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Datasheet for the decision of 28 November 2022

Case Number: T 2923/19 - 3.3.04

Application Number: 10724631.6

Publication Number: 2437762

IPC: A61P27/04, A61K36/47, A61K36/55, A61K47/44, A61K9/00, A61K9/107

Language of the proceedings: EN

Title of invention:
Artificial tears and therapeutic uses

Patent Proprietor:
ALLERGAN, INC.

Opponent:
Johnson & Johnson Vision Care, Inc.

Headword:
Artificial tears/ALLERGAN

Relevant legal provisions:
EPC Art. 56

Keyword:
Inventive step - (no)

Europäisches Patentamt
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Case Number: T 2923/19 - 3.3.04

D E C I S I O N
of Technical Board of Appeal 3.3.04
of 28 November 2022

Appellant: (Patent Proprietor)	ALLERGAN, INC. 2525 Dupont Drive Irvine, CA 92612 (US)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Respondent: (Opponent)	Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway, Suite 100 Jacksonville, Florida 32256 (US)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 22 August 2019 revoking European patent No. 2437762 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chair	B. Rutz
Members:	R. Hauss
	L. Bühler

Summary of Facts and Submissions

I. European patent No. 2 437 762 (the patent in suit) was granted with a set of five claims. Claim 1 reads as follows:

1. A composition for use as an artificial tear, which comprises a mixture of castor oil with linseed oil, wherein said mixture comprises from 20 to 80 weight percent castor oil and from 20 to 80 weight percent linseed oil, wherein said mixture of castor oil and linseed oil is emulsified in an aqueous phase.

II. The patent in suit was opposed under Article 100(a) and (c) EPC on the grounds that the claimed subject-matter lacked novelty and inventive step and extended beyond the content of the application as filed.

III. The patent proprietor requested that the opposition be rejected and the patent be maintained as granted (***main request***), and it submitted - in the course of the proceedings before the opposition division - several amended sets of claims as auxiliary requests.

Claim 1 of ***auxiliary request 1*** is identical to claim 1 as granted except that it specifies additionally that the composition comprises 0.1 to 30 weight percent oil mixture and 99.9 to 70 weight percent aqueous phase.

Claim 1 of ***auxiliary request 2*** is identical to claim 1 as granted except that it specifies additionally that the composition comprises 0.25 weight percent oil mixture and 99.75 weight percent aqueous phase.

In ***auxiliary requests 3 and 4***, claim 1 is identical to claim 1 as granted as the amendments made in these requests did not affect claim 1.

IV. The documents cited in the proceedings before the opposition division included the following:

D2: US 5,981,607 A

D6: Supplementary Technical Information - Animal Tolerability Study (dated 23 August 2016)

D7: WO 2007/130960 A2

D9: M. M. Hom, P. A. Simmons, "*Understanding Emulsion Eye Drop Technology*", Review of Optometry 140(03), 1-5 (2003).

V. The decision under appeal is the opposition division's decision revoking the patent for lack of inventive step (Articles 100(a), 52(1) and 56 EPC), posted on 22 August 2019.

Inventiveness was assessed starting from the technical teaching of prior-art document D2, which relates to emulsion eye drop compositions containing castor oil.

The opposition division considered that the data provided in the patent in suit and in document D6 did not demonstrate a particular technical effect of the compositions defined in claim 1 as granted in comparison with compositions according to D2. The objective technical problem was to provide an alternative artificial tear composition. Using an oil mixture as defined in claim 1 would have been an obvious solution since linseed oil was already known, *inter alia* from document D7, as a suitable component for such compositions.

The same reasoning applied to claim 1 of auxiliary requests 3 and 4 and to claim 1 of auxiliary request 1.

In the case of auxiliary request 2, the objective technical problem was defined as the provision of an artificial tear that is tolerated by the eye. The subject-matter of claim 1 of this request did not involve an inventive step either.

VI. The patent proprietor (appellant) filed an appeal against the opposition division's decision and stated that its main request was still for maintenance of the patent as granted. The claims of auxiliary requests 1 to 4 (filed with the statement setting out the grounds of appeal) are identical to those of the corresponding requests considered by the opposition division in the decision under appeal (see points I. and III. above).

VII. Oral proceedings before the board took place on 28 November 2022. After hearing the parties in relation to the assessment of inventive step starting from the disclosure in D2, the board dismissed the appeal.

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

The objective technical problem was the provision of another artificial tear composition having improved tolerability and undiminished spreadability.

Reference examples 2 and 3 in the patent in suit and the post-filed data presented in document D6 made it credible that these technical effects were indeed attained by the compositions defined in claim 1 as granted.

The cited prior-art documents would not have provided the skilled person with an incentive to combine castor oil and linseed oil in the claimed range of ratios in order to solve the objective technical problem. Doing so went against the teaching of both D2 and D7 and would have required hindsight.

Since document D2 taught a specific emulsion system (its functioning was further explained in D9), the person skilled in the art would not have modified that system. As none of the prior-art documents suggested oil mixtures, the person skilled in the art would have been reluctant to use mixtures. Instead, they would simply have reduced the concentration of castor oil in order to improve the tolerability of the compositions.

In auxiliary requests 1 and 2, the concentration of oil had been restricted in order to delimit the claimed compositions further from those of the prior art and to address the respondent's objection that an effect had not been demonstrated for compositions having all oil contents covered by claim 1. The oil concentration in auxiliary request 2 was also in line with the concentrations used according to D6. None of the cited prior-art documents taught that improved tolerability could be achieved with the claimed oil concentrations and ratios.

IX. The respondent's (opponent's) arguments can be summarised as follows:

D2 disclosed emulsion eye drop compositions containing castor oil. The application as filed envisaged the use of mixtures of castor oil with other oils in general. It mentioned linseed oil only as a non-preferred alternative and did not provide any data for linseed oil. It was therefore questionable that the appellant's post-filed data provided in D6 should be considered at all.

Even if D6 were to be considered, there was no conclusive evidence of a particular technical effect achieved by the claimed compositions on account of the technical features distinguishing them from D2, and across the whole scope claimed. As a consequence, the objective technical problem was to provide an alternative composition for use as an artificial tear.

Emulsions using a combination of castor oil and linseed oil would have been obvious alternatives, since linseed oil was known to have been used in this type of product for the same purpose (e.g. from D7, which taught, *inter alia*, the relief of dry eye). There was no technical prejudice that would have kept the person skilled in the art from combining castor oil with another oil.

Since castor oil was known to be mildly irritating to the eye (D2: column 5, lines 16 to 17; D9: page 3), the person skilled in the art would also have been motivated to lower the content of castor oil and provide an alternative to "castor oil only" compositions. Even if the alleged technical effect of increased tolerability were to be taken into account, the claimed compositions would thus have been obvious to the skilled person.

X. The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted (main request), or, in the alternative, that the patent be maintained in amended form on the basis of the claims of one of auxiliary requests 1 to 4 filed with the statement setting out the grounds of appeal.

XI. The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. Admissibility of the appeal

The appeal complies with Articles 106 to 108 EPC and Rule 99 EPC. It is admissible.

2. Inventive step - main request

Patent in suit

2.1 As acknowledged in the patent in suit, artificial tear compositions in the form of emulsions based on castor oil were known in the art. Although there was a high level of interest in using other oils in ocular formulations for dry eye treatment, the spreading ability of these other oils was found to be poor as compared to castor oil (see paragraphs [0019] and [0020] of the patent specification).

2.2 The patent in suit presents the option of using mixtures of castor oil with other oils, in particular food oils, as such mixtures still have good spreading properties and are less viscous than castor oil. The compositions according to the current claim requests are limited, with respect to the oil mixtures, to mixtures combining castor oil with linseed oil.

Starting point in the prior art

2.3 It was common ground that document D2 was the closest prior art.

2.4 D2 relates to emulsion eye drop compositions for alleviating dry-eye-related symptoms including those of keratoconjunctivitis sicca (title; column 1, second paragraph). The compositions according to D2 comprise a higher fatty acid glyceride (this may, in particular, be castor oil), which is combined with polysorbate 80 as an emulsifier (column 3, lines 41 to 60; column 4, lines 57 to 61; example 1; claims 1 and 3).

Objective technical problem and solution

2.5 The composition defined in claim 1 differs from compositions according to D2 in the mandatory presence of linseed oil (also known as flaxseed oil or flax oil). The weight ratio of castor oil to linseed oil must be in the range of 1:4 to 4:1.

2.6 The technical effects alleged to be achieved on account of these distinguishing technical features relate to the spreadability and tolerability of the compositions. In support of the alleged technical effects, the appellant relied on comparative tests (reference examples 2 and 3 and the experiment reported in D6).

2.7 If comparative tests are chosen to demonstrate inventive step on the basis of a particular technical effect, the nature of the comparison must be such that the alleged advantage or effect is convincingly shown to have its origin in the distinguishing feature of the claimed subject-matter compared with the closest prior art (see also Case Law of the Boards of Appeal of the European Patent Office, 10th edition 2022, I.D.4.3.2). The following criteria may be relevant in this context:

(a) The comparative sample must be adequately representative of the closest prior art, and the "inventive" sample must be adequately representative of the claimed subject-matter.

(b) A technical effect cannot be convincingly attributed to a particular technical feature if several features are varied in the comparative test.

(c) Furthermore, it must be credible that the effect can be obtained over the entire scope claimed for it to be taken into account in determining the objective technical problem.

2.8 Alleged effect of undiminished spreadability

2.8.1 In support of the alleged technical effect of undiminished spreadability, the appellant relied on reference example 2.

2.8.2 Reference example 2 of the patent in suit corresponds to example 2 in the application as filed.

- It reports superior spreadability of castor oil ("drop disperses readily") in comparison with several food oils, such as soybean oil or olive oil ("drop does not disperse") (see Table 3), upon contact with a model tear solution in a small cell culture dish.
- The data also shows better spreadability for mixtures of castor oil that have varying ratios of soybean or olive oil ("drop disperses readily"), in comparison with soybean or olive oil alone ("drop does not disperse").

2.8.3 However, the starting point in the closest prior art is not a formulation based on soybean oil or olive oil, but one based on castor oil (see D2 and points 2.3 to 2.4 above). Reference example 2 does not show improved spreadability for any oil mixture in comparison with castor oil (see point 2.5 above). It merely reports that castor oil dispersed readily, and that the tested oil mixtures also dispersed readily (see point 2.8.2 above). Moreover, mixtures of castor oil with linseed oil were not among the samples tested.

2.8.4 According to the appellant, it was nevertheless fair to conclude from the data provided that the claimed compositions were at least characterised by undiminished spreadability compared to "castor oil only" compositions. This was because linseed oil could be expected to behave in the same way as soybean or olive oil.

2.8.5 The appellant also maintained that it was surprising that the spreadability of compositions according to claim 1, containing a combination of castor oil and linseed oil, was not inferior to that of compositions containing only castor oil.

2.8.6 In actual fact, however, reference example 2 does not demonstrate undiminished spreadability of the claimed compositions compared with those of the closest prior art.

The compositions tested according to reference example 2 did not comprise an aqueous phase in which the oil mixtures were emulsified, and none of them contained linseed oil either (see Table 3 in the patent in suit). As the compositions based on mixtures of castor oil with other oils were not in conformity with claim 1, the set-up of the experiment did not enable a valid observation of the alleged technical effect in relation to the distinguishing technical features to be carried out.

2.8.7 Consequently, the data provided in reference example 2 does not justify taking the alleged technical effect of undiminished spreadability into account in the formulation of the objective technical problem.

2.8.8 In support of the alleged effect, the appellant also referred to D9, pointing out that this document related to the same emulsion formulations as D2. D9 taught that upon instillation of the compositions into the eye, ions in the tear film interacted with the emulsifying system to destabilise the emulsion. This allowed the castor oil component to separate from the aqueous and demulcent components and to merge with - and enhance - the natural lipid layer (see D9: page 2 and Figure 4). Still according to the appellant, there was no reason to expect other oils, such as linseed oil, to behave differently from castor oil in the same setting. Based on the mechanism explained in D9, it was credible that the same level of spreadability could be attained with oil mixtures, including those of claim 1.

2.8.9 The board notes that D9 does not specifically address oil mixtures or the behaviour of linseed oil at all. The appellant's argument appears to be based on the fact that any further oil would, like castor oil, be present in emulsified, i.e. pre-dispersed, form. This would presumably facilitate its integration into the natural lipid layer.

2.8.10 However, the question whether this argument is sufficient in support of the alleged technical effect of undiminished spreadability can be left open, for the following reasons.

To modify the compositions while maintaining satisfactory spreadability, the skilled person would have considered varying the oil component. This includes the option of using mixtures of castor oil with suitable other oils (linseed oil being known as suitable for eye drop formulations, e.g from document D7 - see points 2.12 to 2.14 below).

The appellant considered D9 as supplementary to D2. As a pre-published document, D9 forms part of the state of the art. If the appellant's argument in point 2.8.8 were valid, then this would also mean that attaining undiminished spreadability with the claimed compositions would have been an entirely expected effect in light of D9, as interpreted by common general knowledge. In other words, the claimed subject-matter would have been obvious to the person skilled in the art.

In conclusion, the board considers that, even if "undiminished spreadability" were to be taken into account as a technical effect, this would not establish an inventive step.

2.9 Alleged effect of improved tolerability

2.9.1 The appellant also contended that the claimed compositions exhibited superior ocular tolerability in comparison with compositions according to D2. In support of this assertion, the appellant relied on comparative tests presented in reference example 3 (which corresponds to example 3 in the application as filed) and document D6.

2.9.2 Reference example 3 relates to an ocular tolerability study in rabbits. However, the "oil mixture" emulsion composition tested did not contain linseed oil and hence it does not represent compositions as defined in claim 1 as granted. For this reason, reference example 3 cannot support the appellant's claim of improved tolerability.

2.9.3 With document D6, the appellant provided additional (post-filed) experimental data purporting to show improved ocular tolerability of compositions according to claim 1 as granted.

2.9.4 In the appellant's favour, the board took the content of D6 into account. In view of the outcome of this approach (i.e., a finding of lack of inventive step, see below), it was not necessary for the board to decide whether the relationship between the distinguishing technical feature(s) and the alleged technical effect of improved tolerability was derivable, at the effective date, from the content of the application as filed in light of common general knowledge.

2.9.5 D6 describes an animal experiment comparing the ocular tolerability of two emulsion formulations:

- "Formula A", containing a combination of castor oil and linseed ("flaxseed") oil (each at 0.125 wt%) as the oil component, and
- "Formula B", containing only castor oil (at 0.25 wt%) as the oil component.

Formula A differed further from formula B in that it also contained 0.05 wt% BHT and 1.25 wt% trehalose as well as 0.25 wt% polyoxyl 40 stearate. Both formulations contained 0.5 wt% polysorbate 80.

According to page 1 (Study Summary) and Table 2 in D6, rabbits treated with formula A experienced less discomfort ("minimal discomfort") than those treated with formula B ("minimal to mild discomfort").

2.9.6 Formula B may be regarded as representative of compositions according to document D2, while formula A is in conformity with claim 1 as granted.

2.9.7 It was a point of dispute between the parties whether the set-up of the experiment described in D6 allowed the observed improvement in tolerability to be attributed to a technical feature distinguishing the claimed compositions from compositions according to D2.

The respondent contended that the reported data was not conclusive in this regard, because several other parameters had been varied (see point 2.9.5 above).

The appellant argued that BHT, trehalose and Polyoxyl 40 stearate did not act to improve short-term tolerability, which was examined in D6, and that it had been correct to reduce the concentration of castor oil in formula A, in order to keep the total oil concentration constant.

2.9.8 The board will assume, in favour of the appellant, that the impact of the additional ingredients BHT, trehalose and Polyoxyl 40 stearate in formula A can be disregarded. In view of the final outcome of the case against the appellant, there is no need to explore this issue any further.

2.9.9 On the basis of the available information, it cannot be confirmed that the better tolerability of formula A reported in D6 was indeed due to the presence of linseed oil or due to the ratio of linseed oil to castor oil in the formulation (i.e. the distinguishing technical features), for the following reasons.

D6 does not examine the effect of a composition containing linseed oil as the only oil, or the effect of varying the ratio of the oils. On the sole basis of the data points provided in D6, it is not possible to conclude that there is a synergy or interaction between castor oil and linseed oil, or that the improved tolerability of formula A was caused by the presence of linseed oil. The effect could just as easily be attributed to the reduced concentration of castor oil, independently of the presence of linseed oil.

The latter possibility was, indeed, confirmed by the appellant, which pointed out that - according to D2 - it was well-known that castor oil could be irritating to sensitive tissues such as the eye (see D2: column 5, first paragraph). The appellant inferred from this that the lowering of the concentration of castor oil would be expected to result in improved tolerability.

In that case, however, the technical effect would not be causally linked to a distinguishing technical feature. Moreover, the effect would not be attained across the scope claimed, because claim 1 covers embodiments with relatively high concentrations of castor oil. According to the teaching of the patent in suit, the preferred upper limit for the oil mixture (mentioned in paragraph [0023]) is, for instance, 50 wt%, more preferably 30 wt%, of the emulsion formulation. This translates as a preferred upper limit of 40 wt% (more preferably 24 wt%) for castor oil when taking into account the ratio of the oils to one another.

2.9.10 In conclusion, the alleged technical effect of improved tolerability was not shown to result from a distinguishing technical feature or to be achieved across the whole scope claimed. Hence, this effect cannot be taken into account in the formulation of the objective technical problem.

2.10 Since no particular technical effect was shown, the objective technical problem is to provide further artificial-tear compositions comprising emulsified castor oil.

2.11 The board considers that this problem is solved by the compositions defined in claim 1 as granted.

Obviousness of the solution

2.12 The person skilled in the art seeking to solve the objective technical problem would have consulted prior-art disclosures of similar ophthalmic formulations, such as document D7, to identify components suitable for modifying the formulations disclosed in D2.

2.13 D7 describes ophthalmic emulsion formulations useful against dry-eye syndrome, which are based on oils containing omega-3 fatty acids. The preferred omega-3 fatty acids easily form spread films. They can be provided in the form of natural oils such as linseed ("flaxseed") oil (see claims 1, 5 and 7; paragraphs [0010] and [0060]).

The formulations are comfortable to the eye and may be used topically to treat dry eye, or as solutions for contact lenses (see paragraphs [0022], [0023], [0046], [0052] and [0061]).

D7 discloses example formulations containing linseed oil (examples 8 to 15) or castor oil (examples 1 to 7).

2.14 Thus, linseed oil was known for its use in the same type of formulations as those of the patent in suit, without any known problems relating to spreadability or tolerability.

2.15 It would, therefore, have been obvious to the person skilled in the art to include linseed oil in the formulations of D2 (including in a weight range of 1:4 to 4:1 of castor oil to linseed oil), in order to solve the objective technical problem of providing further compositions.

2.16 In this context, the appellant submitted the following counter-arguments:

(a) The invention taught in D2 related to a specific emulsion system which combined a higher fatty acid glyceride oil with polysorbate 80 and cross-linked polyacrylates such as Pemulen®. The polysorbate 80 was important for providing an emulsion with a high comfort level overcoming irritation (see column 3, lines 32 to 48; column 5, lines 22 to 35). Therefore, the person skilled in the art would not have modified the emulsion system taught in D2.

(b) Furthermore, linseed oil as taught in D7 was not in conformity with the teaching of D2. Linseed oil was not a triglyceride oil, but consisted of fatty acids. It also differed from castor oil as taught in D2 in that it did not have hydroxy group substituents on its carbon chains.

(c) Neither D2 nor D7 suggested the use of a combination of oils. The formulation examples in these documents contained only one oil.

2.17 The board does not find these arguments convincing, for the following reasons:

(a) Claim 1 requires that the oils be emulsified in an aqueous phase. The claim does not exclude the presence of emulsifiers such as polysorbate 80, or of further stabilising components such as the secondary emulsifier Pemulen® (the latter being, in any case, only optional in D2). This is illustrated by the fact that the actual formulations disclosed in the patent in suit equally contain polysorbate 80 and Pemulen (see Tables 1 and 4 in reference examples 1 and 3).

Thus, the person skilled in the art would not have had to omit or modify the emulsifier system of D2 in order to arrive at a composition as defined in claim 1.

(b) As far as the oil component is concerned, D2 does not restrict its teaching to castor oil but speaks in more general terms of higher fatty acid glycerides. Further examples mentioned are corn oil and sunflower oil, neither of which has hydroxy group substituents on its fatty acid chains (see D2: column 6, lines 28 to 33).

Contrary to the appellant's further argument, it belongs to common general knowledge in the field of chemistry that linseed oil is a triglyceride oil (as is also evident from its acid value and saponification value indicated in D7, paragraph [0049]) and that its fatty acid chains are predominantly C_{18} chains.

In any case, the premise of the appellant's argument is not correct. The technical teaching of D2 is already implemented because castor oil is present as a higher fatty acid glyceride according to D2. Adding a further suitable oil component (such as linseed oil, taught in D7) is not in conflict with the technical teaching of D2.

(c) While D2 does not explicitly disclose oil mixtures, it does not contain any passage that rules out the presence of more than one oil. The definition of the oil component is open to that possibility on account of the use of the open term "comprise" (see D2: column 3, lines 46 to 48: *"The higher fatty acid glyceride may comprise, for example, castor oil, corn oil, sunflower oil or light mineral oil"*).

D7 does not exclude mixtures either. On the contrary, it contains several passages indicating that more than one oil may be used, for instance:

- paragraph [0010]: *"In preferred embodiments, the oil component of the composition <u>includes</u> flaxseed oil, Perilla seed oil or another natural or synthetic oil that is a source of Omega-3 fatty acids."*
- paragraph [0058]: *"the (...) oil <u>or oils</u> employed (...)"*
- paragraph [0060]: *"<u>One or more oils</u> or oily substances are used to form the present compositions (...)"*
- paragraph [0072]: *"Two surfactants may also be selected to match a particular oil <u>or oils</u> (...)"; "an affinity for the selected oil <u>or oils</u> based upon non-covalent bonding interactions between the hydrophobic structures of the surfactant and the <u>oil(s)</u> (...)"*

Thus, contrary to the appellant's view, the person skilled in the art had no reason not to use oil mixtures. The absence of a direct explicit disclosure of oil mixtures in D2 is not sufficient to establish an expectation of failure or a technical prejudice against oil mixtures.

2.18 For these reasons, the subject-matter of claim 1 of the main request does not involve an inventive step within the meaning of Article 56 EPC.

3. Inventive step - auxiliary requests

Auxiliary requests 3 and 4

3.1 Claim 1 in auxiliary requests 3 and 4 is identical to claim 1 of the main request, and its subject-matter does not involve an inventive step for the same reasons.

Auxiliary request 1

3.2 Claim 1 of auxiliary request 1 only differs from claim 1 of the main request in that it further specifies that the concentration of the oil mixture is 0.1 to 30 wt% (complemented by 99.9 to 70 wt% aqueous phase).

3.3 No particular technical effect was shown to be achieved in connection with this broad concentration range of the oil mixture. Also, the oil concentration is not a distinguishing feature as examples 1 and 2 in D2 disclose oil concentrations between 0.625 and 5.00 wt% (this relates to castor oil, as the only oil present in those formulations).

3.4 As a consequence, the definition of the objective technical problem does not change, and the assessment of obviousness set out in section 2 above for claim 1 of the main request applies in the same way to claim 1 of auxiliary request 1.

3.5 Accordingly, the subject-matter of claim 1 of auxiliary request 1 does not involve an inventive step within the meaning of Article 56 EPC.

Auxiliary request 2

3.6 Claim 1 of auxiliary request 2 differs from claim 1 of the main request in that it defines the concentration of the oil mixture as 0.25 wt% (complemented by 99.75 wt% aqueous phase).

3.7 The appellant stated that this was to better align the oil concentration with the experiment reported in D6.

3.8 The oil concentration of 0.25 wt% is a further distinguishing technical feature in addition to that mentioned in point 2.5 above. Combined with the required range of 1:4 to 4:1 for the ratio of the oils, it translates into a concentration range of 0.05 wt% to 0.20 wt% for each of the oils.

3.9 The question is thus whether D6 demonstrates a specific technical effect that can be attributed to this distinguishing feature.

3.10 Formula A of D6 contains 0.125 wt% linseed oil and 0.125 wt% castor oil, which is in the middle of the required concentration range for each oil, whereas the comparative sample (formula B) contains 0.25 wt% castor oil, which is outside of the claimed range of 0.05 to 0.20 wt%.

3.11 No comparison is provided, however, with a formulation containing 0.02 wt% castor oil, i.e. reproducing the upper limit of the claimed concentration range for castor oil. Thus, the data provided in D6 does not show that an improvement in tolerability is indeed achieved across the whole concentration range claimed.

3.12 As a consequence, the objective technical problem remains the same as set out in point 2.10 above, and the reasoning set out in relation to obviousness for claim 1 of the main request applies in the same way (see points 2.12 to 2.17 above).

3.13 Furthermore, the added feature defining the concentrations of the oil mixture and complementary aqueous phase (see point 3.6 above) does not establish an inventive step.

The board is not aware of any specific reason which would have kept the person skilled in the art from choosing 0.25 wt% as the concentration of the oil mixture. While D2 tends to use higher concentrations of at least 0.625%, claim 1 of D2 does not indicate a mandatory lower concentration limit for the oil. D7 discloses relatively low concentrations for each oil (Table 3: 0.313 wt% castor oil; Tables 12 and 19: 0.1 wt% and 0.2 wt% linseed oil). It is, in any case, routine for a galenic formulator to optimise, in particular to minimise, the content of active ingredients required for efficacy in a formulation.

3.14 As an additional remark, taking the effect of improved tolerability into account would not have led to a different result in the assessment of inventive step:

As both parties agreed, it was known - and it is acknowledged in D2 (column 5) - that castor oil, besides its known benefits, may also have an irritating effect on sensitive tissues such as the eyes.

Although D2 taught that the combination of castor oil and polysorbate 80 provided compositions with a low irritation potential, the skilled person would still have sought to keep the irritation potential as low as possible.

Knowing that castor oil could have an irritating effect, the skilled person would have had the expectation that reducing the amount of castor oil would be an appropriate measure for improving ocular tolerability. This could be achieved in an obvious manner by reducing the amount of castor oil present in the compositions, which included the option of replacing part of it with another oil known to be a suitable ingredient for artificial tear compositions (e.g. in cases where it was desired not to diminish the total oil content).

3.15 For these reasons, the subject-matter of claim 1 of auxiliary request 2 does not involve an inventive step within the meaning of Article 56 EPC.

4. Documents filed during the appeal proceedings

The documents filed by the parties in the course of the appeal proceedings (D15 to D18) are not relevant to the present decision, as they were intended to address different issues from those discussed above. Hence, there was no need to decide on their admittance.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

I. Aperribay B. Rutz

Decision electronically authenticated