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# Datasheet for the decision of 24 November 2022

**Case Number:** R 0005/22

**Appeal Number:** T 1160/18 - 3.3.07

**Application Number:** 14172398.1

**Publication Number:** 2801355

**IPC:** A61K9/20, A61K9/50

**Language of the proceedings:** EN

**Title of invention:**
Controlled release pharmaceutical compositions comprising a fumaric acid ester

**Patent Proprietor:**
FWP IP APS

**Opponents:**
ZAKLADY FARMACEUTYCZNE POLPHARMA S.A.
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Zentiva k.s.
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Interquim S.A.
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Actavis Group PTC EHF
Generics [UK] Limited
STADA Arzneimittel AG

**Headword:**
Violation of right to be heard (no)
"surprise" reasoning in decision (no) - no causal link to decision (obiter dictum) - point 6 reasons

**Relevant legal provisions:**
EPC Art. 76(1), 112a(2)(c), 113(1), 123(2)
EPC R. 106

**Keyword:**

**Decisions cited:**
R 0016/13

**Catchword:**

Europäisches Patentamt
European Patent Office
Office européen des brevets

**Große Beschwerdekammer**

**Enlarged Board of Appeal**

**Grande Chambre de recours**

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**Case Number: R 0005/22**

# D E C I S I O N
# of the Enlarged Board of Appeal
# of 24 November 2022

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| **Decision under review:** | **Decision T 1160/18 of the Technical Board of Appeal 3.3.07 of the European Patent Office of 6 September 2021.** |

**Composition of the Board:**

| | |
|---|---|
| **Chairman** | I. Beckedorf |
| **Members:** | D. Rogers |
| | T. Häusser |

## Summary of Facts and Submissions

I. The petition for review ("Petition") concerns appeal proceedings T 1160/18 of board of appeal 3.3.07 ("the Board"). The appeal was lodged by the Proprietor ("the Petitioner") against the decision of the Opposition Division to revoke the patent.

II. Oral proceedings were held before the Board on 6 September 2021. At the end of the oral proceedings the Chairman of the Board announced that the appeal was dismissed. The revocation of the patent was thus confirmed.

III. The decisions of the Opposition Division and the Board in this case are solely concerned with added matter, Articles 76(1) and 123(2) EPC.

IV. The structure of claim 1 of the main request before the Board was set out in the Board's communication of 17 January 2020 in preparation of the oral proceedings, ("the Communication") at point 16.2:

> "Claim 1 is therefore a combination of the following main features:
> a) …
> b) …
> c) …
> d) A daily dosage of 480 mg in one to three doses
> e) A list of diseases to be treated."

This structure was followed by the Petitioner in its subsequent submissions to the Board, and by the Board in its decision. This structure is also followed in this decision.

V. The Petitioner considers that its right to be heard has been violated as it was not given an opportunity to comment on the reasoning of the Board on a key issue, this issue only becoming apparent in the written decision. This reasoning is found in the last paragraph of point 1.3 on page 34 of the Board's decision, (the square brackets have been added by the Enlarged Board), which states:

> "In the present case, even if there has not been a singling out from the list of disorders [feature (e)], the original lists of disorders to be treated has been significantly shrunk and, for this reason, cannot be considered to remain generic".

According to the Petitioner (pages 9 – 10 of the Petition):

> "This objection, based on the notion that a shrunken list can be non-generic without leading to a singling out, was never raised in the Board's communication and was not explained by the Board at the oral proceedings...
>
> 3.3.1
> …
> … In particular, the Board has not given the parties a chance to present arguments on the standard that is to be applied in the determination of whether a shrunken list is still generic or not."

The Petitioner further argues, (page 11 of the Petition):

> "While the Board expressed doubts [in its Communication] regarding the disclosure of feature(e)

in the parent application as filed, it did not indicate that it intended to rely on a new standard for assessing the disclosure in the parent application, namely the 'significant' shrinking of a list such that the list is no longer generic."

VI. In the Communication, the Board discussed in para 16.1 to 16.3 whether claim 1 of the main request complied with Article 76(1) EPC. In its discussion of features d) and e) of claim 1 of the main request, the Board stated:

"The feature d) is a selection among numerous possible daily dosages disclosed on page 36 of the parent application. The value of 480 mg is furthermore the restriction to a range limit.

The feature d) [sic, the Board meant feature e)] corresponds to the diseases claimed in original claims 44 or 45 with a restriction to some diseases. Original claims 44 and 45 referred however to claims 1 – 43 which object is different from present claim 1. The only possible basis for the claimed diseases can be found on the list of diseases disclosed on pages 37 – 39 of the parent application, wherein the claimed diseases constitute a selection among the list of originally disclosed diseases.

Consequently, the combination of at least features a), c), d) and e) constitute a combination from selections in multiple lists and is not disclosed or derivable from the parent application …"

VII. The Petitioner responded to the Communication with a letter dated 5 May 2020. The Petitioner noted (page 2 of its letter, fourth paragraph) that: "… it has been argued, and the Board appears to preliminarily agree,

that the combination of features of the claim of the Main Request is the result of 'selections' from 'lists' in the disclosure of the parent application".

The Petitioner went on in its letter to discuss, amongst other things, features d) and e) of claim 1 of the main request. As regards feature d), the Petitioner gave arguments for its disclosure and concluded that a skilled person seeking to implement the invention would seriously contemplate a daily dosage of 480 mg (para 3.4, pages 7 - 8 of the letter). As regards feature e), the Petitioner noted that in the description the diseases are split into two groups and argued that the deletion of psoriasis from the first group and the exclusion of all of the second group in the main request did not lead to a singling out of any subject-matter. Although conditions had been omitted from the main request (see page 10 of the letter):

> "The list of conditions remains generic. It has reduced size, which is not objectionable. It is established case law that the deletion of elements from lists, which does not lead to singling out specific elements is not objectionable …
> …
> It is further noted that the primary focus of the invention is the treatment of autoimmune, inflammatory or hyperproliferative conditions …
> …
> Thus, the treatment of the conditions of the second group is a less preferred aspect of the original disclosure. The present claim relates to the more preferred aspect.
>
> From the above discussion it follows that in the present case the remaining claimed subject-matter,

namely the shrunk list of conditions, is directly and unambiguously disclosed in the parent application."

VIII. The minutes of the oral proceedings before the Board record that the first matter discussed with the parties was whether the subject matter of claim 1 of the main request complied with the requirements of Article 76(1) EPC. After deliberation, the Chairman announced the conclusion of the Board that the subject-matter of claim 1 of the main request did not meet the requirements of Article 76(1) EPC.

IX. The written decision of the Board deals with whether the subject matter of claim 1 of the main request complies with the requirements of Article 76(1) EPC in para 1.1 to 1.5 (6 pages of reasoning). In paragraph 1.1 of the decision, (paragraph spanning pages 29 and 30), the Board states:

"According to established jurisprudence, a combination of features originally disclosed in separate embodiments or lists must emerge clearly and unambiguously from the content of the application as filed and, in case of divisional applications, also from the parent application."

The Board then goes on to discuss whether feature d) complies with Article 76(1) EPC. The conclusion of the Board on this issue is as follows (see last paragraph of para 1.2 on page 31 of the decision):

"Consequently, the feature 'wherein the daily dosage is 480 mg active substance given in one to three doses' constitutes an arbitrary selection among several equally ranking possibilities."

X. The Board continues by addressing feature e) of claim 1 of the main request in para 1.3 of the decision. Para 1.3 is two and a half pages long. The Board first looks at the list of diseases to be treated as set out in claims 44 and 45 of the parent application. The Board notes that only a selection of these diseases has been taken from these claims into claim 1 of the main request. The Board then goes on to look at the disclosure on pages 37 to 39 of the disorders to be treated. This disclosure gives two lists and in addition a list of treatments in which the novel composition or kit according to the invention can be used. The Board notes on page 33 of the decision:

> "The Board cannot see in the lists given in these pages any kind of hierarchical split or subdivision between a first group of preferred disorders to be treated and forming the basis of the claimed disorders, and a second group of less preferred disorders to be treated which has been excluded from the subject-matter of claim 1 of the main request, as argued by the appellant. There is indeed nothing in the wording used in the description which would indicate a preference for a list or another. Besides, the two first paragraphs of page 39 group again the indications in a single list, as do original claims 44 and 45."

XI. In para 1.4 of the decision (page 34) the Board states that the "shrinkage" of a list as such is not contestable under Article 76(1) EPC, and goes on to give its reasons for finding a non-compliance with Article 76(1) EPC:

> "The selection of an explicitly disclosed range value or the shrinkage of a list are, as such, not contestable under Article 76(1) EPC. However, the combination of the features resulting from these limitations must emerge directly and unambiguously from

the content of the parent application. This can occur in particular, in the presence of a pointer to choose exactly such a combination of features.

…

In the present case, there is nothing like this. The claimed daily dosage of '480 mg' is indeed an arbitrary selection among several equally ranking limits of ranges of daily dosages, and the claimed disorders to be treated result from an arbitrary limitation of the list of original disorders to be treated. Thus, claim 1 is based on a new particular combination of features which cannot be derived directly and unambiguously from the parent application."

XII. The Petitioner claims that a fundamental violation of the right to be heard had taken place. It was only in a position to recognise this once the written decision had been issued. The reasons given in the written decision as to why claim 1 of the main request did not comply with Article 76(1) EPC were based on reasoning and arguments that had never been put forward during the opposition and appeal proceedings.

XIII. The Enlarged Board sent a communication setting out its preliminary views on the case. The Enlarged Board was of the view that the Petition was not clearly inadmissible, but was clearly unallowable.

XIV. In response to said communication of the Enlarged Board, the Petitioner, without making any substantive submissions, withdrew its request for oral proceedings and requested a decision on the merits of its case.

XV. The Petitioner requests that:

1. the decision under review be set aside and that the proceedings before the Board of Appeal be re-opened; and
2. the members of the Board of Appeal that were participating in the decision under review be replaced; and
3. the fee for the petition for review be reimbursed.

## Reasons for the Decision

1. The Enlarged Board considers this Petition to be a petition under Article 112a(2)(c) EPC. A petition under such a ground is only admissible if an objection in respect of the procedural defect was raised during the appeal proceedings and dismissed by the Board, except where such objection could not be raised during the appeal proceedings (Rule 106 EPC).

2. The Enlarged Board takes the view that the Petitioner's objection could not have been raised until the Petitioner had read the written decision of the Board.

3. The Petition is therefore not clearly inadmissible

4. However, the Enlarged Board considers the Petition to be unallowable.

5. The Petitioner's case is that the Board violated its right to be heard as it had no opportunity to present arguments specifically addressing the issue of the

standard that is to be applied in the determination of whether a shrunken list is still generic or not – see point V. above.

6. On pages 15 and 16, para 3.3.7 of the Petition, the Petitioner argues that if it had been able to present arguments that the definition of feature e) is not based on a significant shrinking of the original list of disorders and that hence the list could be considered to remain generic, this would have led to a different outcome. That is, that the Board would have had to conclude that claim 1 of the main request met the requirements of Article 76(1) EPC. The Enlarged Board does not agree, it is of the view that this issue was not relevant to the Board's decision and that the last paragraph of para 1.3 of the decision is obiter. For ease of reference, the last paragraph of para 1.3 reads as follows:

> "In the present case, even if there has not been a singling out from the list of disorders, the original lists of disorders to be treated has been significantly shrunk and, for this reason, cannot be considered to remain generic."

The Enlarged Board reaches this conclusion due to the presence of the words "even if" in this paragraph; due to the para 1.4, which immediately follows the above quoted text; and due to the fact that para 1.3 sets out in two and a half pages detailed reasoning why there has been a singling out from the list of disorders.

It is to be noted that the first paragraph of para 1.4 acknowledges that shrinking a list is not objectionable in itself, see point XI. above, and the second paragraph of

para 1.4 states that a shrinking of a list is not the issue being dealt with.

If the last paragraph of para 1.3 were to be deleted from the decision, the decision would still be complete, logical, reasoned and understandable.

7. The Enlarged Board thus considers the "significantly shrunk" argument to be only one of two objections upon which the Board found that the request did not comply with Article 76(1) EPC. Thus even if the Petitioner had established a procedural violation in respect of this objection, there would have been no causal link between that violation and the decision. By a causal link, the Enlarged Board means that it cannot be ruled out that a different decision would have been reached if a party had been heard on the point on which it alleges its right to be heard had been infringed. Thus any violation of the right to be heard in respect of this objection cannot be considered as being fundamental (see R 19/09, reasons 6 to 9.2).

8. The Enlarged Board notes that the Board’s reasoning in its decision for finding non-compliance with Article 76(1) EPC, set out in point XI. above, is the same as the reasoning set out in the Board's Communication, see point VI. above. The Enlarged Board further notes that the Petitioner specifically addressed these points in its letter of 5 May 2020, see point VII. above.

9. Decisions of a board of appeal may only be based on grounds or evidence on which the parties have had an opportunity to present their comments (Article 113(1) EPC). This implies that a party may not be taken by surprise by references in the reasons for the decision,

to unknown grounds or evidence. Grounds or evidence under Article 113(1) EPC is to be understood as the essential legal and factual reasoning on which a decision is based (see decision R 16/13, reasons 3.3). A party must have an opportunity to comment on the decisive aspects of the case. For the reasons set out above, the Enlarged Board considers that these requirements have been fulfilled.

10. On page 3 of the Petition, the Petitioner states that the Opposition Division did not apply the correct legal standard under Article 76(1) EPC. On page 4 of the Petition, the Petitioner states that the Board did not refer to the Opposition Division's decision in either its communication or decision, and on pages 12 and 13 of the petition, the Petitioner argues that the Board applied the wrong legal standard as regards list shrinking and Article 76(1) EPC. The Enlarged Board considers all these points to be irrelevant as regards the issue of a violation of the right to be heard. In addition, none of these points provides grounds for filing a petition for review as set out in Article 112a EPC.

11. It follows from the above that no violation of the Petitioner's right to be heard can be established regarding its allegations of surprise reasoning in the written decision. Hence, the Petition is clearly unallowable in this respect, so that the Enlarged Board cannot accede to any of the Petitioner's requests.

**Order**

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

The petition for review is unanimously rejected as being clearly unallowable.

The Registrar: The Chairman:

N. Michaleczek I. Beckedorf

Decision electronically authenticated