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**Datasheet for the decision
of 3 July 2025**

Case Number: T 1047/23 - 3.3.03

Application Number: 15729230.1

Publication Number: 3140332

IPC: C08F220/34, C08L75/16, G02B1/04

Language of the proceedings: EN

Title of invention:
A FORMULATION AND LENS MANUFACTURING PROCESS FOR THE
PRODUCTION OF INTRAOCULAR LENS (IOL)

Patent Proprietor:
Tubitak

Opponent:
Johnson & Johnson Surgical Vision, Inc.

Relevant legal provisions:
EPC Art. 100(b), 116
RPBA 2020 Art. 12(4), 12(6), 13(2)

Keyword:

Oral proceedings - oral submissions by an accompanying person
(yes)

Late-filed evidence - admitted (no)

Grounds for opposition - insufficiency of disclosure (yes)

Amendment to case - amendment admitted (no)

Decisions cited:

G 0004/95, T 0523/89, T 0019/90



Beschwerdekammern

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Case Number: T 1047/23 - 3.3.03

D E C I S I O N
of Technical Board of Appeal 3.3.03
of 3 July 2025

Appellant:

(Patent Proprietor)

Tubitak
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Representative:

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Respondent:

(Opponent)

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Representative:

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Decision under appeal:

**Decision of the Opposition Division of the
European Patent Office posted on 30 March 2023
revoking European patent No. 3140332 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

Chairman

D. Semino

Members:

O. Dury

A. Bacchin

Summary of Facts and Submissions

I. The appeal by the patent proprietor lies from the decision of the opposition division revoking European patent No. 3 140 332.

II. In this decision, the following documents were cited:

D1: WO 2013/096587 A1
D2: US 2004/0158020 A1
D3: WO 2012/109228 A1
D4: WO 2012/166948 A1
D5: US 5 224 957 A
D6: T. Y. Inan et al., J. Mater. Sci.: Mater. Med.,
2014, 25, pages 2027-2039
D7: US 2005/0055090 A1
D8: US 6 200 732 B1
D9: US 5 725 576 A
D10: US 5 891 931 A
D11: US 2005/0143751 A1
D12: WO 2004/029675 A1
D13: US 2008/0306587 A1
D14: WO 2006/119304 A1

III. In the decision under appeal, which was based on the patent in suit as single request, the opposition division held that the patent in suit did not meet the requirements of sufficiency of disclosure. Therefore, the patent proprietor's sole request was not allowable and the patent was revoked.

IV. With their statement setting out the grounds of appeal the patent proprietor (appellant) filed several sets of claims as auxiliary requests. Also, the following

documents were submitted:

- P1: identical to D2
- P2: US 2012/0232648 A1
- P3: identical to D9
- P4: D. Bozukova et al., Journal of Cataract & Refractive Surgery, 2013, 39(9), pages 1404-1414
- P5: US 2009/0248150 A1
- P6: US 2002/0045706 A1
- P7: RU 2 487 726 C1 and English translation thereof
- P8: US 7 815 308 B2
- P9: identical to D4

V. The opponent (respondent) replied to the statement of grounds of appeal.

VI. The parties were summoned to oral proceedings and a communication pursuant to Article 15(1) RPBA was then issued by the Board on 4 March 2025.

VII. With letter of 28 May 2025 the appellant made further submissions, whereby the following documents were referred to (see footnotes 1 and 2 on page 8):

- P10: T. Y. Inan et al., Macromolecular Chemistry and Physics, 202, 4, 2001, pages 532-540
- P11: M. N. A. Said et al., ACS Omega, 2022, 7 (51), pages 47490-47503

VIII. Oral proceedings were held on 3 July 2025 in the presence of both parties.

IX. **The final requests of the parties were as follows:**

The appellant requested that the decision under appeal

be set aside and the opposition be rejected. Alternatively, the appellant requested that the patent be maintained in amended form on the basis of the claims of any of auxiliary requests 1 to 8 filed with the statement of grounds of appeal.

The respondent requested that the appeal be dismissed. Alternatively, should the appellant's appeal be successful and any of the appellant's requests be found to satisfy the requirements of sufficiency of disclosure, the respondent requested that the case be remitted to the opposition division for further prosecution.

- X. The **main request (patent as granted)** comprised eleven claims, which read as follows:

"1. A formulation, used in the method for manufacturing flexible, inexpensive, hydrophobic, having high reactive [sic] index value with a UV-blocking feature and smooth surfaces suitable for intraocular-use lenses by photopolymerization, **characterized in that** the formulation comprises

between 20 to 80 percent by weight acrylate and / or methacrylate-based oligomer as a binder,

between 5 to 40 percent by weight acrylate and / or methacrylate-based monomer as a reactive diluent,

between 1 to 5 percent by weight acrylate and /or methacrylate-based UV blocker for absorbing light, and

between 0.1 to 5 percent by weight photoinitiator to initiate the reaction."

"2. A formulation according to claim 1 **characterized in that** the oligomer used in the formulation is a urethane acrylate-based oligomer."

"3. A formulation according to claim 1 **characterized in that** the oligomer used in the formulation is a urethane methacrylate oligomer."

"4. A formulation according to claim 1 **characterized in that** the monomer used in the formulation is a monofunctional acrylate based monomer."

"5. A formulation according to claim 1 **characterized in that** the monomer used in the formulation is amethacrylate-based [sic] monomer."

"6. A formulation according to claim 1 **characterized in that** the monomers used as reactive diluent can be selected from the group comprising; methacrylic acid, metilkarbitol methacrylate, phenoxyethyl methacrylate, octyl methacrylate, methyl methacrylate, hydroxyethyl methacrylate, ethoxyethyl methacrylate, ethyleneglycol dimethacrylate, N-vinyl pyrrolidone, allyl methacrylate, N, N-Dimetakrilamif, glyceryl methacrylate and tetraethylene glycol dimethacrylate."

"7. A formulation according to claim 1 **characterized in that** the photoinitiator can be selected from the group comprising; 2,4,6-trimetilbenzoildifenilfosf oxide, (2-benzyl-2-N-dimethylamino-1-(4-morpholinopropan-1), (hydroxycyclohexyl) phenyl ketone, 2-benzyl-2-N-dimethylamino-1-(4-morfolinopenil)-1-butanone, benzene, dimethyl ketal, isopropyl benzoin ketal, 2-n-propoxy-9H-thioxanthenes-9, ethyl 4-(dimethylamino)benzoate."

"8. A formulation according to claim 1 **characterized in that** the UV blocker can be selected from the group comprising 2- (4-Benzoyl-3-hidrokisfenoks) ethyl acrylate), 4-Methakriloks-2-hydroxybenzophenone), 2- (2'-Hydroxy-5'-metakriloksietilfenil) -2H-benzotriazole, coumarin or the polyaryl ether."

"9. A method for manufacturing flexible, inexpensive, hydrophobic, having high reactive [sic] index value with a UV-blocking feature and smooth surfaces suitable for intraocular-use lenses by photopolymerization, **characterized in that** the method comprises the following steps;

- Preparation of the formulation,
- Placing the formulation into the die,
- Curing the formulation by photopolymerization method,
- Removing cured formulation from the die,
- Extraction with isopropyl alcohol and performing sterilization to the dedied formulations,

characterized in that the formulation is prepared by using; between 20 to 80 by weight percent [sic] acrylate and /or methacrylate-based oligomer(s) as binders; between 5 to 40 weight percent acrylate and / or methacrylate-based monomers, as reactive diluent; between 0.1 to 5 weight percent photoinitiator to initiate the reaction; between 1 to 5 weight percent acrylate / or [sic] methacrylate-based UV blocker as UV absorbing ingredient."

"10. A method according to claim 9 **characterized in that** the formulation The formulation [sic] is transferred preferably into a quartz (quartz) die."

"11. A method according to claim 9 **characterized in that** the LED and/or Ultraviolet LED or both is used in the step of curing the formulation by photopolymerization method."

XI. **Auxiliary request 1** only differed from the main request in that in claim 1 thereof the word "comprises" was replaced by "consists essentially of". The wording of all other claims, in particular claim 9, was identical to the one of the corresponding claims of the main request.

XII. **Auxiliary request 2** only differed from the main request in that in claim 1 thereof the word "comprises" was replaced by "consists of". The wording of all other claims, in particular claim 9, was identical to the one of the corresponding claims of the main request.

XIII. **Auxiliary request 3** only differed from the main request in that the following amendments were made in claim 1 thereof:

- The word "comprises" was replaced by "consists essentially of"; and
- The lower end of the range of the binder was modified to read "at least 50" (instead of "between 20").

The wording of all other claims, in particular claim 9, was identical to the one of the corresponding claims of

the main request.

XIV. **Auxiliary request 4** only differed from the main request in that the following amendments were made in claim 1 thereof:

- The word "comprises" was replaced by "consists of"; and
- The lower end of the range of the binder was modified to read "at least 50" (instead of "between 20").

The wording of all other claims, in particular claim 9, was identical to the one of the corresponding claims of the main request.

XV. Claim 1 of **auxiliary request 5** corresponding to claim 1 of auxiliary request 2, whereby the following sentence was added at the end of the claim:

"To make up 100% in the formulation the required parts will be completed with the acrylate and/or methacrylate-based oligomer."

The wording of all other claims, in particular claim 9, was identical to the one of the corresponding claims of the main request.

XVI. Claim 1 of **auxiliary request 6** corresponded to claim 1 of the main request, whereby the definition of the amount of binder was amended as follows (deletion as compared to claim 1 of the main request in ~~striketrough~~):

~~"between 20 to 80 percent by weight acrylate and / or~~

methacrylate-based oligomer as a binder,".

The wording of all other claims, in particular claim 9, was identical to the one of the corresponding claims of the main request.

- XVII. **Claim 1 of auxiliary request 7** corresponded to claim 1 of auxiliary request 6, whereby the word "comprises" was replaced by "consists essentially of".

The wording of all other claims, in particular claim 9, was identical to the one of the corresponding claims of the main request.

- XVIII. **Claim 1 of auxiliary request 8**, corresponded to claim 1 of auxiliary request 6, whereby the word "comprises" was replaced by "consists of".

The wording of all other claims, in particular claim 9, was identical to the one of the corresponding claims of the main request.

- XIX. The parties' arguments, in so far as they are pertinent for the present decision, may be derived from the reasons for the decision below. The main points of dispute concerned the following issues:

- The question if one of the inventors would be allowed to make oral submissions during the oral proceedings before the Board;
- The admittance of documents that were filed and/or referred to by the appellant for the first time during the appeal proceedings;

- The question if claims 1 and 9 of the main request met the requirements of sufficiency of disclosure (Article 100(b) EPC);
- The admittance into the proceedings of auxiliary requests 1 to 8.

Reasons for the Decision

1. Hearing of an accompanying person
 - 1.1 During the oral proceedings before the Board, the appellant's representative requested that one of the inventors of the patent in suit, Tülay Inan (referred to as "the inventor" in the following), who was present as an accompanying person, be allowed to make oral submissions. The respondent's representative disagreed and argued that, had he known that the inventor would be speaking, he would have contemplated being accompanied by a technical expert as well. Therefore, for fairness reasons, the appellant's request should not be allowed by the Board.
 - 1.2 According to decision G 4/95 (see in particular Headnote II) oral submissions by an accompanying person in opposition appeal proceedings cannot be made as a matter of right, but only with the permission and at the discretion of the Board, whereby the following main criteria should be considered when exercising this discretion:
 - (i) The professional representative should request permission for such oral submissions to be made. The request should state the name and qualifications of the

accompanying person and should specify the subject-matter of the proposed oral submissions.

(ii) The request should be made sufficiently in advance of the oral proceedings so that all opposing parties are able properly to prepare themselves in relation to the proposed oral submissions.

(iii) A request made shortly before or at the oral proceedings should, in the absence of exceptional circumstances be refused, unless each opposing party agrees to the making of the oral submissions requested.

(iv) The EPO should be satisfied that oral submissions by an accompanying person are made under the continuing responsibility and control of the professional representative.

- 1.3 In the present case, the respondent's objection was directed to above criterion (ii) of G 4/95. However, as also clarified with the parties during the oral proceedings before the Board, the appellant had announced with letter dated 28 August 2024 and filed on 29 August 2024 (first and only page: third and fourth paragraphs), i.e. about ten months ahead of the oral proceedings scheduled on 3 July 2025, that Tülay Inan, "as the inventor and a technical expert", would "participate in the oral proceedings" and would "provide explanations and address technical questions during the proceedings". Therefore, the respondent should not have been surprised that the appellant asked for the permission that the inventor makes oral submissions during the oral proceedings before the Board. To the contrary, in the light of these statements of the appellant, the decision to attend the oral proceedings without a technical expert on their

side can only be the result of a deliberate choice made by the respondent. Therefore, the respondent's arguments do not justify that the appellant's request be refused by the Board.

1.4 Although the Board had some concerns as to whether criterion (i) of G 4/95 was effectively met in view of the very general statements made by the appellant in their letter of 28 August 2024 (see Case Law of the Boards of Appeal of the EPO, 10th edition, 2022, III.V.5.2.1 and III.V.5.2.5, fourth to sixth paragraphs), the Board decided, in view of the lack of any objection in respect of that criterion made by the respondent either during the relatively long period of time between the appellant's request filed in writing and the date at which the oral proceedings took place (about ten months) or even during the oral proceedings themselves, to allow the inventor to speak under the responsibility and control of the appellant's representative. In particular, should any objection in respect of criterion (i) of G 4/95 have been made in writing by the respondent in good time ahead of the oral proceedings, the appellant would have had the opportunity to provide more detailed information regarding the nature of the oral submissions that would be made by the inventor. In the absence of such objections, it is considered that the respondent had no concerns in this respect.

1.5 It is pointed out that the above decision was reached by the Board independently of the events related to a similar point of dispute between the parties that occurred during the opposition proceedings. In particular, the question if the inventor would be allowed to make oral submissions already arose during the oral proceedings before the opposition division

(see minutes: page 2, third paragraph). However, the appellant had at this stage not filed any formal request for the inventor to speak (either in writing or at the oral proceedings before the opposition division). Therefore, the inventor eventually did not make any oral submissions during the oral proceedings before the opposition division and that issue was (correctly) not dealt with in the decision under appeal. An official complaint was filed at the EPO by the inventor with email of 21 February 2023, whereby it was considered that the inventor had not been allowed to speak at the oral proceedings before the opposition division (see public file of the present case: complaint of the inventor based on an email dated 21 February 2023: end of first full paragraph).

2. Admittance of documents

Documents P2 and P4 to P8

2.1 The respondent requested that each of documents P2 and P4 to P8 be not admitted into the proceedings because they were late-filed and not relevant to the issues addressed in the decision under appeal. In addition, admitting these documents into the proceedings would be detrimental to procedural economy, so the respondent (rejoinder: points 3 and 47).

2.1.1 The filing of documents P2 and P4 to P8 and of the submissions based thereon with the statement of grounds of appeal constitutes an amendment to the appellant's case (Article 12(2) and (4) RPBA), the admittance of which undergoes the stipulations of Articles 12(4) to 12(6) RPBA.

- 2.1.2 In this regard, it is agreed with the respondent (rejoinder: point 47) that the appellant has not justified in the statement of grounds of appeal why these documents were filed for the first time on appeal.
- 2.1.3 In addition, it can be inferred from the appellant's submissions put forward in the statement of grounds of appeal that these documents were filed in support of their line of defence regarding the objection of lack of sufficiency of disclosure that was already addressed during the opposition proceedings. However, the appellant has not shown, not even argued, that there were any reasons which would justify the filing of new documents at this stage of the proceedings. The Board also sees no compelling reasons in that respect. In particular the Board cannot recognise any new circumstances, for instance deriving from the course of the opposition proceedings or from the opposition division's decision, which could justify admittance of these documents in appeal proceedings. In particular, it is noted that the opposition division provided a negative opinion on sufficiency of disclosure in two communications dated 4 March 2022 (point 6.5) and 21 April 2022 (point 4.5), whereby the same concerns as the one retained in the decision under appeal were addressed therein (i.e. the patent in suit was held by the opposition division not to allow the invention to be performed over the whole range claimed). Therefore, the appellant undoubtedly had several opportunities to file new documents in support of their line of defence already during the opposition proceedings, which was not done.
- 2.1.4 In the statement of grounds of appeal (page 12, last full paragraph) and during the oral proceedings before

the Board, the appellant put forward that P2 and P4 to P8 should be admitted because they were evidence of the common general knowledge of the skilled person working in the technical field of the patent in suit, namely intraocular lenses (IOLs), at the priority/filing date of the patent in suit.

However, P2 and P5 to P8 are patent documents and P4 is a scientific article. Therefore, the Board agrees with the respondent's view (which was put forward during the oral proceedings) that these documents do not constitute common general knowledge in the sense of established case law, according to which common general knowledge is directed to basic handbooks, monographs, encyclopaedias, textbooks and reference books, i.e. it is knowledge that an experienced person in the field in question is expected to have, or at least to be aware of, to the extent that (s)he knows (s)he could look it up in a book if (s)he needed it (Case Law, *supra*, I.C.2.8.1). Also, the appellant's arguments do not show that there were any reasons to deviate from this well accepted view and are even fully in line with it (see statement of grounds of appeal: top of page 8 to middle of page 9). In that regard, the Board does not agree with the appellant's argument put forward during the oral proceedings that any document available to the public as a rule constitutes common general knowledge. For that reason, the appellant's argument is rejected.

- 2.1.5 In their letter of 28 May 2025 (page 1, last full sentence), the appellant briefly indicated that documents P2 and P4 to P8 had been filed with the statement of grounds of appeal "to support the explanations made against objections" retained by the opposition division.

However, this argument does not show that any unexpected development of the case occurred at a late stage of the opposition proceedings. In addition, it was neither shown, let alone argued, that the conclusion reached in respect of sufficiency of disclosure in the decision under appeal was based on considerations that had taken the appellant by surprise. Also the Board sees no reason to deviate from this view. Therefore, the appellant's argument did not convince.

- 2.1.6 In the statement of grounds of appeal (middle of page 10 to bottom of page 12) and during the oral proceedings before the Board the appellant put forward that P2 and P4 to P8 had been filed to show which components were generally used to make intraocular lenses (IOLs), which were the main object of the patent in suit. In that regard, since the inventor had not been heard during the oral proceedings before the opposition division (see point 1.5 above), the appellant's arguments had to be complemented in appeal, which had been done with the filing of these documents at the first opportunity, namely with the statement of grounds of appeal. In addition, the documents had been filed about two years before the oral proceedings, which had left sufficient time to the respondent and the Board to take them into account, so the appellant.

a) However, it is derivable from the file history that no formal request to hear the inventor during the oral proceedings before the opposition division was eventually made by the appellant during the opposition proceedings (see minutes of the oral proceedings before the opposition division: page 2, third paragraph, in particular the last sentence). Therefore, the argument of the appellant related to the fact that the inventor

was not allowed to speak during the oral proceedings before the opposition division cannot succeed already for this reason. To the contrary, this argument further confirms that the appellant would have had good reasons to file P2 and P4 to P8 already during the opposition proceedings, if they intended to rely on them. Indeed, it is derivable from the minutes of the oral proceedings that the issue on which the inventor intended to make oral submissions was related to the nature of the components that are generally used to make the formulations defined in the granted claims (minutes: page 2, second and third paragraphs), which is an issue that was already at stake in the written phase of the opposition proceedings, as identified in both preliminary opinions of the opposition division (see point 6.5 of the communication dated 4 March 2022 and point 4.5 of the one dated 21 April 2022).

b) In addition, the fact that the respondent may have had sufficient time to consider the documents is not relevant for the issue of the admittance thereof. Rather, the question to be answered is whether the circumstances of the present case justify the filing of P2 and P4 to P8 for the first time with the statement of grounds of appeal, which was not shown to be the case here.

2.1.7 In the Board's view, the question of the relevance of documents P2 and P4 to P8, which was also mentioned by the respondent, is related to the probative value of these documents. However, these arguments are not pertinent to the question of admittance, but actually pertains to substance.

2.1.8 For these reasons, the circumstances of the present case do not justify the filing of documents P2 and P4

to P8 with the statement of grounds of appeal (Article 12(6) RPBA). Therefore, these documents were not admitted into the proceedings.

Documents P10 and P11

- 2.2 Documents P10 and P11 were referred to for the first time by the appellant in their letter of 28 May 2025 (footnotes 1 and 2 on page 8). Since this letter was submitted after receipt of the Board's communication, the admittance of P10 and P11 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.
- 2.2.1 However, the appellant has not justified why documents P10 and P11 were only relied upon at such a late stage of the proceedings. In addition, the Board cannot recognise any exceptional circumstances justifying such a late submission of these documents. In particular, it was neither shown, nor even argued (in particular at the oral proceedings before the Board), that the filing of these documents was a reaction to new issues raised for the first time in the Board's communication. Therefore, no exceptional circumstances according to Article 13(2) RPBA prevail.
- 2.2.2 In addition, it is established case law that the criteria set out in Articles 12(4) to 12(6) RPBA are also applicable when a Board exercises its discretion to decide on the admittance of an amendment to a party's case pursuant to Article 13(2) RPBA (Case Law, *supra*, V.A.4.5.1, last two paragraphs).

In the present case, P10 and P11 were not even filed by the appellant but only referred to, which is not in accordance with Article 12(3)(a) RPBA. Therefore, these documents can be not admitted for that additional reason (Article 12(5) RPBA).

- 2.2.3 In view of the above, the Board decided not to take documents P10 and P11 into account according to Article 13(2) RPBA.

Main request (patent as granted)

3. Sufficiency of disclosure

- 3.1 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 i) to prepare a formulation according to claim 1 as granted and ii) to carry out a method according to claim 9 as granted, both of which was contested by the respondent (rejoinder: point 34).

Claim 1 as granted

- 3.2 The formulation according to claim 1 as granted is characterised by the definition of

- some of its constituents, i.e. it has to comprise an acrylate and/or methacrylate-based oligomer as a binder, an acrylate and/or methacrylate-based monomer as a reactive diluent, an acrylate and/or

methacrylate-based UV blocker and a photoinitiator, all in specific amounts, which will be referred to hereinafter as the "structural definition" and

- the requirement related to its intended use and according to which it is "used for manufacturing flexible, ... suitable for intraocular-use lenses by photopolymerization". According to established case law (see e.g. Case Law, *supra*, I.C.8.1.5, in particular T 523/89, point 2 of the reasons), said requirement is interpreted to mean that the formulation being claimed should be suitable for making by photopolymerization IOLs that are flexible, inexpensive, hydrophobic and have a high refractive index, UV-blocking properties and smooth surface. Therefore, that requirement is considered by the Board to impose, implicitly, some additional limitation(s) on the formulation being claimed (as compared to the structural definition), which will be referred to hereinafter as the "functional definition". In that regard, it is noted that since the properties of the IOLs specified in claim 1 as granted are not defined in absolute terms, they have to be read in their broadest, technical sensible meaning.

In these circumstances, in order to meet the requirements of sufficiency of disclosure, the patent in suit, optionally in combination with common general knowledge, should not only provide a sufficient teaching as to how to appropriately select the various components according to the above structural definition, but also provide enough guidance regarding what has to be done so that said functional definition is satisfied.

Meeting the challenge of preparing formulations satisfying the structural and functional definitions according to claim 1 as granted, in particular with low amounts of binder

- 3.3 In the decision under appeal, the opposition division considered that the patent in suit did not allow the invention to be carried out over the whole breadth of the claims, in particular for formulations comprising an amount of binder in the lower end of the range specified in claim 1 as granted (reasons: points 1.1.7-1.1.9).
- 3.3.1 In this respect, it is noted that, as argued by the opposition division, claim 1 as granted is directed to formulations that may contain relatively low amounts of acrylic oligomeric binders (as low as 20 wt.%). However, the patent in suit contains no evidence that formulations according to claim 1 and containing such a low amount of acrylic oligomeric binder are indeed suitable to prepare IOLs satisfying the functional definition of claim 1. To the contrary, even the appellant considered that for IOL production the amount of oligomers (i.e. binder) is usually of 50 wt.% or higher (statement of grounds of appeal: bottom of page 6), i.e. significantly higher than the lower amounts of binder specified in claim 1 as granted.
- 3.3.2 In addition, as pointed out by the respondent (rejoinder: point 18), it was the choice of the appellant to define the subject-matter being claimed as was done in claim 1 as granted, in particular to define ranges of the four components that have to be present in the formulation being claimed (binder, reactive diluent, UV blocker and photoinitiator). Therefore, in

order to fulfil the requirements of sufficiency of disclosure, it is their duty to show or at least render credible that the invention so defined may be carried out over the whole range(s) claimed, i.e. also in the lower part of the ranges specified in claim 1 as granted, in particular in the lower part of the range of binder considered by the opposition division.

- 3.3.3 In this respect, the appellant argued that although the formulations according to claim 1 as granted were defined in an open manner ("comprising") and allowed relatively low amounts of e.g. binder (as low as 20 wt.%) or reactive diluent (as low as 5 wt.%), the skilled person would not be expected to try the lowest ends of the respective ranges for these components (statement of grounds of appeal: page 7, first full paragraph). Also, the skilled person would not consider using additional components that are not specifically defined in claim 1 as granted in too high amounts, so the appellant (statement of grounds of appeal: paragraph bridging pages 9 and 10).

However, the Board does not find the appellant's argument convincing. Indeed, since it was the appellant's choice to define the formulations being claimed according to claim 1 as granted, it is also up to the appellant to include information in the patent application/the patent that is sufficient to show or render credible that the invention is indeed enabled over the whole breadth of the claim, i.e. including for the lower ends of the ranges of components defined therein (see rejoinder: points 17-18). In particular, as already indicated above, it is in the present case to be taken into account that using amounts of acrylic oligomeric binder as low as 20 wt.% does not, according to the appellant's own view, correspond to usual

practice. Under these circumstances, it is not clear to the Board how the skilled person could rely on common general knowledge to complement the disclosure of the patent specification in that regard (statement of grounds of appeal: page 7, last paragraph to page 9, third full paragraph). Also, in these circumstances, the Board considers that trying out different amounts of components as defined by the structural definition of claim 1 as granted and then checking whether the formulation satisfies the functional definition of that claim 1 as proposed by the appellant (statement of grounds of appeal: page 9, third full paragraph) would amount to a mere trial-and-error procedure, which, in the absence of any guidance in the patent specification as to how to proceed, cannot be held to constitute a routine procedure, contrary to the appellant's view (statement of grounds of appeal: page 9, third full paragraph; paragraph bridging pages 9 and 10).

- 3.3.4 In addition, it is also the appellant's opinion that preparing the formulations being claimed is "very challenging" and requires that the ranges of constituents and specific types thereof as well as "optimized UV-source energy parameters" be "carefully selected" (statement of grounds of appeal: page 4, last paragraph and page 5, second paragraph; letter of 28 May 2025: bottom of page 13). In this respect, it has to be taken into account that the gist of the patent in suit is directed to formulations for making IOLs using a (meth)acrylate functional UV blocker and a photoinitiator (which initiates the polymerisation of the (meth)acrylate functional species present) that work in the same region of the light spectrum. However, while the UV blocker is blocking the light in a specific range of wavelengths, the photoinitiator requires the same type of light to initiate the

polymerisation of the (meth)acrylate functional species (paragraph 12 of the patent in suit; see also statement of grounds of appeal: page 4, last paragraph to page 5, second paragraph). In these circumstances, the Board considers that the preparation of formulations according to claim 1 as granted, in particular using a low amount of binder, is a priori not an easy task but is a challenging one, as even put forward by the appellant themselves.

- 3.3.5 In view of the above, it is concluded that the selection of at least the four mandatory components that are necessary to prepare formulations according to claim 1 as granted (namely the four components defined therein as binder, reactive diluent, UV blocker and photoinitiator) is not trivial, in particular for the formulations containing low amounts of binders considered by the opposition division. This is all the more true for the whole composition, which can further contain additional components (in view of the open wording "comprises") in relatively high amounts (the four mandatory components may make up only 26.1 percent by weight of the whole composition).

Lack of guidance in the patent in suit

- 3.4 Regarding the selection of the four mandatory components specified in claim 1 as granted, the Board agrees with the respondent's view put forward during the oral proceedings before the Board that the patent in suit contains very little information beyond the one defined in the claims as granted: after an introductory paragraph and the description of the relevant prior art (paragraphs 1-10), the patent specification only contains a brief description of the invention (paragraphs 11-16), followed by a more detailed

description of the invention (paragraphs 17-25), which mostly consists in the repetition of the granted claims.

3.4.1 In addition, as was put forward by the respondent (rejoinder: points 15 and 23-28), the patent in suit provides only two nominal examples of the "acrylate and/or methacrylate-based oligomer" that can allegedly be suitably used as binder, namely urethane acrylate-based and methacrylate-based oligomers (claims 2 and 3 as granted). Not only does the patent in suit provide no information regarding which other binders apart from the ones specified in claims 2 and 3 can be suitably used, but it also fails to provide any information regarding the precise chemical nature of the repeating units thereof, even for the more specific oligomers specified in a still relatively generic manner in claims 2 and 3 as granted ("urethane acrylate-based oligomer" or "urethane methacrylate-based oligomer"). Similar concerns are valid regarding the definition of the reactive diluent, of the UV blocker and photoinitiator, for which no other information than the one indicated in claims 4 to 7 and 8 as granted is provided by the patent in suit. In that regard, the respondent pointed out that also the selection of the reactive diluent might not be an easy task (rejoinder: point 28).

3.4.2 In addition, the skilled person is also not provided with any indication regarding which precise combination of the four mandatory components specified in claim 1 as granted effectively works and is suitable to provide an IOL satisfying the functional definition according to said claim 1. In that regard, even the appellant indicated that the selection of a suitable combination of photoinitiator and UV blocker was not trivial but

rather "very challenging" (statement of grounds of appeal: page 4, last paragraph; page 5, second paragraph). In particular, as the specification does not contain any example, there is no evidence on file demonstrating the successful preparation of a formulation satisfying both the structural and the functional definitions thereof according to claim 1 as granted. This is all the more the case for any combination of components different from the ones based on the components indicated in dependent claims 2/3, 6, 7 and 8 (considering that even a combination of these components has not been shown to work).

- 3.4.3 Furthermore, the patent in suit contains no guidance regarding what should be done if a formulation satisfying the structural definition of claim 1 as granted and with low amounts of acrylic oligomeric binder (e.g. 20 wt.% or slightly more) does not satisfy the functional definition of claim 1, i.e. how to turn a failure into success. In particular, no preferred ranges of the four mandatory components of the formulation (binder, reactive diluent, UV blocker and photoinitiator) are indicated in the description, nor are any examples given to provide any guidance. Also, the patent in suit fails to provide a general discussion regarding the nature and amounts of component(s) to be used in order to control the combination of properties of the IOLs specified in claim 1 as granted, let alone any of these properties. The patent in suit further fails to elucidate the interplay between these individual properties and provides no guidance to assist the skilled person, when confronted with a composition that meets some but not all the requirements of claim 1, in identifying which aspects should be modified and in what manner in order to obtain, in a structured and guided manner, a

composition meeting the requirements of claim 1. It was also not shown that such information makes part of common general knowledge.

3.4.4 As an aside, it is noted that, as pointed out by the respondent (letter of 20 June 2025: page 3, end of first paragraph), the patent in suit also contains no information regarding the "optimized UV-source energy parameters" that were indicated by the appellant to be needed in addition to the careful selection of the four mandatory components specified in claim 1 as granted to prepare the formulations being claimed (statement of grounds of appeal: bottom of page 4; letter of 28 May 2025: page 13, last paragraph).

3.4.5 In view of the above, the Board considers that the patent specification does not provide the skilled person with any concrete starting point how to successfully prepare a formulation according to claim 1 as granted that contains an amount of binder in the lower part of the range defined therein while satisfying the functional definition contained therein. This, in the Board's view, can only be achieved by trial and error, which, in the light of the broad definitions given already for the four mandatory components of the formulations being claimed and the limited information contained in the patent specification, constitutes an undue burden.

Relying on common general knowledge

3.5 During the whole proceedings, the appellant considered that the requirements of sufficiency of disclosure were met because, according to established case law, the information provided in the patent specification could be complemented if needed with the skilled person's

common general knowledge (statement of grounds of appeal: bottom of page 7 to middle of page 9 and bottom of page 9 to bottom of page 12; letter of 28 May 2025: middle of page 2; minutes of the oral proceedings before the Board: top of page 5). According to the appellant, the skilled person working in the field of IOLs would be well aware which components could be used to prepare the formulations defined in claims 1 and 9 as granted, either in respect of the four mandatory components contained therein (namely the binder, the reactive diluent, the UV blocker and the photoinitiator) or the optionally present other components (considering the open formulation of claim 1 as granted "in that the formulation comprises...").

- 3.5.1 Although it is correct that sufficiency of disclosure is to be assessed also taking into account common general knowledge (as indicated in above point 3.1; see also Case Law, *supra*, II.C.4.1), the Board considers that there is no evidence on file that the above indicated lack of sufficient information of the patent in suit could be complemented by common general knowledge.
- 3.5.2 In that respect, documents D1 to D14 were either mentioned or relied upon by the appellant during the appeal proceedings (D2, D4 and D9 are cited as P1, P9 and P3, respectively in the statement of grounds of appeal; D1 to D13 are mentioned in the last paragraph on page 8 of the appellant's letter of 28 May 2025, whereby detailed arguments are provided in the following pages for each of D1 to D5, D8 to D11 and D14 - see below). However, for the reasons indicated in section 2.1.4 above, since these documents are either patent documents (D1 to D5 and D7 to D14) or a scientific article (D6), they do not constitute common

general knowledge. In addition, while these documents may indicate that some binders, reactive diluents, UV blockers and/or photoinitiators as defined in claim 1 as granted were known in the art at the priority/filing date of the patent in suit, it was not shown by the appellant that these documents, either taken alone or in combination, provide any guidance regarding which specific combination(s) of the four mandatory components specified in claim 1 as granted and of optional additional components possibly present would be suitable to prepare with a good chance of success and without undue burden a formulation as claimed, in particular when using an amount of binder in the lower end of the range specified in claim 1 as granted. In particular, the compositions of the prior art relied upon by the appellant differ from the ones according to claim 1 as granted or are not relevant to fill the gap in view of the following reasons:

- The compositions according to either table 1 of D5 (letter of 28 May 2025: top of page 9), table 1 on page 13 or the claims of D4 (letter of 28 May 2025: middle of page 10 to middle of page 11), D10 or D11 (letter of 28 May 2025: middle of page 12 to top of page 13) and D1 (letter of 28 May 2025: top of page 14 to bottom of page 17) do not contain a combination of oligomeric binder and reactive diluent as defined (also in terms of their amounts) in claim 1 as granted.
- The compositions according to table 2 of D14 (letter of 28 May 2025: bottom of page 9) do not contain any oligomers as defined in claim 1 as granted.

- The compositions of D2 and D3 (letter of 28 May 2025: page 10, second paragraph) were apparently cited in order to show which components could be used in addition to the four mandatory components specified in claim 1 as granted in order to prepare a formulation in which all components add up to 100 wt.%.
- The compositions of D8 (letter of 28 May 2025: page 11, last full paragraph) were neither shown to be suitably used for making IOLs, nor to contain a UV blocker according to claim 1 as granted.
- The compositions of D9 (letter of 28 May 2025: paragraph bridging pages 11 and 12) were neither shown to contain an amount of oligomeric binder in the lower end of the range according to claim 1 as granted, nor to contain a UV blocker as defined therein.

In view of the above, these documents do not provide any hint to the skilled person how to meet the - in the appellant's own view - challenge of carefully selecting the appropriate combination of components in order to prepare successfully and without undue burden a formulation according to claim 1 as granted, in particular with an amount of binder in the lower end of the range defined therein (see statement of grounds of appeal: bottom of page 4 and second paragraph on page 5; appellant's letter of 28 May 2025: bottom of page 13).

- 3.5.3 During the oral proceedings before the Board, the inventor indicated that she disagreed with the fact that the patent specification should provide too many explanations regarding the precise nature of the

formulations being claimed. In particular, the inventor considered (in line with the statements made in the statement of grounds of appeal: page 7) that the patent in suit was directed to a skilled person with some experience in the technical field of IOLs: such a person would readily know, on the basis of her/his technical knowledge and/or common general knowledge, which components and combinations thereof could be suitably used to carry out the invention.

However, in the absence of any evidence of such common general knowledge corroborating the inventor's statements regarding e.g. which combinations of the four mandatory components would be expected to work, this argument fails to convince. To the contrary, this line of argument rather confirms that, in order to successfully carry out the invention without undue burden, additional knowledge that goes beyond the teaching of the patent complemented by common general knowledge (such as the one of the skilled person with sufficient technical knowledge mentioned by the inventor), would be necessary. This conclusion is further confirmed by the fact that, according to the appellant's own view, finding out such a combination of components is a challenging task.

- 3.5.4 The inventor further put forward that she had been working for years with IOLs according to claim 1 as granted and that these formulations were the subject of several patents in various jurisdictions. In addition, the inventor stated that the fact that the respondent, one of the biggest companies in the present technical field, fought to have the patent in suit revoked, further demonstrated the importance of this patent and indirectly indicated the value of the subject matter being claimed.

However, these arguments are irrelevant to the question of sufficiency of disclosure here at stake. This actually involves the question whether the patent in suit, optionally in combination with common general knowledge, provides sufficient information and guidance on how to carry out the invention as defined in claim 1 as granted. In this respect, it is further stressed that the point of dispute between the parties is not if claim 1 as granted encompasses any specific working embodiment(s) at all (which may be of economic interest) but rather if the patent in suit provides sufficient guidance how to prepare, with a good chance of success and without undue burden, a formulation that allows to manufacture an IOL according to the functional definition of claim 1 as granted over the whole breadth of the claim, including in particular the lower part of the range for the amount of the binder.

- 3.5.5 In view of the above, the Board considers that the patent specification, even when complemented by common general knowledge, does not provide sufficient guidance how to select the binder, reactive diluent, UV blocker and photoinitiator over the whole breadth of claim 1 as granted, in a reliable manner and with a good chance of success of meeting the functional definition of claim 1. In other words, the scope of claim 1 as granted is not commensurate to the technical contribution of the patent in suit in terms of technical teaching disclosed and, for that reason, the invention according to claim 1 as granted is not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art (Article 100(b) EPC).

Burden of proof

- 3.6 The respondent argued that, in the present case, the burden of proof for establishing sufficiency of disclosure was on the appellant/patent proprietor (rejoinder: points 13-14), which was contested by the appellant (minutes of the oral proceedings: page 5, first paragraph, last sentence).
- 3.6.1 In this respect, according to established case law, a successful objection of insufficiency of disclosure presupposes that there are serious doubts substantiated by verifiable facts that the skilled person is not able to carry out the invention as claimed without undue burden (see e.g. T 19/90, point 3.3 of the reasons). In order to establish insufficiency of disclosure in *inter partes* proceedings, the burden of proof initially lies with the opponent to establish, on the balance of probabilities, that a skilled person reading the patent, and using common general knowledge, would be unable to carry out the invention. The weight of the submissions required for a successful objection of insufficient disclosure is commensurate with the teaching provided in the patent in suit. This implies that whether the respondent's arguments in relation to sufficiency of disclosure in the present case are no more than assertions without any firm basis (as alleged by the appellant) depends on the teaching provided in the patent in suit and the relevant common general knowledge. The general principle applies, namely that each party bears the burden of proving the submissions it presents.
- 3.6.2 In the present case, the Board notes that the respondent's objection of lack of sufficiency of disclosure is not supported by any evidence. In

particular, the respondent has not conducted any experiment to show that the skilled person would have any difficulty to prepare a formulation according to claim 1 as granted.

3.6.3 However, on the other hand, there is no single functioning embodiment available on file and there are reasonable doubts corroborated by the submissions of the appellant concerning at least the lower part of the range of the amount of the binder. In this respect, also the argument of the appellant that the skilled person could rely on common general knowledge to prepare the formulations being claimed on the whole breadth of claim 1 as granted is not supported by any evidence. In particular, an explanation is missing regarding which specific combination of the four mandatory components specified therein (binder, reactive diluent, UV blocker and photoinitiator) - apart from the specific ones that are listed in dependent claims 2, 3, 6, 7 and 8, for which there is also no evidence on file which combinations of components effectively work - would be considered to be suitable to prepare a formulation according to claim 1 as granted, in particular a formulation that comprises e.g. a low amount of acrylic oligomeric binder and that satisfies the functional definition thereof.

3.6.4 In the present case, as outlined in sections 3.3 to 3.5 above (in full), the Board shares the view of the opposition division that considering the (very limited) disclosure of the patent specification, even complemented by common general knowledge, the invention is not sufficiently disclosed over the whole breadth of claim 1 as granted (reasons: point 1.1.9, bottom of page 6). Therefore, the Board considers that, in the circumstances of the present case, it is sufficient for

the respondent to discharge its burden to argue that common general knowledge does not enable the skilled person to put the invention into practice. The burden of proof for establishing sufficiency of disclosure was thus shifted to the appellant/patent proprietor (Case Law, *supra*, II.C.9.1). For the reasons indicated in above sections 3.3 to 3.5, the Board arrived at the conclusion that, in the circumstances of the present case, the requirements of sufficiency of disclosure were not met.

- 3.7 In view of the above, the arguments submitted by the appellant do not justify that the decision of the opposition division regarding (lack of) sufficiency of disclosure of claim 1 as granted be overturned, i.e. the ground of opposition under Article 100(b) EPC prejudices maintenance of the patent as granted.

Claim 9 as granted

- 3.8 Claim 9 as granted is directed to a method in which use is made of a formulation defined in a very similar manner to the one according to claim 1 as granted. As pointed out by the respondent (rejoinder: point 34), the method steps of claim 9 as granted are broad and generic and provide no specific teaching which can help to fix the problems of (lack of) sufficiency of disclosure indicated above with respect to claim 1 as granted. This view, which was indicated in the Board's communication (point 6.5), remained undisputed, in particular at the oral proceedings before the Board (minutes, page 5, third and fourth paragraphs). Therefore, the same conclusion regarding sufficiency of disclosure as the one reached for claim 1 as granted is bound to be reached for claim 9 as granted.

- 3.9 In view of the above, the appellant's arguments do not justify that the Board overturns the decision of the opposition division that the ground of opposition under Article 100(b) EPC prejudices maintenance of the patent as granted also with respect to the method of claim 9 as granted.

Auxiliary requests 1 to 8 - Admittance

4. It was common ground that operative auxiliary requests 1 to 8, whose admittance was contested by the respondent (rejoinder: points 2 and 58-60), were all submitted by the appellant for the first time with the statement of grounds of appeal. Therefore, their admittance is subject to the Board's discretion pursuant to Articles 12(4) to 12(6) RPBA.
- 4.1 In that respect, the appellant has not explained in the statement of grounds of appeal why these auxiliary requests were submitted for the first time in the appeal proceedings.
- 4.1.1 In addition, as already indicated in point 2.1.3 above, it is apparent from the file history that the objection of lack of sufficiency of disclosure retained by the opposition division in their decision against the patent in suit was based on an objection that had been identified at least in both of their preliminary opinions, which were negative for the appellant (then patent proprietor). However the appellant never filed auxiliary requests, as fall back positions, in the course of the opposition proceedings, including at the oral proceedings before the opposition division once the main request was held not to meet the requirements of sufficiency of disclosure. In particular, in the light of the opposition division's negative preliminary

opinions issued in preparation of the oral proceedings, the appellant should have been aware that the opposition division could decide to their disadvantage in respect of the sole request then being defended and had therefore good reasons to prepare the defence of their case accordingly, including by filing any of auxiliary requests 1 to 8, either in reply to (any of) the preliminary opinions or, at the latest, during the oral proceedings, which was not done.

- 4.1.2 Also, it was neither shown, nor even argued by the appellant that the filing of auxiliary requests 1 to 8 with the statement of grounds of appeal was justified in the light of new circumstances, for instance deriving from the course of the opposition proceedings or from the opposition division's decision, that had taken the appellant by surprise. The Board also sees no reason to deviate from this view.
- 4.1.3 Furthermore, by not submitting any of auxiliary requests 1 to 8 already during the opposition proceedings, the appellant (then patent proprietor) eventually prevented the opposition division from taking a decision on the subject-matter of these requests, in particular regarding the main issue already at stake (sufficiency of disclosure).
- 4.1.4 For these reasons, the Board considers that the circumstances of the present case do not justify the filing of auxiliary requests 1 to 8 for the first time with the statement of grounds of appeal (Article 12(6) RPBA).
- 4.2 In addition, admitting any of these requests into the proceedings may have led to a situation in which new issues would have had to be discussed for the first

time during the appeal proceedings (see objections pursuant to Article 84 EPC and Article 123(2) EPC put forward by the respondent in the rejoinder, points 61-83), which would run against both the primary object of the appeal proceedings to review the decision under appeal in a judicial manner (Article 12(2) RPBA) and the need for procedural economy (Article 12(4) RPBA).

- 4.2.1 In particular, it was taken into account that the appellant did not reply in writing to the objections pursuant to Article 123(2) EPC and Article 84 EPC that were put forward by the respondent against each of auxiliary requests 1 to 8 (rejoinder, points 61-83), and this, even after this was specifically indicated in the Board's communication (point 7.3; see also respondent's letter of 20 June 2025: page 1, third full paragraph). Therefore, had any of the auxiliary requests been admitted, these issues would have had to be dealt with for the first time during the oral proceedings before the Board, which runs counter to the need for procedural economy.
- 4.2.2 Also, as pointed out by the respondent (rejoinder: point 60) and remained undisputed (in particular at the oral proceedings before the Board), claim 9 of each of auxiliary requests 1 to 8 is identical to claim 9 of the main request (see points X. to XVIII. above). Therefore, the same conclusion regarding (lack of) sufficiency of disclosure as the one drawn for claim 9 as granted would have had to be reached for claim 9 of each of auxiliary requests 1 to 8, i.e. none of these auxiliary requests would be allowable.
- 4.2.3 Therefore, not only would the admittance of auxiliary requests 1 to 8 not be in favour of procedural economy

but also none of these auxiliary requests would be suitable to overcome the objection of lack of sufficiency that was retained against the main request (Article 12(4) RPBA).

- 4.3 For these reasons, the Board made use of its discretion to decide by not admitting into the proceedings any of auxiliary requests 1 to 8 (Articles 12(4) and (6) RPBA).
5. Although the appellant contemplated filing amended versions of auxiliary requests 1 to 8 during the oral proceedings before the Board, they eventually decided not to do so (minutes of the oral proceedings: page 6, third and fifth to seventh paragraphs). Therefore, considering that the main request defended by the appellant is not allowable and that none of their auxiliary requests was admitted into the proceedings, the appeal is to be dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



D. Hampe

D. Semino

Decision electronically authenticated