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Datasheet for the decision of 26 March 2025

Case Number: T 0976/23 - 3.3.03

Application Number: 17822430.9

Publication Number: 3555696

IPC: G02C7/04, B29D11/00, G02C7/08

Language of the proceedings: EN

Title of invention:
CONTACT LENSES WITH INCORPORATED COMPONENTS

Patent Proprietor:
CooperVision International Limited

Opponent:
Alcon Inc.

Relevant legal provisions:
EPC Art. 56, 100(b), 112(1)(a)
RPBA 2020 Art. 12(1)(a), 12(2), 13(2)

Keyword:

Primary object of appeal proceedings to review decision - appeal case directed to facts on which decision was based (yes)
Referral to the Enlarged Board of Appeal - (no)
Grounds for opposition - insufficiency of disclosure (yes: main request, claim 8)
Auxiliary requests filed during the oral proceedings - admitted (yes)
Inventive step - (no: all auxiliary requests)

Decisions cited:

G 0001/12, T 0390/90, T 0939/92, T 1242/04, T 0713/14, T 1294/16, T 0494/18, T 1598/18, T 2091/18, T 2920/18, T 2988/18, T 0339/19, T 2295/19, T 0247/20, T 0499/20

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Case Number: T 0976/23 - 3.3.03

D E C I S I O N
of Technical Board of Appeal 3.3.03
of 26 March 2025

Appellant: (Opponent)	Alcon Inc. Rue Louis-d'Affry 6 1701 Fribourg (CH)
Representative:	Breuer, Markus Sendlinger Straße 29 80331 München (DE)
Respondent: (Patent Proprietor)	CooperVision International Limited Delta Park Concorde Way Segensworth North Fareham PO15 5RL (GB)
Representative:	Abel & Imray LLP Westpoint Building James Street West Bath BA1 2DA (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 3 March 2023 concerning maintenance of the European Patent No. 3555696 in amended form.**

Composition of the Board:

Chairman	D. Semino
Members:	O. Dury
	L. Basterreix

Summary of Facts and Submissions

I. The appeal of the opponent is against the interlocutory decision of the opposition division regarding maintenance of European Patent No. 3 555 696 in amended form on the basis of the claims of the main request filed with letter of 18 October 2021 and an adapted description.

II. The following documents were, among others, cited in the decision under appeal:

D6: S. Srinivasan, "Today's Contact Lens Materials and Designs", Review of Optometry, 15 August 2017
D18: Balafilcon A: Statement on a non-proprietary name adopted by the USAN council
D19: US 6 213 604 B1
D23: US 8 678 584 B2
D24: US 2015/0145155 A1
D26: US 8 874 182 B2
D30: Characteristic properties of Silicone Rubber Compounds, Shin-Etsu 2005.3/2020.3, March 2020
D31: Declaration (1) by R. Marullo, including Annexes A and B, dated 14 November 2022
D32: Declaration (2) by R. Marullo, including an Annex C, dated 14 November 2022
D33: Annex D containing a set of photographs, referred to in the last paragraph of D32

III. As far as relevant to the present case, the following conclusions were, among others, reached in the decision

under appeal:

- Documents D31 and D32 were admitted into the proceedings.

- Regarding sufficiency of disclosure, while the objections raised against claim 1 of the main request were rejected, the objection against claim 8, which was raised for the first time at the oral proceedings, was not admitted into the proceedings.

- The subject-matter of the claims of the main request involved an inventive step when document D26 was taken as the closest prior art.

Further considering that none of the other objections raised succeeded, the patent as amended on the basis of the main request was held to meet the requirements of the EPC.

IV. The opponent (appellant) appealed against the above decision.

V. With the rejoinder to the statement of grounds of appeal the patent proprietor (respondent) requested, among others, that the appeal be dismissed or, in the alternative, that the patent be maintained in amended from on the basis of any of the first to the twenty-first auxiliary requests filed with letter of 24 November 2022.

VI. The parties were summoned to oral proceedings and a communication pursuant to Article 15(1) RPBA indicating specific issues to be discussed at the oral proceedings

was then sent to the parties.

VII. With letter of 24 February 2025 the appellant, among others, requested that a question be referred to the Enlarged Board of Appeal.

VIII. Oral proceedings were held on 26 March 2025 in the presence of both parties.

IX. **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 appeal be dismissed and the patent be maintained according to the main request allowed by the opposition division (main request) or, alternatively, that the patent be maintained according to any of the first, second, third, tenth, eleventh and twelfth auxiliary requests filed during the oral proceedings before the Board.

X. Claims 1, 8 and 9 of the **main request** read as follows:

"1. A contact lens comprising:

a. a hydrogel lens body having a modulus (M); and

b. a non-expandable object having a surface energy (SE) embedded within the hydrogel lens body,

wherein the hydrogel of the hydrogel lens body is a silicone hydrogel;

the hydrogel lens body is formed from a polymerisable

composition comprising at least 10 wt% and up to 75 wt% hydrophilic N-vinyl amide-containing monomer that contains a single N-vinyl polymerizable group and no other polymerizable group,

the hydrogel lens body comprises an N-vinyl amide component, which is a polymer or copolymer of the hydrophilic N-vinyl amide-containing monomer; and

wherein the hydrogel lens body is characterized by a bonding factor, X, of 0.01 to 1.0,

wherein X is calculated using Equation I:

$$X=SE/(M*100) \quad (I)$$

wherein M is in units of megapascal (MPa) and is determined using the ANSI Z80.20 standard method described in Example 1 of the description, and SE is in units of millinewton per meter (mN/m) and is determined using the Owens-Wendt method as described in Example 2 of the description."

"8. The contact lens of any preceding claim, wherein the non-expandable object is located in a cavity within the hydrogel lens body."

"9. A method of manufacturing a contact lens, said method comprising:

a. contacting a non-expandable object having a surface energy (SE) with a polymerizable hydrogel composition comprising at least 10 wt% and up to 75 wt% of a hydrophilic N-vinyl amide-containing monomer that contains a single N-vinyl polymerizable group and no other polymerizable

group;

b. curing the polymerizable hydrogel composition and forming a hydrogel lens body having a modulus (M) with the non-expandable object embedded within the hydrogel lens body; and

c. washing the hydrogel lens body with a washing liquid to form a contact lens comprising a hydrated hydrogel lens body and a non-expandable object embedded within the washed hydrogel lens body,

wherein the hydrogel of the hydrogel lens body is a silicone hydrogel and the hydrogel lens body comprises an N-vinyl amide component, which is a polymer or copolymer of the hydrophilic N-vinyl amide-containing monomer,

and is characterized by a bonding factor, X, of 0.01 to 1.0,

wherein X is calculated using Equation I:

X=SE/(M*100) (I)

wherein M is in units of megapascal (MPa) and is determined using the ANSI Z80.20 standard method described in Example 1 of the description, and SE is in units of millinewton per meter (mN/m) and is determined using the Owens-Wendt method as described in Example 2 of the description."

XI. Claims 1 and 8 of the **first auxiliary request** filed during the oral proceedings before the Board were identical to claims 1 and 9, respectively, of the main

request.

XII. Claim 1 of the **second auxiliary request** filed during the oral proceedings before the Board differed from claim 1 of the first auxiliary request in that:

- The definition of the hydrogel lens body was modified as follows (additions in **bold**):

  "wherein the hydrogel of the hydrogel lens body is a silicone hydrogel; the hydrogel lens body is formed from a polymerisable composition comprising **a cross-linking agent and** at least 10 wt% and up to 75 wt% hydrophilic N-vinyl amide-containing monomer that contains a single N-vinyl polymerizable group and no other polymerizable group, the hydrogel lens body comprises an N-vinyl amide component, which is a polymer or copolymer of the hydrophilic N-vinyl amide-containing monomer";

- The upper limit of the range of the bonding factor X was amended to 0.75 (instead of 1.0).

XIII. Claim 1 of the **third auxiliary request** filed during the oral proceedings before the Board differed from claim 1 of the first auxiliary request in that the range of the bonding factor X was amended to "0.1 to 0.5" (instead of "0.01 to 1.0").

XIV. Claim 1 of the **tenth auxiliary request** filed during the oral proceedings before the Board differed from claim 1 of the first auxiliary request in that the definition of the hydrogel lens body was modified as follows (additions in **bold**; deletions in ~~strikethrough~~):

"wherein the hydrogel of the hydrogel lens body is a

silicone hydrogel; the hydrogel lens body is formed from a polymerisable composition comprising at least ~~10 wt%~~ **25 wt.%** and up to 75 wt.% of hydrophilic N-vinyl amide-containing monomer that contains a single N-vinyl polymerizable group and no other polymerizable group, **selected from N-vinyl-N-methyl acetamide (VMA), or N-vinyl pyrrolidone (NVP), or a combination thereof**; the hydrogel lens body comprises an N-vinyl amide component, which is a polymer or copolymer of the hydrophilic N-vinyl amide-containing monomer".

XV. Claim 1 of the **eleventh auxiliary request** filed during the oral proceedings before the Board combined the amendments made in the second and tenth auxiliary requests.

XVI. Claim 1 of the **twelfth auxiliary request** filed during the oral proceedings before the Board combined the amendments made in the third and tenth auxiliary requests.

XVII. The appellant's arguments, in so far as they are relevant to the present decision, may be derived from the reasons for the decision below. They are essentially as follows:

(a) Documents D31 to D33 were wrongly admitted into the proceedings by the opposition division and should not be admitted by the Board. Should the Board consider that it was not empowered to do so for the reasons indicated in the Board's communication, it was requested that the Board referred a question to the Enlarged Board of Appeal in this regard.

(b) The objection of lack of sufficiency against claim 8 of the main request that had been put

forward in the statement of grounds of appeal should be admitted into the proceedings.

(c) Claim 8 of the main request did not meet the requirements of sufficiency of disclosure.

(d) The first, second, third and tenth to twelfth auxiliary requests should not be admitted into the proceedings.

(e) The subject-matter of claim 1 of each of the first, second, third and tenth to twelfth auxiliary requests did not involve an inventive step when document D26 was taken as the closest prior art.

XVIII. The respondent's arguments, in so far as they are relevant to the present decision, may be derived from the reasons for the decision below. They are essentially as follows:

(a) Documents D31 to D33 should be admitted into the proceedings.

(b) The objection of lack of sufficiency against claim 8 of the main request that had been put forward in the statement of grounds of appeal should not be admitted into the proceedings.

(c) Claim 8 of the main request met the requirements of sufficiency of disclosure.

(d) The first, second, third and tenth to twelfth auxiliary requests should be admitted into the proceedings.

(e) The subject-matter of claim 1 of each of the first, second, third and tenth to twelfth auxiliary requests involved an inventive step when document D26 was taken as the closest prior art.

Reasons for the Decision

1. Admittance of documents D31 to D33 - Request for a Referral to the Enlarged Board of Appeal

1.1 The appellant requested that the decision of the opposition division to admit documents D31 to D33 into the proceedings be overturned.

1.1.1 In that regard, it is derivable from the last paragraph on page 1 of D32 that D33 is an annex which is referred to in D32, i.e. D33 makes part of D32. Therefore, although the admittance of D33 *per se* is not explicitly dealt with in the decision under appeal, the Board is satisfied that D33 was effectively admitted into the proceedings by the opposition division simultaneously with D32.

1.1.2 Regarding the admittance of D31 to D33, it was undisputed that these documents were all admitted into the proceedings by the opposition division and referred to in the decision under appeal. The Board sees no reason to be of a different opinion (reasons for the decision: points 19.1 and 21.2.3). In these circumstances, the Board is not aware of any provision of the EPC under which documents which were admitted to the proceedings by the opposition division and dealt with in the contested decision could be excluded from the proceedings at the appeal stage. In addition, it is

established Case Law that, since these documents make part of the proceedings, the Board is not empowered to exclude them - retroactively - from the proceedings (see Case Law of the Boards of Appeal of the EPO, 10th edition, 2022, V.A.3.4.4, in particular third and fourth paragraphs). Therefore, the Board must take into account these pieces of evidence and the submissions based thereon (Article 12(1)a) and 12(2) RPBA).

Request for a referral to the Enlarged Board of Appeal

1.2 Pursuant to Article 112(1)(a) EPC a Board of Appeal shall refer a question to the Enlarged Board of Appeal if it considers that a decision is required in order to ensure uniform application of the law or if a point of law of fundamental importance arises.

1.2.1 In the present case, the issue at stake was if a Board of appeal was empowered to retroactively exclude from the proceedings documents that had been admitted into the proceedings by the opposition division and dealt with in the decision under appeal. In this regard, the appellant disagreed with the view of the Board indicated in point 1.1.2 above (which was part of the Board's communication, see point 4.2.2) and considered that it could not be correct since it would mean that an essential part of the first instance decision would be exempt from any review by the Board (letter of 24 February 2025: point 2; oral proceedings before the Board). In addition, according to the appellant, since the admittance of the documents in question was part of the decision under appeal and the decision in this respect adversely affected the appellant, this part of the decision should be open to review by the Board (Article 106(1) EPC and Article 107, first sentence, EPC). Although the appellant acknowledged at the oral

proceedings before the Board that they were not aware of any Case Law diverging from the position of the Board indicated in point 1.1.2 above, they considered that the approach was contrary to the provisions of the EPC guaranteeing the right to appeal to any party adversely affected by a decision, which implied the right of having the decision overturned. Moreover, this issue was of fundamental importance which justified the request that the Board referred a question in this regard to the Enlarged Board of Appeal (letter of 24 February 2025: point 2; oral proceedings before the Board).

1.2.2 In this respect, a point of law of fundamental importance is present if the question is relevant for a substantial number of similar cases and is therefore of great interest not only to the parties to the specific appeal proceedings in question (G 1/12, point 11 of the reasons). The Board does not dispute that the question raised by the appellant could be relevant to a number of similar cases beyond the present one. However, even in such a case, the Board maintains a discretionary power to refer a question to the Enlarged Board of Appeal (cf. T 390/90: point 2.1 of the reasons).

1.2.3 In this context, one of the criteria to be considered by the Board is whether the question can be answered beyond all doubt by the Board itself (cf. T 1242/04: point 10.3 of the reasons). In the present case the issue addressed by the appellant was dealt with by the present Board by applying Article 12(1)(2) RPBA and following the application of the usual procedural principles to the facts of the case, in particular in view of the established jurisprudence (see passage of the Case Law mentioned at the end of point 1.1.2 above). Moreover, the Board considered that the

provisions of the RPBA and the established case law were not contrary to the provisions in the EPC concerning the right to appeal of any party adversely affected by a decision. Indeed, the lack of empowerment of the Board to exclude retroactively documents admitted to the proceedings does not imply that the decision adversely affecting the appellant (in the present case the decision that the patent as amended met the requirements of the EPC) may not be overturned by the Board (in the present case by revoking the patent).

1.2.4 In reaching its conclusion, the present Board also considered whether a referral in the present case would be needed because of a lack of uniform application of the law. However, in the present case, the appellant explicitly acknowledged during the oral proceedings before the Board - in reply to a question of the Chairman - that the issue at stake and proposed for referral did not concern a lack of uniform application of the law by the Boards. The Board sees no reason to be of a different opinion and even considers, to the contrary, that the jurisprudence considered above (see point 1.1.2) is fully consistent and the Board does not intend to deviate from it.

1.2.5 In these circumstances, the present Board made use of its discretion and decided that there was no need for a referral to the Enlarged Board of Appeal.

1.2.6 Since none of the conditions set by Article 112(1)(a) EPC is fulfilled, the request of the appellant to refer a question to the Enlarged Board of Appeal was rejected.

1.3 In view of the above, documents D31 to D33 are in the proceedings.

Main request

2. The operative main request is the main request dealt with in the decision under appeal that was allowed by the opposition division.

Objection of lack of sufficiency of disclosure against claim 8 of the main request - Admittance

3. The appellant requested that the decision of the opposition division not to admit the objection of lack of sufficiency of disclosure that had been raised against claim 8 of the main request for the first time at the oral proceedings before the opposition division be overturned. According to the appellant, the opposition division had wrongly exercised their discretion when they decided not to admit this objection and did not sufficiently took into account that this objection had been prompted by the data contained in D32, that had been filed by the patent proprietor about two months ahead of the oral proceedings and had been admitted into the proceedings at the oral proceedings (statement of grounds of appeal: point 7.4.2).

3.1 In this regard, independently of whether or not the opposition division used the right principles to take their decision, the fact that the opposition division did not admit a late-filed objection and did not exceed the proper limits of their discretion by not admitting it does, in principle, not prevent the Board from admitting such an objection, in particular if the

circumstances of the case may justify its admittance (Article 12(6) RPBA).

3.2 The appellant's objection of lack of sufficiency of disclosure raised against claim 8 of the main request was directed to the requirement defined therein that "the non-expandable object is located in a cavity within the hydrogel lens body" (this feature is hereinafter referred to as the "cavity feature"). In this regard, it is derivable from the parties' submissions that the main passage of the patent in suit that is directed to this cavity feature is paragraph 31 thereof (which was also referred to in points 17.4.4 and 17.4.5 of the reasons of the decision under appeal), which reads as follows:

"[0031] Selecting the hydrogel lens body and non-expandable object to provide a bonding factor of one or less, as described above, reduces the likelihood that shape distortion will occur upon hydration of the hydrogel, thereby providing distortion-free contact lenses. As used herein, the term "distortion-free" means that the hydrogel lens body is free of defects such as tears, is lens-shaped, and is not misshapen (i.e. the lens body has an appropriate lens shape with no wavy edges, curling, folding or surface indentations) as viewed from a contact lens dimension analyser (e.g. Optimec model JCF). In some examples, a washing liquid, such as an organic solvent that more rapidly hydrates the hydrogel, relative to the use of a washing liquid that consists essentially of water, results in more even swelling of the hydrogel lens body, which may assist in the production of distortion-free lens. As the hydrogel lens body swells during the hydration step, it may pull away from the non-expandable object thereby forming a space between the

object and the hydrogel such that the object is located in a cavity within the hydrogel lens body. The size of this cavity can depend on the percent swell of the lens material, where hydrogels having a higher percent swell tend to result in more space. In a packaged state, the space tends to fill with the packaging solution used to store the contact lens."

3.2.1 In the Board's view, the content of said paragraph 31 is very general and only indicates that the cavity feature may be obtained upon swelling of the hydrogel lens body. In this respect, it is noted that paragraph 20 of the patent in suit provides some additional information regarding the "percent swell" feature mentioned at the end of paragraph 31 and how it would be possible to control it. In the absence of any other information in the patent in suit regarding when/ how the cavity feature is obtained or not (in particular the examples are silent in this regard and paragraph 7 of the patent in suit only mentions that the cavity feature was met "in some examples", without further information), the Board considers that there were no reasons for the appellant to consider that the skilled person would have any difficulties to prepare a lens satisfying the cavity feature in view of the information provided in the patent in suit and, if necessary, common general knowledge. Therefore, the Board cannot conclude that the appellant should have raised an objection of lack of sufficiency of disclosure against the cavity feature which was in particular present in claim 8 as granted or in claim 8 of the main request filed with the rejoinder to the notice of opposition in view of the information provided in the patent in suit and, optionally, common general knowledge.

3.2.2 Together with the rejoinder to the notice of opposition, the respondent/patent proprietor filed among others a fifth auxiliary request, whose claim 1 corresponded to claim 8 as granted, i.e. it was *inter alia* defined by the "cavity feature". However, the respondent at this stage only argued that said claim 1 met the requirements of sufficiency of disclosure in view of the disclosure of paragraph 31 of the patent in suit and that the cavity feature helped to resolve the problems addressed by the patent in suit (rejoinder to the notice of opposition: points 7.2.1 and 7.4.2, regarding sufficiency and inventive step, respectively). The Board cannot recognise in these arguments any reasons that may have justified to raise an objection of lack of sufficiency of disclosure against the cavity feature in reaction to those submissions. As an aside, it is noted that this conclusion is in accordance with the preliminary opinion of the opposition division in respect of claim 1 of the fifth auxiliary request filed with the rejoinder to the notice of opposition that the cavity feature seemed to result from the swelling of the hydrogel lens body, that it did not appear to be correlated to any particular hydration technique or solution and that the patent in suit did not disclose any technical effect linked with this feature (preliminary opinion: point 10.4.2).

3.2.3 In view of the above, although the cavity feature was already present in claim 8 as granted the Board considers that there were no compelling reasons that may have justified that the appellant should have raised an objection of lack of sufficiency against this feature in view of the information provided in the patent in suit and/or of the line of defence of the patent proprietor/respondent in the rejoinder to the

notice of opposition. The same is valid for e.g. claim 8 of the main request or for claim 1 of the fifth auxiliary request, both filed with the rejoinder to the notice of opposition, i.e. at the outset of the opposition proceedings and whose subject-matter is *inter alia* defined by the cavity feature.

3.2.4 However, in reaction to the preliminary opinion of the opposition division, the respondent/patent proprietor filed document D32 with their letter of 24 November 2022. D32 is a declaration by one of the inventors of the patent in suit that contains additional information regarding the examples of the patent in suit.

a) It is in particular indicated in the table of Annex C of D32 which examples of the patent in suit effectively illustrate the cavity feature and which do not. As indicated by the appellant, in particular at the oral proceedings before the Board, the following results may be derived from the data of the patent in suit and the data reported in this table: although contact lenses B to D, G and H prepared in examples 3 and 4 of the patent in suit are according to claim 1 of the main request (i.e. they are lenses as defined in claim 8 of the main request, except for the cavity feature) and were *a priori* prepared according to the teaching of the patent in suit,

i) all but one of these contact lenses did not exhibit a cavity after the hydration step with water (table of Annex C: columns H2O, Cavity = "N");

ii) contact lenses B, G and H with polyimide film in addition did not exhibit a cavity after the hydration step with ethanol (table of Annex C: column Distortion

with PI/EtOH, Cavity = "N" or "I.D.").

b) In addition, the table of the Annex of D32 contains new information regarding the "percent swell" of the hydrogel used in the examples of the patent in suit (see the fifth column of the table of Annex C, whereby the meaning of this feature is given in paragraph 20 of the patent in suit). In this respect, the author of D32 indicated on page 1 of D32 (eighth and ninth paragraphs) that these data demonstrated a relationship between the presence of a cavity and whether or not the hydrogel lens body exhibited distortion (i.e. defects as indicated in paragraph 31 of the patent in suit).

c) In view of the above additional information provided in D32 regarding the examples of the patent in suit, the Board agrees with the appellant that the filing of D32 constitutes a late development of the present case shortly before the oral proceedings before the opposition division. In addition, the Board shares the appellant's view that although there were no reasons for them to file an objection of lack of sufficiency of disclosure related to the "cavity feature" before D32 was filed (for the reasons given in the precedent sections 3.2.1 to 3.2.3), it is understandable that the content of D32 and the submissions of the patent proprietor/respondent made in this regard can legitimately be held to have given rise to new concerns regarding the question whether the patent in suit provided sufficient information in order to prepare a lens according to claim 8 of the main request. In this regard, this conclusion is reached in view of the information provided in D32 regarding the absence of a cavity in some of the lenses prepared in the examples of the patent in suit that illustrate the teaching

thereof.

d) It is further pointed out that, since D32 was filed only about two months ahead of the oral proceedings before the opposition division, the opponent/appellant was left with little time to react during the opposition proceedings. This fact was also taken into account by the Board and was held to constitute an additional procedural circumstance that contributed to justify the filing of an objection of lack of sufficiency of disclosure at the outset of the appeal proceedings.

3.2.5 In view of the above, the Board considers that the filing of an objection of lack of sufficiency of disclosure against claim 8 of the main request (again) with the statement of grounds of appeal was prompted by the filing of D32 only about two months ahead of the oral proceedings before the oral proceedings before the opposition division. Therefore, in view of these specific circumstances of the present case and independently of whether the opposition division exercised its discretion in a reasonable way, the Board decided to make use of its discretion in order to admit the objection of lack of sufficiency of disclosure that was put forward by the appellant against claim 8 of the main request in the statement of grounds of appeal (Article 12(6) RPBA).

3.2.6 The respondent put forward that the appellant's argument that the objection of lack of sufficiency of disclosure raised against claim 8 of the main request had been prompted by D32 was doubtful because it had been raised for the first time in appeal (rejoinder: page 7, second full paragraph; page 14, end of first paragraph regarding claim 8 of the main request).

In this regard, the Board took into account that D32 was filed only about two months ahead of the oral proceedings before the opposition division, which effectively left little time to the opponent/appellant to react. Therefore, although the Board agrees that the appellant could have raised earlier the objection put forward in the statement of grounds of appeal, the circumstances of the case do not justify to conclude that they should have done so. Rather, in view of the short period of time left between the filing of D32 and the patent proprietor's submissions based thereon and the date on which the oral proceedings were held, the submission of the objection of lack of sufficiency of disclosure at the outset of the appeal proceedings is considered to be the result of normal developments in appeal opposition proceedings, i.e. it constitutes a legitimate and timely reaction to the decision under appeal. The Board further considers that the same conclusion is valid regarding the respondent's view that the argument should have been filed in writing in advance of the oral proceedings before the opposition division and/or that the appellant should have requested a postponement of the oral proceedings. For these reasons, the respondent's arguments did not convince.

3.3 For these reasons, the objection of lack of sufficiency of disclosure against claim 8 of the main request filed with the statement of grounds of appeal was admitted into the proceedings (Article 12(6) RPBA).

Sufficiency of disclosure - Claim 8 of the main request

4. In order to meet the requirements of sufficiency of disclosure, an invention has to be disclosed in a

manner sufficiently clear and complete for it to be carried out by the skilled person, without undue burden, on the basis of the information provided in the patent specification, if needed in combination with the skilled person's common general knowledge. This means in the present case that the skilled person should in particular be able to prepare a contact lens according to claim 8 of the main request, which was contested by the appellant.

4.1 As indicated above, the appellant's objection was that the patent in suit, even if complemented by common general knowledge, did not provide sufficient information in order to prepare, with a good chance of success, a contact lens that exhibited a cavity as defined in claim 8 of the main request.

4.2 In that regard, claim 8 is dependent on claim 1 of the main request and only differs therefrom in that the contact lens being claimed is further defined by the cavity feature, i.e. apart from the cavity feature, the contact lenses are defined in the same manner in both claims.

4.3 It was common ground that while the contact lenses B to D, G and H prepared in examples 3 and 4 of the patent in suit were according to claim 1 of the main request, this was not the case for examples A, E and F (as summarised in the table of Annex C of D32: i) none of the two embodiments of example A meets the requirement in terms of the bonding factor X and ii) the embodiments of examples E and F are carried out with a silicon hydrogel that does not contain a N-vinyl amide-containing monomer). However, although the contact lenses B, G and H are according to claim 1 of the main request and were prepared according to the teaching of

the patent in suit, it is indicated in the table of Annex C of D32 (last column: see also the statements made in the seventh paragraph on page 1 of D32) that they do not satisfy the requirement in terms of the cavity feature defined in claim 8 of the main request (which is dependent on claim 1). Therefore, the information provided for examples B, G and H in the patent in suit and in D32 show that a cavity according to claim 8 of the main request is not obtained, although the contact lenses have been prepared in accordance with the teaching of the patent in suit.

4.4 At the oral proceedings before the Board, the respondent argued that it was derivable from paragraphs 4, 8 and 31 of the patent in suit that the formation of a cavity resulted from the control of the swelling step of the preparation process of a lens, whereby the idea underlying the patent in suit was to decrease the physical interactions between the non-expandable object and the hydrogel composition upon swelling. This was achieved by controlling the modulus of the lens and/or the surface energy of the non-expandable object, i.e. by controlling the bonding factor X as defined in claims 1 and 8 of the main request (see paragraph 8 of the patent in suit) together with the swelling of the hydrogel (as indicated at the end of paragraph 31 of the patent in suit). According to the respondent, the additional information contained in D32 regarding the presence or not of a cavity and the "percent swell" (that were not reported in the patent in suit) merely confirmed what was derivable from paragraphs 4, 8 and 31 of the patent in suit, namely that, in order to obtain a cavity, a low bonding factor X together with high swell properties were required.

4.4.1 However, it is derivable from the table in Annex C of D32 that the lenses prepared in examples B, G and H of the patent in suit with a polyimide film as a non-expandable object all satisfy the requirements in terms of the bonding factor X specified in claims 1 and 8 of the main request. In addition, also the "percent swell" of these examples is rather high (see column "Swell (%)" of the table of Annex C of D32) and are in accordance with the disclosure of paragraph 20 of the patent in suit in this respect, i.e. these examples are according to the teaching of paragraph 31 of the patent in suit. However, the "percent swell" of lenses B, G and H (for which no cavity is formed with a polyimide film) is higher than the one of lenses C and D (for which a cavity is formed with a polyimide film), which is not in accordance with the indication in paragraph 31 of the patent in suit that higher percent swell tends to result in more space. For these reasons, the respondent's arguments did not convince as they do not allow to elucidate why the lenses prepared in examples B, G and H of the patent in suit with a polyimide film did not exhibit a cavity although they were prepared following the teaching of the patent in suit. In particular, it was neither shown, nor explained, what would have to be modified in the preparation process of these contact lenses in order to obtain a cavity as defined in claim 8 of the main request. It is further noted that it was also not shown that such measures were known in the art.

4.5 In view of the above, the Board considers that the patent in suit does not provide sufficient information on how to proceed in order to prepare, in a reliable way, a contact lens "wherein the non-expandable object is located in a cavity within the hydrogel lens body" as specified in claim 8 of the main request. In these

circumstances, the skilled person wanting to prepare a contact lens according to claim 8 is left with the task of performing an elaborate program in order to find out under which conditions a cavity can be reliably obtained and can only establish by trial and error how to obtain a cavity according to claim 8 of the main request, which amounts to an undue burden.

4.6 For these reasons, claim 8 of the main request does not satisfy the requirements of sufficiency of disclosure and the main request as a whole is not allowable (Article 100(b) EPC).

First auxiliary request - Admittance

5. Admittance pursuant to Article 13(2) RPBA

5.1 The operative first auxiliary request is the first auxiliary request filed during the oral proceedings before the Board. Therefore, its admittance into the proceedings is governed by Article 13(2) RPBA, according to which any amendment to a party's appeal case is, in principle, not taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

5.2 The Board concurs with the approach taken in several decisions (T 247/20, point 1.3 of the Reasons; T 2988/18, point 1.2 of the Reasons; T 2920/18, point 3.4 of the Reasons) that the examination under Article 13(2) RPBA is carried out in two steps. The first question to be answered is whether the submission objected to is an amendment to a party's appeal case (first step). If that question is answered in the negative, then the Board has no discretion not to take the submission into account. If, however, that question

is answered in the affirmative, then the Board needs to decide whether there are exceptional circumstances, justified by cogent reasons (second step).

5.2.1 Regarding the first step, it was common ground that the first auxiliary request only differed from the main request in that all claims of the main request that were directed to the cavity feature were deleted and the remaining claims renumbered accordingly (i.e. claims 8 and 15 of the main request were deleted).

In the present case, it was not argued by any of the parties that the first auxiliary request did not constitute an amendment to the respondent's case. In that regard, the Board endorses the line of case law set out e.g. in decisions T 713/14 (reasons: points 4.2 and 4.3), T 494/18 (reasons: point 1.4), T 2091/18 (reasons: points 4.1 and 4.2), T 2920/18 (reasons: point 3.6) or T 2295/19 (reasons: point 3.4), which likewise concerned deletions of claims or of alternatives embodiments within claims, and regarded them as amendments.

5.2.2 Therefore it remains to be assessed if there are exceptional circumstances, supported by cogent reasons, which justify the admittance of the first auxiliary request into the appeal proceedings.

a) In this regard, the amendments carried out in the main request in order to arrive at the first auxiliary request were undoubtedly made in view of the decision reached by the Board during the oral proceedings that the subject-matter of claim 8 of the main request lacked sufficiency of disclosure in view of its feature "wherein the non-expandable object is located in a cavity within the hydrogel lens body", i.e. the first

auxiliary request was filed in order to overcome this objection.

b) It was undisputed that the (successful) objection of lack of sufficiency of disclosure against claim 8 of the main request had been filed and pursued by the appellant since the outset of the appeal proceedings. Therefore, the Board agrees with the appellant's position during the oral proceedings before the Board that the filing of a set of claims according to the first auxiliary request, i.e. corresponding to the one of the main request in which claims 8 and 15 were deleted, would already have been possible and reasonable earlier in the proceedings, e.g. with the rejoinder to the statement of grounds of appeal.

c) However, in similar cases, some Boards have acknowledged exceptional circumstances when the admittance of the amendments was neither detrimental to procedural economy, nor to the convergent approach laid down in the RPBA, nor to the legitimate interests of a party to the proceedings. This specific procedural situation was considered an "exceptional circumstance" within the meaning of Article 13(2) RPBA, see e.g. T 1598/18 (reasons: point 25.1), T 1294/16 (reasons: points 18.3 and 19), T 339/19 (reasons: point 1.5), T 2920/18 (reasons: points 3.13 to 3.15), T 2295/19 (reasons: points 3.4.12 to 3.4.14), T 499/20 (reasons: point 7.3.3). The present Board agrees with this approach and finds it applicable to the present case for the following reasons:

Considering that the first auxiliary request only contains claims that were present in the main request allowed by the opposition division and that was defended by the respondent since the beginning of the

appeal proceedings, the Board is satisfied that the convergent approach laid down in the RPBA (see explanatory remarks to Article 12 and 13 RPBA and e.g. T 1294/16, point 18.3 of the reasons) and the need for procedural economy are respected. In particular, the admittance of the first auxiliary request neither alters the factual or legal framework of the proceedings, nor compromises the procedural rights of the appellant. In addition, the Board is satisfied that admitting the first auxiliary request into the proceedings does not complicate the case since all the claims of the first auxiliary request were already part of the main request. Therefore, the first auxiliary request cannot take the appellant by surprise, nor requires that new objections/issues have to be addressed for the first time at the oral proceedings before the Board. In particular, the Board does not share the view of the appellant that the conclusion reached on sufficiency of disclosure for claim 8 of the main request may impact and complicate the assessment of the inventive step of the claims of the first auxiliary request. Indeed, considering that (for instance) the subject-matter of claim 1 of the main request is identical to the one of claim 1 of the first auxiliary request and the facts in hand remain the same, the assessment of the probative value of the arguments of the parties remains the same.

5.2.3 In addition, the Board also took into account that, in the present case, the respondent was confronted with a negative opinion regarding sufficiency of disclosure of claim 8 of the main request for the first time at the oral proceedings before the Board. Indeed, the objection raised in this respect was not admitted into the proceedings by the opposition division and the preliminary opinion of the Board regarding the

admittance of the objection raised in this respect by the appellant in the statement of grounds of appeal was in their favour. Therefore, also this development of the proceedings is considered by the Board to constitute an exceptional circumstance which justifies that the respondent be given a possibility to react, as a matter of fairness.

5.2.4 For these reasons, in view of the exceptional circumstances of the present case, the Board made use of its discretion in order to admit into the proceedings the first auxiliary request filed during the oral proceedings before the Board (Article 13(2) RPBA).

First auxiliary request - Inventive step

6. In the present decision, the denomination of the features of claim 1 of the first auxiliary request is the same as the one indicated in point 10 of the section Facts and Submissions of the decision under appeal (as was done by the parties). The list of features is as follows:

(1A) A contact lens comprising:

(1B) a. a hydrogel lens body having a modulus (M); and

(1C) b. a non-expandable object having a surface energy (SE)

(1D) embedded within the hydrogel lens body,

(1E) wherein the hydrogel of the hydrogel lens body is a silicone hydrogel;

(1F) the hydrogel lens body is formed from a polymerisable composition comprising at least 10 wt% and up to 75 wt% hydrophilic N-vinyl amide containing monomer that contains a single N-vinyl polymerizable group and no other polymerizable group,

(1G) the hydrogel lens body comprises an N-vinyl amide component, which is a polymer or copolymer of the hydrophilic N-vinyl amide-containing monomer; and wherein the hydrogel lens body is

(1H) characterized by a bonding factor, X, of 0.01 to 1.0, wherein X is calculated using Equation I:

$$X=SE/(M*100) \qquad (I)$$

(1H1) wherein M is in units of megapascal (MPa) and is determined using the ANSI Z80.20 standard method described in Example 1 of the description, and

(1H2) SE is in units of millinewton per meter (mN/m) and is determined using the Owens-Wendt method as described in Example 2 of the description.

7. Inventive step

7.1 Closest prior art

The appellant argued that claim 1 of the first auxiliary request did not involve an inventive step when document D26 was taken as the closest prior art. In that regard, it was not (further) disputed by the respondent that D26 was a suitable starting point. Also the Board has no reason to be of a different opinion, in particular for the reason already indicated by the opposition division (point 21.2.10 of the reasons).

7.2 Distinguishing features

7.2.1 Claim 1 of D26 is directed to an eye-mountable device comprising an encapsulated electronics structure at least partially embedded in a transparent polymeric material, whereby the encapsulation material is a bio-compatible material. According to the whole disclosure of D26, there is no doubt that the eye-mountable device according to D26 is in fact a contact lens (see e.g. figures 2A-2C; column 3, lines 15-17). Specific embodiments of D26 are directed to eye-mountable devices in which the electronics structure is fully enclosed in an annealed layer of a bio-compatible material, i.e. in which the electronics structure is according to figure 5F (see also D26: column 4, lines 36-37; column 22, lines 12-34; column 24, lines 23-33). The embodiments of D26 directed to an eye-mountable device comprising such a fully enclosed electronics structure constitute a particularly relevant starting point for the assessment of inventive step. This view was indicated in the Board's communication (points 9.2.1 and 9.2.2) and remained undisputed, in particular at the oral proceedings before the Board.

7.2.2 As indicated in the decision under appeal (reasons: section 21.2.1, first paragraph), considering that any encapsulating material implicitly has a surface energy, the Board is satisfied that an eye-mountable device comprising a fully encapsulated electronics structure according to D26 is an embodiment according to features 1A, 1C and 1D as defined in point 6 above.

7.2.3 It is further agreed with the opposition division that although D26 discloses that the transparent polymeric material may be a hydrogel, in particular hydrogel

materials employed for ophthalmic contact lenses such as silicon hydrogels, the disclosure of D26 in that regard is not limited to such silicon hydrogels (D26: column 5, lines 30-33; column 12, lines 26-31). In addition, D26 does not disclose any information regarding the nature of these silicon hydrogels. Also, various suitable bio-compatible materials for encapsulating the electronics structure are disclosed in D26, such as parylene C (dichlorodi-p-xylylene), polyethylene terephthalate, polydimethylsiloxane or other silicone elastomers (D26: column 4, lines 37-39; column 18, line 62 to column 19, line 1). However, as pointed out by the opposition division, D26 does not disclose any specific example of realisation of such an eye-mountable device, in particular of any specific combination of transparent polymeric material and bio-compatible material. Under these circumstances, the Board shares the view of the opposition division that D26 does not directly and unambiguously disclose the specific combination of features 1A to 1E and 1H as defined in section 6 above (decision under appeal: page 10, penultimate paragraph).

7.2.4 In addition, it remained undisputed between the parties that D26 does not disclose the specific requirements of claim 1 regarding the nature of the silicone hydrogel according to features 1F and 1G as defined in point 6 above.

7.2.5 In the statement of grounds of appeal (section 9.5.1), the appellant considered that D26 disclosed that parylene and silicone hydrogels would be a preferred combination of materials to be used. However, for the reasons indicated in point 7.2.3 above, the Board does not share that view. In addition, it is noted that the bonding factors calculated by the appellant at the top

of page 41 of the statement of grounds of appeal are based on specific selections of materials which were not shown to be directly and unambiguously disclosed in D26. Therefore, these arguments did not convince.

7.3 Problem effectively solved over the closest prior art

7.3.1 The parties disagreed how the problem effectively solved is to be formulated.

a) The respondent put forward in writing that the problem solved over D26 resided in the provision of a lens and embedded object combination capable of surviving (without distortion) at least one type of extraction and hydration (E&H) process (rejoinder: bottom of page 18 to middle of page 19; see also page 21, second paragraph). At the oral proceedings before the Board, the respondent pointed out that the E&H process disclosed in the patent in suit was in fact a two-step process, in which the dry lens bodies prepared by curing were in a first step hydrated with water and then inspected for distortion and in a second - subsequent - step the lenses were swelled in ethanol with a final treatment with water and inspection for distortion (patent in suit: page 7, line 57 to page 8, line 4 and page 8, lines 32-33). During the oral proceedings, the respondent then argued that the problem solved over D26 was to provide a contact lens that could be extracted and hydrated without distortion in one or both washes according to the patent in suit.

For both problems relied upon, the respondent further considered that the examples of the patent in suit showed that these problems were indeed solved: in particular, lenses A, E and F as prepared in examples 3 and 4 of the patent in suit were comparative examples

that showed that the above problems were not solved if the specific requirements in terms of bonding factor X (lens A) and nature of the silicone hydrogel (lenses E-F) specified in claim 1 of the first auxiliary request were not met. To the contrary, lenses B to D, G and H showed that lenses according to claim 1 of the first auxiliary request solved the problems posed, so the respondent. At the oral proceedings before the Board, the respondent further argued that although lenses G and H prepared with a polyimide film as non-expandable object were unsatisfactory after the second wash with ethanol, they were satisfactory after the first wash with water (see table 2 of the patent in suit, last two columns). For these lenses, the examples of the patent in suit showed that a single water wash was enough, i.e. the second wash with ethanol was not required.

b) To the contrary, the appellant argued that examples 3 and 4 of the patent in suit were not representative of the closest prior art and that the patent in suit contained no relevant comparative data. In this regard, the appellant in particular pointed out that claim 1 of the first auxiliary request was directed to a contact lens in its hydrated state and not to a material for making a contact lens. Therefore, claim 1 of the first auxiliary request was directed to a lens that had been subjected to (a) washing step(s) either with water and/or with ethanol and the examples of the patent in suit showed that several of these contact lenses did not solve the problem of distortion relied upon by the respondent (statement of grounds of appeal: page 37, fourth full paragraph to page 38, first paragraph; letter of 24 February 2025: sections 7.3.2 to 7.3.5, see in particular the first paragraph of section 7.3.5; oral proceedings before the Board). In these circumstances, according to the

appellant, no improvement over the closest prior art had been demonstrated and the problem solved over D26 resided in the provision of (arbitrary) silicone hydrogel materials for the preparation of contact lenses including the encapsulated electronics, such as encapsulated in parylene (statement of grounds of appeal: sections 9.5.2 and 9.5.3; letter of 24 February 2025: point 7.4) or, in other words, to the provision of a mere alternative polymeric material for a contact lens body (oral proceedings before the Board).

7.3.2 In view of the parties' submissions, a decisive point for the definition of the technical problem solved over D26 is whether or not the examples of the patent in suit allow to make a comparison between a contact lens that is according to claim 1 of the first auxiliary request with a contact lens that is not (but which is illustrative of the teaching of D26), i.e. if these examples are suitable to demonstrate that a technical effect is achieved in relation to the distinguishing features identified above.

a) In this respect, operative claim 1 is directed to a contact lens which is among others defined in that it comprises a hydrogel lens body which is a silicone hydrogel and a non-expandable object embedded therein.

b) As explained in paragraph 4 of the patent in suit (which is directed to background prior art), hydrogel contact lenses are typically made by a cast molding process in which a polymerizable composition is dispensed into a contact lens mold and subjected to curing conditions. The resulting lens is removed from the mold and hydrated to form a hydrogel (which typically comprises from about 20% to 70% water by

weight), whereby the lens may swell appreciably in size during the hydration process. Also, as indicated in paragraphs 3 and 4 of the patent in suit, a non-expandable component such as an electronic device may be incorporated into the bulk of the lens during the curing step, which may however leads to disadvantages in terms of distortion during the hydration step.

c) Such a preparation process of a contact lens is also used in the examples of the patent in suit. In example 3, silicone hydrogel formulations A to D were prepared and dispensed into a mould and a non-expandable object (either a polyimide film or a parylene film) was positioned within the dispensed compositions such that upon curing the films were completely embedded within the lens body (patent in suit: page 7, lines 43-54). After curing, the dry lens bodies so prepared were hydrated with water and then inspected for distortion and subsequently swelled in ethanol with a final treatment with water and inspection for distortion (patent in suit: page 7, line 55 to page 8, line 4). A similar procedure was used in example 4 in order to prepare lenses E to H (paragraph 40 of the patent in suit). In view of this, the Board agrees with the appellant that the subject-matter of claim 1 of the first auxiliary request surely encompasses hydrated contact lenses according to the understanding of the skilled person working in the present technical field, which is perfectly in accordance with the disclosure of the patent in suit. Indeed, in the patent in suit, the same distinction is made between the (dry) lens body that is obtained directly after curing and the (hydrated) contact lens. This is not only derivable from the preparation process described in relation with examples 3 and 4 of the patent in suit (see passages indicated above), but this

is also reflected by the method claim 8 of the first auxiliary request according to which a hydrogel lens body is prepared upon curing (steps a-b) and then washed to form a contact lens (step c). The same conclusion is reached when considering paragraphs 27-29 of the patent in suit, which are directed to the (dry) hydrogel lens body (up to and including the washing step(s)) and paragraph 32 of the patent in suit, which is directed to the (hydrated) contact lens after washing (which is addressed in paragraphs 30 and 31 of the patent in suit). In this respect, the Board points out that, while it may be doubtful if the subject-matter of claim 1 of the first auxiliary request also covers the (dry) hydrogel lens body (i.e. the intermediate product obtained directly after curing but before the hydration step), which was the position of the respondent, this question can remain unanswered as it is not relevant to the present decision.

d) In view of this, it is agreed with the appellant that claim 1 of the first auxiliary request encompasses in particular any of the hydrated lenses B to D, G and H prepared in examples 3 and 4 of the patent in suit, for which it was undisputed that they satisfied all the requirements specified in claim 1 of the first auxiliary request. As a consequence, claim 1 of the first auxiliary request encompasses both contact lenses that exhibit distortion after the first hydration with water (e.g. lenses B to D, G and H with a parylene film or lenses B and C with a polyimide film) and lenses which cannot be rendered satisfactory in terms of distortion by a further hydration treatment with ethanol (lenses G and H with a polyimide film). In these circumstances, it is agreed with the appellant that the examples of the patent in suit cannot demonstrate that the effect relied upon by the

respondent is effectively solved over the whole breadth of the claim. Indeed, the effects mentioned by the respondent could at most be relevant for the (dry) hydrogel lens body, i.e the intermediate product directly obtained upon curing, but not for the (hydrated) contact lenses that are covered by claim 1 of the first auxiliary request.

7.3.3 In view of the above, even if the examples of the patent in suit are relied upon, they are not suitable to demonstrate that the problem contemplated by the respondent is effectively solved. In these circumstances, there is no need to address the additional objections of the appellant that the examples of the patent in suit could not be relied upon because they were not illustrative of the teaching of D26 (statement of grounds of appeal: point 9.5.2). For the same reasons, there is also no need to address in the present decision the question of the alleged lack of reproducibility of these examples (statement of grounds of appeal: section 7.2, in respect of sufficiency of disclosure).

7.3.4 In view of the above, the Board considers that the problem effectively solved over D26 resides in the provision of another contact lens that comprises an embedded object in alternative to the eye-mountable device comprising a fully encapsulated electronics structure.

7.4 Obviousness

7.4.1 The question remains to be answered if the skilled person, desiring to solve the problem(s) identified as indicated above, would, in view of the closest prior art, possibly in combination with other prior art or

with common general knowledge, have modified the disclosure of the closest prior art in such a way as to arrive at the claimed subject matter.

7.4.2 In the present case, the question has to be answered whether it was obvious to solve the problem indicated in point 7.3.4 above by selecting a material for the lens body and for an encapsulated electronics structure so as to arrive at the subject-matter of claim 1 of the first auxiliary request. In doing so, it has in particular to be taken into account that:

- The disclosure of D26 is very general regarding the nature of the transparent material (that may correspond to the hydrogel lens body according to claim 1 of the main request) and the bio-compatible material (that may correspond to the materials to be considered for the determination of the surface energy SE of the non-expandable object according to claim 1 of the main request) to be used. Also, it was not shown that D26 provides any specific guidance regarding the specific combination of materials to be used;

- The problem to be solved over D26 resides in the provision of a mere alternative to the eye-mountable device comprising a fully encapsulated electronics structure.

Suitable material for the lens body according to D26

7.4.3 In order to prepare an eye optical device according to D26, it is disclosed therein that the transparent polymeric material that can be used to prepare the lens body is a biocompatible material similar to those employed to form vision correction and/or cosmetic

contact lenses in optometry, such as polyethylene terephthalate ("PET"), polymethyl methacrylate ("PMMA"), polyhydroxyethylmethacrylate ("polyHEMA"), silicone hydrogels and combinations of these (D26: column 12, lines 26-31). Therefore, as pointed out by the appellant (statement of grounds of appeal: section 9.5.4, second paragraph), D26 explicitly discloses that silicone hydrogels may be used as the lens body. In addition, the Board notes that silicon hydrogels are disclosed as the product of choice for making contact lenses in paragraph 3 of the patent in suit, which describes the prior art. Therefore, the choice of silicon hydrogels within the alternative materials disclosed in D26 in order to solve the problem posed is obvious.

In addition, the appellant's view (statement of grounds of appeal: section 9.5.4: third and fifth paragraphs) that it is known in the art that such silicon hydrogel materials are commercially available as products balafilcon A, stenfilcon A, enfilcon A and comfilcon A (D6: table 1 on page 2; D18: chemical formula; D19: table 1 in combination with column 12, lines 45-46; see also the description of these products on pages 23 to 27 of the statement of grounds of appeal, which was not refuted by the respondent) was not contested. In view of the above, it is concluded that although silicon hydrogels known as balafilcon A, stenfilcon A, enfilcon A and comfilcon A are not specifically disclosed in D26, they are nevertheless products covered by the generic term "silicone hydrogels" according to the general teaching of D26.

Suitable encapsulated electronics structures according to D26

7.4.4 Regarding the encapsulated electronics structures, it is disclosed in D26 that materials such as parylene C (e.g. dichlorodi-p-xylylene), polyethylene terephthalate (PET) or polydimethylsiloxane (PDMS) and other silicone elastomers may be used for the encapsulation of the electronics structures (D26: column 18, line 62 to column 19, line 4). In addition, parylene C is disclosed specifically e.g. in the description of a fully encapsulated electronic structure (D26: column 4, lines 36-41), whereby it is further indicated that it requires lower annealing temperatures than PET or PDMS (D26: column 5, lines 12-23). Parylene C is further the object of dependent claim 5 of D26. In these circumstances, it is agreed with the appellant that D26 discloses parylene C as a preferred embodiment among all the suitable alternatives described therein for encapsulating the electronic structure.

Combination of a suitable silicone hydrogel and encapsulation material within the ambit of D26 in order to arrive at the subject-matter of operative claim 1

7.4.5 In order to arrive at the subject-matter of claim 1 of the first auxiliary request, the appellant's objection was based on the combination of a silicone hydrogel such as balafilcon A, stenfilcon A, enfilcon A and comfilcon A for the lens body with parylene C for encapsulating the electronic structure.

Materials for the lens body according to D26 and defined by operative claim 1

a) In that respect, the appellant's view that balafilcon A, stenfilcon A, enfilcon A and comfilcon A were all silicone hydrogels according to claim 1 of the

first auxiliary request (statement of grounds of appeal, in respect of novelty of claim 1 of the main request, which is identical to claim 1 of the first auxiliary request: page 29, sixth paragraph; page 23, first line to bottom of page 26; page 42, third and second paragraphs from the bottom) was not contested by the respondent (see e.g. rejoinder: page 14, second paragraph to page 16, third paragraph: to counter the appellant's objections regarding lack of novelty, the respondent never argued that balafilcon A, stenfilcon A, enfilcon A and comfilcon A were not silicone hydrogels according to claim 1 but rather argued that novelty was given for other reasons; pages 21-22: section regarding obviousness of the solution), in particular at the oral proceedings before the Board.

In addition, it was not contested by the respondent that, as put forward by the appellant, balafilcon A, stenfilcon A, enfilcon A and comfilcon A have a Young's modulus (M) of 1.1 MPa, 0.4 MPa, 0.5 MPa and 0.75 MPa, respectively (statement of grounds of appeal: page 42, section 9.5.4, third paragraph; page 27, second, fourth, and sixth paragraphs).

Encapsulation materials according to D26 and defined by operative claim 1

b) The appellant argued that, as indicated in paragraph 38 of the patent in suit, parylene C according to D26 had a surface energy of 32 mN/m (statement of grounds of appeal: page 32, second paragraph; upper table on page 34; page 41, first line).

In that regard, the respondent put forward that the value of surface energy of 32 mN/m for parylene

indicated in the patent in suit was only valid for neat (i.e. untreated) parylene. However, according to the respondent, the disclosure of D26 should be read having in mind the then accepted knowledge of the skilled person that when plastic materials were embedded within hydrogel lenses, the plastics were if necessary modified to match the properties of the lens material to ensure greater adhesion. This was derivable e.g. from paragraphs 5, 28 and 64 as well as from table 1 of D24 or from the passage at column 19, lines 42-44 of D23. Therefore, should the skilled person contemplate an embodiment of D26 in which an object encapsulated with parylene was fully embedded in a silicone hydrogel, the skilled person would understand that the (neat) parylene material which had a low surface energy of 32 mN/m would have had to be surface treated in order for it to match the properties of the silicone hydrogel that was known to have a high surface energy. In any case, it could not be excluded that the parylene that was to be used in D26 had to be surface treated. Therefore, according to the respondent, the value of surface energy of 32 mN/m disclosed in the patent in suit for parylene was not valid for the embodiments of D26 comprising the use of parylene as encapsulating material contemplated by the appellant (rejoinder: page 17, last full paragraph to page 18, second full paragraph; paragraph bridging pages 21-22; oral proceedings before the Board).

However, in the absence of any indication in D26 of a surface treatment of the encapsulating material, the respondent's considerations are speculative and, therefore, did not convince. For that reason, the Board considers that there is no reason to consider that parylene C as disclosed in D26 has a surface energy, which is a property of a material *per se*, different

from the one indicated in paragraph 38 of the patent in suit, namely 32 mN/m.

Bonding factor X

c) In view of the above, a contact lens comprising a fully encapsulated electronics structure according to D26, made with balafilcon A, stenfilcon A, enfilcon A or comfilcon A as silicon hydrogel and parylene C as the encapsulating material of the electronic component exhibits a bonding factor X as defined in claim 1 of the first auxiliary request of 0.29 (= 32/(100*1.1)), 0.80 (= 32/(100*0.4)), 0.64 (= 32/(100*0.5)) and 0.43 (= 32/(100*0.75)), respectively, i.e. a bonding factor within the range of 0.01 to 1.0 specified in claim 1 of the first auxiliary request.

No need of a pointer to the specific combination of materials comprised within the ambit of D26

7.4.6 At the oral proceedings before the Board, the respondent put forward that in the absence of any indication in D26 or in any of the prior art documents cited in the proceedings to the specific combination of balafilcon A, stenfilcon A, enfilcon A or comfilcon A as silicon hydrogel with parylene C for the encapsulating material, the objection of the appellant was based on hindsight, which was not allowable.

a) However, since the problem to be solved is to provide a mere alternative to the eye-mountable device comprising a fully encapsulated electronics structure according to D26, there is no need for a pointer in the prior art to the specific combination of any of balafilcon A, stenfilcon A, enfilcon A or comfilcon A with parylene C that are all known materials within the

ambit of D26. In the present case, since the problem to be solved resides in the provision of a mere alternative, no suggestion in the prior art is needed in order to render the subject-matter claimed obvious. Rather, it is sufficient to show that the missing (distinguishing) features constitute an arbitrary selection within a host of available alternatives. Indeed, the established decisive principle governing the answer to the question as to what a person skilled in the art would have done depends on the result they wished to obtain (T 939/92, point 2.5.3 of the reasons). In the present case, the problem posed can be obviously solved using any silicone hydrogel for the lens body together with any encapsulating material for the electronic material that are within the ambit of D26, including the components indicated in points 7.4.3 and 7.4.4 above. Also, as outlined above, by choosing balafilcon A, stenfilcon A, enfilcon A or comfilcon A as silicone hydrogel and parylene C as encapsulating material, one arrives at the subject-matter of claim 1 of the first auxiliary request.

b) In addition, although it is correct that balafilcon A, stenfilcon A, enfilcon A and comfilcon A are not explicitly disclosed in D26 (as argued by the respondent during the oral proceedings before the Board), these specific silicone hydrogels surely fall under the more generic term "silicone hydrogels" disclosed in D26. The fact that the disclosure of D26 has to be combined with another prior art document in order to arrive at the subject-matter of claim 1 of the first auxiliary request is not sufficient to confer an inventive step. Indeed, as already indicated in the preceding paragraph, even if such a combination is necessary, the subject-matter of claim 1 of the first auxiliary request remains an arbitrary selection within

a host of alternatives that was made available by the disclosure of D26.

7.5 In view of the above, it was obvious to solve the problem posed, namely to provide an alternative to the eye-mountable device comprising a fully encapsulated electronics structure according to D26 by using any of balafilcon A, stenfilcon A, enfilcon A or comfilcon A to prepare the lens body together with using parylene C as the encapsulation material of the electronics structure of an eye-mountable device comprising a fully encapsulated electronics structure according to D26.

7.6 For these reasons, the subject-matter of claim 1 of the first auxiliary request does not involve an inventive step in view of the relevant disclosure of D26 as the closest prior art. As a consequence, the first auxiliary request is not allowable.

Second, third, tenth, eleventh and twelfth auxiliary requests - Admittance

7.7 Admittance pursuant to Article 13(2) RPBA

7.7.1 It remained undisputed that the second, third, tenth, eleventh and twelfth auxiliary requests filed during the oral proceedings before the Board only differed from the first, fourth, fifteenth, sixteenth and nineteenth auxiliary requests filed with letter of 24 November 2022, respectively, in that all the claims that were directed to the cavity feature were deleted and the remaining claims renumbered if necessary.

7.7.2 In addition, it was common ground - in particular at the oral proceedings before the Board - that the first, fourth, fifteenth, sixteenth and nineteenth

auxiliary requests filed with letter of 24 November 2022 had been defended by the respondent since the outset of the appeal proceedings and that no objection against the admittance of these auxiliary requests had been put forward in writing by the appellant.

7.7.3 In view of the above, the Board saw no reasons to come to a conclusion regarding the admittance of any of the second, third, tenth, eleventh and twelfth auxiliary requests filed at the oral proceedings before the Board different from the one taken for the first auxiliary request filed at the oral proceedings before the Board.

8. Therefore, the Board made use of its discretion in order to admit into the proceedings each of the second, third, tenth, eleventh and twelfth auxiliary requests filed during the oral proceedings before the Board (Article 13(2) RPBA).

Second, third, tenth, eleventh and twelfth auxiliary requests - Allowability

9. Objections raised by the appellant

9.1 At the oral proceedings before the Board, the respondent noted that although the claims of the second auxiliary request had been already present in auxiliary request 1 filed with letter of 24 November 2022 during the oral proceedings and continuously defended since the outset of the appeal proceeding, the appellant had raised an objection of lack of inventive step against these claims for the first time with their latest written submission in appeal, namely with letter of 24 February 2025. In the absence of any exceptional circumstances justifying such a late submission of

these objections, it was questionable that these objections were to be taken into account, so the respondent.

9.2 In view of these remarks of the respondent, the Chairman clarified during the oral proceedings before the Board that, as long as the arguments of the appellant in support of an objection of inventive step against the lower ranked requests remained within the framework of the (successful) objection dealt with for the first auxiliary request, they had to be considered by the Board and it was the duty of the respondent to explain how the amendments made in the lower ranked requests effectively overcame the objection retained against the first auxiliary request. In view of this, no further comments were made by the respondent in this regard. In particular, no formal request concerning the admittance of the objection of lack of inventive step against the second auxiliary request was made. Therefore, there was no reasons for the Board to disregard the objection of lack of inventive step raised against the second auxiliary request.

9.3 Similar arguments were put forward by the respondent during the oral proceedings before the Board for the third and tenth auxiliary requests. However, the same conclusion as the one indicated above for the second auxiliary request is to be reached, for the same reasons.

Inventive step

10. Claim 1 of the **second auxiliary request** filed during the oral proceedings before the Board differs from claim 1 of the first auxiliary request in that it was specified that the hydrogel lens body should

additionally comprise a cross-linking agent and in that the upper limit of the range of the bonding factor X was limited to 0.75.

10.1 Considering that it is not explicitly disclosed in D26 that the silicone hydrogels mentioned therein should comprise a crosslinker, the respondent argued that the amendment made in this respect constituted an additional feature that distinguished the subject-matter of claim 1 of the second auxiliary request from the relevant disclosure of D26 considered for the assessment of inventive step of claim 1 of the first auxiliary request.

In this regard, although the Board tends to agree with the argument of the appellant that the presence of a crosslinker is implicitly mandatorily present in order to prepare a silicone hydrogel (letter of 24 February 2025: point 8.2, second paragraph; oral proceedings before the Board; as an aside, it is noted that this seems to be in line with the general disclosure in column 5, lines 13 to 24 of D19), this issue is not decisive for the present decision and may remain unanswered.

10.2 Regarding the formulation of the problem solved over D26, the amendments made lead to the fact that further contact lenses prepared in the examples of the patent in suit that illustrated the subject-matter of claim 1 of the first auxiliary request are now excluded from the scope of claim 1 of the second auxiliary request. In particular, it is derivable from the table of Annex C of D32 that the following examples are not covered by claim 1 of operative auxiliary request 2: contact lens B with a polyimide film, which has a bonding factor X of 0.93; lenses G with both a

polyimide film or a parylene films, which - following the respondent's view - were apparently prepared without a crosslinker.

a) However, it remains that, as was concluded for claim 1 of the first auxiliary request, claim 1 of the second auxiliary request still encompasses hydrated contact lenses that do not solve the problem relied upon by the respondent. In particular, claim 1 of the second auxiliary request still covers hydrated contact lenses that exhibit distortion and contact lenses that cannot be rendered satisfactory by a further hydration treatment (lens C with parylene or polyimide film and hydration with water; lens D with parylene film and hydration with water; lens H with parylene film and hydration with water; lens H with polyimide film and hydration with ethanol).

b) In that respect, the respondent's consideration that lens H with polyimide film and hydration with ethanol was a single failure did not convince considering the limited numbers of examples contained in the patent in suit that illustrated the subject-matter being claimed.

c) In these circumstances, the problem solved over D26 remains the same as the one indicated above for claim 1 of the first auxiliary request.

10.3 Regarding the obviousness of the solution, it is derivable from paragraph 19 of the patent in suit that the presence of a crosslinker in silicone hydrogels is well known in the art (which is also in line with the Board's view on the basis of the common general knowledge of the skilled person in the present technical field). Therefore, said feature is held to be obvious.

In addition, the limitation of the upper limit of the range of the bonding factor X does not change the line of reasoning indicated above for claim 1 of the first auxiliary request. Although the combination of stenfilcon A for the hydrogel lens body with parylene C for the encapsulation material does not lead to a bonding factor X in the amended range according to claim 1 of the second auxiliary request (see point 7.5.4.c above), it remains that the other embodiments addressed in respect of claim 1 of the first auxiliary request that were directed to balafilcon A, enfilcon A and comfilcon A do.

For these reasons, the subject-matter of claim 1 of the second auxiliary request also constitutes an arbitrary selection within the ambit of D26. In these circumstances, claim 1 of the second auxiliary request does not involve an inventive step for the same reasons as the ones indicated above for claim 1 of the first auxiliary request.

11. Claim 1 of the **third auxiliary request** differs from claim 1 of the first auxiliary request in that the range of the bonding factor X was limited to 0.1 to 0.5.

Inventive step

11.1 It was common ground that the amendment made did not further distinguish the subject-matter being claimed from the relevant disclosure of D26 (as compared to claim 1 of the first auxiliary request).

11.2 Regarding the problem solved, the amendment made lead to the fact that additional contact lenses prepared in

the examples of the patent in suit are now excluded from the scope of claim 1 of the third auxiliary request: lenses B with parylene film or polyimide film; lens C with polyimide film; lens G with polyimide film (see table of Annex C of D32). However, it remains that claim 1 of the third auxiliary request still encompasses hydrated contact lenses that do not solve the problem relied upon by the respondent (lens C with parylene film and hydration with water; lens D with parylene film and hydration with water; lenses G and H with parylene film and hydration with water; lens H with polyimide film and hydration with ethanol). Therefore, the problem solved over D26 remains the same as the one indicated above for claim 1 of the first auxiliary request.

Regarding the obviousness of the solution, the limitation of the range of the bonding factor X does not change the line of reasoning indicated above for claim 1 of the first auxiliary request. Although the combination of stenfilcon A and enfilcon A for the hydrogel lens body with parylene C for the encapsulation material does not lead to a bonding factor X in the amended range according to claim 1 of the second auxiliary request (see point 7.5.4.c above), it remains that the other embodiments balafilcon A and comfilcon A do. Therefore, the subject-matter of claim 1 of the third auxiliary request also constitutes an arbitrary selection within the ambit of D26. In these circumstances, claim 1 of the third auxiliary request does not involve an inventive step for the same reasons as the ones indicated above for claim 1 of the first auxiliary request.

12. Claim 1 of the **tenth auxiliary request** differs from claim 1 of the first auxiliary request in that in

feature 1F as defined in point 6 above the definition of the hydrogel lens body was limited by increasing the lower limit of the range of the amount of hydrophilic N-vinyl amide-containing monomer and by imposing the presence of a specific N-vinyl amide-containing monomer (VMA and/or NVP).

12.1 It was common ground that the amendments made further distinguished the subject-matter being claimed from the relevant disclosure of D26 (as compared to claim 1 of the first art) since D26 did not provide any information regarding the nature of the silicone hydrogels disclosed therein.

12.2 Regarding the problem solved, it was acknowledged during the oral proceedings before the Board that the amendments made do not lead to the exclusion of any additional contact lenses prepared in the examples of the patent in suit that were according to claim 1 of the first auxiliary request from the scope of claim 1 of the tenth auxiliary request, i.e. lenses B to D, G and H with either parylene film or polyimide film are all covered by claim 1 of the tenth auxiliary request. Therefore, the analysis provided above in respect of the first auxiliary request is also valid for claim 1 of the tenth auxiliary request and the problem solved over D26 remains the same as the one indicated above for claim 1 of the first auxiliary request.

12.3 Regarding the obviousness of the solution, as argued by the appellant at the oral proceedings before the Board, it remains that at least balafilcon A is a silicone hydrogel as defined in claim 1 of the fifteenth auxiliary request. Therefore, for this reason alone, the subject-matter of claim 1 of this request does not involve an inventive step for the same reason as the

ones indicated for claim 1 of the first auxiliary request, i.e. the subject-matter of claim 1 of the tenth auxiliary request also constitutes an arbitrary selection within the ambit of D26.

In addition, it is derivable from the tables on pages 23-25 of the statement of grounds of appeal, that stenfilcon A, enfilcon A and comfilcon A are all silicon hydrogels that contain at least some N-vinyl-N-methyl acetamide (VMA), or N-vinyl pyrrolidone (NVP). In this respect, it was neither shown, nor even argued by the respondent that the amendment made regarding the amount of the hydrophilic N-vinyl amide-containing monomer contributed to an inventive step. Therefore, said modification can only be held to be arbitrary. As a consequence, claim 1 of the tenth auxiliary request does not involve an inventive step for the same reasons as the ones indicated above for claim 1 of the first auxiliary request.

13. As acknowledged by the parties at the oral proceedings before the Board, claim 1 of the **eleventh and twelfth auxiliary requests** combine the amendments made in claim 1 of the tenth auxiliary request with the one made in claim 1 of the second auxiliary request or the one made in claim 1 of the third auxiliary request, respectively. However, no additional or separate arguments were put forward by the respondent in respect of inventive step of claim 1 of the eleventh and twelfth auxiliary requests (as compared to the higher ranked requests). Therefore, claim 1 of these auxiliary requests can only share the same fate as claim 1 of the higher ranked requests, i.e. it does not involve an inventive step when D26 is taken as the closest prior art.

14. Although a decision was taken by the Board during the oral proceedings regarding the admittance of document D30 and of some arguments put forward by the appellant regarding an objection pursuant to Article 123(2) EPC raised against the claims of the main request, these issues are not relevant to the present decision. Therefore, it is not necessary to deal with them in this decision. The same is valid regarding the conclusions reached during the oral proceedings regarding sufficiency of disclosure and novelty of claim 1 of the main request.

15. Since none of the requests defended by the respondent is allowable, the decision under appeal is to be set aside and the patent to be revoked.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

N. Schneider D. Semino

Decision electronically authenticated