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Datasheet for the decision of 28 November 2019

Case Number: T 0645/17 - 3.3.05

Application Number: 14190681.8

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IPC: B01L3/00, G01N33/49

Language of the proceedings: EN

Title of invention:
Curable polymer separator

Applicants:
THE REGENTS OF THE UNIVERSITY OF CALIFORNIA
University Of Maryland

Headword:
Curable polymer separator/UC & UMD

Relevant legal provisions:
EPC Art. 123(2), 84, 111(1)

Keyword:
Amendments - added subject-matter (yes) -main and first to sixth auxiliary requests - allowable (yes) -seventh auxiliary request
Claims - clarity (yes) -seventh auxiliary request
Remittal to the examining division

Decisions cited:

Catchword:

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Beschwerdekammern

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Case Number: T 0645/17 - 3.3.05

D E C I S I O N
of Technical Board of Appeal 3.3.05
of 28 November 2019

Appellant: (Applicant 1)	THE REGENTS OF THE UNIVERSITY OF CALIFORNIA 1111 Franklin Street, 12th Floor Oakland, CA 94607-5200 (US)
Appellant: (Applicant 2)	University Of Maryland 0133 Cole Student Activities Bldg. College Park, MD 20742-1001 (US)
Representative:	Dennemeyer & Associates S.A. Postfach 70 04 25 81304 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 25 October 2016 refusing European patent application No. 14190681.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chair	E. Bendl
Members:	G. Glod
	R. Winkelhofer

Summary of Facts and Submissions

I. The present appeal from the applicants (appellants) lies from the decision of the examining division to refuse European patent application EP 14 190 681.8 for not meeting the requirements of Articles 123(2) and/or 84 EPC.

II. Oral proceedings took place on 28 November 2019.

III. Claim 1 of the main request is as follows:

"*1. A sample collection tube, comprising:*
a tube having a lumen;
a polymerizable composition having density of between 1.00-1.09 g/cm^3 that sediments the composition under a centrifugal force to a position between a cell-depleted phase of whole blood and a cell-enriched phase of whole blood; wherein the polymerizable composition is disposed within the lumen and comprises:
an oligomer;
a photoinitiator present in a concentration of less than 2 wt% of the polymerizable composition;
a stabilizer; and
tocopherol present in a concentration of at least 135mM of the polymerizable composition; and
wherein the polymerizable composition can withstand irradiation sterilization at a dosage of less than 20 kGy while maintaining a density of between 1.00-1.09 g/cm^3, and is subsequently polymerization curable via UV curing."

Claim 1 of the first auxiliary request differs from claim 1 of the main request on account of the replacement of "*comprises*" with "*consists essentially of*".

In claim 1 of the second auxiliary request "*comprises*" has been replaced with "*consists of*".

In claim 1 of the third auxiliary request the following amendments compared with the main request were made:

"*1. A sample collection tube, comprising:*
a tube having a lumen;
an irradiation sterilized polymerizable composition disposed within the lumen, wherein the polymerizable composition is irradiation sterilized at a dosage of less than 20 kGy, and heated post-sterilization for a period of 1 hour at between 50-70C; wherein the polymerizable composition ~~having density of between 1.00-1.09 g/cm^3 that~~ sediments ~~the composition~~ under a centrifugal force [...]; wherein the polymerizable composition ~~is disposed within the lumen and~~ comprises: [...] polymerizable composition; and wherein the polymerizable composition is curable in the position between the cell-depleted phase and the cell enriched phase via UV light to form a solid interface. ~~wherein the polymerizable composition can withstand irradiation sterilization at a dosage of less than 20 kGy while maintaining a density of between 1.00-1.09g/cm^3, and is subsequently polymerization curable via UV curing.~~"

In claim 1 of the fourth auxiliary request the following amendments compared with the main request were made:

"*1. A sample collection tube, comprising: a tube having a lumen; a polymerizable composition ~~having density of between 1.00-1.09 g/cm^3 that sediments the composition under a centrifugal force to a position between a cell-depleted phase of whole blood and a cell-enriched phase~~*

~~of whole blood; wherein the polymerizable composition is~~ disposed within the lumen and ~~comprises~~ comprising: [...] least 135mM of the polymerizable composition; ~~and~~ wherein the polymerizable composition is ~~can withstand~~ irradiation ~~sterilization~~ sterilized in the lumen at a dosage of less than 20 kGy, and wherein the polymerization composition is heated post-sterilization for a period of 1 hour at between 50-70°C ~~while maintaining a density of between 1.00-1.09g/cm^3~~, ; wherein the polymerizable composition sediments, post irradiation sterilization, under a centrifugal force to a position between a cell depleted phase of whole blood and a cell enriched phase of whole blood; and wherein the polymerizable composition is curable ~~and is subsequently polymerization curable~~ via UV curing to form a solid interface between the cell depleted phase of whole blood and the cell enriched phase of whole blood."

In claim 1 of the fifth auxiliary request the following amendments compared with the main request were made:

"*1. Use of tocopherol in the manufacture of a ~~A~~ sample collection tube, comprising [...] least 135mM of the polymerizable composition; ~~and wherein~~ such that the polymerizable [...].*"

In claim 1 of the sixth auxiliary request the following amendments compared with the main request were made:

"*1. Use of tocopherol in the manufacture of a ~~A~~ sample collection tube, comprising a tube having a lumen; a polymerizable composition having a density of between 1.00-1.09 g/cm^3 that sediments [...] least 135mM of the polymerizable composition; ~~and wherein~~ such that the polymerizable composition ~~can withstand~~ is irradiation*

~~sterilization~~ sterilizable at a dosage of less than 20 kGy while maintaining the density of between 1.00 and 1.09 g/cm^3, and ~~is~~ subsequently polymerization curable via UV curing."

In claim 1 of the seventh auxiliary request the following amendments compared with the main request were made:

"*1. A sample collection tube, comprising: [...]* and ~~comprises~~ consists of: an oligomer; *[...]* ; and *wherein the polymerizable composition ~~can withstand irradiation sterilization~~ can be sterilized via irradiation without curing at a dosage of less than 20 kGy while maintaining a density of between 1.00-1.09g/cm^3, and is subsequently polymerization curable via UV curing.*"

Claims 2 to 5 describe preferred embodiments thereof.

IV. The appellants' arguments relevant to the present decision can be summarised as follows:

There was no indication that the density was only disclosed for compositions consisting of LAI and tocopherol, since it was not disclosed that other compositions, including LARID, failed to maintain density between 1.00 and 1.09. The fact that LARID failed the flowability test on page 21 [of the description] meant it did not have a density between 1.00 and 1.09. The result of the flowability test had no relationship with the density of the compositions. It was evident from the overall disclosure that the desired compositions should maintain their density in the range of 1.00 and 1.09 g/cm^3. Consequently the use of the language "comprising" was justified.

It was conceivable that having minor additional ingredients such as impurities would not significantly change the density of the composition. Thus, using the term "consists essentially of" was justified.

V. The appellants request that the decision under appeal be set aside and a patent be granted on the basis of the main request, or on the basis of auxiliary requests 1 or 2, all submitted on 14 October 2019, or auxiliary requests 3 to 6 as filed on 27 February 2019, or auxiliary request 7, submitted during the oral proceedings before the board.

Reasons for the Decision

Main request

1. Article 123(2) EPC

It needs to be determined whether the subject-matter of claim 1 is directly and unambiguously derivable from the application as filed.

1.1 Claim 1 as filed does not contain any indication about the density of the polymerizable composition, but rather only defines the composition with respect to flowability.

The density range of 1.00-1.09 g/cm^3 is only disclosed in paragraph [0024], in which it is indicated that LAI is especially preferred, since it can have the desired density range of 1.00 to 1.09 g/cm^3. Other possible components of the photocurable sealant are disclosed in the same paragraph, but no reference is made to the density range. The skilled person reading said passage would not recognise that the indicated density range

should apply to all the polymerizable compositions mentioned in paragraph [0024] and even less to all those covered by claim 1.

The only direct and unambiguous disclosure of a composition having a density of between 1.00 and 1.09 g/cm^3 is the composition consisting of LAI, with LAI having the definition given in the table on page 9.

The examples shown in the table on pages 19 to 21 do not mention the density at all, so no density values can be extracted from them for compositions different from LAIE.

The open formulation "comprises" with respect to the polymerizable composition allows for the presence of undefined components as long as the density is maintained in the claimed range. Such a broad disclosure is not present in the application as filed.

The predetermined flowability cannot be directly linked to a specific density, so indications on the flowability such as those presented in the examples do not make it possible to predict the density.

1.2 Furthermore, "withstand irradiation sterilization" is understood to mean resisting the sterilization, which can be interpreted as meaning that no sterilization occurs; this is in fact contrary to the intended meaning (see page 9, lines 6 to 10) and without basis in the application as filed.

1.3 The requirements of Article 123(2) EPC are not met and the request must fail.

First auxiliary request

2. Article 123(2) EPC

2.1 The replacement of the wording "comprises" with "consists essentially of" does not alter the conclusion reached for the main request since the application as filed does not contain any information that LAI having the desired density could contain other undefined components. It cannot be argued that the skilled person would immediately recognise that the presence of impurities was allowed, since firstly no such indication is present in the application as filed and secondly the term "impurities" does not make it clear which components would still be allowed besides LAIE.

2.2 The objection under point 1.2 still applies.

2.3 The requirements of Article 123(2) EPC are not met here either and the request must fail.

Second auxiliary request

3. Article 123(2) EPC

The objection under point 1.2 still applies, so the requirements of Article 123(2) EPC are not met and the request must also fail.

Third and fourth auxiliary requests

4. Article 123(2) EPC

Notwithstanding the question whether the indicated temperature range is directly and unambiguously

derivable in the context of the claim, the subject-matter of claim 1 is at least not directly and unambiguously derivable from the application as filed for the following reasons:

In paragraph [0040] as originally filed a concentration of at least 135 mM antioxidant/tocopherol is disclosed to maintain flowability during irradiation sterilization of LAI compositions. No other preparations in accordance with the invention are mentioned in this passage. This interpretation of paragraph [0040] is consistent with the examples, as all preparations passing the test on pages 19 to 21 are LAI preparations containing tocopherol (i.e. LAIE preparations).

As claim 1 of both the third and fourth auxiliary requests uses the term "comprising" or "comprises", undefined ingredients other than LAI may be present. However, such combinations of undefined compounds with at least 135 mM antioxidant/tocopherol are not described in the application as filed and therefore go beyond the original disclosure.

The requirement of Article 123(2) EPC is not complied with.

Fifth and sixth auxiliary requests

5. Article 123(2) EPC

Both these requests contain the wording "comprises" and refer to a density of between 1.00-1.09 g/cm^3. The reformulation of claim 1 of these requests does not restrict the meaning of the wording "comprises" with respect to the composition. Therefore, the objection of

point 1.1 also applies to these requests and these requests must also fail.

Seventh auxiliary request

6. Article 13(1) RPBA

This request was submitted at the latest possible moment during oral proceedings before the board. Since it contains an easily understandable amendment compared with auxiliary request 2, including the correct adaptation of the dependent claims, and thereby overcomes the previous objections, it was admitted into the proceedings.

7. Article 123(2) EPC

Claim 1 is directly and unambiguously derivable from claims 1 and 2 and paragraphs [0024], [0025] and [0040] of the description of the application as filed. As indicated above (point 1.1), paragraph [0024] discloses that a composition consisting of LAI has the desired density. It is evident from the passage on page 9 that tocopherol is added to allow the composition to be sterilized without curing. Evidently the density will not be impacted by the low amount of tocopherol present. Tocopherol is the preferred radical scavenger as is also clear from the examples. Its preferred range is disclosed at the end of paragraph [0040].

Claims 2 to 5 are based on claims 3 to 5 and 10 as filed, with claims 3 and 4 being restricted to oligomers containing acrylate and methacrylate, respectively (see original claims 3 and 4).

The requirements of Article 123(2) EPC are thus met.

8. Article 84 EPC

The polymerizable composition is now defined by the density, which is a well-known parameter. The claim is understood such that this density will make it possible to sediment the composition under a centrifugal force to a position between a cell-depleted phase of whole blood and a cell-enriched phase of whole blood. In addition, the composition does not cure when sterilized and maintains the density in the claimed range. This is also supported by most of the examples still falling within the scope of the claims.

The requirements of Article 84 EPC are met.

9. Article 111 EPC

Since the decision ("according to the state of the file") only dealt with Articles 84 and 123(2) EPC, the case is remitted 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 examining division for further prosecution.

The Registrar: The Chair:

C. Vodz E. Bendl

Decision electronically authenticated