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**Datasheet for the decision
of 29 April 2019**

Case Number: T 1622/15 - 3.3.07

Application Number: 08251713.7

Publication Number: 1992362

IPC: A61K47/18, A61K47/36, A61K9/08

Language of the proceedings: EN

Title of invention:
Methods for preparing preserved compositions containing
hyaluronic acid or a pharmaceutically-acceptable salt thereof

Patent Proprietor:
Johnson & Johnson Consumer Inc.

Opponent:
Strehlke, Ingo Kurt

Headword:
Preserved compositions / JOHNSON & JOHNSON

Relevant legal provisions:
EPC Art. 56
RPBA Art. 12(4)

Keyword:

Request not to admit documents and the main request filed in
the first-instance proceedings and resubmitted on appeal
(refused)

Main request - inventive step (no)



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Case Number: T 1622/15 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 29 April 2019

Appellant: Strehlke, Ingo Kurt
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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
17 July 2015 concerning maintenance of the
European Patent No. 1992362 in amended form.**

Composition of the Board:

Chairman J. Riolo
Members: S. Albrecht
Y. Podbielski

Summary of Facts and Submissions

- I. European Patent No. 1 992 362 was granted on the basis of a set of 11 claims.
- II. An opposition against the patent was filed on the grounds that its subject-matter lacked novelty and inventive step (Article 100(a) EPC), that it was not sufficiently disclosed (Article 100(b) EPC) and that it extended beyond the content of the application as filed (Article 100(c) EPC).

The evidence filed during the opposition proceedings included the following:

D2: JP 2004-315472 A

D2c: JAPIO fulltext translation of D2 into English

D37: "Declaration of Kenneth T. Holeva Pursuant to 37 C.F.R. §1.132", filed by the patent proprietor on 17 July 2014

D38: "Experimental report by Kenneth T. Holeva; July 2012", filed by the patent proprietor on 17 July 2014

D41: "Experimental report by Kenneth T. Holeva II", filed by the patent proprietor on 3 October 2014

- III. The opponent (hereinafter "the appellant") and the patent proprietor both filed an appeal against the interlocutory decision of the opposition division finding that, on the basis of the fifth auxiliary request filed during the oral proceedings before the opposition division, the patent in suit (hereinafter "the patent") met the requirements of the EPC.

Independent claim 1 of this request read as follows:

"A method for preparing a preserved hyaluronic acid composition, the method comprising:

dissolving benzalkonium chloride (BAK) in a first quantity of a solvent;

dissolving a quantity of hyaluronic acid (HA) or physiologically-acceptable salt thereof in a second quantity of the solvent;

wherein the ratio of the first quantity of solvent to the second quantity of solvent is between 1.8:1 and 2.2:1; and

adding the dissolved HA or physiologically-acceptable salt thereof to the dissolved benzalkonium chloride,

wherein precipitation of the benzalkonium chloride and the HA or physiologically-acceptable salt thereof is substantially prevented by preparing separate HA or physiologically-acceptable salt thereof and separate benzalkonium chloride solutions which are then combined, and wherein the composition contains between 0.001 to 0.02 w/v% benzalkonium chloride."

In the appealed decision, the opposition division admitted i.a. documents D37, D38, D41 as well as auxiliary request 5 into the proceedings.

With regard to the latter, the opposition division found that the amendments made to its claims fulfilled the requirements of Article 84 EPC, that the invention claimed fulfilled the requirements of sufficiency of

disclosure and that the claimed subject-matter complied with the criteria of Articles 123(2) and 54 EPC.

As regards inventive step of this request, the opposition division considered D2 as the closest prior art, in particular working example 2 thereof, from which the claimed subject-matter differed in terms of the ratio claimed. The technical effect linked to this distinguishing feature was the prevention of precipitation of the BAK and the HA or a physiologically acceptable salt thereof (hereinafter "HA or a salt thereof"), as credibly shown by the experimental data of D41. The composition of D2, on the other hand, did contain such precipitates, as evidenced by example 2 of D38. Accordingly, the objective technical problem constituted the provision of an improved method for making preserved hyaluronic acid compositions which prevented precipitation of BAK and HA or a salt thereof. The solution provided by the claimed subject-matter was considered to be inventive, given the lack of suggestion in the prior art that precipitation of BAK and HA or a salt thereof could be specifically prevented by selecting the claimed ratio, whilst mixing ratios slightly outside the claimed ratio led to precipitation of these compounds.

- IV. On 23 July 2018 the Board summoned the parties to oral proceedings, to be held on 4 April 2019.

- V. In a letter dated 4 February 2019, the patent proprietor (hereinafter "the respondent") withdrew its appeal as well as its request for oral proceedings, and informed the Board that it would not be attending the oral proceedings scheduled for 4 April 2019.

Furthermore, the respondent requested maintenance of the patent in amended form as set out in the opposition division's decision, i.e. on the basis of the fifth auxiliary request filed during the oral proceedings before the opposition division which became the respondent's sole request (hereinafter referred to as "main request").

VI. On 8 March 2019 the Board cancelled the oral proceedings.

VII. The appellant's written arguments, as far as they are relevant for the present decision, may be summarised as follows:

(a) Admittance of documents D37, D38 and D41

The opposition division should not have admitted these documents into the opposition proceedings, because they had been filed at a late stage of these proceedings, contained complex experimental data and were not relevant to the case. By nevertheless admitting these documents into the opposition proceedings, the opposition division deprived the appellant of its right to be heard and thereby committed a substantial procedural violation. Accordingly, documents D37, D38 and D41 should not be admitted into the appeal proceedings.

(b) Admittance of the main request

Not only had this request been filed as auxiliary request 5 at a very late stage of the opposition proceedings, but it also contained complex matter. Furthermore, its filing could not have been foreseen and was thus surprising, since its claims

included features which had their sole basis in the description of the patent application as filed underlying the patent in suit. Accordingly, this request should not be admitted into the appeal proceedings in that the opposition division should not have admitted it as former auxiliary request 5 into the opposition proceedings in the first place.

(c) Main request - claim 1 - Article 56 EPC

Starting from paragraph 0029 of D2 as the closest prior art and assuming that this paragraph did not disclose the claimed ratio of the first quantity of solvent to the second quantity of solvent, then this ratio would constitute the sole distinguishing feature vis-à-vis the closest prior art. In the absence of any special or surprising technical effect linked to this feature, the objective technical problem consisted in the provision of an alternative method for preparing a preserved hyaluronic acid composition. The solution proposed to this problem, i.e. a method in accordance with claim 1, wherein the ratio of the first quantity of solvent to the second quantity of solvent was between 1.8:1 and 2.2:1, was arbitrary and therefore not inventive, given the fact that the skilled person would arrive at the claimed invention in an obvious manner by performing routine experimentation.

VIII. The respondent did not present any arguments with respect to the admittance of documents D37, D38 and D41 and the admittance of the main request.

As regards the inventive step of claim 1 of the main request, the respondent's written arguments, as far as

they are relevant for the present decision, may be summarised as follows:

The claimed subject-matter differed from the closest prior art D2, and in particular paragraph 0029 thereof, in terms of the ratio of the first quantity of solvent to the second quantity of solvent. As the method described in D2 employed a different ratio, it did not substantially prevent precipitation of the BAK and the HA or a salt thereof in the final, preserved hyaluronic acid composition, as evidenced by D38. The claimed method, on the other hand, did provide for a substantial prevention of such precipitation. Hence, the objective technical problem to be solved in light of D2 consisted in the provision of a method of preparing a preserved hyaluronic acid composition free of precipitates. The solution provided by the claims of the invention which consisted of preparing a first solution of BAK in a solvent, and a second solution of hyaluronic acid in the same solvent, and combining the two together in a specific ratio to provide a final composition with a specific concentration of BAK, was not rendered obvious by the cited prior art. In particular, D2 did not contain any teaching that would lead the skilled person to consider modifying the method disclosed therein in order to prepare a solution that was free of precipitates without performing an additional filtering step. Moreover, even if the skilled person were to consider modifying the method of D2, he/she would nevertheless not arrive at the claimed invention, given the fact that neither the cited prior art nor the common general knowledge contained any suggestion to select the ratio as claimed in order to solve the technical problem as posed.

IX. Requests

The appellant requested that the decision under appeal be set aside and that the patent be revoked.

Furthermore, it requested that:

- documents D37, D38 and D41 not be admitted into the appeal procedure;
- the main request not be admitted into the appeal procedure.

The respondent requested that the patent be maintained on the basis of the main request.

Reasons for the Decision

2. Admittance of documents D37, D38 and D41

- 2.1 Documents D37, D38 and D41 had all been filed by the respondent in the opposition proceedings.
- 2.2 In the appellant's view, the opposition division should not have admitted these into the opposition proceedings. Not only were these documents filed at a late stage of these proceedings, but they also contained complex experimental data. Against this background, the appellant considered that it did not have sufficient time at its disposal to verify these data and to conduct further tests itself in reaction thereto. Accordingly, by nevertheless admitting these documents into the opposition proceedings, the opposition division violated the appellant's right to be heard and hence committed a substantial procedural violation.

2.3 The Board notes in this regard that the respondent had filed D37 and D38 on 17 July 2014 together with its reply to the notice of opposition. As these documents had been filed within the period set by the opposition division for filing the reply, they formed part of the opposition proceedings and the opposition division had no discretion not to admit them. These documents have been resubmitted on appeal and form part of the appeal proceedings (Article 12(4) RPBA).

Document D41 was submitted by the respondent with letter of 3 October 2014, i.e. shortly before the opposition division had issued a summons to oral proceedings and had set a final date of 18 May 2015 for making written submissions. The Board considers that the appellant had sufficient time at its disposal to verify the experimental data contained in these documents and to conduct further tests itself in reaction to these data and that its right to be heard was not violated. In these circumstances the Board sees no reason to set aside the opposition division's decision to admit D41 into the opposition proceedings. As a consequence, D41, which has been resubmitted on appeal, forms part of the appeal proceedings (Article 12(4) RPBA).

3. Admittance of the main request

3.1 This request has been filed by the respondent as auxiliary request 5 in the oral proceedings before the opposition division, i.e. on 18 June 2015. The opposition division decided to admit this request, because it considered the request to be an attempt to overcome several objections raised by the opponent (see point 7.1 of the impugned decision).

3.2 The appellant submitted that it could not have foreseen the filing of this request at such a late stage of the proceedings and was thus surprised by it.

3.3 The Board does not find the appellant's arguments convincing. The present main request differs from the former main request filed on 15 May 2015 merely by specifying the concentration of BAK and HA or a salt thereof as w/v% and by deleting some of the dependent claims. That an additional request with such low complexity would be filed during the oral proceedings in response to the discussion that took place can, in the Board's view, not be regarded as surprising. The Board also notes that the appellant did not object to the admittance of auxiliary request into the opposition proceedings (see point 1.12.2 of the minutes). Accordingly, the Board considers that there was no violation of the appellant's right to be heard. The Board sees no reason to set aside the opposition division's decision to admit the request into the proceedings. As a consequence, the request forms part of the appeal proceedings (Article 12(4) RPBA).

4. Main request - Article 56 EPC - claim 1

4.1 Claimed subject-matter:

4.1.1 Claim 1 of the main request pertains to a method for preparing a preserved hyaluronic acid composition, the method **comprising** (emphasis in bold added by the Board):

(a) dissolving BAK in a first quantity of a solvent;

(b) dissolving a quantity of HA or a salt thereof in a second quantity of the solvent;

- (c) wherein the ratio of the first quantity of solvent to the second quantity of solvent is between 1.8:1 and 2.2:1; and
- (d) adding the dissolved HA or salt thereof to the dissolved BAK,
- (e) wherein precipitation of the BAK and the HA or a salt thereof is substantially prevented by preparing separate HA or a salt thereof and separate BAK solutions which are then combined, and
- (f) wherein the composition contains between 0.001 to 0.02 w/v% BAK.

4.1.2 In agreement with the appellant the Board considers that due to the use of the term "comprising" in claim 1, the claimed method is not limited to the steps listed therein, but may comprise further steps including such steps which consist in adding further ingredients to the respective, separate solutions of BAK and of HA or a salt thereof. The Board further notes that claim 1 refers to a substantial prevention of precipitation, i.e. it does not require the complete absence thereof. Minor precipitates may be subsequently removed by a filtering step (see claims 6 to 8 as dependent claims of claim 1).

4.2 The closest prior art

4.2.1 Both parties as well as the opposition division identified D2/D2c as a suitable starting point, in particular working example 2 thereof (see paragraph 0028, the last three lines; paragraph 0029 of D2 and D2c respectively). The Board sees no reason to deviate from this view.

4.2.2 Working example 2 describes in particular a method for preparing an ophthalmic, preserved composition comprising i.a. hyaluronate sodium, BAK, and purified water as solvent. The method comprises *inter alia* the following steps:

- (a) dissolving 1.6 mg of BAK in about 10 ml of purified water;
- (b) dissolving 100 mg of hyaluronate sodium (hereinafter HA sodium) in about 35 ml of purified water;
- (c) adding the solution prepared in step (b) to about 50 ml of a solution comprising *inter alia* purified water as solvent and thiamine dilaurylsulfate;
- (d) adding the solution obtained in step (a) to the solution prepared in step (c).

The volume of the preserved composition amounts to 100 ml in total. Accordingly, the concentration of BAK in this composition corresponds to 1.6 mg / 100 ml, i.e. 0.0016 w/v% which falls within the range of 0.001 to 0.02 w/v% of claim 1.

The ratio of the first to the second quantity of solvent (hereinafter referred to as "solvent ratio"), on the other hand, is 10:85 (i.e. about 0.12:1), whereas claim 1 requires a ratio of between 1.8:1 and 2.2:1. These facts have not been disputed by any of the parties.

Accordingly, the subject-matter of claim 1 differs from the closest prior art in terms of the claimed solvent ratio.

4.3 Technical problem and solution

In order to formulate the objective technical problem effectively solved by the claimed subject-matter vis-à-vis the closest prior art, the technical effects associated with the distinguishing feature need to be identified.

- 4.3.1 In the respondent's view, the solvent ratio of the aqueous solution of working example 2 of D2/D2c had the effect that this formulation contained precipitates and had to be filtered. In support of this statement, the respondent referred to the experimental data of test 2 of D38 (hereinafter "evidence of D38").

Conversely, the claimed solvent ratio substantially prevented precipitation of BAK and HA or a salt thereof in a final, preserved composition comprising the claimed concentration of BAK, without the need to include additional components to the composition. This effect had been credibly shown with the data of solutions D and E of D37 and with the data of compositions C1 to C7 of D41.

- 4.3.2 The Board does not share the respondent's point of view:

(a) Firstly, the Board notes that working example 2 of D2/D2c does not explicitly disclose the presence of any precipitates in the preserved, not yet filtered hyaluronic acid composition. As regards the evidence of D38, the appellant correctly points out on page 54 of its appeal brief that the composition of D38 does not solely contain BAK and HA sodium, but also further components including buffers and emulsifiers which may influence the solubilising

properties of HA and BAK. As these further ingredients are not exactly the same in the preserved composition of working example 2 of D2/D2c, the composition tested in test 2 of D38 does not reflect the composition of this example. Accordingly, no reliable conclusions can be drawn from the data disclosed in test 2 of D38 with regard to the alleged presence of precipitates in the preserved, not yet filtered composition of working example 2 of D2/D2c prior to being filtered. The reasons why this composition is subsequently filtered in this example may be various and unrelated to the presumed presence of precipitates of BAK and HA or a salt thereof. Indeed, the scope of claim 1 equally includes methods, wherein the preserved composition is filtered after its preparation, yet this composition is already substantially free of any precipitates of BAK and HA or a salt thereof prior to being filtered (see under point 4.1.2 above).

Since there are no further data on file which could support the presence of precipitates in the aforementioned composition of working example 2 of D2/D2c, the Board is not satisfied that the preserved, not yet filtered composition of working example 2 of D2/D2c does indeed contain precipitates of BAK and HA or a salt thereof.

- (b) As far as the technical effect of the claimed solvent ratio is concerned, the Board concurs with the respondent in so far as the data obtained with the solutions D and E of D37 and the compositions C1 to C7 of D41 do indeed demonstrate that compositions exhibiting the claimed solvent ratio are substantially free of any precipitates. The

Board notes, however, that these compositions solely contain BAK, HA sodium and water. In contrast, the compositions prepared by the method of claim 1 may comprise further ingredients including components which prevent the precipitation of BAK and HA or a salt thereof (see under point 4.1.2 above and appellant's letter of 4 April 2016, in particular the paragraph bridging pages 7 and 8). In view of the foregoing, the Board is satisfied that the claimed method does indeed substantially prevent precipitation of BAK and HA or a salt thereof, however for the reasons provided above this effect cannot be linked solely and exclusively to the distinguishing feature of the claimed solvent ratio.

- 4.3.3 Accordingly, the objective technical problem to be solved by the claimed invention resides in the provision of alternative means to prepare a preserved hyaluronic acid composition which comprises BAK in a concentration of 0.001 to 0.02 w/v% and which is substantially devoid of any precipitates of BAK and HA or a salt thereof.
- 4.3.4 The solution proposed to this problem is a method in accordance with claim 1, i.e. a method wherein the ratio of the first quantity of solvent to the second quantity of solvent is between 1.8:1 and 2.2:1.
- 4.4 Obviousness

In agreement with the appellant (see page 47 of its appeal brief), the Board considers that the skilled person confronted with the stated technical problem would adjust one or the other parameter of the method disclosed in working example 2 of D2/D2c. In the course

of this routine work he/she would also test various solvent ratios, and thereby arrive at the subject-matter of claim 1 in an obvious, arbitrary manner.

Consequently, the main request does not fulfil the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



B. Atienza Vivancos

J. Riolo

Decision electronically authenticated