

**Internal distribution code:**

- (A) [ - ] Publication in OJ
- (B) [ - ] To Chairmen and Members
- (C) [ - ] To Chairmen
- (D) [ X ] No distribution

**Datasheet for the decision  
of 16 October 2018**

**Case Number:** T 0733/14 - 3.3.07

**Application Number:** 02801042.9

**Publication Number:** 1458367

**IPC:** A61K9/70, A61K9/00, A61K9/16

**Language of the proceedings:** EN

**Title of invention:**

UNIFORM FILMS FOR RAPID DISSOLVE DOSAGE FORM INCORPORATING  
TASTE-MASKING COMPOSITIONS

**Patent Proprietor:**

MonoSolRX, LLC

**Opponents:**

LTS LOHMANN Therapie-Systeme AG  
Ahrens, Gabriele

**Headword:**

UNIFORM FILMS FOR RAPID DISSOLVE DOSAGE FORM INCORPORATING  
TASTE-MASKING COMPOSITIONS/MonoSolRX, LLC

**Relevant legal provisions:**

RPBA Art. 12(2), 12(4), 13(3)  
EPC Art. 111(1), 114(1)

**Keyword:**

Auxiliary request 4 - Admission into the proceedings (yes)  
Remittal to the opposition division

**Decisions cited:**

G 0009/91

**Catchword:**



**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 0733/14 - 3.3.07

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.07**  
**of 16 October 2018**

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

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

**Respondent:** LTS LOHMANN Therapie-Systeme AG  
(Opponent 1) Lohmannstrasse 2  
56626 Andernach (DE)

**Representative:** Schweitzer, Klaus  
Plate Schweitzer Zounek  
Industriepark Kalle-Albert  
Rheingaustrasse 196  
65203 Wiesbaden (DE)

**Respondent:** Ahrens, Gabriele  
(Opponent 2) Jasperallee 1A  
38102 Braunschweig (DE)

**Representative:** Ahrens, Gabriele  
Patentanwälte Einsele & Kollegen  
Jasperallee 1A  
38102 Braunschweig (DE)

**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 16 January 2014  
revoking European patent No. 1458367 pursuant to  
Article 101(3) (b) EPC.**

**Composition of the Board:**

**Chairman**            J. Riolo  
**Members:**            D. Boulois  
                             P. Schmitz

## Summary of Facts and Submissions

- I. European patent No. 1 458 367 was granted on the basis of a set of 36 claims.

Independent claims 1, 20 and 25 as granted read as follows:

"1. A drug delivery composition comprising:

(i) a flowable at least partially water-soluble or at least partially water-swelling film forming matrix;

(ii) a particulate bioeffecting agent uniformly stationed therein; and

(iii) a taste-masking agent coated or intimately associated with said particulate to provide taste-masking of the bioeffecting agent, wherein said taste-masking agent is selected from the group consisting of acrylic polymers, cellulosic polymers, vinyl polymers, crown ethers, hydrogenated oils and waxes, and combinations thereof;

wherein the combined particulate and taste-masking agent have a particle size of 200 microns or less and said at least partially water-soluble or at least partially water-swelling film forming matrix is capable of being dried without loss of uniformity in the stationing of said particulate bioeffecting agent therein."

"20. A drug delivery vehicle comprising:

(i) a water-soluble film matrix; and

(ii) a particulate bioeffecting agent uniformly suspended within said matrix and having associated with it a taste-masking agent;

wherein said taste-masking agent is coated or intimately associated with said particulate to provide taste-masking of the bioeffecting agent, wherein said

taste-masking agent is selected from the group consisting of acrylic polymers, cellulosic polymers, vinyl polymers, crown ethers, hydrogenated oils and waxes, and combinations thereof; and wherein the combined particulate and taste-masking agent have a particle size of 200 microns or less; and wherein the uniformity is determined by the presence of no more than a 10% by content variance of said bioeffecting agent throughout said matrix."

"25. A method of preparing a film drug delivery vehicle comprising:

- (a) providing a component comprising a particulate bioeffecting agent associated with a taste-masking agent, wherein said taste-masking agent is selected from the group consisting of acrylic polymers, cellulosic polymers, vinyl polymers, crown ethers, hydrogenated oils and waxes, and combinations thereof;
- (b) combining said component with an at least partially water-soluble or at least partially water-swellable polymer and a solvent to form a mixture with uniform distribution of said component therein;
- (c) casting said mixture onto a planar carrier surface to form a film on said carrier surface; and
- (d) controllably drying said film to form a distribution variance of said bioeffecting agent of less than or equal to a 10% by weight variance throughout any given area of said film."

- II. Two oppositions were filed against the granted patent under Article 100 (a), (b), (c) EPC on the grounds that its subject-matter lacked novelty and inventive step, was not sufficiently disclosed, and extended beyond the content of the application as filed.

III. The present appeal lies from the decision of the opposition division to revoke the patent. The decision was based on 4 sets of claims, namely the claims as granted as main request and auxiliary requests 1-3 filed during the oral proceedings of 6 December 2013.

IV. The documents cited during the opposition proceedings included the following:

D1: EP-B-1 143 940

D2: EP-A-1 674 018

D8: EP-A-0 241 178

D9: WO01/70184

V. According to the decision under appeal, the replacement of the feature "water-soluble" by "at least partially water-soluble or at least partially water-swellable" in claim 1 of the main request extended beyond the content of the application as filed. The subject-matter of claims 23 and 24 were also not derivable from the content of the application as filed.

The amended product claims 1 and 19 of auxiliary request 1 did not meet the requirements of Article 123(2) EPC.

The product claims 1 and 19 of auxiliary request 2 were not novel over D2/D9.

In the absence of indications on the molecular weight of the disclosed polymers in D2/D9, the independent product claim 1 of auxiliary request 3 was novel, but was not considered as inventive over document D2/D9.

VI. The proprietor (hereinafter the appellant) filed an appeal against said decision. With the statement setting out the grounds of appeal dated 26 May 2014,

the appellant submitted a new Main Request and auxiliary requests A, B, C, C1, C2, D, D1, D2, E, E1, E2, F and the following pieces of evidence:  
D42: Varanda et al, Ind. Eng. Chem. Res. 2006, 45, 6368-6374.

- VII. With a letter dated 2 October 2014, opponent 02 (hereinafter respondent 02) requested that all requests not be admitted into the proceedings.
- VIII. With a letter dated 14 December 2017, the appellant submitted new auxiliary requests 3-5 and renumbered the previous auxiliary requests A, B, C, C1, C2, D, D1, D2, E, E1, E2, and F to respectively auxiliary requests 1, 2, 6-15. It also submitted the new evidence D43-D45.  
D43: USSN 10/074,272  
D44: Perumal et al, Drug. Dev. And Ind. Pharm., 2008, 34, pp 1036-1047  
D45: Experimental Data - Repetition of Example 8 of D10 from the file history of EP1542903B1 and headed « Appendix A »
- IX. With a letter dated 13 February 2018, respondent 02 requested that auxiliary requests 3-5 and documents D43-D45 not be admitted into the proceedings.
- X. With a letter dated 25 June 2018, opponent 01 (hereinafter respondent 01) requested that documents D43-D45 not be admitted into the proceedings. It also submitted new pieces of evidence, D46, D46a, D46b and D46c.
- XI. A communication from the Board, dated 3 August 2018, was sent to the parties. In this, it was considered in particular that D2/D9 and D8 were relevant for novelty of the main request and auxiliary requests 1-8 and



12-15 and that the subject-matter of auxiliary requests 9-11 did not appear to be inventive.

XII. With a letter dated 27 September 2018, the appellant filed a new main request and auxiliary requests 1-4, 4A, 5, 5A, 5B, 5C, 6, 6A, 6B, 6C.

The subject-matter of independent claim 1 of auxiliary request 4 was identical to claim 23 of the main request as filed with the statement of grounds of appeal. It read as follows, differences compared with claim 25 as granted being shown in bold:

"1. A method of preparing a film drug delivery vehicle comprising:

- (a) providing a component comprising a particulate bioeffecting agent associated with a taste-masking agent, wherein said taste-masking agent is selected from the group consisting of acrylic polymers, cellulosic polymers, vinyl polymers, crown ethers, hydrogenated oils and waxes, and combinations thereof;
- (b) combining said component with an at least partially water-soluble or at least partially water-swellaible polymer and a solvent to form a mixture with uniform distribution of said component therein;
- (c) casting said mixture onto a planar carrier surface to form a film on said carrier surface; and
- (d) controllably drying said film to form a distribution variance of said bioeffecting agent of less than or equal to a 10% by weight variance throughout any given area of said film;

**wherein said particular bioeffecting agent associated with a taste-masking agent comprises particles that are about 200 microns or less."**

XIII. Oral proceedings took place on 10 October 2018. During oral proceedings, the appellant declared that he withdrew the main request and auxiliary requests 1 to 3 and requested that the case be remitted to the opposition division.

XIV. The arguments of the appellant may be summarized as follows:

Claim 1 of auxiliary request 4 corresponded to claim 25 as granted, and as such did not present any complexity. This request had therefore to be admitted into the proceedings.

XV. The arguments of the respondents may be summarized as follows:

According to respondent 02, none of the requests filed with the statement of grounds of appeal were admissible since they were all late-filed and prima facie not clearly allowable. The requests filed with the letter of 14 December 2017 were filed after oral proceedings had been appointed and were not admissible under Article 13(3) RPBA. Auxiliary request 4 as filed with letter of 27 September 2018 corresponded to auxiliary request 5 and was thus not admissible since it was late-filed, not clearly allowable, and gave rise to fresh issues.

XVI. Requests

The appellant (patent proprietor) requested that the decision under appeal be set aside and that the case be remitted to the opposition division on the basis of auxiliary request 4 filed with letter of 27 September 2018.

The respondents (opponents) requested that the appeal be dismissed.

Respondent 2 additionally requested that all requests not be admitted into the proceedings, because they were late filed.

### **Reasons for the Decision**

1. Auxiliary request 4 - Admission into the proceedings

This request corresponds to auxiliary request 5 filed with letter dated 14 December 2017, which has been objected by respondent 02 under Article 13(3) RPBA. Present auxiliary request is objected under the same Article 13(3) RPBA.

Claim 1 of auxiliary request 4 is identical to independent claim 23 of the main request filed with the statement of grounds of appeal, and corresponds thus to an independent claim present in a request filed at the earliest stage of the appeal proceedings. It therefore cannot be considered as late-filed, as argued by respondent 02. Moreover, its subject-matter cannot constitute a surprise, since it is based on independent claim 25 as granted with the subject-matter of its dependent claim 31 as granted incorporated therein.

Hence, the Board does not see any reason not to accept this request into the proceedings under Article 13(3) RPBA.

2. Auxiliary request 4 - Remittal to the opposition division

The opposition division has not yet ruled on the process claims, since the discussion during the oral proceedings before the opposition division focused only on the product claims. It is not the duty of the Boards of Appeal to consider and decide upon questions raised for the first time during the appeal proceedings. Instead, the main purpose of appeal proceedings is to give the losing party the opportunity to challenge the decision of the opposition division (cf. G 9/91, *loc. cit.*, point 18 of the Reasons). Taking into account that the the decision of the opposition division does not deal with the process claims, the Board considers it appropriate to exercise its power conferred on it by Article 111(1) EPC to remit the case to the opposition division for further prosecution on the basis of the claims according to the auxiliary request 4. This remittal has not been objected by any party to the appeal proceedings.

## **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 for further prosecution.

The Registrar:

The Chairman:



S. Fabiani

J. Riolo

Decision electronically authenticated