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Datasheet for the decision of 18 February 2022

Case Number: T 1352/19 - 3.3.03

Application Number: 11769800.1

Publication Number: 2614090

IPC: C08B37/08, C08L5/08, A61K31/728, C08B31/00, C08B37/00, C08J3/28

Language of the proceedings: EN

Title of invention:
HYBRID COOPERATIVE COMPLEXES OF HYALURONIC ACID

Patent Proprietor:
Altergon S.A.

Opponent:
Fidia Farmaceutici S.p.A.

Relevant legal provisions:
EPC Art. 54, 56, 100(b), 123(2)
RPBA Art. 12(4)
RPBA 2020 Art. 13(1), 13(2)

Keyword:

Extension of subject-matter (no)
New objections (novelty and inventive step) after summons - no exceptional circumstances
Novelty - (yes)
Inventive step (yes) - no bonus effect
New documents submitted in relation to sufficiency of disclosure after rejoinder and before summons - admitted (yes)
Sufficiency of disclosure (yes)

Decisions cited:

G 0003/14

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Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 1352/19 - 3.3.03

D E C I S I O N
of Technical Board of Appeal 3.3.03
of 18 February 2022

Appellant: (Patent Proprietor)	Altergon S.A. Via Dogana Vecchia 2 6900 Lugano (CH)
Representative:	Gerli, Paolo Botti & Ferrari S.p.A. Via Cappellini, 11 20124 Milano (IT)
Appellant: (Opponent)	Fidia Farmaceutici S.p.A. Via Ponte della Fabbrica 3/A 35031 Abano Terme (PD) (IT)
Representative:	De Gregori, Antonella Studio Legale Bird & Bird Via Borgogna, 8 20122 Milano (IT)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 1 March 2019 concerning maintenance of the European Patent No. 2614090 in amended form.**

Composition of the Board:

Chairman	D. Semino
Members:	F. Rousseau
	W. Ungler

Summary of Facts and Submissions

I. The appeal lies from the interlocutory decision of the opposition division according to which European patent No. 2 614 090 as amended according to the claims of auxiliary request 4 filed during the oral proceeding on 23 January 2019 and a description adapted thereto met the requirements of the EPC. The contested decision was also based on a main request submitted with letter of 12 January 2018 and additional auxiliary requests 1 to 3.

II. The decision was taken having regard to the following documentary evidence amongst others:

E2: WO 00/44367
E3: EP 0 499 164 A1
E4: US 5,621,093
E5: European Pharmacopoeia 7.0, pages 503 and 504
E10: Synovium Surgical, (LCA) product
E12: Set of documents concerning laluril® (sodium hyaluronate and chondroitin sulfate sterile solution for intra vesical instillation) IBSA
E18: E.J. Welsh *et al.*; *J. Mol. Biol.*; (1980) **138**, 375-382
E19: T.F. McAlindon *et al.*; JAMA; March 15, 2000; Vol. 283; No 11, 1469-1475
E20: The Journal of Family Practice; Vol. 52, N. 12, December 2003; pages 919-920
E21: US 6,482,401 B1
E22: C. Schiraldi *et al.*, Appl Microbiol Biotechnol (2010) 87:1209-1220
E23: US 2003/0104601 A1
E25: WO 2012/089537 A1

E26: A. D'Agostino *et al.*; *BMC Cell Biology* (2015)16:19
E27: Leaflet Profhilo®, IBSA 3.2% - 16 mg (H-HA) + 16 mg (L-HA)/1 ml Hyaluronic acid sodium salt
E27a: http://www.youmed.it/video.d0?id=2133.

III. According to the reasons for the contested decision which are pertinent in the appeal proceedings, claims 1 and 12 of the main request did not extend beyond the content of the application as filed. The subject-matter of the main request was sufficiently disclosed, but its claim 1 was anticipated by E2. The main request was therefore rejected. Auxiliary requests 1 to 3 lacked also novelty over E2 for the same reason. Auxiliary request 4 restricted to the process of obtaining the product defined in the main request was allowable, an inventive step being acknowledged over each of E10 and E2, should those documents be considered as a suitable starting point for assessing inventive step.

IV. Both the patent proprietor and the opponent appealed the decision of the opposition division.

V. The patent proprietor submitted with its statement of grounds of appeal a main request and auxiliary requests 1 to 5. The claims of the main requests correspond to those of the main request underlying the contested decision.

VI. The opponent with its statement of grounds of appeal submitted the following document:

E28: A. La Gatta *et al.*; JOURNAL OF OCULAR PHARMACOLOGY AND THERAPEUTICS; Vol. 34, Number 10, 2018, pages 1-8.

VII. With its rejoinder the opponent submitted the following document:

E31: A. Stellavato *et al.*; PLOS ONE | DOI:10.1371/journal.pone.0163510

VIII. With its rejoinder the patent proprietor submitted the following document:

E28a: Declaration of Dr. De Rosa dated 11 November 2019.

IX. The opponent submitted after the rejoinders, but before issuance of the summons to oral proceedings, the following evidence:

E35: WO 2017/016873 A1.

X. Subsequently and before issuance of the summons to oral proceedings, the patent proprietor submitted the following document:

E38: published correction to E28
E39: Declaration of Dr. De Rosa dated 17 December 2020.

XI. After issuance of the summons to oral proceedings, the opponent submitted the following document:

E40: US 2007/0059276 A1

XII. Subsequently, the patent proprietor filed with letter of 22 November 2021 an auxiliary request A and auxiliary requests 1 to 5.

XIII. Oral proceedings before the Board were held on 18 February 2022.

XIV. The patent proprietor requested that the decision of the opposition division be set aside and the patent be maintained on the basis of the main request submitted with the statement of grounds of appeal, or in the alternative, in this order, of auxiliary request A and auxiliary requests 1 to 5, all submitted with letter of 22 November 2021, or auxiliary requests 1 to 5 submitted with the statement of grounds of appeal.

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

XVI. Claims 1, 2 and 12 of the main request read as follows:

"1. Stable, hybrid cooperative L/H-HA complexes prepared by submitting to thermal treatment, at temperature comprised between 100° and 120°C, solutions containing simultaneously L-HA hyaluronic acid or hyaluronans and H-HA hyaluronic acid or hyaluronans wherein the molecular weight of L-HA is comprised between $1 \cdot 10^4$ to $1 \cdot 10^6$ Da and that of H-HA is given by the formula $MW_{H-HA} \geq MW_{L-HA}/0.9$ and wherein H-HA and L-HA are present in relative quantities comprised between 0.5 - 2.

2. L/H-HA complexes according to claim 1, having a viscosity from 1.1 to 200-fold less than that of a solution containing the H-HA hyaluronic acid alone used for forming the complex.

12. Hybrid cooperative complexes according to claims 1 to 11, wherein the low molecular weight hyaluronic acid is replaced by the low molecular weight polysaccharide chondroitin."

XVII. The patent proprietor's submissions, in so far as they are pertinent, may be derived from the reasons for the decision below. They are essentially as follows:

(a) Claims 1 and 12 of the main request met the requirements of Article 123(2) EPC.

(b) Sufficiency of disclosure was to be acknowledged. In this respect documents E28 and E35 should not be admitted, whereas E28a, E38 and E39 should be admitted.

(c) Example 4 of E2 and E18 did not described stable complexes within the meaning of claim 1 of the main request. Novelty was therefore given.

(d) E40 and the objection of lack of novelty based on that document should not be admitted into the proceedings.

(e) An inventive step was to be acknowledged starting from any of E2, E18 or E10 as the closest prior art.

(f) The inventive step objection based on E12 as the closest prior art should not be admitted.

XVIII. The submissions of the opponent, in so far as they are pertinent, may be derived from the reasons for the decision below. They are essentially as follows:

(a) Claims 1 and 12 of the main request extended beyond the content of the application as filed.

(b) In view of the experiments shown in E26, E28 and E35 the invention was not sufficiently disclosed

over the whole scope claimed. As regard this objection E28 and E35 should be admitted, while E28a, E38 and E39 should not be admitted.

(c) Claim 1 of the main request lacked novelty over each of example 4 of E2 and E18 which described mixtures of H-HA and L-HA forming stable hybrid complexes.

(d) E40 and the objection of lack of novelty based on that document should be admitted into the proceedings.

(e) The subject-matter of claim 1 lacked an inventive step over each of E2, E18 and E10 taken as the closest prior art. The subject-matter of claim 12 lacked also an inventive step starting from the disclosure of E10.

(f) The inventive step objection based on E12 as the closest prior art should be admitted.

Reasons for the Decision

Background art to the invention

1. Owing to their biological properties hyaluronic acid and its salts hyaluronans (referred to as HA in present claim 1) are highly water-soluble polysaccharides finding application in the medical sector (paragraphs [0002] to [0004] of the specification). The biological response of HA as a function of its molecular weight means that for some applications mixtures of low molecular weight HA (L-HA) and high molecular weight HA

(H-HA) must be used (paragraph [0006] of the patent in suit). As shown by the opponent's submissions on page 22 of the statement of ground of appeal, this prior art knowledge is illustrated in E2 in which the usefulness of these mixtures is explained. While the L-HA molecules act quickly, the H-HA molecules which are broken down by enzymes in the body to smaller molecules provide a longer release of the more active smaller molecules producing a longer period of efficacy (E2, paragraph bridging pages 15 and 16; page 18, lines 7-13).

2. According to paragraph [0008] of the specification which indisputably reflects the general knowledge of the skilled person, the molecules of HA in solution are characterized by cooperative phenomena of interaction based on formation of hydrophobic bonds and interchain hydrogen bonds, the cooperativeness of these interactions depending on the length and therefore on the molecular weight of the chains. Whereas long chains of HA give stable interactions between them, which involve all the molecules present in solution, giving rise to a three-dimensional network, molecules having much shorter chains give interactions that are less stable. The latter rather tend to form aggregates that do not simultaneously involve all the molecules present.

This differing modes of aggregation of HA in solution as a function of their molecular weight result in large differences in rheological behaviour, such as for example the viscosity of their solutions (paragraph [0008]).

The opponent did not dispute the presentation of the background art described in the patent in suit.

The technical problem as set out in the specification

3. According to paragraph [0042] of the patent in suit the presence of L-HA with molecular weight in the order of 10^4Da in a solution of H-HA induces formation of L/H-HA cooperative complexes which "*begins, even if slowly, even at room temperature, because the lower cooperativeness that exists between the short chains of L-HA allows these to compete in the cooperative interactions existing between the long chains of H-HA, giving rise to the formation of hybrid systems*". For this reason "*the solutions obtained by mixing, at room temperature, H-HA and L-HA with MW of the order of 10^4Da, display a dynamic viscosity that varies over time*".

This is in line with the information provided in paragraph [0009] according to which addition of a L-HA, in particular those with a molecular weight of less than 10^5Da, results in a slow but constant decrease in viscosity which cannot be attributed to hydrolytic processes. This was not disputed by the opponent whose reasoning for lack of novelty over the mixtures of L-HA and H-HA prepared in E2 is also based on the formation of said complexes at room temperature.

According to paragraph [0009] of the specification, the continual variation of the physicochemical properties, in particular the viscosity, of these solutions, however, makes them unsuitable for practical applications in the medical field, as those instead require constant rheological characteristics.

Meaning of claims 1 and 12

4. Claim 1 is directed to "*stable, hybrid cooperative L/H-HA complexes*" defined in terms of a process for their preparation. The meaning of the expression "*stable, hybrid cooperative L/H-HA complexes*", in particular the term "*stable*", is essential for an assessment of the objections raised by the opponent. Whereas that expression has not been shown, let alone argued, to have a well recognized meaning in the art at the date of filing of the granted patent, this ambiguity is not open to objections under Article 84 EPC in accordance with the ruling of G 3/14 (OJ EPO 2015, A102), as it does not result from amendments to the granted patent. On that basis, in order to deal with the objections raised by the opponent, it is necessary for the Board to give to the expression "*stable, hybrid cooperative L/H-HA complexes*" the broadest sensible interpretation in the light of the specification as a whole.

4.1 In agreement with temperatures comprised between 100° and 120°C employed for the thermal treatment defined in present claim 1, it can be taken from paragraph [0032] of the specification that "*stable, hybrid cooperative L/H-HA complexes*" are prepared in a first step by heating for a sufficient period of time under said temperature conditions a solution that contains H-HA and L-HA simultaneously. This results in quantitative rupture of the hydrogen bonds that previously existed within each of the H-HA and L-HA components.

4.2 It can be understood from the same paragraph [0032] that the chains of various lengths originating from the H-LA and L-HA components which are randomly present in the solution after the heat treatment interact upon cooling, leading to randomized rearrangement or

redistribution of the chains of various molecular weight originally present in the H-LA and L-HA components.

4.3 Having regard to the fact that a new distribution equilibrium has been reached due to the heat treatment and subsequent cooling, the "*cooperative hybrid complexes*" "*do not display a change in their dynamic viscosity over time*" (paragraph [0042] of the specification). It can be taken from paragraph [0032] and the results shown in table 1 of the specification that the reduction of viscosity accompanying the formation of the complexes cannot be attributed to hydrolysis of the HA chains, but rather to the rearrangement between the H-LA and L-LA chains.

4.4 Whereas the formation of L/H-HA cooperative complexes begins, even if slowly, at room temperature, as indicated in paragraph [0042] (see above point 3), a thermal treatment is necessary to generate in a shorter lapse of time a randomized rearrangement or redistribution of the chains of various molecular weights originally present in the H-HA and L-HA components so as to obtain a new distribution equilibrium, i.e. to obtain "*cooperative hybrid complexes*" which are not susceptible to change in their dynamic viscosity over time. The L/H-HA hybrid, in the absence of interactions with other molecules or surfaces, remains stable at room temperature (paragraph [0032], lines 20-21), contrary to the initial solution comprising the H-HA and L-HA components.

4.5 Accordingly, it can be concluded that the term stable in operative claim 1 is understood by the skilled person to correspond to a degree of rearrangement achieved between the HA chains originally contained in

the H-HA and L-HA components which degree of rearrangement does not result in a change of the dynamic viscosity over time at room temperature. Additional considerations in respect of the meaning to be attributed to the term stable are addressed below to the extent they are necessary to assess the opponent's objections.

4.6 Having regard to paragraph [0022] and example 7 in paragraphs [0049] to [0051] of the specification, similar considerations apply when the low molecular weight polysaccharide chondroitin (C) is used in place of the L-HA in order to form the hybrid cooperative C/ H-HA complexes defined in operative claim 12.

Article 123(2) EPC

5. The opponent submits that claim 1 extends beyond the content of the application as filed because the wording "*between 0.5 - 2*" defining the relative quantities of H-HA and L-HA does not find a basis in the application as filed. According to the opponent's position the relative quantities "*from 0.5 to 2*" defined on page 4, line 26 of the application as filed would not include the end values 0.5 and 2.

5.1 The opponent's objection fails to convince, not only because attributing to both expressions a different technical meaning is artificial, but also because the application as filed defines in its claim 3 relative quantities of H-HA and L-HA comprised between 0.1 and 10, preferably 0.5 - 2, i.e. relative quantities of H-HA and L-HA preferably comprised between 0.5 - 2.

6. The opponent also submits that the replacement of the low molecular weight hyaluronic acid by the low

molecular weight polysaccharide chondroitin as defined in operative claim 12 results from a selection in claim 15 as filed which defines that "*the low molecular weight hyaluronic acid is replaced by other low molecular weight polysaccharides, such as chondroitin, chondroitin sulphate, dextrins, cyclodextrins, dextrans*". The opponent acknowledges that claim 12 would find a basis in the application as filed, if the wording "*such as*" were equivalent to "preferably". This, however, would not be the case according to the opponent, meaning that claim 12 would represent an intermediate generalization which finds no basis in the application as filed.

6.1 The Board cannot follow the reasoning of the opponent. Even though the wording "*such as*" taken literally does not have the same meaning as "preferably", the mention of the five alternative specific low molecular weight polysaccharides in the context of claim 15 as filed when no other additional alternatives are specifically mentioned highlights or puts the focus on those five mentioned specific low molecular weight polysaccharides expressing thereby a particular utility for those compounds. The sole mention of chondroitin as a replacement for the low molecular weight hyaluronic acid in operative claim 12 is nothing else than the limitation to only one of these specifically mentioned compounds, which are all individually disclosed in the application as filed in combination with the high molecular weight hyaluronic acid.

Finally, the opponent's additional argument that compounds other than chondroitin listed in original claim 15 would not form complexes or are toxic is not relevant to the question whether a combination of the high molecular weight hyaluronic acid and chondroitin

as a substitute for the low molecular weight hyaluronic acid is disclosed in the application as filed.

On that basis, claim 12 has not been shown to extend beyond the content of the application as filed.

7. In view of this and in the absence of additional objections in that respect, the claims of the main request meet the requirements of Article 123(2) EPC.

Novelty of claim 1 over E2

8. Example 4 of E2 held by the opponent to anticipate the subject-matter of claim 1 describes a solution of a high molecular weight (>750 000) cosmetic grade hyaluronic acid in a concentration of 1.0% wt/vol (page 36, lines 5-10). This example 4 also describes by reference to example 1 of the same document the treatment of the high molecular weight (>750 000) cosmetic grade hyaluronic acid at high pH and high temperature to break down the molecular weight to < 30 000 (page 28, lines 7-14 and page 36, lines 10-13). A separate 1.0% wt/vol solution of a low molecular weight cosmetic grade hyaluronic acid is thereby obtained.

A mixture of equal volumes of these high molecular weight and low molecular weight hyaluronic acid solutions is then prepared (page 36, lines 13-16).

Various essential oils were added to four portions of that mixture, whereas one additional portion did not contain any essential oil (page 37, lines 1-3). These preparations were held at 4°C for 7 days after which they were evaluated for their suspension characteristics, before being remixed and aliquoted

into smaller amounts in order to be tested by patients (page 37, lines 3-9). Example 4 does not describe how long and under which conditions the preparation were kept before being tested.

8.1 It is undisputed that the sole features of operative claim 1 from which a distinguishing feature over the disclosure of example 4 of E2 might result are the terms "*stable, hybrid cooperative L/H-HA complexes*" and the process features "*prepared by submitting to thermal treatment, at temperature comprised between 100 and 120°C*". As indicated in above points 4.1 to 4.3 the latter only expresses a means to achieve the degree of rearrangement of the HA chains originally present in the H-HA and L-HA components which is associated to the degree of stability of the hybrid cooperative L/H-HA complex. That temperature, however, does not define a specific degree of stability or rearrangement of the HA chains, even implicitly, since those depends on other process parameters (among others the duration of the heat treatment) which are not specified in operative claim 1.

8.2 The opponent submitted that third parties had to know which mixtures of H-HA and L-HA were falling within the definition of operative claim 1. The task of the Board is however not to define the limits of an ambiguous claim with a view to define for third parties the extent of its protection. The facts that the degree of stability is not expressed in operative claim 1 and that the resulting ambiguity cannot be objected (see above point 4) do not mean, however, that the feature "*stable*" can be merely ignored either, as that term is part of the definition of the claimed invention. It is rather necessary to analyse the meaning of that term to the extent necessitated for an assessment in the

present case, of novelty, sufficiency of disclosure and inventive step.

8.3 The reasoning of the opposition division and of the opponent leading to the conclusion that example 4 would be novelty destroying is based on the assumption that the mixtures disclosed in example 4 of E2 are implicitly disclosed to have been maintained for a certain time at room temperature. As indicated in above point 8, the samples prepared in that example were held at 4°C for 7 days after which they were evaluated for their suspension characteristics, before being remixed and aliquoted into smaller amounts in order to be tested by patients. Example 4 does not describe how long and under which conditions the preparation were kept before being tested. The question therefore arises wether the conditions described in E2 are sufficient for the formation of a stable complex within the meaning of operative claim 1.

8.4 Turning to paragraph [0042] and table 4 of the patent in suit, the mere mixing at room temperature of an aqueous solution of H-HA (MW 1.4 10^6Da; Mw/Mn 1.5) with an aqueous solution of L-HA (MW 3.3 10^4Da; Mw/Mn 1.8) or L-HA (MW 2.2 10^5Da; Mw/Mn 1.7) is without thermal treatment not sufficient to obtain a stable complex even after 24 days. Having regard to the results shown in table 4 of the specification the solutions obtained after a thermal treatment which do not give rise to a change of dynamic viscosity within ten days when stored at room temperature represent stable complexes within the meaning of the patent in suit.

The dynamic viscosity is determined in the patent in suit at 25°C at a constant shear rate of 2.0 s^{-1} which comes within the range of Newtonian viscosity of the

polymer solution (paragraph [0030] of the specification). This shear rate is appropriate to measure dynamic viscosity, as indicated in the opponent's submissions in letter of 25 November 2019, page 20, lines 16-17.

Having regard to the dynamic viscosity values obtained with a thermal treatment for complexes exhibiting a stable dynamic viscosity after 10 days (table 4), it can be concluded that a mixture of L-HA and H-HA as shown in table 4 which has been obtained without heat treatment should be kept at room temperature for a much longer period of time than 24 days to achieve the kind of rearrangement/stability addressed in the patent in suit.

8.5 It follows from the above that the experimental conditions described for the comparative examples of the patent in suit which do not lead to the formation of a stable complex, as indicated in the patent in suit, are in any event much more favorable to the rearrangement of the HA chains and the formation of a complex than the conditions disclosed in E2, since a higher temperature (room temperature vs. 4°C) and a longer time (24 days vs. 7 days) are used. Under these circumstances, and taking into account that the duration and the storage conditions until administration to test patients are not specified in example 4 of E2, example 4 of E2 cannot be held to result in a degree of rearrangement of the HA chains corresponding to that obtained in the comparative examples of the patent in suit and *a fortiori* in a higher degree of rearrangement corresponding to a complex which is stable within the meaning of the patent in suit. In other words, despite the absence in the patent in suit of a quantitative definition of the

term stable, it can be concluded that E2 does not disclose in a direct and unambiguous manner a product falling within the ambit of claim 1 of the main request.

8.6 The opponent's argument about the disclosure of E2 made in relation to the inventive step issue (statement of grounds of appeal, paragraph bridging pages 22 and 23) according to which E2 would disclose on page 17, lines 11 ff. that the core of the invention in E2 is the formation of the complex of at least two carbohydrates equal or different, but with a different molecular weight, does not convince. This passage of E2 reads "*It is a preferred embodiment of this invention that at least two molecular weight ranges of complex carbohydrates be included in the pharmaceutical composition*". The Board agrees with the patent proprietor's view that the term "*complex*" in this passage does not refer to the formation of hybrid complexes within the meaning of the patent in suit, but to the complexity of the carbohydrates molecules as such. This is confirmed on page 1, lines 13-19 of E2 according to which "*Complex carbohydrates, for purposes of this invention are defined as any polymer comprising more than two sugar moieties including such classes of compounds as polysaccharides and oligosaccharides*".

8.7 The other passages of E2 cited by the opponent concerning novelty (page 15, line 27 ff; page 18, lines 6-13 and page 23, lines 6-10) do not concern features of operative claim 1 which would not be disclosed in example 4 of E2. They only concern the molecular weight of the L-HA and H-HA in accordance with the general teaching of E2, but do not concern conditions under which the mixture of said L-HA and H-HA compounds would be treated or stored. Those additional passages of E2

are therefore not relevant to the issue of novelty of the subject-matter of operative claim 1 over example 4 of E2.

8.8 Consequently, E2 has not been shown to be prejudicial to the novelty of the subject-matter of claim 1 of the main request.

Novelty of claim 1 over E18

9. The opponent submits that the subject-matter of claim 1 also lacks novelty over E18, reference being made to the experiment shown in figure 4 on page 380 of that document. This experiment concerns a mixture of a L-HA and a H-HA having 60 disaccharide units (corresponding to a molecular weight of 2.4 10^4 Da) and 3500 disaccharide units (corresponding to a molecular weight of 1.4 10^6 Da), respectively, both at a concentration of 1% w/v. As reported on page 381, lines 7-10 of D18, the addition of the L-HA to the H-HA leads to a reduction of the dynamic viscosity by an order of magnitude. This mixture is close to that described in the experimental part of the patent in suit (paragraph [0042], table 4 and paragraph [0043]) using L-HA and H-HA components having a molecular weight of 3.3 10^4 Da and 1.4 10^6 Da, respectively, also both at a concentration of 1% w/v. Having regard to the teaching provided in the patent in suit concerning the formation of hybrid complexes provided in paragraph [0042] (see point 3 above) and the similarities between the mixtures used in the experiment reported with figure 4 of D18 and in the patent in suit, it can be concluded that the experiment shown in figure 4 of D18 describes at least the first stage of the formation of a cooperative complex.

9.1 As to whether this complex is stable, as also required by present claim 1, the opponent submits that it would be exclusively a question of time for the mixture prepared in E18 to lead to a stable hybrid cooperative complex. This, however, is not the point. The question to be answered is whether E18 describes the time required for obtaining said stable complexes. Similarly to the analysis provided above in relation to E2, E18 does not disclose the conditions under which the mixture of the L-HA and a H-HA components is prepared (temperature, duration) which information would be necessary to determine whether the experiment described in figure 4 of E18 results at least in a degree of rearrangement of the HA chains corresponding to that obtained with the comparative examples of the patent in suit, which indisputably do not concern stable complexes. For these reasons the experiment described in figure 4 of E18 cannot be considered to necessarily result in a degree of rearrangement corresponding to a complex stable within the meaning of the patent in suit, which degree is necessarily higher than that obtained with the comparative examples of the patent in suit.

9.2 The opponent also submits that the formation of the complex in the experiment shown in figure 4 of E18 goes along with a reduction of the dynamic viscosity by an order of magnitude (page 381, lines 7-9), which reduction corresponds to the preparation of a complex in accordance with dependent claim 2 of the main request, and therefore operative claim 1. This, however, does not convince. The reduction of viscosity defined in claim 2 merely expresses the rearrangement of the H-LA and L-LA chains (see above point 4.3) which can be obtained for a stable complex. The patent in suit does not defines that such level of viscosity

reduction *per se* necessarily corresponds to the production of a stable complex. This is illustrated by the variation of the dynamic viscosity obtained without thermal treatment for the mixture comprising a L-HA with a molecular weight of 3.3 10^4 Da (table 4 in paragraph [0042] of the specification). In that case, a variation of at least one order of magnitude is obtained before 14 days without thermal treatment for complexes which cannot be qualified as stable, since their dynamic viscosity is still varying towards lower values as shown by the viscosity values obtained after 24 day at which point the comparative test was stopped.

9.3 On that basis, the subject-matter of claim 1 is also novel over the disclosure of E18.

Novelty of claim 1 over E40 - admittance

10. The opponent submits that E40 filed with letter of 27 September 2021, i.e. after the summons to attend oral proceedings dated 23 June 2021, anticipates the subject-matter of claim 1. The admittance of E40 and of the objection raised on its basis is subject to the provision of Article 13(2) RPBA 2020 which stipulates that amendment to a party's case made after notification of a summons to oral proceedings shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

10.1 The opponent argues that E40 has been submitted in response to the patentee's remarks on page 4, point 5 of the letter of 7 January 2021 according to which HA is not a small molecule, but a complex natural polymer with a significant degree of structural differences

depending on its origin, supplier, aging, methods of storing, handling. It is brought forward that the influence of the handling of HA with respect to sterilization of the polymer through autoclaving is underlined and stressed in E40. This, however, does not constitute a reaction to the remark of the patentee invoked by the opponent, as E40 at most confirms or illustrates the patentee's position expressed with said remark.

Last but not least, the new objection of lack of novelty over E40 was not triggered by the filing of new claims or a new interpretation of the wording of claims already pending. Accordingly, it cannot be held to have been necessitated by the development of the appeal proceedings.

10.2 On that basis, since there are no exceptional circumstances which would justify the filing of E40 at this stage of the proceedings, the Board makes use of its discretionary power under Article 13(2) RPBA 2020 not to take into account E40 and the novelty objection based on that document.

Inventive step of claim 1 over E2

11. As already outlined in above point 3, the patent in suit aims at providing solutions of L-HA and H-HA for medical applications exhibiting less variation of their rheological characteristics over time. Both parties consider E2 as a suitable starting point for assessing inventive step. The Board has no reason to have a different view, since E2, e.g. its example 4, is also concerned with such mixtures used in the same field of application (see above point 8) and because the rheological characteristics of solutions of L-HA and H-

HA were undisputedly implicitly known to lack stability over time before the date of filing of the patent in suit.

Problem successfully solved

12. The opponent did not dispute the patent proprietor's formulation of the problem solved by the subject-matter of claim 1 over E2, namely the provision of solutions comprising both L-HA and H-HA whose dynamic stability has been improved. Having regard to the functional definition in operative claim 1, and the analysis provided above in relation to novelty over example 4 of E2, the Board is satisfied that said problem is effectively solved.

Obviousness of the solution

13. It remains to be decided whether the skilled person desiring to solve the problem identified above would, in view of the disclosure of E2, possibly in combination with other prior art documents or with common general knowledge, have modified the solutions of L-HA and H-HA of E2 in such a way as to arrive at the complexes defined in operative claim 1.

13.1 The opponent did not refer to any document of the prior art which would show or even suggest the idea underlying the present invention, namely the use of a heat treatment to rearrange or redistribute the chains of various molecular weight originally present in the H-LA and L-HA components in order to achieve a state corresponding to a "cooperative hybrid complex" which does not display a change in dynamic viscosity.

Instead the opponent submitted that the medical products disclosed in E2 required a sterilization step and that steam sterilization which was the method of choice for aqueous solutions according to E5 would require thermal conditions necessarily resulting in the formation of a stable cooperative hybrid complex. The stabilization of the L-HA and H-HA solution would be a bonus effect, i.e. a further effect that is unavoidably achieved when the sterilization by autoclaving is carried out.

13.2 While using sterile pharmaceutical products or medical devices is well-known in the art, it was not shown that a sterilization would necessarily be carried out on the solutions of L-HA and H-HA described in E2 or that said sterilization step would necessarily be carried out using a thermal treatment. Whether solutions comprising a mixture of L-HA and H-HA require a sterilization step depends not only on the intended use for these products, but also on the origin of the ingredients contained in the composition. In that respect E2 already suggests that the ingredients used in the examples are already sterile (passage from page 31, lines 14 to page 32, line 2).

Although prefilled syringes containing injectable compositions might need to be sterilized, as submitted by the opponent, the compositions exemplified in E2 are topically applied (page 37, lines 24-28). E2 does not indicate that those are also intended for injections. This is rather questionable having regard to the fact these composition comprise in addition to L-HA and H-HA essential oils.

13.3 Moreover, there is no necessity to perform a steam sterilization step subsequent to the preparation of the

mixture of the L-HA and H-HA components. In this respect, it is referred to the last section "Aseptic preparation" on page 504 of E5 which is an excerpt of the European Pharmacopoeia and therefore concerns the common general knowledge in the art. This section of E5 addresses the assembling under sterile conditions of components, each of which has been sterilised by one of the methods described in the previous sections, which methods include among others in addition to steam sterilisation (heating in an autoclave), ionising radiation sterilisation and filtration.

13.4 Also, as stated by the opponent in support of the argument that thermal treatment would be the required method for HA sterilization (statement of grounds of appeal, page 18, second full paragraph), E4 shows that "*HA solutions submitted to thermal treatment in autoclave present a relevant decrease of MW*" (statement of grounds of appeal, page 30, first full paragraph). In conformity with claim 1 of E4 directed to a method for sterilizing solid HA, the passages of E4 cited by the opponent (columns 1 and 2 and the table of column 3) teach that HA solids sterilized by autoclaving suffer significantly less degradation than HA solutions sterilized by the same method, which is explicitly stated in column 3, lines 10-15 of that document. Accordingly, even if the skilled person contemplated to use a thermal treatment to sterilize the L-HA and H-HA components of the compositions described in E2, such sterilization step would not be necessarily applied when said L-HA and H-HA components are present in solution, let alone in admixture.

13.5 Furthermore, sterilization is not exclusively carried out by thermal treatment, as already pointed out in above point 13.3 by reference to E5. In this respect,

E3 cited by the opponent to demonstrate that injectable compositions, inclusive those based on HA, would require a sterilization step, confirms in column 5, lines 50-55 that filtering or irradiation can be used in addition to autoclaving.

13.6 It follows from the above that starting from the compositions of E2 comprising a mixture of L-HA and H-HA, the skilled person whishing to provide a sterile mixture would be bound to obtain a cooperative hybrid complex only after having made multiple selections, namely sterilization of the L-HA and H-HA components in solution, but not as separate components, using a heat treatment. The opponent, however, did not cite any document available to the skilled person before the filing date of the patent in suit which would teach a sterilization step using these three options in combination. Such knowledge is only derivable from the patent in suit or from additional post published evidence, reference being made to E25, E26, E27, E27a (statement of grounds of appeal of the opponent, pages 14 to 19), whereby E25, E26 and E27a originate from the present inventors and/or the patent proprietor. E25, E26 and E27a show that the heat treatment used to prepare the hybrid complex can be conveniently carried out during a sterilization step therefore underline the advantage of the invention, but they cannot demonstrate its obviousness, as they were post published. Reference was also made to E10 alleged to disclose before the priority date of the patent in suit a process to stabilize hybrid complexes made of chondroitin sulfate (CS) and HA by steam sterilization. This, however, is not correct as detailed in point 17 below.

13.7 Under these circumstances, the Board concludes that the opponent's submissions concerning the obviousness to

thermal sterilize the solutions of E2 comprising both L-HA and H-HA is based on hindsight knowledge of the teaching provided in the patent in suit and post-published document confirming said teaching. Consequently, the opponent's submissions cannot lead to the conclusion that the subject-matter of present claim 1 lacks an inventive over E2.

Inventive step of claim 1 over E18

14. The opponent submits that the inventive step objection against claim 1 based on E18 as the closest prior art is in essence the same as that based on the teaching of E2, those documents being seen by the opponent as alternative starting points. On that basis and noting that the teaching of E18 does not come closer to the teaching of the patent in suit than the one of E2, in particular since E18 does not describe conditions under which the mixture of L-HA and H-HA components is prepared (see above point 9.1) and does not address sterilization of a L-HA and a H-HA mixture, the Board concludes that the reasoning and the conclusion reached in relation to inventive step of claim 1 starting from E2 as the closest prior art equally apply to the additional objection starting from E18. Consequently, the objection that the subject-matter of present claim 1 lacks an inventive over E18 also fails to convince.

Inventive step of claims 1 and 12 over E10

15. The opponent argues that the skilled person starting from the disclosure of E10 and taking the disclosure of E2 into consideration would arrive in an obvious manner at the subject-matter of claim 1. The opponent argues that the steam sterilization of Synovium Surgical 3ML disclosed in E10 leads to the formation of a stable

chondroitin sulfate (CS)/H-HA hybrid complex and that the skilled person aiming at finding an alternative to said product would find it obvious in the light of E2 to replace CS by L-HA. As regards claim 12 a similar objection is made when taking into account documents E19 to E23 which concern chondroitin (C). The skilled person would find also obvious in view of E19 to E23 to replace in E10 CS by C.

16. Document E10 concerns a product allegedly sold before the priority date of the patent in suit. This document consists of three pages originating from different sources, as confirmed by the opponent.

The first page whose source and publication date are not specified provides undated technical information in French language about a product identified as Synovium surgical, in particular the steam sterilisation of the prefilled syringe in autoclave. The active ingredients are described to be a H-HA and CS.

The second page dated 5 July 2017 shows a screen shot of the home screen of an online register of pharmaceutical and para-pharmaceutical products which according to the opponent's submissions report a detailed and daily updated history of drugs, devices and parapharmaceutical products sold in Italy. The home screen does not provide any information concerning a product.

Page 3 of E10 is according to the opponent the information provided by said online register in respect of the product named "SYNOVIUN SURGICAL 1SIR 3ML". According to the various entries shown on said page 3, the product was first put on the market on 1 September 2009, i.e. before the priority date of the

patent in suit. The date indicated on the top right corner of page 3, i.e. 21 October 2016 is understood to correspond to the date at which the online registered was consulted. Page 3 of E10 indicates that the active ingredient of "SYNOVIUN SURGICAL 1SIR 3ML" is "CS/HA SODIUM SALT". Moreover, at the benefit of the opponent and in view of the indication "Siringhe preriempite intra-articolari" at the bottom left on page 3 of E10 it is considered that the designation "SYNOVIUN SURGICAL 1SIR 3ML" would be understood on 21 October 2016 to concern 3 ml of a product prefilled in a syringe.

17. However, neither page 1 of E10 which bears no date, nor page 3 of E10 which is dated 21 October 2016 constitute evidence of the technical information about "SYNOVIUN SURGICAL 1SIR 3ML" which was available to the public before the date of priority of the patent in suit. No other evidence was submitted in respect of the technical information about "SYNOVIUN SURGICAL 1SIR 3ML" available to the skilled person, let alone before the priority date of the patent in suit. Accordingly, the only information proven on the basis of E10 is that a product "SYNOVIUN SURGICAL 1SIR 3ML" was made available to the public before the priority date of the patent in suit.

18. Having regard to the absence of any evidence concerning the availability to the public before the priority date of the critical elements of the opponent's reasoning concerning "SYNOVIUN SURGICAL 1SIR 3ML", in particular that it would be obtained after steam sterilization of the prefilled syringe, the reasoning provided in above points 13.1 and 13.3 to 13.7 equally applies to the issue whether it would have been obvious for the

skilled person to provide a stable solution of L-HA and H-HA or of L-C and H-HA.

19. Consequently, the subject-matter of operative claims 1 and 12 has not been shown to lack an inventive step within the meaning of Article 56 EPC over E10 (to the extent it is not prior art pursuant to Article 54(2) EPC) or over "SYNOVIUN SURGICAL 1SIR 3ML" commercialized before the priority date of the patent in suit.

Inventive step over E12

20. The opponent raised during the oral proceedings a new objection for lack of inventive step, namely over the disclosure of E12 as the closest prior art. The admission of this objection is also subject to the provision of Article 13(2) RPBA 2020.

The opponent justified this new objection on the ground that its grounds of appeal already referred on page 32 to documents E10 to E13. This passage of the statement of grounds of appeal belongs to section 2.4B1) which begins on page 31. It concerns an inventive step objection starting from the disclosure of E10 as the closest prior against the subject-matter of auxiliary request 4 maintained by the opposition division, corresponding to present claim 12. The passage referring to E10 to E13 cited by the opponent reads "*So considering all the prior art cited in the Opposition brief against the novelty of the granted claim 13, namely any of E10-E13, and in particular starting from E10, it must be understood which is the objective technical problem solved by the use of chondroitin*". Even if to the benefit of the opponent one understood that this comment was an indication that the inventive

step of the subject-matter of claim 12 could be analysed starting also from E12, no indication is provided in this whole section as to which inventive step reasoning starting from E12 as the closest prior art would be intended. The rest of this section is also silent on E12.

A mere indication in the statement of ground of appeal that an inventive step objection starting from E12 as the closest prior art might be also considered is not a justification to submit said objection only on the day of the oral proceedings.

Consequently, in the absence of exceptional circumstances, the Board makes use of its discretionary power under Article 13(2) RPBA 2020 not to take into account the inventive step objection based on E12 as the closest prior art.

Sufficiency of disclosure

21. As regards sufficiency of disclosure the parties declared at the oral proceedings that they would base their submissions solely on experimental data reported in the patent in suit, E26, E28, E28a, E35, E38 and E39. Additional experiments submitted as Annexes 1 to 3 and E32 were not relied upon any longer.

Admittance of E28, E28a, E35, E38 and E39

21.1 The admittance into the proceedings of E28 submitted by the opponent with its statement of grounds of appeal and of E28a submitted by the patent proprietor with its rejoinder is to be decided on the basis of Article 12(4) RPBA 2007.

The admittance of E35 submitted by the opponent after the rejoinders and before issuance of the summons to oral proceedings is to be decided on the basis of Article 13(1) RPBA 2020.

The admittance into the proceedings of E38 and E39 submitted by the patent proprietor after the rejoinders and before issuance of the summons to oral proceedings is to be decided on the basis of Article 13(1) RPBA 2020.

21.2 The opponent's written submissions based on the experimental data contained in documents E28 concern the question whether the skilled person on the basis of the teaching of the patent in suit is able to prepare hybrid complexes within the meaning of operative claim 1 when low concentrations of L-HA and H-HA are used. This objection had been already addressed before the opposition division. It was however decided that the experimental results shown in E26 did not allow a clear interpretation on the basis of which the opponent's objection could be successful (Reasons for the decision, point 4.3).

21.3 Having regard to the brief reasoning provided in the reasons for the contested decision and the absence of explanation as to why "*there remains a certain level of uncertainty concerning the interpretation of the results in table 2 of E26*", the Board holds it for legitimate for the opponent to submit new experimental evidence presented in E28 and additional argument in support of the objection which the opposition division did not find convincing.

Additional documents E28a, E35, E38 and E39, which were submitted in turn at different stages of the appeal

proceedings, as indicated in above point 21.1, relate all to the influence of the concentrations of L-HA and H-HA on the formation of a hybrid complex. Their successive filing constitutes in each case a legitimate and timely reaction to the submissions of the opposing party on that issue. In other words, the subsequent filing of all documents addressed in this section is the result of normal developments in the opposition appeal proceedings.

21.4 Under these circumstances the Board finds it appropriate to admit into the proceedings documents E28 and E28a pursuant to Article 12(4) 2007 RPBA and documents E35, E38 and E39 pursuant to Article 13(1) RPBA 2020.

Analysis of the objections

22. The opponent does not dispute that the mechanism underlying the formation of the hybrid complexes which is proposed in paragraph [0032] of the specification (see above points 4.1 to 4.6) is reasonable. The formation of the hybrid complexes requires a heating step for an appropriate time using the temperature defined in operative claim 1 in order to disrupt the hydrogen bonds that previously existed within each of the H-HA and L-HA components and a cooling step to hold a new distribution equilibrium of the chains of various molecular weights originally present in the H-HA and L-HA components. It is undisputed that the measures such as duration and temperature specifically taught in the patent in suit for obtaining the "*cooperative hybrid complexes*" defined in operative claim 1 are adequate. This mechanisms forms in fact the basis for the essential point of the opponent's objection of lack of inventive step, namely that a steam sterilization

(autoclaving) of an aqueous composition comprising a H-HA and a L-HA would result in a stable hybrid complex when using the time and temperatures conditions specified in the patent in suit.

23. The opponent, however, submits that the ability to form a hybrid complex depends on the concentration of H-HA, which formation would not take place if the concentration of H-HA were too low. Reference is made in this respect to the results shown in table 2 of an article E26 whose authors comprise all inventors of the contested patent. E26 also concerns HA/L-HA hybrid complexes (abstract). The results shown in its table 2 are reproduced below.

Table 2 Dynamic viscosity (η_0) of H-HA and H-HA/L-HA at 0.05, 0.1,0.5 and 1 % w/v calculated with a oscillatory rheometer, extrapolated in a shear rate ranging from 1 to 10 s^{-1}, in the Newtonian range *plateau*

Samples (w/v) in DMEM medium supplemented with 1 % FBS	Dynamic viscosity (η) (mPa·s)
H-HA 0.05 %	1.73 ± 0.05
H-HA 0.1 %	2.55 ± 0.07
H-HA 0.5 %	55.2 ± 1.20
H-HA 1 %	378 ± 3.00
H-HA/L-HA COMPLEX 0.1 %	1.65 ± 0.04
H-HA/L-HA COMPLEX 1 %	18.0 ± 1.00

The opponent argues that "*comparing the viscosity value of the hybrid complex H-HA/L-HA at 0.1% (1.65 ± 0.04, i.e. from 1.61 to 1.69) with the viscosity value of H-HA at 0.05% (1.73 ± 0.05, i.e. from 1.68 to 1.78), considering the value of 1.68, for example,*" shows "*that no viscosity reduction is observed after the thermal treatment, as indicated also at the end of the chapter*" in E26. The opponent's reasoning is based on the argument that the application as filed would indicate on page 4, lines 12-14 that the formation of

an hybrid complex must be accompanied by an immediate and dramatic decrease of the viscosity.

23.1 The passages on page 4 of the application cited by the opponent are taken out of context. They refer to a particular experiment used by the inventors to confirm the validity of the mechanism proposed for the formation of the complex. For this purpose two solutions, one of L-HA and one of H-HA, are separately subjected to a thermal cycle, after which they are mixed together after cooling. The goal of this experiment is to show that all other conditions being the same the mixing of the L-HA and H-HA components prior to the thermal cycle leads to a lower viscosity attributed to the formation of the complex. There is no doubt that such experiment will be purposely made with higher concentrations of L-HA and H-HA, as shown in table 1 of the patent in suit, namely 1 % w/v for each compound, instead of 0.05 w/v as reported for the experiment of E26 relied on by the opponent, in order to properly illustrate the effect accompanying the complex formation. The patent in suit does not state that the formation of a complex is necessarily accompanied by a dramatic decrease of the viscosity.

23.2 Moreover, the opponent is not comparing like-for-like, as the comparison made concerns the value for H-HA 0.05 % after deduction of the margin of experimental error, so as to obtain the lowest possible value, with the highest values for the hybrid complex H-HA/L-HA 0.1 % when account is taken of the respective margin of error. The experiments relied upon by the opponent, however, rather show a decrease of the dynamic viscosity also at those concentrations, even if minimal, i.e. from 1.73 to 1.65 mPa.s. Contrary to the opponent's remark, D26 does not indicate for this

experiment that no viscosity reduction takes place, but that "*the combination of high and low molecular weight at reduced concentrations has minor influence on fluido-dynamic*" (page 6, left-hand column, lines 15-19), i.e. that a decrease of the viscosity is observed but to a much lesser degree than at higher concentrations.

23.3 For similar reasons, the opponent's argument that a hybrid complex must have a viscosity that which is from 1.1 to 200 fold less than that of a solution containing the H-HA alone used for forming the complex does not convince. Such relationship is solely given in dependent claim 2 of the granted patent, i.e. it does not constitute according to the teaching of the patent in suit a necessary condition for obtaining a hybrid complexes. This is confirmed by paragraph [0018] of the specification according to which "*the complexes according to the invention normally*", but not necessarily "*have a viscosity from 1.1 to 200-fold less than that of a solution containing the H-HA hyaluronic acid alone used for forming the complex*".

24. The opponent also refers to the viscosity measurements shown in Figure 2a of E28, comparing the viscosity values of a "*HCC formulation*" containing 0.55% of a hybrid complex indicated to be prepared in accordance with published PCT application WO/2012/032151, i.e. the patent in suit in its form as filed, and a "*HHA formulation*" comprising 0.28% of a H-HA compound, which the opponent understands to be the H-HA compound used for forming the hybrid complex of the HCC formulation. It is argued that the "*HHA formulation*" has the same viscosity as the "*HCC formulation*", which would demonstrate that no hybrid complex was formed for the "*HCC formulation*".

However, E28 does not describe that the "*HHA formulation*" whose viscosity curve is shown in Figure 2a corresponds to the H-HA solution used for preparing the hybrid complex of the "*HCC formulation*". The "*HHA formulation*" whose viscosity curve is shown in Figure 2a is according to E28 (page 2, right-hand column, lines 22-25; legend of Figure 2) an optimized H-HA-based preparation, representative of the best performing among the analyzed HA-based eye drops on the market. The lack of identity between the H-HA used for preparing the "HHC formulation" and the H-HA used for the "*HHA formulation*" is confirmed by the published correction to article E28 (E38) and the declarations E28a and E39 of Dr. De Rosa, who is an author of E28. According to said addition documents, a molecular weight of 1120 kDa for the H-HA of the "*HHA formulation*", i.e. which is lower than the molecular weight of the H-HA used for forming the hybrid complex of the "HCC formulation" (1500 kDa) explains the lower viscosity for the "*HHA formulation*".

25. Referring in addition to the experiments of example 4 of E35 (page 13, line 11 to page 16, line 5) the opponent submits that the use of a H-HA at a concentration of 0.30% does not necessarily lead to the formation of a hybrid complex. It is submitted that a solution of H-HA at a concentration of 0.30% w/w and a solution of a L/H-HA component in a concentration of 0.60% w/w, which is the result of treating a L/H-HA mixture under the conditions preconised in the patent in suit to form a hybrid complex, would exhibit the same dynamic viscosity value. This would demonstrate that a complex is in fact not formed for said L/H-HA component.

The information that the solutions have the same viscosity is taken from the legend of table 5 on page 15. These results concern the mucoadhesion index of the H-HA and L/H-HA components whose viscosity is indicated to be the same. The viscosity is however unambiguously indicated to have been measured at a shear rate of 33.9 s^{-1}, which rate however is not appropriate to detect viscosity variations which would be observed at a lower share range at which the polymer solution is a Newtonian fluid. This follows from the opponent's own submissions (letter of 25 November 2019, page 19, three last paragraph and page 20, lines 16-17), reference being made to Figure 1 of E31. In table 4 of example 4 of E35, additional mucoadhesion indices are reported for compounds having the same dynamic viscosity at shear rates of 33.9 and 222.2 s^{-1}.

The opponent's argument that the viscosity was measured at a share rate of 2 s^{-1} for the results shown in tables 4 and 5, as would be mentioned on page 10, line 22, in the context of example 1 of E35, is not correct. Example 4 merely refers to example 1 for defining the L/H-HA component tested, nothing more. The clear indication about the shear rate used for the example 4 and 5 indicated in tables 4 and 5 themselves is confirmed in paragraph bridging pages 15 and 16 which describes that H-HA is the most mucoadhesive form of the biopolymer in a wide shear rate range (3-200 s^{-1}).

Accordingly, the opponent's submissions made on the basis of E28 and E35 do not cast doubt on sufficiency of disclosure of the claimed invention.

26. On that basis, the opponent's objections in relation to sufficiency of disclosure fail to convince. The Board

is therefore satisfied that the present invention is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

27. In the absence of other objections, the main request is allowable.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to maintain the patent on the basis of the claims of the main request filed with the statement of grounds of appeal and after necessary consequential amendments to the description.

The Registrar: The Chairman:

B. ter Heijden D. Semino

Decision electronically authenticated