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Datasheet for the decision of 29 July 2026

Case Number: T 0225/25 - 3.3.09

Application Number: 13163179.8

Publication Number: 2638879

IPC: A61F2/14, G02B1/04, G02C7/04

Language of the proceedings: EN

Title of invention:
Silicone hydrogel lenses with water-rich surfaces

Applicant:
Alcon Inc.

Headword:
Silicone hydrogel lenses/ALCON

Relevant legal provisions:
EPC R. 103(1)(a)
EPC Art. 111(1), 113(1)
RPBA 2020 Art. 11

Keyword:
Remittal - fundamental deficiency in first-instance proceedings (yes)
Reimbursement of appeal fee - violation of the right to be heard (yes)

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It can be changed at any time and without notice

Decisions cited:
T 0435/07

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Case Number: T 0225/25 - 3.3.09

D E C I S I O N
of Technical Board of Appeal 3.3.09
of 29 July 2026

Appellant: (Applicant)	Alcon Inc. Rue Louis-d'Affry 6 1701 Fribourg (CH)
Representative:	Breuer, Markus Sendlinger Straße 29 80331 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted/electronically transmitted on 1 August 2024 refusing European patent application No. 13163179.8 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	A. Haderlein
Members:	M. Ansorge
	G. Decker

Summary of Facts and Submissions

I. This case concerns an appeal against the examining division's decision refusing the patent application.

II. In the European search opinion the examining division cited, *inter alia,* the following documents:

D1: US 6,582,754 B1
D2: US 2009/0200692 A1

The examining division raised, *inter alia*, novelty objections in view of D1 and D2 (see points 6.1 and 6.2 of the European search opinion).

III. By letter dated 14 November 2018, the applicant filed a set of claims intended to overcome the objections raised by the examining division and provided arguments as to why, in its opinion, the subject-matter of claim 1 was allowable, e.g. being novel over D1 and D2.

IV. Claim 1 (as filed on 14 November 2018) reads as follows:

"A silicone hydrogel contact lens having a layered structural configuration and a water content gradient from inside to outside of the silicone hydrogel contact lens, comprising: a lower water content silicone hydrogel core (or bulk material) completely covered with an outer (surface) hydrogel layer having a higher water content and a thickness of 0.1 µm to 20 µm as measured with atomic force microscopy across a cross section from the posterior surface to the anterior surface of the silicone hydrogel contact lens in fully hydrated state, wherein the outer hydrogel layer is

substantially free of silicone, preferably totally free of silicone, and wherein the water content of the outer hydrogel layer is at least 1.2 folds (or 120%) of the water content of the silicone hydrogel bulk material when being fully hydrated."

Claims 2 to 4 are dependent claims.

V. The novelty objections over D1 and D2 were maintained in the examining division's communication dated 15 November 2021 (see points 6.1 and 6.2 thereof).

VI. After considering the applicant's reply to the communication, the examining division summoned the applicant to oral proceedings on 2 July 2024.

VII. In the annex to the summons the examining division provided a line of argument as to why the subject-matter of claim 1 was not novel over D2. It argued that D2 disclosed a silicone hydrogel contact lens of which the anterior and posterior surfaces were completely coated with a 1–10 µm thick layer of a hydrophilic biomedical material, thereby providing a hydrophilic surface having high oxygen permeability. Since the disclosed coating materials were capable of absorbing significant amounts of water and contact lenses were stored in an aqueous preservation solution, the contact lens of D2, when fully hydrated, also fulfilled the water-content requirement of claim 1.

The novelty objection over D1 was no longer mentioned in the annex to the summons.

VIII. Oral proceedings took place before the examining division on 2 July 2024. The question of novelty over D2 was discussed during the oral proceedings.

IX. As can be taken from point 1 of the minutes of the oral proceedings, "*the primary examiner detailed the objections of the examining division against claim 1*" and it was "*emphasised that the claim defines the contact lens also via its physical properties in the fully hydrated state, in particular, the water content of the coating versus that of the core material*". The examining division was of the opinion that water was not part of the lens itself and would, for example, evaporate if the lens was left, for example, to dry on a table. It was further held that, for the assessment of novelty, the chemical nature of the silicone hydrogel used for preparing the core of the contact lens and the nature of the hydrogels used in the coating material had to be taken into consideration. In the examining division's opinion the water absorption capacity of the materials used was of critical importance to the amount of water present in the respective layers in the fully hydrated state.

The remainder of the minutes mainly summarised the applicant's arguments.

At the end of the oral proceedings, the examining division concluded that the claimed subject-matter was not novel over D2.

X. In the decision under appeal, the examining division provided detailed reasoning for the lack of novelty over D2, the most relevant parts thereof being as follows (emphasis as in the original):

"***10.3. Document D2 discloses***

Document D2 (US2009/00692 A1) *discloses a silicone contact lens having a hydrophilic surface, the contact lens comprising a core comprising a soft silicone gel or a silicone hydrogel and a biomedical material coating. According to par. [0018] of D2 the lens core is coated on both, the anterior and the posterior side (male and female side) with a hydrogel based coating material and the coating material has a thickness of 1-10 µm (in the dry state). Hence, even if the thickness of the hydrogel coating layer upon hydration were to increase by 100%, the resulting thickness of the coating layer would arrive in the 2-20 µm range, thereby still falling under the definition in claim 1. The coating material is selected from the group HEMA, glycerol methacrylate (GMA), glycerol methyl methacrylate (GMMA), N-vinyl pyrrolidone (NVP), methacrylic acid (MAA), poly vinyl alcohol (PVA), chitosan, collagen etc. All of these materials when polymerized and potentially crosslinked (except for methyl methacrylate, MMA, in its pure form) form hydrogels and can absorb significant amounts of water. Hence the contact lenses of D2 inherently fulfil the requirement concerning the water content defined in claim 1, when fully hydrated (cf. further details below). Given that contact lenses are commonly stored in aqueous preservation media the fully hydrated state can be considered as being implicitly disclosed by D2.*

...

11 Arguments of the applicants

...

11.3. No enabling disclosure of D2 and no hydrogels formed in D2

The applicants[sic] argue that some of the compounds listed in claim 2 (of D2) cannot form hydrogels, and that D2 contains no disclosure as to how to prepare hydrogels or contact lenses at all.

The examining division is not convinced by this argument since in principle all hydrophilic compounds possessing a polymerisable bond i.e. a vinylic bond, isocyanate groups, hydroxyl groups (diols, polyols) or amine groups can form hydrogels.

Accordingly any compound in claim 2 can form a hydrogel when polymerized alone or in combination with of[sic] a hydrophilic cross-linker, as for example defined in claim 7 of D2.

The same holds with regard to the polymers disclosed in claim 2 of D2, which are polyvinylalcohol (PVA), polyurethane (PU) and hyaluronic acid. Suitable crosslinkers are well known in the art and include epoxides, diisocyantes etc.

Additionally paragraphs [0018 and 0019] of D2 lists a plurality of concrete technical ways and possibilities for forming hydrogel coating materials. The skilled person can work this teaching across the whole range.

Furthermore the definition of the polymers in D2 is also considered to imply the use of the respective monomers for the formation of the polymeric hydrogels, PVA implies vinylic alcohol, PU implies diisocyanates etc.

The potential use of a large variety of materials for the formation of hydrogels is also confirmed by the present application, which reads:

'any water-soluble and crosslinkable hydrophilic polymeric material containing crosslinkable groups can be used in the invention to form the anterior and posterior outer hydrogel layers of a SiHy contact lens'. (description p.31, end of paragraph 2). Additionally the compounds and hydrogel-forming materials disclosed in D2 are also mentioned in the application as 'hydrophilicity-enhancing agents' (description, p.33,34), which are co-polymerized with other hydrophilic monomers to produce water absorbing hydrogels.

The way how such hydrogels are prepared and how the monomers mentioned above can be polymerized is well known in the art and can be carried out by the person skilled in the field.

In summary D2 is considered to provide enough information for the skilled person for the preparation of a coated contact lens comparable to the contact lens defined in claim 1. The chemistry, reactivity and the properties of the monomers and polymers mentioned are well known. Therefore the disclosure of D2 is considered to be enabling the skilled person to prepare a contact lens having a silicone hydrogel core and a complete hydrogel coating.

..."

XI. The applicant (appellant) lodged an appeal against the examining division's decision refusing the patent application.

XII. Requests

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the set of claims filed on 14 November 2018. As an auxiliary measure, the appellant requested that the case be remitted to the examining division for further prosecution. Reimbursement of the appeal fee was also requested.

Reasons for the Decision

1. Substantial procedural violation in the proceedings before the examining division

1.1 The appellant objected that the examining division had relied at several points in the decision under appeal on reasoning that had not previously been brought to the appellant's attention and on which it had had no opportunity to comment. In the appellant's opinion this amounted to a violation of its right to be heard.

1.2 The right to be heard under Article 113(1) EPC is an important procedural right intended to ensure that no party is caught unaware by reasons given in a decision turning down its request on which it has not had the opportunity to comment. A decision which is based on a ground on which the party has had no opportunity to present its comments infringes Article 113(1) EPC and constitutes a substantial procedural violation (see Case Law of the Boards of Appeal, 11th edition, 2026 revision ("CLBA"), V.A.11.6.8).

1.3 In this context, the board emphasises that, according to established case law, a board of appeal - and, by

the same token, a department of first instance - is not required to provide the parties in advance with all foreseeable arguments in favour of or against a request. In other words, parties are not entitled to advance indications of all reasons for a decision in detail (see CLBA, V.B.4.3.5 and III.B.2.4.1).

1.4 However, the grounds on which a decision is based must be communicated to the applicant in such a way that it is put in a position to defend its rights. An objection against the grant of a patent must be raised in such a way that the applicant is able to understand its factual basis and to react accordingly (see T 435/07, Catchword). "Grounds or evidence" under Article 113(1) EPC are to be understood as the essential legal and factual reasoning on which the decision is based (see CLBA, III.B.2.4.2).

1.5 For the purposes of safeguarding the right to be heard, it is sufficient that the essential legal and factual reasoning has been discussed during the oral proceedings. In determining whether this is the case, a board can rely only on the minutes, since they are the sole means of ascertaining what actually occurred during the oral proceedings (see CLBA, III.C.8.10.3).

1.6 For the following reasons, the appellant's right to be heard was violated.

1.6.1 In the written examination proceedings the examining division provided reasons as to why, in its opinion, the subject-matter of claim 1 was not novel over D2. The examining division's reasoning of lack of novelty throughout the entire written phase, including the most detailed reasoning as given in the annex to the summons, was quite concise. Shortly before the date of

the oral proceedings, the appellant responded by submitting comprehensive and detailed counter-arguments, explaining why it considered that the claimed subject-matter was novel over D2 (see the appellant's letter dated 28 May 2024).

1.6.2 The decision contains numerous new arguments compared with the examining division's lack-of-novelty reasoning based on D2 during the written examination proceedings.

1.6.3 In point 10.3 of the decision the examining division amended a key passage in its lack-of-novelty reasoning over D2 compared to its reasoning provided in the annex to the summons as follows (amendments in the decision not included in the annex to the summons are indicated by highlighted and struck-through text):

"The coating material is selected from the group HEMA, glycerol methacrylate (GMA), glycerol methyl methacrylate (GMMA), N-vinyl pyrrolidone (NVP), methacrylic acid (MAA), ~~methyl methacrylate (MMA) and~~ poly vinyl alcohol (PVA), **chitosan, collagen etc.** All of these materials **when polymerized and potentially crosslinked (except for methyl methacrylate, MMA, in its pure form) form hydrogels and** can absorb significant amounts of water ~~such that the lenses of D2 fulfill the requirement concerning the water content defined in claim 1, when hydrated~~."

Accordingly, the examining division supplemented chitosan and collagen as possible materials of the coating material, deleted the term "methyl methacrylate (MMA)" from the list and incorporated the wording "when polymerized and potentially crosslinked (except for methyl methacrylate, MMA, in its pure form) form hydrogels". These changes amount to new arguments and a

significant change in meaning compared to the original reasoning provided in the annex to the summons.

In the annex to the summons it was argued that all the listed monomers or polymers could absorb significant amounts of water, such that the claimed water content was achieved in the hydrated state. By contrast, the decision relied on a different line of reasoning, namely that all those materials (except for MMA in its pure form) formed hydrogels when polymerised and, where appropriate, crosslinked. It is evident that the meaning of the original passage in the annex to the summons was significantly changed through the new passage in the decision. These new arguments are considered essential to the examining division's lack-of-novelty reasoning in the decision and are not merely minor supplementing arguments of the line of argument of lack of novelty over D2.

1.6.4 In addition, the following new arguments, which were not part of the lack-of-novelty reasoning over D2 provided in the annex to the summons, were added in point 11.3 of the decision:

- "The examining division is not convinced by this argument since in principle all hydrophilic compounds possessing a polymerisable bond i.e. a vinylic bond, isocyanate groups, hydroxyl groups (diols, polyols) or amine groups can form hydrogels. Accordingly any compound in claim 2 can form a hydrogel when polymerized alone or in combination with a hydrophilic cross-linker, as for example defined in claim 7 of D2. The same holds with regard to the polymers disclosed in claim 2 of D2, which are polyvinylalcohol (PVA), polyurethane (PU) and hyaluronic acid. Suitable crosslinkers are

well known in the art and include epoxides, diisocyantes etc." (see point 11.3 of the decision)

- "Furthermore the definition of the polymers in D2 is also considered to imply the use of the respective monomers for the formation of the polymeric hydrogels, PVA implies vinylic alcohol, PU implies diisocyanates etc." (see point 11.3 of the decision)

These new arguments incorporate significant new aspects into the reasoning compared to the reasoning provided in the annex to the summons and significantly change the meaning of the original reasoning in the annex to the summons.

The reasoning set out in the annex to the summons stated that all the cited materials, when hydrated, could absorb significant amounts of water and thus meet the claimed water-content requirement. By contrast, the reasoning in the decision distinguished between the monomers and the polymers referred to in claim 2. With respect to the monomers, it was argued that they can form hydrogels when polymerised or crosslinked. With respect to the polymers, it was argued that they can also form hydrogels. There is no doubt that these new lack-of-novelty arguments were not mentioned at any point in the entire written examination phase. Due to the significant change in meaning compared to the original reasoning, these new arguments are considered essential arguments to the examining division's lack-of-novelty reasoning in the decision and not just minor supplementing arguments of the line of argument of lack of novelty over D2.

2. There would be no violation of the right to be heard if the new arguments set out in the reasons for the decision had already been discussed during the oral proceedings. However, there is no indication in the minutes that the new arguments were communicated to the appellant and discussed with the appellant at the oral proceedings.

(a) Point 1 of the minutes notes that the primary examiner explained the examining division's objections to claim 1 in detail. This is followed by a summary of the line of reasoning already set out in the annex to the summons. Beyond that summary, the minutes contain no indication that any new arguments going beyond those set out in the annex to the summons were discussed with the appellant.

(b) In addition, it can be taken from points 1 and 2 of the minutes that the primary examiner explained how the subject-matter of claim 1 was interpreted. This observation is also insufficient to establish that the new aspects on which the decision under appeal was based were discussed during the oral proceedings.

(c) Aside from the above-mentioned statements, the minutes merely summarise the appellant's submissions during the oral proceedings.

To summarise, the board is of the opinion that the appellant was not in a position to comment on the new arguments in the examination proceedings, including the oral proceedings. These arguments were only brought to the appellant's attention by the decision, but not during the written phase or at the oral proceedings.

Under these circumstances, the board concludes that the appellant's right to be heard was violated, which amounts to a substantial procedural violation.

3. Remittal of the case to the examining division

3.1 Under Article 11 RPBA, the board is not to remit a case to the department whose decision was appealed for further prosecution unless special reasons present themselves for doing so. As a rule, fundamental deficiencies which are apparent in the proceedings before that department constitute such special reasons.

3.2 As established in point 1 above, the proceedings before the examining division were tainted by a substantial procedural violation. The case is therefore to be remitted to the examining division for further prosecution pursuant to Article 111(1), second sentence, EPC, in accordance with the rule laid down in Article 11 RPBA. In the present case, the board sees no reason to depart from that rule.

4. Reimbursement of the appeal fee

4.1 Under Rule 103(1)(a) EPC, the appeal fee is to be reimbursed in full in cases in which the board deems an appeal to be allowable if such reimbursement is equitable by reason of a substantial procedural violation.

4.2 As established in point 1 above, the proceedings before the examining division were tainted by a substantial procedural violation. Consequently, the decision under appeal is to be set aside and the case remitted to the examining division for further prosecution (see point 2 above). The appeal is therefore allowable. Moreover,

the board sees no reason why reimbursement of the appeal fee would not be equitable.

5. Observations concerning the further prosecution of the case

For the further prosecution of the case, the board wishes to point out that, in view of its communication under Article 15(1) RPBA, the third-party observations and the appellant's counter-arguments submitted in the appeal proceedings, document D1 appears to be highly relevant to the assessment of inventive step.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the examining division for further prosecution.

3. The appeal fee is reimbursed.

The Registrar: The Chairman:

K. Götz-Wein A. Haderlein

Decision electronically authenticated