

**Internal distribution code:**

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

**Datasheet for the decision  
of 15 July 2015**

**Case Number:** T 1924/14 - 3.3.03

**Application Number:** 06076274.7

**Publication Number:** 1754728

**IPC:** C08F230/08, C08F290/06,  
G02B1/04

**Language of the proceedings:** EN

**Title of invention:**  
Soft contact lenses

**Patent Proprietor:**  
Johnson & Johnson Vision Care Inc.

**Opponent:**  
Bausch & Lomb Incorporated

**Headword:**

**Relevant legal provisions:**  
EPC Art. 123(2)  
EPÜ Art. 56

**Keyword:**  
Amendments - added subject-matter (no)  
Inventive step - obvious alternative (all requests)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern  
Boards of Appeal  
Chambres de recours**

European Patent Office  
D-80298 MUNICH  
GERMANY  
Tel. +49 (0) 89 2399-0  
Fax +49 (0) 89 2399-4465

Case Number: T 1924/14 - 3.3.03

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.03**  
**of 15 July 2015**

**Appellant:** Johnson & Johnson Vision Care Inc.  
(Patent Proprietor) 7500 Centurion Parkway  
Suite 100  
Jacksonville, FL 32223 (US)

**Representative:** Kirsch, Susan Edith  
Carpmaels & Ransford LLP  
One Southampton Row  
London WC1B 5HA (GB)

**Appellant:** Bausch & Lomb Incorporated  
(Opponent 3) 1400 North Goodman Street, Area 62  
Rochester, New York 14609 (US)

**Representative:** Glas, Holger  
Maiwald Patentanwalts GmbH  
Elisenhof  
Elisenstrasse 3  
80335 München (DE)

**Decision under appeal:** **Interlocutory decision of the Opposition**  
**Division of the European Patent Office posted on**  
**16 July 2014 concerning maintenance of the**  
**European patent No. 1754728 in amended form.**

**Composition of the Board:**

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

## Summary of Facts and Submissions

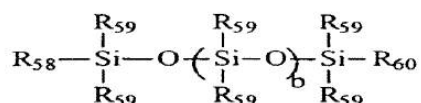
- I. European patent No. 1 754 728 was based on a divisional application of European patent application 00961768.9 published as EP-A-1 235 866. It claims three priorities, the first priority date claimed being 7 October 1999, based on US application 09/414 365.
- II. Three notices of opposition by opponents 1 to 3 were filed, requesting revocation of European patent No. 1 754 728 in its entirety on the grounds that its subject-matter lacked novelty and an inventive step (Article 100(a) EPC) and was insufficiently disclosed (Article 100(b) EPC). A further opposition by opponent 4 requesting revocation of the patent in its entirety on the same grounds and, in addition, that of added subject-matter (Article 100(c) EPC) was withdrawn before the opposition division.
- III. The following documents were cited by the parties during the opposition proceedings:
- D2: Silicone hydrogel contact lenses Part 1 Evolution and Current Status, Jones et al., [www.optometry.co.uk](http://www.optometry.co.uk), published September 2002
- D3: The Evolution of Silicone Hydrogel Lenses, Dr Chou, Contact Lens Spectrum June 2008 (<http://www.clspectrum.com/article.aspx?article=101744>)
- D5: Silicone Hydrogels - what are they and how should they be used in everyday practice? - Tighe et al., Contact Lens Monthly, No 5726, Vol 218, November 1999
- D7: Accuracy and Reproducibility of One-Day Disposable Contact Lenses, Efron et al., ICLC, Vol 26, 1999
- D8: EP-A-0 940 693

- D13: A Hypothesis for the Aetiology of Soft Contact Lens-Induced Superior Arcuate Keratopathy, Young et al., ICLC Volume 20, 1993
- D14: Contact-lens related case studies - Superior epithelial arcuate lesions (SEAL) 'Epithelial splitting' OPTICIAN, November 1998
- D15: Martin et al. - Optometry and Vision Science 1989, Vol. 66, No. 2, pages 87-91
- D16: Summary for safety and effectiveness for Balafilcon A lenses
- D17: Summary of Safety and Substantial Equivalence for Lotrafilcon A lenses
- D18: WO 96/31792
- D28: "The Genesis of Silicone Hydrogels", Contact Lens Spectrum, October 2010 issue
- D29: Dumbleton, Contact Lens Anterior Eye 25, 2002, 137-146
- D30: Dumbleton, Optom. Vis. Sci. 2000; 77(12s): 216
- D31: Holden et al. Optom. Vis. Sci., 78, pages 9-12
- D35: Extract from Schwartz, "Speciality contact lenses, a fitter's guide", 1996, page 286
- D36: Malinovsky et al. "Epithelial Splits of the Superior Cornea in Hydrogel Contact Lens Patients", 1989,
- D37: Bennett, "Contact Lens Problem Solving", 1995, pages 51-53
- D38: McMonnies "After care symptoms, signs and management" from Contact Lenses, 3rd Ed. pages 714-715.
- D39: Gerry, Clinical and Experimental Optometry, 78, 194- 195
- D40: Sweeney, Silicone Hydrogels, 2000, pages 192-198
- D51: Holden, Sankaridurg and Jalbert, Optician, 14 January 2000, No. 5733, vol. 219.
- D51a: CLAE Calendar, Contact Lens and Anterior Eye, Vol. 22, No. 2, p. 74, 1999

- D53: EP-A-2 202 254
- D58: EP-A-1 243 960
- D60: Extract from "Contact Lenses" by Phillips,  
pages 189-193 and 445-449
- D61: US-B2-6 849 671.

IV. According to the interlocutory decision of the opposition division posted on 16 July 2014, the patent as amended according to the documents of auxiliary request 2 submitted with letter of 13 March 2014 met the requirements of the EPC. Claim 1 of that request read as follows:

"1. A silicone hydrogel contact lens comprising a center thickness (CT) of 50 to 160µm and a Young's modulus (E) of 275.8 to 2068 kPa (40 to 300 psi), wherein (E)(CT<sup>2</sup>) is less than 6.895 kPa.mm<sup>2</sup> (1 psi.mm<sup>2</sup>), and further comprising a mono-alkyl terminated polydimethylsiloxane having the structure:



where b = 0 to 100; R<sub>58</sub> is a monovalent group comprising an ethylenically unsaturated moiety; each R<sub>59</sub> is independently a monovalent alkyl, or aryl group, which may be further substituted with alcohol, amine, ketone, carboxylic acid or ether groups; and R<sub>60</sub> is a monovalent alkyl, or aryl group, which may be further substituted with alcohol, amine, ketone, carboxylic acid or ether groups."

- V. According to the reasons for the decision, the subject-matter according to auxiliary request 2 did not contain added subject-matter and met the requirement of clarity. In addition, novelty over the contact lens described in example 4 of D58 was acknowledged. With respect to inventive step, D8 was considered as the closest prior art. The problem solved over that prior art was providing silicone hydrogel contact lenses with a reduced occurrence of superior epithelial arcuate lesions (hereafter SEALS). This was achieved by selecting a particular combination of Young's modulus and centre thickness, as demonstrated by the data of the patent in suit and of the later document D61. In view of the general lack of understanding of the SEALS phenomenon shown by D35 to D39 and despite the indication in D13 and D14 that the modulus of the lens was a possible cause of the occurrence of SEALS, it was considered that none of the cited documents would lead to selecting the particular combination of Young's modulus, centre thickness and  $(E)(CT^2)$  value in order to reduce the occurrence of SEALS.
- VI. The patent proprietor and opponents 1 to 3 appealed the decision with letters of 18 September 2014, 16 September 2014, 16 September 2014 and 15 September 2014 respectively.
- VII. The statement of grounds of appeal of the patent proprietor was submitted with letter of 26 November 2014 to which auxiliary requests 1 and 2 were attached. Auxiliary request 2 was indicated to be identical to auxiliary request 2 underlying the contested decision.
- VIII. The statements of grounds of appeal of opponents 1, 2 and 3 were submitted with letters of 25 November 2014, 24 November 2014 and 25 November 2014, respectively.

- IX. A notice of intervention dated 18 February 2015 was also filed, requesting revocation of the patent in its entirety on the grounds of Article 100(a) EPC (lack of novelty and inventive step), Article 100(b) EPC and Article 100(c) EPC.
- X. Opponents 1, 2 and 3 replied to the statement of grounds of the patent proprietor with letters of 13 April 2015, 14 April 2015 and 13 April 2015, respectively.
- XI. The patent proprietor replied to the statements of grounds of appeal of opponents 1, 2 and 3 with a letter of 14 April 2015 to which were attached auxiliary requests labelled 1a, 1b, 1c, 3, 4, 4a, 4b, 4c, 5, 5a, 5b, 6, 6a, 6b and 7 to 14. The following documents were also submitted with that letter:
- D103: A graphical representation of the data regarding the incidence of SEALS as reported in the patent and D61
- D106: Back et al., "The rate of corneal infiltrative events and SEALS in silicone hydrogel continuous wear studies", 2006, American Academy of Optometry.
- XII. Opponent 2 provided additional arguments with letters of 7 May 2015 and 30 June 2015. Document D108a (Brennan & Morgan, "Clinical highs and lows of Dk/t", Parts 1 and 2, Optician, 2009, 238, 16-20 as reproduced in Contact Lens Monthly) was submitted with said letter of 7 May 2015.
- XIII. The patent proprietor replied to the intervention and the additional submissions of opponent 2 with a letter of 16 June 2015 with which it withdrew its main request



and auxiliary requests 1, 1a, 1b, 1c, 4, 4a, 4b and 4c. Former auxiliary requests 13 and 14 were replaced by two new auxiliary requests 13 and 14 attached to that letter.

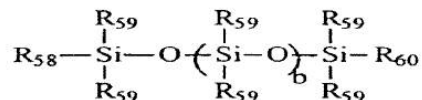
- XIV. Opponents 1 and 2 withdrew their appeals and oppositions with letters of 11 July 2015. The intervener withdrew its intervention with letter of 13 July 2015.
- XV. Oral proceedings took place before the Board on 14 and 15 July 2015, during which auxiliary request 8 submitted on 14 April 2015 was promoted to first auxiliary request. Accordingly, the order of the requests maintained by the patent proprietor and discussed during the oral proceedings is as follows, the wording of their claim 1 being indicated where necessary:

*Auxiliary request 2 submitted with letter of 13 March 2014 and resubmitted with the statement setting out the grounds of appeal (main request)*

The wording of claim 1 of that request is given in point IV above.

*Auxiliary request 8 submitted with letter of 14 April 2015 (first auxiliary request)*

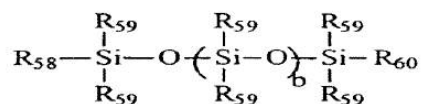
- "1. A silicone hydrogel contact lens comprising a center thickness (CT) of 50 to less than 85  $\mu\text{m}$  and a Young's modulus (E) of 275.8 to 2068 kPa (40 to 300 psi), wherein  $(E)(CT^2)$  is less than 6.895  $\text{kPa}\cdot\text{mm}^2$  (1  $\text{psi}\cdot\text{mm}^2$ ), and further comprising at least 5% wt of a mono-alkyl terminated polydimethylsiloxane having the structure:



where b = 0 to 100; R<sub>58</sub> is a monovalent group comprising an ethylenically unsaturated moiety; each R<sub>59</sub> is independently a monovalent alkyl, or aryl group, which may be further substituted with alcohol, amine, ketone, carboxylic acid or ether groups; and R<sub>60</sub> is a monovalent alkyl, or aryl group, which may be further substituted with alcohol, amine, ketone, carboxylic acid or ether groups."

*Auxiliary request 3 submitted with letter of 14 April 2015 (second auxiliary request)*

- "1. A silicone hydrogel contact lens comprising a center thickness (CT) of 50 to 160 μm and a Young's modulus (E) of 275.8 to 2068 kPa (40 to 300 psi), wherein (E)(CT<sup>2</sup>) is less than 6.895 kPa.mm<sup>2</sup> (1 psi.mm<sup>2</sup>), and further comprising at least 5% wt of a mono-alkyl terminated polydimethylsiloxane having the structure:



where b = 0 to 100; R<sub>58</sub> is a monovalent group comprising an ethylenically unsaturated moiety; each R<sub>59</sub> is independently a monovalent alkyl, or aryl group, which may be further substituted with alcohol, amine, ketone, carboxylic acid or ether groups; and R<sub>60</sub> is a monovalent alkyl, or aryl

group, which may be further substituted with alcohol, amine, ketone, carboxylic acid or ether groups."

*Auxiliary requests 5, 5a and 5b submitted with letter of 14 April 2015 (third to fifth auxiliary requests)*

The patent proprietor indicated that auxiliary requests 5, 5a and 5b differed from auxiliary request 2 submitted with letter of 13 March 2014 (now the main request) in that each of claim 1 of these auxiliary requests contained a disclaimer having a different wording and aimed at overcoming the objection that example 4 of D58 was novelty-destroying.

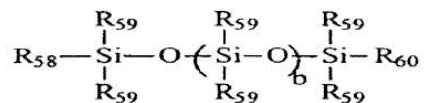
*Auxiliary requests 6, 6a and 6b submitted with letter of 14 April 2015 (sixth to eighth auxiliary requests)*

As with auxiliary requests 5, 5a and 5b, the patent proprietor indicated that auxiliary requests 6, 6a and 6b differed from auxiliary request 3 submitted with letter of 14 April 2015 (now the second auxiliary request) in that their claims 1 contained the disclaimers used in claims 1 of auxiliary requests 5, 5a and 5b, again in order to overcome the objection that example 4 of D58 was novelty-destroying.

*Auxiliary request 7 submitted with letter of 14 April 2015 (ninth auxiliary request)*

"1. A silicone hydrogel contact lens comprising a center thickness (CT) of 50 to less than 85  $\mu\text{m}$  and a Young's modulus (E) of 275.8 to 2068 kPa (40 to 300 psi), wherein (E) (CT<sup>2</sup>) is less than 6.895 kPa. $\text{mm}^2$  (1 psi. $\text{mm}^2$ ), and further comprising a mono-

alkyl terminated polydimethylsiloxane having the structure:



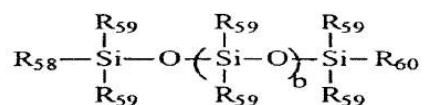
where  $b = 0$  to  $100$ ;  $\text{R}_{58}$  is a monovalent group comprising an ethylenically unsaturated moiety; each  $\text{R}_{59}$  is independently a monovalent alkyl, or aryl group, which may be further substituted with alcohol, amine, ketone, carboxylic acid or ether groups; and  $\text{R}_{60}$  is a monovalent alkyl, or aryl group, which may be further substituted with alcohol, amine, ketone, carboxylic acid or ether groups."

*Auxiliary requests 9 to 12 submitted with letter of 14 April 2015 (tenth to thirteenth auxiliary requests)*

According to the patent proprietor, auxiliary requests 9 to 12 submitted with letter of 14 April 2015 corresponded to the above-mentioned auxiliary requests 2, 3, 7 and 8, respectively, except that the definition of  $\text{R}_{60}$  was limited to monoalkyl  $\text{C}_{3-8}$  groups.

*Auxiliary request 13 submitted with letter of 16 June 2015 (fourteenth auxiliary request)*

"1. A silicone hydrogel contact lens comprising a mono-alkyl terminated polydimethylsiloxane having the structure:



where  $b = 0$  to 100;  $R_{58}$  is a monovalent group comprising an ethylenically unsaturated moiety; each  $R_{59}$  is independently a monovalent alkyl, or aryl group, which may be further substituted with alcohol, amine, ketone, carboxylic acid or ether groups; and  $R_{60}$  is a monovalent alkyl, or aryl group, which may be further substituted with alcohol, amine, ketone, carboxylic acid or ether groups; and either

- a. comprising a center thickness (CT) of 50 to 160  $\mu\text{m}$  and a Young's modulus (E) of 275.8 to 2068 kPa (40 to 300 psi), wherein  $E(\text{CT}^2)$  is less than 6.895  $\text{kPa}\cdot\text{mm}^2$  (1  $\text{psi}\cdot\text{mm}^2$ ) with the proviso that the silicone hydrogel lens does not consist of lens B from example 22, or lens B with an  $E(\text{CT}^2)$  value of 6.69  $\text{kPa}\cdot\text{mm}^2$  (0.97  $\text{psi}\cdot\text{mm}^2$ ) from example 23; or
- b. consisting of lens B from example 22, or lens B with an  $E(\text{CT}^2)$  value of 6.69  $\text{kPa}\cdot\text{mm}^2$  (0.97  $\text{psi}\cdot\text{mm}^2$ ) from example 23.

*Auxiliary request 14 submitted with letter of 16 June 2015 (fifteenth auxiliary request)*

Claim 1 of the fifteenth auxiliary request corresponds to claim 1 of the fourteenth auxiliary request, except that lens B from example 22, or lens B with an  $E(\text{CT}^2)$  value of 6.69  $\text{kPa}\cdot\text{mm}^2$  (0.97  $\text{psi}\cdot\text{mm}^2$ ) from example 23 referred to in claim 1 of the fourteenth auxiliary request is defined in accordance with their description in the patent.

XVI. The arguments of the opponent can be summarised as follows:

*Main request (auxiliary request 2 submitted with the statement setting out the grounds of appeal)*

- a) The divisional and parent applications as filed did not disclose the use of the mono-alkyl terminated polydimethylsiloxane defined in claim 1 of the present main request without the definition of a minimum amount for that compound. Hence, claim 1 of the main request did not fulfil the requirements of Articles 76(2) and 123(2) EPC. Claim 12 also was not in keeping with those requirements.
- b) Claim 1 of the main request was not merely based on the combination of two claims as granted. Accordingly, claim 1 had to fulfil the requirements of Article 84 EPC, which however were not met in view of the ambiguity resulting from the co-existence of the terminology mono-alkyl terminated polydimethylsiloxane and the definition of the substituents R<sub>59</sub> and R<sub>60</sub>.
- c) The closest prior art was represented by the lenses disclosed in D8 or D18, as they had the most technical features in common with the lenses of the patent in suit. In particular, example 18 of D8 was a legitimate starting point for assessing inventive step, since a mere selection of centre thickness of at most 135 µm was sufficient to arrive at the claimed lenses. In addition, D8 addressed the need to provide more elastic silicone hydrogels, i.e. lenses with a lower Young's modulus. Moreover, the patent in

suit was a development of D8, as shown by the fact that the corresponding US patent of the patent in suit was a continuation-in-part of the US equivalent of D8.

- d) Starting from the lenses of the first generation of silicone hydrogel materials Balafilcon A or Lotrafilcon A as the closest prior art, the problem solved by the claimed subject-matter was seen as merely to provide further contact lenses. Claim 1 was so broadly defined with respect to centre thickness and Young's modulus that it covered almost every silicone hydrogel contact lens. The occurrence of SEALs was documented (D61, D108a, D13) as depending on many factors, such as lens design, elasticity (Young's modulus) and wettability, but claim 1 was not specific with respect to some of those characteristics. In addition, the examples contained in the patent in suit only concerned lenses with a Young's modulus of 88 psi, whereas the claim allowed values of up to 300 psi, which were more likely to increase the occurrence of SEALs. Also, the methods for measuring the centre thickness were not reliable and claim 1 did not specify any. Hence, the claimed  $E.CT^2$  range which the patent proprietor held to be the core of the invention could not credibly solve the problem of suppressing or significantly reducing the occurrence of SEALs. Mono-alkyl terminated polydimethylsiloxanes defined in claim 1 were known from D8 as a component of contact lens materials. That document, which sought to solve the same general problem as the patent in suit, suggested contact lenses having all the features of present claim 1 apart from the centre thickness. The centre

thickness defined in claim 1 was conventional in the art and the parameter  $E.CT^2$  had been arbitrarily chosen. Accordingly, the subject-matter of claim 1 of the main request was obvious in view of the prior art and the requirements of Article 56 EPC were not met.

*Auxiliary requests*

- e) The first auxiliary request (auxiliary request 8 submitted with letter of 14 April 2015) should not be admitted into the proceedings, since it could have been submitted before the first instance. In addition, it could not overcome the inventive step objection against the main request, as it had been submitted merely to overcome the novelty objection over D18. The fourteenth and fifteenth auxiliary requests (submitted with letter of 16 June 2015 as auxiliary requests 13 and 14 respectively) had been submitted shortly before the oral proceedings. They should not be admitted into the proceedings either. The subject-matter of claim 1 of all the auxiliary requests lacked an inventive step for the same reasons as claim 1 of the main request.

XVII. The arguments of the patent proprietor can be summarised as follows:

*Main request (auxiliary request 2 submitted with the statement setting out the grounds of appeal)*

- a) According to the original description, the compound defined in amended claim 1 could be used in any amount the lower limit of 5% wt defined in both claims 5 and 35 of the divisional and parent



applications as filed was not essential. Claim 1 of the main request therefore met the requirements of Articles 76(1) and 123(2) EPC.

- b) Commercial contact lenses PureVision™ of Bausch & Lomb and Focus® NIGHT & DAY™ of CIBA Vision, which were available to the public before the first priority date were made with the first generation of silicone hydrogel materials called Balafilcon A and Lotrafilcon A. Those lenses were prone to cause SEALs, as shown in particular by D51. The patent in suit aimed at a significant reduction of that problem, whereas D8 and D18 did not address the issue. Therefore, the closest prior art was constituted by the contact lenses PureVision™ and Focus® NIGHT & DAY™.
- c) The problem solved vis-à-vis that closest prior art was to provide silicone hydrogel contact lenses that significantly reduced or prevented the occurrence of SEALs. The definition  $E.CT^2 < 1 \text{ psi.mm}^2$  in combination with the defined ranges for E and CT constituted a safety threshold under which SEALs were prevented or their occurrence significantly reduced. This was shown by the experimental results provided in the patent in suit, as well as D61 and D106, which demonstrated that the parameter  $E.CT^2$  was not arbitrary. Reference was made to the graphical representation of those tests in D103, showing the existence of that safety threshold. It was also highlighted that it was not possible to prepare a comparative test with lenses made of the materials Balafilcon A and Lotrafilcon A in which only the features distinguishing the claimed subject-matter from the closest prior art had been varied, because it was

not known how to prepare lenses made of the materials Balafilcon A and Lotrafilcon A. From the numerous examples and comparative examples submitted by the patent proprietor, only lens 7 (comparative) and lens 2 (according to the present claims) of D61, lens B of example 23 (comparative) and two further lenses B of examples 22 and 23 (according to the claims) in the patent in suit provided a fair comparison for assessing the influence of Young's modulus, centre thickness and  $E.CT^2$  on the occurrence of SEALs. Those showed a reduction of SEALs brought about by the selection of parameters defined in claim 1. The relevance of the parameter  $E.CT^2$  came from the modeling used by the patent proprietor, which was based on the existence of the deflection force exerted by the eyelid at the centre of the lens.

- d) If the improvement was not considered to be credibly achieved, the problem solved over the prior art should be formulated as providing further silicone hydrogel contact lenses suitable for commercial use and extended wear.
  
- e) The solution to that problem was not obvious, as the skilled person had no motivation to modify the complex composition of the lens according to the closest prior art that had been tailored to provide a delicate balance between essential lens properties for extended wear, such as oxygen permeability or hydrophilicity. Moreover, the skilled person would know the disadvantage of thin lenses, in particular with respect to their mechanical properties and dehydration. Therefore he would not be prompted to select the centre thickness defined in the present claims. In view

of its oxygen permeability, which was lower than that of the material according to the closest prior art, the skilled person would not choose the silicone material used in example 18 of D8. If the skilled person wanted to provide further hydrogel silicone lenses suitable for commercial use and extended wear, he would try other, more straightforward modifications such as changing the coating of the lens. Thus, the solution defined by claim 1 was not obvious.

*Auxiliary requests*

- f) The first auxiliary request had been submitted in response to the appeal of the opponent and therefore could not be rejected as inadmissible. Its scope had been restricted, as claim 1 required a minimum amount of 5% wt of the mono-alkyl terminated polydimethylsiloxane and a centre thickness CT within the range of 50 to less than 85  $\mu\text{m}$ . Starting from the Balafilcon A and Lotrafilcon A lenses, the high number of modifications to be performed in order to provide a commercial successful lens was not trivial. The arguments presented were in essence the same as for the main request.
  
- g) Further arguments in support of inventive step of the other auxiliary requests were not provided. Auxiliary requests 13 and 14 submitted with letter of 16 June 2015 should be admitted into the proceedings. Compared to previous auxiliary requests 13 and 14 submitted with letter of 14 April 2015, they had been amended merely in order to incorporate the same limitations as those contained in previous auxiliary request 2 which

had been promoted to main request with said letter of 16 June 2015.

- XVIII. The patent proprietor requested that the opponent's appeal be dismissed and that the patent be maintained on the basis of the claims of the patent in the version as maintained by the opposition division (auxiliary request 2 as filed with the statement of grounds of appeal), or alternatively that the decision under appeal be set aside and the patent be maintained in amended form on the basis of auxiliary request 1 (filed as auxiliary request 8 with the letter of 14 April 2015), or on the basis of one of auxiliary requests 3, 5, 5a, 5b, 6, 6a, 6b, 7 or 9 to 12 submitted with letter of 14 April 2015, or on the basis of one of auxiliary requests 13 or 14 submitted with letter of 16 June 2015.
- XIX. The opponent requested that the decision under appeal be set aside and that the patent be revoked.

## **Reasons for the Decision**

*Main request (filed as auxiliary request 2 with letter of 13 March 2014 and filed again with the statement setting out the grounds of appeal)*

1. Amendments
- 1.1 According to the case law of the Boards of Appeal, a patent based on a divisional application can only be amended if the amended patent meets both the requirements of Article 76(1) EPC and the requirements

of Article 123(2) EPC. It is not disputed that lenses according to claim 1 are disclosed in the parent and divisional applications as filed, to the extent that they require at least 5% wt of the mono-alkyl terminated polydimethylsiloxane specified in claim 1 (see claim 35 and claim 5 of the parent and divisional applications respectively). Claim 35 and claim 5 of the parent and divisional applications respectively, define, in particular by reference to claim 31 and claim 1 of the parent and divisional applications respectively, a centre thickness (CT) of 50 to 160µm, a Young's modulus (E) of 40 to 300 psi and the requirement that  $(E)(CT^2)$  is less than 1 psi.mm<sup>2</sup>. The issue to be decided concerning claim 1 is whether the divisional and parent applications as filed also provide the use of the mono-alkyl terminated polydimethylsiloxane without the required minimum amount of 5 wt% disclosed in those claims.

- 1.2 The mono-alkyl terminated polydimethylsiloxane is disclosed in the divisional and parent applications as filed (paragraph bridging pages 4 and 5) as allowing a reduction of the Young's modulus of the silicone hydrogel. According to page 7, lines 10 to 14 of both the parent and the divisional application as filed, the range of Young's modulus between 20 and 180 psi may be obtained with an amount of 2 to 70 wt% of that compound, depending on the other monomers used for preparing the silicone hydrogel. Taking into account said disclosed effect of the mono-alkyl terminated polydimethylsiloxane on the Young's modulus, the skilled person understands that the upper value of that range of Young's modulus (180 psi) can be obtained with the lower amount of 2% of that compound defined in the same passage. On the basis of the same disclosed effect, it also follows that Young's moduli above 180

psi, including those up to the maximum value of 300 psi allowed by claims 35 and 5 of the parent and divisional applications respectively, and now by present claim 1, can be obtained with an amount of mono-alkyl terminated polydimethylsiloxane that is below 2% wt. Furthermore, the Young's modulus is indicated in the above-mentioned passage to depend on the other monomers used for preparing the silicone hydrogel. Accordingly, it can be concluded that the maximum value of 300 psi is not inextricably linked with a specific minimum amount of 5% wt mono-alkyl terminated polydimethylsiloxane, but can be obtained by adjusting the amount of that compound and the other monomeric constituents of the silicone hydrogel.

1.3 Hence, the subject-matter of claim 1 does not extend beyond the content of both the parent and divisional applications as filed.

1.4 Having regard to the outcome of the appeals, there is no need for the Board to take a decision on the allowability of the amendments with respect to claim 12.

2. Inventive step

2.1 Closest prior art

2.1.1 It is undisputed that the contact lenses PureVision<sup>TM</sup> of Bausch & Lomb and Focus<sup>®</sup> NIGHT & DAY<sup>TM</sup> of CIBA Vision were made with the first generation of silicone hydrogel materials Balafilcon A and Lotrafilcon A, respectively, as shown in particular in Tables 1 of D2, D3 and D5. It is also undisputed that those lenses were commercially available before the first priority date claimed by the patent in suit, as demonstrated by

example 23 of the first priority document (US 09/414 365) in which lenses made with Balafilcon A and Lotrafilcon A were tested, as well as by D5 - an article based on a "BCLA continuing education day" meeting that took place on 27 May 1999 as indicated in D51a, i.e. before the first priority date claimed.

- 2.1.2 Those lenses made with the first generation of silicone hydrogel materials were known to cause superior epithelial arcuate lesions (SEALs), as indicated in D51, an article sponsored by Bausch & Lomb and CIBA Vision, also based on the above-mentioned "BCLA continuing education day" meeting and confirmed by D3 (penultimate paragraph of page 2). SEALs are a complication of soft contact lens wear. They present themselves as a thin arcuate white lesion in the superior cornea, within 1 to 3 mm of the superior limbus between 10 and 2 o'clock, in an area normally covered by the superior eyelid (D40, page 194).
- 2.1.3 In paragraph 9 of the patent in suit it is generally indicated that the technical problem underlying the claimed invention is to provide silicone hydrogels that are soft enough to make soft contact lenses that possess high oxygen permeability, a suitable water content and sufficient elasticity, and are comfortable for the wearer. Although the problem of SEALs is not mentioned in that paragraph, examples 22 and 23 of the patent in suit more specifically indicate that the patent in suit also aims at reducing or eliminating the occurrence of SEALs which was observed for lenses made with the first generation of silicone hydrogel materials Balafilcon A and Lotrafilcon A.
- 2.1.4 According to the case law (see Case Law of the Boards of Appeal of the EPO, 7th edition 2013, I.D.3.2), the

closest prior art is normally a document that mentions the purpose or objective indicated in the patent in suit as a goal worth achieving. The aim is that the assessment process should start from a situation as close as possible to that encountered by the inventor.

- 2.1.5 The Board therefore comes to the conclusion that the contact lenses PureVision<sup>TM</sup> of Bausch & Lomb and Focus® NIGHT & DAY<sup>TM</sup> of CIBA Vision, made with the first generation of silicone hydrogel materials Balafilcon A and Lotrafilcon A respectively, represent a realistic starting point for the purpose of assessing inventive step.
- 2.1.6 The opponent held that D8 and D18 did not only aim at the same objective as the claimed invention, in particular with respect to wear comfort of the contact lenses, but also concerned lenses that were structurally closer to those claimed in the patent in suit than the lenses PureVision<sup>TM</sup> and Focus® NIGHT & DAY<sup>TM</sup>. It is not disputed, however, that those documents do not mention SEALS. No evidence has been provided that the mere mention of the general term "wear comfort" in those documents would mean prevention of all adverse events that might be associated with extended wear. Hence, as SEALS are only one possible adverse reaction among the various known adverse events related to the extended wear of contact lenses, neither D8 or D18 can be considered to deal with the issue of SEALS and therefore constitute a realistic starting point for a skilled person aiming at reducing or eliminating their occurrence. According to the case law (supra, I.D.3.3, in particular T 686/91), ex post facto considerations should be avoided in the determination of the closest state of the art. Therefore a document not mentioning a technical problem that is at least



related to that derivable from the patent in suit does not normally qualify as the closest state of the art, regardless of the number of technical features it may have in common with the subject-matter of the patent.

2.1.7 Moreover, contrary to the opponent's view, the fact that the US application corresponding to the patent in suit was a continuation-in-part of the US equivalent of D8 does not imply that one should start from D8 when assessing inventive step of the subject-matter of the patent in suit. Indeed, the earlier application may provide the solution of an invention as claimed in the subsequent application and is not necessarily its starting point. In other words, the additional teaching contained in a continuation-in-part may e.g. address a problem not addressed in the earlier application, which problem is solved by using the technical means of this earlier application.

2.1.8 Hence, the decisive point in the present case is that neither D18 nor D8 deals with the issue of SEALS. Accordingly, the issue of inventive step is to be decided starting from the lenses PureVision<sup>TM</sup> of Bausch & Lomb and Focus<sup>®</sup> NIGHT & DAY<sup>TM</sup> of CIBA Vision, which form the closest prior art.

## 2.2 Problem

2.2.1 Having regard to the lenses PureVision<sup>TM</sup> of Bausch & Lomb and Focus<sup>®</sup> NIGHT & DAY<sup>TM</sup> of CIBA Vision, the patent proprietor submitted that the technical problem solved by the subject-matter of claim 1 of the main request was providing silicone hydrogel contact lenses that significantly reduce or prevent the occurrence of SEALS. The patent proprietor submitted that the requirement  $E \cdot CT^2 < 1 \text{ psi} \cdot \text{mm}^2$  in combination with the E

and CT values defined in claim 1 provided a safety threshold under which SEALS were prevented or their occurrence significantly reduced.

2.2.2 In order to show that the claimed subject-matter provided a successful solution to the suppression or significant reduction of SEALS, the patent proprietor relied on the comparative tests provided in examples 22 and 23 of the patent in suit, the comparative tests of D61 and the results indicated in D106.

2.2.3 According to the established jurisprudence, if comparative tests are relied on to demonstrate an inventive step on the basis of an improved effect, the nature of the comparison with the closest state of the art must be such that the alleged advantage or effect is convincingly shown to have its origin in the features distinguishing the invention from the closest state of the art. For this purpose it may be necessary to modify the elements of comparison so that they differ only by such a distinguishing feature (case law, supra, I.D.10.9). This is in particular relevant to the present case since, as indicated by the patent proprietor and outlined in the numerous documents submitted before the Board (D13, D14, D35, D36, D37, D39, D31, D51, D2, D40, D28, D29, D30 and D108a), the causes of SEALS were held to be multiple before and even after the priority and/or filing date of the patent in suit. In this respect reference is made in particular to D31 which, although published shortly after the filing date of the patent in suit, is considered by the patent proprietor to show the state of the art regarding SEALS at the time the invention was made, which was not disputed by the opponent. In nearly all of the above-cited documents, SEALS are indicated as likely to be caused by mechanical effects,

i.e. friction or pressure of the lens on a particular part of the cornea, resulting from the force exercised by the upper lid on the contact lens. Some of those documents also mention hypoxia. Among the characteristics of the lens mentioned in those prior art and post published documents as influencing the occurrence of SEALS are the design of the lens - in particular its thickness profile, including that of the edge - the lens material - in particular its elasticity or rigidity - as well as the wettability of the lens surface.

*Comparisons of lenses according to claim 1 with Lotrafilcon A and Balafilcon A lenses*

2.2.4 The tests of examples 22 and 23 of the patent in suit and those of D61 offer a comparison between lenses according to present claim 1 and Lotrafilcon A and Balafilcon A lenses in accordance with the closest prior art. They are meant to demonstrate the influence of the centre thickness CT, the Young's modulus E and the value  $E \cdot CT^2$  on the occurrence of SEALS. The tests reported in D106 concern a comparison of the occurrence of SEALS for Cooper Vision Biofinity<sup>TM</sup> Lenses (indicated by the patent proprietor to be according to present claim 1) with PureVision<sup>TM</sup> (Balafilcon A) and Focus<sup>®</sup> NIGHT & DAY<sup>TM</sup> (Lotrafilcon A).

2.2.5 There is however no indication that those tests, based on a comparison with Lotrafilcon A and Balafilcon A, were carried out in a way that ensured that characteristics other than CT, E and  $E \cdot CT^2$  - in particular those generally thought to influence the occurrence of SEALS, such as design of the lens and wettability of the surface - were kept constant. Thus, the experimental tests submitted by the patent

proprietor which are based on a comparison of lenses according to present claim 1 with Lotrafilcon A and Balafilcon A lenses cannot demonstrate a causal link between the purported reduction or suppression of SEALs and the features distinguishing the claimed lenses from those of the closest prior art.

*Comparisons of lenses according to claim 1 with lenses other than Lotrafilcon A and Balafilcon A lenses*

2.2.6 The patent proprietor has acknowledged that among that type of tests submitted only a comparison in D61 between lens 7 (comparative example) and lens 2 (according to present claim 1) and two further comparisons in the patent in suit between a lens B of example 23 (comparative example) and two further lenses B of examples 22 and 23 (according to claim 1) make it possible to establish a causal link between the occurrence of SEALs and values of Young's modulus  $E$ , centre thickness  $CT$  and  $E.CT^2$ . It is however apparent that said comparisons are based on only one value (88 psi) of the Young's modulus  $E$ .

2.2.7 Therefore, the only comparative tests submitted that might establish a causal link between the occurrence of SEALs and the claimed values of Young's modulus  $E$ , centre thickness  $CT$  and  $E.CT^2$  do not take into account variations in the Young's modulus, which is a factor known to influence the occurrence of SEALs (see point 2.2.3 above, D31, page 11 under the heading "Etiology" and D28, paragraph bridging pages 2 and 3, that indicate that the stiff or high modulus early silicone hydrogels are now known to have caused SEALs). Whether the value below  $1 \text{ psi.mm}^2$  for  $E.CT^2$  - in combination with the  $E$  and  $CT$  values defined in claim 1 - provides a safety threshold under which SEALs are

prevented or their occurrence is significantly reduced for lenses having a Young's modulus other than 88 psi, in particular higher Young's moduli of up to 300 psi as defined in claim 1 - i.e. materials that are less elastic and consequently more likely to give rise to SEALS - is therefore not demonstrated by those comparative tests.

2.2.8 According to the patent proprietor, the criticality of the parameters  $E$ ,  $CT$  and  $E.CT^2$  for the reduction of SEALS was based on a model according to which the blinking eyelid exerted a deflection force on the centre of the lens, which force was transmitted across the entire lens. The mere indication of this model, however, does not explain the relationship between this phenomenon, the parameters  $E$ ,  $CT$  and  $E.CT^2$  and the occurrence of SEALS. Accordingly, the patent proprietor has not provided a technical explanation that - despite the absence of convincing experimental evidence showing the alleged improvement - might render credible that a particular value for  $E.CT^2$  in combination with the ranges of values defined for  $E$  and  $CT$  would provide a safety threshold for preventing or significantly reducing the occurrence of SEALS.

2.2.9 Consequently, the selection of centre thickness and Young's modulus defined in claim 1, even if considered in combination with the restrictive condition that  $E.CT^2$  must be below  $1 \text{ psi.mm}^2$ , is not associated with the solution to any particular problem and must therefore be considered to be arbitrary.

2.2.10 Moreover, it is reported in the literature that the shape design of the lens is one of the factors considered to influence the occurrence of SEALS (see point 2.2.3 above). In that respect reference is made

for example to D31 (page 11, first three paragraphs of the section "Etiology"), a document providing an indication of the state of the art regarding SEALS at the time the invention was made (see point 2.2.3 above) and D51 (page 2, right-hand column, second paragraph). However, a centre thickness is not representative of the whole shape of the lens (see for example D60, pages 189-193). The lens according to claim 1 may have any design (in particular any thickness profile from the centre to the edge) known in the art at the relevant date of the present application, including that of lenses that had been reported to induce SEALS.

2.2.11 Consequently, it follows from the above analysis that the patent proprietor has not presented any corroborating evidence or explanations rendering it credible that the purported technical effect of suppressing or significantly reducing SEALS is achieved over the whole scope of claim 1. Accordingly, any such advantage of the claimed lenses over the closest prior art cannot be taken into account for the purpose of assessing inventive step. Even providing further hydrogel silicone lenses suitable for commercial use and extended wear cannot be considered to be a problem credibly solved over the whole scope of claim 1, as in the absence of a more specific definition of the lens, including a more specific definition of the material for preparing the lens and its design, it is not plausible that the lenses defined in such a general manner exhibit properties making them suitable for commercial use and extended wear.

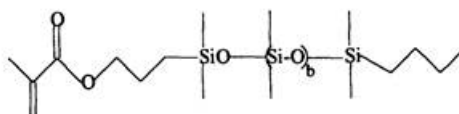
2.2.12 Accordingly, the problem solved over the closest prior art by the subject-matter of claim 1 can only be formulated as to provide further silicone hydrogel contact lenses.

2.3 Solution

2.3.1 It remains to be decided whether or not the proposed solution for the problem defined above, namely the silicone hydrogel contact lenses according to claim 1, is obvious in view of the state of the art.

2.3.2 It is not disputed that the Young's modulus and centre thickness were conventional parameters for defining contact lenses (see for example D5, D7, D8, D15, D16, D17 and D18).

2.3.3 Lenses having a Young's modulus falling in the range of 40 to 300 psi are for example described in D8, in particular in example 18 with a lens having a Young's modulus of 55 psi, prepared with more than 40% wt methacryloxypropylpentamethyl disiloxane (based on the total amount of the monomers), i.e. a mono-alkyl terminated polydimethylsiloxane of the formula defined in operative claim 1. This monomer, as well as the mono-methacryloxypropyl terminated polydimethylsiloxane



of formula II also disclosed in D8 (claim 3, page 3) are both indicated to be examples of silicone monomers that are effective at lowering the modulus of silicone hydrogels (D8, paragraphs 16 and 13). In other words, D8 teaches the use of monomers according to present claim 1 as a means of reducing the Young's modulus of a silicone hydrogel lens, which Young's modulus can be varied by changing the amount of those monomers so as to arrive in the range defined in present claim 1. Hence, the selection of some of the mono-alkyl terminated polydimethylsiloxanes of the formula defined in claim 1 and of Young's moduli within the range defined

in that claim only for providing further silicone hydrogel contact lenses is suggested in D8.

2.3.4 Centre thicknesses in the claimed range are generally mentioned in the art (see for example D7, page 2, D15, page 2 and table, D16, page 3 or D18, page 9, lines 22-25), varying for example from 30 to 200  $\mu\text{m}$ . In particular, choosing a centre thicknesses of 50 to less than 135  $\mu\text{m}$  for the silicone hydrogel of example 18 of D8 which exhibits a Young's modulus of 55 psi and is prepared with more than 40% wt of methacryloxypropylpentamethyl disiloxane leads to lenses fulfilling the relationship  $E \cdot CT^2 < 1$  ( $55 \times 135^2 = 1 \text{ psi} \cdot \text{mm}^2$ ) and therefore to lenses falling within the ambit of claim 1 of the main request.

2.3.5 Furthermore, as shown above (point 2.2.9), the mere selection of the ranges for centre thickness and Young's modulus for a lens comprising a mono-alkyl terminated polydimethylsiloxane of the formula defined in claim 1, even in combination with the additional restriction on CT and E imposed by the relationship that  $E \cdot CT^2$  must be below  $1 \text{ psi} \cdot \text{mm}^2$ , is arbitrary. On that basis, the choice of a lower and upper limit of the centre thickness CT from values generally known in the art, the selection of a range of Young's modulus E on both sides of the value disclosed in Example 18 of D8 (which had been obtained with said mono-alkyl terminated polydimethylsiloxane), and the further restriction on CT and E imposed by the relationship  $E \cdot CT^2 < 1 \text{ psi} \cdot \text{mm}^2$ , for the mere purpose of providing further hydrogel silicone contact lenses do not go beyond the normal activity of the skilled person.

2.4 Consequently, claim 1 of the main request (submitted as auxiliary request 2 on 13 March 2014) lacks an



inventive step, so that that request cannot be allowed. Under these circumstances there is no need to take a decision with respect to the additional objection that claim 1 lacks clarity.

*First auxiliary request (filed as auxiliary request 8 with letter of 14 April 2015)*

### 3. Admissibility

3.1 The first auxiliary request was submitted in reply to the statements of grounds for appeal submitted by opponents 1 to 3. As shown by the patent proprietor's submission of 12 April 2015 (page 83), the request relates to the case under appeal and meets the requirements set out in Article 12(2) RPBA. Thus, it should be taken into account by the Board, unless the Board using its discretion under Article 12(4) RPBA holds it inadmissible on the ground it could have been presented in the first instance proceedings. As in theory every claim request could have been presented before the first instance, the issue to be decided is rather whether it should have been presented at that stage.

3.2 Claim 1 of the first auxiliary request differs from claim 1 of the main request in that the centre thickness has been restricted to the range of 50 to less than 85  $\mu\text{m}$  and the amount of mono-alkyl terminated polydimethylsiloxane has been defined to be at least 5% wt. Hence the modifications made do not shift the issues that were under debate before the opposition division. Moreover, it should be borne in mind that the opposition division was satisfied that the claims of the present main request (at that stage second auxiliary request) met the requirements of the EPC.

Therefore, there was no need for the patent proprietor to file any further request at that stage. Consequently, it would be unjustified for the Board to use its discretion under Article 12(4) RPBA and hold the first auxiliary request inadmissible. The first auxiliary request is therefore to be taken into account by the Board pursuant to Article 12(4) RPBA).

4. Inventive step

- 4.1 It follows from point 2.2 above that neither the broadness of the range of values defining the centre thickness in claim 1 of the main request nor the absence of a definition of a minimum amount of monoalkyl terminated polydimethylsiloxane was the reason for concluding that the subject-matter of claim 1 did not successfully solve the problem of providing silicone hydrogel contact lenses that prevent or significantly reduce SEALS.
- 4.2 The restrictions in the first auxiliary request do not address the lack of proper comparative tests with Lotrafilcon A and Balafilcon A lenses (see point 2.2.5 above) or with lenses having various Young's moduli (see point 2.2.7 above). They cannot address the lack of definition in claim 1 with respect to features known to influence the occurrence of SEALS either (see point 2.2.10 above). Accordingly, the restrictions in claim 1 have no effect on the conclusion regarding the arbitrariness of the measures defined in claim 1 and the definition of the problem solved over the closest prior art, namely to provide further silicone hydrogel contact lenses. Moreover, the range of centre thicknesses defined in claim 1 is still based on a selection of conventional values described in the prior art, for example D7, D15 and D18, D18, describing

centre thicknesses which are more preferably between 50 and 120  $\mu\text{m}$  and most preferably between 60 to 100  $\mu\text{m}$  (see page 9, last full paragraph). In addition, the lens of example 18 of D8 suggests, as shown in point 2.3.3 above, the use of a silicon hydrogel material which exhibits a Young's modulus of 55 psi and contains an amount of mono-alkyl terminated polydimethylsiloxane that is more than 5% wt as now required by claim 1 of the first auxiliary request. The selection of that silicon hydrogel material with the conventional range of thickness defined in present claim 1 leads also to lenses fulfilling the requirement  $E \cdot CT^2 < 1 \text{ psi} \cdot \text{mm}^2$ .

- 4.3 Accordingly, the amendments incorporated into claim 1 cannot change the Board's finding that the claimed subject-matter constitutes an obvious solution to the problem of providing further silicone hydrogel contact lenses. Hence, the first auxiliary request also is not allowable (Article 56 EPC).

*Second auxiliary request (filed as auxiliary request 3 with letter of 14 April 2015)*

5. Claim 1 of the second auxiliary request differs from that of the first auxiliary request only in that the centre thickness is more broadly defined as in claim 1 of the main request, i.e. with a range of 50 to 160  $\mu\text{m}$  instead of 50 to less than 85  $\mu\text{m}$ . Thus, its subject-matter corresponds to that of claim 1 of the main request with the additional restriction that the amount of mono-alkyl terminated polydimethylsiloxane is at least 5% wt. Accordingly, claim 1 of the second auxiliary request encompasses the subject-matter defined by claim 1 of the first auxiliary request which has been found to lack an inventive step. Consequently,

the second auxiliary request is not allowable either (Article 56 EPC).

*Third to fifth auxiliary requests (filed as auxiliary request 5, 5a and 5b with letter of 14 April 2015)*

6. Claims 1 of the third to fifth auxiliary requests differ from claim 1 of the main request only in that they contain three different versions of a disclaimer in order to address the novelty attack based upon the lens disclosed in example 4 of document D58. However, those disclaimers cannot change the Board's finding with respect to lack of an inventive step of the main request. They have no influence on the definition of the problem solved over the closest prior art, and claim 1 still encompasses non-inventive embodiments such as lenses based on the material disclosed in example 18 of D8 which have been indicated in point 2.3.4 above to constitute an obvious solution to the problem of providing further hydrogel silicone contact lenses. Accordingly, the third to fifth auxiliary requests are also not allowable (Article 56 EPC).

*Sixth to eighth auxiliary requests (filed as auxiliary requests 6, 6a and 6b with letter of 14 April 2015)*

7. Claims 1 of the sixth to eighth auxiliary requests differ from claim 1 of the second auxiliary request in that they contain the same disclaimers defined in claims 1 of the third to fifth auxiliary requests. Accordingly, and for the same reasons as given with respect to the third to fifth auxiliary requests, the sixth to eighth auxiliary requests are not allowable (Article 56 EPC).

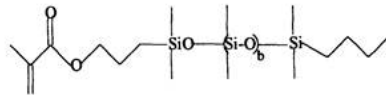
*Ninth auxiliary request (filed as auxiliary request 7 with letter of 14 April 2015)*

8. Claim 1 of the ninth auxiliary request differs from the first auxiliary request in that it does not define a minimum amount for the mono-alkyl terminated polydimethylsiloxane. The amendment to claim 1 of the first auxiliary request resulting in a broader definition of the lens therefore cannot overcome the lack of an inventive step with respect to claim 1 of the first auxiliary request. Accordingly, the ninth auxiliary request is also not allowable (Article 56 EPC).

*Tenth to thirteenth auxiliary requests (filed as auxiliary requests 9 to 12 with letter of 14 April 2015)*

9. Compared to claims 1 of the main, second, ninth and first auxiliary requests, respectively, claims 1 of the tenth to thirteenth auxiliary requests have been amended by restricting the definition of substituent  $R_{60}$  of the mono-alkyl terminated polydimethylsiloxane to a monovalent  $C_{3-8}$  alkyl group. That amendment was submitted in response to the novelty attack based on example 4 of D58 but not in response to the objection that the claimed subject-matter lacked an inventive step. As shown in points 2.2.4 to 2.2.11 above, the broadness of the definition of substituent  $R_{60}$  of the mono-alkyl terminated polydimethylsiloxane was not the reason for concluding that the subject-matter of claims 1 of the main and second auxiliary request had not been shown to solve effectively the problem of providing silicone hydrogel contact lenses that prevent or significantly reduce the occurrence of SEALs. Analogous to the reasoning provided for the first auxiliary request in point 4.2 above, the present

restriction does not address in particular the lack of proper comparative tests. Nor can it serve to address the lack of definition with respect to features known to influence the occurrence of SEALs. Accordingly, the technical problem underlying the patent in suit remains that of providing further silicone hydrogel contact lenses. As shown in point 2.3.3 above, the mono-methacryloxypropyl terminated polydimethylsiloxane of



formula II disclosed in D8 (claim 3, page 3) falls within the present restricted definition of the mono-alkyl terminated polydimethylsiloxane and is effective for lowering the modulus of silicone hydrogels (D8, paragraphs 16 and 13). D8 suggests therefore the use of a specific mono-alkyl terminated polydimethylsiloxane in accordance with the definition of claim 1 as a means for preparing silicon hydrogel lenses with a Young's modulus falling within the range of claim 1.

Therefore, the considerations set out above in connection with the obviousness of the subject-matter claimed in the main, second, ninth and first auxiliary requests also apply to the tenth to thirteenth auxiliary requests. The subject-matter of claim 1 of the tenth to thirteenth auxiliary requests does not involve an inventive step (Article 56 EPC).

*Fourteenth and fifteenth auxiliary requests (filed as auxiliary requests 13 and 14 with letter of 16 June 2015)*

10. As indicated by the patent proprietor, claims 1 of the fourteenth and fifteenth auxiliary requests are identical in scope to claim 1 of the main request, but use different wording in order to separate the embodiments having different priority dates. That

difference in wording addresses the contention of the intervener that the patent in suit was anticipated by its own divisional application D53. Accordingly, the Board is satisfied that the fourteenth and fifteenth auxiliary requests were submitted in reply to the intervention, relate to the case under appeal and meet the requirements set out in Article 12(2) RPBA. For the same reasons as those given in points 3.1 and 3.2 above with respect to the first auxiliary request, the Board considers it appropriate not to hold the fourteenth and fifteenth auxiliary requests inadmissible. However, as claims 1 of those requests and claim 1 of the main request are meant to define the same matter for which protection is sought, the amendments introduced in claim 1 of the fourteenth and fifteenth auxiliary requests cannot change the conclusion drawn with respect to the main request that its subject-matter lacks an inventive step. Accordingly, the fourteenth and fifteenth auxiliary requests are not allowable (Article 56 EPC).

**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