

PATENT COOPERATION TREATY

Translation

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Applicant's or agent's file reference 25 PA 03001		Date of mailing (day/month/year)
International application No. PCT/EP2004/002889		International filing date (day/month/year) 19.03.2004
International Patent Classification (IPC) or both national classification and IPC		Priority date (day/month/year) 21.03.2003
Applicant MÜLLER, Klaus		

FOR FURTHER ACTION
See paragraph 2 below

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/EP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I

Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
 a sequence listing
 table(s) related to the sequence listing
 - b. format of material
 in written format
 in computer readable form
 - c. time of filing/furnishing
 contained in the international application as filed.
 filed together with the international application in computer readable form.
 furnished subsequently to this Authority for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. II Priority

1. The following document has not yet been furnished:

copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

the entire international application

claims Nos. 2, 3, 20

because:

the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

no international search report has been established for said claims Nos. 2, 3, 20

the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form has not been furnished
 does not comply with the standard

the computer readable form has not been furnished
 does not comply with the standard

the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

See Supplemental Box for further details.

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Box No. IV Lack of unity of invention

1. In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:
- paid additional fees
 - paid additional fees under protest
 - not paid additional fees
2. This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- complied with
 - not complied with for the following reasons:
 - 1. Despite a request by the search department, no additional fees have been paid, which means that a search report is only available for the 1st invention (**claim 1 and claims 4-19**). This opinion therefore also only covers the subject matter of the searched claims.
4. Consequently, this opinion has been established in respect of the following parts of the international application:
- all parts
 - the parts relating to claims Nos. 1, 4-19

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Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement	Novelty (N)	Claims <u>1-19</u>	YES
		Claims _____	NO
	Inventive step (IS)	Claims _____	YES
		Claims <u>1-19</u>	NO
	Industrial applicability (IA)	Claims <u>1-19</u>	YES
		Claims _____	NO
<p>2. Citations and explanations:</p> <p>1. Document D1=WO96/15734 (member of the same family as document EPO793460B), which describes an intraocular, accommodatively moveable implant for insertion in the capsular bag of an eye (D1: Title; Fig. 1, BZ 12 in BZ 16) having at least one lens (BZ14) and at least one first and one second transmission element(BZ 22) is considered to be representative of the closest prior art.</p> <p>The at least one transmission element with one terminal zone each (Fig. 6B, last member before BZ 24), in which the flexible (page 8, lines 9 and 14-15) transmission elements (BZ 22) designed for independent centring (Fig. 2A, 2B) have a terminal zone (page 10, lines 1-7) designed to be in contact with the capsular bag and to receive the force from the capsular bag and an angle of incidence between a lens plane and an action plane extending through a transmission element and its terminal zone (Fig. 6B) is defined.</p> <p>2. The subject matter of claim 1 therefore differs from the prior art in that</p> <p style="margin-left: 20px;">[a] the contact with the capsular bag and the reception of force from the capsular bag occur directly (not via ring BZ 24) and in that</p> <p style="margin-left: 20px;">[b] the terminal zone of the at least one transmission element is offset in its entirety in a direction posterior to the lens in a rest position of the implant.</p> <p>3. Feature [a] can at most be considered to be an equivalent and obvious alternative. If ring BZ 24 is defined as part of the terminal zone in D1, the feature is actually anticipated by D1. Nor can making the terminal zone posteriorly offset in relation to the lens in the said zone's rest position be regarded as an inventive step, especially as accommodation is also to occur as a result of an anterior movement along the optical axis (e.g. see Fig. 6A, 6B), which is to be facilitated as a result. Because these two features do not cause any unexpected effect even in combination, the subject matter of claim 1 cannot be regarded as an inventive step (PCT Article 33(3)).</p> <p>4. Because the subject matters of the following dependent claims are already known from D1, no inventive input of any kind is necessary to retain these features:</p> <p style="margin-left: 20px;">Claim 4: Elastic modulus of the material for transmission elements differs from that of the lens material (page 35, lines 13-18)</p> <p style="margin-left: 20px;">Claim 5: Transmission elements are haptics that extend in an arcuate manner from the lens with radial and axial suspension (Fig. 2A, 2B)</p> <p style="margin-left: 20px;">Claim 19: The lens forms an optics system with a second lens inserted in the capsular bag (Fig. 12)</p>			

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

5. The subject matters of **claims 6** (no bending of the transmission elements in the rest position without the action of force), **7** and **8** (lens mounting integral with transmission elements, whereby it is then obvious that the mount must include a hinge for connecting the haptics because of the accommodation movement, see for example **D2=:EPO337390A Fig. 1), 9-11** (bearing surfaces, see **D3=: USA4790847A Fig. 10), 12-17** (clamping to the capsular bag, see for example **D4=: WO99/29266A Fig. 57-59**) and **18** (second lens filled with gel, see **D5=: EPO493090A column 8, lines 15-49**) will be considered to be obviously possible or at least implied by the prior art without special technical effects.

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Box No. VI	Certain documents cited								
1.	<p>Certain published documents (Rule 43<i>bis</i>.1 and 70.10)</p> <table style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width: 35%; text-align: center; border-bottom: 1px solid black; padding: 2px;">Application No. Patent No.</th> <th style="width: 20%; text-align: center; border-bottom: 1px solid black; padding: 2px;">Publication date (day/month/year)</th> <th style="width: 20%; text-align: center; border-bottom: 1px solid black; padding: 2px;">Filing date (day/month/year)</th> <th style="width: 25%; text-align: center; border-bottom: 1px solid black; padding: 2px;">Priority date (valid claim) (day/month/year)</th> </tr> </thead> <tbody> <tr> <td style="padding: 5px; text-align: center;">WO2004/004606</td> <td style="padding: 5px; text-align: center;">15.01.2004</td> <td style="padding: 5px; text-align: center;">30.06.2003</td> <td style="padding: 5px; text-align: center;">03.07.2002</td> </tr> </tbody> </table> <p style="margin-top: 20px;">An accommodative intraocular lens with transmission elements for implantation in the ocular bag is described (see for example Figures 10-15)</p>	Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)	WO2004/004606	15.01.2004	30.06.2003	03.07.2002
Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)						
WO2004/004606	15.01.2004	30.06.2003	03.07.2002						
2.	<p>Non-written disclosures (Rule 43<i>bis</i>.1 and 70.9)</p> <table style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width: 40%; text-align: center; border-bottom: 1px solid black; padding: 2px;">Kind of non-written disclosure</th> <th style="width: 25%; text-align: center; border-bottom: 1px solid black; padding: 2px;">Date of non-written disclosure (day/month/year)</th> <th style="width: 35%; text-align: center; border-bottom: 1px solid black; padding: 2px;">Date of written disclosure referring to non-written disclosure (day/month/year)</th> </tr> </thead> <tbody> <tr> <td style="height: 150px;"></td> <td></td> <td></td> </tr> </tbody> </table>	Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)					
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Box No. VII **Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

1. Although the independent claim has been duly drafted in the two-part form, it does not meet the requirements according to **PCT Rule 6.3(b)**, according to which all the features known from the closest prior art (see **D1**) are to be included in the preamble [see **PCT guidelines PCT/GL/3 III, 2.3a**].

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Box No. VIII **Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. The subject matter of **claim 6** relates to the eye (“outside the eye”), which cannot be claimed as part of a technical invention. Presumably “without external force” is meant.
2. Because the “mount” is only listed in **claim 7**, **claim 8** should only relate to **claim 7**.

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**

Continuation of:

BOX III

1. Neither a search nor a substantive examination can be carried out for the method according to **claim 20** because it comprises a method for the **treatment** of the animal or human body. In particular, if it performs the method of **claim 20**, the implanted lens is intended to achieve the fullest possible visual rehabilitation of a cataract patient (see **description page 1, line 15**).