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**Datasheet for the decision
of 11 May 2017**

Case Number: T 0125/15 - 3.3.07
Application Number: 06844046.0
Publication Number: 1976562
IPC: A61K47/36, A61K9/70, A61P25/34,
A61P29/00, A61K36/03
Language of the proceedings: EN

Title of invention:

WATER-SOLUBLE FILMS COMPRISING LOW-VISCOSITY ALGINATES

Applicant:

Uppsalagruppen Medical AB

Headword:

WATER-SOLUBLE FILMS COMPRISING LOW-VISCOSITY ALGINATES/
Uppsalagruppen Medical AB

Relevant legal provisions:

EPC Art. 123(2), 84, 54

Keyword:

Amendments - Yes
Clarity of the term "water-soluble" - Yes
Novelty - Yes

Decisions cited:

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 0125/15 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 11 May 2017

Appellant: Uppsalagruppen Medical AB
(Applicant) Lahällsvägen 48
183 30 Täby (SE)

Representative: Brann AB
P.O. Box 3690
Drottninggatan 27
103 59 Stockholm (SE)

Decision under appeal: **Decision of the Examining Division of the European Patent Office posted on 4 August 2014 refusing European patent application No. 06844046.0 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman J. Riolo
Members: D. Boulois
I. Beckedorf

Summary of Facts and Submissions

- I. The appeal lies from the decision of the examining division to refuse European patent application n°06 844 046.0. The decision was based on 2 sets of claims filed with letter of 24 March 2014 as main request and auxiliary request 1 filed during the oral proceedings on 14 July 2014.

Claim 1 of the main request read as follows:

"1. A water-soluble film comprising, as a film-forming agent, an alginate salt of monovalent cation or a mixture of alginate salts containing at least one alginate salt of monovalent cation, the film-forming agent having a mean guluronate (G) content of from 50 to 85% by weight, a mean mannuronate (M) content of from 15 to 50% by weight, a mean molecular weight of from 30,000 g/mol to 90,000 g/mol and being such that a 10% aqueous solution thereof at a temperature of 20°C has a viscosity of 100-1000 mPas, as measured at a shear rate of 20 rpm by use of a Brookfield viscometer with a spindle No. 2, said film being obtainable by preparing a solution of said film forming agent, distributing the solution onto a solid surface, and permitting the solution to dry on said surface."

The subject-matter of claim 1 of auxiliary request 1 differed in the specification of the claimed film, namely as shown in bold:

"1. A water-soluble film **capable of adhering to mucous membranes in the mouth and of rapidly dissolving in contact therewith**, comprising, ...".

- II. The documents cited during the examination proceedings included the following:

D1: US 2005/013847

- III. According to the decision under appeal, the feature "water-soluble" in claim 1 of the main request was not clear under the circumstances of the present case in the light of:
- The term "water-soluble" being the alleged differing technical feature between claim 1 and D1,
 - The repeated assertions of the applicant, without evidence, that a gel-film according to D1 was not a water-soluble film as stated in present claim 1.
 - The term "water-soluble" in the present context lacked clarity also because colloidal solutions formed by the alginate claimed in claim 1 of the main request were suspensions of colloidal particles, which depending on the quantity of water available could take the state of a gel.

Claim 1 of the main request did not meet the requirements of Article 84 EPC.

The subject-matter of claim 1 of the main request was not novel over D1, which disclosed in example 1-1 a film comprising Protanal® LFR5/60 (sodium alginate). This product was known as being "slowly soluble, forming a viscous, colloidal solution", and necessarily formed a gel, and consequently the term "water-soluble film" in claim 1 had to be considered as encompassing gel-films, like those disclosed in D1. Moreover, the presence of further excipients in example 1-1 of D1 could not be a basis to establish novelty and all the process features stated in claim 1 were also present in the process disclosed in D1.

Claim 1 of the auxiliary request did not meet the requirements of Article 84 EPC in view of the wording

"capable of adhering to mucous membranes in the mouth and of rapidly dissolving in contact therewith". This feature could also not establish novelty over D1.

- IV. The applicant (appellant) filed an appeal against that decision. With the statement of grounds of appeal, it submitted the main request which was the subject of the decision of the examining division.
- V. With the communication sent in preparation for oral proceedings, the Board expressed a preliminary view with respect to novelty over D1 and clarity.
- VI. With the letter of 9 May 2017 the appellant submitted further arguments, a new main request and auxiliary requests 1-11.

The subject-matter of claim 1 of in particular auxiliary request 6 was further specified by the following feature, the difference with respect to the main request which was the subject of the decision of the examining division being indicated by **bold**:

1. A water-soluble film comprising **at least one biologically active substance and/or at least one therapeutically active substance** and a film-forming agent, said film forming agent **consisting of** an alginate salt of monovalent cation or a mixture of alginate salts of monovalent cation, and said film-forming agent having a mean guluronate (G) content of from 50 to 85% by weight, a mean mannuronate (M) content of from 15 to 50% by weight, a mean molecular weight of from 30,000 g/mol to 90,000 g/mol and being such that a 10% aqueous solution thereof at a temperature of 20°C has a viscosity of 100-1000 mPas, as measured at a shear rate of 20 rpm by use of a

Brookfield viscometer with a spindle No. 2, said film being obtainable by preparing a solution of said film forming agent, **which solution also contains the at least one biologically active substance and/or at least one therapeutically active substance**, distributing the solution onto a solid surface, and permitting the solution to dry on said surface.

VII. Oral proceedings before the board of appeal took place on 11 May 2017, during which the appellant maintained auxiliary request 6 as the only request while withdrawing all other requests.

VIII. The appellant's arguments can be summarised as follows:

Auxiliary Request 6 was based on the previous main Request, wherein the language of claim 1 had been amended so as to limit the film-forming agent to only a alginate of monovalent cation or a mixture of alginates of monovalent cation. Support for the amendment could be found in the description, e.g. at page 5, lines 31-34, and at page 6, lines 18-22, as well as in the Examples.

A film obtained by use of such film forming agent was not disclosed in D1, since D1 does not provide an enabling disclosure of a film containing, as only film forming agent, an alginate of monovalent cation.

IX. Requests

The appellant requested that the decision under appeal be set aside and that the case be remitted to the examining division for further prosecution on the basis of auxiliary request 6 filed with letter of 9 May 2017.

Reasons for the Decision

1. Article 123(2) EPC

1.1 The subject-matter of claim 1 of auxiliary request 6 differs from the subject-matter of claim 1 of the main request discussed before the first instance, and which was not objected under Article 123(2) EPC, by the introduction of the features shown in bold:

a) "comprising **at least one biologically active substance and/or at least one therapeutically active substance**",

b) "said film forming agent **consisting of** an alginate salt of monovalent cation or a mixture of alginate salts of monovalent cation",

c) "**which solution also contains the at least one biologically active substance and/or at least one therapeutically active substance**, distributing the solution onto a solid surface...".

1.2 As to features a) and c), the description of the application as originally filed relates repeatedly to film-forming compositions comprising and active substance or at least one therapeutically active substance (see international publication WO 2007/073346). The description mentions for instance on page 1, lines 6 and 7 that "the invention relates to a composition in the form of an alginate film, comprising at least one biologically active substance, such as a therapeutically active substance". Features a) and c) are therefore disclosed directly and unambiguously in the application as filed.

1.3 As to feature b), the description mentions on page 6, lines 31-34 that "the present invention is based on the

surprising finding that by use of an alginate composition as defined herein, as a stand-alone film forming agent, a film that is adhesive...can be formed". This stand-alone use of an alginate is confirmed by all example 1-10 of the application as filed. Feature b), namely the restriction to a single film-forming agent by the term "consisting of" is therefore disclosed directly and unambiguously in the application as filed.

- 1.4 All other features of claims 1- 15 of auxiliary request 6 were present in the claims of the original application.
- 1.5 Auxiliary request 6 meets the requirements of Article 123(2) EPC.
2. Article 84 EPC
 - 2.1 The term "water-soluble" had been objected by the examining division in its decision for lack of clarity. Said term was indeed used by the appellant to bring a further restriction towards the cited prior art, which disclosed films which were, according to the applicant, not "water-soluble".
 - 2.2 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 as regards its water-solubility. Hence, to clearly establish the scope of protection of the claims, a clear definition might be necessary to establish the level of solubility and the limits of the claimed "water-soluble" character of the claimed film.

2.3 The European and US Pharmacopoeiae provide different standard quantified definitions of the level of solubility of a compound directly applicable to the solubility in water, such as "very soluble", "freely soluble", "soluble", "sparingly soluble" "slightly soluble", "very slightly soluble" and "practically insoluble". These levels of solubility are given in volume of solvent per gram of product and range thus widely, from infinitely soluble to poorly soluble, "practically insoluble" meaning that the material is insoluble or does almost not dissolve in the solvent.

In the present case and in the absence of any specification, a "water-soluble" film relates to a film able to be dissolved in any amount of water. The general definition of "water-soluble" used in claim 1 does indeed not give further indication regarding the level of solubility, and encompasses thus limited as well as high solubility levels in water. This goes from the standard defined "very soluble" level to the to "very slightly soluble" level or even the "practically insoluble" level, as given by the Pharmacopoeiae.

Hence, the term "water-soluble" is a very broad term and can hardly be considered as characterizing precisely the solubility level of the claimed film or also as a feature able to provide a distinction over a prior art film showing even a limited water-solubility. It remains however that determining whether a product is "water-soluble" is within the scope of the skilled person, and said term meets the requirements of clarity.

2.4 The other feature objected by the examining division for lack of clarity is not present anymore in the claims.

2.5 Auxiliary request 6 meets the requirements of Article 84 EPC.

3. Article 54 EPC

Document D1 was mentioned as novelty-destroying document by the examining division in its decision.

D1 discloses in example 1-1 the preparation of a film made from water, Protanal LFR5/60, which is the alginate film-forming agent of the present application, in combination with guar gum, starch, sorbitol and glycerine. The mixture was heated, deaerated and cast as a film (see par. [0039]-[0044]).

Sad composition of example 1-1 comprises thus more than a single film-forming compound, since at least starch possesses film-forming properties. The presence of more than a single film-forming compound being excluded in claim 1 by the term "consisting of", the subject-matter of claim 1 of auxiliary request 6 is therefore novel over D1.

All other claims are dependent on claim 1 or relate to a process or an use involving a composition comprising a film-forming agent consisting also of an an alginate salt.

Auxiliary request 6 meets therefore the requirements of Article 54 EPC.

4. Remittal to the examining division

Although Article 111(1) EPC does not guarantee a party an absolute right to have all the issues in the case considered by two instances, it is well recognised that any party should, whenever possible, be given the opportunity to said consideration by two instances of the important elements of the case. The essential function of an appeal proceedings is to consider whether the decision under appeal is correct. Hence, a case is normally remitted if further criteria of patentability have not yet been examined and decided in the proceedings leading to the decision under appeal. This is the situation here. Hence, the Board considers it appropriate to remit the case to the examining division for further prosecution on the basis of auxiliary request 6. The remittal was agreed to by the appellant.

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 on the basis of auxiliary request 6 filed with letter of 9 May 2017.

The Registrar:

The Chairman:



S. Fabiani

J. Riolo

Decision electronically authenticated