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Datasheet for the decision of 16 September 2022

Case Number: T 1119/19 - 3.3.03

Application Number: 13728602.7

Publication Number: 2855546

IPC: C08F293/00, G02B1/04, C08J7/00, B82Y30/00, C08L53/00, C08F220/58

Language of the proceedings: EN

Title of invention:

CONTACT LENSES COMPRISING WATER SOLUBLE N-(2 HYDROXYALKYL) (METH)ACRYLAMIDE POLYMERS OR COPOLYMERS

Patent Proprietor:

Johnson & Johnson Vision Care, Inc.

Opponent:

Novartis AG

Relevant legal provisions:

RPBA Art. 12(4)
EPC Art. 56

Keyword:

Late-filed documents - admitted (yes)
Inventive step - (no)

Decisions cited:
T 0892/08, T 1742/12

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Case Number: T 1119/19 - 3.3.03

D E C I S I O N
of Technical Board of Appeal 3.3.03
of 16 September 2022

Appellant: (Opponent)	Novartis AG Lichtstrasse 35 4056 Basel (CH)
Representative:	Breuer, Markus Brienner Straße 1 80333 München (DE)
Respondent: (Patent Proprietor)	Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway Suite 100 Jacksonville, FL 32256 (US)
Representative:	Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 4 February 2019 concerning maintenance of the European Patent No. 2855546 in amended form.**

Composition of the Board:

Chairman	D. Semino
Members:	D. Marquis
	A. Bacchin

Summary of Facts and Submissions

I. The appeal lies with the decision of the opposition division concerning maintenance of European patent No. 2 855 546 in amended form according to the claims of the main request corresponding to auxiliary request 3 filed with letter of 26 November 2018 and an amended description.

II. The following documents were cited in the opposition procedure:
D9: US 7 841 716
D11: US 2011/0275734

III. As far as it is relevant to the present appeal, the decision of the opposition division can be summarized as follows:

Document D11 was the closest prior art. Although D9 was concerned with the wettability of contact lenses, it was more remote than D11 which disclosed the same problem as the patent in suit, namely the provision of a good wettability and improved biometric performance evidenced by reduced lipocalin, lipid and mucin uptake levels. Claims 1, 2 and 20 of the main request differed from D11 in that the non-reactive hydrophilic polymer was free of terminal hydrophobic polymer blocks. The objective technical problem was the provision of alternative polymers having a similar performance in the reduction of lipocalin, lipids and mucin uptake. The skilled person starting from D11 would not have arrived at claim 1 of the main request since the silicone segment present in the polymers of D11 was disclosed as being essential in that document. Claim 1 of the main request was therefore inventive. For the

sake of completeness, an inventive step was acknowledged also starting from D9 as the closest prior art.

IV. The opponent (appellant) lodged an appeal against the decision of the opposition division and filed documents HBP14-HBP17 (renumbered D14 to D17 hereafter) with the statement of grounds of appeal:

D14: Rompp Chemie Lexikon, 9th Edition 1989, Entry "Polymerisationsgrad"
D15: R.B. Mandell, "Contact Lens Practice", Fourth Edition (1988), pages 628-636
D16: L. Jones, M. Senchyna, "Protein and Lipid Deposition of Silicone Hydrogel Contact Lens Materials", 2003, http://www.siliconehydrogels.org/editorials/previous_editorial_jones_senchyna.asp
D17: D. Luensmann, L. Jones, "Albumin adsorption to contact lens materials: A review", Contact Lens & Anterior Eye, 31, (2008), pages 179-187

V. The patent proprietor (respondent) filed auxiliary requests 1-8 with the reply to the statement of grounds of appeal and auxiliary requests 1a, 3a, 4a and 5a by letter of 2 September 2022.

VI. The parties were summoned to oral proceedings and a communication pursuant to Article 15(1) RPBA 2020 indicating specific issues to be discussed at the oral proceedings was sent to the parties.

VII. Oral proceedings were held on 16 September 2022 in the presence of both parties.

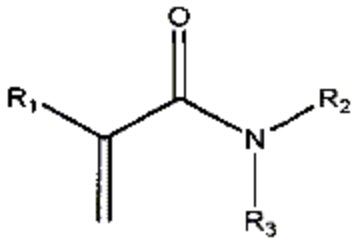
VIII. The final requests of the parties were as follows:

(a) The appellant requested that the decision of the opposition division be set aside and that the patent be revoked.

(b) The respondent requested that the appealed decision be set aside and the patent be maintained on the basis of one of auxiliary request 2 or 5, filed with the reply to the statement of grounds of appeal.

Claim 1 of auxiliary request 2 read as follows:

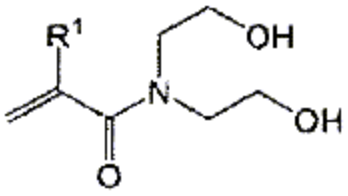
"1. A contact lens comprising a cross-linked polymer matrix and at least one water soluble, non-reactive hydrophilic polymer comprising less than 20 mol% anionic repeating units and between 20 and 100 mol% repeating units derived from N-(2-hydroxyalkyl)(meth)acrylamide of Formula I



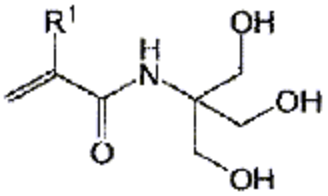
wherein R^1 is hydrogen or methyl,
R^2 is H or a C_{1-4} alkyl substituted with at least one hydroxyl group; and
R^3 is a C_{1-4} alkyl substituted with at least one hydroxyl group;
wherein said water soluble, non-reactive hydrophilic polymer has a degree of polymerization of between about 500 and about 10,000 and is free of terminal, hydrophobic polymer blocks, and wherein said polymer matrix comprises a silicone hydrogel".

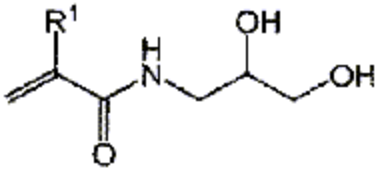
Claim 1 of auxiliary request 5 differed from claim

1 of auxiliary request 2 in that the water soluble, non-reactive hydrophilic polymer was a homopolymer of the defined repeating units and wherein "(a) R^3 is selected from the group consisting of, 2-hydroxypropyl, 3-hydroxypropyl, 2,3-dihydroxypropyl, 4-hydroxy butyl, 2-hydroxy-1,1-bis(hydroxymethyl) ethyl; and/or
(b) said N-(2-hydroxyalky)(meth)acrylamide is selected from the group consisting of N-(2-hydroxy propyl)(meth)acrylamide, N-(3-hydroxypropyl) (meth)acrylamide, N-(2-hydroxyethyl)acrylamide, and



N,N-bis(2-hydroxyethyl)acrylamide,





and mixtures thereof".

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

(a) D9 was a valid document to be taken as the closest prior art. Claim 1 of auxiliary request 2 lacked an inventive step over D9. Also claim 1 of auxiliary request 5 lacked an inventive step over D9.

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

(a) D9 was not a valid document to be taken as the closest prior art. Claim 1 of auxiliary request 2 was inventive over D9. Also claim 1 of auxiliary request 5 was inventive over D9.

Reasons for the Decision

1. Admittance of D14-D17

1.1 D14-D17 are documents filed by the appellant with their statement of grounds of appeal.

1.2 D14 is an extract of a chemical encyclopedia that contains a definition of the term degree of polymerization and provides evidence for the common general knowledge of the skilled person. D15-D17 were cited in appeal as supporting evidence that the object of D9 was related to that of the patent in suit (statement of grounds of appeal, page 25).

1.3 The respondent indicated at the oral proceedings before the Board that they no longer maintained their objection against the admittance of these documents into the proceedings. Under the present circumstances, the Board confirms its preliminary opinion expressed in the communication under Article 15(1) RPBA 2020 and sees no reason to hold D14-D15 inadmissible pursuant to Article 12(4) RPBA 2007 (which applies in view of Article 25(2) RPBA 2020). Documents D14-D17 are therefore admitted in the proceedings.

Auxiliary request 2 (present main request)

2. Inventive step
Suitable starting point

2.1 The boards have repeatedly pointed out that the closest prior art for assessing inventive step was normally a prior art document disclosing subject-matter conceived for the same purpose or aiming at the same objective as the claimed invention and having the most relevant technical features in common, i.e. requiring the minimum of structural modifications. A further criterion for the selection of the most promising starting point is the similarity of the technical problem (Case Law of the Boards of Appeal, 10th Edition 2022, I.D.3.1).

2.2 The patent in suit is in the field of contact lenses, especially lenses made from silicone hydrogels (paragraphs 1 and 2). The patent in suit teaches that users of prior art lenses could experience discomfort and excessive ocular deposits as a result of the hydrophobic character of the lens surface and the interaction of the lens surface with proteins, lipids and mucin and the hydrophilic surface of the eye (paragraph 2).

2.3 The patent in suit discloses that these disadvantages have been addressed in the prior art by incorporating a polymeric wetting agent into the contact lens matrix and/or the lens packaging solution (paragraph 3). Polyvinylpyrollidone and N-substituted poly(meth)acrylamides in particular have been used for that purpose (paragraph 4).

2.4 In that context, the objective set out in paragraph 8 of the patent in suit is to find additional high molecular weight hydrophilic polymers which could be incorporated into a lens formulation to improve wettability of the lens without a surface treatment. That objective is allegedly achieved by using a water soluble, non-reactive hydrophilic polymer based on N-hydroxyalkyl(meth)acrylamides of Formula I as set forth in claim 1 of auxiliary request 2.

2.5 Paragraph 126 of the patent in suit further discloses that the incorporation of at least one block copolymer according to the invention provides silicone hydrogel contact lenses displaying contact angles of less than about 60°, decreases in contact angles of less than about 40° as well as reduced lipocalin, lipid and mucin uptake levels. It is apparent from paragraph 130 that the contact angle measurement is an indicator of the wettability of the lens and from paragraph 2 that reduced lipocalin, lipid and mucin uptake levels are indicative of reduced deposits on the lens and ultimately of an increased wearing comfort for the user. In that regard, the contact angle measurements and uptake levels are specific properties of the lenses that support the general objective set out in the patent of improving wettability and wearing comfort of silicone hydrogel based contact lenses.

2.6 The opponent submitted before the opposition division that D9 and D11 could be seen as equally valid starting points to assess the presence of an inventive step. The opposition division concluded in their decision that D11 and not D9 was the closest prior art (section 6.2). That conclusion was disputed by the appellant in their statement of grounds of appeal (section 10.2).

2.6.1 D9 is in the field of ophthalmic lenses, a field that comprises soft contact lenses and in particular lenses preferably based on silicone hydrogels (column 1, lines 49-61). The objective of D9 set out in column 1, lines 27-40 is to alleviate any wear discomfort by improving the wettability of the lens. D9 further discloses that the ophthalmic lenses according to the invention are treated with a wetting agent (column 1, line 51; column 2, lines 41-43) which ultimately leads to a swelling of the lens (column 2, lines 60-64), thereby achieving a certain incorporation of the wetting agent on the lens surface. In that regard, the association between the contact lens and its wetting agent that is disclosed in D9 essentially corresponds to the entrapment of at least a portion of the hydrophilic polymer that is addressed in paragraph 13 of the patent in suit.

2.6.2 The wetting agents of D9 are defined in the passage in column 3, line 58 to column 4, line 3 and among the preferred wetting agents poly(meth)acrilamides, including poly(N-2-hydroxyethylmethacrylamide), and polyvinylpyrrolidone are disclosed. These two wetting agents are also cited as known wetting agents of the prior art in paragraph 4 of the patent in suit. While polyvinylpyrrolidone wetting agents are the only ones exemplified in D9 and may from other passages of D9 be seen as being the most preferred wetting agents, there is no teaching in D9 from which it could be concluded that poly(N-2-hydroxyethylmethacrylamide) wetting agents would not be as suitable as the ones based on polyvinylpyrrolidones for the uses disclosed therein.

2.6.3 The decision of the opposition division contested the choice of D9 as the closest prior art because D9 was not seen as an "equally valid" document as D11, in particular because contrary to D11, D9 did not mention

the contact angle and the biometric performance of the lens as evidenced by reduced lipocalin, lipid and mucin uptake levels that were reported in the patent in suit (section 6.2 of the decision). That argument was also pursued by the respondent in appeal.

2.6.4 The Board in agreement with the case law (e.g. T 1742/12 and further indicated in Case Law, *supra*, I.D.3.1) considers that the selection of the closest prior art is not necessarily a process by which a single document arises as being the closest to the invention disclosed in the patent in suit. Often, the evaluation of inventive step based on the analysis of the prior art is such that the skilled person has a choice between several workable routes, i.e. routes starting from different documents, which may reasonably be seen as documents realistically leading to the invention. In that situation, the rationale of the problem and solution approach requires that the invention be assessed relative to all these possible routes before an inventive step can be acknowledged.

2.6.5 In the present case, it is apparent from sections 2.6.1 and 2.6.2 of the present decision that D9 is in the same field of contact lenses as the patent in suit and has the same objective of improving the contact lens wettability and wearing comfort. Even if D9 does not mention the contact angle and the lipocalin, lipid and mucin uptake levels of its lenses, it was known from the prior art cited by the parties in appeal that these properties were in fact indicative of the wettability and wearing comfort of the produced contact lenses (contact angle defined in D11, paragraph 105; proteins and lipids deposits in D15, page 628, first full paragraph, D16, first page, third paragraph and D17, abstract). In that regard, the specific properties

determined in the patent in suit correspond to the objective as set out in D9. Furthermore, the silicone hydrogel lenses of the patent in suit are among the preferred lenses of D9 and poly(N-2-hydroxyethylmethacrylamide) cited as a preferred wetting agent of D9 falls under the definition according to claim 1 of auxiliary request 2.

2.6.6 In view of that and irrespective of the content of D11, D9 is surely not an unrealistic starting point for an inventive step assessment of claim 1 of auxiliary request 2. Such an inventive step assessment is therefore necessary in order to evaluate whether the presence of an inventive step can be acknowledged.

2.7 D9 as the closest prior art

2.7.1 The disclosure in D9 that was cited as starting point is the polymer disclosed as a wetting agent for contact lenses in column 3, line 64, namely poly(N-2-hydroxyethylmethacrylamide). That polymer does not contain terminal hydrophobic polymer blocks and is based on a repeating unit that falls under Formula I defined in claim 1 of auxiliary request 2, a conclusion that was not in dispute in appeal.

2.7.2 It is correct, as submitted by the appellant, that the passage in column 3, line 58 to column 4, line 3 of D9 concerning the wetting agent chosen as starting point for the assessment of inventive step does not formally mention the use of the preferred poly(N-2-hydroxyethylmethacrylamide) in silicon hydrogel based contact lenses. It is however immediately apparent from the passage on column 1, lines 54-61 teaching that soft contact lenses made from silicone hydrogels are preferred that a skilled reader of D9 would have

understood, that the preferred wetting agents, including poly(N-2-hydroxyethylmethacrylamide), were applicable to silicone hydrogels contact lenses.

2.7.3 D9 does not disclose the degree of polymerization of the poly(N-2-hydroxyethylmethacrylamide). The patent in suit does not establish, however, that the selection of a degree of polymerization between about 500 and about 10000 as defined in claim 1 of auxiliary request 2 is causally linked to a technical effect.

2.7.4 It follows that the problem starting from D9 is to be formulated as the provision of a further silicone hydrogel contact lens including a water soluble, non-reactive hydrophilic polymer as wetting agent.

2.7.5 The prior art documents D3 and D11 already describe non-reactive hydrophilic polymers for silicone hydrogel based contact lenses with degrees of polymerization in ranges that largely overlap with the range of between 500 to 10000 according to claim 1 of auxiliary request 2 (D3: degree of polymerization of at least 300, page 16, fourth paragraph and claim 17; D11: degree of polymerization of between about 300 to about 5000, paragraph 6). Poly(N-2-hydroxyethylmethacrylamides) being generally known as wetting agents for contact lenses from D9, the selection of a poly(N-2-hydroxyethylmethacrylamide) with a degree of polymerization between about 500 and about 10000 just represents an equally suggested solution when looking for further silicon hydrogel contact lenses including a wetting agent, which does therefore not involve an inventive step (cf. e.g. T 892/08, reasons 1.7).

2.7.6 The respondent additionally submitted at the oral proceedings before the Board that D11 taught the

presence of hydrophobic terminal siloxanes on the non-reactive hydrophylic polymers in order to obtain an improved association of the wetting agent with the matrix of the contact lens (paragraph 11), ultimately resulting in an improved wettability and reduced protein uptake (paragraph 2). According to the respondent D11 would therefore teach away from claim 1 of auxiliary request 2 since that claim excluded terminal, hydrophobic polymer blocks on the wetting agent.

2.7.7 There is, however, for the Board no basis to conclude that the skilled person starting from the poly(N-2-hydroxyethylmethacrylamide) of D9 (and not from D11) and simply facing the problem of providing a further silicone hydrogel contact lens including a water soluble, non-reactive hydrophilic polymer as wetting agent would have considered it necessary to follow the teaching of D11 that required the chemical modification of the poly(N-2-hydroxyethylmethacrylamide) by addition of hydrophobic terminal siloxanes. The simple adjustment of the degree of polymerization without any further necessary modification is therefore an obvious measure in order to solve the posed problem for the reasons given above.

2.7.8 Claim 1 of auxiliary request 2 therefore lacks an inventive step over D9.

Auxiliary request 5 (new first auxiliary request)

3. Inventive step

3.1 Claim 1 of auxiliary request 5 differs from claim 1 of auxiliary request 2 in that the water soluble, non-reactive hydrophilic polymer is a homopolymer and the

repeating unit of Formula I is further limited (see point VIII., above). The additional limitations are meant to exclude the N-2-hydroxyethyl**meth**acrylamide on which the polymer chosen as a starting point in D9 for auxiliary request 2 is based.

3.2 The respondent submitted that the modifications performed in claim 1 of auxiliary request 5 would render D9 more remote for the patent in suit and therefore would disqualify it as closest prior art.

3.3 The poly(N-2-hydroxyethylmethacrylamide) chosen as starting point in D9 is already a homopolymer so that the modifications performed in claim 1 of auxiliary request 5 only result in one additional distinguishing feature by comparison to claim 1 of auxiliary request 2. The limitation of the definition of the repeating unit of Formula I was not shown to result in a new technical effect over the use of poly(N-2-hydroxyethylmethacrylamide) in D9. The modifications performed in claim 1 of auxiliary request 5 are also not linked to a different objective than that identified for auxiliary request 2. In view of that, there is no reason to discard D9 as a document to be used as the closest prior art.

3.4 In the absence of an effect resulting from the additional distinguishing feature over D9 the problem defined with regard to claim 1 of auxiliary request 2 remains valid for claim 1 of auxiliary request 5. The problem is therefore the provision of a further silicone hydrogel contact lens including a water soluble, non-reactive hydrophilic polymer as wetting agent.

3.5 Claim 1 of auxiliary request 5 encompasses water soluble, non-reactive hydrophilic polymer that are homopolymers of N-(2-hydroxyethyl)acrylamide or N-(2-hydroxypropyl)(meth)acrylamide. These monomers differ marginally in their structure from N-(2-hydroxy**ethyl**)**meth**acrylamide as disclosed in D9 (either by the presence of an acrylamide instead of a methacrylamide or by a propyl instead of an ethyl substituent).

3.6 The teaching of D9 with respect to wetting agents is not limited to the use of poly(N-2-hydroxyethylmethacrylamide) but is much more general in that poly(meth)acrylamides as a class of polymers are generally preferred (column 3, lines 61-65 and claim 2). In that regard, it is apparent from that teaching that N-(2-hydroxyalkyl)acrylamide or N-(2-hydroxypropyl)(meth)acrylamide both of which belong to the generic class of poly(meth)acrylamides and are structurally very close to the N-2-hydroxyethylmethacrylamide disclosed in D9, can be used as repeating unit in a water soluble, non-reactive hydrophilic homopolymer. These two repeating units would thus be considered by the skilled person in the light of the general disclosure of D9 when aiming at solving the posed problem, thereby rendering claim 1 of auxiliary request 5 obvious starting from D9.

3.7 Claim 1 of auxiliary request 5 lacks therefore an inventive step over D9 as the closest prior art.

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:

D. Hampe D. Semino

Decision electronically authenticated