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**Datasheet for the decision  
of 21 January 2021**

**Case Number:** T 0525/17 - 3.3.07

**Application Number:** 02782151.1

**Publication Number:** 1463491

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

**Language of the proceedings:** EN

**Title of invention:**

THIN FILM WITH NON-SELF-AGGREGATING UNIFORM HETEROGENEITY,  
PROCESS FOR THEIR PRODUCTION AND DRUG DELIVERY SYSTEMS MADE  
THEREFROM

**Patent Proprietor:**

MonoSolRX, LLC

**Opponents:**

Germann, Sandra  
Acino Pharma AG

**Headword:**

Thin film with non self-aggregating uniform heterogeneity/  
MONOSOL

**Relevant legal provisions:**

EPC Art. 123(2), 123(3), 84, 111(1)  
RPBA 2020 Art. 11

**Keyword:**

Main request - Article 123(2) EPC, Article 123(3) EPC, Article 84 EPC (Yes)

**Decisions cited:**

T 1966/16, T 0547/14, T 0275/15



**Beschwerdekammern**

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Case Number: T 0525/17 - 3.3.07

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.07**  
**of 21 January 2021**

**Appellant:** MonoSolRX, LLC  
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**Decision under appeal:** **Decision of the Opposition Division of the  
European Patent Office posted on 10 February  
2017 revoking European patent No. 1463491  
pursuant to Article 101(3) (b) EPC.**

**Composition of the Board:**

**Chairman**           A. Uselli  
**Members:**         D. Boulois  
                      Y. Podbielski

## **Summary of Facts and Submissions**

- I. European patent No. 1 463 491 was granted on the basis of a set of 56 claims.

Independent claim 1 as granted read as follows:

"1. A film product formed by the steps of:

(a) combining a water soluble polymer and water to form a material with a non-self-aggregating uniform heterogeneity;

(b) forming said material into a film having a top side and a bottom side; and

(c) drying said film from the bottom of said film to the top of said film at a temperature of 100 °C or less by applying heat to the bottom side wherein the drying occurs within the first 0.5 to 4.0 minutes."

- II. Two oppositions were filed against the granted patent under under Article 100 (a), (b) and (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 appeal lies from the decision of the opposition division to revoke the patent.

The decision was based on 15 sets of claims with the claims as granted as the main request and 14 auxiliary requests.

- IV. According to the decision under appeal, no clear basis could be found for the wording of part c) of claim 1, namely for the feature "wherein the drying occurs

within the first 0.5 to 4.0 minutes". The time period of 0.5 to 4.0 minutes in step c) of claim 1 did indeed not refer to an initial setting period but only to "the drying." Given that the claim was silent about the existence of different drying phases, there was no reason not to interpret this term in its broadest sense, i.e. as meaning the whole drying process. There did not exist any basis for such an embodiment in the application as originally filed. The main request did not meet the requirements of Article 123(2) EPC for this reason.

Auxiliary requests 1-6 and 9 were not admitted into the opposition proceedings.

Claim 1 of auxiliary requests 7, 8, 10, 11, 13 and 14 did not meet the requirements of Article 123(3) EPC in view of the term "wherein the drying forms a solid, visco-elastic structure during an initial setting period which occurs within the first 0.5 to 4.0 minutes".

Auxiliary request 12 did not meet the requirements of Article 123(2) EPC for the same reasons as the main request.

- V. The patent proprietor (hereinafter the appellant) filed an appeal against said decision. With the statement setting out the grounds of appeal dated 16 June 2017, the appellant filed auxiliary requests 1-14. It also requested that the case be remitted to the opposition division for examination of the remaining grounds of opposition.

Independent claim 1 of auxiliary request 1 read as follows, difference(s) compared with claim 1 as granted of the main request shown in bold:

"1. A film product formed by the steps of:

(a) combining a water soluble polymer and water to form a material with a non-self-aggregating uniform heterogeneity;

(b) forming said material into a film having a top side and a bottom side; and

(c) drying said film from the bottom of said film to the top of said film at a temperature of 100 °C or less by applying heat to the bottom side wherein the drying **forms a solid, visco-elastic structure during an initial setting period which** occurs within the first 0.5 to 4.0 minutes."

VI. With its reply dated 18 October 2017, the opponent 01 (hereinafter the respondent 01) requested that a decision about the raised objections under Articles 100(a) and (b) EPC be taken during the appeal procedure. The respondent 01 also requested that auxiliary requests 3-14 not be admitted into the appeal proceedings.

VII. In its communication dated 5 December 2019 the Board expressed its preliminary opinion that claim 1 of the patent as granted did not meet the requirements of Article 123(2) EPC.

VIII. With a letter dated 23 December 2019, the appellant submitted new auxiliary requests 1-4. Auxiliary requests 1 to 14 filed with the statement of grounds of appeal were renumbered as auxiliary requests 5 to 18.

IX. With a letter dated 16 December 2020, opponent 02 (hereinafter respondent 02) announced that it would not be attending the oral proceedings.

X. The oral proceedings took place on 21 January 2021 by videoconference in the presence of the appellant and the respondent 01.

During the oral proceedings, the appellant withdrew the main request, and changed the order of the auxiliary requests. Hence auxiliary request 1 filed with the grounds of appeal became the main request, auxiliary requests 1-4 filed with letter dated 23 December 2019 remained auxiliary requests 1-4 and auxiliary requests 2-14 filed with the grounds of appeal became auxiliary requests 5-17.

In the course of the oral proceedings, respondent 01 withdrew its request that the grounds of opposition under Article 100(a) and 100 (b) EPC be decided by the Board, and requested remittal instead.

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

The main request corresponded to auxiliary request 7 which was the subject of the decision of the opposition division. Compared to the claims as granted, claim 1 and the other independent claims had been amended to recite in step (c) of claim 1 and the equivalent step in the other independent claims that the drying "forms a solid, visco-elastic structure during an initial setting period". This amendment was based on page 36, lines 7-9 of the application as filed.



The opposition division had held that this request contravened Article 123(3) EPC in that the claim amendment had the effect of extending the protection to films in which the whole of the drying process did not take place within 0.5 to 4.0 minutes. The drying was however not taking place in its entirety during the first 4 minutes, so that the "drying" referred to in the second part of step (c) of claim 1 did not relate to the whole of the drying process, but only to an initial setting period of the overall drying process. On this interpretation, the amendment in claim 1 of the main request could not result in a broadening of protection.

There was no unallowable intermediate generalisation caused by the omission of the words "substantially no air flow is present across the top of the film during its initial setting period" which was disclosed in the 2nd paragraph of page 36 of the application as originally filed in close context with the time period of 0.5 to 4.0 minutes, because this feature was an optional one.

The term "visco-elastic structure" was known in the art and was thus clear (Article 84 EPC).

Since the opposition division did not reach any decision on the other substantive issues raised by the opponent, it was considered justified that the case be remitted to the Opposition Division under Article 111(1) EPC for further prosecution of the remaining substantive issues.

XII. The arguments of the respondent 01 may be summarised as follows

The main request contravened the requirements of Article 123 (3) EPC, Article 123 (2) EPC and Article 84 EPC.

With the amendment brought to the independent claims, the time period of 0.5 to 4.0 minutes did not relate to the complete drying process anymore, but only to the initial setting period in which the solid, visco-elastic structure was formed. Accordingly, the complete drying process could now require longer drying times than 0.5 to 4.0 minutes with the consequence that the scope of protection conferred by the first auxiliary request was broadened compared to the claims as granted. This was furthermore confirmed by the subject-matter of dependent claims 5 or 6, which specified further how to carry out the drying. The amendment carried out contravened thus the requirements of Article 123(3) EPC.

Moreover, the main request still represented an intermediate generalization contrary to the requirements of Article 123(2) EPC since the feature that "substantially no air flow is present across the top of the firm during its initial setting period" which was disclosed in the 2nd paragraph of page 36 of the application as originally filed in close context with the time period of 0.5 to 4.0 minutes was omitted.

All independent claims of the main request required now the formation of a solid, visco-elastic structure during the initial setting period. According to the wording of the independent claims, this initial setting period in which the solid, visco-elastic structure was

formed required 0.5 to 4.0 minutes. Accordingly, the specific point of time when this initial setting period is finished needed to be determined. Considering this requirement, it was also necessary to evaluate at what point of time the solid, visco-elastic structure was formed which further required to know when a structure was solid and visco-elastic. However, the feature "solid" and in particular the feature "visco-elastic" were ambiguous and the claims of the main request gave no guidance to the person skilled in the art how to determine whether the structure fulfilled these requirements or not. Accordingly, all independent claims of the main request lacked clarity.

XIII. Requests

The appellant requested that the decision under appeal be set aside and the case be remitted to the opposition division for consideration of the other grounds of opposition on the basis of the main request filed as auxiliary request 1 with the statement of grounds of appeal dated 16 June 2017, or alternatively on the basis of one of auxiliary requests 1-4 filed with letter dated 23 December 2019, or one of auxiliary requests 5-17 filed as auxiliary requests 2-14 with the statement of grounds of appeal dated 16 June 2017.

Respondent 01 requested that the appeal be dismissed. Respondent 01 also requested that the case be remitted to the opposition division for consideration of the other grounds of opposition under Article 100(a) EPC and Article 100(b) EPC.

Respondent 02 did not file any requests.

## Reasons for the Decision

### 1. Main request - Article 123(2) EPC

1.1 Claim 1 has been amended in comparison to claim 1 as granted by adding the following feature in bold in step (c):

"(c) drying said film from the bottom of said film to the top of said film at a temperature of 100 °C or less by applying heat to the bottom side wherein the drying **forms a solid, visco-elastic structure during an initial setting period which** occurs within the first 0.5 to 4 minutes".

Corresponding amendments were made to independent claims 25, 31, 44 and 49.

Said feature is explicitly disclosed in the original description on page 36, lines 6-11. The cited passage belongs to the part of the original application entitled "Drying of the film" starting on page 35, and relates therefore directly and explicitly to the drying step (c) as claimed. Said passage reads:

"Desirably, substantially no air flow is present across the top of the film during **its initial setting period, during which a solid, visco-elastic structure is formed**. This can take place within the first few minutes, e. g. about the first 0.5 to about 4.0 minutes of the drying process."

In view of this passage, the subject-matter of step (c) present in claim 1 and in the other independent claims is derivable directly and unambiguously from the application as originally filed.

1.2 The Board could in particular not see in the incorporation of said feature "wherein the drying **forms a solid, visco-elastic structure during an initial setting period which** occurs within the first 0.5 to 4 minutes" an unallowable intermediate generalization as argued by the respondent 01.

According to the respondent 01, the technical feature "substantially no air flow is present across the top of the film during its initial setting period" was disclosed in the same passage in close context with the time period of 0.5 to 4.0 minutes, but was nevertheless omitted.

The Board notes that the feature, being introduced by the word "desirably" is an optional one, and is thus not inextricable linked with the feature of step (c). In addition, step (c) as claimed comprises a direct reference to this aspect of the drying step by specifying precisely that the drying heat originates exclusively from the bottom of the film, thus implicitly without any air flow across the top of the film. This aspect of the drying is indeed immediately derivable from the feature "(c) drying said film from the bottom of said film to the top of said film at a temperature of 100 °C or less by applying heat to the bottom side".

It is therefore not possible to see in the introduction of the feature "wherein the drying **forms a solid, visco-elastic structure during an initial setting period which** occurs within the first 0.5 to 4 minutes" an intermediate generalization, even less an unallowable intermediate generalisation.

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

2. Main request - Article 123(3) EPC

2.1 Interpretation of the independent claims as granted

Independent claims 1 as granted related to a film formed by a process with a terminal drying step as follows:

"(c) drying said film from the bottom of said film to the top of said film at a temperature of 100 °C or less by applying heat to the bottom side wherein the drying occurs within the first 0.5 to 4.0 minutes."

The same feature of step (c) was present in the further independent claims 25, 31, 44 and 49.

2.1.1 In step (c) of all independent claims as granted, the presence of the term "first" is a clear indication that the drying step lasts longer than 0.5 to 4 minutes and might comprise further steps. Hence, the presence of the term "first" excludes clearly and logically that the claimed time range of 0.5 to 4 minutes applies to the whole drying process and distinguishes said whole drying process from a more limited drying step, namely the "drying [which] occurs within the first 0.5 to 4 minutes".

The presence of the term "wherein" furthermore links the time range of "the first 0.5 to 4 minutes" to the specific drying of the bottom side of the film and not to the whole drying step c), and confirms thereby the existence of an initial period of the drying process.

Consequently, the interpretation of step c) of the independent claims as granted leads to the conclusion that the whole drying does not take place in its entirety during the first 0.5 to 4 minutes, as stated by the opposition division in its decision and argued by the respondent, but said claimed time range relates instead to a initial period of the overall drying process.

2.1.2 Even if the basis for interpreting the subject-matter of a claim and its consequent scope lies in the strict, literal meaning of the claims, the interpretation as given above appears consistent with the disclosure of the description of the application as filed. The description on *inter alia* page 36, lines 6-11 highlights the existence of an initial setting period of the drying, by stating it explicitly in said passage; the same passage also excludes explicitly that the time range of 0.5 to 4 minutes applies to the whole drying process, and suggests that it applies to an initial setting period:

"substantially no air flow is present across the top of the film during its initial setting period, during which a solid, visco-elastic structure is formed. This can take place within the first few minutes, e. g. about the first 0.5 to about 4.0 minutes of the drying process". Said interpretation is also consistent with the disclosure of the examples which show a drying time of about 4 to 6 minutes in examples A-I, while the same process is used in examples J-L.

This interpretation is furthermore not inconsistent with the subject-matter of dependent claims 5 or 6, contrary to the argumentation of respondent 01. Said dependent claims respectively require that "said drying of said film reduces the weight percent of water to

about 8 % or less" or "said drying of said film reduces the weight percent of water to about 6 % or less". Respondent 01 observed that according to the sentence of the description following Table 1, the drying to less than about 6% by weight water takes place in about 4 to 6 minutes. However, according to the wording of dependent claims 5 or 6, this water reduction refers indeed to the whole drying process claimed in step c), and not to the initial setting period. Thus, the interpretation of claim 1 provided above, is not at variance with the content of claims 5 and 6.

## 2.2 The independent claims of the main request

In claim 1, as well as in the other independent claims 25, 31, 44 and 49 of the main request, said step (c) has been modified by the following feature in bold in step (c):

"(c) drying said film from the bottom of said film to the top of said film at a temperature of 100 °C or less by applying heat to the bottom side wherein the drying **forms a solid, visco-elastic structure during an initial setting period which** occurs within the first 0.5 to 4 minutes".

In view of the interpretation of the independent claims as granted given above, the introduction of the feature "forms a solid, visco-elastic structure during an initial setting period" is a specification of the initial drying setting period which occurs during the first 0.5 to 4 minutes. It gives a further detailed description of what was meant by said initial drying period, namely that it forms a solid, visco-elastic structure. The introduction of this feature introduces therefore a further restriction to the drying step (c),



and it is not possible to see in this amendment an extension of the scope of the claim.

Moreover, the scope of step c) has not changed, since it relates, in the preamble of step (c), still to "(c) drying said film from the bottom of said film to the top of said film at a temperature of 100 °C or less", and the further incorporation of any feature relating to any more limited step encompassed by the whole drying step (c) cannot extend the scope of step (c) as present in all independent claims as granted.

Consequently, the main request meets the requirements of Article 123(3) EPC.

3. Main request - Article 84 EPC

3.1 According to respondent 01, all independent claims of the first auxiliary request lack clarity, since the specific point of time when the initial setting period of drying step c) is finished needs to be determined and it is necessary to evaluate at what point of time the "solid, visco-elastic" structure is formed, which further requires to know when a structure is "solid" and "visco-elastic" and what is meant by these terms.

3.2 The question to be answered with respect to clarity under Article 84 EPC is whether it is possible to determine if an embodiment falls within the scope of the claims or not, i.e. to determine in the present case when the initial setting period of drying step c) has formed "a solid, visco-elastic structure".

The terms "solid" and "visco-elastic" defining the structure formed within the first 0.5 to 4 minutes are commonly used in the art and therefore understandable

by those skilled in the art. The skilled person would indeed understand that "a solid, visco-elastic structure" relates to a firm non-liquid structure being both viscous and elastic and would be able to determine when the formation of such structure has occurred. The absence of a quantitative definition for the term "visco-elastic" may result in a weak restrictive function, but this does not imply a lack of clarity of the claims.

Consequently, the evaluation at what point of time the "solid, visco-elastic" structure" is formed is within the scope of the skilled person, and the term "wherein the drying forms a solid, visco-elastic structure during an initial setting period which occurs within the first 0.5 to 4 minutes" is clear. The main request thus meets the requirements of Article 84 EPC.

4. Remittal to the opposition division

4.1 As mentioned above, the main requests meets the requirements of Articles 123(2), 123(3) and 84 EPC. However, the main request has not yet been examined with regard to the remaining grounds of opposition under Article 100(a) EPC and Article 100(b) EPC, since the decision of the opposition division only related to the allowability of the amendments under Articles 123(2) and 123(3) EPC.

4.2 Under Article 111(1) EPC, the Board may in the present case either proceed further with the examination of the application, or remit the case to the opposition division for further prosecution.

Since the present appeal was pending on 1 January 2020, the revised version of the RPBA applies (OJ EPO 2019,

A63), subject to the transitional provisions set out in Article 25 of said RPBA. In particular Article 11 RPBA 2020 is applicable. Article 11 RPBA 2020 provides that the Board shall not remit a case to the department whose decision was appealed for further prosecution, unless special reasons present themselves for doing so. The Board holds that such special reasons are apparent in the present case.

The provision of Article 11 RPBA 2020 has indeed to be read in conjunction with Article 12(2) RPBA 2020, which provides that it is the primary object of the appeal proceedings to review the decision under appeal in a judicial manner (see also T 1966/16, point 2.2 of the reasons, T 547/14 points 7.1 and 7.2, and T 275/15 point 4. of the reasons). This principle would not be respected if the Board were to conduct a complete examination of the application.

- 4.3 As discussed above, in the present case the opposition division decided only on the grounds of opposition under Article 100(c) EPC and did not consider the further grounds of opposition, which were also not presented by the respondent in the appeal proceedings. Said grounds under Article 100(a) EPC and 100(b) EPC were also not discussed during the oral proceedings before the opposition division. Moreover, both the appellant and respondent 01 have requested that the case be remitted to the opposition division for further prosecution.

Under these circumstances, the Board considers it appropriate to exercise its discretion under Article 111(1) EPC and to remit the case to the opposition division for further prosecution.

## 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:



B. Atienza Vivancos

A. Uselli

Decision electronically authenticated