application as filed did not provide enough information to enable the control of the sialic acid content of any glycoprotein in any mammalian host cell in a manner that the sialic acid content varies inversely with the cell specific productivity. This was supported by the evidence in documents (8) and (21).

Moreover, as apparent from documents (15), (16) and (21), the specific factors affecting cell specific productivity disclosed in the application did not necessarily act on any protein in the way disclosed in the application. Thus, the requirements of Article 83 EPC were not fulfilled.

Article 54 EPC

The step of selecting cell specific parameters in the process of claim 1 was not a physical but a mental act and did not limit the scope of the claim. Except for this feature, all other features of the claimed process were apparent from document (8) which therefore anticipated the subject-matter of claim 1.

Article 56 EPC

The teaching of document (8) was not limited to a direct relationship between cell specific productivity and sialic acid content. The document rather generally suggested controlling sialic acid content by influencing the expression rate of the glycoprotein. Hence, the skilled person would apply this teaching to other proteins and end up with the process as claimed. Consequently, the subject-matter of claim 1 lacked an inventive step.

XIV. The submissions by the party as of right were essentially as follows:

Articles 123(2) and 76(1) EPC

According to the application as filed (see passages on page 3, lines 33 to 40; page 3, last line to page 4, line 4; page 7, lines 28 to 30; page 11, lines 10

and 11; and page 12, lines 10 to 13), the process for controlling the sialic acid content of a glycoprotein not only comprised a production phase, but also a growth phase and a subsequent transition phase preceding the final production phase. Contrary to the opposition division's view, in the transition phase the culture parameters having been set for the growth phase were actually and factually changed to become parameters for the production phase, that meant that the selection and engaging steps took place. Removing the growth and transition phase from the claimed teaching clearly confronted the skilled person with a different ("new") information which was not derivable from the application as filed or the parent application. Consequently, Articles 123(2) and 76(1) EPC were contravened.

Article 83 EPC

Documents (8) and (20) to (23) raised serious doubts that the claimed invention was enabled over its full range.

Article 54 EPC

The feature "*selected according to the criterion that the sialic acid content varies inversely with the cell specific productivity during the production phase*" had to be understood as a feature which referred in functional terms to a cell culture parameter. The inverse relationship specified in claim 1 was an inherent or implicit feature of any known process like that described in document (8). Therefore, claim 1 lacked novelty over document (8).

Article 56 EPC

The solution proposed in claim 1 was not an alternative to the teaching of document (8), but the same solution. Hence, an inventive step should be denied.

XV. Appellants I requested that the decision under appeal be set aside and the patent be maintained upon the basis of auxiliary request 2, filed under cover of their letter dated 23 April 2012.

XVI. Appellant II requested in writing that the decision under appeal be set aside and the patent be revoked.

Reasons for the Decision

Continuation of the appeal proceedings after expiry of the term of the patent (Article 63(1) EPC)

1. The divisional application for which the present patent was granted is deemed to have been filed on the filing date of the parent European application No. 96 918 251.8, i.e. on 6 June 1996 (Article 76(1) EPC). Accordingly, unless special circumstances apply, the term of the patent expired in June 2016 (Article 63(1) EPC).
2. In a communication sent in preparation of the oral proceedings, the board drew attention to this circumstance and the parties were invited to inform the board whether they wished the appeal proceedings to be continued, otherwise to withdraw their appeals. Since appellants I's expressed their intention to attend the oral proceedings (see section IX above), the board

maintained them as scheduled and takes a decision on the merits of the case.

Admission of new evidence filed in appeal proceedings

3. Pursuant to Article 12(4) RPBA, it lies within the discretion of the board to admit and consider evidence and requests filed in appeal proceedings which could have been presented in the previous proceedings.
4. Together with its statement of grounds of appeal, appellant II submitted new evidence in support of its objections concerning Articles 123(2) and 83 EPC (documents (24) and (25), respectively). Document (24) was filed in order to address the opposition division's findings concerning the disclosure on page 11, lines 4 to 9 of the application as filed (see section 10.3 of the decision under appeal), in particular to support appellant II's argument that the terms "maintaining" and "controlling" cannot be used as synonyms. Appellants I have not opposed the admission and consideration of this document. Hence, document (24) is admitted into the appeal proceedings.
5. Document (25), which allegedly provides experimental results that are inconsistent with the teaching of the patent, was submitted by appellant II to support the objection of lack of sufficient disclosure (Article 83 EPC). As this objection had been raised already in appellant II's notice of opposition, the board sees no reason why document (25) could not have been submitted in the previous proceedings, either together with the notice of opposition or at a later stage of the opposition proceedings. Although the board addressed this issue in its communication, appellant II did not put forward any reasons that justify the late

filing. Hence, the board, exercising the discretion conferred by Article 12(4) RPBA, decides not to admit this document into the proceedings.

Articles 123(2) and 76(1) EPC

6. In the decision under appeal, the opposition division found that none of the objections raised with respect to Articles 123(2) and 76(1) EPC were justified.
7. In appeal, this finding was contested by appellant II arguing that both the application as filed and the parent application disclosed only a process involving three phases (growth, transition and production phase), and that the omission from claim 1 of the explicit requirement for a growth phase and a transition phase contravened Article 123(2) EPC.
8. This argument is unconvincing. As stated in the decision under appeal, a process for controlling the amount of sialic acid of a glycoprotein which does not include a growth phase is directly and unambiguously derivable from the passage on page 10, lines 26 to 28 of the application as filed ("*In a single step culture the host cells are inoculated into a culture environment and the **processes of the instant invention** are employed during a **single production phase** of the cell culture*"; emphasis added by the board). In the light of the whole disclosure in the application as filed the wording "*processes of the instant invention*" can only be understood to refer to processes in which the cell culture parameters are selected according to the criterion that the sialic acid content of the glycoprotein produced varies inversely with the cell specific productivity.

9. It should be noted that, as an alternative, the passage on page 10, lines 28 to 32 of the application as filed discloses a multiple step culture procedure including a growth phase (*"Alternatively, a multi-stage culture is envisioned. In the multi-stage culture cells may be cultivated in a number of steps or phases. For instance, cells may be grown in a first step or growth phase culture ..."*). A multi-stage culture comprising a growth phase, a transition phase and a production phase is described on page 3, lines 33 to 40 of the application as filed as a "particular embodiment" of the invention.

10. As regards the alleged omission of a transition phase, the opposition division was right in finding that a selecting/engaging step as disclosed in the application as filed in connection with the term "transition phase" (see page 3, lines 37 and 38 *"... a transition phase in which cell culture parameters ... are selected and engaged"*; and page 7, lines 28 and 29 *"'Transition phase' of the cell culture refers to the period of time during which culture conditions for the production phase are engaged"*) is explicitly required in claim 1.

11. Appellant II also disputed that there is a basis in the application as filed for the requirement that the cell culture parameters are selected, engaged and **maintained for the production phase**. The passage on page 11, lines 4 to 9 which the opposition division considered to be the basis for this feature (see section 10.3, lines 7 to 10 of the decision under appeal) discloses that *"... factors which increase cell specific productivity are controlled during the production phase ..."*, the term "factors" being understood to refer to the cell culture parameters. Appellant II asserted - referring to various dictionary excerpts filed as document (24) -

that the verb "maintain" as in claim 1 is not synonymous to "control" as in the passage in question, because "controlling" also comprises "... *the step of regulating, i.e. engaging suitable parameters*". This argument fails to convince the board. It should be noted that claim 1 reads "*selecting, **engaging and maintaining** cell culture parameters*". Hence, the claim in fact requires that suitable parameters are engaged and then kept at the selected level during the production phase, i.e. "controlled" during the production phase, as disclosed in the passage on page 11 of the application as filed.

12. A further objection raised by appellant II concerned the feature "*for controlling the amount of sialic acid present on an oligosaccharide side chain of a glycoprotein **produced in the production phase***" (emphasis added), which the opposition division considered to be directly and unambiguously derivable from the passage on page 3, lines 3 to 8 of the application as filed (see section 10.5 of the decision under appeal). The board shares the opposition division's view. The passage to which the opposition division referred reads:

"Accordingly, the invention provides for a process for controlling the sialic acid content of a glycoprotein produced by mammalian cell culture. According to this aspect of the invention, varying the production rate of the glycoprotein in the production phase of the cell culture leads to variations in the sialic acid content of the mature glycoprotein. More particularly, an increase in cell specific productivity during the glycoprotein production phase results in a decrease in sialic acid content of the mature protein. Conversely, a

decrease in cell specific productivity results in an increase in sialic acid content in the mature protein."

13. The findings on Article 123(2) EPC in sections 10.6 to 10.11 of the decision under appeal concerning dependent claims were not contested in appeal.
14. Summarizing the above, the board concludes that the subject-matter of claim 1 does not extend beyond the content of the application as filed. The same applies with respect to the parent application (WO 96/39488) because the disclosure in both applications is identical.

Article 83 EPC

15. The findings on sufficiency of disclosure in sections 16.1 to 16.7 of the decision under appeal were contested by appellant II referring to documents (8), (21), (15) and (16). The party as of right cited documents (20), (22) and (23).
16. Contrary to appellant II's view, the skilled person seeking to control the amount of sialic acid in a glycoprotein other than TNFR-IgG would not have to embark on a research program to reveal the inverse relationship between cell specific productivity and sialic acid content. This information has already been provided by the inventors in the patent. The skilled person only needs to apply the teaching of the patent to select cell culture parameters that affect the cell specific productivity in a manner that results in the desired sialic acid content.

17. None of the documents cited by either appellant II or the party as of right shows that the teaching of the patent cannot be reliably applied to control the amount of sialic acid on other glycoproteins, or that a person skilled in the art would not be able to do so without undue burden or applying inventive skills. As stated in the decision under appeal, documents (20) and (22) do not provide any data on cell specific productivity, and it is not apparent from document (21) whether or how the sialic acid content varies in relation to the variation of the cell specific productivity. Finally, documents (15) and (16) describe cell culture parameters leading to an increase of the cell specific productivity, but do not contain any data on the sialic acid content of the protein and cannot support the objection that the claimed process cannot be carried out by a person skilled in the art.
18. For these reasons, the board concludes that the findings on Article 83 EPC in the decision under appeal are correct.

Claim interpretation and Article 54 EPC

19. The board shares the opposition division's view that the step of selecting cell culture parameters which, by engaging and maintaining them during the production phase, result in an increase or a decrease of the amount of sialic acid present in the glycoprotein produced in a culture of mammalian host cells, is to be regarded as a technical feature of the process of claim 1. The selection step in claim 1 is guided by technical information, namely the inverse relationship between the sialic acid content of the produced glycoprotein and the cell specific productivity during the production phase, which, as it was found in the

decision under appeal, was not available to the public from document (8).

20. The board cannot accept the argument that claim 1 does not require that during the process any change in the cell specific productivity or the sialic acid content or both takes place, as claim 1 expressly requires that "*said cell culture parameters*", i.e. those selected, engaged and maintained in the production phase, affect cell specific productivity and, consequently, also the amount of sialic acid in the glycoprotein.

21. The findings on novelty in the decision under appeal were contested in appeal only insofar as they concerned document (8) (see section 15.15 of the decision). In this document, the authors report the results of a study aimed at elucidating the effect of the expression rate on the glycoform distribution of human follicle stimulating hormone (hFSH) produced by recombinant CHO cells. It was observed that, as the specific productivity increased, there was a shift in the FSH isoforms to the lower pI fractions, corresponding to increased sialic acid content (see Abstract).

22. Like the opposition division, the board is of the opinion that a person skilled in the art cannot derive directly and unambiguously from document (8) a process comprising selecting, engaging and maintaining cell culture parameters for the production phase based on an inverse relationship between the cell specific productivity and the sialic acid content. Contrary to the view of the party as of right, the results shown in Figures 1 and 3 and Table 1 of document (8) clearly suggest a direct relationship between cell specific productivity and sialic acid content, rather than an inverse relationship as specified in claim 1. Also the

argument that an inverse relationship would be inherent to the process described in document (8) because claim 1 only requires that the cell culture parameters are suitable for affecting cell specific productivity, is without merit.

23. It follows from the above that the subject-matter of claim 1 is novel over document (8).

Article 56 EPC

24. The parties agreed with the opposition division in that document (8) represents the closest state of the art, and that starting from this document the technical problem to be solved was the provision of an alternative process for controlling the sialic acid content of a glycoprotein produced in a mammalian host cell.
25. The opposition division held that the problem was solved by a process as defined in claim 1. The board shares this view. As stated in the decision under appeal, the objection raised by the party as of right that, in view of the content of document (8) the problem cannot be regarded as solved over the whole scope of the claim, is rather an objection of lack of sufficient disclosure than one of lack of inventive step, because claim 1 is limited to processes which allow controlling the amount of sialic acid in a glycoprotein produced in a mammalian host cell.
26. As regards the question whether the solution proposed in claim 1 was obvious to a person skilled in the art, the opposition division found that document (8), disclosing a direct relationship between cell specific

productivity and sialic acid content, would teach away from the invention. The board agrees with this finding.

27. The board disagrees with appellant II's view that the teaching of document (8) is not limited to a direct relationship between cell specific productivity and sialic acid content, but that this document generally suggests controlling sialic acid content by influencing the expression rate of the glycoprotein. In the board's view, the passage on which appellant II relied to support its argument (paragraph bridging left- and right-hand column on page 221) would be read by the skilled person in connection with the previous paragraph describing a direct relationship between cell specific productivity and sialic acid content. If the skilled person following the teaching of document (8) tried to, e.g., reduce the amount of sialic acid by selecting cell culture parameters that result in a reduction of the cell specific productivity, he/she would end up obtaining a glycoprotein with an unexpectedly high content of sialic acid. Hence, not only would the skilled person not succeed in controlling the amount of sialic acid of a glycoprotein produced in a mammalian host cell, without knowledge of the invention he/she could not determine the reason for this failure.

28. In view of the above, the board concludes that the process as defined in claim 1 of the auxiliary request 2 involves an inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division with the order to maintain the patent as amended in the following version:

Description:

Pages 2 to 17 of the patent specification.

Claims:

Nos. 1 to 20 of Auxiliary Request 2, filed under cover of a letter dated 23 April 2012.

Drawings:

Figs 1 and 2 of the patent specification.

The Registrar:

The Chairman:



L. Malécot-Grob

B. Stolz

Decision electronically authenticated