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**Datasheet for the decision
of 18 July 2019**

Case Number: T 0583/17 - 3.3.07

Application Number: 11157819.1

Publication Number: 2332523

IPC: A61K31/4545, A61K9/00,
A61K9/70, A61K9/16, A61K45/00

Language of the proceedings: EN

Title of invention:
Uniform films for rapid dissolve dosage form incorporating
taste-masking compositions

Patent Proprietor:
MonoSol RX LLC

Opponent:
Ahrens, Gabriele

Headword:
Uniform films / MONOSOL RX LLC

Relevant legal provisions:
EPC Art. 113(1), 123(3), 100(c), 76(1), 123(2)
EPC R. 103(1)(a)

Keyword:

Substantial procedural violation - reimbursement of appeal fee
(no)

Divisional application - added subject-matter (no) - after
amendment

Decisions cited:

T 2362/08



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Case Number: T 0583/17 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 18 July 2019

Appellant: MonoSol RX LLC
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 3 January 2017
revoking European patent No. 2332523 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman A. Uselli
Members: E. Duval
Y. Podbielski

Summary of Facts and Submissions

I. European Patent 2 332 523 (hereinafter "the patent") was granted on a divisional application of European patent application 02801042.9 (hereinafter "the earlier application"). Claim 1 of the patent as granted read as follows:

"A cast wet film delivery system comprising;

(i) a flowable at least partially water soluble or at least partially water swellable wet film forming matrix;

(ii) a particulate bioeffecting agent uniformly stationed within and/or on said wet matrix; and

(iii) a taste-masking agent coated or intimately associated with said particulate bioeffecting agent;

wherein the average particle size of the combined particulate bioeffecting agent and said taste-masking agent is less than the thickness of said wet film matrix [500-1500 μ m (20-60mils)]."

II. An opposition was filed against the patent on the grounds that its subject-matter lacked novelty and inventive step, it was not sufficiently disclosed and it extended beyond the content of the earlier application as filed.

III. The opposition division took the decision to revoke the patent. The decision was based on a main request (filed on 23 September 2016) and on auxiliary requests J, K, L, M (filed during the oral proceedings), A, D, E, F, G (filed on 23 September 2016), B, C, H, I (filed on 29 September 2016) and A', C', E', G' (filed on 18 November 2016).

In particular, the opposition division decided that:

- (a) In the earlier application as filed, a thickness of 500-1500 μ m was only disclosed in relation with a wet film as initially cast, i.e. before any drying. Claim 1 of the main request did not contain this limitation, and thus included products comprising a wet film matrix having said thickness but resulting from partial drying, which could not be derived from the earlier application as filed. Moreover, the earlier application as filed did not disclose said thickness in association with the quality of a delivery system. For these reasons, the requirements of Article 76(1) EPC were not fulfilled.
- (b) Auxiliary requests J, K, L, M, B, D, F and H did not overcome the non-compliance with Article 76(1) EPC because these requests introduced a combination of the feature "initially cast" with "delivery system", or still combined the thickness of 500-1500 μ m with "delivery system " or "delivery composition", which combination went beyond the content of the earlier application as filed.
- (c) In auxiliary requests A, C, E, G, I, A', C', E' and G', the particle size was less than the initial cast thickness of said wet film matrix, but no longer needed to be less than the thickness of the wet film matrix of the delivery system as required by claim 1 of the patent. As a consequence, the requirements of Article 123(3) EPC were not fulfilled by auxiliary requests A, C, E, G, I, A', C', E', and for similar reasons by auxiliary request H.

(d) The patent proprietor's request for adjournment of the oral proceedings was not granted. Contrary to the patent proprietor's view, the line of argument, according to which the matrix with a thickness of 500-1500µm was only disclosed in relation with a film as initially cast and such initially cast film had not been disclosed in conjunction with any delivery properties, had been raised by the opponent in his letter dated 22 September 2016. The patent proprietor's right to be heard was therefore not violated.

IV. The appeal was filed by the patent proprietor (appellant) against that decision.

With its statement of grounds of appeal, the appellant argued that a violation of its right to be heard had occurred in the proceedings at first instance. Additionally, the appellant filed a main request and auxiliary requests 1-23.

V. In a communication pursuant to Article 15(1) RPBA, the Board expressed the preliminary view that none of the requests on file complied with the requirements of Article 76(1) EPC, and that no substantial procedural violation had occurred in the proceedings before the opposition division.

VI. By letter dated 28 June 2019, the appellant filed a new main request and auxiliary requests 0A-0E, 1, 1A-1E, 2 and 3.

Claim 1 of auxiliary request 0C read as follows:

"A cast wet film delivery system as initially cast comprising;

(i) a flowable water soluble wet film forming matrix;

(ii) a particulate bioeffecting agent uniformly stationed within said wet matrix; and

(iii) a taste-masking agent coated onto said particulate bioeffecting agent;

wherein the thickness of said wet film matrix is 500-1500 μ m (20-60 mils); and

wherein the combined particulate and taste-masking agent have a particle size of 200 microns or less."

VII. Oral proceedings were held before the Board in the absence of the respondent. During the oral proceedings, the appellant withdrew its main request and auxiliary requests 0A and 0B, thus making auxiliary request 0C its main request.

VIII. The appellant's arguments, insofar as relevant to the present decision, can be summarised as follows:

(a) The opposition division raised a new objection pursuant to Article 76(1) EPC at the oral proceedings, namely that the combination of a thickness of 500-1500 μ m with the quality of a delivery system was not disclosed in the earlier application as filed. This objection did not equate with the arguments put forward by the opponent in his preceding letter dated 22 September 2016. By refusing to postpone the oral proceedings and not giving the appellant a proper opportunity to be heard on this new objection, the opposition division committed a substantial procedural violation. In this respect, the present situation was factually similar to the case T 2362/08.

- (b) The combination of the feature "cast wet film delivery system" with the claimed film thickness complied with the requirements of Articles 76(1) and 123(2) EPC. The passage on pages 3 to 4 of the original application referred to an intermediate flowable composition to be formed into a film and dried, and described it as a "drug delivery composition". The skilled person would read the descriptor "delivery" broadly in the context of the intermediate flowable composition and the initially cast film thereof as disclosed on page 35, as indicating the suitability in the field of drug delivery.

- (c) The feature pertaining to the particle size of the combined particulate and taste-masking agent would not be considered by the skilled reader to be inextricably linked with the capability of the matrix to be dried without loss of uniformity in the stationing of the particulate bioeffecting agent therein. Accordingly, the particle size feature did not result from an unallowable intermediate generalisation.

IX. The respondent's arguments, insofar as relevant to the present decision, can be summarised as follows:

- (a) The right to be heard of the appellant had neither been violated by the opposition division. Nor had the appellant been confronted with a new argument. The critical point of potential lack of original disclosure for the combination of "an initial wet film" and the "delivery property" had been discussed long before the oral proceedings before the opposition division took place. Additionally,

the present case differed from T 2362/08 in that the objection was a formal objection rather than a substantive one, and in that the appellant was not faced with an unexpected reversal of opinion from the opposition division. Sufficient time was given to the appellant to present his case, and an adjournment of the oral proceedings was not necessary.

- (b) With respect to the main request and auxiliary requests 1-23 filed by the appellant with the statement of grounds of appeal, the respondent raised the following objections pursuant to Articles 76(1) and 123(2) EPC:
- (i) The intermediate wet product as initially cast disclosed on page 35 of the (earlier) application as filed, and having a thickness of 500-1500µm, was not disclosed to be suitable as a delivery system, i.e. having the capacity to deliver the drug to a patient. A delivery system only resulted after appropriate further processing, in particular drying. Thus, the combination of the feature "cast wet film delivery system" with the claimed film thickness contravened the requirements of Articles 76(1) and 123(2) EPC.
 - (ii) The isolation of the feature "wherein the combined particulate and taste-masking agent have a particle size of 200 microns or less" from the combination of features disclosed on pages 3-4 of the original application represented an intermediate generalisation.

(iii) The (earlier) application as filed disclosed in one alternative that the taste masking agent was coated with the particulate bioeffecting agent. An inverse of this arrangement, i.e. the claimed feature according to which the taste masking agent was coated onto the particulate bioeffecting agent, was not derivable from the (earlier) application as filed.

(iv) The subject-matter of claim 1 furthermore introduced undisclosed combinations of features regarding the water soluble matrix, the particulate bioeffecting agent uniformly stationed within said matrix, and the taste-masking agent coating.

X. The appellant requests that the decision under appeal be set aside and that the case be remitted to the opposition division for further prosecution on the basis of the main request (filed as auxiliary request 0C) or alternatively on the basis of one of auxiliary requests 0D-0E, 1, 1A-1E, 2 or 3, all filed with letter dated 28 June 2019. Reimbursement of the appeal fee under Rule 103(1) EPC is also requested.

XI. The respondent requests that the appeal be dismissed.

Reasons for the Decision

Absence of the respondent at the oral proceedings

1. As announced in its letter dated 16 July 2019, the respondent did not attend the oral proceedings.

In accordance with Rule 115(2) EPC and Article 15(3) RPBA, the oral proceedings were held without the respondent. By its decision not to attend the oral proceedings, the respondent has chosen not to make any further submissions during such proceedings.

In the present case, the duly summoned respondent has to be treated as relying only on its written case.

Request for remittal for reason of a substantial procedural violation and reimbursement of the appeal fee

2. In the decision under appeal, the finding of non-compliance of claim 1 of the main request with the requirements of Article 76(1) EPC is based *inter alia* on the following reason: the combination of a thickness of 500-1500µm with the quality of a delivery system was not disclosed in the earlier application as filed.

According to the appellant, this objection was newly raised at the oral proceedings. The appellant considers that it was not given a proper opportunity to be heard on this new objection, in contravention of Article 113(1) EPC.

- 2.1 Article 113(1) EPC provides that decisions of the EPO may only be based on grounds or evidence on which the

parties concerned have had an opportunity to present their comments. Accordingly, the appellant must have been informed not only of the ground for opposition (here: the ground of Article 100(c) EPC), but also of the essential legal and factual reasons (i.e. its substantiation) which led to a finding of invalidity and revocation. Thereafter the appellant must have had a proper opportunity to present comments in reply to the ground and its substantiation.

2.2 In the present case, the essential legal and factual reasons underlying the finding of non-compliance with Article 76(1) EPC were laid out in writing well before the oral proceedings before the opposition division.

Already in the notice of opposition, the ground for opposition under Article 100(c) EPC was raised, and the relevant passages of the earlier application as filed (page 3, line 29 to page 4, line 15; page 35, lines 12-15) were discussed. The respondent (then opponent) objected (generally) that the features of claim 1 were not disclosed in combination.

In its preliminary opinion annexed to the summons to oral proceedings, the opposition division drew attention to the question whether the features of claim 1 were disclosed in combination in the earlier application.

In its letter dated 22 September 2016 (paragraph 2.6), on the topic of the "support for the combination of features of claim 1", the respondent (then opponent) argued that said passages on pages 3-4 referred to "a drug delivery composition", not to "a cast wet film delivery system" as defined in claim 1 of the main

request, and that said passage on page 35 referred to an "initial film", not to "a wet film".

- 2.3 Accordingly, the alleged legal issue, namely the absence of support for the combination of features of claim 1, and its factual basis, in particular the cited passages on pages 3-4 and 35, were identified in the written phase and in particular in the letter dated 22 September 2016.

The Board agrees with the appellant that this substantiation does not pertain explicitly to the specific combination of features mentioned at the beginning of the oral proceedings before the opposition division and in the decision under appeal, namely a thickness of 500-1500µm and the quality of a delivery system.

Nonetheless, the line of argument submitted in writing defines a narrow framework encompassing the specific reason given in the decision under appeal, since the feature pertaining to the film thickness of 500-1500µm appears in the cited passage on page 35, whereas the quality of a drug delivery system or composition was mentioned in the embodiment disclosed on pages 3-4.

The focus, during the oral proceedings, on these specific features of each passage is a further refinement supporting the objection previously raised, which was well within the scope of the discussion that the opposition division could expect the parties to address in the course of the oral proceedings.

- 2.4 In these circumstances, the Board does not share the appellant's view that the objection raised at the beginning of the oral proceedings, according to which

the feature "cast wet film delivery system" had not been disclosed in conjunction with the claimed film thicknesses, represented a new line of argumentation justifying a postponement of oral proceedings. The facts of the present case thus differ essentially from the circumstances of T 2362/08, where a completely new line of argumentation had been raised for the first time at the oral proceedings, and the opposition division had reversed its previously expressed opinion. Lastly, for the Board, the appellant was given sufficient time to address the objection by filing amended claim requests J, K, L and M during the oral proceedings.

- 2.5 Accordingly, no substantial procedural violation occurred. Consequently, the reimbursement of the appeal fee is not justified.

Main request (filed as auxiliary request 0C)

3. Article 123(3) EPC

In claim 1 of the main request, as compared with claim 1 as granted, the following feature is removed:

- "the average particle size of the combined particulate bioeffecting agent and said taste-masking agent is less than the thickness of said wet film matrix [500-1500µm (20-60 mils)]",

while the following features are added:

- "the thickness of said wet film matrix is 500-1500µm (20-60 mils)", and

- "the combined particulate and taste-masking agent have a particle size of 200 microns or less".

Any combined particulate having a *particle size* of 200 μm or less, whether it is an average particle size or an absolute maximum particle size, necessarily also has an *average particle size* of 200 μm or less. Such a combined particulate must consequently have an *average particle size* which is less than the thickness of the wet film matrix, since this thickness is at least 500 μm . In other words, the feature pertaining to the average particle size in granted claim 1 has been replaced with a more limiting feature relating to the particle size.

The remaining amendments consist in further limitations, namely the addition of the feature "as initially cast", the limitation to a "flowable water soluble wet film forming matrix" and the selection of the alternative in which the taste-masking agent is "coated onto said particulate bioeffecting agent". Accordingly, any composition falling within the scope of the amended claims is necessarily covered by the claims as granted.

As a result, the requirements of Article 123(3) EPC are fulfilled.

4. Article 100(c) EPC

4.1 Pursuant to Article 100(c) EPC, the subject-matter of the patent cannot extend beyond the content of the earlier application as filed.

4.2 The subject-matter of claim 1 of the main request differs from the composition disclosed on page 3, line

29 to page 4, line 3, of the earlier application as filed as follows:

- (a) the expression "drug delivery composition" (pages 3-4) is replaced with "cast wet film delivery system as initially cast" (claim 1);
- (b) the taste-masking agent (iii) is "coated onto said particulate bioeffecting agent" (claim 1), rather than being "coated or intimately associated with the particulate to provide taste-masking of the bioeffecting agent" (pages 3-4);
- (c) the feature "the thickness of said wet film matrix is 500-1500µm (20-60 mils)" is introduced; and
- (d) of the two features shown on page 3, line 32 to page 4, line 1, only the feature "the combined particulate and taste-masking agent have a particle size of 200 microns or less" is present in claim 1, whereas the feature pertaining to the flowable water-soluble film forming matrix is not present in claim 1.

4.3 Regarding amendment (d), the respondent is of the opinion that the feature "wherein the combined particulate and taste-masking agent have a particle size of 200 microns or less" is only disclosed in the earlier application as filed in combination with the feature "the flowable water-soluble film forming matrix is capable of being dried without loss of uniformity in the stationing of the particulate bioeffecting agent therein". The amendment would therefore represent an intermediate generalisation.

For the Board, even though the two features are disclosed together in the earlier application as filed and linked by the word "and", no structural or functional link between the two features can be identified. The features pertain to separate components of the composition, i.e the particulate bioeffecting agent (ii) and the matrix (i). No inextricable link between the particle size of component (ii) and this characteristic of the matrix (i) is derivable from the earlier application as filed.

Accordingly, the alleged isolation of the particle size feature from the combination of features initially disclosed does not introduce added subject-matter.

- 4.4 Regarding amendment (b), the Board shares the opposition division's view that the definition of the taste-masking agent as being coated onto the particulate bioeffecting agent is derivable from the earlier application as filed. In light of the passages cited in the decision under appeal (page 13, lines 18-23; page 22, lines 12-14), the expression "a taste-masking agent coated or intimately associated with the particulate" can be read as referring, in one alternative, to a taste-masking agent coated onto the particulate, and not coated with the particulate as the respondent suggests.
- 4.5 Regarding amendment (c), it is not contested that the feature of the wet film as initially cast having a thickness of 500-1500µm (20-60 mils) is derivable from page 35, especially lines 12-15. In this respect, as a result of this limitation to a wet film as initially cast, claim 1 no longer covers films resulting from a partial drying, which would necessarily have a different thickness. The corresponding objection of the

respondent, which also formed part of the decision under appeal (point 2.1), is thus addressed.

4.6 Lastly, regarding amendment (a), the feature "delivery" is to be understood as "drug delivery", and is disclosed on page 3, line 29. However, the question arises as to whether the combination of amendment (c) with amendment (a) is derivable from the earlier application as filed, or in other words, whether the the combination of the wet film thickness of 500-1500µm with the quality of a delivery system was disclosed in the earlier application as filed.

4.6.1 For the Board, the earlier application as filed generally relates to uniform films comprising taste-masked pharmaceutically active agents. Such films are produced by methods comprising mixing the film components (see page 30), forming the film e.g. by casting (see page 31), and drying the film (see page 33).

The passage on pages 3-4 of the earlier application as filed relates to a drug delivery composition comprising, in particular, a flowable water-soluble film forming matrix (i). The Board shares the appellant's view that this passage relates to an intermediate composition to be dried, and not to the final composition in the form of a dry film. This is apparent from the fact that the composition contains a "flowable water-soluble film forming matrix" which should be "capable of being dried without loss of uniformity". Thus the passage on pages 3-4 must refer to an intermediate flowable composition which is then to be formed into a film and dried. Contrary to the opposition division's view, the matrix is defined as

being "flowable" itself and not merely as being suitable for forming a flowable film.

The Board sees not reason for assuming that this intermediate flowable product will have a different composition after being formed, i.e. cast into a wet film. It follows that, whichever meaning is given to the expression "drug delivery composition" in the context of this intermediate product, the cast composition is necessarily as suitable for drug delivery as the composition before casting.

Consequently, the combination of the film thickness (from page 35) with the quality of the composition making up the film to be suitable for drug delivery (pages 3-4) does not introduce added subject-matter.

- 4.7 In summary, the main request complies with the requirements of Article 76(1) EPC. Since the earlier application as filed and the (divisional) application as filed are identical with respect to the relevant passages, the criteria of Article 123(2) EPC are also met.

Remittal to the opposition division

5. Under Article 111(1) EPC the Board of Appeal may either decide on the appeal or remit the case to the department which was responsible for the decision appealed. Remittal is taken into consideration by the boards in cases where a first instance department issues a decision solely upon one particular issue which is decisive for the case against one party and leaves other essential issues outstanding. If, following appeal proceedings, this party's appeal on the particular issue is allowed, the case is normally

remitted to the first instance department for consideration of the undecided issues.

Since the opposition division decided only on the question of compliance with the requirements of Articles 76(1) and 123(3) EPC, and did not consider the further grounds for opposition, the Board considers it appropriate to allow the appellant's request for remittal of the case to the opposition division.

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.
3. The request for reimbursement of the appeal fee is refused.

The Registrar:

The Chairman:



B. Atienza Vivancos

A. Uselli

Decision electronically authenticated