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Datasheet for the decision of 6 March 2023

Case Number: T 2211/19 - 3.3.02

Application Number: 10800558.8

Publication Number: 2453743

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Language of the proceedings: EN

Title of invention:

N-ACETYL CYSTEINE COMPOSITIONS AND THEIR USE IN IMPROVING THE THERAPEUTIC EFFICACY OF ACETAMINOPHEN

Patent Proprietor:

The Board of Trustees of the Leland Stanford Junior University

Opponent:

Prüfer & Partner mbB

Headword:

Relevant legal provisions:

EPC Art. 123(3)

Keyword:
Amendments - broadening of claim

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

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Case Number: T 2211/19 - 3.3.02

D E C I S I O N
of Technical Board of Appeal 3.3.02
of 6 March 2023

Appellant: (Patent Proprietor)	The Board of Trustees of the Leland Stanford Junior University Office of the General Counsel Building 170, Third Floor, Main Quad P.O. Box 20386 Stanford, CA 94305-2038 (US)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Respondent: (Opponent)	Prüfer & Partner mbB Sohnckestrasse 12 81479 München (DE)
Representative:	Prüfer & Partner mbB Patentanwälte · Rechtsanwälte Sohnckestraße 12 81479 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 23 May 2019 revoking European patent No. 2453743 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	M. O. Müller
Members:	S. Bertrand
	L. Bühler

Summary of Facts and Submissions

I. The appeal by the patent proprietor ("appellant") lies from the decision of the opposition division to revoke European patent No. 2 453 743.

II. In the impugned decision, the opposition division's conclusions included that the claims according to the main request and auxiliary requests 1 to 11 then on file did not meet the requirements of Articles 84 and 123(2) and (3) EPC.

III. In its statement of grounds of appeal, the appellant submitted a copy of claim sets of the main request and auxiliary request 1, both filed before the opposition division. It furthermore submitted a claim set according to auxiliary request 2.

IV. In its reply to the grounds of appeal, the opponent ("respondent") provided submissions on extension of scope of the claimed subject-matter.

V. The board issued a communication pursuant to Article 15(1) RPBA 2020 in preparation for the oral proceedings, scheduled at the parties' requests. The board gave its preliminary opinion, including that claim 1 of each of the main request and of auxiliary requests 1 and 2 did not meet the requirements of Article 123(3) EPC.

VI. The appellant in a further letter withdrew the main request and provided further submissions regarding extension of scope of the claimed subject-matter.

VII. Oral proceedings before the board were held by videoconference on 6 March 2023 in the presence of both parties.

VIII. The parties' relevant requests were as follows:

- The appellant requested that the decision under appeal be set aside and the case be remitted to the opposition division for further prosecution, in particular with respect to Articles 54, 56 and 83 EPC, on the basis of the main request or auxiliary request 1, filed as auxiliary requests 1 and 2, respectively, with the statement of grounds of appeal. The appellant also requested that document D27 and the objections made by the respondent in its reply to the grounds of appeal under Article 84 EPC and enumerated by the board in its communication under Article 15(1) RPBA 2020 as objections 2 to 6 not be admitted into the proceedings.

- The respondent requested that the appeal be dismissed.

IX. The respondent's case, where relevant to the present decision, can be summarised as follows. For further details, reference is made to the Reasons.

- Main request and auxiliary request 1

  - The deletions of two exemplified embodiments, which were previously required in claim 1 as granted for certain categories of subjects to be treated, meant that these subjects could be treated with a higher maximum daily dose than that stated in claim 1 as granted. This resulted in an extension of scope of the claimed subject-

matter, contrary to the requirements of Article 123(3) EPC.

X. For the appellant's case, reference is made to the Reasons below.

Reasons for the Decision

Main request

1. Article 123(3) EPC

1.1 Claim 1 of the main request reads as follows (emphasis added by the board; strikethrough and bold text representing deletion and addition respectively compared with claim 1 as granted):

"*1. ~~A composition~~ **An oral formulation** for use in a method of treating pain in a subject in need of analgesic relief, ~~the composition comprising an oral formulation~~ comprising:*

(a) a unit dose of acetaminophen and

(b) a therapeutic efficacy-enhancing amount of N-acetylcysteine;

wherein a total of all unit doses to be administrated per day according to said method is an amount less than a standard maximum daily dose of acetaminophen, wherein the standard maximum daily dose of acetaminophen is:

200 mg for a subject 0-3 months of age, 2.72-4.99 kg (6-11 lb) body weight, receiving 40 mg/dose;

400 mg for a subject 4-11 months of age, 5.44-7.71 kg (12-17 lb) body weight, receiving 80 mg/dose;

600 mg for a subject 12-23 months of age, 8.16-10.43 kg (18-23 lb) body weight, receiving 120 mg/dose;

800 mg for a subject 2-3 years of age, 10.89-15.85 kg (24-35 lb) body weight, receiving 160 mg/dose;
1200 mg for a subject 4-5 years of age, 16.33-21.32 kg (36-47 lb) body weight, receiving 240 mg/dose;
1600 mg for a subject 6-8 years of age, 21.77-26.76 kg (48-59 lb) body weight, receiving 320 mg/dose;
~~1625 mg for a subject 6-11 years of age, receiving 325 mg/dose;~~
2000 mg for a subject 9-10 years of age, 27.22-32.21 kg (60-71 lb) body weight, receiving 400 mg/dose;
2400 mg for a subject 11 years of age, 32.66-43.09 kg (72-95 lb) body weight, receiving 480 mg/dose;
3200 mg for a subject 12 years of age, 43.55 kg (96 lb) body weight receiving 640 mg/dose;
~~4000 mg for a subject >12 years of age to adult, receiving 650 mg/dose;~~
4000 mg for a subject >12 years of age to adult, receiving 500 mg/dose;

wherein ***the N-acetylcysteine supplements the analgesic activity of the acetaminophen in the formulation such that a lower dose of acetaminophen can be used to achieve the same therapeutic effect as would be achieved with a higher dose of unsupplemented acetaminophen, and wherein:***
(i) acetaminophen and N-acetylcysteine are present in the ~~composition~~ ***formulation*** *in a molar ratio of acetaminophen to N-acetylcysteine ranging from 1:15 to 1:0.000977; and*
(ii) the formulation is effective to provide pain relief equivalent to ~~a~~ ***said*** *standard maximum daily dose of acetaminophen* ***when administered alone.***"

Claim 1 of the main request has thus been amended, when compared with claim 1 as granted, by *inter alia* deleting two standard maximum daily doses with the

related patient group ("1625 mg for a subject 6-11 years of age, receiving 325 mg/dose" and "4000 mg for a subject >12 years of age to adult, receiving 650 mg/dose").

1.2 The deletion of the standard maximum daily dose of 1625 mg with respect to subjects 6-11 years of age receiving a 325 mg/dose, in claim 1 of the main request, implies that the standard maximum daily dose for these subjects may be more than 1625 mg. The standard maximum daily dose for these subjects is however limited to 1625 mg in claim 1 as granted. The above deletion thus results in an extension of scope of the claimed subject-matter.

The same extension applies for the deletion of the standard maximum daily dose of 4000 mg with respect to subjects >12 years of age to adult receiving 650 mg/dose.

1.3 The appellant submitted that the deletion of a standard maximum daily dose together with the corresponding patient group from the list of claim 1 as granted excluded the treatment of this patient group and thus limited the scope of the claimed subject-matter.

The board does not agree. As set out by the chairman during the oral proceedings, if the appellant's logic were correct, deleting all the standard maximum daily doses and patient groups of claim 1 as granted would imply that the scope of claim 1 would be reduced to zero. Claim 1 in such a situation, however, would be worded as an ordinary second medical use claim without any patient group being defined. It cannot be correct that such a claim has a scope that is reduced to zero. Therefore the appellant's submission must fail.

1.4 For these reasons, claim 1 of the main request does not meet the requirements of Article 123(3) EPC. The main request is not allowable.

Auxiliary request 1

2. Claim 1 of auxiliary request 1 differs from claim 1 of the main request in that the molar ratio of acetaminophen to N-acetylcysteine was changed from "*1:15 to 1:0.000977*" to "*1:1, or 1:0.5, or 1:0.25, or 1:0.125*".

3. The reasons given for claim 1 of the main request regarding the extension of scope of the claimed subject-matter apply, *mutatis mutandis*, to claim 1 of auxiliary request 1. This was not disputed by the appellant.

4. Therefore claim 1 of auxiliary request 1 does not meet the requirements of Article 123(3) EPC and auxiliary request 1 is not allowable.

5. None of the appellant's claim requests is allowable.

Order

For these reasons it is decided that:

The appeal is dismissed

The Registrar: The Chairman:

N. Maslin M. O. Müller

Decision electronically authenticated