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**Datasheet for the decision
of 7 May 2025**

Case Number: T 2202/22 - 3.3.04

Application Number: 17169929.1

Publication Number: 3219316

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A61K45/06, A61K9/08, A61K9/14

Language of the proceedings: EN

Title of invention:
MIXTURE OF FATTY ACIDS (F.A.G., FATTY ACIDS GROUP) FOR USE IN
THE TREATMENT OF INFLAMMATORY PATHOLOGIES

Patent Proprietor:
Again Life Italia Srl

Opponent:
N.V. NUTRICIA

Relevant legal provisions:
EPC Art. 56
RPBA 2020 Art. 13(2)

Keyword:

Amendment after notification of Art. 15(1) RPBA communication
(yes)

Inventive step - (yes)



Beschwerdekammern

Boards of Appeal

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Case Number: T 2202/22 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 7 May 2025

Appellant:

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Decision under appeal:

**Decision of the Opposition Division of the
European Patent Office posted on 28 July 2022
revoking European patent No. 3219316 pursuant to
Article 101(3) (b) EPC**

Composition of the Board:

Chairman

J.-M. Schwaller

Members:

S. Albrecht

R. Romandini

Summary of Facts and Submissions

- I. This decision concerns the appeal filed by the proprietor of European patent 3 219 316 against the opposition division's decision to revoke the patent.
- II. Document D1: US 2010/0113387 A1, filed during the opposition proceedings, is relevant to this decision.
- III. In the statement of grounds of appeal, the appellant requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or, alternatively, maintained in amended form on the basis of one of the sets of claims according to auxiliary requests 1 to 23.
- IV. In the reply, the opponent (respondent) requested *inter alia* the dismissal of the appeal.
- V. In reply to the Board's communication pursuant to Article 15(1) RPBA, with letter dated 29 April 2025 the appellant withdrew auxiliary requests 1 to 23 and filed four sets of claims as auxiliary requests 1 to 4, respectively. Claim 1 of auxiliary request 3 reads:

"1. Pharmaceutical composition comprising a mixture characterized in that it comprises palmitic acid, oleic acid, stearic acid, linoleic acid and alpha linolenic acid and the physiologically acceptable excipient N-2 hydroxyethyl palmitamide, for use in the treatment of inflammation of the genital mucosa."
- VI. Oral proceedings took place on 7 May 2025 by videoconference in the presence of both parties. In the course of these proceedings, the appellant withdrew the

main request and auxiliary requests 1 and 2. With regard to auxiliary request 3, the respondent stated that it did not object to this request being admitted into the proceedings and that its sole objection against this request was lack of inventive step. The parties' final requests were the following

The appellant requested that the patent be maintained on the basis of the set of claims filed as auxiliary request 3 with letter of 29 April 2025.

The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. *Auxiliary request 3 - admittance (Article 13(2) RPBA)*

At the oral proceedings, the Board exercised its discretion to admit this request into the appeal proceedings and the respondent did not object thereto.

2. *The claimed subject-matter*

2.1 Independent claim 1 of auxiliary request 3 ("claim 1") is a purpose-limited product claim drawn up in accordance with Article 54(5) EPC.

2.2 The claimed product is a pharmaceutical composition comprising a mixture of at least six components, namely

(a) the fatty acids palmitic acid, oleic acid, stearic acid, linoleic acid, and alpha-linolenic acid, and

(b) the physiologically acceptable excipient N-2 hydroxyethyl palmitamide ("PEA").

2.3 The claimed purpose is the use in the treatment of inflammation of the genital mucosa. It was not in dispute that this use constitutes a specific use in a method of treatment by therapy referred to in Article 53(c) EPC.

2.4 According to established case law, attaining the claimed therapeutic effect is a functional technical feature of claims directed to medical uses. In the case at issue, the feature providing for the claimed anti-inflammatory effect is the pharmaceutical composition defined in claim 1.

3. *Inventive step*

3.1 *Starting point ("the closest prior art")*

It was common ground that inventive step of the subject-matter of claim 1 should be assessed starting from the fatty acid extract disclosed in Table 2 of document D1 (see right-most column of this Table). This extract consists of a multitude of fatty acids including palmitic acid, oleic acid, stearic acid and serves different therapeutic purposes (see claim 13 of document D1).

3.2 *Distinguishing features vis-à-vis the closest prior art*

3.2.1 Undisputedly, document D1 fails to disclose PEA and the specific therapeutic use recited in claim 1.

3.2.2 Consequently, the subject-matter of claim 1 differs from the closest prior art at least in that the claimed composition comprises the physiologically acceptable excipient PEA and in that the therapeutic indication of inflammation of the genital mucosa is to be treated.

3.2.3 The respondent contested the appellant's position that the subject-matter of claim 1 further differed from the closest prior art in that the mixture recited in this claim contained alpha-linolenic acid and in that the overall number of fatty acids in this mixture was restricted to five.

3.2.4 In the following assessment of inventive step, the Board assumes, for the sake of argument and in the respondent's favour, that the distinguishing features identified by the respondent constitute the sole distinguishing features with respect to the closest prior art.

3.3 *Objective technical problem and solution*

3.3.1 To formulate the objective technical problem, it is necessary to establish the technical effect(s) achieved by the aforementioned distinguishing features.

3.3.2 In agreement with the respondent, the Board finds that no technical effect can be assigned to the presence of the physiologically acceptable excipient PEA in the mixture recited in claim 1.

- 3.3.3 As regards the claimed therapeutic use, the appellant submitted that this feature provided for an effective treatment of inflammation of the genital mucosa. In support of its case, the appellant referred to the *in-vivo* human study disclosed in paragraphs [0217] to [0234] of the patent.
- 3.3.4 The respondent did not contest the appellant's submissions in this respect and the Board does not see any reason to put these into question either.
- 3.3.5 Consequently, the objective technical problem to be solved starting from the closest prior art is to provide a further therapeutic use of a fatty acid-based composition.
- 3.3.6 The proposed solution to this problem is the treatment of inflammation of the genital mucosa with the pharmaceutical composition recited in claim 1.
- 3.4 *Obviousness of the proposed solution*
- 3.4.1 The sole prior art disclosure referred to by the respondent to support obviousness of the subject-matter of claim 1 is claim 13 of document D1. This claim pertains to a method of stimulating and/or initiating the process of defecation comprising administering to the rectum and/or intestines one or more fatty acids in order to stimulate the polymodal nociceptors in the rectal mucosa.
- 3.4.2 At the oral proceedings, the respondent contended that this disclosure would have led the skilled person in the direction of the claimed therapeutic use.

- 3.4.3 The Board does not concur, because undisputedly, the rectal and the genital mucosa are mucous membranes which are closely located to one another in the human body. However, as correctly observed by the appellant at the oral proceedings, the therapeutic use disclosed in claim 13 of document D1 is distinct from that recited in claim 1. In the method described in claim 13 of document D1, the one or more fatty acids initiate and/or stimulate the process of defecation through stimulation of polymodal nociceptors located in the mucosa in question (rectal mucosa). This is in clear contrast to claim 1 under consideration which requires the claimed composition to exert an anti-inflammatory action to treat an inflamed (genital) mucosa.
- 3.4.4 The respondent did not point the Board to any prior art disclosure on the basis of which the skilled person would have extrapolated the therapeutic effect described in claim 13 of document D1 (stimulation of polymodal nociceptors in the rectal mucosa) to the treatment of inflammation of the genital mucosa.
- 3.4.5 In the absence of any such disclosure, the Board concludes that the subject-matter of claim 1 and, by the same token, that of dependent claims 2 to 12 would not have been obvious to the skilled person having regard to the cited prior art.
4. No other objections were raised against the allowability of the claims of auxiliary request 3, and the Board does not see any reason for raising anyone on its own motion under Article 101(3) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division with the order to maintain the patent in amended form on the basis of the claims of auxiliary request 3 filed with letter of 29 April 2025, and a description and drawings to be adapted where appropriate.

The Registrar:

The Chairman:



I. Aperribay

J.-M. Schwaller

Decision electronically authenticated