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**Datasheet for the decision
of 13 October 2016**

Case Number: T 2602/12 - 3.3.10

Application Number: 04741077.4

Publication Number: 1648534

IPC: A61L27/54, A61L27/26, G02B1/04,
G02C7/04

Language of the proceedings: EN

Title of invention:
ANTIMICROBIAL MEDICAL DEVICES

Patent Proprietor:
Novartis AG

Opponent:
Johnson & Johnson Vision Care, Inc.

Headword:

Relevant legal provisions:
EPC Art. 56, 83
RPBA Art. 12(2), 13(1), 13(3)

Keyword:

Admissibility of main request (yes) - restriction of granted claim 1 to subject-matter for which no negative decision has been issued by the Opposition Division is legitimate behaviour of losing party, no abuse of procedure

Sufficiency of disclosure (yes) - sufficient guidance in patent in suit to make dispersions with the required stability

Inventive step (yes) - argument raised for first time at oral proceedings against embodiment of invention never previously attacked under Article 56 EPC not admitted; Board sees no reason to examine of its own motion

Decisions cited:

T 0270/90, T 0061/14, T 1414/08

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

European Patent Office
D-80298 MUNICH
GERMANY
Tel. +49 (0) 89 2399-0
Fax +49 (0) 89 2399-4465

Case Number: T 2602/12 - 3.3.10

D E C I S I O N
of Technical Board of Appeal 3.3.10
of 13 October 2016

Appellant:
(Patent Proprietor)

Novartis AG
Lichtstrasse 35
4056 Basel (CH)

Representative:

Bohest AG
Holbeinstrasse 36-38
4051 Basel (CH)

Respondent:
(Opponent)

Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway, Suite 100
Jacksonville, Florida 32256 (US)

Representative:

Fisher, Adrian John
Carpmaels & Ransford LLP
One Southampton Row
London WC1B 5HA (GB)

Decision under appeal:

**Decision of the Opposition Division of the
European Patent Office posted on 19 October 2012
revoking European patent No. 1648534 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman P. Gryczka
Members: J. Mercey
C. Schmidt

Summary of Facts and Submissions

I. The Appellant (Proprietor of the Patent) lodged an appeal against the decision of the Opposition Division revoking European patent No. 1 648 534.

II. Claim 1 as granted reads as follows:

"A method for making an antimicrobial medical device, comprising the steps of:

(a) forming a polymerizable dispersion comprising silver nanoparticles and having a stability of at least 60 minutes, wherein the step of forming the polymerizable dispersion is carried out according to a process selected from the group consisting of:

(i) adding a desired amount of a soluble silver salt into a fluid composition which comprises a siloxane-containing macromer and a vinylic monomer capable of reducing silver cations,

(ii) adding at least one biocompatible reducing agent into a fluid composition which comprises a siloxane-containing macromer and a soluble silver salt, and

(iii) first obtaining a stabilized silver nano-particle solution or lyophilized stabilized silver nano-particles and then directly dispersing a desired amount of the stabilized silver nano-particle solution or lyophilized stabilized silver nano-particles in a polymerizable fluid composition comprising a siloxane-containing macromer,

(b) introducing an amount of the polymerizable dispersion into a mould for making a medical device; and

(c) polymerizing the polymerizable dispersion in the mould to form the antimicrobial medical device containing silver nano-particles."

- III. Notice of Opposition had been filed by the Respondent (Opponent), requesting revocation of the patent in its entirety on the grounds of lack of inventive step and sufficiency of disclosure (Articles 100(a) and (b) EPC), the Opponent raising inventive step objections against those embodiments of the method comprising process steps (ii) or (iii) only.
- IV. The Opposition Division found that the invention was sufficiently disclosed, but that the subject-matter of claim 1 of the then pending main request (patent as granted), more particularly the method wherein step (a) was carried out according to process (ii), was not inventive.
- V. With its statement of grounds of appeal dated 26 February 2013, the Appellant filed auxiliary requests 1 to 7, claim 1 of auxiliary requests 4 to 7 thereof being restricted to the embodiment comprising process step (i) according to granted claim 1.
- VI. In the communication of the Board accompanying the summons to oral proceedings dated 24 June 2016 (see point 5), the Board indicated that the inventiveness of the method comprising process step (i) had not been contested.
- VII. With a letter dated 13 September 2016, the Appellant filed claim 1 of each of a main request and of an auxiliary request 1 and 2, said requests replacing all requests previously on file. Claim 1 of the main request is almost identical to claim 1 of auxiliary request 4 filed with letter dated 26 February 2013, differing therefrom only by virtue of replacement of the term "comprises" in claim 1 by other language. At the oral proceedings before the Board, held on

13 October 2016, the Appellant filed dependent claims 2 to 14 of the main request, said claims corresponding to granted claims 2 to 14.

VIII. Claim 1 of the main request reads as follows:

"A method for making an antimicrobial medical device, comprising the steps of:

(a) forming a polymerizable dispersion comprising silver nanoparticles and having a stability of at least 60 minutes, wherein the step of forming the polymerizable dispersion is carried out by:

adding a desired amount of a soluble silver salt into a fluid composition which comprises a siloxane-containing macromer and a vinylic monomer capable of reducing silver cations,

(b) introducing an amount of the polymerizable dispersion into a mould for making a medical device; and

(c) polymerizing the polymerizable dispersion in the mould to form the antimicrobial medical device containing silver nano-particles."

IX. The Appellant submitted that all requests were admissible, as the reasons for filing, withdrawing or maintaining certain requests were at no time motivated by an attempt to gain a procedural or tactical advantage, but rather by business considerations. By restriction to the embodiment of the method comprising process step (i) according to claim 1 as granted, all of the Respondent's inventive step objections became redundant.

The Appellant agreed with the positive findings regarding sufficiency of disclosure in the contested decision. In addition, it argued for the first time at

the oral proceedings before the Board that the feature that the silver nanoparticle containing dispersion had a stability of at least 60 minutes was in fact superfluous, since by carrying out the step of adding a desired amount of a soluble silver salt into a fluid composition which comprised a siloxane-containing macromer and a vinylic monomer capable of reducing silver cations, such a dispersion was inevitably obtained, there being nothing in the patent specification, nor had the Respondent provided any evidence, that this was not the case. Even if this were not the case and the skilled person had to choose only those dispersions which fulfilled this stability requirement, the patent specification gave sufficient information in order to achieve such a dispersion, such as order of addition of components, addition of suitable amounts of a stabilizer, and sonication. The test conditions under which it was determined whether or not a particular silver nanoparticle containing dispersion had a stability of at least 60 minutes, such as agitation and temperature, were not important. The observation of agglomeration and/or precipitation was performed with the naked eye, as this method was quick, convenient and, nevertheless, sufficiently accurate for its purpose.

The subject-matter of claim 1 of all requests was inventive, the Respondent never having challenged the inventiveness of the embodiment of the method comprising process step (i), either before the first instance or before the Board. Any arguments that the Respondent wished to raise against said method for the first time at the oral proceedings before the Board should not be admitted, as the Appellant clearly had no possibility to defend itself properly at such short notice.

X. The Respondent requested that all claim requests submitted by the Appellant on 13 September 2016 should not be admitted into the proceedings as they could have been presented in the first instance proceedings. Indeed, a request almost identical to the present main request had in fact been filed before the Opposition Division, but was withdrawn during oral proceedings before the Opposition Division, which made it apparent that the Appellant had adopted this tactic to gain a procedural advantage.

The Respondent indicated at the oral proceedings before the Board that it had no objections under Articles 123(2) and (3) EPC to the subject-matter of the main request.

The Respondent submitted that the invention was not sufficiently disclosed, the feature that the silver nanoparticle containing dispersion had a stability of at least 60 minutes being indeed limiting, as indicated by the Appellant itself in its letter dated 6 December 2010 before the Opposition Division, wherein it stated that "From any polymerization dispersion theoretically obtainable through said steps, the skilled person is taught to use only those with a stability of 60 minutes in the method for making an antimicrobial medical device as of the present invention". There was, however, not sufficient guidance in the patent specification about how to make those particular dispersions which satisfied the stability requirement, the skilled person instead having to rely on trial and error, which represented an undue burden, citing T 61/14 (point 4 of the reasons, not published in OJ EPO) in this respect. Moreover, the skilled person did not know which test conditions to use in

order to determine in a reliably reproducible manner whether or not a silver nanoparticle containing dispersion had a stability of at least 60 minutes, nor how agglomeration and/or precipitation was to be observed.

The Respondent challenged the inventiveness of a method comprising process step (i) according to claim 1 as granted for the first time in the opposition-appeal proceedings at the oral proceedings before the Board. As reasons for the lateness of this line of attack, the Respondent argued that it had until this point in time been sufficient to attack the methods comprising process steps (ii) or (iii).

XI. The Appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request (claim one as filed as with letter dated 13 September 2016 and claims 2 to 14 as filed at the oral proceedings before the Board) or, alternatively, on the basis of one of the auxiliary requests 1 and 2, both filed with letter dated 13 September 2016.

The Respondent requested that the appeal be dismissed.

XII. At the end of the oral proceedings, the decision of the Board was announced.

Reasons for the Decision

1. The appeal is admissible.

Main request

2. *Admissibility of request*

- 2.1 The Respondent requested that *inter alia* the main request filed by the Appellant with letter dated 13 September 2016 should not be admitted into the proceedings, citing Article 12(4) RPBA in this respect. More particularly, it argued that a request almost identical to this request was withdrawn during oral proceedings before the Opposition Division, which made it apparent that the Appellant had adopted this tactic to gain a procedural advantage. More particularly, it was withdrawn to prevent the department of first instance from giving a reasoned decision on critical issues, possibly even to avoid an adverse decision thereby. Moreover, the withdrawal of the request misled the general public into believing that the Appellant no longer intended to pursue its subject-matter. Furthermore, its reintroduction on appeal led to an overall delay to the proceedings.

- 2.2 Appeal proceedings are based *inter alia* on the statement of grounds of appeal filed pursuant to Article 108 EPC, said statement containing the party's complete case (see Article 12(1) and (2) RPBA). The Board may however hold inadmissible requests which could have been presented in the first instance proceedings (see Article 12(4) RPBA).

- 2.3 The Appellant has restricted claim 1 of the main request to a method of making an antimicrobial medical

device, wherein step (a) is carried out according to process (i) according to claim 1 as granted. Said request is almost identical to auxiliary request 4 filed with the statement of grounds of appeal, differing therefrom only by virtue of replacement of the term "comprises" in claim 1 by other language. The inventiveness of this particular embodiment of the method has never been attacked by the Respondent.

2.4 The Board holds that the filing with the statement of grounds of appeal of a request, namely auxiliary request 4, wherein subject-matter which was found unallowable by the first instance has been deleted, said request thereby being restricted to subject-matter for which no negative decision has been issued by the Opposition Division, deprives the contested decision of its basis, and is legitimate behaviour of a losing party. The minor amendment to claim 1 of this request, which resulted in the present main request, was to overcome the Respondent's objections under Articles 123(2) and (3) EPC thereto, and is therefore considered to be necessary and appropriate. This behaviour of the Appellant is thus not considered to constitute an abuse of procedure.

2.5 For the following reasons, the Board cannot conclude that the Appellant had adopted this tactic to gain a procedural advantage.

2.5.1 The withdrawal before the Opposition Division of a request directed to a method comprising process step (i) did not prevent the department of first instance from giving a reasoned decision on this subject-matter, since said method was a part of the subject-matter of granted claim 1 on which the Opposition Division did indeed take a decision. However, inventive step of a

method comprising process step (i) had not been challenged by the Opponent before the Opposition Division. It is thus not plausible that such a request was withdrawn to avoid an adverse decision on it.

2.5.2 With regard to the Respondent's argument that the general public was misled by the behaviour of the Appellant in withdrawing said request before the Opposition Division, the Board draws attention to the fact that there are many reasons why a patent proprietor may file and withdraw requests. However, withdrawal of a request does not constitute abandonment of its subject-matter, such that the public should not interpret withdrawal of a request before the first instance in this manner.

2.6 Thus, the Board holds that the Appellant gains no procedural disadvantage by filing the present main request at this stage of the proceedings. Nor is the Respondent disadvantaged, as it has had the opportunity to develop a case against the subject-matter of this request since the grant of the patent.

2.7 Under these circumstances, the Board in the exercise of its discretion under Article 12(4) RPBA, admits the main request into the proceedings.

3. *Amendments (Articles 123(2) and (3) EPC)*

The Respondent had no objections under Articles 123(2) and (3) EPC to the subject-matter of the main request, nor does the Board see any reason to question its allowability under this article of its own motion.

4. *Sufficiency of disclosure*

4.1 Claim 1 relates to a method for making an antimicrobial medical device, comprising *inter alia* the steps of:

(a) forming a polymerizable dispersion comprising silver nanoparticles and having a stability of at least 60 minutes, wherein the step of forming the polymerizable dispersion is carried out by adding a desired amount of a soluble silver salt into a fluid composition which comprises a siloxane-containing macromer and a vinylic monomer capable of reducing silver cations and (b) introducing an amount of the polymerizable dispersion into a mould for making a medical device.

4.2 It is the established case law of the Boards of Appeal that the requirements of sufficiency of disclosure are met if the invention as defined in the independent claim can be performed by a person skilled in the art in the whole area claimed without undue burden, on the basis of the disclosure in the patent specification and the general technical knowledge in the art (see, for example, T 61/14, *ibid.*).

4.3 In the present case, the essence of the Respondent's attack on sufficiency of disclosure is that there was not sufficient guidance in the patent specification about how to make those particular dispersions which satisfied the stability requirement, the skilled person instead having to rely on trial and error, which represented an undue burden. Moreover, the stability of the polymerizable dispersion comprising nanoparticles of at least 60 minutes was not well-defined, since the skilled person did not know which test conditions (e.g. temperature, agitation) to use in order to determine

whether or not a particular silver nanoparticle containing dispersion has a stability of at least 60 minutes, nor how agglomeration and/or precipitation was to be observed (e.g. with the naked eye or microscope).

4.4 The question which first needs to be answered is whether or not the feature that the stability of the polymerizable dispersion comprising silver nanoparticles of at least 60 minutes is in fact limiting on the subject-matter of the claim, since if it were not, as alleged by the Appellant, then **any** method of adding a soluble silver salt into a fluid composition which comprises a siloxane-containing macromer and a vinylic monomer capable of reducing silver cations as defined in the claims would result in a dispersion having the desired stability, such that the invention would thereby be sufficiently disclosed.

4.4.1 The Board holds that in view of the Appellant's statement in a letter before the Opposition Division (see point X, paragraph 3, above) that from any polymerization dispersion theoretically obtainable through methods comprising any of steps (i), (ii) or (iii) according to granted claim 1, the skilled person should use **only those** with a stability of 60 minutes in the method for making an antimicrobial medical device as of the invention, said letter also stating that "the stability of at least 60 minutes is a **limiting feature** of the polymerization dispersion within the claimed method" (emphasis added), the Appellant's argument, submitted for the first time during oral proceedings before the Board, that any method as defined in the claims would result in a dispersion with the desired stability, is not credible. This is particularly so in view of the fact that no reaction conditions are given in claim 1 for the step of forming the polymerizable

dispersion. As a consequence, the Board holds that the feature that the stability of the polymerizable dispersion comprising nanoparticles of at least 60 minutes is indeed limiting on the subject-matter of the claim.

4.5 Hence, it needs to be examined whether the disclosure in the patent specification and the general technical knowledge is sufficient for the person skilled in the art to make those particular dispersions which satisfy the stability requirement. More particularly, does the skilled person know how to perform the step of adding a soluble silver salt into a fluid composition which comprises a siloxane-containing macromer and a vinylic monomer capable of reducing silver cations in order to obtain the dispersion having the required stability.

4.5.1 The patent specification teaches that "**any** known suitable siloxane-containing macromer can be used to prepare a polymerizable fluid composition" (emphasis added) (see paragraph [0085]) and then gives a detailed description of the preferred macromers (see paragraphs [0087] to [0191]). The patent specification also teaches that a stabilizer for stabilizing silver nanoparticles may be added and describes which type of compounds these may be (e.g. polyacrylic acid), how much should be added, and the importance of the order of its addition (see paragraphs [0211] to [0220] and [0296]). Furthermore, stirring would appear to stabilize the dispersion (see paragraphs [0283] and [0285]).

4.5.2 In the light of the above information, the Board holds that there is sufficient information in the patent specification for the skilled person to perform step (a) of the method in order to obtain a polymerizable

dispersion comprising silver nanoparticles having a stability of at least 60 minutes, such that the invention is repeatable over the entire breadth of the claim without undue burden.

- 4.5.3 The Respondent argued that only siloxane-containing macromers having hydrophilic units could stabilize silver nanoparticles, citing paragraph [0210] of the patent specification.

However, said paragraph does not indicate that **only** siloxane-containing macromers having hydrophilic units are suitable, paragraphs [0087] to [0191] teaching many other suitable siloxane-containing macromers which do not have hydrophilic units. Furthermore, no evidence has been provided by the Respondent, who carries the burden of proof for the facts it alleges (see e.g. decision T 270/90, OJ EPO 1993, 725, point 2.1 of the reasons), that particular siloxane-containing macromers are not suitable for carrying out the invention.

- 4.6 The Respondent also argued that the invention was not sufficiently disclosed, since the skilled person did not know which test conditions to use in order to determine whether or not a particular silver nanoparticle containing dispersion has a stability of at least 60 minutes, such that there was uncertainty as to the exact limits of the stability of the dispersion, which resulted in the skilled person not knowing which process conditions to select in order to obtain a dispersion falling within the terms of the claim.

- 4.6.1 Claim 1 specifies forming a polymerizable dispersion comprising silver nanoparticles having a stability of at least 60 minutes, said dispersion thereafter being introduced into a mould for making a medical device.

The patent specification (see paragraph [0072]) indicates in this respect "As used herein, the term "stability" in reference to a dispersion means a period of time over which no observable agglomeration and/or precipitation occurs in the dispersion".

4.6.2 The skilled person would thus understand that said dispersion may be held under **any** conditions, provided that no observable agglomeration and/or precipitation occurs under these conditions for at least 60 minutes, before the dispersion is further processed. The skilled person would thus choose a suitable temperature and agitate the dispersion, if necessary, in order to maintain the dispersion, Example 2 (see paragraphs [0283] and [0285]) teaching, for example, that agitation prevents precipitation. As such, the Board agrees with the Appellant that the exact conditions under which agglomeration and/or precipitation is observed, are not critical, the skilled person merely choosing conditions, such as those disclosed within the patent specification itself, which discourage agglomeration and/or precipitation, in order to maintain the dispersion until it is further processed. The Board thus holds that the skilled person does indeed know how to form a polymerizable dispersion comprising silver nanoparticles having a stability of at least 60 minutes.

4.7 Finally, with regard to how the skilled person would observe agglomeration and/or precipitation, the Board holds that this is merely a matter of precision of the method for determining the stability, and not a matter of whether the skilled person can carry out the method of the claim or not, it not having been disputed that observation methods, e.g. with the naked eye or with a

microscope, belong to the common general knowledge of the skilled person.

4.7.1 Thus, whilst being true that the patent specification does not specifically disclose how to observe agglomeration and/or precipitation, and that there is no doubt that different methods of observation have an influence on what may be observed or not, this uncertainty merely amounts to a lack of clarity as to the limits of the claim.

4.7.2 For these reasons, and analogous to the findings in decision T 1414/08 (see points 2 to 4 and 8 of the reasons, not published in OJ EPO), the Board takes the view that under the present circumstances the question of whether a skilled person can determine the exact limits of the claims is a question of clarity of the claimed subject-matter, hence Article 84 EPC, rather than of sufficiency of disclosure (Article 83 EPC).

4.8 Consequently, the claimed invention is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

5. *Inventive step*

5.1 In the oral proceedings before the Board, the Respondent objected for the first time in opposition-appeal proceedings to the inventiveness of the subject-matter of the present main request, namely to the embodiment of the method comprising process step (i) according to granted claim 1. In the communication of the Board accompanying the summons to oral proceedings (see point VI above), the Board expressly indicated that the inventiveness of the method comprising process step (i) had not been contested.

5.2 Article 99(1) and Rule 76(c) EPC require that as a general rule an opponent's case against an opposed patent should be set out fully and completely in the notice of opposition, and should not be presented and developed piecemeal. In addition, according to Article 12(2) RPBA, the statement of grounds of appeal and reply shall contain a party's complete case and should specify expressly all the facts, arguments and evidence relied on. Any amendment to a party's case after it has filed its grounds of appeal or reply may be admitted and considered at the Board's discretion (Article 13(1) RPBA).

5.3 In the present case, prior to the oral proceedings before the Board, the Respondent had never raised any objection under Article 56 EPC to the subject-matter of the present main request, either before the Opposition Division or before the Board, said subject-matter being an embodiment of granted claim 1 and being comprised in claim 1 of every request ever on file in this case. Allowing the Respondent to raise an inventive step argument against an embodiment of the method never previously attacked under Article 56 EPC at this late

stage of the proceedings would raise issues which the Board and the Appellant could not reasonably be expected to deal with without adjournment of the oral proceedings (Article 13(3) RPBA).

- 5.4 As reason for this late submission, the Respondent argued that until the oral proceedings before the Board, it had been sufficient to attack the methods comprising process steps (ii) or (iii) in order to destroy the patent.

However, together with its statement of grounds of appeal (see point V above), the Appellant filed *inter alia* auxiliary requests 4 to 7, wherein the subject-matter of claim 1 of each request was restricted to a method comprising process step (i) according to granted claim 1, such that at the latest at this stage of the proceedings, the Respondent could, and should have attacked this subject-matter under Article 56 EPC, had it so wished.

- 5.5 Thus, under the present circumstances, the Board exercises its discretion not to admit the late filed argument into the appeal proceedings.

- 5.6 In view of the prior art cited in these proceedings, the Board sees no reason to raise its own objections under Article 114(1) EPC against the inventive step of the claimed subject-matter, such that the patent may be maintained in this amended form.

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 on the basis of the main request (claim 1 as filed with letter dated 13 September 2016 and claims 2 to 14 as filed during the oral proceedings before the Board) and a description to be adapted.

The Registrar:

The Chairman:



C. Rodríguez Rodríguez

P. Gryczka

Decision electronically authenticated