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Datasheet for the decision of 22 December 2010

Case Number: T 0538/08 - 3.3.04

Application Number: 01954606.8

Publication Number: 1297172

IPC: C12P 21/00

Language of the proceedings: EN

Title of invention:
Methods for producing modified glycoproteins

Patentee:
GlycoFi, Inc.

Opponents:
GLYCODE SAS
Novozymes A/S

Headword:
Modified glycoproteins/GLYCOFI

Relevant legal provisions:
EPC Art. 123(2), 123(3)
RPBA Art. 12, 13

Relevant legal provisions (EPC 1973):
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Keyword:
"Main request - added matter (yes)"
"Auxiliary requests - extension of scope of protection (yes)"

Decisions cited:
T 0127/85, T 0316/85

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0538/08 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 22 December 2010

Appellant: (Patent Proprietor)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 30 November 2007 revoking European patent No. 1297172 pursuant to Article 102(1) EPC.

Composition of the Board:

Chairman: C. Rennie-Smith
Members: B. Claes
R. Gramaglia

Summary of Facts and Submissions

I. The appellant (patentee) lodged an appeal against the decision of the opposition division revoking European patent No. 1 297 172, with the title "*Methods for producing modified glycoproteins*" which was granted for European patent application No. 01954606.8 (published as WO02/00879).

II. Claim 1 of the patent read:

"1. A host cell that is a unicellular or filamentous fungus that does not display alpha-1,6 mannosyltransferase activity with respect to the N-glycan on a glycoprotein, having in its endoplasmic reticulum (ER) or Golgi apparatus a hybrid enzyme selected to have optimal activity in the ER or Golgi of said host cell, so that **said host cell is capable of forming 50 to 100 Mole% $Man_5GlcNAc_2$ on a substrate glycoprotein**, the hybrid enzyme comprising:
(a) an exogenous mannosidase catalytic domain having optimal activity in said ER or Golgi at a pH between 5.1 and 8.0; fused to
(b) a cellular targeting signal peptide not normally associated with the catalytic domain of (a), wherein said cellular targeting signal peptide targets said exogenous mannosidase catalytic domain to said ER or Golgi apparatus." (emphasis added by the board)

III. The opposition division revoked the patent. It found that claim 1 of the sole and main request before them, which, besides having an identical wording to claim 1 as granted, contained one additional feature, did not comply with the requirements of Article 100(c) EPC. It

found *inter alia* that the feature "said host cell is capable of forming 50 to 100 Mole% $Man_5GlcNAc_2$ on a substrate glycoprotein" (see section II) did not find a basis in the application as filed (Article 123(2) EPC).

IV. With its statement of the grounds of appeal the appellant submitted a new main request. Claim 1 of this request was in essence identical to claim 1 of the main request before the opposition division. It now contained the feature "**said host cell thus being capable of forming a glycoprotein comprising 50-100 Mole% $Man_5GlcNAc_2$** converted by said GnT I to $GlcNAcMan_5GlcNAc_2$" (emphasis added by the board).

V. Respondent I (opponent 01) replied to the statement of the grounds of appeal.

VI. In a communication pursuant to Article 15(1) of the RPBA, the board expressed its preliminary opinion that the finding of the examining division concerning the feature "said host cell is capable of forming 50 to 100 Mole% $Man_5GlcNAc_2$ on a substrate glycoprotein" that it infringed the requirements of Article 123(2) EPC still applied to claim 1 of the new main request.

VII. In response to the communication the appellant filed on 18 October 2010 a new main request and a first and second auxiliary request.

Claim 1 of the main request read:

"1. A host cell that is a unicellular or filamentous fungus that

(a) does not display alpha-1,6 mannosyltransferase activity with respect to the N-glycan on a glycoprotein;

(b) has in its endoplasmic reticulum (ER) or Golgi apparatus a hybrid enzyme selected to have optimal activity in the ER or Golgi of said host cell comprising:

(ba) an exogenous mannosidase catalytic domain having optimal activity in said ER or Golgi at a pH between 5.1 and 8.0; fused to

(bb) a cellular targeting signal peptide not normally associated with the catalytic domain of (ba) that targets the catalytic domain of (ba) to said ER or Golgi apparatus;

and

(c) has in its ER or Golgi apparatus a hybrid enzyme selected to have optimal activity in the ER or Golgi of said host cell comprising:

(ca) a GnT I catalytic domain having optimal activity in said ER or Golgi at a pH between 5,1 and 8.0; fused to

(cb) a cellular targeting signal peptide not normally associated with the catalytic domain of (ca) that targets the catalytic domain of (ca) to said ER or Golgi;

said host cell thus being capable of forming a glycoprotein comprising 50-100 Mole% $Man_5GlcNAc_2$."
(emphasis added by the board)

Claim 1 of the first auxiliary request differed from claim 1 of the main request in that the highlighted feature was replaced by the feature "**said host cell**

thus being capable of forming $Man_5GlcNAc_2$, which is able to accept *in vivo* GlcNAc by the action of a GlcNAc transferase 1 at a yield in excess of 30 % of the total N-glycans" (emphasis added by the board). Claim 1 of the second auxiliary request differed from claim 1 of the first auxiliary request in that the latter feature was replaced by the feature " **said host cell thus being capable of forming a specific precursor structure of $Man_5GlcNAc_2$, which is able to accept *in vivo* GlcNAc by the action of a GlcNAc transferase 1 at a yield in excess of 30 % of the total N-glycans**" (emphasis added by the board).

VIII. Oral proceedings were held in the absence of opponent 02 (respondent II) which had notified the board of its non-attendance.

IX. The following document is cited in the decision:

(D1): Chiba *et al* (1998), J. Biol. Chem, Vol. 273, No. 41, pages 26298-26304.

X. The arguments presented by the appellant which are relevant for the present decision were the following:

Admissibility of the requests filed on 18 October 2010

– The normal course of appeal proceedings is for the parties to provide written arguments on which the board gives a preliminary opinion. It would be impolite and unreasonable not to respect that opinion and unreasonable not to react under Article 13 RPBA (see also the board's decision T 316/08). The new requests were filed on

18 October 2010 in response to the preliminary opinion in the board's communication. Without that opinion, the appellant could not foresee what amendments would have been useful when filing the appeal. Thus any further requests filed then would have been ultimately unproductive. The criteria in Article 13(1) RPBA were satisfied - the new requests reduced the complexity of the case, did not cause delay and were procedurally economic.

Main request - Claim 1 - Article 123(2) EPC

– The feature "said host cell thus being capable of forming a glycoprotein comprising 50-100 Mole% $Man_5GlcNAc_2$" was supported by the passage at page 16, lines 6 to 9, of the patent application as published.

– Although the passage had been interpreted by the opposition division as to relate to a certain Mole% of a glycoprotein which comprised a high portion of an attached compound, it should rather be interpreted in the context of the entire application as well as in the light of the state of the art, such as document (D1) as referred to on page 12, lines 1 to 15 of the application as published. The person skilled in the art would then readily understand that the passage on page 16 should rather be interpreted as to relate to a glycoprotein which comprises a certain Mole% of a certain attached compound ($Man_5GlcNAc_2$) and thus as to support the contested feature in claim 1.

– Document (D1) described the method that was commonly used by those skilled in the art for determining the *N*-glycan composition of proteins, in particular for determining the amount of $Man_5GlcNAc_2$ on glycoproteins. The 27 Mole% of $Man_5GlcNAc_2$ obtained in document (D1) from the protein preparation meant that of the total of *N*-glycans in the preparation 27 Mole% were $Man_5GlcNAc_2$ with the remainder being a mixture of other *N*-glycan species. The 27 Mole% $Man_5GlcNAc_2$ achieved by document (D1) was below the lower limit that the teaching of the patent in suit had achieved. The skilled person would have realised that this was thus the reference point to be exceeded by the invention, i.e. that the gist of the invention was to produce in lower eukaryotic cells recombinant modified (human-like) glycoproteins wherein more than 27 Mole% of the *N*-glycans on the recombinant glycoproteins were $Man_5GlcNAc_2$. This view was supported by the passages on page 15, lines 13 to 15, page 17, line 30 to page 18, line 4, page 18, lines 9 to 12, page 25, lines 17 to 20 and original claim 19.

– Accordingly, when the patent in suit referred to Mole%, it was, in line with document (D1), referring to Mole% of an *N*-glycan such as $Man_5GlcNAc_2$ in a population of total N-glycans isolated from the substrate glycoproteins produced in the lower eukaryote modified in accordance with the invention. The passage at page 16, lines 6 to 9, of the published application would therefore be understood by the skilled person as referring to the Mole% of $Man_5GlcNAc_2$ *N*-glycans on the

glycoprotein in the glycoprotein composition and therefore as referring to the Mole% of $Man_5GlcNAc_2$ *N*-glycans out of the total Moles of *N*-glycans released from the glycoproteins in the composition and analysed. Any other meaning would lead to an illogical reading of the published patent application.

– There did not exist any quantitative means for accurately measuring the Mole% of glycoproteins that have a $Man_5GlcNAc_2$ *N*-glycan based solely on separating proteins based on their *N*-glycan content in the art. The only method available was that described in document (D1).

– Furthermore, interpreting the passage on page 16 as to relate to a certain Mole% of protein which comprised a high proportion of an attached compound resulted, in the context of the application as filed, in an illogical premise that would have been immediately recognized by the skilled reader. This interpretation would mean that the yield of the desired *N*-glycan, here $Man_5GlcNAc_2$, was in fact less than 27 Mole% of the total *N*-glycans, i.e. below the yield disclosed in document (D1). Indeed, when taking the lower end point of the range in claim 1, i.e. 50 Mole%, this would mean that only 50% of the total glycoproteins in a host cell had (a high proportion of) $Man_5GlcNAc_2$. This did not teach the Mole% of the $Man_5GlcNAc_2$ of the total N-glycans in the host cell, which was however necessary to compare it with the available prior art. In the passage on page 16 it was merely indicated that 50

Mole% of the glycoprotein had a "high proportion", which meant that the majority, i.e. more than 50%, of the *N*-glycans in the selected glycoprotein fraction were $Man_5GlcNAc_2$. The passage on page 16 accordingly referred to 50 Mole% of glycoproteins of which more than 50% of N-glycans had $Man_5GlcNAc_2$. Accordingly, this translated into 25 Mole% $Man_5GlcNAc_2$ of the total *N*-glycans of the host. This interpretation of the passage on page 16, lines 7 to 9 would thus translate into 25 to 50 Mole% of the N-glycans on the total glycoproteins of the host, i.e. a value which is partly lower than the one already achieved in the prior art (see document (D1), i.e. 27 Mole%). Therefore, adopting such an interpretation would mean that the goal of the invention, which was to increase the percentage of $Man_5GlcNAc_2$ within a particular glycoprotein over that of the prior art, was wholly abandoned in this passage of the application as filed. This interpretation of the passage on page 16 in isolation clearly could not therefore be correct because it did not conform with either the intended invention nor the application as filed.

First and second Auxiliary request - Claim 1 - Article 123(3) EPC

– Claim 1 of both the first and second auxiliary request required the host cells to produce an extra hybrid enzyme (feature (c)) as compared to the host cell as subject-matter of claim 1 of the patent as granted. The scope of protection provided by claim 1 of the auxiliary requests was

therefore restricted as compared to that of claim 1 as granted.

– As explained in the context of claim 1 of the main request, the host cells of claim 1 as granted would be capable of producing more than 25 Mole% $Man_5GlcNAc_2$ of the total *N*-glycans when the passage on page 16 was interpreted as not to form a basis for claim 1 under Article 123(2) EPC. In that case namely the scope of protection of claim 1 of the auxiliary requests was therefore also restricted as compared to that of claim 1 as granted concerning the Mole% of $Man_5GlcNAc_2$.

XI. The arguments presented by respondent I which are relevant for the present decision were the following:

Admissibility of the requests filed on 18 October 2010

– The appellant's new requests should not be admitted into the proceedings because of the lateness of their filing. The appellant explained that it needed the board's preliminary opinion in order to know what amendments would be useful but the decision under appeal had shown that the patent contravened Article 123(2) EPC because the feature "50-100 Mole% on a glycoprotein" was not to be found in the description so the appellant should have expected the board to consider that point and could have filed auxiliary requests covering fall-back positions with its grounds of appeal. However, it chose only to file a request which still included the feature in issue and to argue that it was allowable. It could in fact have

done that and filed auxiliary requests as well. Only two and a half years after filing its grounds of appeal and five months after the communication did the appellant think to change its requests. This was an abuse of procedure (see the decision T 127/85) and did not lead to any procedural economy.

– In reply to questions from the board, the respondent agreed that it had had sufficient time to consider the new requests and to prepare its arguments in relation to them and submitted that, if the result of its admissibility request would be to end the proceedings, then at least the new main request should be held inadmissible.

Main request - Claim 1 - Article 123(2) EPC

– The feature "said host cell thus being capable of forming a glycoprotein comprising 50-100 Mole% $Man_5GlcNAc_2$" was not supported by the passage at page 16, lines 6 to 9, of the application as published. The opposition division had been correct in its decision that the contested feature would directly be understood by the skilled person as the relative amount of the $Man_5GlcNAc_2$ structure in a glycoprotein, whereas the passage referred to concerned the percentage yield of glycoproteins comprising $Man_5GlcNAc_2$.

First and second Auxiliary request - Claim 1 - Article 123(3) EPC

– Claim 1 of the first and second auxiliary request related to host cells which were capable of forming merely more than 30% $Man_5GlcNAc_2$ or a precusor thereof of the total N-glycans. The host cell of claim 1 as granted however, had to produce the same compound in excess of 50 Mole%. Claim 1 of these requests therefore extended the scope of protection as compared to that provided by claim 1 of the patent as granted.

XII. The appellant (patentee) requested that the decision under appeal be set aside and the case be remitted to the first instance for further prosecution on the basis of one of the main or first or second auxiliary requests, all filed on 18 October 2010.

Respondent I (opponent 01) requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

Admissibility of the requests filed on 18 October 2010

2. For the reasons given in the board's earlier decision cited by the appellant - T 316/85 of 26 May 2010, see Reasons, points 19 to 28 - the board in part agrees with the submissions of the respondent and disagrees with those of the appellant. The appellant could have

foreseen the need to file auxiliary requests before receiving the board's preliminary opinion but it chose not to file any such requests with its grounds of appeal. The appellant's professed respect for the board's communication overlooks the fact that such communications are not always issued and, when issued, do not necessarily cover all aspects of an appeal. The appellant's view of "normal" appeal proceedings appears therefore to have been formed with hindsight after the respondent's admissibility objection was raised - significantly it did not argue that the requests had to be considered under Article 12(1) and (4) RPBA as part of an answer to a communication but only that they were admissible in the board's discretion under Article 13(1) RPBA. It is clear that, if the appellant wished to cover the fall-back positions represented by the new requests filed on 18 October 2010, it could and should have filed those requests with its grounds of appeal and, by failing to do so, did not file its complete case as required by Article 12(2) RPBA.

3. However, this was not so grave as to amount to an abuse of procedure as the respondent argues. The decision cited by the respondent - T 127/85 (OJ 1989, 271) - is not in point. That decision held that it could lead to an abuse of opposition proceedings if a patentee were allowed merely to tidy up and improve its disclosure by amendments not necessitated by a ground of opposition. In the present case, as the respondent itself argues, the appellant patentee could and should have filed amended requests to deal with a ground of opposition which succeeded before the opposition division.

4. The board accepts the appellant's argument that the requests should be found admissible in the board's discretion under Article 13(1) EPC. That the criteria in that Article appear to be satisfied is confirmed by the respondent's concession at the oral proceedings that it had sufficient time to deal with the new requests, as indeed its substantial written submissions in response of 2 November 2010 also show. The requests caused neither delay nor surprise - indeed, on the respondent's own arguments, they were to have been expected earlier. In all the circumstances, while the requests were beyond doubt late-filed and could have been filed with the grounds of appeal, it was none the less appropriate for the board to exercise its discretion to find the requests admissible.

Main request - Claim 1 - Article 123(2) EPC

5. Claim 1 of the main request refers to the feature "said host cell thus being capable of forming a glycoprotein comprising 50-100 Mole% $Man_5GlcNAc_2$". The parties were in agreement that this feature defines the glycoprotein capable of being formed by the host cell to comprise 50-100 Mole% of the total of *N*-glycans species present to consist of $Man_5GlcNAc_2$.

6. The appellant has referred to page 16, lines 6 to 9, of the application as published, the sole passage in the application as published which mentions the range of 50-100 Mole%, as the basis for this feature. The passage on page 16, lines 4 to 9 reads: "*$Man_5GlcNAc_2$ must be formed in vivo in a high yield, at least transiently, since all subsequent glycosylation reactions require $Man_5GlcNAc_2$ or a derivative thereof.*

Accordingly a yield is obtained of greater than 27 mole%, more preferably a yield of 50-100 mole%, glycoproteins in which a high proportion of N-glycans have $Man_5GlcNAc_2$."

7. The board agrees with respondent I that upon fair reading the last sentence in this passage refers to a yield of glycoproteins which is obtained of 50-100 Mole% in which a high proportion of N-glycans have $Man_5GlcNAc_2$. In the opinion of the board there exists however a clear technical difference between a protein which comprises a certain Mole% of a certain attached compound, i.e. in the present case of claim 1 $Man_5GlcNAc_2$, and a certain Mole% of protein which comprises a high portion of the same attached compound, i.e. in the allegedly supporting passage. It follows that the feature "said host cell thus being capable of forming a glycoprotein comprising 50-100 Mole% $Man_5GlcNAc_2$" finds no direct basis in the indicated passage on page 16 of the application as published.

8. The appellant has argued that the feature was nevertheless supported by the passage at page 16, lines 6 to 9, of the application as published because the passage had to be read in the context of the entire application as published and the state of the art.

8.1 A first and main line of argument was based on the fact that prior art document (D1), as referred to on page 12, lines 1 to 15 of the application as published, had achieved 27 Mole% $Man_5GlcNAc_2$ in a particular glycoprotein. This yield was below the lower limit that the patent in suit had achieved. 27 Mole% was actually the reference point to be exceeded by applying the

invention. Document (D1) described the method that was commonly used by those skilled in the art for determining the amount of $Man_5GlcNAc_2$ on glycoproteins and the 27 Mole% of $Man_5GlcNAc_2$ obtained from the preparation of CPY protein in document (D1) meant that of the total of *N*-glycans in the preparation, 27 Mole% were $Man_5GlcNAc_2$ with the remainder being a mixture of other *N*-glycan species. Accordingly, when the patent in suit referred to Mole% it was referring to Mole% of an *N*-glycan such as $Man_5GlcNAc_2$ in a population of total N-glycans isolated from the substrate glycoproteins produced in the host cell modified in accordance with the invention. The passage on page 16, lines 6 to 9 (see point 4, above) would therefore be understood by the skilled person as referring to the Mole% of $Man_5GlcNAc_2$ *N*-glycans on the glycoprotein in the glycoprotein composition and therefore as referring to the Mole% of $Man_5GlcNAc_2$ *N*-glycans out of the total Moles of *N*-glycans released from the glycoproteins in the composition and analysed.

The board concurs with the appellant's view that the application as published at various instances refers in a technically meaningful manner to the Mole% of $Man_5GlcNAc_2$ in a population of total *N*-glycans isolated from the substrate glycoproteins produced in a host cell being either modified in accordance with the invention or in accordance with the teaching in document (D1). The board judges however that the mere presence of these passages cannot change the nature of the technical teaching in the sentence on page 16, lines 6 to 9, of the application as published. In fact, despite the possibly unfortunate drafting of the

passage on page 16, it is technically meaningful and clear.

8.2 A second line of argument by the appellant was based on the fact that there did not exist any quantitative means for accurately measuring Mole% of glycoproteins that have a $Man_5GlcNAc_2$ *N*-glycan based solely on separating proteins based on their *N*-glycan content. The only method available was that described in document (D1).

The board considers however that this argument relates to issues of clarity and/or sufficiency of disclosure rather than to the issue of added matter and cannot have any bearing on the finding in point 5 above.

8.3 The appellant's third line of argument considered that when interpreting the passage on page 16 so as to relate to a certain Mole% of protein which comprises a high proportion of an attached compound would mean that the yield of $Man_5GlcNAc_2$, was in fact less than 27 Mole% of the total *N*-glycans, i.e. below what is disclosed in document (D1). This would mean that the goal of the invention, which was to increase the percentage of $Man_5GlcNAc_2$ within a particular glycoprotein over that of the prior art, was wholly abandoned in this passage of the application as filed. This illogical premise based on the interpretation of the passage on page 16 taken in isolation would have been immediately recognised by the skilled reader because it did not conform with either the intended invention or the application as filed.

The board notes however that the mere fact that a technical teaching in the description could possibly lead to or result in claimed subject-matter being anticipated by prior art cannot justify ignoring the true technical meaning of this teaching. This argument must therefore also fail.

9. In view of the above considerations and in line with the established case law of the boards of appeal, the board considers the feature introduced in claim 1 not to be directly and unambiguously derivable from the patent application as published. Claim 1 of the main request conflicts therefore with the requirements of Article 123(2) EPC.

First and second auxiliary request - Claim 1 - Article 123(3) EPC

10. Claim 1 of the patent as granted defined the fungal host cells to be "capable of forming 50 to 100 Mole% $Man_5GlcNAc_2$ on a substrate glycoprotein" (see section II), whereas claim 1 of the first and second auxiliary requests defines the fungal host cell to be "capable of forming $Man_5GlcNAc_2$, which is able to accept *in vivo* GlcNAc by the action of a GlcNAc transferase 1 at a yield in excess of 30 % of the total N-glycans" and "capable of forming a specific precursor structure of $Man_5GlcNAc_2$, which is able to accept *in vivo* GlcNAc by the action of a GlcNAc transferase 1 at a yield in excess of 30 % of the total N-glycans", respectively (see section VII).

11. The appellant has not disputed that a range "in excess of 30%" is broader than the range "50 to 100 Mole%".

Accordingly, the subject matter of claim 1 of the first and second auxiliary requests relates also to host cells which are capable of producing $Man_5GlcNAc_2$ or a precursor thereof in a lower percentage of the total N-glycans than the host cells of claim 1 as granted.

12. The appellant has argued that claim 1 of both the first and second auxiliary requests required the host cells to form an extra hybrid enzyme (feature (c)) as compared to the host cell of claim 1 of the patent as granted and the scope of protection provided by claim 1 of the auxiliary requests therefore had to be restricted as compared to that of claim 1 as granted. The board notes however that indeed such host cells capable of forming an extra hybrid enzyme (feature (c)) were within the scope of protection of claim 1 as granted, but not however such cells which are capable of producing just in excess of 30 % of $Man_5GlcNAc_2$ or a precursor thereof of the total N-glycans.

13. The appellant has furthermore argued that, as explained in the context of claim 1 of the main request, the host cells of claim 1 as granted would be capable of producing more than 25 Mole% of the total *N*-glycans. The scope of protection of claim 1 of the auxiliary requests was therefore also restricted as compared to that of claim 1 as granted. The board notes however that these arguments of the appellant were made in the context of Article 123(2) EPC, about the interpretation of a passage in the description of the application as published. What is decisive in the context of Article 123(3) EPC in the present case is however the interpretation of claim 1 of the granted patent. This argument must therefore fail.

14. In view of the above considerations, claim 1 of both the first and second auxiliary requests do not meet the requirements of Article 123(3) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar | The Chairman

P. Cremona | C. Rennie-Smith