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Datasheet for the decision of 3 March 2015

Case Number: T 2608/11 - 3.3.03

Application Number: 01924651.1

Publication Number: 1286823

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Language of the proceedings: EN

Title of invention:
OPHTHALMIC LENSES AND COMPOSITIONS, AND METHODS FOR PRODUCING SAME

Patent Proprietor:
CooperVision International Holding Company, LP

Opponent:
Johnson & Johnson Vision Care, Inc.

Headword:

Relevant legal provisions:
RPBA Art. 12(4)
EPC Art. 56

Keyword:
Experimental report submitted with the statement of grounds - not disregarded
Inventive step (no) - all requests - obvious alternative

Decisions cited:
T 1329/04

Catchword:

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European Patent Office
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Case Number: T 2608/11 - 3.3.03

D E C I S I O N
of Technical Board of Appeal 3.3.03
of 3 March 2015

Appellant: (Opponent)	Johnson & Johnson Vision Care, Inc. 7500 Centurion Parkway, Suite 100 Jacksonville, Florida 32256 (US)
Representative:	Kirsch, Susan Edith Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Respondent: (Patent Proprietor)	CooperVision International Holding Company, LP Suite 2, Edghill House Wildey Business Park St. Michael (BB)
Representative:	Fletcher, Matthew James Edwin Abel & Imray 20 Red Lion Street London, WC1R 4PQ (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 19 October 2011 concerning maintenance of the European Patent No. 1286823 in amended form.**

Composition of the Board:

Chairwoman B. ter Laan
Members: F. Rousseau
R. Cramer

Summary of Facts and Submissions

I. The appeals by the patent proprietor and the opponent lie against the interlocutory decision of the opposition division according to which European patent No. 1 286 823 as amended according to the documents of the third auxiliary request submitted during the oral proceedings on 28 September 2011 met the requirements of the EPC.

II. Claim 1 of that request read as follows:

"1. Use of a second polymeric material to increase the equilibrium water content of a lens body of an ophthalmic lens relative to a substantially identical lens body without the second material, the lens body comprising a composition including a first crosslinked polymer material which is water swellable; the second polymeric material, other than the first material, selected from the group consisting of water soluble polymeric materials and mixtures thereof, the second material being water soluble linear or branched chain polymer(s) or copolymer(s) physically immobilized by the first material by physical entanglements of the polymer(s) or copolymer(s) in the first material in a pseudo-interpenetrating network,

characterized in that the ophthalmic lens is produced by providing said lens body comprising a composition including said first crosslinked polymer material, introducing a monomeric component into the lens body; and subjecting the monomeric component in the lens body to effective conditions to form the second polymeric material."

III. The patent in suit had been opposed in its entirety on the grounds that its subject-matter lacked novelty and

an inventive step (Article 100(a) EPC), was insufficiently disclosed (Article 100(b) EPC) and extended beyond the content of the application as filed (Article 100(c) EPC). The following documents had been cited in the impugned decision:

D1 WO-A-99/29750
D2 US-A-5 258 024
D3 US-A-5 726 733
D4 WO-A-00/02937
D6 D. Klempner et al. "Interpenetrating Polymer Networks", Advances In Chemistry Series, Vol. 239, 5 May 1994, pages 3-38
D7: J.C. Salomone: "Concise Polymeric Materials Encyclopedia", 31 December 1999, pages 684-687

IV. The use claims according to the third auxiliary request were found to be based on an inventive step when starting from D4, which constituted the closest state of the art as it was also explicitly directed to a water soluble second polymer and its almost identical use in pseudo-interpenetrating networks in order to increase water content. In the absence of any evidence of a technical effect arising from a reverse way of preparing the lens that distinguished the claimed use from that disclosed in D4, the objective problem solved over D4 was to provide an improved equilibrium water content in an alternative lens body. The process according to the third auxiliary request did not constitute an obvious solution to that problem, in particular in view of D1, in which two crosslinked polymers were employed and therefore did not relate to pseudo-interpenetrating networks.

V. With their statement setting out the grounds for the appeal submitted on 24 February 2012, the patent

proprietor submitted inter alia one experimental report entitled Annex 2 (hereinafter D14) and eight sets of claims forming the main request and first to seventh auxiliary requests. The claims 1 of those requests read as follows:

Main Request

"1. An ophthalmic lens comprising:
a lens body comprising a composition including a first crosslinked polymer material which is water swellable; and a second polymeric material, other than the first material, selected from the group consisting of water soluble polymeric materials and mixtures thereof, the second material being physically immobilized by the first material characterized in that the second polymeric material is a water soluble linear or branched chain polymer(s) or copolymer(s) physically immobilized by the first material by physical entanglements of the polymer(s) or copolymer(s) in the first material in a pseudo-interpenetrating network,

wherein the ophthalmic lens is obtainable by providing the lens body comprising a lens composition including the first crosslinked polymer material, introducing a monomeric component into the lens body and subjecting the monomeric component in the lens body to effective conditions to form the second polymeric material."

First Auxiliary Request

"1. An ophthalmic lens comprising:

a lens body comprising a composition including a first crosslinked polymer material which is water swellable; and a second polymeric material, other than the first

material, selected from the group consisting of water soluble polymeric materials and mixtures thereof, the second material being physically immobilized by the first material characterized in that the second polymeric material is a water soluble linear or branched chain polymer(s) or copolymer(s) physically immobilized by the first material by physical entanglements of the polymer(s) or copolymer(s) in the first material in a pseudointerpenetrating network,

wherein the ophthalmic lens is obtainable by providing the lens body comprising a lens composition including the first crosslinked polymer material, introducing a monomeric component into the lens body and subjecting the monomeric component in the lens body to effective conditions to form the second polymeric material,

wherein the lens body exhibits increased equilibrium water content relative to a substantially identical lens body without the second material."

Second Auxiliary Request

"1. An ophthalmic lens comprising:

a lens body comprising a composition including a first crosslinked polymer material which is water swellable; and a second polymeric material, other than the first material, selected from the group consisting of water soluble polymeric materials and mixtures thereof, the second material being physically immobilized by the first material characterized in that the second polymeric material is a water soluble linear or branched chain polymer(s) or copolymer(s) physically immobilized by the first material by physical entanglements of the polymer(s) or copolymer(s) in the

first material in a pseudointerpenetrating network, the second material being present in an amount of 0.1 to 40% by weight based on a water-free weight of the composition,

wherein the ophthalmic lens is obtainable by providing the lens body comprising a lens composition including the first crosslinked polymer material, introducing a monomeric component into the lens body and subjecting the monomeric component in the lens body to effective conditions to form the second polymeric material,

wherein the lens body exhibits increased equilibrium water content relative to a substantially identical lens body without the second material."

Third Auxiliary Request

"1. A method for producing an ophthalmic lens comprising: providing a lens body comprising a lens composition including a first crosslinked polymer material which is water swellable;

introducing a monomeric component into the lens body; and subjecting the monomeric component in the lens body to effective conditions to form a second polymeric material selected from the group consisting of water soluble polymeric materials and mixtures thereof, the second material being water soluble linear or branched chain polymer(s) or copolymer(s) physically immobilized by the first material by physical entanglements of the polymer(s) or copolymer(s) in the first material in a pseudo-interpenetrating network."

Fourth Auxiliary Request

"1. A method for producing an ophthalmic lens comprising: providing a lens body comprising a lens composition including a first crosslinked polymer material which is water swellable;

introducing a monomeric component into the lens body; and subjecting the monomeric component in the lens body to effective conditions to form a second polymeric material selected from the group consisting of water soluble polymeric materials and mixtures thereof, the second material being water soluble linear or branched chain polymer(s) or copolymer(s) physically immobilized by the first material by physical entanglements of the polymer(s) or copolymer(s) in the first material in a pseudo-interpenetrating network,

wherein the lens body exhibits increased equilibrium water content relative to a substantially identical lens body without the second material".

Fifth Auxiliary Request

"1. A method for producing an ophthalmic lens comprising: providing a lens body comprising a lens composition including a first crosslinked polymer material which is water swellable;

introducing a monomeric component into the lens body; and subjecting the monomeric component in the lens body to effective conditions to form a second polymeric material selected from the group consisting of water soluble polymeric materials and mixtures thereof, the second material being water soluble linear or branched chain polymer(s) or copolymer(s) physically immobilized by the first material by physical entanglements of the polymer(s) or copolymer(s) in the first material in a

pseudo-interpenetrating network, the second material being present in an amount of 0.1 to 40% by weight based on a water-free weight of the composition,

wherein the lens body exhibits increased equilibrium water content relative to a substantially identical lens body without the second material."

Sixth Auxiliary Request

"1. Use of a second polymeric material to increase the equilibrium water content of a lens body of an ophthalmic lens relative to a substantially identical lens body without the second material,

the lens body comprising a composition including a first crosslinked polymer material which is water swellable; and the second polymeric material, other than the first material, selected from the group consisting of water soluble polymeric materials and mixtures thereof, the second material being water soluble linear or branched chain polymer(s) or copolymer(s) physically immobilized by the first material by physical entanglements of the polymer(s) or copolymer(s) in the first material in a pseudo-interpenetrating network,

characterized in that the ophthalmic lens is produced by providing the lens body comprising a lens composition including the first crosslinked polymeric material, introducing a monomeric component into the lens body and subjecting the monomeric component in the lens body to effective conditions to form the second polymeric material."

Seventh Auxiliary Request

"1. Use of a second polymeric material to increase the equilibrium water content of a lens body of an ophthalmic lens relative to a substantially identical lens body without the second material,

the lens body comprising a composition including a first crosslinked polymer material which is water swellable; the second polymeric material, other than the first material, selected from the group consisting of water soluble polymeric materials and mixtures thereof, the second material being water soluble linear or branched chain polymer(s) or copolymer(s) physically immobilized by the first material by physical entanglements of the polymer(s) or copolymer(s) in the first material in a pseudo-interpenetrating network, and the second material being present in an amount of 0.1 to 40% by weight based on a water-free weight of the composition,

characterized in that the ophthalmic lens is produced by providing the lens body comprising a lens composition including the first crosslinked polymeric material, introducing a monomeric component into the lens body and subjecting the monomeric component in the lens body to effective conditions to form the second polymeric material."

The patent proprietor's rejoinder to the opponent's appeal was submitted with a letter of 25 June 2012, to which were attached further extracts of D7 (pages 644-646, 1681 and 1706).

Additional submissions by the patent proprietor were made with letter of 9 November 2012.

VI. The statement setting out the grounds for appeal of the opponent was submitted on 29 February 2012.

The opponent's rejoinder to the patent proprietor's appeal was submitted with a letter dated 16 July 2012 to which were attached *inter alia* the following documents:

D9: "Synthesis and properties of semi-interpenetrating polymer networks composed of (3-chitin and poly(ethylene glycol) macromer" Kim *et al.*, Polymer (1995); Vol. 36; (230; pp. 4497-4501) and
D10: Delivery information confirming the availability of Vifilcon A lenses in June 2012.

Further submissions by the opponent were made with letter of 26 June 2013 to which were attached the following documents:

D11: Declaration of Dr Vanderlaan and
D12: Material Safety and Data Sheet (MSDS) for SR 344.

VII. Oral proceedings took place on 3 March 2015 at the end of which the decision of the Board was announced.

VIII. The arguments of the patent proprietor can be summarized as follows:

a) No multiple selections were necessary to arrive at the subject-matter of the present claims, which was directly and unambiguously disclosed in the application as filed and therefore met the requirements of Article 123(2) EPC.

b) The objection that the amended claims resulted in an extension of protection was based on a misinterpretation of the wording of claim 1.

c) As to sufficiency of the disclosure, the claimed subject-matter could be readily put into practice by the skilled person. In particular the term "water soluble polymer" was well known in the art, as shown by D7. The requirements of Article 83 EPC were therefore met.

d) Novelty over D2 and D3 was to be acknowledged, as those documents did not describe all the claimed features in their present combination. Novelty over D4 was also given, since in D4 a different (reverse) process to prepare the lens was used which changed the morphology of the semi-interpenetrating network (IPN), as shown by D5 and D6.

e) As to inventive step, the closest prior art was not constituted by D1 which did not concern the problem of water retention, but rather by D4 which specifically addressed that issue. As demonstrated by D14, the problem successfully solved over D4 was to provide lenses that had an improved modulus but retained a similar tensile strength. D14 had been submitted in response to the finding of the opposition division (point 12.3 of the reasons) that no evidence for a technical effect arising from the preparation of a lens made in the reverse way had been provided. The problem of providing lenses that had an increased modulus compared to conventional lenses was consistently addressed in the patent in suit and therefore should be taken into account for assessing inventive step.

f) Even if the problem solved over D4 was formulated as to provide alternative lenses, an inventive step should be acknowledged because the process steps necessary for the synthesis of the present lenses, i.e. the reverse order of polymerization, solved the handling problems encountered in D4, namely increased viscosity of the monomeric composition due to the presence of polyvinylpyrrolidone (PVP) and the necessity to degas the solution before polymerisation. In addition, using a reverse order of polymerisation had never been attempted before and was not suggested by the documents on file.

g) The claims of the first, second and fourth to seventh auxiliary request also required that the second polymer had the function to increase the water content of the lens. Neither D2 nor D3 disclosed that the formation of the second polymer in a lens body would provide that function. The claims of the second, fifth and seventh auxiliary requests defined the amount of the second polymer which was not disclosed in those documents. Hence, the claims of the auxiliary requests were also inventive for those additional reasons.

IX. The arguments of the opponent can be summarized as follows:

a) The combination of features defined in the claims 1 of the main and first to seventh auxiliary requests resulted from an undisclosed multiple selection of features, contrary to the requirements of Article 123(2) EPC. Moreover, claim 1 of the main request and of the first,

second, sixth and seventh auxiliary requests did not define that the polymerisable monomer composition had to be present in the first crosslinked material, as had been the case in claim 1 of the granted patent (Article 123(3) EPC).

b) The second polymeric material was made in situ and immobilized in the first polymeric material. Accordingly, it could not by definition be water soluble. Moreover, it could not be extracted with the consequence that its solubility in water could not even be determined. Thus, the claimed invention lacked sufficiency of disclosure.

c) The claims of the main request and of the first, third, fourth and sixth auxiliary requests were not novel over D2 and D3. Novelty over D4 was acknowledged in view of D5 and D6, as those documents indicated that the reverse process led to a different morphology of the semi-IPN.

d) The closest prior art was constituted by D1, as it also referred to reducing the accumulation of deposit on the lens. In addition, it had more structural features in common, the only change required to arrive at the present invention being the removal of the crosslinker.

e) Should one start from D4 as the closest prior art, it would not be permissible to take into account an improvement of modulus with retention of a similar tensile strength for the formulation of the problem, because the application as filed did not indicate that such effect resulted from the reverse order of polymerization. The only data

provided to support that assertion had been submitted with D14, on appeal, and according to T 1329/04 that should not be taken into account. In addition D14 could have been submitted before the opposition division and thus should be disregarded pursuant to Article 12(4) RPBA.

Should D14 not be disregarded, that evidence could not demonstrate that the reverse order of polymerization brought about the alleged advantage since the comparison offered was based on lenses that did not contain the same amount of PVP. Also, in that case, the Board should admit counter-evidence D9 to D12 to the proceedings.

f) Thus, the problem solved over D4 was merely to provide an alternative. Furthermore, the advantages in terms of handling brought about by the reverse order of polymerization were known to the skilled person. Accordingly, the use of a reverse order of polymerization to solve that problem was obvious to the skilled person. In addition, the purpose and the amount of the second polymer as defined in the auxiliary requests were already disclosed in the closest prior art, so that those features could not contribute to an inventive step. Accordingly, those requests were not allowable either.

X. The patent proprietor requested that the decision under appeal be set aside and that the patent be maintained in amended form on the basis of the main request or on the basis of any of the first to seventh auxiliary requests, all requests filed with their statement of grounds of appeal.

XI. The opponent requested that the decision under appeal be set aside and that the European patent be revoked.

Reasons for the Decision

1. The appeals are admissible.

Main Request

2. Apart from an objection of lack of an inventive step, various additional objections against the main request were raised with respect to Articles 123(2) and Article 123(3) EPC, sufficiency of disclosure and novelty. In view of the negative conclusion reached by the Board with respect to the issue of inventive step, it was not necessary to take a decision with respect to the above additional objections.

Inventive step

Closest prior art

3. The closest prior art for the purpose of assessing inventive step is generally that which corresponds to a purpose or effect similar to that of the invention and requiring the minimum of structural and functional modifications (Case Law of the Boards of Appeal of the EPO, 7th edition 2013, I.D.3.1). The patent in suit is directed to ophthalmic lenses. According to paragraph [0003] of the patent in suit, conventional hydrophilic contact lenses tend to lose water. That loss of water content is not only known to result in a deterioration of the physical structure and/or optical properties of the lens, but also to cause discomfort and/or damage to

the eye. Therefore the purpose of the present invention, as explained in paragraphs [0003] and [0007] of the patent in suit is to provide hydrophilic contact lenses having an increased water content and/or increased water retention and/or reduced surface evaporation of water.

3.1 Document D4 relates to an interpenetrating polymer network (IPN) composition, in particular a hydrophilic hydrogel composition for contact lenses (page 1, lines 13-14). D4 primarily concerns the problem of water retention in contact lenses (page 7, lines 22-23; page 8, lines 1-2). The IPN composition is obtained by polymerizing a mixture of monomers and a crosslinking agent or a mixture of crosslinking agents in the presence of a synthesized non-ionic polymer as an IPN-agent. It is undisputed that the IPN obtained in D4 is a semi-IPN according to the terminology used in D6 (page 6, third line after the figure) - i.e. one or more polymers are cross-linked and one or more polymers are linear or branched - or a pseudo-IPN within the meaning of claim 1 of the patent in suit. After polymerization the produced crosslinked polymer is hydrated to form the hydrogel (page 9, lines 11-16). A prominent feature of the IPN agents used in D4 is water solubility, PVP being a preferred IPN-agent (page 15, lines 1-11). According to D4, page 18, lines 6-12, the hydrophilic hydrogels prepared by the IPN process using PVP as an IPN-agent show markedly lower water loss that is attributable to dehydration when compared to non-IPN processed analogues. It is also reported in this passage that PVP is meant to provide a higher degree of water attraction ability in the hydrophilic hydrogel which in turn prevents water evaporation from the hydrogel surface.

3.2 D1, for which the Opponent expressed a preference as the closest prior art document, only concerns the problem of reducing the tendency of the lens surface to accumulate biological material present in tear fluid. Though that issue is also addressed in the patent in suit as a subsidiary problem, a solution to that problem is not provided by the claimed lenses according to their broadest definition. In fact a reduction of deposit accumulation on the surfaces of the lenses is implicitly indicated to be achieved only by the features of dependent claim 26, using features known in the art for that purpose (see paragraphs [0030] and [0031] of the patent in suit). Furthermore, since the problem of deposit accumulation on the surface of the lenses addressed in D1 has not been shown to imply or to be associated with a reduction of water loss, there is no reason for the skilled person wishing to solve the problem of providing hydrophilic contact lenses having increased water content and/or increased water retention and/or reduced surface evaporation of water, to start from the disclosure of D1.

3.3 Accordingly, D4 constitutes the starting point for assessing inventive step. The parties agreed that the only distinguishing feature between the ophthalmic lens according to claim 1 of the patent in suit and the lens according to D4 results from the order of synthesis of the interpenetrated polymers: in claim 1 of the patent in suit the lens body comprises the crosslinked material to which the appropriate monomer is introduced and polymerized, thus preparing the water soluble polymer *in situ*, while in D4 the lens body is made by polymerizing the appropriate monomers to form a crosslinked material in the presence of the preformed water soluble polymer. Although the monomeric units of the cross-linked and water soluble polymers of the

patent in suit cannot be distinguished from the monomeric units forming the corresponding polymers in D4, in view of D6 - which presents an overview of the knowledge in the art on IPN - the parties agreed that those two ways of proceeding would lead to structural differences, i.e. differences in morphology, of the lens of the patent in suit and that of D4. The Board is therefore satisfied that the lens according to claim 1 is distinguishable from that of D4.

Problem and solution

4. Having regard to the disclosure of D4, the patent proprietor formulated the technical problem solved by the subject-matter of claim 1 of the main request as to provide an ophthalmic lens having an enhanced modulus whilst retaining an effective tensile strength. The opponent objected to allowability of that formulation.

4.1 The patent in suit consistently refers to the aim of providing ophthalmic lenses having increased high modulus and tensile strength, as such improvement provided lenses that have longer useful lives and/or can be made thinner so as to enhance lens wearer comfort (paragraphs [0007], [0012], [0013], [0022] and [0062]). That improvement refers to conventional lenses within the meaning provided in paragraph [0002], i.e. those formed from hydrophilic crosslinked polymers referred to as hydrogels which do not contain an additional water soluble linear or branched chain polymer or copolymer. Hence the patent in suit contains a general and consistent teaching that the ophthalmic lenses as defined in present claim 1 provide advantageous modulus or tensile strength.

4.2 According to established jurisprudence of the boards of appeal (Case Law, supra, I.D.4.4.1), where a specific problem is identified in the description, the patentee may be allowed to put forward a modified version of the problem if the issue of inventiveness has to be considered on an objective basis against a new prior art that comes closer to the invention than that considered in the original patent application or granted patent specification. Since the problem objectively solved is the result actually achieved in relation to the closest state of the art, there is nothing to prevent the problem as first formulated from being modified as long as the spirit of the original disclosure of the invention is respected.

4.3 In the present case, the purpose of the invention, as explained in paragraphs [0003] and [0007] of the patent in suit, was to provide hydrophilic contact lenses having increased water content and/or increased water retention and/or reduced surface evaporation of water compared to conventional lenses that do not contain the water soluble polymer. Further, the lenses of the patent in suit, in particularly those defined in claim 1 of the main request, are consistently presented to have advantageous modulus and tensile strength. It is therefore legitimate for the patent proprietor in view of the closest prior art D4, i.e. one that also concerns lenses containing a water soluble polymer in addition to the cross-linked polymer and therefore provides higher degree of water attraction ability and reduction of water loss (see point 3.1 above), to rely on the additional advantages of the claimed lenses to which reference is consistently made in the patent in suit. Accordingly, it is reasonable for the patent proprietor to argue that the level of modulus or tensile strength of the claimed ophthalmic lens is not

not only better than that of lenses without the second material but also compared to those of D4 which now are considered to represent the starting point for assessing inventive step. The opponent's argument that the patent proprietor should not be entitled to reformulate the problem on the basis of an improvement over D4 must therefore fail.

5. Whether evidence has been provided that the claimed subject-matter provides a successful solution to the problem of providing ophthalmic lenses with enhanced modulus whilst retaining an effective tensile strength, remains to be seen. The patent proprietor referred to D14 submitted with the statement setting out the grounds of appeal.

5.1 D14 is an experimental report that provides a comparison between two lenses obtained by reproducing Example 4 of document D4 and by a reverse process as used in claim 1 of the patent in suit. It aims at demonstrating the effect of the reverse process on the Young's modulus and tensile strength. It was submitted in response to the position taken by the opposition division in the contested decision (see point 12.3 of the reasons) that "*there was no evidence for a technical effect of a lens and process thereto which are being made in the reverse way*".

5.2 Article 12(4) RPBA requires the Board to take into account everything presented by the parties under Article 12(1) RPBA if and to the extent that it relates to the case under appeal and meets the requirements in Article 12(2) RPBA. However, according to Article 12(4) RPBA, the Board has the discretionary power to hold inadmissible facts, evidence and requests

that could have been presented or were not admitted in the first instance proceedings.

5.3 As shown above, D14 relates to the case under appeal and constitutes a response to one of the essential aspects of the reasons for the contested decision. Although the data of D14 could have been submitted in the first instance, there is no indication of a lack of diligence by the patent proprietor, nor does its later filing cause unfairness to the other party. Moreover, the submission before the first instance would not have led to a more efficient processing of the case. Under the present circumstances, the Board sees no reason to make use of its discretionary power under Article 12(4) EPC to hold inadmissible D14 which therefore is taken into consideration in these appeal proceedings.

5.4 The opponent argued that D14 should not be relied upon to demonstrate the presence of an inventive step on the basis of the catchword of decision T 1329/04 "*The definition of an invention as being a contribution to the art, i.e. as solving a technical problem and not merely putting forward one, requires that it is at least made plausible by the disclosure in the application that its teaching solves indeed the problem it purports to solve. Therefore, even if supplementary post-published evidence may in the proper circumstances also be taken into consideration, it may not serve as the sole basis to establish that the application solves indeed the problem it purports to solve*".

5.5 Decision T 1329/04 cited by the Opponent concerns polynucleotides, the property or function of which, meant to justify the existence of an inventive step for those polynucleotides, had been merely presumed but not rendered plausible by the disclosure in the application

as filed. This decision therefore does not concern a situation similar to the present one where the claimed subject-matter, i.e. contact lenses, had, also in view of experimental evidence contained in the application as filed, been indicated to have appropriate mechanical properties, such as modulus and tensile strength. Thus, the property on the basis of which an inventive step is sought to be acknowledged had not been merely presumed but even rendered plausible in the application as filed. Decision T 1329/04 is therefore irrelevant to the present case and the opponent's argument based on it cannot be followed.

5.6 D14 provides a comparison of a lens formed in Example 4 of the closest prior art D4 in which a pseudo-IPN is produced by formation of a water-swellable polymer in the presence of a linear IPN-agent, namely PVP (polyvinyl pyrrolidone) (formulation B), and a lens prepared according to the procedure of the patent in suit, where a lens body is treated with a solution comprising N-vinyl pyrrolidone and an initiator to form a pseudo-IPN through the lens body (formulation A).

5.7 The comparison with the closest state of the art should be such that the alleged advantage or effect is convincingly shown to have its origin in the feature distinguishing the invention from closest state of the art, in the present case the change of morphology resulting from the reverse order of polymerization. In the comparative test of D14 there is at least one element that has not been shown to be the same in the examples to be compared, namely the amount of PVP in the final lens. Based on the patent proprietor's written submissions of 9 November 2012, the average dry weight of lenses of formulation A after treatment with the solution of N-vinyl pyrrolidone was 24,3 mg,

whereas before treatment it was on average 23,4 mg, meaning that on average 0.9 mg PVP linear polymer had been incorporated into the lens body, i.e. 3,7 wt.% based on the dry weight of the lens. However, the exact proportion of PVP in the lenses obtained with formulation B (containing 10 wt.% PVP and about 90 wt.% of monomers for preparing the cross-linked water-swellable first material, i.e. after the various soaking and extraction steps), is not known. That was confirmed by the patent proprietor during the oral proceedings before the Board. If all monomer used for the preparation of the first crosslinked material had been retained in the lens, the proportion of PVP in the lens would be at least the same as in formulation B. It can also be higher when the polymerization is not complete or when material has been washed out after extraction. It results from the above that the lenses prepared with formulation B contain considerably more PVP than the lenses prepared with formulation A.

5.8 However, the amount of PVP in the lens influences modulus as well as tensile strength (see paragraphs [0007], [0012] and [0022] of the patent in suit). That amount should therefore have been kept constant in order to demonstrate a causal link between the difference in morphology resulting from the reverse order of polymerisatio and any enhanced modulus whilst retaining an effective tensile strength. Accordingly, D14 does not constitute evidence that the claimed lenses bring about the alleged improvement.

6. Since in the present case the alleged improvement lacks the required experimental support, the technical problem as defined in point 4 above needs reformulation (Case Law, supra, I.D.4.2). Thus, in view of the teaching of document D4, the problem underlying the

patent in suit is merely to be seen as providing further ophthalmic lenses.

Obviousness

7. It remains to be decided whether or not the proposed solution to the problem underlying the patent in suit is obvious in view of the state of the art.

7.1 D6 (pages 5 and 6) provides a general teaching about sequential IPNs, i.e. wherein a polymer network I is made and monomer II plus cross-linker and activator are swollen into network I and polymerized in situ. This suggests that semi-IPNs, which are also indicated in D6 in the list of possible kinds of IPNs, can be obtained by the same process but prepared in the absence of a cross-linker as polymer II is linear.

7.2 The passage in D7, page 684, last paragraph, concerning IPNs indicates "at least one polymer must be polymerized and/or cross-linked in the immediate juxtaposition of the other", which means that one polymer can be prepared but not needs to be cross-linked in the presence of the other cross-linked polymer.

7.3 That a sequential polymerisation can be used in the field of ophthalmic lenses is taught in D2. Claim 1 of that prior art concerns a method for producing an ophthalmic lens, comprising in a first step impregnation of a self-supportable matrix of cured polymer material in the form of said ophthalmic lens with a photopolymerizable liquid composition containing a monomer and a photoinitiator. In a second step the material thus impregnated is subjected to local irradiation over the surface of said matrix according

to a desired pattern of refractive index modulation corresponding to a desired bifocality of said lens, whereby said composition is cured locally according to said pattern. Claim 1 also specifies that the excess quantity of non-hardened composition is then removed from the material.

7.3.1 According to D2, column 4, lines 1-12, the greatest advantage is achieved with polymers that have a cross-linked network, the polymerization and cross-linking reactions being completely terminated prior to the index modulation treatment. The method is said to be particularly simple and useful in the case of hydrophilic polymers of the hydrogel type, i.e. water-swellable crosslinked polymer materials. This is confirmed in column 6, lines 56-61, where it is stated that the polymers constituting the lenses are preferably hydrophilic polymers of the hydrogel type endowed with a high capacity for absorption of water and that the photopolymerizable composition is accordingly soluble in water. Inscription of the refractive index profile within the hydrogel by the method of the invention accordingly takes place directly in the water-swollen hydrogel by impregnating the hydrogel to saturation with an aqueous solution of the monomer and of a water-soluble photoinitiator.

7.3.2 The monomers of that aqueous solution can be of the same type as those employed in the manufacture of the basic lens material (column 4, lines 22-54), in particular N-vinylpyrrolidone (column 4, line 47). The passages in column 6, lines 19-21 and in the paragraph bridging columns 6 and 7 make clear that the use of a cross-linker in the treating solution is merely optional, in line with Example I and the wording of claim 1.

7.3.3 Finally, the paragraph bridging columns 5 and 6 indicates that the sequential polymerization employed in D2 does not bring about chemical reactions of fixation of the second polymer produced with the previously hardened polymer of the basic matrix. It discloses therefore that the method used in D2 results in the formation of semi-IPNs.

7.3.4 Summing up, on the basis of D2 the skilled person is aware that N-vinylpyrrolidone can be polymerized in situ in a lens body made of a crosslinked water-swellable polymer material.

7.4 Therefore, on the basis of the general teaching regarding the synthesis of semi-IPN in D6 and D7, and of the more specific teaching of D2 regarding the possibility of polymerizing in situ N-Vinylpyrrolidone in a body lens of a water-swellable crosslinked polymer material, the skilled person who, starting from D4, sought to provide further ophthalmic lenses would have regarded reversing the order of polymerization employed in D4as a feasible option and would thus have been led to produce first a lens body comprising a crosslinkked water-swellable material, then to introduce N-vinylpyrrolidone into the lens body and to polymerize the monomer in situ, arriving thereby in an obvious way to an ophthalmic lens as defined in claim 1.

7.5 The statement in D2, column 7, lines 56-66, that "*the lens is not deformed by the treatment of the invention in spite of what might have been expected, for example, from hydrophobic molecules of methyl polymethacrylate imprisoned in a hydrophilic matrix or from zones of polyHEMA which are hydrophilic but have a swelling ratio of 40%, in a MMA/NVP matrix having a swelling*

ratio of 70%" does not teach away from applying reverse polymerization, as argued by the patent proprietor. That statement does not concern impregnation with N-vinylpyrrolidone. It is even clearly indicated that the deformation that one might have expected in fact does not take place.

8. Hence, claim 1 of the main request lacks an inventive step and is therefore not allowable.

First Auxiliary Request

9. The subject-matter of claim 1 of the first auxiliary request differs from that of the main request in that the lens body is defined to exhibit increased equilibrium water content relative to a substantially identical lens body without the second material.

10. According to D4, the paragraph bridging pages 17 and 18, a higher concentration of PVP as an IPN-agent results in a hydrogel having an increased water content. The presence of PVP as an IPN-agent in the hydrophilic hydrogel is described to increase water attraction ability which in turn prevents water evaporation from the hydrogel surface. Accordingly, the increased equilibrium water content relative to a substantially identical lens body without the second material is the result of the presence of PVP in the lens body. As this effect is due to the known hydrophilic character of PVP, it is also obvious that that effect is obtained independently of whether the lens is made according to D4 or according to the reverse process. Consequently, the additional feature defined in claim 1 of the first auxiliary request has no effect on the definition of the problem solved over the closest prior art and the conclusion that the

reverse process constitutes an obvious solution to it. Thus, claim 1 of the first auxiliary request also lacks an inventive step.

Second Auxiliary Request

11. The subject-matter of claim 1 of the second auxiliary request differs from that of the first auxiliary request in that the second material is defined to be present in an amount of 0.1 to 40% by weight based on the water-free weight of the composition. The concentration of PVP used in D4 is typically in the range of 1% to 14% (paragraph bridging pages 17 and 18, as well as Examples 1-5, 7 and 8 wherein PVP is used as IPN agent). Therefore, the additional feature contained in the second auxiliary request does not introduce a further distinguishing feature over the lens of the closest prior art. It has therefore no influence on the inventive step reasoning provided for the main and the first auxiliary request. Hence, claim 1 of the second auxiliary request also lacks an inventive step.

Third to Fifth Auxiliary Requests

12. Each of the claims 1 of the third, fourth and fifth auxiliary request defines a method for producing the ophthalmic lens specified in each of the claims 1 of the main request, first auxiliary request and second auxiliary request, respectively. As shown above with respect to the main request, the use of the reverse process for providing further ophthalmic lenses was obvious to the skilled person. Moreover, the use of a reverse process is also obvious in order to avoid the handling problems linked to the method used in D4, namely the use of a filtration step and of a degassing step rendered necessary by the introduction of PVP in

the solution of monomers (see examples of D4), as well as the increase of viscosity of the solution resulting from the incorporation of PVP into that solution. In the absence of any surprising technical effect in process terms brought about by the reverse polymerization and in view of the above conclusions with respect to the main, first and second auxiliary requests, the methods according to claims 1 of the third, fourth and fifth auxiliary requests are also considered to lack an inventive step.

Sixth and Seventh Auxiliary Requests

13. The claims 1 of the sixth and seventh auxiliary request define the use of the second polymeric material of the ophthalmic lenses defined in the claims 1 of the main request and the second auxiliary request, respectively, to increase the equilibrium water content of the lens body relative to a substantially identical lens body without the second material. As indicated in above point 10, it is not only described in D4 that that effect is associated with the use of PVP, but it is also obvious to the skilled person that it would be achieved independently of whether the lens is made according to D4 or according to the reverse process. Therefore, the transformation of the claims 1 of the main request and the second auxiliary request into use claims defining that the second material increases the equilibrium water content of the lens body relative to a substantially identical lens body without the second material, cannot change the conclusion on inventive step regarding those requests. Accordingly, the subject-matter of claim 1 of any of the sixth and seventh auxiliary requests also lacks an inventive step.

14. The above finding is not based on the pieces of evidence D9 to D12, so that there is no need to decide whether those documents cited by the Opponent in support of their objection of lack of an inventive step should be taken into consideration.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairwoman:

B. ter Heijden B. ter Laan

Decision electronically authenticated