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Datasheet for the decision of 19 January 2021

Case Number: T 1877/18 - 3.3.07

Application Number: 05821259.8

Publication Number: 1811959

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Language of the proceedings: EN

Title of invention:
OPHTHALMIC COMPOSITIONS AND METHODS FOR TREATING EYES

Patent Proprietor:
ALLERGAN, INC.

Opponent:
Bausch & Lomb Incorporated

Headword:
Ophthalmic compositions / ALLERGAN

Relevant legal provisions:
EPC Art. 83, 123(2), 56
RPBA Art. 12(4)

Keyword:

Late-filed objection - admitted (yes)
Amendments - added subject-matter (no)
Sufficiency of disclosure - (yes)
Inventive step - auxiliary requests 6A, 7A and 8A (no) - auxiliary request 9A (yes)

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Case Number: T 1877/18 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 19 January 2021

Appellant: (Patent Proprietor)	ALLERGAN, INC. 2525 Dupont Drive Irvine, CA 92612 (US)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Appellant: (Opponent)	Bausch & Lomb Incorporated 1400 North Goodman Street, Area 62 Rochester, NY 14609 (US)
Representative:	Glas, Holger Maiwald Patentanwalts- und Rechtsanwaltsgesellschaft mbH Elisenhof Elisenstraße 3 80335 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 17 May 2018 concerning maintenance of the European Patent No. 1811959 in amended form.**

Composition of the Board:

Chairman	A. Usuelli
Members:	E. Duval
	P. Schmitz

Summary of Facts and Submissions

I. European patent 1 811 959 ("the patent") was granted on the basis of 15 claims.

Claim 1 of the patent related to ophthalmic compositions comprising in particular a tonicity component comprising a material selected from erythritol, xylitol and carnitine components. Claim 14 related to such ophthalmic compositions for use in a method of treating dry eye syndrome.

II. An opposition was filed against the patent on the grounds that its subject-matter lacked novelty and inventive step, it was not sufficiently disclosed and it extended beyond the content of the application as filed.

III. The opposition division took the interlocutory decision that, on the basis of auxiliary request 1 filed during the oral proceedings, the patent met the requirements of the EPC.

The decision was based on a main request filed (as auxiliary request 1) by letter dated 8 December 2017, and on said auxiliary request 1 filed during the oral proceedings.

IV. In the present decision, reference is made to the following documents:

D4: WO 00/29030
D6: JPH10-36255
D6a: English machine translation of D6

D8: "Carnitine: An Osmolyte That Plays a Metabolic Role" by G. Peluso

V. In particular, the opposition division decided that:

(a) Claims 1 and 2 of the main request did not fulfill the requirements of Article 123(2) EPC, because they lacked essential features regarding osmolality.

(b) Auxiliary request 1 fulfilled the requirements of Article 123(2) EPC. In particular, the omission of the expression "an effective amount" did not introduce added subject-matter.

It was credible that the claimed ophthalmic compositions were effective in the claimed treatments. The opponent had provided no evidence that the invention could not be performed over the scope of the claims. The criteria of sufficiency of disclosure were thus met.

The claimed subject-matter was novel over D1-D11.

Regarding inventive step for claim 1, D4 represented the closest prior art. The subject-matter of claim 1 differed in the tonicity range of 300-1000 mOsmols/kg. An effect on osmoprotection for the distinguishing technical feature being carnitine within the claimed tonicity range had been made credible. The technical problem was the provision of ophthalmic formulations providing improved treatment of dry eye. The claimed solution involved an inventive step.

VI. Both the patent proprietor (appellant P) and the opponent (appellant O) appealed the decision of the opposition division.

VII. With its statement setting out the grounds of appeal, appellant P defended the patent on the basis of a main request filed therewith. By letter dated 7 February 2019, filed in reply to appellant O's grounds of appeal, appellant P further filed auxiliary requests 1-A to 14-A and 1-B to 15-B.

VIII. The Board set out its preliminary opinion in a communication under Article 15(1) RPBA.

IX. Oral proceedings were held before the Board on 19 January 2021. During the oral proceedings, appellant P withdrew its main request and auxiliary requests 1A-5A and 1B-6B.

X. Accordingly, appellant P's highest ranking requests became the following requests, each consisting of a single claim.

- Claim 1 of auxiliary request 6A read as follows:

"An ophthalmic composition for use in a method of treating dry eye syndrome, comprising:
an aqueous carrier component; and
a tonicity component comprising a material selected from:
erythritol components and mixtures thereof;
xylitol components and mixtures thereof; or
carnitine components and mixtures thereof,
wherein if the tonicity component comprises a material selected from carnitine components and mixtures

thereof, the composition has an osmolality in a range of 300 to 1000 mOsmols/kg."

- Claim 1 of auxiliary request 7A additionally contained the feature "wherein the material is present in an amount in a range of 0.01 % (w/v) to 3% (w/v)".

- Claim 1 of auxiliary request 8A differed from auxiliary request 6A in that the osmolality was defined to be 300 to 1000 mOsmols/kg for all three alternatives (namely erythritol, xylitol and carnitine components).

- Claim 1 of auxiliary request 9A read as follows:

"An ophthalmic composition for use in a method of treating dry eye syndrome, comprising:
an aqueous carrier component; and
a tonicity component comprising a material selected from:
erythritol components and mixtures thereof; or
xylitol components and mixtures thereof."

XI. Appellant P's arguments can be summarised as follows:

(a) Admittance of appellant O's new attacks of insufficiency of disclosure

Appellant O's new objection regarding the lack of information on standard deviations or significance of the values in the patent constituted specific new attacks raised for the first time in appeal. These objections should be dismissed for not having been raised at first instance. The amendment into use claims had been the subject of focus already during the first-instance proceedings and thus did not justify the lateness of these objections. The new line of attack

based on the data in Figures 6-8 should also be dismissed for not having been raised at first instance.

(b) Article 123(2) EPC

In the application as filed, claims 10 (directed to xylitol) and 19 (directed to carnitine) included features regarding the osmolality. Nonetheless, the application as filed made it clear that these osmolality features were preferable but not essential (see page 6, lines 19-26; page 10, lines 5-8). Hence the absence of the osmolality features in claim 1 of the present requests did not add subject-matter.

Likewise, the omission of the feature "effective amount" did not add subject-matter. This feature was implied by the expression "tonicity component", which meant that there is enough tonicity component in the composition to contribute to the tonicity of the composition. Furthermore, the application provided basis for leaving this feature out (see page 9, lines 27-33).

The use of the claimed compositions in the treatment of dry eye was disclosed in the description as filed (see page 5, lines 28-34).

Thus no added subject-matter had been introduced.

(c) Sufficiency of disclosure

Contrary to appellant O's opinion, the claim did not encompass the use of sub-effective amounts of tonicity agent to treat the conditions in question.

Furthermore, the patent stated that new compositions had been discovered that effectively treated eyes (see paragraph [0017]) and provided a credible reason why these compositions were effective (see [0030]). Experiments had also been performed, showing that carnitine, erythritol and xylitol had osmoprotective ability since they increase TEER relative to the hypertonic control (see example 1 and paragraph [0100]). These data, and the explanation provided in the patent (see paragraph [0046]), made it credible that the agents would be suitable for treating dry eye. A statistical evaluation was for this purpose not necessary. Hence the requirements of sufficiency of disclosure were met.

(d) Inventive step

- carnitine alternative:

D4 (see the clinical trial on page 10) discussed the effect of a hyaluronic acid/carnitine combination on barrier function in patients with dry eye. In D4, both carnitine and hyaluronic acid were considered essential elements. It was not obvious from D4 to use an ophthalmic composition comprising carnitine and having a supratonic osmolality of 300-1000 mOsmols/kg to treat dry eye. D4 said nothing about the osmolality of the composition used to treat dry eye. Furthermore, the patent demonstrated that applying organic compatible solutes such as carnitine as a supratonic composition provided additional benefits, since it served to both stimulate or maintain uptake of the compatible solutes into the corneal surface cells, thereby providing abundant supplies of these materials (see paragraph [0053]). There was no teaching in the prior art to use a supratonic composition to treat dry eye.

- polyol (erythritol, xylitol) alternatives:

The skilled person's knowledge at the filing date could not be established based on paragraphs [0005] and [0047]-[0049] of the patent, because these passages had been drafted after the invention was conceived and did not refer to any prior art. As to the scientific article D8, it only related to the role of endogenous carnitine and said nothing about formulating carnitine in an ophthalmic compositions. Therefore there was no basis for the assertion that it was obvious to select xylitol and erythritol as candidates for up-regulating the transport mechanism of non-ionic solutes.

XII. Appellant O's arguments can be summarised as follows:

(a) Admittance of appellant O's new attacks of insufficiency of disclosure

The objections regarding the lack of information on standard deviations or significance of the values belonged to the discussion of the data in appellant P's own patent and the existence of a technical effect. Since the claims had been limited to use claims, this discussion now pertained to sufficiency of disclosure. These attacks should accordingly be admitted into the proceedings.

(b) Article 123(2) EPC

The specific medical indication of claim 1, namely the treatment of dry eye, in combination with the particular tonicity agents of claim 1 (namely erythritol, xylitol or carnitine components) was not disclosed in the application as filed.

Furthermore, claim 1 of each request omitted both the feature relating to "an effective amount" and the specific osmolalities required by original claims 1, 10 and 19. The text passages which, according to the respondent, suggested that no specific osmolality or tonicity was required, were contradicted by other text passages in the originally filed application (see page 17, lines 13-20).

Hence the amendments contravened Article 123(2) EPC.

(c) Sufficiency of disclosure

Firstly, the claim was not operable over the whole range since it included sub-effective amounts of tonicity agent.

Secondly, the patent did not contain any direct medical test showing that any of the claimed compositions was suitable for treating dry eye, and also contained statements explicitly confirming that the claimed effect could not be achieved over the claimed range:

Regarding the TEER test results of examples 1, 4 and 5, information about standard deviations or the significance of any value increase or decrease was lacking. Furthermore, the patent itself (see paragraphs [0100], [0102] or [103]) showed that the TEER test could not be used for clearly and unambiguously reflecting the therapeutic effect, namely the treatment of dry eye. It was merely speculated in the patent that the obtained test results may point to a potential suitability of the tested components. The tests additionally showed that for some components no effect

was observed (see example 5), while others exhibited a dose-dependent effect (see example 4).

The JNK tests (see example 2) did not clearly and unambiguously reflect the claimed therapeutic effect either. Furthermore, this test also revealed that no effect was detectable for erythritol and xylitol (see paragraph [0114]). In example 3, only small effects were apparent at 300 osm if any, and no standard deviation or statistical analysis was given, such that it could not be determined if this reduction was statistically significant or merely within the error margin.

The remaining tests were hypothetical and unsuitable for showing any effect of the claimed tonicity agents. Examples 6-9 and 17-20 described the polypeptide and carboxymethylcellulose (CMC) as mandatory for achieving any effect. However, these components were not contained in the claimed composition.

Consequently, the requirements of sufficiency of disclosure were not met.

(d) Inventive step

- Carnitine alternative:

D4 explicitly suggested carnitine for the treatment of dry eye (see clinical study at page 10). The difference resided in the osmolality. However, the selection of the broad osmolality range of 300 to 1000 mOsmols/kg, could not be linked to any technical effect. The *in vitro* tests of the patent were carried out at 300 or 400 mOsmols/kg, i.e. only within the claimed range. No data outside the claimed range were provided, hence no

improvement over the prior art could be acknowledged. The selection of the osmolality range was thus arbitrary.

- xylitol and erythritol alternatives:

As confirmed in the patent specification (see paragraphs [0005], [0007] and [0047]-[0049]) and in D8 (see figure 1), it was known that polyols such as glycerol and amino acids such as carnitine acted against the "hypertonic challenge" caused by dry eye, and that the tonicity agents/compatible solutes functioned as osmoprotectants.

Xylitol and erythritol were polyols comprising a different number of CH-OH moieties (see paragraphs [0038]-[0039]). In view of the foregoing knowledge, the selection of carnitine, xylitol and erythritol as candidates for up-regulating the transport mechanism of non-ionic solutes was obvious. The use of the polyols xylitol and erythritol for treating dry eye was not inventive as no suitability or effect for the treatment of dry eye had been shown.

Accordingly, the requirements of Article 56 EPC were not met.

XIII. Appellant P requests that the decision under appeal be set aside and that the patent be maintained on the basis of the main request filed on 7 February 2019 as auxiliary request 6-A, or on the basis of one of auxiliary requests 7-A to 14-A or 7-B to 15-B filed on the same date.

Furthermore, appellant P requests that appellant O's new attacks, raised in relation to sufficiency of

disclosure, on the data in the patent and regarding the lack of information on standard deviations or significance of the values not be admitted into the proceedings.

XIV. Appellant O requests that the decision under appeal be set aside and that the patent be revoked.

Reasons for the Decision

Admittance of appellant O's new attacks of insufficiency of disclosure

1. As part of the reasoning on insufficiency of disclosure in its grounds of appeal, appellant O criticises the data given in the patent and objects that information on standard deviations or significance of the values is not presented. Appellant P requests that these new attacks on the data in the patent not be admitted since they should have been raised at first instance.

Appellant O's grounds of appeal were submitted before 1 January 2020. Following the transitional provisions set out in Article 25(2) RPBA 2020, the question whether or not these new submissions should be admitted must be decided on the basis of Article 12(4) RPBA 2007, which gives the Board discretion not to admit, on appeal, facts or evidence that could have been presented in the first instance proceedings.

The Board notes that, during the first-instance proceedings, the opposition division initially considered the criteria of sufficiency of disclosure not to be met by the second medical use claims of the

(then) auxiliary requests. This opinion was subsequently reversed, and the appealed decision relies in particular on the data in the patent (example 1-4) to conclude that the requirements of sufficiency of disclosure are met. Under these circumstances, the Board sees the new attacks raised by appellant O as a reaction to developments in the previous proceedings.

Accordingly, the Board admits these new objections.

Main request (filed as auxiliary request 6A on 7 February 2019)

2. Article 123(2) EPC

2.1 Claim 1 of auxiliary request 6A recites three alternative tonicity components, namely erythritol (corresponding to claim 1 of the application as filed), xylitol (corresponding to claim 10 of the application as filed) and carnitine (corresponding to claims 19 and 21 of the application as filed).

2.2 For each alternative, claim 1 of auxiliary request 6A differs from claims 1, 10 and 19 as filed by the omission of the feature that the tonicity component be present in an "effective amount". The Board agrees with appellant P that these effective amounts for each tonicity component are not disclosed as essential in the application as filed, considering the general statement on page 9, lines 27-35. In this passage, an "effective amount" is disclosed as advantageous but not as essential. The fact that this amount is not limited is confirmed on page 13, line 27-28.

2.3 Compared with claim 10 as filed, the alternative "xylitol" in claim 1 of auxiliary request 6A lacks the feature that the osmolality of the composition is in

the range of at least 310 to about 1000 mOsmols/kg. Likewise, the alternative "carnitine" of claim of auxiliary request 6A lacks the feature of claim 19 as filed that the composition has a non-isotonic osmolality. However, these features are presented as being not mandatory in the corresponding passages of the description as filed (see page 6, lines 19-26 and 27-33). On page 10 (lines 5-8), the application as filed explicitly indicates that the compositions may have any suitable tonicity or osmolality. The further passage cited by appellant O (see page 17, lines 13-20) presents a supra-tonicity of the composition as necessary in order to achieve the additional benefit of increased uptake of the compatible solutes into the corneal surface cells, but not as mandatory in the general context.

2.4 Accordingly, the absence of the features regarding effective amount and osmolality in claim 1 of auxiliary request 6A does not infringe Article 123(2) EPC.

2.5 Contrary to appellant O's view, the combination of the selected condition (namely dry eye syndrome) with the selected tonicity agents (erythritol, xylitol and carnitine) does not present the skilled person with new technical information either. The application as filed generally states that the "present compositions" effectively treat eyes afflicted or susceptible to a number of conditions including firstly dry eye syndrome (see page 5, lines 29-35). Considering the generality of this statement and the emphasis on compositions comprising erythritol, xylitol and carnitine in the application as filed (see claims 1, 9, 10, 18, 19 and 26), the Board does not regard the claimed use of these compositions in the treatment of dry eye syndrome as adding subject-matter.

2.6 Accordingly, the requirements of Article 123(2) EPC are met.

3. Sufficiency of disclosure

3.1 Claim 1 of auxiliary request 6A is a product claim drawn up in accordance with Article 54(5) EPC and relating to ophthalmic compositions for use in methods of treating dry eye syndrome. Thus, attaining the claimed therapeutic effect is a functional technical feature of the claim that needs to be assessed in the context of examining the sufficiency of disclosure.

3.2 According to the patent, dry eye conditions are characterised by a tear film which is not present in a sufficient amount and by chronic hypertonicity. Corneal surface cells compensate for hypertonic conditions through the natural accumulation or manufacture of compatible solutes that work like electrolytes to balance osmotic pressure yet do not interfere with cellular metabolism like electrolytes (see in particular the background of the invention). According to the patent (see paragraph [0030]), xylitol and erythritol are tonicity components which accumulate in the eye cells and remain for prolonged periods of time relative to known osmotic agent glycerol. Carnitine is also stated to be an effective tonicity component. Thus, the patent discloses a credible reason why the claimed compositions are effective.

3.3 The patent also discloses experimental results (see example 1, table 1) supporting the allegation that erythritol, xylitol, and carnitine are effective in protecting corneal epithelial cells that have been subjected to hypertonic conditions, which hypertonic

conditions characterise dry eye syndromes. In example 1, epithelial corneal cells are subjected to isotonic conditions (300 mOsmols/kg), or to hypertonic conditions (400 mOsmols/kg) with or without compatible solute. A resulting TEER value is given as a measure of cell health (see paragraph [0098]), the value 100% being attributed to the control isotonic conditions. Hypertonic conditions alone lead to a sharp decrease in TEER value (23%). In contrast, the compatible solutes xylitol, erythritol and carnitine exhibit an osmoprotective effect against hypertonic conditions since they restore the TEER values to levels around those of the control (94.1-118.9%). Irrespective of the language used in subsequent passages of the patent (e.g. paragraph [0103], "are likely", "may"), this evidence convincingly reflects the claimed use in treating dry eye syndrome. Contrary to appellant O's opinion, the lack of information about standard deviations or the significance of the value increase or decrease does not invalidate this conclusion, considering the extent of the observed variations.

3.4 No evidence was adduced that the claimed xylitol, erythritol and carnitine compositions fail to achieve the claimed therapeutic effect. In particular, the results of example 1 are not contradicted by the further examples and figures of the patent, for the following reasons.

3.4.1 According to appellant O, the data in the patent show that the tonicity components of claim 1 have no effect for 300 mOsmols/kg (see e.g. figures 1-5). However, this osmolality value corresponds to the isotonic control (see paragraph [0047] and [0099]), and hence does not reflect the hypertonic conditions characteristic of dry eye syndrome. Consequently, these

data do not prove that xylitol, erythritol and carnitine are ineffective against hypertonic challenges.

3.4.2 Examples 2-3 examine the effect of the claimed tonicity components on the expression of particular stress-related proteins under hypertonic conditions. Xylitol, erythritol and carnitine each reduce the amount of some of these proteins, but do not influence all of them. The Board shares the opinion of appellant P that this mechanistic study at protein level cannot invalidate the overall results on cell health reported, using TEER measurements, in example 1.

3.4.3 In example 4 and figure 6 of the patent, a dose-related response is observed for L-carnitine and erythritol. In example 5 and figures 7-8, the effect of compositions comprising a combination of compatible solutes and glycerol is studied. None of these examples or figures demonstrate that a composition comprising xylitol, erythritol or carnitine fails to exhibit an osmoprotective effect against hypertonic conditions. Likewise, examples 7-20, relating to the activity of polypeptides or carboxymethyl cellulose (CMC), do not show that the claimed tonicity components are ineffective in the treatment of dry eye syndrome.

3.5 Lastly, despite the lack of limitation regarding the amounts of these tonicity components in claim 1, the Board considers that the skilled person is enabled by the whole content of the patent to select the appropriate concentrations to obtain the claimed effect.

3.6 In conclusion, the subject-matter of claim 1 is sufficiently disclosed.

4. Inventive step, carnitine alternative

4.1 In relation with the carnitine alternative of claim 1 of auxiliary request 6A, both parties agree to the choice of D4 as closest prior art.

D4 discloses the use of a composition comprising hyaluronic acid and carnitine in the form of a collyrium in the treatment of dry eye syndrome (see clinical study on page 10). The presence of carnitine is shown to lead to a significant improvement of the barrier function (see page 11, lines 3-12).

4.2 Starting from D4, the subject-matter of claim 1 of auxiliary request 6A differs in that the composition has an osmolality in a range of 300 to 1000 mOsmols/kg. Contrary to appellant P's suggestion, claim 1 uses an open language ("comprising") and thus allows for the presence of hyaluronic acid, which is therefore not a further differentiating feature. The Board emphasizes that the therapeutic effect is already linked in D4 to the presence of carnitine.

4.3 Appellant P considers the selected osmolality range to represent supratonic conditions leading to additional benefits. These supratonic conditions, due to an increased activity of transport proteins, stimulate or maintain uptake of compatible solutes such as carnitine in the corneal surface cells.

However, no evidence was presented which would allow a comparison between compositions having an osmolality in the range of 300-1000 mOsmols/kg with compositions having an osmolality outside this range. As noted by appellant O, the *in vitro* tests of the patent are

carried out at 300 or 400 mOsmols/kg, i.e. only within the claimed range. Accordingly, the distinguishing feature cannot be linked to any improvement.

4.4 Consequently, the technical problem is the provision of alternative ophthalmic compositions for use in the treatment of dry eye syndrome.

4.5 The claimed solution consists in selecting an osmolality range of 300-1000 mOsmols/kg for the composition. However, this selected osmolality range covers values, such as 300 mOsmols/kg, which are regarded as isotonic in the patent. Thus, the Appellant P's argument that it was not obvious from D4 to use an ophthalmic composition having a supratonic osmolality is not relevant because claim 1 is not limited to such compositions. Indeed, according to paragraph [0047] of the patent, typical values for tear osmolarity range from 290 to 310 mOsmols/kg in normal individuals. The same value of 300 mOsmols/kg is explicitly regarded as isotonic in example 1 of the patent (see paragraph [0099]). In D6, a value of 290 mOsmols/kg is regarded as isotonic (see the translation D6a, paragraph [0017] on page 5). However, it cannot be inferred from D6 that 300 mOsmols/kg represents hypertonic conditions. Thus, the claimed osmolality range covers normal tonicity levels and is not associated with any particular technical effect. This selection does not provide any inventive contribution over the teaching of D4.

4.6 Accordingly, auxiliary request 6A does not meet the requirements of Article 56 EPC.

Auxiliary requests 7A, 8A

5. Inventive step, carnitine alternative

5.1 The alternative of claim 1 of auxiliary request 7A pertaining to carnitine differs from auxiliary request 6A by the additional feature "wherein the material is present in an amount in a range of 0.01 % (w/v) to 3% (w/v)". However, appellant P did not provide any argument why this feature should establish an inventive step over the closest prior art D4. In particular, it has not been shown that the selected amounts would be associated with any technical effect or would depart in any way from the usual amounts which the skilled person would consider.

D4 does not disclose that the composition used in the treatment of dry eye syndrome (see clinical study on page 10) comprises 0.01-3% (w/v) of carnitine. In the absence of any associated technical effect, the technical problem remains the provision of alternative ophthalmic compositions for use in the treatment of dry eye syndrome. The arbitrary selection of the claimed range for the amount of tonicity component does not involve an inventive step.

5.2 The alternative of claim 1 of auxiliary request 8A relating to carnitine is identical to that of auxiliary request 6A, and as such does not involve an inventive step either.

5.3 Accordingly, none of auxiliary requests 7A and 8A complies with the requirements of Article 56 EPC.

Auxiliary request 9A

6. Articles 123(2), 83 and 56 EPC

6.1 In comparison with auxiliary request 6A, claim 1 of auxiliary request 9A has been limited to the erythritol and xylitol alternatives, and does not cover carnitine compositions.

6.2 Auxiliary request 9A meets the requirements of Article 123(2) EPC and of sufficiency of disclosure for the reasons given above for auxiliary request 6A (see 2. and 3.)

6.3 Regarding inventive step for the claimed erythritol and xylitol alternatives, appellant O bases its objection of lack of inventive step on an alleged knowledge at the filing date inferred from paragraphs [0005] and [0047]-[0049] of the patent and confirmed by D8. According to appellant O, amino acids and polyols were known to act as osmoprotectants against the hypertonic challenge caused by dry eye. In appellant O's view, the selection of polyols such as erythritol and xylitol does not involve an inventive step.

The Board cannot share this view. The passages of the patent cited by appellant O discuss the mechanism by which the compositions of the invention, comprising defined amino acids and polyols, act as osmoprotectants against the hypertonic challenge caused by dry eye syndrome. However, these passages do not indicate that this mechanism or activity was in any way part of the prior art before the filing date of the patent.

As to D8, it relates to the metabolic role of endogenous osmolytes such as carnitine or certain

polyols (e.g. myo-inositol or glycerol, see Figure 1 and page 2, top right column) but it does not relate to the treatment of dry eye syndrome or hypertonic conditions in the eye. Furthermore, D8 discloses neither erythritol nor xylitol.

Thus, starting from D8 as closest prior art, the technical problem is the provision of an ophthalmic composition for the treatment of dry eye syndrome. This problem is solved by the claimed erythritol and xylitol compositions, for the reasons given above regarding sufficiency of disclosure (see 3.). D8 does not teach that all polyols could be used as compatible solute, let alone that erythritol or xylitol could be useful in ophthalmic compositions for the treatment of dry eye syndrome.

Accordingly, Auxiliary request 9A complies with the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent on the basis of claim 1 of the request which had been filed as auxiliary request 9-A with letter of 7 February 2019 and a description to be adapted.

The Registrar: The Chairman:

B. Atienza Vivancos A. Usuelli

Decision electronically authenticated