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D E C I S I O N
of 8 April 2002

Case Number: T 0269/97 - 3.3.4

Application Number: 90200532.1

Publication Number: 0387945

IPC: A61K 37/62

Language of the proceedings: EN

Title of invention:
A composition for the treatment of exocrine insufficiency of the pancreas, and the use of said composition

Patentee:
Scharpé, Simon Lodewijk

Opponent:
Solvay Pharmaceuticals GmbH

Headword:
Composition for treating insufficiency of the pancreas/SHARPÉ

Relevant legal provisions:
EPC Art. 54

Keyword:
"Novelty (no)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0269/97 - 3.3.4

D E C I S I O N
of the Technical Board of Appeal 3.3.4
of 8 April 2002

Appellant: (Proprietor of the patent)
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Respondent: (Opponent)
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Representative:
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 24 January 1997 revoking European patent No. 0 387 945 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairwoman: U. M. Kinkeldey
Members: R. E. Gramaglia
S. C. Perryman

Summary of Facts and Submissions

I. The appeal is against the decision of the opposition division revoking European patent No. 0 387 945 (application No. 90 200 532.1) filed on 6 March 1990, which had been opposed by the respondent (opponent) on the grounds of lack of novelty and inventive step. Independent claim 1 as granted read as follows:

"1. Composition for the treatment of exocrine insufficiency of the pancreas, comprising as active components a microbial lipase and a mammalian pancreatic extract, and a pharmaceutically acceptable carrier or diluent".

Claims 2 to 9 related to specific embodiments of the composition of claim 1, whereas claims 10 and 11 were addressed to medical uses of said compositions.

II. The reasons given for the refusal was that the subject-matter of claim 1 filed on 17 March 1995, amended to include the wording "wherein the carrier or diluent are substantially not resistive against gastric acid" did not satisfy the requirements of Article 123(2)(3) EPC. The opposition division also expressed the view that the composition according to claim 1 as granted lacked novelty over Lipazym® disclosed by documents:

(D1a) Rote Liste 1975, Lipazym® Klinge (65241 Cb);

(D1b) Lipazym® Klinge (accompanying leaflet) and

(D2) Helwig Arzneimittel, Vol. II, Chapter 38, pages 42-51, Wissenschaftliche Verlagsgesellschaft mbH, Stuttgart

(October 1988)

and was obvious in view of the combined teachings of documents:

(D3) DE-A-3642853 and

(D5) Chemical Abstracts, Vol. 97, No. 25, Abstract No. 211076v & Farm. Tijdschr. Belg., Vol. 59, No. 3, pages 231 to 256 (1982).

III. With the statement setting out the grounds of appeal the appellant (patentee) submitted a new claim 1 differing from the granted one by the addition at its end of the wording "disclaiming a composition in which the microbial lipase and the mammalian pancreatic extract are enclosed by an acid insoluble envelope".

IV. The submissions by the appellant can be summarized as follows:

Novelty (Article 54 EPC)

- Revised claim 1 was novel because it disclaimed Lipazym® disclosed by documents (D1a), (D1b) and (D2), wherein the mammalian pancreatic extract (pancreatin) and the microbial lipase (from Rhizopus arrhizus) were enclosed by an acid insoluble envelope.

- The pharmaceutical compositions disclosed by document (D3) comprised pancreatin and/or lipase from Rhizopus arrhizus and a pH-lowering compound such as $NaHCO_3$ or $Al(OH)_3$. Since all these components were enclosed in an acid insoluble

envelope, these pharmaceutical compositions did not fall under the scope of revised claim 1.

Inventive step (Article 56 EPC)

- The patent in suit obviated the need for an acid-resistant envelope for compositions comprising a mammalian pancreatic extract and a microbial lipase. Combining the teaching of document (D5) with that of document (D3) or documents (D1a)/(D1b)/(D2) would not have led to the claimed composition, devoid of an acid insoluble envelope, as documents (D1a)/(D1b)/(D2) taught this to be mandatory.

V. The submissions by the respondents can be summarized as follows:

Novelty (Article 54 EPC)

- The disclaimer in claim 1 merely excluded from protection those compositions wherein **both** pancreatin and the microbial lipase were enclosed within an acid insoluble envelope. Therefore, the claimed pharmaceutical composition lacked novelty in view of the prior use of Lipazym®, wherein only pancreatin was enclosed by an acid insoluble envelope, while the microbial lipase from Rhizopus arrhizus was not. This was shown by the passage in document (D1b): "die gegenüber die Magensäure empfindlichen Pankreasenzyme in Kügelchen vorliegen, die durch eine säureunlösliche Hülle geschütz sind" and by document:

(D6) Test report dated 27 May 1977 of Dr. Peschke

and Dr. Freytag.

Moreover, it was already known from document (D5) that the lipase from Rhizopus arrhizus was stable over the pH range found in the stomach and that hence it could be administered without an acid insoluble envelope.

Inventive step (Article 56 EPC)

- The claimed composition was obvious by combining the teaching of document (D5) with that of document (D3) or (D2).

VI. The appellant (patentee) requested that the decision under appeal be set aside and that the patent be maintained on the basis of claim 1 submitted with the statement of grounds of appeal and claims 2 to 11 as granted.

The respondents (opponents) requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

Novelty

2. Claim 1 at issue is directed to a composition for the treatment of exocrine insufficiency of the pancreas comprising as active components (i) a microbial lipase and (ii) a mammalian pancreatic extract (besides a

pharmaceutically acceptable carrier or diluent). Owing to the disclaimer in the claim ("disclaiming a composition in which the microbial lipase and the mammalian pancreatic extract are enclosed by an acid insoluble envelope"), **both** active components (i) and (ii) have to be devoid of an acid-resistant envelope. Claim 1 thus does not exclude compositions in which only one of active components (i) and (ii) is enclosed by an acid insoluble envelope, while the other lacks such envelope.

3. According to document (D1b), Lipazym® consists of an acid-soluble gelatin capsule containing "enzyme pellets", which capsule dissolves in the stomach and the enzyme pellets distribute homogeneously throughout the stomach content ("Die kurz nach Einnahme der Gelatinkapsel frei werdenden Enzymkügelchen verteilen sich bereits im Magen gleichmäßig im Nahrungsbrei"). In order to avert pancreatin inactivation by the gastric juice, it is stated in the document that the pellets containing pancreatin (component (ii)) are enclosed by an acid insoluble envelope ("die gegenüber der Magensäure empfindlichen Pankreasenzyme in Kügelchen vorliegen, die durch eine säureunlösliche Hülle geschütz sind"). A reference is made again to the "pancreatin pellets" ("die Pankreatin-Kügelchen").

4. The fact that document (D1b) places much emphasis on acid-resistant "pancreatin pellets" rather than on eg acid-resistant "Lipazym® pellets" (comprising both components (i) and (ii) listed under the heading "Zusammensetzung") shows that the gelatin capsule contains two kinds of enzyme pellets, only one of which is anti-acid coated, namely the "pancreatin pellets" (containing component (ii)), while the other pellets

(containing component (i)) are not. This is further supported by document (D6) (see Section V above), which the appellant has never questioned since its introduction into the proceedings in September 1997. The respondent has also drawn attention (see bottom of page 3 of the submission dated 15 September 1997) to document:

(D4): DE-A-1 642 654

showing that lipase from Rhizopus arrhizus (component (i) of Lipazym®) to be taken orally in the treatment of insufficiency of the pancreas (see page 27, line 11) does not require any anti-acid coating (see page 26: "die erfindungsgemäße Lipase ihre Wirkung sowohl im Darm als auch im Magen entfalten kann"; emphasis added).

5. In conclusion, Lipazym® disclosed by documents (D1a), (D1b) and (D2) is a composition in which only one of active components (i) and (ii) is enclosed by an acid insoluble envelope, while the other lacks such envelope, a feature not covered by the disclaimer and an embodiment falling under the scope of claim 1 at issue (see point 2 supra), which thus lacks novelty.

6. Lack of novelty on the above basis is an issue raised by the respondent, so that the appellant has had the opportunity to present his comments on this, in accordance with the requirements of Article 113(1) EPC. There is thus no need to raise or consider any other issues under Article 123(2) or 56 EPC as a basis for the present decision.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairwoman:

P. Cremona M. Kinkeldey