Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 26 April 2018

Case Number: T 2003/13 - 3.3.07

Application Number: 05823311.5

Publication Number: 1814515

IPC: A61K9/00, G02B1/04

Language of the proceedings: EN

Title of invention:
Ophthalmic compositions comprising polyether substituted polymers

Patent Proprietor:
Johnson and Johnson Vision Care, Inc.

Opponent:
Novartis AG

Headword:
Ophthalmic compositions/ J&J

Relevant legal provisions:
EPC Art. 56, 111(1)
RPBA Art. 13(3)

Keyword:

Inventive step - Main and auxiliary requests 1 to 9 (no)
Late-filed auxiliary requests - admitted (yes)
Appeal decision - remittal to the department of first instance (yes)

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 2003/13 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 26 April 2018

Appellant: (Patent Proprietor)	Johnson and Johnson Vision Care, Inc. 7500 Centurion Parkway, Suite 100 Jacksonville, FL 32256 (US)
Representative:	Kirsch, Susan Edith Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Appellant: (Opponent)	Novartis AG Lichtstrasse 35 4056 Basel (CH)
Representative:	Breuer, Markus Henkel, Breuer & Partner Patentanwälte Brienner Str. 1 80333 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 4 July 2013 concerning maintenance of the European Patent No. 1814515 in amended form.**

Composition of the Board:

Chairman	J. Riolo
Members:	A. Usuelli
	P. Schmitz

Summary of Facts and Submissions

I. European Patent 1 814 515 was opposed on the grounds that its subject-matter lacked novelty and inventive step and it was not sufficiently disclosed.

The following documents were among those cited during the first-instance proceedings:

BM1: JP 2002-2-56030
BM1E: English translation of BM1
BM10: US 6,440,366
BM23: US 5,401,327
BM24: US 5,275,838

II. The appeals of the patent proprietor and of the opponent lie against the decision of the opposition division according to which the subject-matter of auxiliary request 1 met the requirements of the Convention. The decision was based on the patent as granted and on an auxiliary request filed on 21 April 2013.

Independent claims 1 and 2 of the patent as granted read as follows:

"1. A [o]phthalmic device comprising at least one water soluble polymer having a molecular weight of at least 500,000 Daltons and comprising linear or branched polyether pendant groups having a molecular weight of at least about 300".

"2. An ophthalmic solution comprising at least one water soluble polymer having a molecular weight of at least 500,000 Daltons and comprising linear or branched

polyether pendant groups having a molecular weight of at least about 300".

Each of claims 1 and 2 of the auxiliary request considered by the opposition division to meet the requirements of the EPC differed from the corresponding claim of the patent as granted in the introduction of the following feature at the end of the claim:

"...wherein the polyether pendant groups provide a hydrophilic, brush or comb-like structure to the water soluble polymer".

III. In the decision under appeal the opposition division considered that example 10 of BM23 and example 2 of BM24 anticipated the subject-matter of claims 1 and 2 of the patent-in-suit.

The independent claims of the auxiliary request were considered novel over BM23 and BM24 on account of the limitation to polymers having a brush or comb-like structure.

As to the inventive step of the auxiliary request, the opposition division regarded document BM10 as the closest prior art for the subject-matter of claims 1 and 2. Example 3 of this document disclosed a solution for storing contact lenses containing a polyoxyethylated polymer. The subject-matter of claims 1 and 2 of the auxiliary request differed from the disclosure of example 3 on account of the requirement that the water soluble polymer had a molecular weight of at least 500,000. The technical problem was the provision of an ophthalmic device or an ophthalmic solution comprising an alternative water soluble polymer. The cited prior art documents did not suggest

solving this problem by increasing the molecular weight of the water soluble polymer. The requirement of Article 56 EPC was therefore met.

IV. In the statement setting out the grounds of appeal the appellant-patent proprietor maintained the requests forming the basis of the impugned decision, namely the patent as granted as main request and the auxiliary request considered by the opposition division to comply with the requirements of the EPC as auxiliary request 1.

V. In its statement setting out the grounds of appeal the appellant-opponent requested that the decision be set aside and the patent be revoked. With regard to the assessment of inventive step of claim 2 of the auxiliary request considered by the opposition division to comply with the requirements of the EPC, it argued that document BM1 was the closest prior art.

VI. On 8 April 2014, with the reply to the appeal of the opponent, the appellant-patent proprietor filed auxiliary requests 2 to 9.

Claim 2 of auxiliary request 2 differed from claim 2 of auxiliary request 1 in the introduction of the following feature at the end of the claim:

"...wherein said polymer comprises at least 20% of backbone units having a pendant group bound thereto";

Claim 2 of auxiliary request 3 differed from claim 2 of auxiliary request 1 in that the water soluble polymers were limited to those having a comb-like structure;

Claim 2 of auxiliary request 4 was based on claim 2 of auxiliary request 1 with the introduction of the amendments made in auxiliary requests 2 and 3;

Claim 2 of auxiliary requests 5 to 9 were identical to claim 2 of the patent and of auxiliary requests 1 to 4 respectively.

VII. In a communication pursuant to Article 15(1) RPBA issued on 26 January 2017, the Board in agreement with the appellant-opponent, considered that BM1 was a suitable starting point for the assessment of inventive step of the subject-matter of claim 2. The Board furthermore observed that the compositions of this claim differed from the compositions disclosed in BM1 in the molecular weight of the water soluble polymer and that there were no experimental data demonstrating the presence of technical effects arising from this distinguishing feature.

VIII. Five additional auxiliary requests were filed by the appellant-patent proprietor with letter of 6 October 2017.

Auxiliary request 10 differed from auxiliary request 5 in the deletion of claim 2. Claim 1 of auxiliary request 10 read as follows:

"1. An ophthalmic device comprising at least one water soluble polymer having a molecular weight of at least 500,000 Daltons and comprising linear or branched polyether pendant groups having a molecular weight of at least about 300, wherein the device is a hydrogel and the water soluble polymer is added to the reaction mixture such that the hydrogel polymerises "around" the

water soluble polymer, forming a semi interpenetrating network".

IX. In a letter sent on 12 March 2018, the appellant-opponent raised *inter alia* objections against the admittance of auxiliary request 10 and the other requests filed on 6 October 2017.

X. By letter dated 20 April 2018, the appellant-patent proprietor filed auxiliary request 15. A corrected version of this request was submitted during the oral proceedings held on 26 April 2018.

XI. The arguments of the appellant-opponent, as far as they are relevant to the decision, can be summarised as follows:

(a) Claim 2 - Inventive step

Document BM1 related *inter alia* to compositions useful for cleaning contact lenses. The same use was disclosed in paragraph [0020] of the patent-in-suit with regard to the ophthalmic solutions of claim 2. The fact that the description of the patent referred to the problem of preventing various conditions of the eye, such as dry eye syndrome, was of no relevance in the selection of the closest prior in the absence of any evidence that this problem was indeed solved. BM1 was therefore a suitable starting point for the assessment of inventive step. The compositions of BM1 contained a copolymer that was described in claim 1. Its molecular weight was suitably in the range of 1 000 to 1 000 000. The general class of polymers defined in claim 2 of the patent-in-suit was at least partially included in the groups of polymers disclosed in BM1. The subject-matter of claim 2 differed from the disclosure of BM1 in the

selection of polymers having a molecular weight of at least 500 000. There were no technical effects arising from the selection of this molecular weight. The technical problem was therefore the provision of an alternative ophthalmic solution. The selection of polymers of high molecular weight was an arbitrary one. Accordingly, it did not provide any inventive contribution to the subject-matter of claim 2.

The same considerations applied to the subject-matter of claim 2 of auxiliary requests 1 to 9.

(b) Admittance of auxiliary request 10

The appellant-patent proprietor had already filed nine auxiliary requests with the statement setting out the grounds of appeal. Auxiliary request 10 was filed later and was not occasioned by new facts or submissions presented by the appellant-opponent. Admitting this request would result in a further prolongation of the proceedings. Auxiliary request 10 was therefore inadmissible.

XII. The arguments of the appellant-patent proprietor, as far as they are relevant to the decision, can be summarised as follows:

(a) Claim 2 - Inventive step

The description of the patent-in-suit addressed *inter alia* the problem of providing compositions useful in the treatment of ocular surface disorders. Example 4 showed that contact lenses made with the polymers defined in the claims were comfortable and did not provide any problem of dryness. Starting from this example, it was reasonable to assume that solutions

containing the same polymers had also useful ophthalmic properties. BM1 was not the closest prior art since it did not address the same problems as the patent-in-suit and did not contain any evidence showing the suitability of the compositions disclosed therein in the ophthalmic field. In any case, starting from BM1 as the closest prior art the skilled person would have not arrived at the subject-matter of claim 2 in an obvious manner. With regard to the molecular weight of the polymer, BM1 disclosed a very broad range and the skilled person had no reason to select polymers of high molecular weight. Indeed BM1 did not exemplify any polymer having a high molecular weight. The subject-matter of claim 2 was therefore inventive starting from BM1 as the closest prior art.

The same considerations applied to the subject-matter of claim 2 of auxiliary requests 1 to 9.

(b) Admittance of auxiliary request 10

Auxiliary request 10 was to be admitted into the proceedings since it differed from auxiliary request 5 filed with the statement setting out the grounds of appeal only in the deletion of claim 2.

XIII. The appellant-patent proprietor requested that the decision under appeal be set aside and the opposition be rejected (i.e. maintenance of the patent as granted) or, in the alternative, that the patent be maintained according to one of the following auxiliary requests:

(a) auxiliary request 1 corresponding to the request allowed by the opposition division;
(b) auxiliary requests 2 to 9 filed on 8 April 2014, with the reply to the appeal of the opponent;

(c) auxiliary requests 10 to 14 filed on 6 October 2017;
(d) auxiliary request 15 filed during the oral proceedings.

XIV. The appellant-opponent requested that the decision under appeal be set aside and that the patent be revoked. He furthermore requested not to admit auxiliary requests 10 to 15 into the appeal proceedings.

Reasons for the Decision

Main request - patent as granted

1. Inventive step - Claim 2

1.1 The patent-in-suit relates to polyether substituted polymers that find application in the field of ophthalmology.

More particularly, the subject-matter of independent claim 2 relates to ophthalmic solutions containing these polymers. Paragraph [0020] of the description explains that the polyether substituted polymers can be incorporated for instance in contact lens rewetting solutions, contact lens packing and/or cleaning solutions and eye drops.

Paragraph [0002] refers to the dry eye syndrome, an ocular surface disorder that may arise from disruptions in any one of the components of the tear film. It is explained that the dry eye syndrome leads to severe irritation, redness and itchiness of the eye.

1.2 Closest prior art

1.2.1 The appellant-opponent argues on inventive step starting from BM1 (hereinafter reference is made to the English translation BM1E) as the closest prior art. It observes that this document is directed to cleaning or antifouling compositions for contact lenses that contain a general class of polymers that includes at least part of the polymers defined in claim 2.

In the appellant-patent proprietor's view, BM1 cannot qualify as the closest prior art since it does not address the problem of treating or preventing ocular disorders, such as the dry eye syndrome, and does not provide any experimental data showing that the solutions disclosed therein are suitable for ophthalmological applications.

1.2.2 The Board notes that one of the objects of the invention described in BM1 is to provide cleaning agent compositions and antifouling compositions containing a polymer (paragraph [0008]). Although these compositions can be used for the treatment of various surfaces, it is underlined in various passages of BM1 that they are suitable in particular for cleaning contact lenses (see paragraphs [0008], [0012], [0029] and claim 5). The experimental part of the description (see paragraphs [0043] to [0048] and Table 1) discloses the preparation of several compositions containing the polymers defined in claim 1 of BM1. These compositions are then tested in experiments which involve the immersion of contact lenses in the compositions and the assessment of the detergency and of the fouling resistance.

Thus, BM1 relates to polymer-containing solutions that, likewise the solutions of claim 2 of the

patent-in-suit, are useful as cleaning solutions for contact lenses. Accordingly, BM1 is a suitable starting point for the assessment of inventive step since it is a prior art document disclosing subject-matter conceived for the same purpose as the invention of claim 2.

1.2.3 The Board concurs with the appellant-patent proprietor that BM1 does not address the problem of treating or preventing ocular disorders, such as the dry eye syndrome. It is also true that BM1 does not describe experiments involving tests in animals or humans.

However, the same considerations can be made in respect of the patent-in-suit. Indeed the patent does not contain any experimental data concerning the ophthalmic solutions of claim 2. Example 4, referred to by the appellant-patent proprietor in its submissions, describes a test in which thirty myopic subjects wore for 1 week contact lenses incorporating the polymers defined in the patent. Hence, the test concerns the assessment of the property of an ophthalmic device, i.e. the subject-matter of claim 1 of the patent. This test does not allow to draw any conclusion as to the property of solutions containing the same polymers, i.e. the subject-matter of claim 2. Furthermore, the subjects involved in the test do not suffer from dry eye syndrome or any other ocular surface disorders. Hence, there is no evidence as to the possibility of using the polymers described in the patent-in-suit in solutions or devices that could help in treating dry eye syndrome.

The Board considers that the mere fact of having inserted in the description of the patent-in-suit some statements referring to ocular surface disorders is not

alone sufficient to disqualify BM1 as suitable closest prior art.

In view of the above, the Board regards BM1 as a suitable starting point for the assessment of inventive step.

1.2.4 The copolymers disclosed in BM1 derive from the polymerisation of the monomers defined in paragraphs [0010] and [0011]. Upon polymerisation the copolymers comprise polyether pendant groups that may have a molecular weight above 300. These pendant groups derive from the acrylate monomers of formula (2) defined in paragraphs [0018] and [0019] of the description. The average molecular weight of the copolymers of BM1 is comprised in the range 1 000 to 1 000 000 (paragraph [0026]).

The general class of copolymers disclosed in BM1 overlaps with the polymers defined in the patent-in-suit. The subject-matter of claim 2 differs from the disclosure of BM1 in the selection of polymers having a molecular weight of at least 500 000.

1.3 Technical problem

1.3.1 There are no experiments in the patent-in-suit in which the properties of the ophthalmic solutions of claim 2 have been assessed. There are furthermore no data demonstrating the presence of technical effects due to the increase of the molecular weight of the polymers.

The technical problem is therefore formulated as the provision of further ophthalmic solutions comprising a polymer.

1.4 Obviousness

1.4.1 BM1 indicates that the molecular weight of the copolymers is suitably in the range 1 000 to 1 000 000 and preferably in the range 5 000 to 500 000 (see paragraph [0026]). Although the ophthalmic solutions described in the experimental part of BM1 contain copolymers having a molecular weight below 500 000 (see Table 1), the skilled person would consider that any copolymer included in the general class of copolymers described in BM1 could be used as a component of ophthalmic solutions. In particular, in view of the information disclosed in paragraph [0026], he would consider that also copolymers of a molecular weight above 500 000 could serve this purpose.

Hence, when confronted with the problem of providing further ophthalmic solutions comprising a polymer, the skilled person would obviously arrive at the subject-matter of claim 2 by replacing the copolymer of one of the solutions described in Table 1 of BM1 with an alternative copolymer covered by the teaching of this document and having a molecular weight of at least 500 000.

1.5 It follows from the above considerations that the selection within the general disclosure of BM1 of a polymer having a molecular weight above 500 000 does not involve any inventive activity.

Therefore, the subject-matter of claim 2 of the patent does not fulfil the requirements of Article 56 EPC.

Auxiliary request 1

2. Inventive step - Claim 2

2.1 Claim 2 of auxiliary request 1 specifies that the polymers have a brush or comb-like structure.

2.2 This limitation does not result in any further distinguishing feature over BM1 since also this document discloses solutions containing polymers having a comb-like structure (see for instance example 5). Furthermore, there are no technical effects associated with the selection of polymers having this particular structure.

2.3 Therefore the considerations set out above regarding the main request apply also to claim 2 of auxiliary request 1. It follows that this request does not fulfil the requirements of Article 56 EPC.

Auxiliary request 2

3. Inventive step - Claim 2

3.1 Claim 2 of this request differs from claim 2 of auxiliary request 1 in the indication that the polymer comprises at least 20% of backbone units having a pendant group bound thereto.

3.2 In its submissions of 12 March 2018 the appellant-opponent calculated that the copolymer of example 5 of BM1 has 29% of backbone units having a polyether pendant group bound thereto. The Board agrees with this finding that was not disputed by the appellant-patent proprietor.

Thus, the limitation introduced in claim 2 of auxiliary request 2 does not result in any further distinguishing feature over BM1. Furthermore, there are no technical effects associated with this limiting feature.

3.3 Thus, claim 2 of auxiliary request 2 is obvious for the same reasons as set out above in respect of claim 2 of auxiliary request 1.

Auxiliary request 3

4. Inventive step - Claim 2

4.1 Claim 2 of this request differs from claim 2 of auxiliary request 1 in that the polymers have been limited to those having a comb-like structure (i.e. deletion of the option "brush structure").

4.2 Thus, claim 2 of this request is obvious for the same reasons as set out above in respect of claim 2 of auxiliary request 1.

Auxiliary request 4

5. Inventive step - Claim 2

5.1 Claim 2 of this request is based on claim 2 of auxiliary request 1 with the introduction of the amendments made in auxiliary requests 2 and 3.

5.2 As explained in points 3 and 4 above, the amendments introduced in claim 2 of auxiliary requests 2 and 3 do not provide any inventive contribution to the subject-matter of the claims.

It follows that auxiliary request 4 does not fulfil the requirements of Article 56 EPC.

Auxiliary requests 5 to 9

6. Inventive step - Claim 2

6.1 Claim 2 of auxiliary requests 5 to 9 are identical to claim 2 of the patent and of auxiliary requests 1 to 4 respectively.

6.2 It follows from the considerations set out in points 1 to 5 that none of these requests meets the requirements of Article 56 EPC.

Auxiliary request 10

7. Admittance

7.1 This request was filed on 6 October 2017, i.e. more than six months before the date of the oral proceedings. Its subject-matter differs from the subject-matter of auxiliary request 5, filed with the reply to the opponent's appeal, in the deletion of claim 2.

7.2 The introduction of auxiliary request 10 does not therefore raise any new issue and does not pose to the appellant-opponent any new difficulty in that the subject-matter of this request is entirely covered by a previous request which is part of the basis of the appeal proceedings pursuant to Article 12(1)(b) RPBA.

Accordingly the Board in the exercise of its discretion under Article 13(3) RPBA decides to admit auxiliary request 10 into the appeal proceedings.

Remittal

8. The primary function of an appeal is to consider whether the decision issued by the first-instance department is correct. Hence, a case is normally remitted if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

8.1 These observations fully apply to the present case.

Claim 1 of auxiliary request 10 specifies that the ophthalmic device "is a hydrogel and the water soluble polymer is added to the reaction mixture such that the hydrogel polymerises "around" the water soluble polymer, forming a semi interpenetrating network" (see point VIII above). This feature relates to an embodiment disclosed in the description of the patent (see paragraph [0025]).

None of the requests considered by the opposition division relates to ophthalmic devices made from hydrogel formulations that form a semi interpenetrating network as defined in claim 1 of auxiliary request 10. Thus, the contribution of this feature to the inventive step of claim 1 has not been assessed during the first instance proceedings.

8.2 Under these circumstances the Board considers it appropriate not to approach the assessment of inventive step of auxiliary request 10 since it may become crucial during this assessment to examine the relevance of the newly introduced feature and this would go beyond the main purpose of the appeal proceedings which

is to review the decision of the department of first instance.

This conclusion was agreed upon by the parties during the oral proceedings.

8.3 In view of the above considerations the Board decides to remit the case to the opposition division for further prosecution (Article 111(1) EPC)

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

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

The Registrar: The Chairman:

S. Fabiani J. Riolo

Decision electronically authenticated