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Datasheet for the decision of 12 July 2007

Case Number: T 0246/04 - 3.4.02

Application Number: 96908116.5

Publication Number: 0819258

IPC: G02B 1/04

Language of the proceedings: EN

Title of invention:
Extended wear ophthalmic lens

Patentee:
Novartis AG, et al

Opponent:
Johnson & Johnson Vision Care, Inc.

Headword:
-

Relevant legal provisions:
EPC Art. 52(1), 54, 56, 83, 100, 123(2)
RPBA Art. 10b(1), 10b(3)

Keyword:
"Late filed facts and evidence"
"Added subject matter (no)"
"Sufficiency of disclosure (yes)"
"Novelty and inventive step (yes)"

Decisions cited:
T 0396/89, T 0435/91, T 0273/92, T 0270/97, T 0378/97, T 1094/97, T 0960/98, T 1062/98, T 0204/00, T 0485/00, T 0619/00, T 0943/00

Catchword:
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Case Number: T 0246/04 **-** 3.4.02

D E C I S I O N
of the Technical Board of Appeal 3.4.02
of 12 July 2007

Appellant: (Patent Proprietor)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 24 November 2003 revoking European patent No. 0819258 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: A. G. Klein
Members: F. J. Narganes-Quijano
B. Müller

Summary of Facts and Submissions

I. The appellant (patent proprietor) lodged an appeal against the decision of the opposition division revoking European patent No. 0819258 based on European patent application No. 96908116.5 (filed as International application No. PCT/EP96/01265 published as WO 96/31792).

The wording of claim 1 of the patent as granted reads as follows:

"An ophthalmic lens having ophthalmically compatible inner and outer surfaces, wherein said ophthalmic lens is selected from the group consisting of contact lenses for vision correction, contact lenses for eye color modification, ophthalmic drug delivery devices, and ophthalmic wound healing devices, said lens being suited to extended periods of wear in continuous, intimate contact with ocular tissue and ocular fluids, said lens comprising a polymeric material which has a high oxygen permeability and a high ion permeability, said polymeric material being formed from polymerizable materials comprising:

(a) at least one oxyperm polymerizable material, as defined in section I. of the description, and

(b) at least one ionoperm polymerizable material, as defined in section I. of the description,

wherein said lens allows oxygen permeation in an amount sufficient to maintain corneal health and wearer comfort during a period of extended, continuous contact with ocular tissue and ocular fluids, and

wherein said lens allows ion or water permeation in an amount sufficient to enable the lens to move on

the eye such that corneal health is not substantially harmed and wearer comfort is acceptable during a period of extended, continuous contact with ocular tissue and ocular fluids,

wherein said ophthalmic lens has an oxygen transmissibility as defined in section I. of the description of at least about 70 barrers/mm and an ion permeability characterized either by (1) an Ionoton Ion Permeability Coefficient of greater than about 0.2×10^{-6} cm^2/sec, or (2) an Ionoflux Diffusion Coefficient of greater than about 1.5×10^{-6} mm^2/min, wherein said coefficients are measured with respect to sodium ions, and according to the measurement techniques described in sections II.F.1 and II.F.2. of the description respectively."

The remaining claims 2 to 65 of the patent as granted are all dependent claims referring back to claim 1.

II. The opposition filed by the respondent (opponent II) was based on the grounds for opposition of lack of novelty and lack of inventive step (Article 100(a) EPC), insufficiency of disclosure (Article 100(b) EPC) and added subject-matter (Article 100(c) EPC).

The opposition filed by opponent I (Bausch & Lomb Inc.) was withdrawn during the appeal proceedings.

III. Among the numerous documents and pieces of evidence relied upon by the parties during the appeal proceedings, the following are pertinent to the present decision:

BL2: US-A-5260000

BL12: experimental test report filed by opponent I with the letter dated 11.06.2003

BL19: "A clinical evaluation of the safety and efficacy of the Bausch & Lomb RD-677 contact lens worn on a 30-day extended wear basis compared to the Acuvue contact lens worn on a 7-day extended wear basis", study 186, Global Field Clinical Services, 2001; pages 97 to 125

BL25: experimental test report filed by opponent I with the letter dated 18.08.2003

JJ2: US-A-5346946

JJ3: experimental test report and declaration of R. C. Baron of 28.03.1997

JJ4: "Contact lens practice" 4th ed., 1988; chapter 25, pages 683 to 717

JJ8: US-A-4260725

JJ10: "Physical properties of high water contained lens materials, compared with Rabbit's Cornea", Y. Kosaka *et al.*, J. Jpn. C. L. Soc. No.21, 1979; pages 151 to 156

JJ11: "Novel polyurethane-silicone hydrogels" Y.-C. Lai, Journal of Applied Polymer Science, Vol. 56, 1995; pages 301 to 310

JJ13: "Morphology requirements for on-eye mobility of soft oxygen permeable contact lenses", A. Domschke *et al.*, Procs. Acs. Div. Polym. Mat. Sci. Eng., 1997; pages 42 and 43

JJ14: "510(k) Summary of safety and effectiveness for Bausch & Lomb Premier 90 (balafilcon A) - Contact lens", 08.12.1994

JJ15: "USAN Council" List No. 377, Clinical Pharmacology & Therapeutics, 1995; pages 603-604

JJ16: WO-A-9104283

JJ17: US-A-5034461

JJ18: declaration of J. M. Schremmer dated 01.03.2000, reexamination proceedings of US-A-5760100 in USPTO

JJ19: declaration of W. Hung and G. Wang dated 29.02.2000 and 06.07.2000, reexamination proceedings of US-A-5760100 in USPTO

JJ20: declaration of D. J. Heiler dated 05.03.1999, reexamination proceedings of US-A-5760100 in USPTO

JJ23: "Transparent multiphasic oxygen permeable hydrogels based on siloxanic statistical copolymers", C. Robert *et al.*, Macromolecular Engineering, Ed. M. K. Mishra *et al.*, 1995; pages 117 to 126

JJ24: declaration of P. C. Nicolson dated 10.07.2000, reexamination proceedings of US-A-5760100 in USPTO

JJ27: US-A-4711943

JJ34: EP-A-0395583

JJ35: letter of Ciba Forschungsdienste dated 30.03.1994 addressed to the EPO in the examination proceedings of patent application No. 90810308.8

JJ39: report by W. M. Hung entitled "Criticism of the experimental report [referred to above as N8]"

JJ40: declaration of W. J. Benjamin dated 24.08.2004

JJ49: "Oxygen permeability if a new type of high Dk soft contact lens material", L. Alvord *et al.*, Optometry and Vision Science, Vol. 75, No. 1, 1998; pages 30 to 36

JJ49': table and graph entitled "inverse stirring speed" filed during the oral proceedings held on 12.07.2007

N4: "Dk1000 - Coulometric oxygen permeation instrument", The JDF Company Inc., Norcross, Georgia, US

N5: US patent application serial No. 301166 filed on 06.09.1994

N8: experimental test report by W. M. Hung filed by the appellant with letter dated 01.04.2004

N15: extracts of the expert report by W. J. Benjamin submitted before the Northern District Court of Georgia (US), Civil Action File No. 2:99-0034-RWS

N24: testimony of Dr. Winterton, 22841-029 B&L v CIBA Georgia Trial Transcripts, trial transcript day 21 4/26/2004; pages 4128 to 4131.

IV. In its decision the opposition division held, ***inter alia***, that the grounds for opposition under Article 100(c) EPC did not prejudice the maintenance of the patent as granted, but that claim 1 of the patent as granted did not define novel subject-matter (Article 100(a) together with Articles 52(1) and 54 EPC) over the disclosure of document BL2 in view of the experimental test reports JJ3, BL12 and BL25. The opposition division also held that claim 1 amended according to each of the auxiliary requests then on file was not clear (Article 84 EPC).

In its decision the opposition division also expressed its negative view on the issue of sufficiency of disclosure of the invention defined in claim 1 as granted (Article 100(b) EPC) and on the issue of inventive step of claim 1 amended according to the auxiliary requests then on file (Article 56 EPC).

V. With the statement setting out the grounds of appeal the appellant submitted amended auxiliary requests and filed, ***inter alia***, document N8 in support of its case.

VI. In reply to the grounds of appeal, the respondent filed, *inter alia*, documents JJ34, JJ35, JJ39 and JJ40 in support of its case.

VII. Oral proceedings were appointed by the Board, as previously requested by both parties on an auxiliary basis, for 12.07.2007.

VIII. In reply to the summons to oral proceedings, the respondent submitted by letter dated 11.06.2007 new arguments and facts, and filed new documents (documents JJ16a and JJ42 to JJ50a), and the appellant filed by letter dated 12.06.2007 new documents (documents N11 to N25) and amended auxiliary requests replacing the previous auxiliary requests on file.

IX. By a communication dated 21.06.2007 the Board noted, among other comments, the following:

"As regards the facts and evidence submitted by the respondent in support of the grounds for opposition under Articles 100(a) and 100(b) EPC initially invoked by the respondent, the Board notes that

- the facts and evidence were submitted by the respondent in support of new lines of argument under the headings of Articles 100(a) and 100(b) EPC (lack of novelty with regard to documents JJ16 and JJ50a, and insufficiency of disclosure of the invention in view of the discrepancies between the equations on page 10 of the patent specification and in view of allegedly incorrect values disclosed in the patent) that amount to fresh challenges to the opposed patent,

- these facts and evidence do not appear to have been submitted as a reaction to the previous submissions of the appellant or to substantive observations by the Board and, in addition, raise new complex issues in the already complex case before the Board,
- the new facts and evidence appear to have been already available to the respondent much earlier than just about one month before the oral proceedings to be held on 12.07.2007, and
- in any case, after consideration of the submissions of the respondent, the new facts and evidence do not appear to be conclusive enough to be considered as ***prima facie*** relevant to the decision.

As regards the documentary evidence ("Exhibits" N11 to N25) submitted by the appellant with the letter dated 12.06.2007, the Board notes that most of the documents constitute mere circumstantial or declaratory evidence in support of some of the arguments of the appellant, that there appears to be no reason that would justify the filing of the evidence at this stage of the procedure, and that in any case the evidence does not appear to be ***prima facie*** relevant for the outcome of the appellant's case.

In view of all these considerations and of Article 10a (2) of the Rules of Procedure of the Boards of Appeal, the Board considers appropriate not to admit into the proceedings the new facts and evidence submitted by the appellant and by the respondent with their respective letters pursuant to Article 10b (1) and (3) of the Rules of Procedure of the Boards of

Appeal (see also OJ EPO 2007, special edition 2, points 8 to 10 on pages 40 to 44)."

X. Oral proceedings before the Board were held on 12.07.2007.

During the oral proceedings the appellant submitted document JJ49'.

The appellant requested that the decision under appeal be set aside and that the patent be maintained unamended or alternatively maintained as amended according to any of the auxiliary requests filed with the letter dated 12.06.2007. A previous request of the appellant for reimbursement of the appeal fee under Rule 67 EPC was withdrawn during the oral proceedings.

The respondent requested that the appeal be dismissed.

At the end of the oral proceedings the Board gave its decision.

XI. The arguments of the appellant in support of its requests can be summarised as follows:

Article 100(c) EPC

According to page 9, penultimate paragraph of the application as published, the oxygen transmissibility of the lens is preferably at least 70 barrers/mm so that this passage together with claims 1, 4 and 18 of the application as published clearly discloses a lens having the claimed values. In addition, a combination of values of the claimed parameters is also supported

by dependent claim 135 which explicitly refers to dependent claim 131 of the application as published.

Article 100(b) EPC

Both the Ionoton and the Ionoflux coefficients are predictors of on-eye movement, and claim 1 is further limited to lenses moving on the eye. Lenses that do not move on the eye - as it is the case of the lens of example E-9 of the patent - are not covered by the claimed invention, and therefore the argument that the claimed invention cannot be carried out over the entire claimed range of Ionoton ion permeability for lenses that do not move on the eye cannot be followed.

Contrary to the respondent's contention, there is no reason why there should be a conversion between the Ionoton and the Ionoflux coefficients and, in addition, no conclusion as regards the measurement errors can be inferred from only the negative value of the Ionoton coefficient of the lens of example E-2 of the patent.

The patent specifically refers to the wet method as the method used in the determination of the oxygen transmissibility. The author of the declaration N15 had no problems in identifying the wet-cell method referred to in paragraph [0094] with the wet method referred to in paragraphs [0334] and [0335] of the patent. Document N5 uses on page 19 the same language used in paragraph [0094] of the patent in defining the method of determination of the oxygen transmissibility; the document refers to fully-hydrated contact lenses and, accordingly, the method cannot be the dry method referred to on page 41, line 8 of the patent

specification. The patent specification itself refers to water vapour pressures of 0 and 40 mm Hg in a dry and in a wet cell, respectively (page 13, lines 25 to 30). In the patent specification the dry method is only applied in one comparative example as a clear warning not to use the dry method.

In the Dk1000 instrument, there is some influence of the stirring speed on the measurement of the oxygen transmissibility. However, this issue pertains to the precision of the measurement under Article 84 EPC and does not compromise sufficiency of disclosure under Article 83 EPC. In addition, the manual of the instrument (document N4) recommends a specific value of the stirring speed, namely 600 rpm, and the fact that the measurements can deviate if another value is used is not sufficient to attack sufficiency of disclosure. In any case, a skilled person would have no problems in finding without undue burden a suitable stirring speed and, in addition, as shown in document N24, stirring speeds between 600 and 1200 do not result in significant variations in the measurement of the oxygen transmissibility. Figure 2 of document JJ49 is a graph representing the inverse of the measured flux versus the inverse of the stirring speed, and a conversion of the graph as shown in the graph of document JJ49' shows that variations in the stirring speed between 600 and 1000 only result in variations of the measured flux of the order of 5%. Document JJ40 reports that oxygen permeability determined with the Dk1000 instrument depends on lens thickness; however, claim 1 refers to oxygen transmissibility, and not to oxygen permeability.

The patent specification specifies alternative materials to be used and the morphology of the lens, numerous specific examples satisfying the claimed features, and a clear teaching on how to measure the different parameters and how to check the possible candidates. Therefore, the skilled person is in a position to provide lenses as claimed on the basis of the ample guidance given in the patent specification as a whole.

Document JJ13 relates to lenses having a specific material and, in addition, Figure 2 of the document shows that for a predetermined value range of the water content the lens moves on the eye. Document JJ19 is a rework of lenses disclosed in a different patent without any relationship with the materials and the manufacturing conditions considered in the present patent. The declaration JJ24 has no bearing on sufficiency of disclosure. Thus, none of these documents compromise sufficiency of disclosure of the present invention. Any adverse conclusion on the issue of sufficiency should be based on verifiable facts, and the respondent has failed to provide clear evidence in support of its view on insufficiency of disclosure.

Article 100(a) EPC - Novelty

As acknowledged by opponent I during the proceedings and as also shown in document N8, when trying to prepare a lens according to example 1 of document BL2, no shaped article can be obtained, it is not even possible to cure the raw material composition, i.e. the preparation of a contact lens fails. Consequently, some critical detail regarding the preparation of the lens

has been omitted in document BL2, and for this reason example 1 of document BL2 cannot be novelty-destroying for the claimed invention. Many alternative modifications may be contemplated in order to cure the lens of example 1. These alternative modifications, however, lead to lenses having different characteristics, and the general reference in the document to conventional curing methods contains no precise teaching or guidance in this respect. There are even conventional curing conditions that do not cure the lens, and a specific selection of curing conditions is required (document N8). Common general knowledge cannot be used to complete the incomplete technical disclosure of document BL2, and any selection of a specific combination of modifications goes beyond the assessment of novelty.

Documents JJ3, BL12 and BL25 all rely on significant modifications of the instructions contained in example 1 of document BL2, and show that different modifications of the preparation conditions of the example lead to different lenses, i.e. that the properties of the lens depend on the selection of the manufacturing conditions, and these modifications cannot prove lack of novelty.

In addition to the curing problems, document BL2 does not unambiguously define other relevant features such as the starting materials (synthesis, exact composition, etc.), and any attempt to reproduce example 1 of document B2 is connected with an undue burden. The thickness of the lens is not specified, so that the oxygen transmissibility of a lens manufactured according to document BL2 is indefinite. There is also

no disclosure in document BL2 of ophthalmic characteristics of an extended wear lens.

The test reports JJ3, BL12, BL25 are based on modifications of example 1 of document BL2 and the results, and in particular the values of the ion and the oxygen permeabilities, reported in the documents are far from being conclusive as regards the claimed combination of values and characteristics. In particular, the oxygen transmissibility of the test lens of documents BL12 and BL25 was determined according to the Mocon method, a method that was not available at the filing date of the patent and that differs substantially from that specified in the patent. Document N8 indicates lack of ophthalmic compatibility of the lenses obtained by modifying example 1 of document BL2. The criticism of the experimental report N8 in document JJ39 cannot be followed and, if applicable, it would also apply to the experimental reports shown in BL12 and BL25.

Document JJ34 does not disclose a specific lens which comprises all the claimed features. Samples 4 and 5 are only film samples and example 2 of this document is concerned with the preparation of films, not contact lenses. The document discloses in claim 1 the general formula of a macromer, without identifying a particular component for manufacturing lenses. The general statement in document JJ35 that document JJ34 achieved a breakthrough in the development of extended wear lenses is not sufficient to anticipate all the claimed features. The values 59.5 and 66.1 barrers of the oxygen permeability of samples 4 and 5 of example 2 specified in the document do not anticipate the claimed

value and, in addition, have been determined for films, not for lenses, and according to a different technique. In addition, there is no reliable and accurate correlation between water content and ion permeability, and the document fails to specify the ion permeability.

Documents JJ14 and JJ15 disclose a daily wear lens, and they contain no disclosure that the lens is suitable for extended wear. The value 81 of Dk reported in the documents does not disclose the claimed oxygen transmissibility, and the document fails to specify how the Dk value is measured. The documents do not disclose the claimed Ionoflux or Ionoton coefficients. The information on the specific composition and on the manufacture of the lenses is too vague to reproduce the lenses. There is also no evidence that the post-published document BL19 refers to the same lens of document JJ14, and the document does not disclose the composition and the preparation method of the lens.

Document JJ2 discloses lenses, but the corresponding tests in document JJ3 do not constitute a faithful reproduction of the teaching of document JJ2, and JJ3 does not constitute evidence that the lenses have inevitably the claimed features. In particular, document JJ3 reports on the difficulties in reproducing the starting materials indicated in document JJ2 (document JJ3, page 5, third paragraph), and is based on a curing process involving a photoinitiator, i.e. a process different from that indicated in document JJ2 and involving thermal curing. In addition, there is no evidence as to the ion permeability of the lenses of document JJ2, and any alleged correlation between water content and ion permeability is mere speculation.

Article 100(a) EPC - Inventive step

The closest prior art is document JJ23 which discloses siloxanic hydrogels with high oxygen permeability and a water content between 20 and 25% and that might be considered for prolonged wear contact lenses. The problem solved by the invention can be seen in the manufacture of an ophthalmically compatible contact lens that is suitable for extended wear and has high oxygen permeability. There is however no clear evidence suggesting making the corresponding lens as thin as possible as submitted by the respondent. In addition, there is no mention of a potential influence of the ion permeability on the suitability for extended wear.

Document BL2 relates to the problem of machining contact lenses, is silent as to extended-wear lenses and, in addition, its disclosure is not enabling; thus, the document does not qualify as closest prior art. In addition, the prior art evidence shows that the improvements of the optical and ophthalmic properties at that time concerned new materials, and not surface treatment of the lens surfaces.

Document JJ17 is a predecessor of document BL2 and contains no disclosure whatsoever suggesting extended wear or parameters influencing the ophthalmic compatibility. Therefore, the document does not qualify as closest prior art either.

Document JJ16 relates to soft gas permeable contact lenses, to prolonged wear, and surface treatment of the lenses. It is however questionable whether the skilled

person would have chosen surface treated lenses as the closest prior art, given that the surface treatment methods were regarded as notoriously unreliable and of temporary nature.

There is also no complete line of argument that would lead to the claimed invention when starting with document JJ14 as closest prior art.

The disclosure of document JJ2 is defective, and the corresponding experimental tests in document JJ3 are based on modifications and selected manufacturing conditions and are therefore not representative of the disclosure of the document.

The respondent's submissions relating to the surface treatment of lenses are not supported by evidence and do not pass the could-would test. In addition, there is no general correlation between water content and ion permeability since the values of these parameters depend on different factors such as the composition and the morphology of the lens. There is no evidence that the claimed lower value of the ion permeability is low as suggested by the respondent. A high ion permeability is a predictor of on-eye movement, but the fact that a lens moves on the eye as it is the case in document JJ8 is not sufficient to conclude that the ion permeability is high or at least within the claimed value range.

The skilled person had no guidance at hand which would have suggested the claimed lens.

XII. The arguments of the respondent in support of its request can be summarised as follows:

Article 100(c) EPC

The feature of claim 1 as granted relating to the values of the oxygen transmissibility and the Ionoflux Diffusion Coefficient results from the combination of dependent claims 4 and 18 of the application as filed. These two claims, however, refer back to claim 1 of the application as published, but not to each other. In addition, in the application there is no clear and unambiguous disclosure of the combination of the particular values according to claim 1 as granted. The oxygen transmissibility and the Ionoflux Diffusion Coefficient run in opposite directions, i.e. they are not independent of each other, and the combination of preferred values of these two parameters results in novel subject-matter not disclosed in the application as published.

For similar reasons, there is no basis for the values of the parameters defined in dependent claims 4, 5, 14 and 15 as granted all referring back to claim 1 as granted.

Article 100(b) EPC

The lower limit of the Ionoton Ion Permeability Coefficient specified in claim 1 does not necessarily yield movement of the lens on the eye as shown by example E-9 of the patent. The claimed lower value of the Ionoton coefficient is much lower than that of the lens of example E-9, this lens not moving on the eye. Thus, the patent specification fails to teach the steps

required to ensure movement on the eye for a lens having such a value of the coefficient.

Similar considerations apply to the lens of example E-2 of the patent which, according to Table E, has a negative value of the Ionoton coefficient devoid of technical meaning; in addition, this negative value can be adopted as the error in the measurement of the Ionoton coefficient and renders the corresponding claimed values meaningless. As shown in the table on page 13 of document JJ3, the Ionoton and the Ionoflux coefficients are not correlated to each other so that these two coefficients do not measure the same property; thus, contrary to the patent specification, these two coefficients cannot constitute simultaneous predictors of on-eye movement.

The patent specification specifies two different methods of determination of the oxygen transmissibility giving widely different results, namely the dry and the wet methods (page 41, line 8). The wet method is disclosed in paragraphs [0334] and [0335] and involves a water layer on the lens, and this method is to be distinguished from the method previously referred to in the patent in paragraph [0094], so that the latter constitutes the dry method. The disclosed characteristics of the two methods such as the relative humidity and the use of the layer of water do not allow the identification of the method in paragraphs [0334] and [0035] and the method in paragraph [0094] as constituting the same method; in particular, the layer of water on the lens according to the wet method will reduce the oxygen flux (document N4, page 9, first sentence). In addition, it is the dry method that was

used for the evaluation of examples A-1 to A-12 of the patent as shown by the respective examples in document N5. The fact that document N5 refers to fully hydrated lenses does not necessarily mean that the dry method was not used. On the other hand, other examples of the patent were evaluated with the wet method. Therefore, the patent refers simultaneously to two different methods of determination of the oxygen transmissibility each resulting in values differing by a factor of about two (page 41, line 8 of the patent). Document N15 shows only extracts with significant omissions and is not helpful in interpreting the disclosure of the patent.

According to the patent specification the oxygen transmissibility is measured with the Dk1000 instrument (paragraph [0094]), and according to the manual of the Dk1000 instrument, the test conditions must be stated (document N4, page 3, last sentence). The patent specification, however, fails to specify the conditions under which the parameter is measured. In particular, the Dk1000 instrument allows control of the stirring motor speed under which the measurement is carried out; the manual of the instrument (document N4) refers to a sample test run with a stirring speed of 600 rpm, but the manual does not direct the user to utilize any particular value of the stirring speed, and other values such as 300 and 1200 rpm are also possible. The values of the oxygen transmissibility obtained using the DK1000 instrument are critically dependent on the experimental technique used, and as shown in document JJ40 the values are critically dependent on the stirring speed; the values can even vary by about 30% according to the selected value of the stirring speed as shown in the table in Figure 2 on page 33 of

document JJ49. The value of the stirring speed, however, is not specified in the patent specification. The declaration JJ40 also shows that the measured values are also dependent on the lens thickness, so that the Dk1000 instrument, and thus the method defined in the patent, is unreliable and not reproducible. The oxygen transmissibility is one of the essential features of the claimed invention and the uncertainty in its determination constitutes an objection under Article 83 EPC.

The disclosure is also insufficient in that the claimed invention is broad, there are substantial technical disparities between the examples given in the patent, and the patent specification does not contain a concept that would allow the skilled reader to work, without undue burden, outside the specific examples given in the patent (T 435/91, headnote). Claim 1 defines many features without it being clear which of them are redundant and without the specification teaching how these features can be achieved; in particular, it is not clear how to select the different components and the manufacturing conditions in order to achieve the claimed lenses. Figure 2 of each of documents JJ11 and JJ13 shows that the oxygen permeability and the diffusion coefficient depend dramatically on the water content of a contact lens, and document JJ19 shows that even a lens with high oxygen and ion permeabilities can be tacky and unsuitable as a contact lens, and these documents illustrate the undue burden in obtaining lenses according to the invention. According to the declarations of one of the inventors of the patent on point 24 of document JJ24, the lenses of the invention require the presence of co-continuous phases and the

treatment of the surfaces, and none of these requirements is specified in claim 1.

Article 100(a) EPC - Novelty

Document BL2 teaches the manufacture of lenses suitable for extended wear, and the disclosure anticipates implicitly the claimed lenses. As shown in documents JJ3, BL12 and BL25, curing of the composition A of document BL2 following three different methods leads to lenses falling within the scope of claim 1 of the patent. It is irrelevant whether the monomer mixture of example 1 of document BL2 cures or not under the specific curing conditions described in the example because the disclosure of BL2 is not limited to the examples. According to the document (column 6, lines 57 to 61), the composition is cured by conventional methods such as static casting or spincasting, and the composition A precedes the examples and belongs to the general teaching of the document, so that the document directly and unambiguously discloses forming a contact lens by curing composition A using conventional methods. The authors of the experimental tests shown in the documents followed the teaching of document BL2 and did not find any major problem in the implementation of the teaching; they were able to prepare starting materials and make contact lenses on the basis of the disclosure of document BL2. A skilled person faced with a publication such as document BL2 must use its skills and knowledge in putting its disclosure into effect; document BL2 directs the reader to cure formulation A using conventional methods, and this is precisely what was done in documents JJ3, BL12 and BL25. The values of the thickness of the test lenses correspond to standard

values of typical thin lenses commonly considered in this art.

The values of the oxygen permeability reported in documents JJ3 and BL25 have been measured according to different methods and the measurements using the Dk1000 instrument are extremely unreliable, so that the different values in documents JJ3 and BL25 do not establish that different methods of manufacture lead to lenses having different oxygen permeability characteristics. On the contrary, documents BL12 and BL25 show that using static casting or spincasting, or using or not degassing, does not substantially affect the characteristics of the lenses.

In documents BL12 and BL25 the measurement of the oxygen permeability was conducted using a Mocon method; this method is a coulometric method, as it is the case of the method considered in the patent. The experimental report N8 is of no probative value whatsoever, because the experimental procedures were flawed, see document JJ39.

Document JJ34 discloses contact lenses of a copolymer containing polysiloxane and polyoxyalkylene oxide units with high oxygen permeability, good wettability, flexibility and optical quality (page 2, lines 2 to 4). Suitable block copolymers are exemplified in example 2, in particular samples 4 and 5 having an oxygen permeability of 66.1 and 59.4 barrers. Since the skilled person would inevitably make lenses significantly thinner than 0.1 mm, the claimed value of the oxygen transmissibility is also anticipated. In addition, according to document JJ35 the lenses can be

worn for several days or weeks without interruption. Samples 4 and 5 have also an exceptionally high water content which is predictive of ion permeability, as can be inferred from Figure 2 of document JJ13. In addition, the polymers of samples 4 and 5 are formed from the same reactants and in substantially the same proportions as the polymer described in example A-1 of the opposed patent. It follows that the disclosed lenses are suitable for extended wear and anticipate the claimed subject-matter.

Documents JJ14 and JJ15 disclose contact lenses suitable for extended wear that anticipate the claimed invention. The lenses move on the eye, i.e. have the appropriate ion permeability, they have a Dk value of 81 (page 2, third paragraph), and their composition corresponds to composition A of document BL2, see document JJ15. Document BL19 (last paragraph) constitutes further evidence that the lenses of document JJ14 are extended wear lenses.

Document JJ2 discloses contact lenses with high oxygen permeability. The composition of the lenses of examples 3 and 8 corresponds to the claimed composition, and these lenses have the appropriate oxygen permeability and water content (Table I). The document does not disclose the ion permeability, but document JJ3 shows that the ion permeability of these lenses has inherently the claimed characteristics; this is in particular the case of the lens of example 3 which has a water content higher than that of example 8 and therefore also a higher ion permeability as can be derived from Figure 2 of document JJ13.

Article 100(a) EPC - Inventive step

Starting from document BL2 as the closest prior art, it is obvious to select the thickness of the lens so as to have an appropriate value of the oxygen transmissibility taking also into consideration the mechanical properties of the lens as taught by document JJ4 which teaches an oxygen transmissibility between 70 and 87 (page 688, third paragraph) and an appropriate value of the thickness for extended-wear lenses (page 693, second column). It is also obvious to endow the lenses of document BL2 with the appropriate ophthalmic characteristics, there being several options well known in the prior art such as the use of surface-treatment techniques. If novelty of claim 1 over the disclosure of document BL2 is acknowledged in view of the undue burden in carrying out the disclosure of the document as alleged by the appellant, the skilled person knew, before the priority dates of the patent in suit, how to complement the disclosure of the document so as to produce the lenses.

Similar considerations apply if document JJ14 is adopted as the closest prior art together with the composition specified in document JJ15. The document specifies a lens thickness of 0.05 mm (page 3, middle paragraph) and the plasma treatment of the lens (page 2, penultimate paragraph).

Document JJ2 also qualifies as closest prior art. In view of the tests shown in document JJ3, the skilled person would find no problems in obtaining lenses according to the disclosure of document JJ2. In order to maximize oxygen transmissibility, it is

straightforward to select the appropriate thickness of the lens.

It is obvious to start from the film sample 4 of example 2 of document JJ34 and to prepare a lens, the document teaching how to balance the requirements of oxygen permeability and water content. The high water content of the lens implies a high ion permeability.

Document JJ16 discloses a soft gas permeable extended-wear lens. The document discusses the problem relating to the wettability, and proposes applying a surface treatment (example 3). The document cites document JJ27 on page 2, this document disclosing in Table XI sample A characterized by high Dk and hydration values. In addition, high hydration provides a high ion permeability satisfying the corresponding claimed condition requiring an extremely low minimum value of the ion permeability. The combination of documents JJ16 and JJ27 therefore results in a lens as claimed.

Document JJ17 discloses in Table 10 materials with high Dk values over 100. Experimental tests based on document JJ17 are reproduced in documents JJ18, JJ19 and JJ20. An obvious surface treatment would lead to lenses satisfying all the claimed conditions.

Document JJ8 is based on the discovery that, when a soft contact lens absorbs water and is hydrophilic, the lens will move on the eye sufficiently so that no physical damage occurs to the cornea (column 14, line 16 ***et seq***.). Water absorption and ion permeability are, however, correlated as shown in the graphs on page 155 of document JJ10 and the invention merely

provides a different definition of the underlying mechanism already taught in document JJ8. In addition, document JJ8 also provides lenses with a high oxygen permeability (column 42, lines 25 to 2, and column 43, lines 30 to 33).

Reasons for the Decision

1. The appeal is admissible.

2. *Admissibility of facts and evidence*

Both the appellant and the respondent submitted new facts and evidence with their respective letters of 12.06.2007 and 11.06.2007, i.e. about one month before the oral proceedings scheduled for, and held on 12.07.2007 (point VIII above). In particular, among other documents, the appellant filed documents N15 and N24 and the respondent filed document JJ49. Subsequently, the Board informed the parties of its preliminary opinion on the admissibility of these facts and evidence as recorded in point IX above.

During the oral proceedings the appellant submitted that document N24 had been filed as a reaction to document JJ40 and that consequently the document should be admitted into the proceedings. The respondent for its part agreed with the introduction of document N24 into the proceedings, but only in the event that document JJ49 was also admitted. During the oral proceedings the respondent also referred to document N15 filed by the appellant, and the appellant filed document JJ49' in reaction to the comments of the

respondent on document JJ49. In view of the submissions of the parties, and since the documents were referred to by the parties only as circumstantial evidence in support of their respective arguments and the specific passages of the documents referred to by the parties did not raise new issues, the Board decided during the oral proceedings to admit documents N15, N24, JJ49 and JJ49' into the proceedings.

On the other hand, none of the parties disputed during the oral proceedings the preliminary opinion of the Board on the non-admissibility of the other facts and documentary evidence submitted by the parties and referred to above.

In view of the above, except for documents N15, N24 and JJ49, the Board decided during the oral proceedings not to admit into the proceedings the new facts and evidence submitted by the appellant and by the respondent with their respective letters of 12.06.2007 and 11.06.2007 pursuant to Articles 10b (1) and (3) of the Rules of Procedure of the Boards of Appeal for the reasons already communicated to the parties and reproduced in point IX above.

3. *Article 100(c) EPC*

The feature of claim 1 as granted according to which the claimed lens has an oxygen transmissibility of at least about 70 barrers/mm and an Ionoflux Diffusion Coefficient of greater than about 1.5 10^{-6} mm^2/min results from the combination of dependent claims 4 and 18 of the application as published. These two dependent claims referred back directly to the lens defined in

claim 1 of the application as published without referring to each other and, as submitted by the respondent, there is no express disclosure in the application as published of the specific values of the parameters as claimed being simultaneously satisfied. However, the application as published discloses the claimed lower value of the Ionoflux Diffusion Coefficient as the most preferable value (dependent claim 18 together with page 16, last paragraph) and, as submitted by the appellant, the description also specifies that the value of the oxygen transmissibility of the lens is preferably at least the value specified in claim 4 of the application as published (page 9, penultimate paragraph, page 22, penultimate paragraph, page 30, second paragraph and page 68, third paragraph). In addition, taking into account the teaching of the application as a whole which relates to a lens having sufficient permeability to both oxygen and ions (page 3, second paragraph to page 4, last paragraph), and as shown explicitly in dependent claim 131 as published specifying an Ionoflux Diffusion Coefficient greater than about 2.6 10^{-6} mm^2/min and in dependent claim 135 as published which refers back to the former and specifies an oxygen transmissibility of 70 barrers/mm and both directed to a method of screening a lens according to the invention, the person skilled in the art would clearly and unambiguously understand from the disclosure of the application as published that the invention is directed to a lens having, among other properties, appropriate high values of both the Ionoflux Diffusion Coefficient and the oxygen transmissibility. Accordingly, the implicit disclosure of the application as published discloses directly and unambiguously a lens simultaneously having

at least the preferred values of the Ionoflux Diffusion Coefficient and the oxygen transmissibility specified in the application, in particular the values defined in dependent claims 4 and 18 of the application as published, and therefore also the corresponding values defined in claim 1 as granted.

Similar considerations apply to the values of the parameters defined in dependent claims 4, 5, 14 and 15 as granted, the specific values of which are respectively based on the alternative preferred values defined in dependent claims 5, 6, 16 and 17 of the application as published.

It follows that, as already concluded by the opposition division in the decision under appeal, the submissions of the respondent relating to subject-matter in the patent as granted allegedly extending beyond the content of the application as filed (Article 100(c) EPC) are not found persuasive.

4. *Article 100(b) EPC*

4.1 According to Table E of the patent specification, the lens of example E-9 has an Ionoton Ion Permeability Coefficient of 0.008 10^{-3} cm^2/sec, i.e. a value above the claimed lower value of the Ionoton coefficient and, contrary to one of the main objects of the invention (paragraph [0009] of the patent specification), the lens does not move on the eye.

The claimed invention, however, does not only require that the lens has an Ionoton coefficient as claimed, but expressly requires, in addition, as a further

limiting feature that the lens "allows ion or water permeation in an amount sufficient to enable the lens to move on the eye". Accordingly, as the lens of example E-9 does not move on the eye, the example does not constitute an embodiment of the claimed invention. In addition, the patent specification contains numerous examples of manufacture of lenses having the claimed structural and functional features and, in these circumstances, the question of whether or not the patent specification contains enough information that would enable the skilled person to modify in a particular way the specific lens of example E-9 so as to obtain a lens exhibiting all of the claimed features goes beyond the requirement of sufficiency of disclosure set forth in Article 100(b) EPC.

In addition, the claim expressly imposes a double condition on the ion permeability of the lens, namely an explicit limitation in terms of the claimed value range of the coefficient and, as mentioned above, a further, implicit limitation in terms of the on-eye movement capability of the lens. In these circumstances, there is no need for the patent to provide enough information for carrying out the invention over the whole claimed value range of the Ionoton coefficient taken in isolation and independently of the remaining features defined in the claim.

The respondent's submission that the lower limit of the Ionoton coefficient specified in claim 1 does not necessarily yield movement on the eye appears to be based on an interpretation of the claimed invention according to which a lens having the claimed value of

the Ionoton coefficient would automatically have to move on the eye; this interpretation, however, is at variance, on the one hand, with the fact that claim 1 imposes on the ion permeability the double condition referred to above and, on the other hand, with the fact that the ion permeability has not been presented in the disclosure of the invention as a sufficient condition ensuring on-eye movement of the lens, but only as "a predictor of on-eye movement" (page 8, line 28).

Accordingly, the respondent's submission that, in view of the features of the lens of example E-9, the lower limit of the Ionoton coefficient in claim 1 does not necessarily yield movement of the lens on the eye does not prejudice sufficiency of disclosure within the meaning of Article 100(b) EPC.

4.2 As regards the lens of example E-2 of the patent specification, the lens has an Ionoton Ion Permeability Coefficient of $-0.063\ 10^{-3}$ cm^2/sec and does not move on the eye (Table E), i.e. the lens does not satisfy the claimed conditions and does not constitute an example of the claimed invention. Therefore, for reasons similar to those set forth above with regard to example E-9, example E-2 does not prejudice sufficiency of disclosure of the claimed invention.

The value of the Ionoton coefficient given for the lens of example E-2 has a negative value, i.e. is devoid of technical meaning. Nonetheless, the - presumably erroneous - negative value of the Ionoton coefficient of one single example is not representative of the way the coefficient is measured and, in the absence of evidence that any other of the numerous values of the

Ionoton coefficient given in the patent specification is erroneous or inaccurate, the respondent's contention that the aforementioned negative value provides evidence of the error in the measurement of the Ionoton coefficient and renders the corresponding claimed values meaningless cannot be followed by the Board.

4.3 The experimental report JJ3 shows on page 13 a table reproducing the measured values of the Ionoton and the Ionoflux coefficients for different lenses. According to the respondent, there is no correlation between the values of the Ionoton and the Ionoflux coefficients so that the two alternative coefficients considered in claim 1 cannot measure the same property and cannot constitute simultaneous predictors of on-eye movement. However, the claimed value ranges of the Ionoton and the Ionoflux coefficients have been defined in the claim not as two synonymous or technically equivalent conditions, but as two independent alternatives and, in addition, as mentioned in point 4.1 above, the ion permeability of the claimed lens is further restricted implicitly by the on-eye movement capability of the claimed lens. Consequently, the question of whether, and to what extent the Ionoflux and the Ionoton coefficients are correlated to each other for a particular material or constitute similar or equivalent predictors of on-eye movement is immaterial to the issue of sufficiency of disclosure of the claimed invention.

4.4 Claim 1 defines the lens of the invention in terms of the oxygen transmissibility of the lens, and the description of the patent contains two descriptions of the measurement of the oxygen transmissibility, namely

a first description in paragraph [0094] involving air and nitrogen streams at about 100% relative humidity passing across opposite sides of the lens in a wet cell, and a second description in paragraph [0334] in which the lens is covered with a layer of water and a mixture of oxygen and nitrogen is passed through the water layer (the "wet method"). In addition, paragraph [0335] of the description refers to values frequently given in the literature and determined on dry material (the "dry method"), and specifies values of the oxygen permeability for a same material measured according to the wet and the dry methods and differing by a factor of about 2 (page 41, line 8).

According to the respondent, the method described in paragraph [0094] is different from the wet method described in paragraph [0334] and corresponds to the dry method referred to in paragraph [0335], and the disparity between the values of the oxygen transmissibility measured by the wet and the dry methods prejudices sufficiency of disclosure of the claimed invention.

The method described in paragraph [0094], however, requires a wet cell and fluxes of gas at about 100% relative humidity. Furthermore, in the passage of the description following paragraph [0094], the description of the patent refers to a water vapour pressure of 0 mm HG "in a dry cell" and of 40 mm HG "in a wet cell" (page 13, lines 12 to 35). In addition, the examples A-1 to A-12 given in the patent specification following paragraph [0094] but preceding paragraph [0334] (paragraphs [0303] to [0319]) as well as the text (paragraph bridging pages 16 and 17) and the

corresponding examples 1 to 12 of the US patent application N5 - which corresponds to an application of which the third of the priorities of the patent is a continuation-in-part and uses the same description of the method defined in paragraph [0094] of the patent (page 19, middle paragraph) - all refer to measurements of the oxygen transmissibility in "fully hydrated" lenses. In this context, the Board cannot follow the respondent's contention that the method described in paragraph [0094] corresponds to the dry method referred to in paragraph [0335] and involving the determination of the oxygen permeability on "dry material (dry measurement)" (page 41, lines 5 and 6).

As regards the question also disputed by the parties of whether or not the description in paragraph [0094] relates to the same wet method described in paragraph [0334], the Board notes that, irrespective of whether the two descriptions relate to the same method as it would appear to be the case (document N15, last paragraph), the method of paragraph [0094] is carried out in a wet cell at 100% humidity and that of paragraph [0334] is carried out with a water layer on the lens, and both methods are therefore carried out in similar conditions that are at least compatible to each other. In addition, there is no evidence that the two methods, if really different, would result in measurements of the oxygen transmissibility differing from each other to the extent that the uncertainty in the measurement of the oxygen transmissibility would be detrimental to sufficiency of disclosure of the claimed invention within the meaning of Article 100(b) EPC, and in particular would result in the impossibility to carry out the invention without undue burden (T 378/97,

point 2 of the reasons, T 960/98, point 3, T 619/00, point 5.3, and T 943/00, points 10 and 11). In particular, document N4 mentions that the presence of an aqueous layer on a contact lens - as it is the case in the wet method - reduces the oxygen flux (page 9, first sentence), but there is no evidence that the oxygen flux would be substantially different for a lens in a wet cell with gas streams at about 100% relative humidity.

4.5 According to the description of the patent (paragraph [0094]), the oxygen transmissibility of the lens of the invention is measured with the Dk1000 instrument. The instrument allows control of the speed of the stirring motor and the manual of the instrument (document N4) refers to a "sample test run" at a stirring motor speed of 600 rpm (page 12, first paragraph). The patent specification, however, does not specify the stirring speed of the instrument in the measurement of the oxygen transmissibility, and according to the respondent the stirring motor can also run with speeds between 300 and 1200 rpm.

However, independently of the degree of influence of the stirring speed on the resulting measurement values (points 28 to 31 of document JJ40, document JJ49' together with Figure 2 on page 33 of the post-published document JJ49, and document N24), and irrespective of whether the uncertainty in the measurement values may give rise to an objection only under Article 84 EPC or - as contended by the respondent - also under Article 100(b) EPC, in the Board's opinion the fact that the patent specification does not specify the particular value of the stirring motor speed with which

the claimed values of the oxygen transmissibility and those presented in the patent specification are measured with the Dk1000 instrument does not represent in the circumstances of the present case an undue burden in carrying out the claimed invention. The patent gives abundant specific examples of manufacture of lenses having specific values of the oxygen transmissibility measured with the Dk1000 instrument, and the skilled person is in a position to reproduce these specific examples and to measure the oxygen transmissibility with the Dk1000 instrument at different stirring speeds, and by comparing the different measurement results with the specific values given in the corresponding examples of the patent, the skilled person may evaluate indirectly the approximate value of the stirring speed at which the measurements according to the patent are carried out (see in this respect T 1062/98, points 2.1.2 and 2.1.3, and T 485/00, point 1.6).

The further line of argument of the respondent that according to document JJ40 the measurement values obtained with the Dk1000 instrument depend on the lens thickness and that therefore the method of determination considered in the patent is unreliable and not reproducible does not convince the Board either. The variations of the measurement values according to the lens thickness are reported in document JJ40 with reference to the oxygen permeability (points 12 and 24 to 27), and not with reference to the oxygen transmissibility specified in claim 1 of the patent and defined according to point 16 of document JJ40 as the quotient of the measured oxygen permeability and the thickness of the lens. The Board

notes that the patent specification states that the oxygen permeability of a lens material does not depend on lens thickness (page 4, last line); however, the respondent has advanced no technical argument or evidence showing that the possible dependence of the actual value of the oxygen permeability of a lens on the thickness of the lens may have an influence on sufficiency of disclosure of the claimed invention defined in terms of the oxygen transmissibility and not in terms of the oxygen permeability.

4.6 The respondent has also submitted that the claim is broad, that it is unclear in the claim which features are redundant, and that the claim fails to specify essential features such as the presence of co-continuous phases and the treatment of the lens surfaces. These objections against the patent as granted, however, relate by their very nature to objections under Article 84 EPC which does not constitute a ground for opposition (Article 100 EPC). In addition, in the absence of evidence to the contrary, none of these objections prejudice sufficiency of disclosure within the meaning of Article 100(b) EPC. In particular, the lens of the invention is defined in claim 1 in terms of aspects relating to the composition and to the properties of the lens, and there is no evidence that the fact that claim 1 does not specify other features relating to the manufacture of the lens such as the surface treatment specified in dependent claims 25 and 26, or to the structure of the lens material such as the morphology of the lens specified in dependent claims 8 to 13 would have an incidence on the issue of sufficiency of disclosure of the claimed invention. As claim 1 is formulated in terms not

requiring the specification of the morphology and the manufacture of the lenses, the declaration JJ24 of one of the inventors addressing in point 24 the morphology and the manufacture of the lens has no bearing on the issue of sufficiency of disclosure. As a matter of fact, both the presence of co-continuous phases in the lens material and the treatment of the lens surfaces are disclosed in the patent specification as possible ways of achieving the features of the claimed lens (paragraphs [0047] to [0049] and [0279] to [0284] of the description).

The further submissions of the respondent relating to the alleged lack of a clear teaching in the patent specification that would allow the skilled person to work in the claimed area beyond the particular examples given in the patent are also found unconvincing. The respondent has based its submissions on documents JJ11, JJ13 and JJ19. However, Figure 2 of each of document JJ11 and post-published document JJ13 shows that the properties of the specific permeable contact lenses considered in the documents vary according to the water content in the lens, but also shows that these properties can be optimized for particular ranges of the water content, and document JJ19 merely shows that a high oxygen and a high ion permeability are not sufficient conditions guaranteeing the suitability of a material for contact lenses. In addition - unlike the situation in decision T 435/91 cited by the respondent and in which the disclosure of the invention described one single way of carrying out the invention and, in the absence of a sufficient technical teaching, the definition of the invention was considered to be not more than an invitation to perform a "research

programme" in order to find other variants of the invention (point 2.2.1 of the decision) -, the description of the patent in suit contains a plurality of specific examples of manufacture of lenses according to the invention and an extensive description of suitable alternative compositions and manufacturing conditions of the lenses that may be used in carrying out the invention and in achieving the main objects of the invention. In these circumstances, the Board considers that the respondent has not discharged its burden of proof that there would be an undue burden in carrying out the claimed invention and, in particular, that carrying out the invention would require skills beyond common general knowledge or an extensive or unreasonable amount of trial and error experimentation.

4.7 In view of the above considerations and conclusions, none of the submissions of the respondent are sufficient to conclude that the disclosure of the claimed invention is not sufficient within the meaning of Article 100(b) EPC.

5. *Article 100(a) EPC - Novelty*

5.1 Document BL2 together with the experimental test reports JJ3, BL12, BL25, N8 and JJ39

5.1.1 Document BL2 discloses the manufacture of silicone-containing hydrogel contact lenses including the step of curing in a mould a monomeric mixture of a silicone-containing monomer, a hydrophilic monomer and a diluent (abstract). The document specifies that the monomeric mixture is cured by conventional methods such as static casting or spincasting (column 6, lines 57 to 61), and

proposes, among other monomeric mixtures, a mixture A containing TRIS-VC, NVP, V_2D_{25}, VINAL, n-nonanol and Darocur (column 7). In example 1 of the document the mixture A is injected in a mould which is spun for about 5 minutes in the presence of UV light and then exposed to UV light for about 30 minutes to complete the cure (column 8, lines 45 to 62).

It has been undisputed by the parties that the monomeric mixture A of document BL2 includes oxyperm and ionoperm polymerizable materials as defined in claim 1 of the patent. The explicit disclosure of the document, however, is silent as to the remaining claimed features. The issue of novelty depends therefore on whether the implicit disclosure of document BL2 anticipates the remaining features of the lens defined in claim 1. During the proceedings the respondent has referred to the inevitable result of carrying out example 1, on the one hand, and to the teaching of document BL2 relating to the conventional methods, on the other hand.

5.1.2 During the opposition proceedings the respondent has alleged that example 1 of document BL2 inevitably results in a lens having all the features of the lens defined in claim 1 of the contested patent. According to established case law, the burden of proof in establishing that the alleged features of the inevitable outcome of a prior art disclosure, which does not itself explicitly disclose the claimed invention, anticipates the invention rests on the party making the allegation. In particular, if evidence is submitted in support of the alleged inevitable outcome and this evidence does not reproduce the conditions

specified in the prior art disclosure, the party has the burden of showing convincingly that any significant deviation from the conditions specified in the prior art disclosure is not material to the alleged outcome (T 396/89, point 4.5, and T 204/00, point 3).

During the proceedings, the parties referred to the experimental test reports JJ3, BL12, BL25 and N8 each of which reports on the properties of lenses manufactured according to processes based on the process of example 1 of document BL2. However, none of the processes followed in these test reports reproduces the process disclosed in example 1 of document BL2, the reason being that - as it has been undisputed by the parties during the proceedings - the precise manufacturing conditions specified in example 1 of document BL2 do not lead to a cured product and therefore do not result in a product that could be qualified as a lens, and modifications to the manufacturing conditions specified in example 1 were required in order to arrive at the manufacture of a lens. In particular:

– Document JJ3, a test report submitted by the appellant itself during prosecution of the corresponding US application, refers to the "inability to produce a solid lens in accordance with the conditions as specified in [example 1 of BL2]" and acknowledges that "some of the conditions used in the preparation of comparative lenses did not correspond entirely with the conditions specified in [example 1 of BL2]" (page 14, penultimate paragraph). In particular, the manufacturing conditions of lenses according

to the test report JJ3 deviate substantially from those in example 1 of document BL2; more particularly, while the test report involved curing of the composition at 4 mW/cm^2 (page 4, middle paragraph), example 1 of document BL2 specifies curing only at 1-2.5 mW/cm^2 (column 8, lines 48 to 52). The manufacture process in document JJ3 also involved the step of degassing the composition because degassing "maximizes the ion permeability" (page 4, penultimate paragraph); however, document BL2 is silent as to any degassing step.

– Documents BL12 and BL25 report on experimental tests carried out by opponent I and based on example 1 of document BL2. The manufacture processes followed in these two reports, however, deviate from the process of example 1 of document BL2 in several respects. In particular, the experimental tests involved curing with UV light at exposure times of 2 hours in BL12 (page 3, second paragraph) and of 45+30 minutes in BL25 (page 3, first paragraph), i.e. at much higher exposure times than that of 5+30 minutes specified in example 1 of document BL2 (column 8, lines 48 to 52). It was not disputed by the parties during the appeal proceedings that these higher exposure times were required in order to ensure that the composition was cured.

– Document N8, a test report submitted by the appellant in support of its view that the disclosure of document BL2 involves an undue burden, also shows that example 1 of document BL2

requires substantial modifications in order to obtain a cured lens material (page 2 and tables 4 to 7). In particular, curing of the composition appears to require UV exposures for at least 60 minutes or with intensities in the range 10.1 to 11.9 mW/cm^2, i.e. values far beyond those indicated in example 1 of document BL2.

– Document JJ39 is a report containing critical observations on the test report N8. Irrespective of these observations, however, document JJ39 does not call into question that, as evidenced by the previous test reports, the process described in example 1 of document BL2 does not result in a cured product.

In view of this evidence, the Board concludes that the process described in example 1 of document BL2 does not result in a contact lens as specified in the document. The information given in the example is therefore defective in that some critical feature is missing and/or some manufacturing condition specified in the document is erroneous, so that, as submitted by the appellant, example 1 of document BL2 is not reproducible. In addition, as shown in the experimental reports JJ3, BL12 and BL25, only substantial modifications of the process described in example 1 appear to result in a cured contact lens; however, none of these modifications is expressly or at least implicitly disclosed in document BL2 in individualised form and, as shown in the tests reproduced in documents JJ3, BL12 and BL25, different modifications lead to lenses having different characteristics. Accordingly, the lenses obtained according to these modifications go

beyond the inevitable result of the disclosure of the document and cannot be opposed to novelty of the claimed lens (decision T 270/97, point 3.4).

It also follows that the extensive submissions of the parties relating to the question of whether, and to what extent the lenses obtained according to the test reports JJ3, BL12 and BL25 and based on example 1 of document BL2 anticipate or not the features of the lens according to the invention are not relevant to the issue of novelty of the claimed subject-matter.

5.1.3 In the decision under appeal the opposition division referred to the statements in document BL2 relating to conventional curing methods (column 6, lines 57 to 61) and to the ability of the skilled person to determine the time, temperature and pressure conditions for the removal step of the organic diluent (column 7, lines 8 to 21), found that such statements supported the modifications shown in documents JJ3, BL12 and BL25 relating to the curing of the composition A and to the manufacture of lenses, and concluded that these documents provided evidence that lenses according to the invention will result inevitably from the disclosure of document BL2. During the appeal proceedings the respondent also made extensive submissions in support of this line of argument.

The Board, however, cannot follow this line of argument. The characteristics of lenses of the type considered in document BL2 and in the patent depend on the composition but also critically on the specific manufacturing conditions of the lenses; document BL2 contains general statements on the manufacturing steps

and specifies some specific manufacturing conditions but, apart from the specific examples in document BL2 - and contrary to the patent in suit which provides an extensive teaching on specific manufacturing conditions (see for example paragraph [0292] *et seq.*) that can be used in implementing the invention -, the document fails to teach how most of the manufacturing conditions are to be selected. In addition, even assuming, for the sake of argument, that the general statements in document BL2 referred to above encompass specific conventional manufacturing conditions (nature and proportion of the starting materials, UV intensity and source, curing time, kind of amount of starter or of diluent, curing temperature, etc.) which, when applied to the composition A of the document, would in combination result in lenses satisfying all the claimed features, then, in the absence of any explicit or implicit disclosure in document BL2 of such specific conventional manufacturing conditions and of any specific combination of such specific manufacturing conditions, the claimed lens would still be novel - by analogy to the doctrine of "novelty-by-selection" - over the disclosure of document BL2 (T 396/89, point 4.4).

5.1.4 The Board concludes that, in view of the evidence on file, the disclosure of document BL2 is not sufficient to anticipate the claimed subject-matter within the meaning of Articles 52(1) and 54 EPC.

5.2 Document JJ34

Document JJ34 discloses a block copolymer containing polysiloxane and polyoxylalkylene oxide units, and

refers to contact lenses made of the block copolymer and that are optically clear, wettable, flexible, and of high oxygen permeability (abstract and page 2, lines 1 to 6 together with claim 1). Example 2 discloses the production of films made of the block copolymer, and the film samples 4 and 5 of the example have a Dk-value of the oxygen permeability of 66.1 and 59.5 barrers, respectively (table on page 20).

The respondent has submitted that the composition of the film samples 4 and 5 is substantially the same as that of example A-1 of the patent, and that the skilled person would inevitably make lenses significantly thinner than 0.1 mm and therefore having an oxygen transmissibility satisfying the claimed value range. However, even assuming the value of the lens thickness suggested by the respondent, there is no evidence that the Dk values of the film samples 4 and 5 specified in document JJ34 and measured following a modification of the ASTM standard D3985-81 (page 6, lines 4 to 10) would anticipate the claimed values of the oxygen transmissibility. In addition, the further submission of the respondent that lenses made with the film samples 4 and 5 would anticipate the remaining features of the claimed lens cannot be followed. In particular, no information can be derived from the disclosure of document JJ34 that would lead to the conclusion that the resulting lenses would have the claimed value of the ion permeability. The statements on page 5 of document JJ35 (a letter of the applicant of the patent application JJ34 addressed to the EPO during the corresponding examination proceedings) that contact lenses made with the block copolymer of document JJ34 worn at night by a person supply the eye with oxygen by

closed eyes, thus achieving a breakthrough in the development of extended-wear lenses, are not sufficient to conclude that the corresponding lenses are suitable for extended wear, let alone that the lenses satisfy the remaining claimed features and in particular the claimed value of the ion permeability.

The further submissions of the respondent that the film samples 4 and 5 have an exceptionally high water content predictive of a high ion permeability as shown by Figure 2 of document JJ13 cannot be followed either. Figure 2 of the post-published document JJ13 shows that, for the specific contact lenses considered in the document, the higher the equilibrium water content, the higher the relative diffusion coefficient of the lenses. However, water content and ion permeability of a polymeric lens are two different properties that generally depend on the composition, the structure and the morphology of the lens and, in the absence of sufficient technical evidence or of technical arguments supporting the respondent's contention that water content and ion permeability correlate with each other in the case of the block copolymer considered in document JJ34 at least to the extent ensuring that the high water content of the copolymer would necessarily imply an ion permeability as claimed, the respondent has not discharged the burden of proof that the disclosure of document JJ34 would inevitably result in lenses having the claimed ion permeability.

Having regard to the above, and in the absence of sufficient evidence to the contrary, document JJ34 does not anticipate the claimed subject-matter.

5.3 Documents JJ14 and JJ15

Document JJ14 is a report on the "Bausch & Lomb premier 90 (balafilcon A) contact lens", and document JJ15 discloses the chemical composition of balafilcon A (page 2). The respondent has submitted that the composition disclosed in document JJ15 corresponds with that of composition A specified in document BL2, and that consequently the composition is of the type defined in claim 1; also according to its submissions, the DK value 81 of the oxygen permeability (page 2, third paragraph) anticipates the claimed oxygen transmissibility and, although document JJ14 specifies that the lens "is similar to other daily wear [...] contact lenses in water content (≤50% H_2O), clinical performance, use indications [...]" (penultimate paragraph), the lens is suitable for extended wear as shown in the post-published clinical evaluation BL19 which states that "the RD-677 contact lens is a safe and effective means of vision correction when worn on a 30-day extended wear basis" (last paragraph), the RD-677 contact lenses being cited in document JJ14 as representative lenses of the corresponding disclosure (paragraphs bridging pages 4 and 5).

However, the line of argument of the respondent is not conclusive. Even accepting the respondent's submissions, there is no evidence that the lens of document JJ14 anticipates the remaining claimed features. In particular, the fact that the lens of document JJ14 moves on the eye would appear to imply a predetermined degree of ion permeability, but there is no evidence that the lens would satisfy the claimed conditions relating to the ion permeability.

5.4 Document JJ2 together with document JJ3

Document JJ2 discloses contact lenses with high oxygen permeability (column 1, lines 4 to 8). The lenses obtained according to examples 3 and 8 have respectively a water content of 38 and 19 wt % and an oxygen permeability coefficient of 83 and 86 (Table 1) measured as defined in column 14, lines 44 to 55.

According to the submissions of the respondent, the composition of the lenses of examples 3 and 8 specified in Table 1 corresponds to the composition of the claimed lenses. However, there is no concluding evidence that the values of the oxygen transmissibility of the lenses of document JJ2 anticipate the corresponding claimed values in view of the different methods used in the patent and in document JJ2, or that the lenses disclosed in document JJ2 have the ion permeability characteristics of the claimed lenses. In particular, the relatively high water content of the lenses of examples 3 and 8 is not sufficient to conclude that the lenses have a sufficient ion permeability to anticipate the corresponding claimed features defined in claim 1 for reasons analogous to those set forth in point 5.2 above, third paragraph. In addition, the results of the experimental tests carried out in document JJ3 and allegedly reproducing the disclosure of document JJ2 (Table on page 13) are not conclusive as the tests performed deviate from the disclosure of document JJ2; in particular, while in document JJ2 the lens material of examples 3 and 8 is formed by thermal curing (column 13, lines 38 to 45 together with column 15, line 65 *et seq.*), the

corresponding tests carried out in document JJ3 involved photocuring using a photoinitiator (page 6, central paragraphs), and there is no evidence that this substantial deviation from the disclosure of document JJ2 would not have a significant effect on the measured value of the ion permeability of the samples obtained in the tests (see in this respect point 5.1.2 above, first paragraph).

Therefore, the line of argument of the respondent that the lenses of examples 3 and 8 of document JJ2 would inevitably have the claimed features does not convince the Board.

5.5 In view of the above considerations and conclusions, the respondent has failed to discharge the burden of providing sufficient evidence and/or arguments that the lenses disclosed in documents BL2, JJ34, JJ14 and JJ2 would inevitably have all the claimed features, at least to the degree required to shift that burden of proof to the appellant's shoulders. Accordingly, the subject-matter of claim 1 of the patent as granted defines novel subject-matter over the prior art disclosures considered by the respondent (Article 100(a) together with Articles 52(1) and 54 EPC).

6. *Article 100(a) EPC - Inventive step*

6.1 The Boards of Appeal consistently apply the problem-solution approach in the objective assessment of whether or not a claimed invention involves an inventive step within the meaning of Article 56 EPC. This approach requires as a first step the identification of the closest state of the art and, in

order to avoid ***ex-post facto*** considerations, the closest state of the art is not generally that merely showing superficially the most similarities, but rather that conceived for solving the same primary problem or aiming at the same objective as the claimed invention and which requires the minimum of structural and functional modifications (see for instance T 273/92, point 3, and T 1094/97, point 5.1.1).

Thus, in the present case, this approach does not involve properly comparing the composition of the lenses of the prior art with those of the claimed lenses, but rather involves considering the suitability of the lenses of the prior art for achieving the main objective achieved with the claimed invention.

6.1.1 The main purpose of the claimed invention is the provision of extended-wear contact lenses, i.e. contact lenses that can be continuously worn during extended periods of time beyond the typical wear time periods proper to daily-wear contact lenses (paragraphs [0001] and [0009] to [0012] together with paragraph [0006], and claim 1 of the patent).

Accordingly, a document aiming at this same purpose is considered to be the most appropriate starting point for the assessment of inventive step. Other prior art disclosures containing structural and/or functional similarities with the claimed invention but not addressing the main purpose of the invention do not generally qualify as objective closest prior art as such an approach would risk relying on hindsight knowledge of the invention and therefore on an

assessment of inventive step that is neither realistic nor objective.

6.1.2 While the appellant has submitted that the closest prior art is represented by document JJ23, the respondent contends that the closest prior art is represented by document BL2 and, alternatively, by each of documents JJ2, JJ8, JJ14, JJ16, JJ17 and JJ34.

Document JJ23 is directed to highly oxygen permeable siloxanic hydrogels (abstract) and the document specifies that the hydrogels "might be considered for soft, prolonged wear contact lenses" (last sentence), and document JJ16 discloses soft gas permeable contact lenses with improved clinical performance (abstract) and suitable for long-term extended wear (page 3, third paragraph), and therefore each of these two documents qualifies as closest state of the art.

As regards the remaining documents considered by the respondent as alternative closest prior art,

- document BL2 (see point 5.1 above) deals with a process for preparing silicone containing hydrogel contact lenses where machining operations are employed to produce a lens having a desired final shape (abstract, column 2, lines 6 to 16 and claim 1), and the document is not concerned with the characteristics of the lens material and, more particularly, with the wear time capability of the resulting lenses, but with predetermined machining operations;
- document JJ17 relates to polyurethane based prepolymers for biomedical devices (abstract) and, in the discussion of the background art, the

document refers to the use of (co)polymers as a material for soft contact lenses (column 1, line 11 *et seq.*); the document is however silent as to the wear time period of the disclosed devices and lenses;

- document JJ14 discloses properties of a lens (see point 5.3 above) and does not contain any express teaching relating to an extended-wear lens, the document even reports on the properties of the lens with reference to "other daily wear [...] contact lenses" (page 6, penultimate paragraph);
- document JJ2 relates to an ocular lens material for use, among others, as a contact lens (column 1, lines 4 to 8) and focuses on properties of the lens such as transparency, oxygen permeability, water absorptivity, etc. (column 1, lines 46 to 62), document JJ8 discloses water absorbing, hydrophilic contact lenses (abstract) and teaches that the lenses will move on the eye sufficiently so that no physical damage will occur to the cornea (column 14, line 16 *et seq.*), and document JJ34 discloses wettable, oxygen permeable contact lenses (page 2, lines 1 to 6); however, all these documents are silent as to the wear time period of the lenses or as to any improvement thereof.

Accordingly, and in view of the considerations in point 6.1.1 above, second paragraph, there is *a priori* no reason why the skilled person would see in any of documents BL2, JJ2, JJ8, JJ14, JJ17 and JJ34 a realistic starting point for the achievement of the primary object of the invention, i.e. extending the wear time capability of the lenses. Consequently, irrespective of the number of possible similarities

with the claimed lenses such as the composition, none of documents BL2, JJ2, JJ8, JJ14, JJ17 and JJ34 qualifies as an alternative closest prior art for an objective assessment of inventive step.

6.1.3 The Board concludes that a realistic and objective assessment of inventive step should start from the closest state of the art represented by the disclosure of document JJ16 or, alternatively, document JJ23.

6.2 The closest prior art document JJ16 discloses hydrophilic soft gas permeable contact lenses (page 1, second paragraph) having a high degree of clinical performance that renders the lenses suitable for long-term extended wear (page 3, third paragraph). The lenses are of a polymer of vinylic siloxane and of hydrophilic vinylic monomers (page 5, line 31 *et seq.*) and, in particular, the lens according to example 3 of the document (page 13, second paragraph) comprises γ-tris(trimethylsiloxy)silylpropyl methacrylate (TSM), N,N-dimethylacrylamide (NNDMA) and 2-hydroxyethyl methacrylate (HEMA). The document identifies a high oxygen permeability Dk and a high wettable and deposition-resistant surface as the most important requirements of the lenses (page 1, third paragraph, and page 1, last paragraph to page 3, first paragraph), and the document proposes a water content of at least 25% (page 4, last paragraph). In addition, in order to achieve the appropriate clinical performances, a surface treatment of the lens is required (page 5, first paragraph, and page 8, line 1 *et seq.*); thus, the lens according to example 3 was found to be unsuitable for extended wear, and a surface treatment of the lens in dehydrated state by stirring the lens in glycerine

reagent rendered the lens suitable for weekly extended wear for a three-week testing period (page 13, second paragraph).

6.2.1 The monomers of NNDMA and HEMA used in example 3 of document JJ16 constitute ionoperm polymerizable materials as defined in the patent in suit (paragraph [0041]), and the monomers of TSM also appear to constitute an oxyperm polymerizable material as defined in the patent (page 6, first paragraph of document JJ16 together with paragraphs [0037] and [0038] of the patent specification).

However, there is no evidence or technical argument that would allow the conclusion that the lens of example 3 or any other of the lenses disclosed in document JJ16 will have an oxygen transmissibility and an Ionoton or an Ionoflux coefficient within the claimed value ranges. In particular, document JJ16 stresses the importance of the oxygen permeability, of the wettable characteristics of the lens surface and of the water content of the lens material (page 1, third paragraph, and page 4, last paragraph), but contains no information as to the degree of oxygen transmissibility and of ion permeability of the lenses.

It follows that - irrespective of the extent to which the lenses of document JJ16 satisfy the functional features of the claimed invention relating to the ophthalmic performances of the lenses of the invention - the claimed lenses differ from the lenses disclosed in document JJ16 at least in the values of the oxygen transmissibility and in the values of the Ionoflux and the Ionoton coefficients.

6.2.2 According to the patent specification (paragraphs [0009], [0013], [0046], [0054], [0056], [0066], [0072], [0092], [0287]), the distinguishing features identified in point 6.2.1 above allow for a balance of oxygen permeability and ion permeability that, together with the remaining features of the lens, are sufficient for corneal health and wearer comfort during extended periods of continuous wear.

Accordingly, the objective problem solved by the claimed subject-matter over the disclosure of document JJ16 can be seen in improving and optimizing the structural characteristics of the lens so as to guarantee a predetermined degree of corneal health and of wearer comfort during extended periods of continuous wear.

6.2.3 Document JJ16 already teaches that the higher the oxygen permeability of the contact lens, the better the ophthalmic properties of the lens (page 1, third paragraph to page 3, second paragraph). This teaching would lead the skilled person to consider the possibility of enhancing the ophthalmic properties of the lens by improving the oxygen permeability of the lens, possibly to a value corresponding to a value of the oxygen transmissibility within the claimed range.

However, none of the documents discloses or suggests endowing a contact lens as that disclosed in document JJ16 with an ion permeability as claimed. In particular, document JJ16 mentions surface wettability and water content of the lens as essential properties of the lens (page 4, last paragraph) and also refers to

the lens as a gas permeable contact lens (page 1, second paragraph), but the document is silent as to any relevance of the ion permeability of the lens.

According to the submissions of the respondent, the high water content of the lens of document JJ16 or the degree of water content disclosed or taught in the prior art, and in particular in example A of document JJ27 (Table XI) cited in document JJ16, would inevitably imply an ion permeability as required by the claimed invention. However, there is no evidence or technical argument that would allow this conclusion (see third paragraph of point 5.2 above), let alone that the ion permeability of the lens would then fall within the claimed range of the Ionoton coefficient or, alternatively, within the claimed range of the Ionoflux coefficient. In particular, document JJ10 referred to by the respondent shows that the permeability to sodium and potassium ions of the lenses considered in the document increases in accordance with the increase in water content, but the document also states that the permeability of the lenses to sodium and potassium ions for the same water content also depends on the composition of the lenses (abstract).

In addition, there is no express teaching in the prior art that would hint at endowing a lens of the type disclosed in document JJ16 with an ion permeability satisfying the claimed alternative ranges of the Ionoton and the Ionoflux coefficients.

The respondent has submitted in this respect that the claimed minimum values of the Ionoton and of the Ionoflux coefficients are extremely low and would

therefore be implicitly satisfied by a lens having a high degree of hydration or of water content. However, in the absence of any supporting evidence that the lower values of the value ranges of the Inoflux and the Ionoton coefficients specified in claim 1 are extremely low as contended by the respondent, or at least low enough to be implicitly satisfied by the prior art, the Board is not in a position to follow the respondent's line of argument in this respect.

During the proceedings the respondent has also submitted that - as also maintained by the opposition division in its decision - it would be obvious to carry out a surface treatment of the lens surfaces in order to improve predetermined characteristics of the lens. Irrespective of whether or not this is the case in the light of the available prior art, this line of argument is not pertinent in the present circumstances as there is no technical argument or evidence that a treatment of the surface of the lens would have a positive effect on the ion permeability of the whole lens.

6.2.4 The Board concludes that the claimed subject-matter does not result in an obvious way when starting from document JJ16 as the closest prior art.

6.3 The same conclusion applies when starting from document JJ23 as the closest prior art. This document is directed to highly oxygen permeable siloxanic hydrogels with 20 to 30 % wt hydration and a value of Dk up to 170 10^{-11} $cm^3(O_2)cm\ cm^2\ s^{-1}\ mmHg^{-1}$ as measured according to the method in point 4 of page 120, the hydrogels being obtained by copolymerization of acrylic acid with tris(trimethyl siloxy)-γ-methacryloxy propylsilane or

dimethacryloxybutyl polydimethylsiloxane (abstract). According to the last paragraph of the document, the materials "might be considered for soft, prolonged wear contact lenses", and the document stresses the relevance of the oxygen permeability and the hydration level of the hydrogel (page 117, last two paragraphs and section 3). In particular, the document discloses that a permeability value Dk of about 120 to 150 10^{-11} $cm^3(O_2)cm$ cm^2 s^{-1} $mmHg^{-1}$ is required for safety of the cornea in the case of prolonged wear (page 118, second paragraph).

However, document JJ23 is silent as to the ion permeability of the lens material. Thus, even assuming for the sake of argument that the skilled person would consider in the light of the teaching of document JJ23 lenses having a high oxygen permeability and a small thickness such that the oxygen transmissibility of the lenses would fall within the value range of the claimed lens, for reasons analogous to those set in point 6.2.3 above there appears to be no teaching in the prior art that would hint at endowing the lenses with an ion permeability satisfying the claimed alternative conditions. Already for this reason, and irrespective of the remaining claimed features, the claimed subject-matter does not result in an obvious way when starting from document JJ23 as the closest prior art.

6.4 Having regard to the above, the prior art, the evidence and the arguments considered by the respondent are insufficient to conclude that the claimed invention would result in an obvious way from the state of the art within the meaning of Article 56 EPC.

7. In view of the above considerations and conclusions, the Board concluded during the oral proceedings that none of the grounds for opposition prejudices the maintenance of the patent as granted, and that there was no need to consider the auxiliary requests of the appellant. Accordingly, the Board decided that the opposition was to be rejected and the patent maintained unamended (Articles 102(2) and 111(1) EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is maintained unamended.

The Registrar: The Chairman:

M. Kiehl A. G. Klein