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**Datasheet for the decision  
of 30 April 2020**

**Case Number:** T 0005/17 - 3.3.07

**Application Number:** 09781176.4

**Publication Number:** 2323672

**IPC:** A61K33/06, A61K33/12, A61P17/00

**Language of the proceedings:** EN

**Title of invention:**

COMPOSITIONS FOR THE PROPHYLAXIS AND TREATMENT OF  
DERMATOLOGICAL/MUCOSAL DISEASES, AND USES THEREOF

**Applicant:**

Despharma Egészségügyi Szolgáltató Korlátolt  
Felelősségű Társaság

**Headword:**

**Relevant legal provisions:**

EPC Art. 84

**Keyword:**

Claims - clarity (no)

**Decisions cited:**

T 1819/07, T 0967/08, T 0045/10



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Case Number: T 0005/17 - 3.3.07

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.07**  
**of 30 April 2020**

**Appellant:** Despharma Egészségügyi Szolgáltató Korlátolt  
(Applicant) Felelősségű Társaság  
Pagony u. 50.  
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**Representative:** Brantsandpatents bvba  
Pauline Van Pottelsberghelaan 24  
9051 Ghent (BE)

**Decision under appeal:** **Decision of the Examining Division of the  
European Patent Office posted on 8 July 2016  
refusing European patent application No.  
09781176.4 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairman** A. Usuelli  
**Members:** E. Duval  
P. Schmitz

## Summary of Facts and Submissions

- I. The appeal was filed by the appellant (applicant) against the decision of the examining division to refuse the European patent application No 09781176.4 (hereinafter "the application").

The decision was based on a main request and auxiliary requests 1-5, all filed by letter dated 13 May 2016. In each request, claim 1 related to a topical composition comprising, *inter alia*, clinoptilolite having a mean particle size of between 100 nm and 20  $\mu$ m.

- II. The decision cited among others the following document:

D22: Prasanna H.R. et al., *Comparative Analysis of Common Particle Sizing Techniques For Pharmaceutical Powders*, FDA Science Day Poster, February, 2001

- III. The examining division decided in particular that the main request did not comply with the requirements of Article 84 EPC, because neither the claim nor the specification specified any method for measuring the mean particle diameter. Since different methods gave different results, the skilled person would not be able to determine whether he was working within the scope of the claims or not. Furthermore, the skilled person would also get different particle size results for the same composition depending on whether he relied on the supplier data sheet or was carrying out the analysis himself.

Additionally, neither the main request nor auxiliary requests 1-5 met the requirements of Article 56 EPC,

and auxiliary request 2 did not meet the requirements of Article 123(2) EPC.

- IV. With the statement setting out the grounds of appeal, the appellant filed a main request and auxiliary requests 1-5, submitted among others the following document (Annex 3), and provided arguments regarding clarity and inventive step.

Annex 3: Zeolite specifications

- V. Claim 1 of the main request reads as follows:

"A topical composition comprising  
a) clinoptilolite, having a mean particle size of between 100 nm and 20 µm;  
b) a physiologically acceptable magnesium salt;  
c) water;  
d) a substantially non-cationic carrier; and  
whereby  
e) the total molar amount of magnesium ions in the composition is higher than the total molar amount of calcium ions."

Claim 1 of auxiliary request 1 corresponds to claim 1 of the main request, with the additional feature that "said composition has a negative zeta potential and is able to form an electric double layer in an aqueous medium".

Claim 1 of auxiliary request 2 corresponds to claim 1 of auxiliary request 1, wherein component b) is replaced with "between 0.2 and 30 w/w% of a separately added magnesium chloride hexahydrate" .

Claim 1 of auxiliary request 3 corresponds to claim 1 of auxiliary request 2, with the additional feature that "the minimal concentration of calcium ions in said composition is 0.04 w/w%".

Claim 1 of each of auxiliary requests 4 and 5 relates to the same preparations as in claim 1 of auxiliary requests 2 and 3, respectively, "for use in the formation and/or recovery of the epidermal barrier in skin diseases or conditions".

VI. The Board summoned the appellant to oral proceedings.

In a communication pursuant to Article 15(1) RPBA dated 6 March 2020, the Board gave its preliminary opinion regarding the issue of clarity as well as inventive step. The Board expressed in particular the view that none of the requests fulfilled the requirement of Article 84 EPC for lack of clarity of the mean particle size parameter.

VII. By letter dated 15 April 2020, the appellant announced that it would not attend the scheduled oral proceedings. The appellant made no further submissions regarding the issues identified in the Board's communication.

The oral proceedings were cancelled.

VIII. The appellant's arguments regarding clarity can be summarised as follows:

The claimed particle size lay between 0.1 and 20 microns. While the different results in measuring methods might be relevant in view of very small particle sizes (below 100 nm), it was highly unlikely

that the measuring methods would give a significant difference for the currently claimed range.

With respect to zeolites such as clinoptilolite, two methods were commonly known for defining particle size for pharmaceutical powders (see D22): one method was laser particle size analysis, the other was visual measurement by microscopy, a technique known as image analysis and light obscuration. Both methods were generally acknowledged to be effective in the claimed range. There was hence no indication that a skilled person would be faced by different results when choosing either one of the available measuring methods.

Furthermore, a correct interpretation of Article 84 EPC was inherently linked to a correct definition of the skilled person in the particular case. The skilled person in the present case was not a producer of raw materials for pharmaceutical purposes, but a pharmacist with focus on dermatologic problems and knowledge of pharmaceutical or active ingredients used in skin care. For the formulation of the composition, he would make use of existing raw materials which are readily bought from suppliers (see for example Annex 3). Knowing that he would need a clinoptilolite with specific particle size, he would thus simply buy the appropriate form. He would thereby not be bothered with performing measurements on particle size, but trust that his supplier provides him with the accurate product.

Consequently, the particle size referred to in claim 1 was clear.

- IX. The appellant requests that the decision under appeal be set aside and that a patent be granted on the basis of the main request or, in the alternative, on the

basis of one of the auxiliary requests 1-5, all filed with the statement of grounds of appeal.

## **Reasons for the Decision**

### 1. Clarity, main request

1.1 Claim 1 of the main request relates to a topical composition comprising, in particular, clinoptilolite having a mean particle size of between 100nm and 20µm.

1.2 Article 84 EPC requires that the claims define the matter for which protection is sought. In the case of present claim 1, where the subject-matter is defined by the mean particle size parameter, the skilled person must be able to easily and unambiguously verify whether he is working inside or outside the scope of the claim.

As noted by the examining division, neither the claims nor the description specify any method for measuring the mean particle size. It is not contested that different methods exist for measuring the particle size.

1.3 The appellant argues that it is highly unlikely that the measuring methods would give a significant difference for the currently claimed range. In its opinion, there is no indication that the two commonly known methods discussed in D22 (namely laser particle size analysis and image analysis and light obscuration) would yield different results.

However, the Board can find no support in D22 for the appellant's assertions. D22 identifies up to 5

different particle size techniques (first page), and suggests that these techniques lead to different mean size distributions (second page). The appellant did not explain why the values given by the different available techniques would not significantly differ in the claimed range of 100nm - 20µm. Consequently, it is neither demonstrated that the skilled person would know from common general knowledge which measurement method to employ, nor that all the available methods would yield substantially the same result.

- 1.4 The appellant further argues that a skilled person was not a producer of raw materials for pharmaceutical purposes, but a pharmacist with focus on dermatologic problems and knowledge of pharmaceutical or active ingredients used in skin care. He would not have any burden knowing whether or not he is working within the claimed range, as he would simply buy the product at the appropriate particle size, thereby eliminating all confusion.

The Board does not agree. The skilled person is an expert in the technical field of the invention. In the present case, the invention is defined in claim 1 by the presence of clinoptilolite with a certain mean particle size. The skilled person, i.e. the pharmacist producing the claimed topical composition, must accordingly be familiar with techniques for the measurement of this parameter. Therefore the Board cannot accept the appellant's view that the skilled person would not be bothered with performing measurements on particle size and would merely rely on supplier information. Furthermore, the mean particle size parameter used for the definition of the subject-matter of claim 1 defines a physical characteristic of the clinoptilolite component. For the purposes of



Article 84 EPC, this physical characterisation must be unambiguous and cannot be substituted with the information provided by suppliers, which could be based on any of the available measuring techniques.

1.5 Thus, in the absence of indication of a method for measuring the particle size, the expression "mean particle size" is ambiguous. This ambiguity is compounded by the fact that, to the extent that "mean" refers to an average, it is not specified which type of average (volume, surface, number) is intended. The Board shares in this respect the reasoning of decisions T 1819/07, T 967/08 and T 45/10 cited in the Case Law of the Boards of Appeal of the European Patent Office, 9th edition 2019, II.A.3.5.

1.6 Therefore, the main request does not meet the requirements of Article 84 EPC.

2. Clarity - auxiliary requests 1-5

Claim 1 of each of the auxiliary requests 1-5 contains the same expression "mean particle size of between 100nm and 20µm". Consequently, each of the auxiliary requests 1-5 also infringes Article 84 EPC.

3. Since none of the appellant's requests can be allowed, the appeal has to be dismissed. The Board could take this decision in writing since the appellant announced not to attend the scheduled oral proceedings. The statement not to attend oral proceedings is treated as equivalent to a withdrawal of the request for oral proceedings (see Case Law of the Boards of Appeal of the European Patent Office, 9th edition 2019, III.C. 4.3.2 and the decisions cited there).

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:



B. Atienza Vivancos

A. Uselli

Decision electronically authenticated