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D E C I S I O N
of 23 September 2004

Case Number: T 1206/01 - 3.3.1
Application Number: 91908435.0
Publication Number: 0594612
IPC: C07J 9/00
Language of the proceedings: EN

Title of invention:

A substance for lowering high cholesterol level in serum and a method for preparig the same

Patentee:

Raisio Benecol Ltd.

Opponent:

Unilever N.V.

Headword:

Isostanol/RAISIO BENECOL

Relevant legal provisions:

EPC Art. 84, 111(1), 123(2)(3)

Keyword:

"Main request and first auxiliary request: added subject-matter (yes)"

"Second auxiliary request: added subject-matter (no) - extension of protection (no) - clarity (yes)"

"Remittal to first instance"

Decisions cited:

G 0002/88, T 0296/96

Catchword:

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Case Number: T 1206/01 - 3.3.1

D E C I S I O N
of the Technical Board of Appeal 3.3.1
of 23 September 2004

Appellant: Raisio Benecol Ltd.
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 11 October 2001
revoking European patent No. 0594612 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: A. J. Nuss
Members: P. P. Bracke
S. C. Perryman

Summary of Facts and Submissions

I. European patent No. 0 594 612 was granted with eleven claims, of which only Claims 1, 8 and 11 are relevant for the present decision. These claims read:

"1. A substance lowering cholesterol levels in serum, characterized in that it comprises a β -sitostanol fatty acid ester or a β -sitostanol fatty acid ester mixture, manufactured with a solvent free food grade process."

"8. A process for the preparation of the substance according to Claim 1, characterized in that free β -sitostanol is esterified with a fatty acid ester or a fatty acid ester mixture in the presence of an interesterification catalyst."

"11. A substance comprising a β -sitostanol fatty acid ester or a β -sitostanol fatty acid ester mixture for use in lowering cholesterol levels in serum."

II. The Opposition Division's decision to revoke the patent was based on sets of claims according to a main and an auxiliary request. Claim 1 according to the main request read:

"1. A substance comprising an amount of a β -sitostanol fatty acid ester or a mixture of β -sitostanol fatty acid esters effective to lower the cholesterol level in serum of a subject consuming the substance, wherein the β -sitostanol fatty acid ester or the mixture of β -sitostanol fatty acid esters was manufactured using a solvent-free, food grade esterification reaction."

Claim 1 according to the auxiliary request read:

"1. A substance adapted to provide 0.2 - 20 g/day of a β -sitostanol fatty acid ester or a mixture of β -sitostanol fatty acid esters effective to lower the cholesterol level in serum of a subject consuming the substance, wherein the β -sitostanol fatty acid ester or the mixture of β -sitostanol fatty acid esters was manufactured using a solvent-free, food grade esterification reaction."

In particular, the Opposition Division was of the opinion that the requirements of Articles 123(2), 83 and 84 EPC and the requirement of novelty were met, but that the claimed substances were not inventive.

III. With telefax of 23 August 2004 the Appellant (Proprietor of the patent) filed a set of twelve claims with the wording of Claim 1 being identical with the wording of Claim 1 of the main request underlying the contested decision.

At the oral proceedings before the Board, which took place on 23 September 2004, the Appellant filed sets of claims according to a first and a second auxiliary request.

The first auxiliary request consisted of three claims with Claim 1 reading:

"1. A substance comprising a β -sitostanol fatty acid ester or a β -sitostanol fatty acid ester mixture, for use in lowering cholesterol levels in serum, which substance is adapted to provide said β -sitostanol fatty

acid ester or said β -sitostanol fatty acid ester mixture at a daily dose of 0.2 - 20 g/d."

The second auxiliary request consisted of 2 claims reading:

"1. A process for the preparation of a substance comprising a β -sitostanol fatty acid ester or a β -sitostanol fatty acid ester mixture in which free β -sitostanol is esterified with a fatty acid ester or a fatty acid ester mixture in the presence of an interesterification catalyst, wherein no substance other than free stanol, a fatty acid ester or a fatty acid ester mixture and a catalyst are used in the esterification reaction."

"2. A process according to Claim 1, characterized in that the reaction is carried out at a temperature of approx. 90-120°C and under a vacuum of approx. 0.67-2.0 kPa."

- IV. The Respondent (Opponent) essentially argued that Claim 1 according to the main request and Claim 1 according to the first auxiliary request did not meet the requirement of Article 123(2) EPC. Moreover, the Respondent contested that Claim 1 of the second auxiliary request met the requirements of Article 123(3) EPC and of clarity according to Article 84 EPC.
- V. The Appellant argued that a skilled person would have interpreted the statement in the sentence bridging pages 6 and 7 of the application as filed, that no substances other than free stanol, a fatty acid ester or a fatty acid ester mixture and a catalyst are used

in the esterification reaction, as meaning that the process is conducted free of solvent. Moreover, the Appellant submitted that substances adapted to provide said β -sitostanol fatty acid ester or said β -sitostanol fatty acid ester mixture at a daily dose of 0.2 - 20 g/d were disclosed in the sentence bridging pages 8 and 9 of the application as filed. Finally, the Appellant submitted that Claim 1 of the second auxiliary request unambiguously defined the esterification reaction and that it did not extend the protection conferred in comparison with granted Claim 11.

VI. The Appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request filed on 23 August 2004, or of the first or second auxiliary requests submitted at the oral proceedings on 23 September 2004 or that the case be remitted to the first instance for further prosecution on the basis of one of the above requests.

The Respondent requested as main request that the appeal be dismissed, or as auxiliary request that the case be remitted to the first instance for further prosecution on the basis of the second auxiliary request submitted by the Appellant at the oral proceedings on 23 September 2004.

Reasons for the Decision

1. The appeal is admissible.

2. *Main request*

2.1 Article 123(2) EPC

In accordance with the established jurisprudence of the Boards of Appeal, the relevant question to be decided in assessing whether an amendment adds subject-matter extending beyond the content of the application as filed, is whether the proposed amendments were **directly and unambiguously** derivable from the application as filed. It was not contested that the PCT application, published as WO 92/19640, represented the application as filed.

The Respondent essentially submitted that WO 92/19640 did not disclose a solvent free esterification reaction as defined in Claim 1.

In this respect, the Appellant submitted that the sentence bridging pages 6 and 7, stating that "no substances other than free stanol, a fatty acid ester or a fatty acid ester mixture, and a catalyst are used in the esterification reaction" would be interpreted by a skilled reader as meaning that nothing else than the cited reactants is present in the esterification reaction and, consequently, that also a solvent is not present therein.

However, in deciding whether subject matter has been added by the amendment, the relevant question is in the

present case not whether the use of a solvent is excluded by the sentence bridging pages 6 and 7 of WO 92/19640, but whether the wording "solvent-free" in Claim 1 restricts the esterification reaction to one wherein only stanol, fatty acid ester(s) and catalyst is present.

Since the wording "solvent-free" only excludes the presence of a solvent in the esterification reaction, but not the presence of other additive, a solvent-free esterification reaction is not to be equated with an esterification reaction wherein no substances other than free stanol, a fatty acid ester or a fatty acid ester mixture, and a catalyst are used.

Consequently, Claim 1 is amended in such a way that it contains subject-matter which extends beyond the content of the application as filed, contrary to the requirement of Article 123(2) EPC. Therefore, the main request must be refused.

3. *First auxiliary request*

3.1 Article 123(2) EPC

3.1.1 The Respondent contested that WO 92/19640 discloses a substance adapted to provide β -sitostanol fatty acid ester or β -sitostanol fatty acid ester mixture at a daily dose of 0.2 - 20 g/d, as defined in Claim 1.

The Appellant, however, submitted that support can be found in the paragraph bridging pages 8 and 9 of WO 92/19640, which reads:

"The studies carried out show clearly that by the addition of β -sitostanol fatty acid esters to, for example, food fats, significant advantages can be achieved both in the national nutrition and in the treatment of hypercholesterolemia, since 1) the mixture lowers cholesterol values in serum, 2) the mixture does not increase serum plant sterol concentrations, 3) the mixture can be used daily as a fat substitute in cooking normal food, even in large doses (0.2 - 20 g/d), whereby the intake of energy from fat decreases."

3.1.2 Whereas present Claim 1 defines a substance adapted to provide β -sitostanol fatty acid ester or β -sitostanol fatty acid ester mixture at a daily dose of 0.2 - 20 g/d, from the above-cited paragraph it may only be directly and unambiguously derived that mixtures obtained by adding β -sitostanol fatty acid esters to, for example, food fats, can be used as a fat substitute at doses of 0.2 - 20 g/d. Nowhere from this paragraph may it be derived that such fat substitute mixtures would **provide** β -sitostanol fatty acid ester or β -sitostanol fatty acid ester mixture at a daily dose of 0.2 - 20 g/d.

3.1.3 As support of his argument, that the mixture mentioned in the above-cited paragraph was to be understood as a mixture of β -sitostanol fatty acid esters and not as a fat substitute mixture, the Appellant referred to the second paragraph on page 7 of the application as filed, wherein it is stated that "the interesterified mixture can be added directly to fat-containing foods or be used as such".

However, the content of a document as originally filed may not be seen as a reservoir of features, from which features pertaining to separate embodiments could be combined in order to artificially create a particular embodiment (T 296/96, not published in the OJ EPO, point 3.1 of the Reasons of the Decision). When assessing whether a feature has been disclosed in a document, the relevant question is whether a skilled person would consider combining the different features cited in that document.

This is not the case here, since nowhere from the application as filed may it be derived that the interesterified mixture disclosed in the second paragraph on page 9 of WO 92/19640 would be identical with the mixture described in the paragraph bridging pages 8 and 9 of WO 92/19640.

Therefore, Claim 1 is amended in such a way that it contains subject-matter which extends beyond the content of the application as filed, contrary to the requirement of Article 123(2) EPC. Thus, also the first auxiliary request must be refused.

4. *Second auxiliary request*

4.1 Article 123(2) EPC

Claim 1 results from a combination of the process features of Claim 8 with the product features of Claim 1 and the process features described in the sentence bridging pages 6 and 7 of WO 92/19640. The process features in Claim 2 correspond with the ones of Claim 9 of WO 92/19640. The Board is thus satisfied

that the claims were not amended in such a way as to contain subject-matter extending beyond the contents of the application as filed. This was not objected by the Respondent.

4.2 Article 123(3) EPC

Granted Claim 8 was restricted by its reference to granted Claim 1 to a process of preparing substances comprising β -sitostanol fatty acid ester or a β -sitostanol fatty acid ester mixture, manufactured with a solvent free food grade process (see point I). Since the process of present Claim 1 does not contain any restriction that the β -sitostanol fatty acid ester or the β -sitostanol fatty acid ester mixture must be manufactured with a solvent free food grade process, the Respondent was of the opinion that by present Claim 1 the protection conferred by the process claim is extended, contrary to the requirement of Article 123(3) EPC.

However, in examining the requirement of Article 123(3) EPC, not only the extent of protection conferred by a particular claim of the granted patent is to be taken into consideration, but the protection conferred by the entire set of granted claims.

Since granted Claim 11, which was directed to a substance comprising a β -sitostanol fatty acid ester or a β -sitostanol fatty acid ester mixture, only further contained an indication of purpose, namely "for use in lowering cholesterol levels in serum", and did not contain any restriction as to the way of manufacture of the β -sitostanol fatty acid ester or the β -sitostanol

fatty acid ester mixture, the protection conferred by granted Claim 11 was not restricted to substances comprising esters manufactured by any particular process.

In accordance with the established jurisprudence of the Boards of Appeal, a product claim confers protection on that product regardless of the process or method by which it is prepared. Therefore, a change of category from a granted product-claim to a process-claim restricted to one or more methods of preparing the product does not extend the protection conferred thereby.

In this respect, the Respondent submitted that granted Claim 11 was restricted by the feature "for use in lowering cholesterol levels in serum".

However, it is generally accepted as a principle underlying the EPC, that a claim to a physical entity per se confers absolute protection upon such physical entity, for all uses of such physical entity, whether known or unknown (see Reason 5 of G 2/88 OJ EPO 1990, 93). Therefore, the protection conferred by granted Claim 11 was not restricted by the feature "for use in lowering cholesterol levels in serum".

Therefore, present Claim 1 meets the requirement of Article 123(3) EPC.

4.3 Clarity according to Article 84 EPC

The Respondent submitted that from the wording of Claim 1 it is not clear whether in the esterification

reaction only free β -sitostanol, fatty acid ester(s) and a catalyst are contained or whether other substances which do not take part in the reaction, such as an inert solvent, may be present. In this respect he referred to page 3, lines 41 to 43, of the patent in suit, where it is stated that the β -sitostanol contains approximately 6% campestanol.

However, the wording of Claim 1 does not exclude that the reaction mixture contains other stanols than β -sitostanol. Moreover, the requirement in the claim that only free stanol, fatty acid ester(s) and an interesterification catalyst are **used** in the esterification reaction excludes the possibility of having, for example, inert solvents present. Indeed, if inert solvents were present, such solvents were effectively **used** in the esterification reaction.

In the absence of any further clarity objections by the Respondent and in view of the fact that the Board has no such objections of its own, Claims 1 and 2 are considered to meet the requirement of clarity according to Article 84 EPC.

4.4 Thus the Board comes to the conclusion that Claims 1 and 2 of the second auxiliary request meet the requirements of Article 123(2) and (3) EPC and the requirement of clarity according to Article 84 EPC.

5. *Remittal*

All reasons given by the Opposition Division's decision for revoking the patent in suit concern the substances claimed in Claim 1 in the sets of claims underlying the

decision; the contested decision is completely silent about the patentability of the claimed process.

Having regard to the fact that the function of the Boards of Appeal is primarily to give a judicial decision upon the correctness of the earlier decision taken by the first instance and in order to give the Parties the possibility of having their case examined and decided by two instances, the Board exercises its discretionary power under Article 111(1) EPC and remits the case to the Opposition Division for further prosecution.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance for further prosecution on the basis of the second auxiliary request submitted at the oral proceedings on 23 September 2004.

The Registrar:

The Chairman

N. Maslin

A. Nuss