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**Datasheet for the decision
of 20 October 2023**

Case Number: T 1090/21 - 3.3.03

Application Number: 12815930.8

Publication Number: 2794723

IPC: C08G77/442, C08F283/12,
C08F290/06

Language of the proceedings: EN

Title of invention:

SILICONE HYDROGELS HAVING A STRUCTURE FORMED VIA CONTROLLED
REACTION KINETICS

Patent Proprietor:

Johnson & Johnson Vision Care, Inc.

Opponent:

Alcon Inc.

Relevant legal provisions:

EPC Art. 56

Keyword:

Inventive step - auxiliary requests 3 and 6 - improvement not
credible - obvious alternative
Inventive step - auxiliary request 8 - non-obvious improvement
shown

Decisions cited:

T 1323/17, T 2342/19



Beschwerdekammern
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 1090/21 - 3.3.03

D E C I S I O N
of Technical Board of Appeal 3.3.03
of 20 October 2023

Appellant:

(Opponent)

Alcon Inc.
Rue Louis-d'Affry 6
1701 Fribourg (CH)

Representative:

Breuer, Markus
Sendlinger Straße 29
80331 München (DE)

Respondent:

(Patent Proprietor)

Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway
Jacksonville, FL 32256 (US)

Representative:

Carpmaels & Ransford LLP
One Southampton Row
London WC1B 5HA (GB)

Decision under appeal:

**Interlocutory decision of the Opposition
Division of the European Patent Office posted on
3 May 2021 concerning maintenance of the
European Patent No. 2794723 in amended form.**

Composition of the Board:

Chairman

D. Semino

Members:

M. Barrère

W. Ungler

Summary of Facts and Submissions

- I. The appeal of the opponent lies against the interlocutory decision of the opposition division concerning maintenance of European Patent number 2 794 723 in amended form on the basis of the claims of the main request filed with letter dated 10 June 2020 and unamended description and drawings.
- II. The following documents were *inter alia* cited in the decision of the opposition division:
- D13: EP 1 090 312 B1
 - D14: US 2011/0313077 A1
 - D16: US 2007/0092830 A1
 - D17: WO 2011/037893 A2
 - D19: US 2008/0182956 A1
 - D21: US 4,719,248
- III. In that decision, the opposition division held, among others, that the subject-matter of claim 1 of the main request involved an inventive step over document D13 as the closest prior art.
- IV. The opponent (appellant) filed an appeal against said decision.
- V. With the rejoinder to the statement of grounds of appeal, the patent proprietor (respondent) filed seventeen sets of claims as main request and auxiliary requests 1 to 16.
- VI. Oral proceedings were held before the Board on 20 October 2023. During the oral proceedings, the

respondent withdrew the main request as well as auxiliary requests 1, 2, 4, 5, 7 and 9 to 16.

VII. The final requests of the parties were as follows:

- (a) The appellant requested that the decision under appeal be set aside and the patent be revoked.
- (b) The respondent requested that the decision under appeal be set aside and the patent be maintained on the basis of one of auxiliary requests 3, 6 or 8 filed with the rejoinder to the statement of grounds of appeal.

VIII. Claim 1 of auxiliary request 3 read as follows:

"1. A silicone hydrogel formed from a reaction mixture comprising

30 to 75 wt% of at least one slow-reacting hydrophilic monomer having a slow-reacting hydrophilic monomer kinetic half life;

at least one silicone-containing component having a silicone-containing component kinetic half life, which may be optionally substituted with at least one hydroxyl containing group;

at least one visible light photoinitiator;

at least one hydroxyl-containing component selected from said silicone-containing components substituted with at least one hydroxyl group, at least one hydroxyalkyl monomer, and mixtures thereof; and

at least one UV absorbing compound,

wherein the ratio of said slow-reacting hydrophilic component half life to said silicone-containing component half life is at least 2,

wherein said reaction mixture is free from additional hydrophilic components, and

wherein polymerization of the reaction mixture is initiated using visible light."

Claim 1 of auxiliary request 6 differed from claim 1 of auxiliary request 3 in that the following feature was added:

"wherein said reaction mixture is free of silicone containing macromers or prepolymers" (emphases here and below added by the Board)

Claim 1 of auxiliary request 8 differed from claim 1 of auxiliary request 6 in that the following features were added:

"wherein said slow-reacting hydrophilic monomer comprises a reactive group selected from the group consisting of vinyls, allyls and combinations thereof and said silicone-containing component comprises a reactive group selected from the group consisting of (meth)acrylates, styryls, amides and mixtures thereof," and

"wherein said reaction mixture further comprises at least one slow-reacting crosslinker and at least one fast-reacting crosslinker wherein said slow-reacting crosslinkers have only vinyl reactive

functionality and said fast-reacting crosslinkers have (meth)acrylate reactive functionality only"

The remaining claims of these requests are not relevant to this decision.

IX. The appellant's submissions, in so far as they are pertinent to the present decision, may be derived from the reasons for the decision below. They were essentially as follows:

(a) Auxiliary requests 3 and 6

The subject-matter of claim 1 of auxiliary requests 3 and 6 did not involve an inventive step over document D19 as the closest prior art.

(b) Auxiliary request 8

The subject-matter of claim 1 of auxiliary request 8 did not involve an inventive step over each of documents D19, D17, D14 and D16 as the closest prior art.

X. The respondent's submissions, in so far as they are pertinent to the present decision, may be derived from the reasons for the decision below. They were essentially as follows:

(a) Auxiliary requests 3 and 6

The subject-matter of claim 1 of auxiliary requests 3 and 6 involved an inventive step over document D19 as the closest prior art.

(b) Auxiliary request 8

The subject-matter of claim 1 of auxiliary request 8 involved an inventive step over each of documents D19, D17, D14 and D16 as the closest prior art.

Reasons for the Decision

Auxiliary request 3

1. Inventive step

According to the appellant, the subject-matter of claim 1 of auxiliary request 3 lacks an inventive step over document D19 as the closest prior art.

1.1 Closest prior art

1.1.1 The appellant considered that example 4 of document D19 could be selected as the closest prior art for the subject-matter of present claim 1.

1.1.2 The respondent, in agreement with the opposition division, held that D13 and not D19 was the closest prior art for operative claim 1. In particular, it was pointed out that D13 had more in common with the invention of the opposed patent than the other cited prior art. While documents such as D19 used a "chemical" approach to the preparation of silicone hydrogels, D13 took a "processing" approach using visible light and UV absorbers similar to the one claimed the patent. In addition, the opponent had presented eight possible starting points in their notice of opposition. To use these multiple lines of attack based on numerous alternative starting points

("shotgun approach") would not be the way in which the problem-solution approach should be applied.

- 1.1.3 Irrespective of whether or not D19 is closer to the subject-matter of claim 1 than D13, the relevant question for the Board is whether D19 represents a realistic starting point for a skilled person aiming at the claimed invention (see Case Law of the Boards of Appeal, 10th edition, 2022, hereinafter "Case Law", I.D.3.4.1). In that respect, a central consideration in selecting the closest prior art is that it must be directed to the same purpose or effect as the invention (see Case Law, I.D.3.2).

The opposed patent pertains to silicone hydrogels for use in contact lenses (see paragraphs [0001] and [0002]). In view of the fact that D19 is directed to the same purpose (see D19, paragraphs [0029] and claim 15), the Board is of the opinion that D19 is not an unreasonable starting point and can therefore be chosen as springboard to analyse inventive step of the subject-matter of claim 1.

- 1.1.4 Moreover, in response to the respondent's arguments, the Board does not see a clear distinction between the so called "processing" and "chemical" approaches. Indeed, it was not disputed by the parties that the monomer formulation (and therefore the "chemistry") influences the kinetics (and therefore the "process" in the sense of the respondent). Although D19 does not necessarily mention that the hydrogel is obtained by controlling the kinetics, it cannot be denied that the monomers used in the formulations of D19 have different reactivities so that the kinetics must have an effect on the hydrogel structure. In other words, it is not because D19 does not use the term kinetics that kinetic

phenomena do not occur or are not relevant in the formulations disclosed therein.

- 1.1.5 On the question of whether only one piece of prior art should be selected for the purpose of assessing inventive step, it is settled case law that there are often several reasonable starting points, each offering a different route that might lead to the invention without the need of hindsight (see Case Law, I.D.3.1). In that case, the rationale of the problem and solution approach requires that the invention be assessed relative to all these possible routes, before an inventive step can be acknowledged, even if in some cases the number of routes might be substantial.

For example, the number of suitable prior art documents may depend on the breadth of a claim, so that a broad claim may lead to a situation where several documents are equally valid starting points. The same is true in a highly competitive technical field where many closely related prior art documents have been published. However, as mentioned above, the fact that several documents are proposed as the closest prior art is not incompatible with the problem-solution approach.

- 1.1.6 For these reasons, the Board considers that D19, and in particular its example 4, is a reasonable starting point for assessing inventive step.

1.2 Distinguishing feature

It was agreed by the parties that the subject-matter of claim 1 differed from D19 in that the silicone hydrogel was obtained by polymerisation initiated by visible light using a visible light photoinitiator (instead of

a thermally initiated polymerisation using an azo initiator in example 4 of D19).

The Board has no reason to depart from that view.

1.3 Problem to be solved

1.3.1 According to the appellant no effect can be derived from the above distinguishing feature (see point 7.2 of the statement of grounds of appeal). Thus the problem to be solved should be formulated as to provide an alternative curing method.

1.3.2 During the oral proceedings before the Board, the respondent argued that the problem as formulated by the appellant would not be correct as it gave a hint as to the solution. Instead, the respondent considered that the problem should be formulated as the provision of an alternative hydrogel suitable for use in contact lenses.

In this respect it was no longer argued by the respondent that an improvement in modulus should be taken into account in the formulation of the objective problem. For the sake of completeness, it is noted that the alleged effect on the hydrogel modulus was derived from examples 19 to 22 of the opposed patent. However, as noted by the parties, none of these examples contain a UV absorbing compound. Hence these examples are neither representative of D19 nor of a hydrogel according to operative claim 1, which both require the presence of a UV absorbing compound.

1.3.3 According to the established case law, the technical problem addressed by an invention has to be formulated in such a way that it does not contain pointers to the

solution or partially anticipate the solution, since including part of a solution offered by an invention in the statement of the problem necessarily results in an *ex post facto* view being taken of inventive step when the state of the art was assessed in terms of that problem (see Case Law, I.D.4.2.1). In the present case, formulating the problem as to provide an alternative curing method already points towards the solution, which is a visible light photoinitiation. Consequently the Board agrees with the respondent that the problem should be formulated in a more neutral way, such as the provision of an alternative hydrogel suitable for use in contact lenses.

1.4 Obviousness of the solution

It remains to be evaluated whether it was obvious to a person skilled in the art wishing to provide an alternative hydrogel for contact lenses to replace the thermal curing process of example 4 of D19 with a curing process initiated by visible light.

1.4.1 The appellant argued that it was an obvious option in view of the disclosures of D19 and D21 to replace the thermal initiation process by a photoinitiation process with visible light.

1.4.2 According to the respondent, the initiation process is complex and not easily interchangeable. While thermal initiation is a slow process (in the sense that few radicals are created at the beginning of the polymerisation), the photoinitiation process creates a high number of radicals from the start before this number decreases over time. The teaching of D21 also shows that it is not easy to achieve sufficient curing when using visible light photoinitiation, as many

examples fail (see Table II of D21). Moreover, it would be shown in examples 19 to 22 of the opposed patent that the initiation process has a significant impact on the hydrogel properties to an extent that the hydrogel may not be suitable for use in contact lenses. In view of these unpredictable effects on the hydrogel properties, a skilled person would not arbitrarily replace the thermal initiation process of D19 with a photoinitiation process, let alone a photoinitiation process using visible light. Eventually, the appellant pointed out that a tinting agent was used in the formulation of example 4 of D19. Document D13 would however teach that it is not possible to effectively polymerise monomer mixtures for contact lenses that include a tinting agent if the process of D21 is used (see D13, paragraph [0006]).

- 1.4.3 The Board first notes that the problem to be solved is merely the provision of an alternative hydrogel suitable for contact lenses. Although example 4 of D19 uses a thermal initiation process, this document also teaches that the curing of the hydrogel may be carried out by photoinitiation (see D19, page 5, paragraph [0037]). Already based on the teaching of D19 alone, it is an obvious option for the skilled person to replace the thermal initiation process with a photoinitiation process. Moreover, document D21, which also belongs to the technical field of compositions for contact lenses, teaches that the polymerisation may be initiated using visible light in the presence of a photoinitiator (see D21, column 2, lines 57 to 65). Therefore, in view of D19 and D21, the Board considers it to be an obvious alternative for the skilled person to replace the thermal initiation process of D19 by a photoinitiation process using visible light as taught in D21.

1.4.4 The respondent argued that the skilled person would refrain from switching from one initiation process to another because it could not be predicted that a material suitable for contact lenses could still be obtained. This argument is however in contradiction with D19 and D21 as these documents both relate to the technical field of the opposed patent and teach that a photoinitiation process is suitable to obtain contact lenses. The Board does not exclude that some adjustments might be needed in the formulation of example 4 of D19 in order to obtain an acceptable curing with visible light however sufficient guidance is provided in the prior art and in particular in D21 to achieve that goal (as shown in table II of D21).

1.4.5 The Board is also not convinced by the argument that a tinting agent would not allow sufficient curing of the monomer formulation when visible light photoinitiation is used, for the following reasons:

First this argument, which is based on paragraph [0006] of D13, is in contradiction with paragraph [0094] of the opposed patent which teaches the reactive mixture may contain "*reactive tints, pigments, copolymerizable and non-polymerizable dyes*". Secondly, if it were indeed known that the presence of tinting agent would be incompatible with a photoinitiation using visible light, it would also be obvious to the skilled person to remove the tinting agent from example 4 of D19 in order to switch from a thermal initiation process to the said photoinitiation process.

1.5 For these reasons, the subject-matter of claim 1 of auxiliary request 3 lacks an inventive step over document D19 in combination with document D21.

Auxiliary request 6

2. Inventive step

According to the appellant, the subject-matter of claim 1 of auxiliary request 6 lacks an inventive step over example 4 of document D19 as the closest prior art.

2.1 Closest prior art

The parties did not submit any additional arguments concerning the choice of the closest prior art. Hence, for the above reasons (see point 1.1), the Board considers that example 4 of D19 is a suitable starting point to assess inventive step.

2.2 Distinguishing feature

Claim 1 of auxiliary request 6 further differs from claim 1 of auxiliary request 3 in that :

the reaction mixture is free of silicone containing macromers or prepolymers.

The parties agreed that:

- in the context of the patent in dispute silicone macromers and silicone prepolymers were compounds having molecular weights of greater than 2000 (see paragraph [0022] of the opposed patent) and that
- the subject-matter of claim 1 differed from example 4 of D19 in that:
 - (i) the silicone hydrogel was obtained by polymerisation initiated by visible light

using a visible light photoinitiator
(instead of a thermally initiated
polymerisation using an azo initiator in
D19) and

- (ii) the reaction mixture was free of silicone containing macromers or prepolymers (while example 4 of D19 includes a silicone macromer with a molecular weight of 3400 g/mol).

The Board has no reason to depart from that view.

2.3 Problem to be solved

The effect of distinguishing feature (i) was already addressed in the context of auxiliary request 3 (see point 1.3). In the absence of additional argument in that respect, the Board has no reason to deviate from the view that this distinguishing feature cannot be associated with a technical effect.

It therefore remains to be evaluated whether the absence of silicone containing macromers or prepolymers (distinguishing feature (ii)) can justify a different formulation of the problem to be solved with respect to the one indicated for auxiliary request 3.

- 2.3.1 The respondent argued that the use of silicone macromers or prepolymers required "pre-polymerisation" of the silicone-rich blocks before they were incorporated into the hydrogel (see letter dated 13 July 2023, page 3, penultimate paragraph). Thus the approach taken in D19 leads to an increased complexity. In contrast, in the process according to the patent, the control of the relative kinetics would imply that the

silicone-rich blocks can be formed *in situ* at the same time as the hydrogel is formed, meaning that a good balance of properties can be achieved when using smaller silicone compounds that are easier to synthesise or commercially available. Consequently, the problem to be solved should be formulated as the provision of a new class of UV-absorbing silicone hydrogels with a good balance of properties which can be more easily manufactured (see page 24, points 6.18 and 6.19 of the rejoinder to the statement of grounds of appeal).

The respondent further criticised that the appellant had initially considered eight different documents as starting point to assess inventive step. It would not be reasonable to require that the patent proprietor provides comparative examples for all possible lines of attack. Moreover even if the Board did not recognise any improvement, it should at least be acknowledged that the hydrogel according to claim 1 had good properties and that the process of the patent was simple (following the rationale of T 2342/19, points 3.3.5 to 3.3.7 of the Reasons).

- 2.3.2 According to the appellant, the exclusion of silicone macromers or prepolymers having a molecular weight above 2000 is arbitrary since no effect can be derived from the examples of the opposed patent. Furthermore, it cannot be said that polymers with molecular weights above 2000 are generally more difficult to synthesise than polymers with molecular weights below this range. Thus, the problem to be solved should be formulated as the provision of an alternative hydrogel.

2.3.3 Two advantages linked to distinguishing feature (ii) were put forward by the respondent. The Board will address them separately below:

(a) Good balance of properties:

As pointed out by the appellant, the opposed patent does not comprise comparative examples derived from silicone macromers or prepolymers having a molecular weight above 2000. In the absence of suitable comparative examples showing an effect related to the molecular weight of the silicone-containing component, it is not credible that any hydrogel according to present claim 1 has improved or at least equivalent properties compared to the hydrogels of D19.

(b) Simplification of the process:

In that respect, it was argued that D19 required a complicated pre-polymerising process to prepare the silicone prepolymer (with a molecular weight above 2000) while the silicone compounds used in the patent were prepared *in situ* or with an easy process. The Board is not convinced that any such conclusion may be derived from the comparison of D19 with the opposed patent.

First contrary to the respondent's view, the silicone compounds of the patent are also prepared separately and not *in situ* during the hydrogel preparation (see opposed patent, page 21, lines 51 to 53). Furthermore, even if silicone components with molecular weights below 2000 were commercially available (which does not appear to be the case for the silicones used in the patent examples), these commercial products must nevertheless be synthesised separately.

Secondly, it has not been shown or made credible that the synthesis of silicone compounds with a molecular weight above 2000 is necessarily more difficult than the synthesis of silicone compounds with lower molecular weights.

- 2.3.4 Finally the Board cannot follow the respondent's argument that, given the large number of possible starting points, it could not be required to provide evidence of effect in each case. As noted previously (see point 1.1.5), the number of suitable prior art documents may, for example, depend on the breadth of a claim, so that a broad claim may lead to a situation where several documents are equally valid starting points. The same applies in a highly competitive technical field where many closely related prior art documents have been published. In such a situation, the Board considers that it would be an unjustified advantage to exempt an applicant or proprietor from providing evidence of a technical effect merely because the claims are broad and/or the number of possible starting points is relatively high.

As to the relevance of T 2342/19, the Board in that decision held that the ambiguous disclosure of the closest prior art did not allow to perform any direct comparison (see point 3.3.5(a) of the Reasons). This situation does not apply to the present case since it would have been possible to reproduce example 4 of D19 or to provide evidence that the molecular weight of the silicone components had an effect on the hydrogel properties.

- 2.3.5 Consequently, the Board cannot recognise any technical effect linked to distinguishing feature (ii). The

objective problem to be solved is therefore formulated as the provision of an alternative hydrogel suitable for use in contact lenses.

2.4 Obviousness of the solution

It remains to be evaluated whether it was obvious to a skilled person wishing to provide an alternative hydrogel for contact lenses:

- (i) to replace the thermal curing process with a curing process initiated by visible light and
- (ii) to avoid using silicone macromers or prepolymers (i.e. silicone compounds having a molecular weight of at least 2000) in the formulation of example 4 of D19.

2.4.2 The obviousness of distinguishing feature (i) was already addressed in the context of auxiliary request 3 (see point 1.4). In the absence of additional arguments in that respect, the Board has no reason to deviate from the view that this distinguishing feature is obvious in view of D19 in combination with D21.

2.4.3 The appellant argued that D19 suggested using silicone-containing compounds having a molecular weight below 2000.

2.4.4 According to the respondent, there would be no incentive in the prior art to reduce the molecular weight of the silicone component as this would affect the hydrogel properties. In particular, reducing the molecular weight of the silicone component of example 4 of D19 while maintaining its amount would increase the

cross-linking density and result in a hydrogel with a significantly higher stiffness. It would therefore be difficult to reduce the molecular weight and still obtain a hydrogel suitable for contact lenses.

- 2.4.5 As noted above, the problem to be solved is merely the provision of an alternative hydrogel for contact lenses. D19 relates to hydrogel suitable for that purpose (see paragraphs [0029] and claim 15). It is therefore the Board's position that any modification within the ambit of the teaching of D19 is suitable to solve the objective technical problem.

Albeit the silicone macromer of example 4 of D19 is characterised by a molecular weight of 3400 corresponding to 39 siloxane repeating units (see page 9, formula), this document also teaches that the number of siloxane units can be varied between 0 and 200 (see paragraph [0008]). It follows that it was obvious to the skilled person wishing to provide an alternative hydrogel to reduce the number of siloxane units in the silicone macromer (for instance below 20) and to automatically select a silicone component having a molecular weight below 2000 (corresponding to distinguishing feature (ii)).

- 2.4.6 As to the effect of reducing the molecular weight on the stiffness of the hydrogel, it is noted that no evidence has been provided by the respondent. In any event, the Board considers that it is a notorious measure to reduce the amount of cross-linking agent in order to compensate for an increase in stiffness. In other words, the skilled person would immediately recognise that a reduction of the silicone crosslinker molecular weight results in an increase of the

crosslinking density which can easily be compensated by a decrease of the amount of crosslinking molecules.

Therefore, in view of D19 alone, the Board considers it to be an obvious option for the skilled person to reduce number of siloxane units and thereby to use a silicone component having a molecular weight below 2000 as set out in present claim 1.

- 2.4.7 As both distinguishing features (i) and (ii) are obvious, the subject-matter of claim 1 of auxiliary request 6 lacks an inventive step over document D19 in combination with document D21.

Auxiliary request 8

3. Inventive step starting from document D19

According to the appellant, the subject-matter of claim 1 of auxiliary request 8 lacks an inventive step over example 4 of document D19 as the closest prior art.

- 3.1 Closest prior art

The parties did not submit any additional arguments concerning the choice of the closest prior art. Hence, for the above reasons (see point 1.1), the Board considers that example 4 of D19 is a suitable starting point to assess inventive step.

- 3.2 Distinguishing feature

Claim 1 of auxiliary request 8 further differs from claim 1 of auxiliary request 6 in that :

the slow-reacting hydrophilic monomer comprises a reactive group selected from the group consisting of vinyls, allyls and combinations thereof and the silicone-containing component comprises a reactive group selected from the group consisting of (meth)acrylates, styryls, amides and mixtures thereof, and

the reaction mixture further comprises at least one slow-reacting crosslinker and at least one fast-reacting crosslinker wherein said slow-reacting crosslinkers have only vinyl reactive functionality and said fast-reacting crosslinkers have (meth)acrylate reactive functionality only.

It was agreed by the parties that the subject-matter of claim 1 differed from example 4 of D19 in that:

- (i) the silicone hydrogel was obtained by polymerisation initiated by visible light using a visible light photoinitiator (instead of a thermally initiated polymerisation using an azo initiator in D19);
- (ii) the reaction mixture is free of silicone containing macromers or prepolymers (while example 4 of D19 includes a silicone macromer with a molecular weight of 3400 g/mol) and
- (iii) the reaction mixture further comprises at least one slow-reacting crosslinker wherein said slow-reacting crosslinker has only vinyl reactive functionality (whereas in example 4 of D19, the formulation contains

a methacrylate terminated silicone macromer as single crosslinker corresponding to a fast-reacting crosslinker as defined in claim 1).

The Board has no reason to depart from that view.

Distinguishing features (i) and (ii) have already been addressed in the context of auxiliary requests 3 and 6 (see points 1.4 and 2.4). It is therefore necessary to focus on the additional distinguishing feature (iii) and assess whether it can justify the acknowledgement of an inventive step.

3.3 Problem to be solved

In order to determine the objective technical problem it needs to be evaluated whether distinguishing feature (iii) (i.e. the presence of a slow-reacting crosslinker as defined in present claim 1) can be associated with a technical effect.

3.3.1 The respondent argued that examples 87 to 114 of the opposed patent provide evidence that the combination of a slow-reacting crosslinker and a fast-reacting crosslinker allows to improve the mechanical properties of the hydrogel (in particular the crease resistance, a lens ability to recover from mechanical stress).

3.3.2 According to the appellant, the composition of example 4 of D19 contains a fast-reacting crosslinker which is a silicone macromer but no slow-reacting crosslinker as defined in present claim 1. However, the examples of the patent are based on small molecules as crosslinkers which do not reflect the disclosure of the closest prior art. Moreover, a comparison between examples 93

and 97 (both with one crosslinker) and example 108 (with two crosslinkers as defined in claim 1) would not demonstrate any advantage as far as the wettability or modulus values were concerned (see letter dated 31 August 2023, page 13). The objective problem to be solved should therefore be formulated as the provision of an alternative hydrogel.

- 3.3.3 According to established case law, the objective technical problem must be derived from effects directly and causally related to the distinguishing features of the claimed invention. In particular the comparison with the closest prior art has to show convincingly that the effect is attributable to the feature distinguishing the invention. The aim of such a comparison is to demonstrate that the technical effect has its exclusive origin in the feature characterising the invention in the claims (see Case Law, I.D.4.3.2).
- 3.3.4 For the Board, the question to be answered is whether a technical effect can be inferred from the available experimental evidence that is related to distinguishing feature (iii), i.e. the presence of a fast-reacting crosslinker and a slow-reacting as defined in claim 1 (instead of the fast-reacting crosslinker as disclosed in D19).
- 3.3.5 With regard to the experimental evidence in the opposed patent, it is pointed out that examples 87 to 114 disclose formulations wherein different crosslinkers were used. Specifically, examples 104 to 114 concern compositions wherein a fast-reacting crosslinker (EGDMA: EthyleneGlycol DiMethAcrylate or TEGDMA: TetraEthyleneGlycol DiMethAcrylate) and a slow-reacting crosslinker (TAC: TriAllyl Cyanurate) were used (see tables 81 and 84 of the opposed patent). These examples

are therefore according to claim 1 of auxiliary request 8. By contrast, examples 87 to 90 and 103 disclose compositions wherein a single crosslinker is used (EGDMA as fast-reacting crosslinker). It is furthermore shown that the hydrogel of examples 104 to 114 are characterised by an improved recovery under stress (specifically crease resistance) compared to (comparative) examples 87 to 90 and 103 (see tables 76, 82 and 86 of the opposed patent).

It can therefore be concluded from these examples that the addition of TAC as slow-reacting crosslinker to a formulation comprising EGDMA as fast-reacting crosslinker leads to contact lenses with improved crease resistance.

3.3.6 The appellant did not contest the crease resistance results but essentially argued that the "chemistry" in the examples of the patent was different from the "chemistry" in D19. In particular, the comparison made in the patent was not suitable to show an effect compared to example 4 of D19 where the fast-reacting crosslinker was a methacrylate terminated silicone macromer instead of a small molecule such as EGDMA or TEGDMA. Instead, a valid comparison would require the use of a comparative formulation that actually reflects a prior art formulation. In that respect, reference was made to points 5.1 and 5.3 of the Reasons in decision T 1323/17.

3.3.7 With respect to the allegedly different "chemistry", the Board notes that the opposed patent and D19 both relate to compositions of unsaturated monomers (mainly vinylic and acrylic monomers) polymerised by radical polymerisation (see example 4 of D19 and opposed patent, examples). Furthermore, in both disclosures,

the formulations include silicone-containing monomers (see D19, claim 7 and opposed patent, paragraph [0011]). For these reasons, the Board does not consider that the "chemistry" in the examples of the patent would not be representative of the teaching of D19.

3.3.8 An additional question to be answered by the Board is whether the comparative examples based on EGDMA ("small" fast-reacting crosslinker) as a single crosslinker can be considered as representative of example 4 of D19 where the fast-reacting crosslinker is a silicone macromer (which is polymeric in nature).

3.3.9 In order to provide evidence of an effect over the closest prior art, the parties do not necessarily have to reproduce embodiments of the closest prior art. It is true that, according to the boards' established case law, tests comparing the invention with the prior art have to be conducted in such a way that any effect can be attributed to the distinguishing feature. However, it is also permitted - and might even be necessary - to modify prior-art embodiments in line with the invention to such a degree that the only remaining difference was the feature distinguishing the claim (see Case Law, I.D.4.3.2).

In the present case, distinguishing feature (iii) is the presence of an additional slow-reacting crosslinker (which is absent in example 4 of D19). As noted previously, the examples of the patent disclose formulations wherein the only difference is the presence of the said slow-reacting crosslinker which corresponds to distinguishing feature (iii) (see example 106 in comparison to examples 88 and 103). Based on these examples, the Board considers that it is credible that the addition of a slow-reacting

crosslinker to a hydrogel composition comprising only a fast-reacting crosslinker leads to an improvement of the crease resistance of contact lenses. Furthermore, in the present assessment of inventive step, the Board does not deviate from the principle applied in decision T1323/17 according to which:

"... considering that the improvement which is sought to be demonstrated by the comparative test is one which is alleged to be achieved over the closest prior art, what counts in the Board's opinion is not only whether a causal link between a distinguishing feature over the closest prior art and an effect is demonstrated in the framework of a comparative test submitted by the applicant or patentee, but also whether the variant of the closest prior art selected as reference (or comparative) example for the comparative test is representative of the closest prior art in the sense that the effect shown to be caused by the distinguishing feature in the context of the comparative test can be expected to take place also in the framework of the closest prior art despite the existence of differences vis-à-vis the reference example of the comparative test." (see point 5.1 of the Reasons)

While it is not disputed that the fast-reacting crosslinkers in the patent (such as EGDMA) and in example 19 of D14 (silicone macromer) are significantly different, the Board has *prima facie* no reason to believe that the effect shown in the examples of the patent would not be observed if the fast-reacting crosslinker (which is not a distinguishing feature between claim 1 and D19) were a silicone macromer. In any case, it is also considered that the respondent has

discharged its onus of proof by providing some evidence of an effect linked to distinguishing feature (iii) and that the appellant has raised doubts about the relevance of this evidence only at a very late stage of the proceedings (see letter of 31 August 2023, pages 12-14, point 5.2). The burden of proof was therefore shifted to the appellant to show evidence that the specific nature of the fast-reacting crosslinker (small molecule vs. silicone macromer) would have led, as alleged, to conflicting results. In the absence of concrete evidence to support the appellant's view, the Board cannot be convinced by it.

3.3.10 Consequently, based on the examples of the patent, the objective problem to be solved is formulated as the provision of contact lenses with improved crease resistance.

3.4 Obviousness of the solution

It remains to be evaluated whether it was obvious for a skilled person wishing to improve the crease resistance of the contact lenses of D19 to add a slow-reacting crosslinker to the hydrogel formulations (distinguishing feature (iii)).

3.4.1 The appellant formulated a different problem to be solved and did not explain why it would be obvious to use a slow-reacting crosslinker in order to solve the above problem. For this reason, its argumentation is not convincing.

For the sake of completeness, the Board agrees with the respondent that there is no suggestion in the prior art of adding a slow-reacting crosslinker to a fast-

reacting one in order to solve the problem of providing contact lenses with improved crease resistance.

3.5 As distinguishing feature (iii) is not obvious, the subject-matter of claim 1 of auxiliary request 8 involves an inventive step over document D19 as the closest prior art.

4. Inventive step starting from other documents

According to the appellant, the subject-matter of claim 1 of auxiliary request 8 also lacks an inventive step over each of documents D14, D16 and D17 taken alternatively as the closest prior art.

4.1 Closest prior art

The choice of D14, D16 and D17 as the closest prior art (although disputed by the respondent) is not relevant to the outcome of the appeal, since the Board concluded below that an inventive step could be acknowledged even if any of these documents were chosen as the starting point.

4.2 Distinguishing feature

It was agreed between the parties that the subject-matter of claim 1 of auxiliary request 8 differed from D14, D16 and D17 at least in that:

the reaction mixture further comprised at least one slow-reacting crosslinker wherein said slow-reacting crosslinker has only vinyl reactive functionality (corresponding to previous distinguishing feature (iii) over document D19) whereas:

- in example 5 of D14 (paragraph [0182]), the formulation contains allyl methacrylate (AMA) instead of a slow-reacting crosslinker as defined in claim 1;
- in test 4 of D16 (paragraph [0068]), the formulation contains 2-hydroxyethyl methacrylate vinylcarbonate (HEMAVC) instead of a slow-reacting crosslinker as defined in claim 1;
- in example 12, formulation 22 of D17 (paragraph [00278]), the formulation contains EGDMA as single crosslinker corresponding to a fast-reacting crosslinker as defined in claim 1) but no additional crosslinker.

The Board has no reason to depart from that view.

For the sake of completeness, further distinguishing features were identified by the parties. However they are not relevant to the outcome of the appeal, since an inventive step could be acknowledged based on distinguishing feature (iii) alone.

4.3 Problem to be solved

It needs to be evaluated whether distinguishing feature (iii) (i.e. the presence of a slow-reacting crosslinker as defined in present claim 1) can be associated with a technical effect.

4.3.1 As regards the problem to be solved, the arguments put forward by the parties were essentially the same as those based on D19 as the closest prior art (see points 3.3.1, 3.3.2 and 3.3.6 of the Reasons). The Board therefore has no reason to depart from the above findings as far as documents D14, D16 and D17 are concerned (see points 3.3.5 and 3.3.7 to 3.3.10 of the Reasons).

4.3.2 Consequently, the objective problem to be solved is formulated as the provision of contact lenses with improved crease resistance.

4.4 Obviousness of the solution

It remains to be evaluated whether it was obvious to a skilled person wishing to improve the crease resistance of the contact lenses of D14, D16 or D16 to use a slow-reacting crosslinker in the hydrogel formulations (distinguishing feature (iii)).

4.4.1 The appellant formulated a different problem to be solved and did not explain why it would be obvious to use a slow-reacting crosslinker as defined in claim 1 in order to solve the above problem. In addition, it was argued that D17 suggested to combine a slow-reacting crosslinker with a fast-reacting crosslinker (see D17, tables 1 and 2). Similarly it would be obvious to replace the second crosslinker in D14 and D16 (respectively AMA and HEMAVC) by a slow-reacting crosslinker as defined in claim 1.

4.4.2 However, for the Board, the relevant question is not whether the skilled person could have carried out the invention, but whether s/he would have done so in the

expectation of solving the underlying technical problem (see Case Law, I.D.5, "Could-would approach").

In this respect, the Board agrees with the respondent that there was no suggestion in the prior art to use a slow-reacting crosslinker to solve the problem of providing contact lenses with improved crease resistance. In other words, even if distinguishing feature (iii) was known from the available prior art (such as D17), there was no incentive to use it in order to solve the underlying technical problem.

- 4.5 As distinguishing feature (iii) is not obvious, the subject-matter of claim 1 of auxiliary request 8 involves an inventive step over each of the documents D14, D16 and D17 as the closest prior art.
5. The appellant had no other objections against auxiliary request 8 (see page 3, fourth paragraph of the minutes). As all inventive step objections against auxiliary request 8 fail, the patent is to maintained on the basis on this request.

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 the claims of auxiliary request 8 filed with the rejoinder to the statement of grounds of appeal and after any necessary consequential amendments to the description.

The Registrar:

The Chairman:



D. Hampe

D. Semino

Decision electronically authenticated