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D E C I S I O N
of 16 March 2006

Case Number: T 0109/03 - 3.3.04

Application Number: 95905840.5

Publication Number: 0733119

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Language of the proceedings: EN

Title of invention:

Method of producing derivatives of lactosamine

Applicant:

BIOFLEXIN AB

Opponent:

-

Headword:

Lactosamine derivatives/BIOFLEXIN

Relevant legal provisions:

EPC Art. 111(1)

Keyword:

"Remittal - reasoning given in the contested decision does not apply to the amended set of claims"

Decisions cited:

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Catchword:

-



Case Number: T 0109/03 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 16 March 2006

Appellant: BIOFLEXIN AB
Andjaktsvägen 6
S-22653 Lund (SE)

Representative: Henriksson, Dan Ragnar Mikael
Awapatent AB
P.O. Box 5117
S-20071 Malmö (SE)

Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 21 June 2002
refusing European application No. 95905840.5
pursuant to Article 97(1) EPC.

Composition of the Board:

Chair: U. Kinkeldey
Members: G. Alt
G. Weiss

Summary of Facts and Submissions

- I. The appeal was lodged by the appellant (applicant) against the decision of the Examining Division to refuse the European patent application no. 95 905 840.5 with the title "Method of producing derivatives of lactosamine" pursuant to Article 97(1) EPC because it did not comply with the requirements of Articles 54, 56 and 84 EPC.
- II. The appellant's last submission in examination proceedings contained the following statement and request: "In the above mentioned European patent application the applicant disagrees with the Examiner's opinion in the Communication issued on 12 January 2001. Instead, the applicant requests that a Rule 51(4) communication is to be issued or for a decision on the file (see J 29/94 OJ 1998, 147)." (emphasis added).
- III. The decision of the Examining Division was then given in a standard form (according to the Guidelines E-X, 4.4). It referred to communications of 22 November 1999 and 12 January 2001 for its grounds and reasoning for refusal.
- IV. In the first communication mentioned in the decision under appeal, the Examining Division had considered the set of claims as published in the PCT application.

Claim 1 read:

"1. A method of producing a lactosamine derivative with β 1-4 linkage, said method comprising:
(1) reacting

- (a) at least one donor substance Gal β OR, where R is an organic group, and
 - (b) at least one acceptor substance which is a glucopyranosamino derivative having the formula GlcNR''-R''', wherein NR'' is an azido, 2-N-acetyl-, 2-N-phthalimido, or another compound containing an inorganic and/or organic group bound to the 2-N-group of glucosamine, wherein R''' is a glycosidically bound fluoro or is an O-, C-, N- or S-glycosidically bound aliphatic or aromatic compound, with the proviso that if NR'' is NHAc then R''' is not OH and if NR'' is not NHAc then R''' may be OH,
 - c) in the presence of Bullera singularis or an E.C. group 3.2 glycosidase of essentially the same structure as an E.C. group 3.2 glycosidase obtained from Bullera singularis to form said lactosamine derivative; and
- (2) optionally isolating said lactosamine derivative."
(emphasis added).

V. The Examining Division had raised an objection of lack of novelty and inventive step in view of document D2 (WO-A-93 03168) and an objection of lack of clarity, both with regard to the embodiment of the claim underlined above.

The relevant passages in the communication read:

"4) The use of the word "essentially" in the claims can thus be interpreted in a variety of ways, and the structural closeness required of any EC group 3.2 enzyme for it to fall within the scope of the claims is unclear. Thus this gives rise to an objection as to lack of clarity of the claim (Art.84 EPC)."

"5) WO-A-93 03168 (D2) discloses, as identified in the International Preliminary Examination Report, methods for the synthesis of carbohydrate derivatives using enzymatic catalysis (see claims). Such methods encompass the methods of the present application, using EC group 3.2 glycosidases such as β -galactosidase (see paragraph bridging pp 2 and 3, and page 8). No mention is made in D2 of the yeast strain *Bullera singularis* which is used in the current application as the source of the enzyme. However, the current application also covers other enzymes having the same activity. Thus the subject matter of claims 1-12, 17, 19 and 23-25 is neither novel nor inventive with regard to D2 (Art.54 and 56 EPC)."

VI. The appellant filed a new set of claims. Claim 1 was identical to previous claim 1 with the exception of its part (c).

The amended part (c) read:

"(c) in the presence of *Bullera singularis* or an E.C. group 3.2 glycosidase having essentially the same structure and high β 1-4 regioselectivity as an E.C. Group 3.2 glycosidase obtained from *Bullera singularis* to form said lactosamine derivative; and" (emphasis added).

VII. In the second communication referred to in the contested decision the Examining Division had informed the appellant that the amended claims still lacked of clarity as well as novelty and inventive step in view of document D2 with regard to the embodiment in claim 1 underlined above.

The relevant passages read:

"3) In point 4) of the previous communication, the examining division raised an objection according to Art.84 EPC relating to the use of the word "essentially". This point has not been addressed by the applicant, and the objection thus still stands."

"5) WO-A-93 03168 (D2) discloses, as identified previously, methods for the synthesis of carbohydrate derivatives using enzymatic catalysis (see claims). Such methods encompass the methods of the present application, using EC group 3.2 glycosidases such as β -galactosidase (see paragraph bridging pp 2 and 3, and page 8). No mention is made in D2 of the yeast strain *Bullera singularis* which is used in the current application as the source of the enzyme. However, the current application also covers other enzymes having the same structure and regioselectivity.

Example 7 of D2 describes the synthesis of derivatives of Gal β 1-4GlcNAc, wherein there is substitution in the glycosyl ring. D2 thus prepares the same types of compounds as the present application, using the same types of enzymes, for which there is no evidence that these enzymes are not effectively regioselective using the substituted substrates.

It has already been explained that the use of the terminology "essentially" in the claims throws the scope of the claims into doubt. In addition, it has not been satisfactorily shown that the disclosure of D2 does not anticipate this. Thus the objections as to

novelty and inventive step with regard to D2 are maintained (Art.54 and 56 EPC)."

- VIII. With its statement of grounds of appeal the appellant filed an amended set of claims in which claim 1 was amended in part (c) and claim 17 was deleted. Claims 5, 7, 10 and 23 (as renumbered) were amended, too. Previous claims 18 to 25 were renumbered.

Part (c) of amended claim 1 read:

"(c) in the presence of Bullera singularis or a glycosidase obtained from Bullera singularis or a glycosidase obtained by recombinant techniques and having at least 70% homology with the amino acid sequence of the glycosidase obtained from Bullera singularis to form said lactosamine derivative; and" (emphasis added).

- IX. The Examining Division did not rectify its decision pursuant to Article 109 EPC.
- X. The appellant requests that the decision of the Examining Division is set aside and that the application is remitted back to the Examining Division for further prosecution.

Reasons for the Decision

1. The features on which the Examining Division had based its objection of lack of novelty, inventive step and clarity are no longer present in claim 1 or any other claim.

2. The reasoning given as an explanation for the objection that the subject-matter of claims 1-12, 17, 19 and 23-25 lacks novelty and inventive step was that document D2 discloses a method for producing a lactosamine derivative as claimed in claim 1 and using glycosidases falling under the definition in claim 1 "an E.C. group 3.2 glycosidase having essentially the same structure and high β 1-4 regioselectivity as an E.C. Group 3.2 glycosidase obtained from *Bullera singularis*".

This reasoning does not apply to the method of claim 1 as amended relating, inter alia, to embodiments where "a glycosidase obtained from *Bullera singularis*" or "a glycosidase obtained by recombinant techniques and having at least 70% homology with the amino acid sequence of the glycosidase obtained from *Bullera singularis*" are claimed.

Moreover, the objected term "essentially" is no longer present in claim 1.

3. Hence, since the reasoning given in the contested decision does not apply to the amended set of claims, the decision under appeal is to be set aside.
4. It follows from the considerations above that the amendments have changed the factual context of the claims. Therefore, a full examination of whether or not the amended claims are in accordance with the formal and substantive requirements of the EPC is necessary. The board considers that the nature of the amendments could give rise to objections. For example, it could be an issue whether claim 1 including the feature "a

glycosidase obtained by recombinant techniques and having at least 70% homology with the amino acid sequence of the glycosidase obtained from *Bullera singularis*" complies with the requirements of Article 123(2) EPC. The passage indicated by the appellant as a basis in the application documents as originally filed seems to suggest that variants of this type may not be used alone - as claimed -, but only together with the naturally occurring glycosidase. Moreover, it may also be an issue whether or not the application fulfils the requirements of Article 83 EPC with respect to this feature because the application documents do not disclose a nucleic acid or amino acid sequence.

Thus, in order to maintain the appellant's right to appeal to a second instance with regard to the amended claims, the Board finds it appropriate to exercise its discretion under Article 111(1) EPC and to remit the case to the department of first instance for further prosecution in accordance with the request of the appellant.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution on the basis of the claims filed with letter dated 1 November 2002.

Registrar:

Chair:

P. Cremona

U. M. Kinkeldey