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**Datasheet for the decision
of 20 September 2021**

Case Number: T 2360/18 - 3.3.07

Application Number: 10749626.7

Publication Number: 2464332

IPC: A61K9/00, A61K31/167,
A61K31/198

Language of the proceedings: EN

Title of invention:

STORAGE-STABLE FORMULATION OF PARACETAMOL IN AQUEOUS SOLUTION

Patent Proprietor:

Neogen N.V.

Opponent:

Fresenius Kabi Deutschland GmbH

Headword:

Storage-stable formulation of paracetamol/Neogen N.V.

Relevant legal provisions:

RPBA Art. 12(4)

EPC Art. 123(2)

Keyword:

Main request - Admission into the proceedings (Yes)

Main request - Amendments (Yes)

Main request not covered by extent of opposition



Beschwerdekammern

Boards of Appeal

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Case Number: T 2360/18 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 20 September 2021

Appellant: Neogen N.V.
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 2 August 2018
revoking European patent No. 2464332 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman A. Usuelli
Members: D. Boulois
A. Jimenez

Summary of Facts and Submissions

- I. European patent No. 2 464 332 was granted on the basis of a set of 15 claims.

Independent claims 1 and 12 as granted read as follows:

"1. A liquid formulation that is stable to oxidation and that is based on paracetamol in an aqueous solvent obtainable by the following steps:

- i) dissolving in a reaction vessel paracetamol in an aqueous solvent having a temperature between 65°C and 95°C, and having pH between 5.0 and 6.0
- ii) cooling the solution so formed to a temperature equal to or above 35°C and below 40°C under an atmosphere of nitrogen,
- iii) adding cysteine hydrochloride and sodium hydroxide simultaneously to the solution without stirring,
- iv) closing the reaction vessel, and stirring the solution of step iii) in a nitrogen atmosphere."

"12. Method for the production of a formulation according to any of the previous claims, comprising the steps of:

- i) dissolving paracetamol in an aqueous solvent having a temperature between 65°C and 95°C, and having pH between 5.0 and 6.0 in a reaction vessel
- ii) replacing the remaining air in the vessel by an inert gas, such as nitrogen, and cooling the solution so formed to a temperature equal to or above 35°C and below 40°C,
- iii) adding cysteine hydrochloride and sodium hydroxide simultaneously to the solution without stirring, and

iv) closing the reaction vessel and stirring the solution of step iii) in a nitrogen atmosphere."

- II. An opposition was filed under Article 100 (a) and (b) EPC on the grounds that its subject-matter lacked novelty and inventive step and was not sufficiently disclosed.
- III. The appeal lies from the decision of the opposition division to revoke the patent. The decision was based on the claims as granted as main request, on auxiliary requests I and II filed with letter of 10 May 2017 and auxiliary request III filed with letter of 3 May 2018.
- IV. The documents cited during the opposition proceedings included *inter alia* the following
D11: Rote Liste 2005 Arzneimittelverzeichnis für Deutschland, 05 166
- V. According to the decision under appeal:
(a) The subject-matter of claim 1 of the main request could not be regarded as novel over the disclosure of D11, which disclosed the product Perfalgan®.
(b) The same conclusion applied to auxiliary request I.
(c) The subject-matter of claim 1 of auxiliary request II did not meet the requirements of Article 123(2) EPC.
(d) The subject-matter of auxiliary request III was also considered to contravene the requirements of Article 123(2) EPC and to extend the protection conferred by the granted claims pursuant to Article 123(3) EPC.
- VI. The patent proprietor (hereinafter the appellant) filed an appeal against said decision.

VII. With the statement setting out the grounds of appeal dated 3 December 2018, the appellant filed a main request corresponding to the claims as granted and auxiliary requests I-IV.

The auxiliary request IV was limited to the process claims, with independent claim 1 reading as follows, the difference with respect to claim 12 as granted being indicated in **bold**:

"12. Method for the production of a **formulation according to any of the previous claims liquid formulation that is stable to oxidation and that is based on paracetamol in an aqueous solvent**, comprising the steps of:

- i) dissolving paracetamol in an aqueous solvent having a temperature between 65°C and 95°C, and having pH between 5.0 and 6.0 in a reaction vessel
- ii) replacing the remaining air in the vessel by an inert gas, such as nitrogen, and cooling the solution so formed to a temperature equal to or above 35°C and below 40°C,
- iii) adding cysteine hydrochloride and sodium hydroxide simultaneously to the solution without stirring, and
- iv) closing the reaction vessel and stirring the solution of step iii) in a nitrogen atmosphere."

VIII. With its reply to the appeal, the opponent (hereinafter the respondent) requested that none of auxiliary requests I-IV be admitted into the proceedings.

IX. A communication from the Board was sent to the parties. In this communication, the Board expressed its preliminary opinion that the main request was not novel over D11, that auxiliary requests I-IV appeared to be admissible, but that Auxiliary requests I-III did not

meet the requirements of Article 123(2) EPC and Article 54 EPC.

X. With a letter dated 1 July 2021, the appellant promoted auxiliary request IV to be the new main request. The appellant also requested that the proceedings were continued in writing.

XI. With a letter dated 11 August 2021, the appellant withdrew the former main request and auxiliary requests I-III, and requested that the patent be maintained on the basis of the main request filed on 1st of July 2021 (previously auxiliary request IV). The appellant also filed an amended description.

XII. With a letter dated 12 August 2021, the respondent withdrew its request for oral proceedings.

XIII. The arguments of the appellant may be summarised as follows:

The novel main request related to a method for producing a stable paracetamol formulation. These method claims had not been opposed by the opponent. Moreover, said request was also not challenged by the opponent in their submission in the appeal proceedings.

XIV. The arguments of the respondent may be summarised as follows:

The auxiliary requests I-IV, should have been filed earlier and should not be admitted into the appeal proceedings under Article 12(4) RPBA.

XV. Requests

The appellant requests that the decision under appeal be set aside and the patent be maintained according to the set of claims filed as main request with the letter dated 1 July 2021.

The respondent requests that the appeal be dismissed. The respondent also requests that the main request not be admitted into the proceedings.

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Reasons for the Decision

1. Admission of the main request into the proceedings

The appeal was filed before 1 January 2020, and therefore Article 12(4) RPBA 2007 applies (Article 25(2) RPBA 2020, OJ 2019, A63).

The main request has been filed with the statement of grounds of appeal as auxiliary request IV, hence at the earliest stage of the appeal proceedings. It was submitted again as main request with a letter dated 1st of July 2021.

Moreover, claim 1 of the main request corresponds to the process claim 12 as granted (former main request) with minor modifications aiming to clarify the reference to the formulation as it was previously claimed in claim 1 as granted; the dependent claims correspond to the dependent claims 13, 14 (or 2 and 3), and 4-11 as granted, with now a reference to the process claim 1. The subject-matter of the main request was therefore already present in the opposition proceedings.

Consequently, the Board sees no reason not to admit the main request into the proceedings (Article 12(4) RPBA 2007).

2. Main request

- 2.1 The subject-matter of claim 1 correspond to the process claim 12 as originally filed with the feature "a liquid formulation that is stable to oxidation and that is based on paracetamol in an aqueous solvent" which was present in the product claim 1 as originally filed. Dependent claims 2-11 find a direct basis in original claims 2 and 3 (or 13 and 14), and 4-11.

Consequently, the main request meets the requirements of Article 123(2) EPC.

- 2.2 This request is restricted to the process claims, which have not been objected to in the opposition proceedings. In its notice of opposition, the opponent requested indeed the revocation of only the product claims 1-11 of the patent based on the grounds of Article 100(a) EPC for lack of novelty and lack of inventive step, and on the grounds of Article 100(b) EPC for insufficiency of disclosure.

The subject-matter of the process claims of the main request and auxiliary requests I-III, as well as the subject-matter of auxiliary request IV as filed with the statement of grounds of appeal, was also not challenged or objected in the appeal proceedings.

Consequently, in the absence of any objections by the opponent the Board decides to maintain the patent in amended form based on the present main request.

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 as amended in the following version:
 - claims 1 to 11 according to the main request filed with the letter dated 1 July 2021.
 - and a description to be adapted thereto.

The Registrar:

The Chairman:



B. Atienza Vivancos

A. Uselli

Decision electronically authenticated