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**Datasheet for the decision
of 17 March 2022**

Case Number: T 2766/17 - 3.2.02

Application Number: 03748966.3

Publication Number: 1542903

IPC: A61J3/07, A61K8/02, B65B25/06,
A61Q11/00, B65B11/50, A61K9/70

Language of the proceedings: EN

Title of invention:
PACKAGING AND DISPENSING OF RAPID DISSOLVE DOSAGE FORM

Patent Proprietor:
MonoSolRX, LLC

Opponent:
LTS LOHMANN Therapie-Systeme AG

Headword:

Relevant legal provisions:
EPC R. 80
EPC Art. 84, 123(2), 54, 56
RPBA 2020 Art. 11

Keyword:

Amendment occasioned by ground for opposition - (yes)
Remittal - special reasons for remittal - (no)
Amendments - added subject-matter (no)
Novelty - (yes)
Inventive step - (yes)
Adaptation of the description (yes)

Decisions cited:

T 0454/89, T 0977/94, T 0523/00, T 0750/11, T 1024/18,
T 1989/18, T 0121/20

Catchword:

Statements in the description contradicting the plain claim wording may cast doubts as to the intended meaning of this wording. Under such circumstances an objection under Article 84 EPC has to be raised.



Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 2766/17 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 17 March 2022

Appellant: MonoSolRX, LLC
(Patent Proprietor) 6560 Melton Road
Portage IN 46368 (US)

Representative: Haseltine Lake Kempner LLP
Redcliff Quay
120 Redcliff Street
Bristol BS1 6HU (GB)

Appellant: LTS LOHMANN Therapie-Systeme AG
(Opponent) Lohmannstrasse 2
56626 Andernach (DE)

Representative: Schweitzer, Klaus
Plate Schweitzer Zounek
Patentanwälte
Rheingaustrasse 196
65203 Wiesbaden (DE)

Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
8 November 2017 concerning the maintenance of
European Patent No. 1542903 in amended form**

Composition of the Board:

Chairman M. Alvazzi Delfrate
Members: D. Ceccarelli
C. Schmidt

Summary of Facts and Submissions

I. The patent proprietor and the opponent appealed against the Opposition Division's decision, posted on 8 November 2017, that account being taken of the amendments made by the patent proprietor according to auxiliary request 3, European patent No. 1 542 903 and the invention to which it related met the requirements of the EPC.

II. The Board summoned the parties to oral proceedings and sent its preliminary opinion in a communication dated 6 September 2021. In this communication, the Board expressed the view that the objections of the appellant/opponent ("the opponent") under Rule 80 EPC and Article 123(2) EPC to the then pending auxiliary request 7b were not convincing and that it did not intend to remit the case to the Opposition Division for further prosecution.

III. Oral proceedings took place on 17 March 2022.

Although having been duly summoned by communication dated 6 September 2021, the opponent was not present at the oral proceedings, as announced by letters dated 19 January 2022 and 7 February 2022. In accordance with Rule 115(2) EPC and Article 15(3) RPBA, the proceedings were continued without the opponent, which is treated as relying only on its written case.

IV. At the oral proceedings, the appellant/patent proprietor ("the proprietor") withdrew its appeal.

The proprietor requested that the patent be maintained on the basis of auxiliary request 7b filed at the oral

proceedings before the Board.

The opponent had requested in writing that the decision under appeal be set aside and that the patent be revoked.

V. The following documents are mentioned in this decision.

D1: DE-A-36 30 603

D2: WO-A-00/18365

VI. Independent claims 1, 10, 21, 27, 28, 33 and 34 of auxiliary request 7b read as follows.

"1. An oral dosage delivery vehicle comprising a layer of cast edible film including a uniformly distributed active ingredient, wherein said film comprises weakened sections which divide the film into segments that represent individual dosage units, wherein the film is self-supporting, and wherein said active ingredient varies no more than 10% among said dosage units."

"10. An oral dosage delivery vehicle comprising a layer of cast edible film, wherein said film comprises dosage units releasably joined by one or more weakened sections, which permit said dosage units to be detached from said film, wherein the film is self-supporting, and wherein an active ingredient varies no more than 10% among said dosage units."

"21. A package for the storage and dispensing of a sheet-like rapid dissolve dosage form, comprising:
a) a pouch comprising a top layer and a bottom layer each having an outer edge, wherein said top and bottom layers are sealed at the respective outer edges to define an enclosed interior surface therewithin, and b)

a sheet-like rapid dissolve dosage form contained within said enclosed space; wherein said dosage form comprises a layer of cast edible film comprising weakened sections which divide the film into segments that represent individual dosage units, wherein the film is self-supporting, and wherein an active ingredient varies no more than 10% among said dosage units."

"27. A method of storing a sheet-like rapid dissolve dosage form comprising the steps of:

- a) preparing a sheet-like dosage form that includes unit doses of an active ingredient; wherein said dosage form comprises a layer of cast edible film comprising weakened sections which divide the film into segments that represent individual dosage units, wherein the film is self-supporting, and wherein the active ingredient varies no more than 10% among said dosage units;
- b) preparing a pouch comprising top and bottom layers each having an outer edge;
- c) placing said dosage form between said top and bottom layers; and
- d) sealing the outer edges of said pouch."

"28. A method of dispensing a sheet-like dosage form comprising the steps of:

- a) preparing a sheet-like dosage form that includes an active ingredient; wherein said dosage form comprises a layer of cast edible film comprising weakened sections which divide the film into segments that represent individual dosage units, wherein the film is self-supporting, and wherein the active ingredient varies no more than 10% among said dosage units;
- b) preparing a pouch comprising top and bottom layers each of said layers having an edge surrounding the

circumference of said layer;
c) placing said dosage form between said top and bottom layers;
d) separably sealing a portion of said edges of said pouch;
e) opening a portion of said pouch;
f) opening one or more of said sections of said dosage form along said perforations; and
g) removing said one or more dosage units from said pouch."

"33. A pouch comprising a top layer comprising a laminate of at least two layers and a bottom layer comprising a laminate of at least two layers, wherein said pouch is sealed along its perimeter, and wherein a layer of cast edible film, comprising weakened sections which divide the film into segments that represent individual dosage units, wherein the film is self-supporting, and wherein an active ingredient varies no more than 10% among said dosage units is included in the pouch."

"34. A pouch comprising a top layer and a bottom layer wherein said pouch is resealable along a portion of its perimeter, and wherein a layer of cast edible film, comprising weakened sections which divide the film into segments that represent individual dosage units, wherein the film is self-supporting, and wherein an active ingredient varies no more than 10% among said dosage units is included in the pouch."

VII. The proprietor's arguments relevant to the present decision can be summarised as follows.

Auxiliary request 7b had been filed at the oral proceedings to address Board's objections raised during

the oral proceedings to claims 33 and 34 and the description of previous auxiliary request 7b. Claim 1, which was identical to claim 1 of the previous auxiliary request 7b, included the limitation that the film was self-supporting. Its subject-matter was novel and inventive over D1 and D2.

VIII. The opponent's arguments (formally presented in respect of the previous version of auxiliary request 7b) relevant to the present decision can be summarised as follows.

The proprietor had not explained why the amendments made in auxiliary request 7b were occasioned by a ground for opposition. Hence, auxiliary request 7b did not comply with Rule 80 EPC. The feature of the film being self-supporting in claim 1 was not suitable, *prima facie*, for establishing novelty.

In the absence of any arguments by the proprietor in favour of novelty and inventive step, it was not possible for the opponent to answer to such arguments. For this reason, remittal to the Opposition Division was requested if the Board admitted the auxiliary request into the appeal proceedings. The parties should be given an opportunity to present their arguments on novelty and inventive step in first-instance proceedings.

The request for remittal also made clear that the opponent had objections of lack of novelty and inventive step to the auxiliary request.

The expression "a layer of cast edible film" was not present in the application as filed, which mentioned "a layer" only in relation to a backing layer 25 shown in

Figures 16 and 17. Hence, there was no original disclosure for this expression.

Reasons for the Decision

1. The invention

The invention relates to a cast edible film for oral delivery of a dosage of an active ingredient.

Figure 1, reproduced below, depicts such a cast edible film. The film (5) comprises an active ingredient and weakened sections (2) which divide the film into dosage units (1). The active ingredient varies no more than 10% among the dosage units. Moreover, the film is self-supporting.

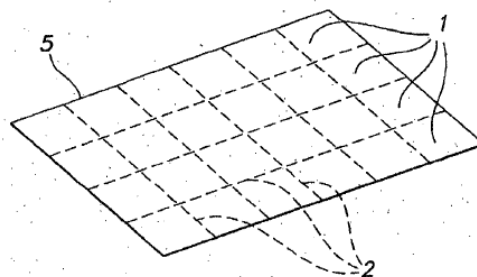


FIG. 1

It is possible to make the film in a convenient size and shape. This makes it practical as a medicament dosage vehicle.

2. Auxiliary request 7b was filed at the oral proceedings before the Board. Compared with the previous auxiliary request 7b (filed by letter dated 7 August 2018), it comprises amendments to claims 33 and 34 which, as explained by the proprietor, address an objection of

the Board raised during the oral proceedings.

Hence, auxiliary request 7b was filed in response to exceptional circumstances justified with cogent reasons by the proprietor. The Board admits it under Article 13(2) RPBA.

Compared with claim 1 of the patent as granted, which was objected to by the opponent and considered unallowable by the Opposition Division in the impugned decision, claim 1 of auxiliary request 7b was amended by the addition of the feature that the cast edible film "is self-supporting".

The opponent argued that the proprietor had not explained why this amendment was occasioned by a ground for opposition. Hence, Rule 80 EPC was not complied with.

Under Rule 80 EPC, amendments occasioned by a ground for opposition are admissible, even if that ground has not been invoked by the opponent. The addition of the feature that the film is self-supporting limits the subject-matter of the claim compared with claim 1 of the patent as granted. By limiting the subject-matter claimed, the amendment inherently addresses the grounds for opposition of lack of novelty and lack of inventive step, for example. There is no need for an express explanation in this respect by the proprietor. Hence, the formal requirements of Rule 80 EPC are complied with (see also T 750/11, point 2.3 of the Reasons). It is not relevant, as far as Rule 80 EPC is concerned, whether the amendment is successful in establishing novelty and inventive step.

It follows that auxiliary request 7b is admissible

under Rule 80 EPC.

3. The opponent requested remittal to the Opposition Division for further prosecution.

Under Article 11 RPBA, the Board must not remit a case to the department whose decision was appealed for further prosecution unless special reasons present themselves for doing so.

The Board notes that claim 1 of auxiliary request 7b corresponds to claim 1 of auxiliary request 6 which was pending before the Opposition Division. The Opposition Division implicitly considered novelty and inventive step of claim 1 of auxiliary request 6 as it allowed a request with a broader scope in view of the opponent's objections to the subject-matter of claim 1.

The opponent's argument that the proprietor did not argue why the definition of the cast edible film being self-supporting contributed to novelty and inventive step is not convincing. On appeal, it would be the task of an appellant/opponent to argue against a claim the subject-matter of which was considered patentable by the Opposition Division.

In conclusion, the Board sees no special reasons for remitting the case to the Opposition Division for further prosecution under Article 11 RPBA.

4. The opponent merely stated that it had objections of lack of novelty and inventive step to auxiliary request 7b, without providing any specific arguments.

The Board does not have any such objections under Articles 54 and 56 EPC. In particular, D1 and D2, on

the basis of which the opponent raised objections of lack of novelty and inventive step to claim 1 of previous, withdrawn requests, do not disclose or suggest a cast edible film which is self-supporting.

This feature, present in all independent claims of auxiliary request 7b, provides for a dosage delivery vehicle which is easier to manufacture since a carrier film could be dispensed with.

5. The opponent also argued that the expression "a layer of cast edible film", present in claim 1 of auxiliary request 7b, added subject-matter in breach of Article 123(2) EPC.

The Board's view is that the terms "film", "sheet-like" (as disclosed on page 4, lines 14 to 17 and page 5, lines 14 to 16 of the application as filed) and "layer" convey the same technical information. Moreover, a film in the form of a layer (5) is shown in Figures 1 to 3 of the application as filed, for example.

More generally, claim 1 of auxiliary request 7b is based on claims 1, 2 and 6; page 4, lines 14 to 17; page 5, lines 14 to 16 (for the term "layer") and page 5, lines 16 to 18 (for the term "cast") of the application as filed.

Hence, the opponent's objection of added subject-matter does not succeed either.

6. Auxiliary request 7b contains amended pages of the description to bring the description into conformity with the amended claims.

It is established case law that if the patentee amends its claims, it has to bring the description into line with them (see decision T 977/94, point 6 of the Reasons and other decisions cited in Case Law of the Boards of Appeal of the European Patent Office, ninth edition, July 2019, II.A.5.3).

The Board is aware of decision T 1989/18, in which the competent Board considered that the provisions of the EPC did not require the adaptation of the description to the subject-matter as claimed (points 4 to 13 of the Reasons). However, in other recent decisions (T 1024/18 point 3.1 of the Reasons and T 121/20, point 10.2 of the Reasons), the competent Boards reached a different conclusion.

The current Board concurs with decision T 1989/18 and, as a rule, with the cited conclusion drawn in T 454/89 (point 4.1 (vii) of the Reasons), that for the purposes of Article 84 EPC, the claims must be clear in themselves. However, if the description cannot be relied upon to resolve a clarity issue in a claim, this does not imply that, *a contrario*, clarity of the claim cannot be affected if the description contains statements contradicting the plain wording of the claim.

A patent specification is a unitary document disclosing and explaining an invention to the person skilled in the art. Article 84 EPC and Rule 42(1)(c) EPC expressly link the claims and the description for the purpose of disclosing the invention. Hence, the patent specification has to be considered as a whole for understanding the claimed invention as a solution to a technical problem.

In some cases, the drafter may choose to give a term a special meaning so that the patent specification becomes its own dictionary (see T 523/00, point 2 of the Reasons and other decisions cited in Case Law of the Boards of Appeal of the European Patent Office, ninth edition, July 2019, II.A.6.3.3, fourth paragraph).

Hence, statements in the description contradicting the plain claim wording may cast doubts as to the intended meaning of this wording. It is the Board's view that under such circumstances, an objection under Article 84 EPC has to be raised.

It was in response to such an objection by the Board that the proprietor filed the amended description pages. The amendments bring the description into conformity with the amended claims by making clear the non-optional character of the feature that the cast edible film is self-supporting. This is in compliance with Article 84 EPC.

7. In conclusion, none of the opponent's objections prejudice the maintenance of the patent on the basis of auxiliary request 7b.

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 in the following version:
 - claims 1 to 37 of auxiliary request 7b, filed at the oral proceedings before the Board
 - description pages 2 to 5 as filed during the oral proceedings before the Board and 6 to 8 of the patent specification
 - Figures 1 to 21 of the patent specification

The Registrar:

The Chairman:



D. Hampe

M. Alvazzi Delfrate

Decision electronically authenticated