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D E C I S I O N
of 14 March 2000

Case Number: T 0868/96 - 3.3.2

Application Number: 89903277.5

Publication Number: 0359829

IPC: A61L 27/00

Language of the proceedings: EN

Title of invention:

Process for producing intraocular lens for correcting cyanopia

Patentee:

HOYA CORPORATION

Opponent:

Alcon Laboratories Inc.

Headword:

Correcting Cyanopia/HOYA

Relevant legal provisions:

EPC Art. 56

Keyword:

"Main request - first, second and third auxiliary request"
"Inventive step - no - obvious choice of a yellow colorant and
obvious use of a UV-absorber in minimum amounts"
"synergistic effect denied"

Decisions cited:

T 0182/89

Catchword:

-



Case Number: T 0868/96 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 14 March 2000

Appellant: HOYA CORPORATION
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Decision under appeal: Decision of the Opposition Division of the
European Patent Office posted 29 August 1996
revoking European patent No. 0 359 829 pursuant
to Article 102(1) EPC.

Composition of the Board:

Chairman: C. Germinario
Members: U. Oswald
R. E. Teschemacher

Summary of Facts and Submissions

- I. European patent No. 0 359 829 with the title "process for producing intraocular lens for correcting cyanopia" was granted with a set of nine claims in response to European patent application No. 89 903 277.5.
- II. Opposition was filed against the granted patent by the Respondent on the grounds of lack of novelty and lack of inventive step under Article 100(a) EPC and for insufficiency of disclosure of the invention under Article 100(b) EPC.

Of the numerous documents cited during the proceedings the following remain relevant to the present decision:

(5a) "Colour Index", Third Edition (1982), "Pigments And Solvent Dyes", Information Compiled from Volumes 2-7 of the Complete Third Edition (Second Revision: 1982), Published by The SOCIETY OF DYERS AND COLOURISTS", page 162.

(6) WO-A-87/05797

(7) US-A-4390676

EP-A-259 532 (cited under Article 54(3) EPC in the specification)

The Opposition Division took the view that document (7) represented the closest prior art because of the fact that it related to a casting process for making polymethyl methacrylate lenses in order to restore the original spectral distribution of the light striking

the retina of aphakic individuals. Since the lenses according to document (7) removed excessive blue light between 350 nm and 400 nm, this prior art also solved the problem of cyanopia.

Since furthermore document (7) taught that dyes other than those used in the examples might be employed for manufacturing intraocular lenses with the desired absorption characteristics, it was obvious to use alternative yellow dyes correcting cyanopia.

Having regard to the fact that document (7) also disclosed the use of a crosslinker in the polymerization process, an auxiliary request relating to such a process was regarded obvious over the prior art.

III. The Appellant (proprietor of the patent in suit) lodged an appeal against the said decision and filed grounds of appeal. Annexed to a letter dated 14 February 2000, the Appellant filed a main request and three auxiliary requests.

Claim 1 of the main request reads as follows:

"A process for producing a cyanopsia-correctable intraocular lens having a light absorption characteristic close to that of human crystalline lens, by monomer cast polymerization, which process is characterized by comprising steps of casting into a mould a monomer solution comprising at least one monomer capable of forming a transparent lens material upon polymerization, a yellow colorant as the sole colorant, an UV-absorber and a polymerization initiator; sealing the mould; and effecting

polymerization."

According to the first auxiliary request, claim 1 additionally relates to "...a yellow colorant as the sole colorant in an amount of 0.01 to 0.03% (W/V) based on the total monomer content...".

Claim 1 of the second auxiliary request further defines "...an UV-absorber in an amount of 0.03 to 0.05% (W/V) based on the total monomer content...".

In accordance with the wording of claim 1 of the main request, claim 1 of the third auxiliary request does not contain the amounts of yellow colorant and UV-absorber but contains additionally a definition of the colorant in that "...said yellow colorant being at least one member selected from the group consisting of C.I. Solvent Yellow 16, C.I. Solvent Yellow 29, C.I. Solvent Yellow 56, C.I. Solvent Yellow 77 and C.I. Solvent Yellow 93...".

IV. Oral proceedings took place on 14 March 2000, during which the Appellant filed a new main request and a new first auxiliary request both including claims 1 to 8 having the wording of the requests annexed to the letter dated 14 February 2000 but lacking product claim 9 relating to a cyanopia correctable intraocular lens produced by a process according to any of claims 1 to 8.

V. During the oral proceedings the Appellant has sought to introduce a fourth auxiliary request relating to the use of an intraocular lens for correcting cyanopia. This request was not admitted into the proceedings since the Board regarded it as not clearly allowable

under Article 52(4) EPC.

VI. As regards the disclosure of document EP-A-0 259 532 referred to in the patent specification and relevant to the question of novelty under Article 54(3) EPC, the Appellant argued that this prior art clearly described a separate prepolymerization step whereas the process of the patent in suit by the wording "sealing the mould and effecting polymerization" excluded a two step polymerization process in which the prepolymer was transferred from one reactor to another between the polymerization steps.

For the discussion of inventive step, the Appellant accepted document (7) as representing the closest prior art but argued that this document neither related to the correction of cyanopia nor disclosed visible light absorbing dyes as an essential component of intraocular lenses, nor described a lens with a yellow colorant as the sole colorant.

In the Appellant's view the problem underlying the patent in suit was to produce an intraocular lens having a light absorption characteristic which in comparison with the lens of document (7) comes closer to that of human crystalline lens and being effective for correcting of cyanopia.

More particularly it was argued that in comparison with the lens material of the patent in suit the test samples of document (7) showed very low transmission values at 400 nm wave length and that document (7) contained the clear teaching to use high amounts of UV-absorbers.

Having regard to the "Experimental Report" annexed to the letter dated 12 August 1998, it was proven by one of the co-inventors of the patent in suit that the light transmittance curve of the lens disclosed in Example 1 of document (7) has a large concave portion at 480 to 550 nm with the minimum point c at around 510 nm, and as a result, it is different from that of a human crystalline lens and it has a light transmittance value of less than 70% at a wavelength range of 480 to 550 nm.

The presence of a UV-absorber and a yellow colorant as the sole colorant according to the patent in suit gave rise to a synergistic effect and as a result the lens material of the patent in suit showed low transmittance values within the wavelength range relevant for correcting cyanopia, and as a further advantage the lens material contained very low UV-absorber amounts which was important to minimizing leakage of toxic components. The low amounts of components to be included in the lens material were reflected by the additional features of the first and second auxiliary requests and could be regarded as further supporting the inventiveness of the claimed subject matter of the patent in suit.

Having regard to the disclosure of document 5(a), it was clear that the group of 5 specific yellow colours as defined in claim 1 of the third auxiliary request represented an inventive selection out of a group of about 100 yellow colours known in the art.

It was accepted that document (6) related to an intra-ocular implanted lens but having a yellowish brown colour, and that this prior art neither related to

specific colours for a light absorption characteristic close to that originally possessed by human crystalline lenses nor disclosed amounts of colours.

- VII. In the Respondent's view the limitation in the process claims to the use of "a yellow colorant as the sole colorant" was a selection out of a list of colorants not disclosed in the application as originally filed and therefore, each of the requests did not fulfil the requirements of Article 123(2) EPC.

As regards the question of novelty, the Respondent disputed that a process step characterized by the wording "sealing the mould and effecting polymerization" could be regarded as excluding a prepolymerization step as disclosed in EP-A-0 259 532.

Taking into account document (7) as the closest prior art, the Respondent agreed that this document did not expressly mention cyanopia but argued that the reference in this document to intraocular lenses and to the problem of avoiding a lack of visual acuity and high chromatic aberration in aphakic individuals could only be regarded as an alternative description of a lens for correcting cyanopia.

In the Respondent's view there was no support in the prior art for a wavelength of 400 nm as the only critical value for deciding on the effectiveness of a lens for correcting cyanopia. Moreover, there was neither proof for a synergistic effect resulting from the use of a yellow colorant and a UV-absorber nor experimental evidence that the alleged advantage of low transmittance was achieved over the whole spectrum of the crystalline lens of a human eye and accordingly, in

the light of the disclosures of document (7) and also (6), it was an obvious alternative to choose yellow as the sole colorant for a cyanopia correcting lens.

Regarding the auxiliary requests, the Respondent argued that there was no surprising effect from using the claimed amounts of colorant and UV-absorber and that document (5a) particularly showed the obviousness of using C.I. Solvent Yellow 93 together with polymethacrylate plastics.

VIII. The Appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of the set of claims according to the main request as submitted during the oral proceedings.

Alternatively, it was requested to maintain the patent on the basis of one of the following sets of claims:

First auxiliary request as submitted during the oral proceedings, second or third auxiliary request as submitted with letter dated 14 February 2000, fourth auxiliary request as submitted during the oral proceedings.

The Respondent requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

Disclosure of the invention

2. The objection under Article 100(b) EPC in the statement

setting out the grounds of opposition regarding insufficiency of disclosure in relation with the use of a specific colorant for correcting cyanopia was merely alleged but not founded on any fact and the Respondent did not substantiate the grounds of insufficiency of disclosure during the appeal proceedings. As already ruled in decision T 182/89 (OJ EPO, 1991, 391), if a notice of opposition contains allegations as to grounds of opposition which are not supported as required by Rule 55(c) EPC, such allegations are to be rejected on the same basis as if they were inadmissible under Rule 56(1) EPC.

Since the specification of the patent in suit contains on page 5, lines 10 to 19 a long list of specific colorants which are undisputedly suitable for correcting cyanopia, the Board sees no reason to discuss this matter further.

Amendments

3. The description of the patent application as originally filed (see page 8, second paragraph) and as granted (see page 5, line 20) clearly indicate that the colorants specified in the preceding paragraphs of the description "can be used alone". Moreover, each of the examples of the patent application originally filed and as granted relates to the use of "a yellow colorant as the sole colorant" in a process for producing a cyanopia-correctable intraocular lens. Accordingly, the feature in claim 1 of each of the requests now on file "a yellow colorant as the sole colorant" does not contravene Article 123(2) EPC.

The Board notes that the Respondent made no objections

under Article 123 EPC as to the remaining features of claims according to the requests now on file.

The Board is also satisfied that each of the other features according to the claims of the requests now on file have a basis in the patent application as originally filed and as granted and the claimed subject matter is not amended in such a way as to extend the protection conferred.

Accordingly, the Board considers that the requirements of Article 123(2) and (3) are satisfied.

Novelty

4. In the Board's view it is questionable whether the wording "casting into a mould a monomer solution....; sealing the mould, and effecting polymerization" clearly excludes the teaching of document EP-A-0 259 532, which document is relevant to the question of novelty under Article 54(3) EPC for claims 1 of the main request and first auxiliary request.

However, it appears at least from Example 1 of document EP-A-0 259 532 that this prior art relates to a polymerization process in which the prepolymerization step and the final polymerization step are carried out in different recipients.

Having regard to the outcome of the proceedings as to the question of inventive step, the Board has decided to **presume novelty** of the process of the main request and first auxiliary request by excluding a polymerization of the monomer solution in two steps in

different recipients.

The Respondent did not raise any further objections under Article 54(1) EPC and having regard to the disclosure of each of the other documents cited during the examination, opposition and appeal proceedings the Board is satisfied that none of these documents destroys the novelty of the subject matter of the claims of the main request as well as that of the first to third auxiliary request.

5. *Main request - inventive step*

- 5.1 It was undisputed by the parties that document (7) represented the closest prior art.

This document relates more generally to suitable lenses which restore the normal elements of vision for aphakic individuals. Intraocular lenses, which are implanted in the interior of the eye are inter alia described as suitable for correcting the vision of aphakics. Reference is made particularly to the problem of adequately compensating for certain changes in light transmission which occur in the absence of the natural human crystalline lens since the result is a lack of visual acuity and high chromatic aberration in aphakic individuals. While the examples only relate to the preparation of corneal contact lenses, it is clearly indicated that the disclosure of document (7) is also applicable to intraocular lenses (see column 1, lines 55 to 57, 21 to 30 and column 2, lines 10 to 14).

According to Example 1 a corneal contact lens is prepared from the following formulation:

Methyl methacrylate	95	Parts by Weight
Ethyleneglycol dimethacrylate	5	
Bisazoisobutyronitrile	0.2	
2,2'-dihydroxy-4,4'-dimethoxy- benzophenone (UV-absorber)	0.1	
D&C Red #17	0.002	
D&C Yellow #11	0.004	

All the components of the formulation are mixed and the mixture poured into glass test tubes of about 3/4 inch diameter. The tubes are then placed in an 80°F (26.67°C) bath until the mixture solidifies. The test tubes are then transferred to an oven and subjected to increasing temperatures reaching a maximum of 105°C. The test tubes are then removed from the oven, allowed to reach room temperature, and the glass broken leaving polymerized plastic rods. Plastic discs are sliced off the rods and the discs converted into corneal contact lenses (see columns 5/6).

Document (7) does not refer to cyanopia as a cause of chromatic aberration in aphakic individuals.

5.2 Taking account of the aforementioned content of document (7), it was undisputed by the parties that this closest prior art disclosed each of the **process features** of claim 1 of the main request except that the monomer solution to be casted into a mould - "the mixture poured into glass test tubes" as it is expressed in document(7) - comprises a yellow colorant as the sole colorant.

5.3 In accordance with the description of the patent in suit the Appellant took the view that the skilled person knowing the disclosure of document (7) is faced

with the problem to produce an intraocular lens having a light absorption characteristic which comes closer to that of the human crystalline lens and being effective for correcting cyanopia (see eg specification page 4, lines 18 to 20). In order to support this point of view, on 12 August 1998, the Appellant has filed an "Experimental Report" including Figure 1 showing the spectral distribution between 350 nm and 650 nm of light transmittance values of a lens of Example 1 of document (7), a lens according to the invention and a human crystalline lens.

- 5.4 During the oral proceedings the Board invited the parties to give, in addition to the phenomenological explanations regarding the spectral distribution of light transmittance according to the "Experimental Report", a more detailed mathematical explanation about the curves representing the transmittance values of the test lenses, which, however, was not provided by the Appellant.
6. In the absence of mathematical calculations **quantifying** the relationship and correlation between the transmittance curves illustrated in Figure 1 of the said "Experimental Report", there is no basis for the conclusion that, expressed in absolute terms, the spectral distribution of the lens according to the patent in suit comes **closer** to the spectral distribution of the human crystalline lens **than** the lens according to the closest prior art from document (7).

Therefore, the Board can accept as experimental evidence only the overall shape of the transmittance curves and as a consequence, the problem underlying the

patent in suit according to the main request can only be seen in the provision of a process for producing a intraocular lens being effective for correcting cyanopia.

7. According to claim 1 of the main request the solution of the problem is the provision of a process for producing a cyanopia-correctable intraocular lens with a yellow colorant as the sole colorant.

Having regard to the worked examples of the patent in suit and Figure 1 referred to under point 5.3 above, the Board is satisfied that the problem has been plausibly solved.

The Respondent did not contest the light transmittance curve of the human crystalline lens according to Figure 1.

8. It therefore remains for the Board to decide whether or not the said solution would, in view of the citations, have been obvious to a person skilled in the art faced with the problem defined above.

- 8.1 Document (7) relates to chromatic aberrations in aphakic individuals in general and therefore the teaching of this document a priori envisages an unspecified correction of colour sight defects. The skilled person, however, knows that among aphakic eye patients cyanopia is a condition of chromatic aberration in which objects look bluish.

In these circumstances the skilled person clearly will regard the process steps for producing chromatic aberration correctable lenses according to document (7)

also suitable for producing a cyanopia-correctable intraocular lens.

Once the skilled person's attention is drawn to the process of document (7) the skilled person will first of all try to reduce the unwanted blue light reaching the retina by using a blue light absorbing dye. Since document (7) relates to an unspecified correction of colour sight defects there is a further incentive to change the colour mixture of the lens proposed in (7) by one specific blue absorbing colour. The skilled person undoubtedly is aware of the fact that yellow is a complementary colour to blue. The physical background of complementary colours belongs even to elementary school knowledge. Accordingly, the skilled person's **first choice** for weakening blue light on the retina is yellow.

8.2 Document (6) also relating to intraocular lenses gives confirmation for the aforesaid common general knowledge in the field of correcting chromatic aberrations in aphakic individuals. Moreover, this document clearly indicates that, caused by a natural ageing process, the human crystalline lens is yellow coloured, and proposes the production of an intraocular lens which by maintaining the transparency is adapted to the colour of the aged but healthy eye (see document (6), page 1, line 20 up to page 2, line 3).

8.3 In the end the Board can only conclude that the skilled person would arrive at the subject matter of claim 1 of the main request without the exercise of inventive skill.

9. *First and second auxiliary request - inventive step*

9.1 These requests define the amounts of yellow colorant and UV-absorber (see point IV above).

9.2 It was undisputed by the parties that document (7) also represented the closest prior art for the subject matter of these requests.

In the Board's view it is within the competence of the skilled person, in an attempt to reduce to practice for correcting cyanopia the general teaching of correcting chromatic aberrations in aphakic individuals of document (7), to introduce minor experimental modifications, which are not expected to affect the desired results but which may be justified by purely practical considerations such as the economics of reducing the technical teaching into practice or the safety of the finished product. Determining the lowest amounts of a used substance which still achieves the desired effect is indeed one of those activities which the skilled person usually performs without an inventive effort.

Indeed there is no evidence that **in comparison with the closest prior art** according to document (7) only the amount of 0.01 to 0.03% (W/V) of a yellow colorant and **any type of** a UV-absorber in amounts of 0.03 to 0.05% (W/V) results in better transmittance values of the intraocular lens produced therefrom.

9.3 There is also no evidence for the Appellant's alleged synergism of a yellow colorant alone and a UV-absorber.

9.4 Accordingly, the amounts of yellow colorant and UV-absorber of claim 1 of the first and second auxiliary requests do not change the problem as stated

under point 6 above.

- 9.5 Since document (6) clearly indicates that a leakage of the components of the lens material, for example the colorant and particularly the UV-absorber could cause toxic reaction in the eye (see page 2 last paragraph), the skilled person will try to use minimum amounts of these components.
- 9.6 Since the reasoning for the rest of the features of claim 1 of the first and second auxiliary requests remains the same as set out under point 8.ff above, the Board can only conclude that the subject matter of these requests also do not involve an inventive step.
10. *Third auxiliary request - inventive step*
- 10.1 It was undisputed by the parties that document (7) also represented the closest prior art for the subject matter of this request.
- 10.2 Claim 1 of this request does not specify the amounts of colorant and UV-absorber but specifies types of yellow colorants. Therefore, in addition to the reasoning above for the main request, for the third auxiliary request it only remains to consider whether or not it was obvious to choose a specific type (types) of yellow colorant(s).
- 10.3 Once it is obvious to choose a yellow colorant as the sole colorant in a process for producing a cyanopia-correctable intraocular lens (see points 5 to 8 above), the skilled person when trying to put the said process into practice will first of all look at commercially available types of yellow colorants.

10.4 Document (5a) discloses in the form of a colour index more than a hundred C.I. Solvent Yellow colorants. On page 162 of this document reference is made to C.I. Solvent Yellow 93 as being especially suitable for polymethacrylate plastics. The Board notes that C.I. Solvent Yellow 93 is cited in claim 1.

10.5 According to the closest prior art as described in document (7), particularly Example 1, the lens is also prepared from methyl methacrylate, the same material as particularly preferred in the patent in suit.

The Board notes furthermore, that the patent in suit as originally filed on page 7 and the description of the patent in suit as granted on page 5, lines 10 to 20, disclose a long list of yellow colorants, inter alia C.I. Solvent Yellow 33 (undisputedly corresponding to D&C Yellow #11 used in Example 1 of document (7)) and C.I. Solvent Yellow 93, all suitable to combine with methyl methacrylate solutions. In the same context the patent in suit clearly indicates that the yellow colorants are not restricted to the species contained in the said list.

10.6 In the absence of any unexpected novel technical effect achievable by the use of C.I. Solvent Yellow 93 or any other cited in claim 1, the Board can only conclude that the use of these colorants must be regarded as an obvious alternative to the use of other equivalent yellow colorants, for example C.I. Solvent Yellow 33, and in no way can be regarded as a selection invention.

Accordingly, claim 1 does not involve an inventive step either.

11. Since at least one independent claim in each of the requests fails to meet the requirements of Article 56 EPC, there is no need to discuss the rest of the claims forming the basis for the requests.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

M. Dainese

C. Germinario