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Datasheet for the decision of 20 April 2023

Case Number: T 1298/19 - 3.3.04

Application Number: 14746905.0

Publication Number: 2830605

IPC: A61K31/137, A61K31/135, A61K31/167, A61P11/02, A61P11/12

Language of the proceedings: EN

Title of invention:
A COMBINATION MEDICAMENT COMPRISING PHENYLEPHRINE AND PARACETAMOL

Applicant:
AFT Pharmaceuticals Limited

Headword:
Medicament comprising phenylephrine hydrochloride and paracetamol / AFT

Relevant legal provisions:
EPC Art. 123(2), 84, 111(1)
RPBA 2020 Art. 11

Keyword:
Appeal decision - remittal to the examining division (yes)

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Case Number: T 1298/19 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 20 April 2023

Appellant: (Applicant)	AFT Pharmaceuticals Limited Level 1, 129 Hurstmere Road Takapuna Auckland 0622 (NZ)
Representative:	Arnold & Siedsma Bezuidenhoutseweg 57 2594 AC The Hague (NL)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 22 November 2018 refusing European patent application No. 14746905.0 pursuant to Article 97(2) EPC**

Composition of the Board:

Chairwoman	M. Pregetter
Members:	S. Albrecht
	R. Romandini

Summary of Facts and Submissions

I. The appeal of the applicant ("the appellant") lies from the decision of the examining division refusing European patent application No. 14 746 905.0 ("the application") entitled "A combination medicament comprising phenylephrine and paracetamol".

II. The decision of the examining division was based on a main request and two auxiliary requests.

The set of claims of the main request was filed on 12 April 2017. The sets of claims of the two auxiliary requests were filed on 18 April 2018.

Claim 1 of the main request reads:

"1. A combination medicament for use in the treatment of upper respiratory mucosal congestion, characterised in that the medicament has phenylephrine hydrochloride (or phenylephrine or a pharmaceutically acceptable alternative salt of phenylephrine) and paracetamol in proportions suitable for, and the medicament is for, providing an adult with:

a) 4 mg - 7.5 mg phenylephrine hydrochloride (or an equivalent amount of phenylephrine or a pharmaceutically acceptable alternative salt of phenylephrine), in combination with 950 mg - 1,000 mg paracetamol; or
b) 5 mg - 7.5 mg phenylephrine hydrochloride (or an equivalent amount of phenylephrine or a pharmaceutically acceptable alternative salt of phenylephrine), in combination with 600 mg - 700 mg paracetamol."

Claim 1 of the first auxiliary request differs from claim 1 of the main request by the following amendments (deletions are indicated in strikethrough, additions underlined):

"1. A combination medicament for use in the treatment of upper respiratory mucosal congestion, characterised in that the medicament has phenylephrine hydrochloride (~~or phenylephrine~~ or a pharmaceutically acceptable alternative form~~salt~~ of phenylephrine) and paracetamol in proportions suitable for, and the medicament is for, providing an adult with

a) 4 mg - 7.5 mg phenylephrine hydrochloride (or an equivalent amount of phenylephrine or a pharmaceutically acceptable alternative form~~salt~~ of phenylephrine) in combination with 950 mg - 1000 mg paracetamol; or
b) 5 mg - 7.5 mg phenylephrine hydrochloride (or an equivalent amount of phenylephrine or a pharmaceutically acceptable alternative form~~salt~~ of phenylephrine) in combination with 600 mg - 700 mg paracetamol."

Claim 1 of the second auxiliary request is identical to claim 1 of the first auxiliary request with the exception that the pharmaceutically acceptable alternative form of phenylephrine has been specified to be a pharmaceutically acceptable alternative chemical form of phenylephrine.

In its decision, the examining division concluded that

(a) claims 1 to 7 of the main request and claims 1 to 6 of each of the two auxiliary requests contained added subject-matter (Article 123(2) EPC),

(a) claims 1 to 6 of each of the two auxiliary requests lacked clarity (Article 84 EPC).

III. With the statement of grounds of appeal, the appellant filed six sets of amended claims as its main and first to fifth auxiliary request, respectively.

Claim 1 of the main request is identical to claim 1 of the main request underlying the impugned decision.

IV. The board issued summons for oral proceedings in line with the appellant's request.

V. With letter dated 15 November 2021, the appellant filed two further sets of claims as its main and first auxiliary request, respectively, and maintained the main request and the five auxiliary requests filed with the statement of grounds of appeal as second to seventh auxiliary request, respectively.

In this letter the appellant requested that a patent be granted on the basis of the set of claims of the main request or, alternatively, on one of the sets of claims of the first to seventh auxiliary requests.

Claim 1 of the main request differs from claim 1 of the main request underlying the impugned decision by the following amendments (deletions are indicated in strikethrough, additions underlined):

"1. A combination medicament for use in the treatment of upper respiratory mucosal congestion <u>in tablet,</u>

capsule, powder or liquid form,
characterised in that the medicament has phenylephrine hydrochloride ~~(or phenylephrine or a pharmaceutically acceptable alternative salt of phenylephrine)~~ and paracetamol in proportions suitable for, and the medicament is for, providing an adult with
a) 4 mg - 7.5 mg phenylephrine hydrochloride ~~(or an equivalent amount of phenylephrine or a pharmaceutically acceptable alternative salt of phenylephrine)~~ in combination with 950 mg - 1000 mg paracetamol,
or
b) 5 mg - 7.5 mg phenylephrine hydrochloride ~~(or an equivalent amount of phenylephrine or a pharmaceutically acceptable alternative salt of phenylephrine)~~ in combination with 600 mg - 700 mg paracetamol."

VI. Subsequently, the board cancelled the oral proceedings and issued a communication. In this communication, the board expressed the view that the main request could be admitted into the appeal proceedings and that this request overcame the objections of added subject-matter under Article 123(2) EPC and lack of clarity under Article 84 EPC raised in the decision under appeal. The board furthermore informed the appellant of its intention to remit the case under Article 111(1) EPC to the examining division for further prosecution on the basis of the main request.

VII. In a letter dated 9 March 2022, the appellant expressed its approval of such a remittal.

VIII. The appellant's written case relevant to the present decision can be summarised as follows.

The main request overcame all previous objections raised during examination proceedings, in that expressions and claim features that were previously found to be unacceptable under Articles 123(2) and 84 EPC, respectively, had been removed from the claims of this request.

Reasons for the Decision

1. The appeal is admissible.

2. The main request is admitted into the proceedings.

3. In the case at issue, the examining division raised the following objections in the decision under appeal.

Article 123(2) EPC

(a) The feature "pharmaceutically acceptable alternative salt of phenylephrine" recited in claim 1 of the main request was not directly and unambiguously derivable from the application as filed.

(b) The application as filed did not directly and unambiguously disclose the subject-matter as claimed in the main request, the first and the second auxiliary request, insofar as directed to combination medicaments comprising phenylephrine as such (i.e. in the form of its free base).

Article 84 EPC

(c) The expression "[or an equivalent amount of] phenylephrine" recited in claims 1 to 6 of each of the first and second auxiliary request rendered the

claimed subject-matter inconsistent. The claims' characterising part initially stated that only phenylephrine hydrochloride or a pharmaceutically acceptable alternative form of phenylephrine were present, but then referred to phenylephrine (free base) as being a further option.

(d) The expression "a pharmaceutically acceptable alternative chemical form of phenylephrine" recited in claims 1 to 6 of the second auxiliary request was vague and unclear.

4. The set of claims according to the current main request differs from the sets of claims of the main, first and second auxiliary request underlying the impugned decision in that the claimed subject-matter is limited to combination medicaments comprising phenylephrine in the form of its hydrochloride salt. This limitation overcomes all the objections raised in the decision under appeal.

5. As a consequence, it is not necessary for the board to deal with the auxiliary requests.

Remittal (Article 111(1) EPC)

6. The primary object of the appeal proceedings is to review the decision under appeal in a judicial manner (cf. Article 12(2) RPBA 2020). In the case at issue, the contested decision was solely based on objections under Article 123(2) and 84 EPC which have been overcome by the amended claims in accordance with the main request. Claim 1 of this request (see point V. above) is directed to combination medicaments "in tablet, capsule, powder or liquid form", and hence contains features which were not present in any of the

independent claims considered by the examining division in their decision. In these circumstances, the board considers that special reasons for remitting the case to the examining division within the meaning of Article 11, first sentence, RPBA 2020, exist. Therefore, and since the appellant has agreed to this procedure (see point VII. above), the board finds it appropriate to remit the case to the examining division for further prosecution (Article 111(1) EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the examining division for further prosecution on the basis of the set of ten claims of the main request filed on 15 November 2021.

The Registrar: The Chairwoman:

I. Aperribay M. Pregetter

Decision electronically authenticated