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Datasheet for the decision of 26 June 2023

Case Number: T 0773/20 - 3.3.07

Application Number: 14176579.2

Publication Number: 2818160

IPC: A61K9/20, A61K9/28, A61K38/43

Language of the proceedings: EN

Title of invention:
Enteric coated, low-strength pancrelipase formulations

Patent Proprietor:
Allergan Pharmaceuticals International Limited

Opponent:
Mathys & Squire LLP

Headword:
Pancrelipase formulations / ALLERGAN

Relevant legal provisions:
EPC Art. 76(1)

Keyword:
Subject-matter extends beyond content of earlier application (yes)

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Case Number: T 0773/20 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 26 June 2023

Appellant: (Opponent)	Mathys & Squire LLP The Shard 32 London Bridge Street London SE1 9SG (GB)
Representative:	Mathys & Squire The Shard 32 London Bridge Street London SE1 9SG (GB)
Respondent: (Patent Proprietor)	Allergan Pharmaceuticals International Limited Clonshaugh Business & Technology Park Dublin, D17 E400 (IE)
Representative:	Forresters IP LLP Skygarden Erika-Mann-Straße 11 80636 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 10 February 2020 concerning maintenance of the European Patent No. 2818160 in amended form.**

Composition of the Board:

Chairman	E. Duval
Members:	M. Steendijk
	Y. Podbielski

Summary of Facts and Submissions

I. European patent 2 818 160 ("the patent") was granted on the basis of twenty-six claims.

Independent claim 1 as granted related to:

"A pharmaceutical composition comprising a digestive enzyme powder blend comprising a digestive enzyme, and a carrier wherein:

a) the total amount of digestive enzyme in the composition is from about 4 to about 19% by weight and the carrier comprises particles with a size greater than 100 µm."

II. The patent resulted from a divisional application with respect to the European patent application 11788223.3 originally published under the international publication number WO2012/042372. The patent was opposed on the grounds that its subject-matter lacked novelty and inventive step, that the claimed invention was not sufficiently disclosed and that the patent comprised subject-matter extending beyond the content of the application and the earlier application as originally filed.

The opponent filed the appeal against the interlocutory decision of the opposition division that the patent as amended in accordance with the main request met the requirements of the EPC.

The main request on which the decision was based related to the set of claims filed as main request on 2 January 2019.

Claim 1 of this main request defines:

"A pharmaceutical composition for use in treating or preventing a disorder or condition associated with a digestive enzyme deficiency comprising a digestive enzyme powder blend comprising a digestive enzyme, and a carrier wherein:
the total amount of digestive enzyme in the composition is from about 4 to about 19% by weight and the carrier is microcrystalline cellulose having a particle size greater than 100 µm."

The opposition division arrived *inter alia* at the following conclusion:

> The definition of a digestive enzyme powder blend in claim 1 of the main request was adequately based on the original disclosure of a low pancrelipase content enzyme powder having desired uniformity, segregation and flowability. The definition in claim 1 of the main request, that the composition comprises a total amount of digestive enzyme from about 4-19% by weight and a carrier which is microcrystalline cellulose having a particle size greater than 100 µm, did not represent a new combination of features with respect to the original disclosure.
>
> Considering the original disclosure as a whole the digestive enzyme powder blend was to be understood as representing a pharmaceutical composition.
>
> The main request therefore complied with Articles 123(2) and 76(1) EPC.

III. With the reply to the appeal the respondent maintained its auxiliary requests 1-3 which had been filed together with the main request on 2 January 2019.

Claim 1 of auxiliary request 1 additionally defines with respect to claim 1 of the main request that the digestive enzyme is pancrelipase.

Claim 1 of auxiliary request 2 additionally defines with respect to claim 1 of auxiliary request 1 that the total amount of the digestive enzyme is about 5 to about 19%.

Claim 1 of auxiliary request 3 additionally defines with respect to claim 1 of auxiliary request 2 that the digestive enzyme is porcine derived pancrelipase.

IV. In its communication pursuant to Article 15(1) RPBA the Board expressed *inter alia* doubts that the main request and auxiliary requests 1-3 complied with Articles 76(1) and 123(2) EPC.

V. The respondent withdrew its request for oral proceedings with its letter of 24 May 2023.

With the communication of 5 June 2023 the Board cancelled the oral proceedings that had been scheduled for 7 July 2023.

VI. The arguments of the appellant relevant to the present decision can be summarized as follows:

The applications as originally filed did not disclose the defined composition comprising a digestive enzyme powder blend as a pharmaceutical composition. The disclosed therapeutical use and

pharmaceutical excipients concerned compositions comprising the enzyme powder blend in the form of beads.

VII. The arguments of the respondent relevant to the present decision can be summarized as follows:

The content of the divisional application as originally filed was identical to the content of the parent application as originally filed, which disclosed the feature of an enzyme powder blend on page 6, lines 6-8 and presented on page 1 (under "Field of invention") and on page 4 (under "Brief summary") a general disclosure of the invention as relating to pharmaceutical compositions.

VIII. The appellant requested that the decision under appeal be set aside and that the patent be revoked in its entirety.

IX. The respondent requested that the appeal be dismissed and that the patent be maintained in accordance with the main request on which the decision under appeal was based.

Subsidiarily, the respondent requested that the patent be maintained on the basis of one of auxiliary requests 1-3 filed on 2 January 2019.

Reasons for the Decision

Subject-matter extending beyond the content of the earlier application as filed

1. Claim 1 in accordance with the main request specifically defines a pharmaceutical composition for use in treating or preventing a disorder or condition associated with a digestive enzyme deficiency comprising a digestive enzyme powder blend. Auxiliary requests 1-3 also define in claim 1 a pharmaceutical composition for use in treating or preventing a disorder or condition associated with a digestive enzyme deficiency comprising a digestive enzyme powder blend wherein the digestive enzyme is specified as a pancrelipase or a porcine derived pancrelipase.

2. The parent application as originally filed (see WO2012/042372) only mentions the feature of an enzyme powder blend on page 6, lines 6-8:

"In the present invention, low pancrelipase content powder blends are disclosed that have high content uniformity and very low segregation while also showing excellent flowability. These blends are particularly suitable for producing the low or diluted pancrelipase beads."

3. The respondent relied on the following passages in the parent application to argue that the original disclosure generally presents the compositions of the invention as pharmaceutical compositions useful in treatment and prevention of disorders as defined in the claims :

"In various embodiments, the present invention is directed to pharmaceutical compositions having a stable, low (diluted) digestive enzyme content comprising at least one digestive enzyme and at least one carrier, or a dosage form thereof. In other embodiments, the invention is also directed to processes of preparation of the composition or the dosage form. In additional embodiments, the invention is directed to the treatment and prevention of disorders associated with a digestive enzyme deficiency in a patient in need thereof, comprising administering to said patient a pharmaceutically acceptable amount of the composition having a stable low digestive enzyme content or dosage form thereof."(page 1, under "Field of invention") and

"To achieve these and other objects, and to meet these and other needs, and in view of its purposes, the present invention relates to a stable low dosage digestive enzyme composition, and dosage form comprised thereof." (page 4, under "Brief summary")

4. The Board observes, however, that the passage on page 6 describing enzyme powder blends explicitly teaches that the enzyme powder blends are suitable for producing the low or diluted enzyme beads.

Notably, in a directly preceding passage the original parent application describes that in the composition of the invention the digestive enzymes are in form of beads (see page 5, lines 23-24):

"In the composition of the invention, the digestive enzymes are in form of beads, preferably in the form of enterically coated pancrelipase beads."

This teaching is consistent with the passage on pages 11-12 of the original parent application, wherein flowable blends of enzyme and carrier are described to be suitable for loading tablets, and beads of the composition or oral dosage forms of the inventions are described to optionally comprise further excipients:

"The blends comprising pancrelipase and carrier/s and optionally further excipients must have excellent flow properties and consistent particle size. The flow characteristics should enable the loading of the tablet die without difficulty. A sieving procedure can be incorporated to ensure a more controlled even particle size. This is important to guarantee thorough mixing of the components and final homogeneity of the blend. In addition to the digestive enzymes and the carrier, the beads of the compositions or oral dosage forms of the present invention can further comprise one or more pharmaceutically acceptable excipients. In one embodiment of the invention the amount of excipient is about 5% w/w of the blend. The term "excipients" includes other pharmaceutically acceptable ingredients added to the active component(s) of a composition (e.g., the diluted digestive enzymes) in order to improve processing, stability, palatability, etc."

5. The Board therefore concludes that the skilled person would not directly and unambiguously derive from the original parent application that a composition comprising a digestive enzyme powder blend represents *per se* a pharmaceutical composition for use as defined in claim 1 of the main request or auxiliary requests 1-3.

6. Accordingly, the main request and auxiliary requests 1-3 do not comply with Article 76(1) EPC

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

B. Atienza Vivancos E. Duval

Decision electronically authenticated