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D E C I S I O N
of 28 September 2000

Case Number: T 0494/96 - 3.3.3

Application Number: 89105424.9

Publication Number: 0335312

IPC: A61F 2/16

Language of the proceedings: EN

Title of invention:
Intraocular lens

Patentee:
HOYA CORPORATION

Opponent:
Allergan Medical Optics

Headword:
-

Relevant legal provisions:
EPC Art. 54(2), 56

Keyword:
"Novelty (yes) - public prior use (no) - confidentiality (yes) - insufficient evidence - no implicit prior diclosure"
"Inventive step (yes) - additional effect"

Decisions cited:
G 0001/92; T 0194/96; T 0332/87; T 0482/89; T 0472/92; T 0952/92; T 0097/94

Catchword:
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Case Number: T 0494/96 - 3.3.3

D E C I S I O N
of the Technical Board of Appeal 3.3.3
of 28 September 2000

Appellant: (Opponent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office dated 28 February 1996 and issued in writing on 15 March 1996 rejecting the opposition filed against European patent No. 0 335 312 pursuant to Article 102(2) EPC.**

Composition of the Board:

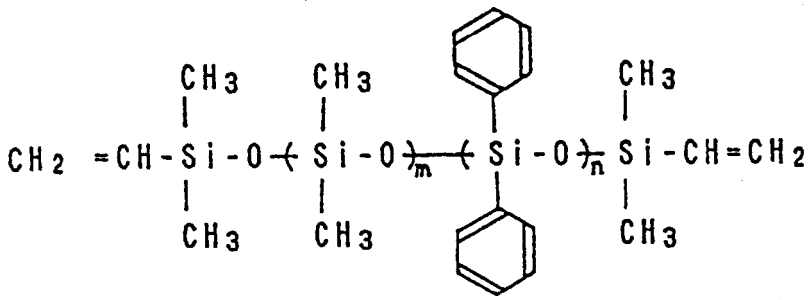
Chairman: C. Gérardin
Members: R. Young
A. Lindqvist

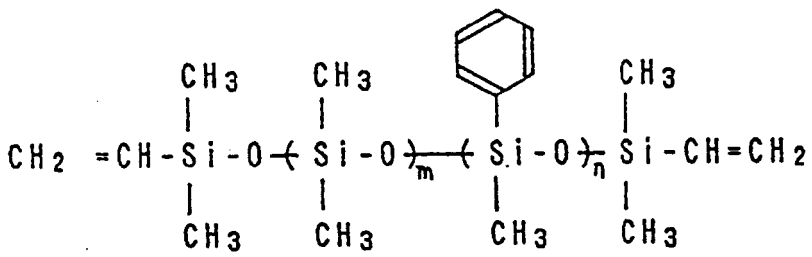
Summary of Facts and Submissions

I. The mention of the grant of European patent No. 0 335 312, in respect of European patent application No. 89 105 424.9, filed on 28 March 1989 and claiming a JP priority of 28 March 1988 (JP 73559/88) was published on 15 June 1994 (Bulletin 94/24). Claim 1 reads as follows:

"An intraocular lens whose optic or optic and haptic are composed of a substantially soft polymer obtained by curing a composition comprising:

(a) a dimethylsiloxane-phenylsiloxane copolymer having a vinyl group at each of the both terminals of the molecular chain represented by either of the following general formulas





wherein m is zero or larger and n is one or larger,

(b) a diorganopolysiloxane having at least three

hydrosilyl groups in the molecule, and

(c) an U.V. absorber."

Claims 2 to 5 are dependent claims directed to elaborations of the intraocular lens according to Claim 1.

Claim 6, an independent claim, has the same wording as Claim 1, except that the final phrase "... (c) and U.V. absorber.", is replaced by:

"... (c) an U.V. absorber, and

(d) a filler.".

Claims 7 to 12 are dependent claims directed to elaborations of the intraocular lens according to Claim 6.

II. A Notice of Opposition was filed on 14 March 1995, by the Opponent, Allergan Medical Optics (AMO), on the grounds of lack of novelty and lack of inventive step. The opposition was supported by the following documents:

D1: Declaration of F. R. Christ;

D2: First Declaration of D. Trentacost;

D3: Declaration of R. Vanryne;

D4: Opponent's sales of intraocular lenses broken down by month and type;

D5: Allergan Medical Optics Informed Consent Form;

D6: "Pathologic Findings of an Explanted lens", D. A. Newman et al, *J. Cataract Refract Surg*, Vol. 12, May 1986, pp. 292-297;

D7: "Evaluation of the chemical, optical and mechanical properties of elastomeric intraocular lens material and their clinical significance", F. R. Christ et al, *J. Cataract Refract Surg*, Vol. 15, March 1989, pp. 176-184;

as well as the later filed, but admitted documents:

D8: First Declaration of D. J. Petraitis;

D9: Declaration of Dr W. J. Fishkind;

D10: FDA Report on intraocular lenses published in *J. Ophthalmology* April 1983;

D11: Explantation Literature Database Search, produced by the Opponent;

D12: Declaration of S. Valenty;

D13: Second Declaration of D. Trentacost;

D14: Second Declaration of D. J. Petraitis;

D15: "The Analytical Chemistry of Silicones", A. L. Smith, John Wiley & Sons Inc;

D16: "Characterization of PDMS Model Junctions and Networks", Beshah et al, *J. Polymer Science: Part B: Polymer Physics*, Vol. 24, 1207-1225 (1986);

D17: "Topology of Poly(dimethylsiloxane) Elastomeric Networks...", Beshah et al, *Macromolecules*, 1986, 19, 2194-2196;

and

D19: US-A-3 996 189 ("Travnicek").

Of these, D8 and D9 were filed with a submission dated 13 April 1995 (received on 18 April 1995);

D10 to D12 were filed with the submission dated 26 January 1996 (received on 31 January 1996);

D13 was filed with a fax dated and received on 23 February 1996; and

D14 to D17 and D19 were filed at oral proceedings held on 28 February 1996 before the Opposition Division.

A further document:

D18: Declaration of N. Satoh, Toray Research Center Inc;

was filed in response by the Patentee (Hoya Corporation) by fax on 23 February 1996.

The Opponent alleged in particular that the subject-matter claimed in the patent in suit lacked novelty in view of prior sales of silicone intraocular lenses by the Opponent, and that it lacked inventive step with regard to the disclosure of D19.

III. By a decision taken after oral proceedings held on

28 February 1996 and issued in writing on 15 March 1996, the Opposition Division rejected the opposition.

According to the decision,

(i) the alleged prior use involved the surgical implantation of a new foldable silicone intraocular lens, called SI-20NB, produced by AMO, by selected clinical investigators, as part of clinical core studies of SI-20NB lenses, between 1986 and 1987, i.e. before the priority date of the patent in suit. Whilst the intraocular lenses (IOLs) had been directly sold from AMO to the hospitals or surgical facilities at prevailing IOL prices, nevertheless under the circumstances of a clinical core study, one had to assume that all knowledge about the nature of the lenses (an important detail of the clinical study) was bound by confidentiality.

Furthermore, once an IOL had been implanted, the implanted IOL could not be detected in the eye by inspection, since it was positioned behind the cornea of the patient. Consequently, a member of the public having contact with a patient of the clinical core study would not have been able to obtain any information about the lens.

Finally, on the question of explantation, whilst this was a theoretical possibility, it was associated with considerable pain, health risks and costs, and a particular case of explantation where the explanted lens would be freely available had not been identified.

In any case, it had not been shown that the SI-20NB IOLs were analysable in the sense of the decision G 1/92 (OJ EPO 1993, 277).

Thus, in the case of the implanted lenses provided by AMO, the hospitals and surgeons were bound by confidentiality, and the lenses, although implanted in members of the public (i.e. patients included in the core study), were not available to the public. Nor had any evidence been provided that SI-20NB IOLs actually fell within the scope of Claim 1 of the patent in suit. Consequently, the alleged prior use could not be accepted.

(ii) As regards the disclosure of D19, this related to optically clear filled silicone elastomers formed of aryl and alkyl siloxanes and useful for soft contact lens. Additionally, a silica filled contact lens was disclosed having an elastomer of two polymers, one having terminal vinyl groups and the other terminal $(R)_2HSi$-O- groups. All the examples provided materials adapted for contact lenses. There was only a mention in the general description and in dependent Claim 5 that an ocular implant could also be moulded from such materials. Thus, the subject-matter of Claim 1 of the patent in suit differed from this state of the art in that the vinyl units in copolymer (a) according to Claim 1 strictly formed terminal groups, whereas in the prior art these groups could take any position in the (statistical) copolymer; there was no teaching that at least three hydrosilyl groups had to be present in the cross-linking siloxane polymer (b), and the materials disclosed did not include a UV absorbing

agent.

In view of the above, the subject-matter of Claim 1 of the patent in suit met the requirements of novelty.

Furthermore, since none of the prior art documents disclosed or suggested the structural modifications of the polymers (a) and (b) as defined in Claim 1 to provide intraocular implants, the subject-matter of the patent in suit also involved an inventive step.

Hence the opposition had to be rejected and the patent maintained as granted.

IV. On 15 May 1996, a Notice of Appeal against the above decision was filed, the prescribed fees being paid on the same day.

The Statement of Grounds of Appeal, filed on 24 July 1996 was accompanied by the following further documents which were cited for the first time:

D20: "The effect of crosslink functionality on the elastomeric properties of bimodal networks", M. Y. Tang et al, *Polymer Communications*, 1984, Vol. 25, November, pp. 347-350;

D21: "Dependence of Elastomeric Properties on Network Junction Functionality", C. Y. Jiang et al, *Journal of Polymer Science, Polymer Physics edition*, Vol. 22, 1984, pp. 2281-2284;

D22: "A Novel Method for preparing Bimodal Elastomeric

Networks", G. S. Sur et al, *Polymer Bulletin* 13, 1985, pp. 505-509;

D23: US-A-3 884 886;

D24: US-A-3 957 713;

D25: US-A-4 072 635;

D26: US-A-3 436 366;

D27: US-A-3 341 490;

D28: US-A-3 284 406;

D29: US-A-3 220 972;

D30: Allergan Clinical Investigator Agreement;

D31: *Merrell Dow v. Norton*, UK House of Lords, 1996 RPC 76-93;

D32: Adverse Reaction Reports submitted in respect of Allergan SI-20 core investigation;

D33: Declaration of Dr Liebowitz;

D34: Third Declaration of D. Trentacost;

D35: Letter dated 13 May 1996, John L. Young, General Electric Plastics;

D36: "Ultraviolet-absorbing intraocular lenses", H. M. Clayman M.D., *Journal of the American Intra-Ocular Implant Society*, Vol. 10, Fall 1984,

pp. 429-432;

D37: Inside cover advertisement, *Journal of Cataract and Refractive Surgery*, Vol. 4, No. 2, March 1988;

D38: "Review; Polymers in Opthalmic Surgery", P. Baranyovits, *Biomedical Polymers*, ©1988 Elsevier Science Publishers BV, Amsterdam, Vol. 3, No. 9, pp. 1-6;

D39: "The Spectra, Classification, and Rationale of Ultraviolet-Protective Intraocular Lenses", M. A. Mainster M.D., *American Journal of Ophthalmology*, 102:727-732, December 1986;

D40: "Ultraviolet Radiation Protection", S. Lerman M.D., *The CLAO Journal*, January 1985, Vol. 11, No. 1;

D41: Inside Cover Advertisements by American Medical Optics (AMO) and Ioptex, *Journal of the American Intraocular Implant Society*, Vol. 10, No. 4, Fall 1984; and

D42: Inside Cover Advertisement by Optical Radiation Corporation, *Journal of the American Intraocular Implant Society*, Vol. 10, No. 1, Winter 1984.

In the Statement of Grounds of Appeal, the Appellant (Opponent) argued substantially as follows:

(a) Prior use

(i) A total of 337 IOLs designated SI-20NB had been sold to a total of 68 surgeons in the USA, the

lenses being sold specifically to the hospitals in which the operations were conducted, at the normal commercial rate (D2, D3, D4 and D9). Furthermore, there was no confidentiality agreement in place between AMO and the hospitals (D13), so that the hospitals would have been free to analyse the lenses and to communicate details of the analyses results to whomsoever they wished. Consequently, sale to the hospitals made information about the lenses available to the public.

(ii) The surgeon and the hospital were quite distinct and independent entities, since in the majority of cases, the surgeon would not be an employee of the hospital. Consequently, any confidentiality agreement that the surgeon might have entered into would not be binding upon the hospital. Again, the hospital would be free to analyse the lenses and communicate details about them.

(iii) Whilst the surgeon did have an agreement in place with AMO, which included confidentiality terms (D30), nevertheless AMO, like any research-based company, whilst wishing to keep relevant clinical data secret, had no interest in concealing information concerning the lens and in particular the polymer formulation used in them. On the contrary, AMO wanted to publish details of their lens (exhibit FRC3 - corresponding to D7 - accompanying document D1).

(iv) The patient as owner of the lens would also have been free to have the lens removed and analysed,

had he or she so wished. This was a commonplace procedure (D6, D10, and D11) and evidence of the explantation of several lenses used in the relevant study had been located.

(v) Explantation was in any case not necessary for the patient to find out what the implanted lens was made from. He had only ask the surgeon who implanted it, specific provisions requiring the surgeon to furnish any additional information required by the patient being provided in the AMO informed consent form (D5). Whereas the surgeon would always have an obligation to keep details of his patient's clinical records confidential, there was never any obligation on the patient to keep such details secret. Consequently, the patient who had paid for the lens, was entitled to be informed as to its structure and was not under any obligation to keep this knowledge secret. Hence, the composition of the lens was made available to the public by direct disclosure to the patient.

(vi) The decision under appeal had been wrong to find that the hospitals had not been free to release or analyse the lens notwithstanding the absence of any contractual agreement to this effect, simply through their involvement in a clinical study, and this on the basis of a German guideline. On the contrary, relevant case law of the UK House of Lords, which was oriented to EPO case law in *Merrell Dow v. Norton* (D31) did not assume or even suggest that confidentiality was an essential accoutrement of a clinical trial.

(vii) The decision under appeal had furthermore been wrong to find that, on the balance of probabilities, the patients had not been told the composition of the lens and this because the surgeon could not know whether a person presenting himself as a patient was, in fact, a competitor. Quite to the contrary, the relevant Declaration of Dr Fishkind (D9) made it clear that Dr Fishkind was legally required to tell his patients all relevant information.

(viii) The decision under appeal had also been wrong to find that the likelihood of explantation was low and that therefore no disclosure had occurred by this route. The argument in particular that such explantation was painful so that its benefit to the patient was outweighed by the cost was contrary to the precedent set out in the case law of the Enlarged Board of Appeal. According to the decision G 1/92 (*supra*), information is disclosed if it is possible to gain access to an analyse the articles in question and reproduce (without undue burden) the structure of those articles. The further argument, that there was no evidence that any lens had actually been explanted, was akin to the simile of the book on a library shelf, since it was the availability of the information that counted. The objection of lack of relevant evidence had in any case been rectified, and evidence of explantation of an implanted SI-20NB lens was enclosed (D32, D33 and D34).

(ix) Finally, the decision under appeal had been wrong to find that the lenses were not

analysable, and this on the basis of the evidence from the Toray Laboratories (D18). Not only was the gas chromatography mass spectrum data of Figures 1 to 17 absent, so that the experimental report was incomplete, but the statement, "therefore in order to identify cross-linking agents, it is necessary to further examine minor peaks in the mass spectra in detail. For this reason it is essential to make a comparison with authentic samples of cross-linking agents.", indicated, if anything, that the lens material was indeed capable of being analysed. In any case, further evidence had been provided, in particular the Declaration of J. Valenty (D12) that, using a combination of techniques, such an analysis could have been carried out. Reference was also made in this connection to the use of Fourier transform infra-red spectroscopy (D7), to a textbook entitled "The Analytical Chemistry of Silicones" (D15), referring to two further papers (D16 and D17), both relating to X-ray fluorescence analysis for determining the type of cure system, and finally to the evidence of D. J. Petraitis (D14) relating to elemental platinum analysis.

(x) In summary, it had been demonstrated that lenses formed from a cross-linked polymeric material having the features defined in the claims of the patent in suit had been sold on a commercial basis before the priority date.

(xi) The legal principles to be applied in the above connection were:

- Information is disclosed by a prior sale where it is possible to discover the composition of that product and reproduce it without undue burden (G 1/92, *supra*);

- It is only necessary to show that the product could be analysed to a sufficient extent to disclose the technical features of a claim (T 952/92, OJ EPO 1995, 755);

- A single sale is sufficient provided that the buyer is not bound by an obligation to maintain secrecy (T 482/89, OJ EPO 1992, 646); and

- The standard of evidence required to establish a given set of facts is the balance of probability (T 332/87 of 23 November 1990, not published in OJ EPO).

(b) The disclosure of D19

(i) D19 contemplated the use of silicone elastomers intraocular lenses (Claim 5) and furthermore disclosed a base polymer having all the features of component (a) in Claims 1 and 6 of the patent in suit, and a hydrosilyl cross-linking agent having all the features of component (b) of these claims of the patent in suit. Consequently, the only feature explicitly omitted was the requirement for a UV-absorbing agent. The addition of such an agent was, however, entirely conventional, as indicated in the patent in suit itself (page 2, lines 31 and 32), as well as documents D36 to D42, and the

document:

DD-A-249 030,

cited in the European Search Report of the application relating to the patent in suit. Consequently, no inventive step could reside in the inclusion of this feature.

(ii) The decision under appeal had been wrong in finding that there was no specific teaching in D19 that the relevant vinyl groups were terminal, and that there was no teaching of at least three hydrosiloxane linking groups. Not only was the interpretation according to which the polymers specifically disclosed in D19 fell within the scope of Claim 1 of the patent in suit the only sensible one, but there was evidence in the form of a letter from General Electric Plastics (D35), confirming that the RTV 655 product referred to in D19 indeed had a structure corresponding to that set out in the relevant part of Claim 1 of the patent in suit.

(iii) The subject-matter claimed in the patent in suit was therefore obvious in view of the disclosure of D19.

(c) The disclosure of D6

D6 was a report of the explantation of an experimental silicone IOL. It would inform the skilled person that recent developments in the IOL art were concerned the use of soft silicone polymers to replace the previously used hard

polymethyl methacrylate (PMMA) polymers, although it would not inform the skilled person as to the chemical structure of silicone polymers. Nevertheless, it would be reasonable for the skilled person to consult the common general knowledge in the silicone polymer chemistry field, which would enable the production of an IOL of soft silicone polymer. The skilled person would furthermore be aware of the use of UV absorbers and fillers in IOLs based on his common general knowledge. He would see it as routine to incorporate these into the silicone IOL. Hence, the skilled person would be led to produce an IOL falling within the terms of the claims of the patent in suit. Thus the subject-matter of these claims was obvious within the meaning of Article 56 EPC.

V. The Respondent (Patentee) disagreed, in a submission filed on 6 February 1997, with the arguments of the Appellant, and argued substantially as follows:

(a) Legal principles

(i) An allegation of prior public use of an invention required proof of the following circumstances:

- the date on which the prior use occurred;

- exactly what was in prior use; and

- the circumstances surrounding the prior use.

The precise constitution of the allegedly prior used SI-20NB intraocular lens had, however, still not been wholly characterised.

(ii) The discussion of the decision G 1/92 (*supra*) omitted reference to the requirement that the product in question had to have been "put on the market". It was self-evident that "sale" of a product to a person bound by a duty of confidence, as in the present case, did not constitute marketing.

(iii) The relevant criterion of certainty was not balance of probability, but proof beyond any reasonable doubt.

(b) Later-filed documents

Documents D20 to D29, filed with the Statement of Grounds of Appeal, related to silicone chemistry in general, which did not constitute the core concept of the subject-matter of the patent in suit. Consequently, the later-filed documents D20 to D29 were irrelevant and should be ruled inadmissible.

(c) Prior use

(i) Whilst the lenses may have been supplied by the Appellant to the hospitals, the lenses were nevertheless shipped directly to the surgeons retained by the Appellant to undertake the implantation. The latter were, furthermore, bound by a confidentiality agreement with the Appellant (D9) which was confirmed by the

Investigator Agreement submitted by the Appellant (D30). The latter specifically indicated that "materials, compounds, formulations and devices" provided by AMO for use in clinical trial represented "confidential information" not to be divulged to third parties without the agreement of the Appellant. Whilst the Appellant had alleged that there was no bond of confidentiality between itself and the hospitals (section IV.(a)(i), above), such a bond was evidently implied by the confidentiality agreement between the Appellant and the surgeons involved (section IV.(a)(iii), above). Consequently, to the extent that the hospitals might have been in possession of the lenses in the course of the clinical trial, they were also held within the confidence of the Appellant regardless of whether a written confidentiality agreement existed.

(ii) The arguments of the Appellant regarding publication and confidentiality (section IV.(a)(iii) above) were irrelevant since they discussed vague general situations and not the relevant specific case. Consequently, public disclosure of the composition of SI-20NB before the relevant priority date had not been established.

(iii) The Appellant's argument regarding the rights of the owner of the lens (section IV.(a)(iv), above) were not accepted, since the lens, once implanted within the eye of a patient became an integral part of him or her and was not available to the public. The argument of the

Appellant, that a doctor might have told the patient the chemical structure of the lens (section IV.(a)(v), above) was not supported by evidence that any of the doctors involved in the clinical trial actually knew the specific chemical structure of the lenses. This situation had not changed, and indeed was confirmed by the Declaration of Dr Fishkind (D9) which, whilst stating that he was "pretty well informed" as to the composition of the SI-20NB IOLs, did not state that he was told the actual chemical structure. It was quite improbable that a doctor involved in the trial of sort of lens would be told the precise chemical structure of the lens by the manufacture. He would have no need of or use for this information.

(v) The reference, by the Appellant, to a recent British Decision (Merrell Dow v. Norton, *supra*) did not support the Appellant's case, since this decision did not give the background to the particular clinical trials nor did it hold that clinical trials in general should be considered as being non-confidential.

(vi) The additional evidence with regard to explantation provided by the Appellant (D32 to D34) was irrelevant as the surgeon (Dr Liebowitz) would still have been under a bond of confidentiality to the Appellant in accordance with the Investigator Agreement (D30). In any case, the explanted lens was apparently destined for the Pathology Department of the hospital. This did not, however, make the lens publicly available, since no member of the

general public could have obtained access to the lens. It had to be assumed that members of a hospital Pathology Department were not at liberty to deal with an explanted lens in an unrestricted manner.

(vii) As to the analyzability of the lens material, it was not correct to assess this based upon hindsight knowledge of the subject-matter of Claim 1 of the patent in suit. The relevant question was rather whether it would have been possible to analyse a AI-20NB lens at the priority date of the patent in suit from first principles, and establish that it possessed a composition which turned out to be encompassed by Claim 1. The decision under appeal had been correct to comment, in relation to the Declaration of S. Valenty (D12), that "it appeared to be impossible to detect the specific cross-linking agent ... without having any comparison with authentic samples of the relevant cross-linking agent." Whilst the Appellant had alleged that this would be possible, technical evidence had been submitted by the Respondent that it would not (D18).

(viii) In summary, whilst the arguments of the Appellant were remarkably lengthy, none of them established the identity of a single individual having possession of one of the lenses in question, in a position to have the lens analysed, and who was not under some duty of confidentiality to the Appellant. Consequently, the ground of opposition of public prior use had to fail.

(d) The disclosure of D19

(i) There were distinctions between the compositions defined in Claims 1 and 6 of the patent in suit and the reinforced silicone elastomer compositions disclosed in D19. In particular, only monomers constituting each copolymer according to D19 had been described and nothing was stated or evident regarding the structure of the copolymers. Consequently, there was no disclosure of component (a) according to Claims 1 and 6 of the patent in suit. Furthermore, it was evident that the cross-linking agent forming component (b) according to Claims 1 and 6 of the patent in suit could only be arrived at from D19 after making a certain choice from the broader disclosure in D19. Finally, Claims 1 and 6 according to the patent in suit required the presence of a UV absorber, which was absent from the disclosure of D19.

(ii) The copolymer produced from components (a) and (b) according to the patent in suit had excellent solubility for the UV absorber constituting component (c), due to the presence of at least one phenyl group in component (a), as was illustrated by Examples 1 to 10 compared with comparative Example 2 of the patent in suit, wherein the compound corresponding to component (a) had been replaced by a siloxane substituted only with methyl groups. There was no disclosure according to D19 that only a very a small amount of the UV absorber had the desired effect of providing an IOL having ultraviolet-light-absorbing capability

equivalent to that possessed by the lens of a human eye.

(e) The disclosure of D6

The arguments put forward by the Appellant were incorrect since they assumed that it would be *prima facie* obvious to produce an IOL having the composition claimed in the patent in suit merely based upon the teaching of silicone-based lenses in general in this reference. This had no basis on the technical facts.

The submission was accompanied by copies of the German guideline (Adalat) and mass spectrum and experimental data (mass spectrum Figures 1-17) requested by the Appellant.

VI. In a further submission received on 8 October 1997, the Respondent filed a Declaration by Prof. Brian F. G. Johnson (D44) in support of the previous submissions on non-analyzability of SI-20NB IOLs.

VII. Finally, in a submission received on 18 August 1998, the Respondent further argued the lack of relevance of the disclosure of D19 to the subject-matter claimed in the patent in suit.

The submission was accompanied by three further documents, D45, D46, and D47, relating to the prosecution, before the United States Patent Office, of US-A-5 236 970 belonging to the Appellant, which had been referred to in the Declaration of Mr Christ (D1). In this connection, D45 and D46 were two Declarations of Mr Petraitis, who was the Declarant of D8 and D14 in

the present proceedings, and D47 was a response filed by the present Appellant during its prosecution of US-A-5 236 970.

D45 to D47 were filed in support of the Respondent's argument that the disclosure of D19 was not relevant to the subject-matter to the patent in suit.

VIII. The Appellant requested that the decision under appeal be set aside and the patent revoked.

The Respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. *Late-filed evidence*

Whilst 19 documents were considered during the proceedings before the Opposition Division, no less than 27 further documents have been filed during the appeal proceedings to date. They may be said to fall into the following groups:

(i) D20 to D29: documents generally relating to the chemistry of silicones.

(ii) D30 to D34 - documents relating to aspects of the alleged prior use.

(iii) D35 - relating to the structure of copolymers disclosed in D19.

(iv) D36 to D42 and DD-A-249 030 - documents relating to ultraviolet radiation protection in intraocular lenses.

All these documents were filed by the Appellant together with the Statement of Grounds of Appeal.

(v) D43 - the German guideline requested by the Appellant.

(vi) D44 - Declaration by Prof. Johnson concerning analyzability of SI-20NB lens.

(vii) D45 to D47 - Declarations and response filed by Appellant during its prosecution of US-A-5 236 970.

(viii) Figures 1 to 17 of experimental data relating to D18.

All the documents listed under items (v) to (viii) were filed by the Respondent; those under items (v) and (viii) with the submission received on 6 February 1997; that under (vi) with the submission received on 8 October 1997; and those under item (vii) with the submission received on 18 August 1998.

These will be dealt with in turn.

(i) With regard to the documents D20 to D29, listed under (i), these are concerned with various aspects of polysiloxane chemistry. None of them, however, concerns an intraocular lens, let alone one having good intraocular stability, excellent biocompatibility, high optical properties and a

UV absorbability close to that of the human lens, with which the patent in suit is concerned (Claim 1; page 2, lines 6 and 7). Nor do they have any relevance to the provision of means for analysing a lens of the type claimed in the patent in suit. These documents were, moreover, filed after the end of the 9 month opposition period, and their admission has been explicitly objected to by the Respondent. In view of their evident lack of relevance, and their lateness, these documents are excluded from consideration under Article 114(2) EPC.

(ii) Documents D30 to D34 are directly related to issues which were crucial to the decision under appeal, specifically the extent of confidentiality implied by the terms and conditions of the clinical trial (D30, D31) and applying in the event of an explantation (D32 to D34). No objection has been raised by the Respondent to the filing of these documents, nor has their relevance been questioned. Consequently, the Board has decided to introduce them into the proceedings pursuant to Article 114(1) EPC.

(iii) Document D35 is a letter, dated 13 May 1996, from an employee of General Electric Plastics concerning the chemical composition of the siloxane formulation RT 665V exemplified in D19. Although of somewhat doubtful probative value, since it is not in the form of a Declaration to the EPO, nor supported by so much as a scrap of corroborative evidence, its significance for the relevance of the content of D19, if accepted at

face value, is neverthless considerable. Since it has neither been objected to, nor indeed even commented on, by the Respondent, the Board has decided, given the circumstances, to introduce this document into the proceedings under Article 114(1) EPC.

(iv) Documents D36 to D42, although generally concerned with ultraviolet-absorbing lenses, do not mention the relevant soft silicone IOLs of the kind with which the patent in suit is concerned. On the contrary, D36 to D39, D41 and D42 are evidently concerned with conventional, hard polymethylmethacrylate (PMMA) lenses which are not relevant to the patent in suit. D40 relates to contact lenses. DD-A-249 030, cited in the European search report does, however, mention such silicone IOLs containing a UV absorber. Of these documents, therefore, only the latter is considered sufficiently relevant to be introduced into the proceedings at this stage. Consequently, DD-A-249 030 is introduced into the proceedings under Article 114(1) EPC, and documents D36 to D42 are excluded pursuant to Article 114(2) EPC.

(v) The German guideline "Adalat", filed as D43 by the Respondent, was provided at the request of the Appellant. It is, however, not of universal relevance. Consequently, it is not to be introduced into the proceedings, but will be disregarded pursuant to Article 114(2) EPC.

(vi) The Declaration D44 by Prof. Johnson relates to the crucial issue of analyzability of the IOLs

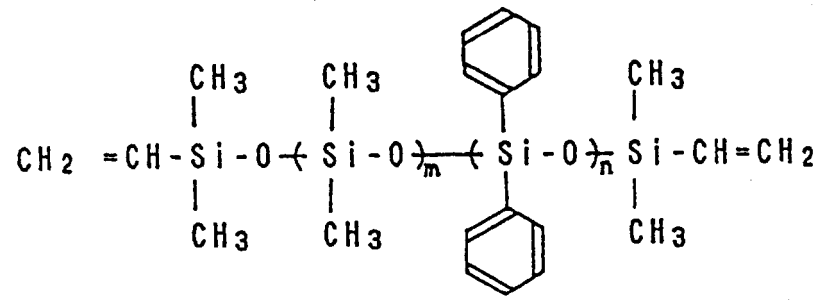
alleged to have been prior used. The Appellant has had sufficient opportunity to object or respond to this Declaration and has not done so. The Board considers it sufficiently relevant to be introduced into the proceedings under Article 114(1) EPC.

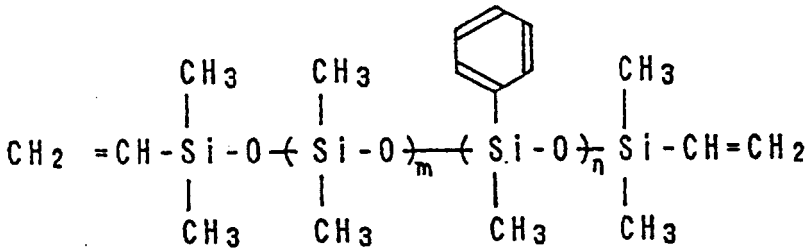
(vii) Similar considerations apply to D45 to D47, also filed by the Respondent. These documents, originating from the prosecution file of a patent belonging to the Appellant company, are pertinent, as a response to the filing of D35 by the Appellant. For reasons of equity, they are introduced into the proceedings under Article 114(1) EPC.

3. *The patent in suit*

The patent in suit is concerned with an IOL whose optic or optic and haptic are composed of a substantially soft polymer obtained by curing a composition comprising:

(a) a dimethyl siloxane - phenyl siloxane copolymer having a vinyl group at each or both terminals of the molecular chain represented by either of the formulae:





where in m is 0 or larger and n is one or larger, and

(b) a diorganopolysiloxane having at least three hydrosilyl groups in the molecule (Claim 1).

The lens may optionally contain, as a further component, a filler (Claim 6).

The product with which the patent in suit is concerned is thus a "product-by-process".

The sole issues in the present case are (a) whether the IOL according to Claim 1 or Claim 6 of the patent in suit has been publicly prior used by the IOL designated SI-20NB made by the Appellant (lack of novelty), and (b) whether the subject-matter of these claims is obvious in the light of the disclosure of D19 and/or D6.

4. *Public prior use*

The conditions for asserting prior public use have been defined in a large number of Board of Appeal decisions, for example T 97/94 (OJ EPO 1998, 467; Reasons paragraph 5, referring to T 194/86 of 17 May 1988, itself not published in OJ EPO). Accordingly, in order to determine whether an invention has been made available to the public by prior use, the following information must be provided:

(a) The date of the prior use.

(b) The precise object of the prior use.

(c) The circumstances of the prior use.

In the present case, furthermore, the lenses designated SI-20NB alleged to have been prior used are themselves a product originating from the Appellant. Consequently, practically all the evidence lies within the power of the Appellant. In such a case, and also according to the established case law of the Boards of Appeal, the assessment of probability which normally underlies the Boards' opinion must cede to a stricter criterion close to absolute conviction. In other words, there should be a degree of certainty which is beyond all reasonable doubt (T 97/94 cf. *supra*; Reasons for the Decision, point 5.1; following T 472/92, OJ EPO 1998, 161).

It is in the light of these general principles which the Board has considered the evidence on file relating to the alleged prior use.

4.1 By sale to the hospitals

According to the Statement of Grounds of Appeal, the lenses were "sold" to both the hospitals and the surgeons (paragraphs 4.2 and 4.3). Yet, according to the First Declaration of D. Trentacost (D2), the lenses were "sold" to the hospitals, but in fact shipped directly to the surgeons who would be performing the surgical implantation of the lenses in patients' eyes. The surgeons, who were bound by the Clinical Investigator Agreement (D30) with the Appellant, then implanted the lenses in the eyes of selected patients taking part in the Clinical Study. Although a commercial rate was charged to the hospitals for the lenses, in fact a proportion of the money was paid by the patient and the rest by the hospital, ultimately to be recouped by the latter from the Medicare Health Insurance System (D2, paragraph 6).

The relevant question is thus whether this deal amounted to a regular "sale" which would put the hospital in the position of being "a member of the public" with respect to the Appellant.

In the Board's view, this was a three-cornered transaction, in which the party in receipt of the lenses (the surgeon) was on the one hand not the same as the party paying for them (the hospital and patient), but on the other hand was under an obligation of confidence to both the Appellant (by virtue of the Investigator Agreement) and the patient (by virtue of the doctor-patient relationship). Thus the hospital evidently functioned solely as a book-keeping entity. It did not have physical access to the lenses before they were implanted, since they were delivered direct to the surgeon, nor after they had been implanted in the patients' eyes, since they then became part of the

patient.

4.1.1 The argument of the Appellant, that the hospital would have had the right to analyse the lenses, is not relevant, since it has not been shown that it was ever intended, as an integral part of the deal, for the hospital to have "hands-on" access to the lenses at any point before their implantation.

4.1.2 Nor is the position of the Appellant in this respect improved by reference to the situation in the "Merrell Dow" case relied upon (Statement of Grounds of Appeal section 4.44), since their Lordships in that case also recognised the reality of the nature of the transaction, whereby the pills were released literally "into the mouths of the patients". In particular, there was no suggestion in that case, that the patient might have decided to spit the drug out and have it analysed instead, although there was nothing physically to prevent this happening.

4.1.3 Consequently, the Board finds that the hospital, whether or not bound in some way by the Investigator Agreement covering the surgeons and the Appellant, was not *de facto* in a position to analyse the lenses. Consequently the "sale" of the lenses to the hospitals did not make the lenses publicly available.

4.2 By communication to the patient

As regards the argument of the Appellant, that the patient, who was not under any obligation of confidence to the Appellant, would have been able to gain information concerning the chemical structure of the lens, there is no evidence on file, nor even any direct

assertion, that any of the doctors were in possession of this information. Even the statement in the declaration of Dr Fishkind (D9), that he was "pretty well informed" as to the composition of the SI-20NB IOLs fails to state that he was ever told the precise the chemical structure of the lens by the Appellant.

4.2.1 This situation is not altered by the right of the patient to be informed according to the "Informed Consent Form" (D5). Such a form does not provide access to information which the surgeon does not possess.

4.2.2 Nor does the fact that the surgeon could have obtained the relevant information from the Appellant alter the fact that he has not been shown to possessed this information at any time when he might have been interrogated by a patient before the priority date of the patent in suit.

4.2.3 The analogy of the "book on the library shelf" is in this connection not apt to describe the situation of the surgeon. A more appropriate simile would be that of a library which in theory had the right to order the relevant book from the publisher, but which had not done so. The latter situation means that the information in the book is not "available" to the user of the library.

4.2.4 Hence, regardless of whether the terms of the Investigator Agreement would have limited the right of the surgeon to pass his patient details of the composition and structure of the SI-20NB lens, had he possessed such information, it has not been shown that any of the surgeons was in possession of the relevant information before the priority date of the patent in

suit.

4.2.5 In summary, the SI-20NB lens was not made publicly available by disclosure or potential disclosure by the surgeon directly to his patient.

4.3 By explantation

The new evidence relating to explantation, especially the Declaration of Dr Liebowitz (D33) makes it clear that the lens, after explantation, was passed directly to the pathology department of the hospital where the explantation had been carried out, whence its fate was not known.

The situation is analogous to that of the "sale" of the lenses by the Appellant in the first place, in the sense that the operation was again a 3-cornered affair, only this time involving the patient, the hospital and the surgeon, instead of the Appellant, the hospital and the surgeon. Furthermore, whilst the true owner of the lens to be explanted was by now the patient, the fact that the lens after explantation was passed directly to the pathology department of the hospital, from which there is no evidence that it ever returned, means that the patient was *de facto* never in a position to take "hands-on" possession of the lens, let alone analyse it. This applied to the surgeon also, since he was bound to abide by the policy of the hospital in this respect. Nor was the hospital entitled to pass the details of any analysis of an explanted lens it might have made, to a third party, because the lens was not its property: it belonged to the patient.

Consequently, even in the case of explantation of a

lens, it has not been shown that any member of the public free to communicate the information was ever in a position to analyse the lens.

4.4 Analyzability

As stated above, the subject-matter of the patent in suit is a product prepared by a specified process, in this case the product of cross-linking a specified vinyl-terminated diphenyl-dimethyl or dimethyl-diphenylmethyl polysiloxane of the formula given in Claim 1, with a diorganopolysiloxane having at least 3-hydrosilyl groups in the molecule.

The evidence filed by the Appellant to show that the skilled person would have been able, at the priority date of the patent in suit, to analyse the structure of the SI-20NB lens, without undue burden, to the relevant extent, consists of D12 (Declaration of S. Valenty), D14 (Second Declaration of D. J. Petraitis), and D15 ("The Analytical Chemistry of Silicones", a post-published book) referring to earlier published articles (D16 and D17).

4.4.1 Whilst D16 and D17 explore the application of ^{29}Si solution and solid-state cross polarization/magic angle spinning (CP/MAS) nuclear magnetic resonance (NMR) techniques to the study of structural features, these disclosures show no more than, that, in certain specified cross-linked polydimethyl siloxane systems, spectral peaks could be observed and assigned to relevant specific groups known to be associated with the cross-linking. Thus, whilst certain types of information may be retrievable, there is nothing to indicate that the techniques described would be capable

of elucidating the internal structure of an unknown silicone to the relevant extent. Consequently, neither D16 nor D17 demonstrate that the SI-20NB lenses were analysable at the relevant date.

4.4.2 D15, which was published after the priority date of the patent in suit, is only relevant to the extent that it incorporates the contents of D16 and D17 by reference, the latter being, however, irrelevant for the reasons given (section 4.4.1, above). Consequently, D15 is not able to show that the lenses were analysable.

4.4.3 Nor would the platinum analysis method referred to by D. J. Petraitis in D14 be capable of yielding the structure of an unknown polysiloxane, since platinum is not necessarily used, or used exclusively, for a vinyl-SiH cross-linking reaction. This is, furthermore, corroborated by the contents of the Declaration of Prof. Johnson (D44; page 4). Hence, D14 does not demonstrate that the lenses were analysable at the relevant date.

4.4.4 Finally, the criticism, in the decision under appeal, of the evidence of S. Valenty (D12), that it appeared to provide merely a theoretical way to find out all important structural features of the lens, but that in the light of the analytical report of Toray Research Center (D18) it appeared to be impossible to detect the specific cross-linking agent without having any comparison with authentic samples of the cross-linking agents, has not, in the Board's opinion, been refuted. In particular, the reference to the article by F. Christ (D7) has not been shown to have been published before the priority date of the patent in suit. Consequently, the information it contains would

not have been available to the skilled person at the relevant date. Nor can the reference to "small peaks" in D18 be understood as meaning that the 3-dimensional structure of a previously cross-linked silicone elastomer could, without undue burden, have been elucidated from such secondary information.

4.4.5 Consequently, the evidence on file does not show that a lens SI-20NB sold by the Appellant would have been analysable, with the requisite degree of precision, in the sense required by the relevant case law, at the priority date of the patent in suit, without access to authentic samples as a basis for comparison; the latter, however, amounting to an *ex post facto* analysis technique.

4.5 In summary, the Appellant has failed to establish the identity of a single individual having *de facto* possession of one of the lenses in question, in a position to have the lens analysed, and at the same time at liberty to divulge the results of such an analysis. Even if such an individual had been identified, however, it has not been shown that he would have been able to analyse the chemical composition and structure of the lens, from first principles without undue burden, or indeed at all, using techniques known at the priority date of the patent in suit, to the extent necessary.

5. *Novelty*

Since no other objection of lack of novelty has been raised, beyond that of the alleged prior use of SI-20NB lenses, which has itself failed for the reasons given (section 4 etc., above), the subject-matter of Claim 1

and 6 of the patent in suit is held to be novel.

6. *Inventive step*

The closest state of the art was, by general consent, D19. According to D19, an optically clear, reinforced vulcanised silicone elastomer contains both phenyl and methyl groups in such proportions that the copolymer has a refractive index which matches that of a silica filler. Such a material is suitable for intraocular implants, lenses and, in particular, contact lenses (column 6, lines 4 to 9).

Such an elastomer comprises 80 to 95% by weight of

a. a copolymer comprising
   i. dimethyl siloxane,
   ii. diphenyl siloxane or phenylmethyl siloxane or mixtures thereof, and
   iii. vinyl siloxane;

b. a copolymer comprising
   i. dimethyl siloxane,
   ii. diphenyl siloxane or phenylmethyl siloxane or mixtures thereof, and
   iii. siloxane having $(R)_2HSi$-O- groups or -O-SiHR-O- groups or both, wherein R is methyl or ethyl,

c. 5 to 20% of a silica filler, the refractive index of the copolymer being substantially the same as that of the silica filler (Claim 1).

Preferably, the vinyl groups are terminal groups. Furthermore, according to a pertinent example

(Example 4), a two-part silicone potting resin from General Electric known as "RTV 655" was mixed with fume silica filler so that the final mixture contained 100 parts of Part A, 10 parts of Part B and 11 parts of fume silica filler (by weight). Part A of this resin was a terpolymer of about 0.3 mole % of a vinyl siloxane, about 6 mole percent of diphenyl siloxane, and the remainder dimethyl siloxane. Part A also contained a catalytic amount of organo platinum catalyst. Part B of the above resin was a copolymer that contained about 1 to 2 mole percent $-O-SiH(CH_3)_2$ units, about 6 mole percent diphenyl siloxane and the remainder dimethyl siloxane units. When the part A and B components are mixed immediately prior to use, the platinum compound catalyses a reaction between the vinyl and hydrosilyl groups to form new chemical bonds and ultimately a cross-linked elastomeric mass. This mixture was used to make contact lenses. It was found to have adequate strength and sufficient optical clarity to be useful for contact lenses. The haze of this filled material was barely measurable in sections less than 1 mm thick. Although the phenyl content of "RTV 655" was selected to give optimum flexibility at very low temperatures for other applications, it had sufficient phenyl content to give optical clarity when used with fume silica filler to be comparable to the optical clarity of a hydrogel soft contact lens. Another advantage of "RTV 655" was its commercial availability (column 4, line 40 to column 5, line 7).

6.1 According to D35 filed by the Appellant (a letter dated 13 May 1996 from the Intellectual Property Counsel of General Electric, the manufacturer of "RTV 655", to a member of the firm of Representatives acting for the Appellant), furthermore, the composition of "RTV 655"

silicone elastomer is stated to have a siloxane backbone unit (precure) structure exactly corresponding to the first of the two formulae given in the definition of component (a) in Claim 1 of the patent in suit, and the cross-linking agent to be a siloxane polymer having precisely the definition of component (b) in Claim 1 of the latter.

The probative value of such a letter is regarded as low, since it is neither in the form of a Declaration before the EPO (or indeed any relevant authority), nor supported by any corroborating evidence (beyond the statement in D19 that "RTV 655" is commercially available, which in any case was not in dispute). On the contrary, it amounts to "hearsay" evidence, since it merely records what one person communicated to another. Nevertheless, it has not been commented upon by the Respondent. In other words, its veracity has not been directly challenged. Consequently, and in favour of the Appellant, the Board is prepared to consider its content in relation to the disclosure of D19 to the extent that it might accurately reflect the facts.

6.2 As regards the properties of the contact lens according to Example 4, account must, however, equally be taken of the evidence filed by the Respondent in the form of two Declarations and a Response (D45, D46 and D47, respectively) to an Official Action before the USPTO in relation to the prosecution of another patent application (US serial No. 870799 of 17 April 1992) resulting in the grant of US-A-5 236 970, of which the present Appellant is the assignee.

6.2.1 According to D45, which is a Declaration by D. J. Petraitis, the optical refractive index of the

composition of Example 4 of D19 (also cited in those proceedings) would have been approximately 1.40, which was too low for an intraocular lens. This was associated with the low content of phenyl groups (around 6 mole percent).

6.2.2 Furthermore, according to D46 (also a Declaration by D. J. Petraitis), a re-working of Example 4 of D19 yielded a cured product which, though having sufficient physical strength was hazy or cloudy, and did not have the optical clarity appropriate for use as an intraocular lens material (Declaration, page 5).

6.2.3 Finally, the Response (D47) states that D19 neither suggests, contemplates nor recognises an intraocular lens body which is foldable for insertion (page 4), nor provides any motivation or incentive for obtaining an foldable/unfoldable intraocular lens (page 6), but on the contrary teaches materials having very high levels of tensile strength and tear strength (passage bridging pages 5 and 6).

6.2.4 This evidence is considered to be of higher probative value than that represented by D35, since both the Declarations D45, D46 and the response D47 have been made before the USPTO, where there are legal penalties provided for giving misleading or incomplete information. Furthermore, the Declarant is D. J. Petraitis, who has already made two Declarations on behalf of the Appellant in the present case. In the absence of any challenge to this evidence, the Board is prepared to accept it at face value.

6.3 In summary, D19 is deemed generally to disclose optically clear filled silicone elastomers formed of

aryl and alkyl siloxanes useful for soft contact or intraocular lenses (Claims 1, 5; column 6, lines 4 to 9) and to exemplify a silica filled contact lens having an elastomer of two polymers, possibly corresponding to components (a) and (b) in Claim 1 of the patent in suit. Such a contact lens does not, however, have a sufficiently high refractive index, or sufficient optical clarity for use as an intraocular lens material. It is not disputed that D19 neither implicitly nor explicitly discloses a UV absorber.

6.4 In view of the above, the technical problem arising from the exemplary disclosure of D19 is the search for one or more modifications providing a different spectrum of properties appropriate for a more sensitive and demanding sphere of utilisation.

The solution proposed by Claim 1 and/or Claim 6 of the patent in suit is (i) to increase the refractive index of silicone elastomer to a level appropriate for an intraocular lens; (ii) to add a UV absorber, and (iii) to form the product as a soft intraocular lens, omitting, if desired, the silica filler, and thus accepting a certain loss of tensile and tear strength, at the same time rendering the lens foldable for insertion through a small incision in the eye.

6.5 It has not been disputed that the patent in suit describes and exemplifies polysiloxane elastomer products (both with and without fillers), which have suitable optical and mechanical properties for use as a soft intraocular lens having a UV absorption close to that of the human lens. Consequently, the Board finds it credible that the claimed measures provide an effective solution of the stated problem.

6.6 The disclosure of D19

6.6.1 Whilst D19 mentions the possibility of using the reinforced polysiloxane elastomers as intraocular implants, it does not exemplify such an application. Thus the use as an intraocular lens is directly associated only with a silicone composition as broadly defined in D19, for instance in Claim 1 of that document. To this extent, the finding, in the decision under appeal, that the siloxane elastomer according to the patent in suit differed in requiring, for component (a), vinyl groups which were in the terminal position, and in relation to component (b), a cross-linker containing at least three hydrosilyl groups, was justified. In any case, there is no indication in the general definition of the silicone elastomer according to D19 that the vinyl groups be dimethylvinyl siloxane groups, as required by the solution of the technical problem. Yet, according to the uncontested submission of the Respondent, the dimethyl environment of the vinyl is an important requirement for the desirable properties of the intraocular lenses according to the patent in suit (submission of 6 February 1997, page 6). Consequently, there is no direct association, in D19, of intraocular lenses with a silicone elastomer including components of the structure (a) and (b) according to the patent in suit.

6.6.2 In particular, there is no association of such an intraocular lens with the "RTV 655" two pot composition according to Example 4. Even if the skilled person were nevertheless to start from the contact lens according to Example 4 and adapt it for intraocular use, further assuming the evidence of D35 to be correct (section 6.1, above), there is no hint to increase the

refractive index above what is disclosed in the relevant example. On the contrary, it is an essential requirement of the teaching of D19 that the refractive index be matched to that of the silica filler. Hence, the skilled person would be restrained from making modification (i) of the solution of the technical problem.

6.6.4 Nor is there any mention of a need to improve the UV absorbency of such a lens, let alone to add a UV absorber. On the contrary, in a contact lens, which is additional to and not in replacement of, the eye's natural lens, there is no immediate need for further protection of the retina from UV radiation. Consequently, there is no hint to make modification (ii) of the solution of the technical problem.

6.6.5 Finally, according to the uncontested evidence of the Respondent (D47), the lens according to Example 4 of D19 is too hard to be used as a foldable intraocular lens. There is, however, no hint to accept a certain reduction in strength of the lens in order to provide the mandatory foldability.

6.6.6 In summary, the skilled person starting from D19 and attempting to refine the lens therein to meet the more demanding requirements associated with intraocular use, would need to make a selection of a particular composition (that of Example 4) not especially identified for this purpose, and then modify this composition in three respects, none of which is suggested by, and two of which contradict, the explicit and implicit teachings ((i) and (iii)), respectively, of D19.

Consequently, there is no hint to the solution of the technical problem in the disclosure of D19.

6.7 Nor do any of the other documents relied upon by the Appellant assist the skilled person to the solution of the stated problem. This applies in particular to D6 (the report of intraocular lens explantation), since, in view of the finding under "novelty" (section 5., above), the latter does not make available the composition of the explanted lens.

6.7.1 Whilst the Appellant has strongly argued, on the basis of DD-A-249 030, referred to in the European Search report, that the addition of a UV absorber to a silicone IOL would be an obvious step to take this concerns a silicone elastomer composition more remote than that according to D19.

6.7.2 If this argument was accepted, therefore, this would lead the skilled person to use as silicone elastomer even more remote from that forming the solution of the technical problem (section 6.6.6, above).

6.7.3 It has in any case been established that there is no hint to the choice of the relevant silicone elastomer.

Consequently, the solution to the technical problem does not arise in an obvious way, starting from D19.

6.8 It is, furthermore, evident from the examples and comparative examples of the patent in suit, that known soft silicone lenses, made of polydimethyl siloxane did not lend themselves to the addition of relevant quantities of UV absorber, since such compounds were difficultly soluble in poly dimethylsiloxane (patent in

suit, page 2, lines 43 to 46). In particular, according to Comparative Example 2, an IOL made of polydimethyl siloxane, to which a benzotriazole-type UV absorber had been added (0.14 parts by weight) was cloudy and not transparent. Consequently, it is not self-evident to add a UV absorber to a silicone elastomer intraocular lens.

It is regarded as all the more surprising, therefore, that a polydimethyl/phenyl siloxane lens according to the patent in suit and containing the same additive in the same proportion has unexceptionable optical properties (Example 5; Table 1, page 10). Furthermore, a lens having a UV absorbency close to that of the human eye can evidently be obtained with the addition of very small amounts of UV absorber, since the latter turn out to have improved solubility in the silicones according to the patent in suit (page 11, lines 33 to 36). The validity of these comparisons has not been challenged by the Appellant.

In other words, the solution of the technical problem results in an unexpected technical effect.

6.9 It follows from the above, that the subject-matter of independent Claims 1 and 6, and therefore that of the associated dependent Claims 2 to 5 and 7 to 12, involves an inventive step within the meaning of Article 56 EPC.

7. In the absence of further requests by the Appellant, the appeal must consequently fail.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

E. Görgmaier C. Gérardin