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**Datasheet for the decision  
of 4 May 2018**

**Case Number:** T 2675/16 - 3.2.08

**Application Number:** 11162125.6

**Publication Number:** 2353546

**IPC:** A61F2/16, A61F9/00, A61B8/10

**Language of the proceedings:** EN

**Title of invention:**  
Toric lenses alignment using pre-operative images

**Patent Proprietor:**  
Novartis AG

**Opponent:**  
Abbott Medical Optics Inc.

**Headword:**

**Relevant legal provisions:**  
EPC Art. 100(c)  
EPC R. 103(1)(a)  
RPBA Art. 12(4)

**Keyword:**

Grounds for opposition - extension of subject-matter (yes)  
Substantial procedural violation - reimbursement of appeal fee  
(no)  
Late-filed evidence - submitted with the statement of grounds  
of appeal - admitted (yes)  
Late-filed request - request withdrawn before the opposition  
division

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**  
**Boards of Appeal**  
**Chambres de recours**

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Case Number: T 2675/16 - 3.2.08

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.08**  
**of 4 May 2018**

**Appellant:**  
(Patent Proprietor)

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(Opponent)

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**Decision under appeal:**

**Decision of the Opposition Division of the  
European Patent Office posted on 17 October 2016  
revoking European patent No. 2353546 pursuant to  
Article 101(3) (b) EPC.**

**Composition of the Board:**

**Chairwoman** P. Acton  
**Members:** C. Herberhold  
Y. Podbielski

## **Summary of Facts and Submissions**

- I. By decision posted on 17 October 2016 the opposition division revoked European patent No. EP-B-2353546 on the ground of Article 100(c) EPC.
- II. The appellant (patent proprietor) lodged an appeal against that decision in the prescribed form and within the prescribed time limit.
- III. Oral proceedings before the Board were held on 4 May 2018.

At the end of the oral proceedings the requests of the parties were as follows:

The appellant requested that the decision of the opposition division be set aside and the case be remitted to the opposition division for further prosecution. As an auxiliary measure, the appellant requested that the decision be set aside and the patent be maintained on the basis of the main request filed with letter dated 29 March 2018, or of the patent as granted (now renamed auxiliary request 1) or of one of auxiliary requests 1-5, and 7-11 filed with letter dated 19 August 2016, now renamed auxiliary requests 2-11.

The appellant furthermore requested that the appeal fee be reimbursed because of a substantial procedural violation during the opposition proceedings.

The respondent requested that the appeal be dismissed.

IV. The independent claims of the main request read as follows:

Claim 1:

"A computer-implemented method for generating a placement guide operable to assist a surgeon when placing an intraocular lens (IOL) within an eye (10), the intraocular lens having lens marks, the method comprising:

capturing (72) information (28) associated with an eye in which an IOL is to be implanted;

calculating a power of a toric lens and an axis orientation for the toric lens within the eye;

characterized by **uploading (74) pre-operative biometry information (28), including** an image of the eye which includes scleral vessels that was captured during pre-operative tests, **corneal topography measurements including a steep axis from which the axis orientation of the toric lens is calculated** and inputs used to determine the center of the eye, to an IOL calculating software program (32) operable to calculate a location and orientation of the IOL within the eye;

calculating (76) the location and orientation of the IOL within the eye; and

generating (78) a placement guide comprising an image that a surgeon may reference during IOL implantation surgery to position the incision and to properly center and orient the IOL, and wherein the placement guide is electronic and overlaid with a live image captured by a surgical microscope and transmitted to a lens removal

console wherein processing modules within the lens removal console recognize and match the scleral vessels from the placement guide to the live image, and wherein the lens removal console can recognize the lens marks and advise the surgeon on how to rotate and place the lens."

Claim 4:

"4. A lens removal console (42) operable to facilitate placement of an intraocular lens (IOL), the intraocular lens having lens marks, comprising:

at least one **input port operable to receive:**

**pre-operative biometry information (28) including** an image of the eye which includes scleral vessels, a calculated power of a toric lens and an axis orientation for the toric lens within the eye, **corneal topography measurements including a steep axis from which the axis orientation of the toric lens is calculated** and inputs used to determine the center of the eye in which an IOL is to be implanted;

a processing module and associated memory coupled to the at least one input port, the processing module operable to execute an IOL calculating software program (32) operable to:

calculate (76) a location and orientation of the IOL within the eye from the information associated with an eye in which an IOL is to be implanted; and

generate (78) a placement guide comprising an image that a surgeon may reference during IOL implantation surgery to position the incision and to properly center

and orient the IOL, and wherein the placement guide is electronic and overlaid with a live image captured by a surgical microscope and transmitted to a lens removal console wherein processing modules within the lens removal console recognize and match the scleral vessels from the placement guide to the live image, and wherein the lens removal console can recognize the lens marks and advise the surgeon on how to rotate and place the lens."

Emphasis in both claims added by the Board. In the following the features

Claim 1: "...**uploading (74) pre-operative biometry information (28), including ..., corneal topography measurements including a steep axis from which the axis orientation of the toric lens is calculated...**"

and

Claim 4: "...**input port operable to receive:**

**pre-operative biometry information (28) including ... corneal topography measurements including a steep axis from which the axis orientation of the toric lens is calculated...**"

will be referred to as "**Feature A and A'**" respectively.

V. Auxiliary requests 1-11

Auxiliary requests 1-9 each comprise at least one of Features A or A'.

By contrast, auxiliary requests 10 and 11, which had been withdrawn in opposition before any discussion on their merits, do not contain features A and A'.

VI. The following documents played a role in the present decision:

O2: "Digital overlay technique for documenting toric intraocular lens axis orientation", Tri M. Nguyen, Kevin M. Miller, MD; Journal of Cataract & Refractive Surgery; Volume 26, October 2000;

A4: "Topography as a Screener", from <https://www.myalcon.com/products/surgical/acrysof-iq-toric-iol/topography-as-a-screener.shtml>;

A5: Printout of [http://www.medicontur.com/files/For\\_professionals/Bi\\_Flex\\_T/B\\_Biflex\\_T\\_brossura201602\\_web.pdf](http://www.medicontur.com/files/For_professionals/Bi_Flex_T/B_Biflex_T_brossura201602_web.pdf);

A7: Product information "Acry Toric - Sterile UV-Absorbing Acrylic Foldable Toric Optic Single-Piece Posterior Chamber Lenses", Alcon Laboratories, 2005;

A9: Waring, G.O. et al., Chapter 6: "Classification of Corneal Topography with Videokeratography", in Schanzlin D.J. et al. (eds.) "Corneal Topography", Springer 1992.

VII. The essential arguments of the appellant can be summarised as follows:

*Substantial procedural violation - reimbursement of the appeal fee*

During oral proceedings before the opposition division, the appellant argued that it was common general knowledge that Intraocular Lenses (IOLs) were commercially available at the priority date and that



alignment of the IOL with the steep axis of the cornea was standard practice at the time. Further evidence was offered in case the opposition division had doubts about this point. In stating that such proof was not necessary, the opposition division misled the appellant into believing that it had convinced the division. It thus did not file document A7 which provided evidence that all the allegedly non-disclosed features were part of the common general knowledge and that these features would have been understood by the person skilled in the art to be implied in the teaching of the earlier application as originally filed. In being hindered from filing A7, the appellant's right to be heard had been violated. As this violation resulted in the patent being revoked, a substantial procedural violation had taken place, justifying reimbursement of the appeal fee.

*Admission of A7 into the proceedings*

As discussed before, A7 had not been presented in opposition proceedings because of the chair's statement. It was of paramount importance as proof of the skilled person's common general knowledge and should certainly be admitted at least in appeal in order to respect the appellant's right to be heard. It was furthermore clearly publicly available, both on the FDA website relating to the AcrySoft Toric IOLs approval as well as with each lens package sold.

*Article 100(c) EPC - Main request*

Features A and A' were clearly and unambiguously disclosed in the earlier application as originally filed. According to the earlier application, paragraph [0016] the system included a corneal topographer to

produce a surface profile and image of the eye that includes vessels in the sclera. Data from that topographer were input into program 32, i.e. they were uploaded, in order to calculate power of the toric lens and the axis orientation. After uploading the image of the eye, the output of the program was the image of the eye with the axis overlaid. The person skilled in the art would necessarily understand from that disclosure that it was the axis of the eye which was to be overlaid on the image of the eye. As explicitly stated in paragraph [0022], it was the steep axis of the eye, i.e. the steep axis of the cornea. Also paragraph [0017] highlighted overlaying the steep axis on the image of the eye, an axis which the person skilled in the art would inherently understand to be the steep axis of the cornea. Uploading pre-operative corneal topography measurements including a steep axis, i.e. including a steep axis of the cornea, and calculating the axis orientation of the toric lens therefrom was thus originally disclosed.

This disclosure was in full agreement with what was known from the common general knowledge. As evidenced by e.g. A3-A5 or A9, topography data inherently comprised a steep and a flat axis of the cornea. Using these topography data, the practitioner selected a suitable lens for the patient, which then needed to be positioned in the proper orientation on the eye by using marks on the lens as a guide for alignment to precisely the steep corneal meridian. This was a procedure well established in the field for which A7 as well as O2 provided evidence. Thus, also from the common general knowledge it was clear that corneal topography data including a steep axis were uploaded.

To conclude, features A and A' were firstly directly derivable from the application as originally filed, and secondly, would also be considered by the person skilled in the art, when reading the application, to be necessarily implied. Thus, the subject-matter claimed in the independent claims of the main request did not extend beyond the content of the earlier application as originally filed.

*Auxiliary requests 1-9*

Each of auxiliary requests 1 to 9 comprised either feature A or feature A'. The reasoning with respect to the main request as to the original disclosure of these features thus applied *mutatis mutandis*.

*Auxiliary requests 10, 11*

While it was true that auxiliary requests 10 and 11 had been withdrawn in the opposition proceedings, they did not contain features A/A' and thus obviously overcame the reasoning on which the opposition division's decision was based. They thus should be admitted into the appeal proceedings.

VIII. The essential arguments of the respondent can be summarised as follows:

*No substantial procedural violation*

The feature found by the opposition division to extend beyond the disclosure of the earlier application as filed concerned uploading of corneal topography measurements including a steep axis. Document A7 was, however, silent on uploading of such measurements. Even by filing document A7 during the opposition

proceedings, the appellant would thus not have been able to show that uploading corneal topography measurements including a steep axis was part of the common general knowledge. Consequently, there was no causal link between the appellant being allegedly hindered from filing A7 in oral proceedings before the opposition division and the patent being revoked. Without a causal link between the alleged procedural violation and the outcome of the decision under appeal, no substantial procedural violation could be acknowledged.

*Admission of A7 into the proceedings*

As to A7, there was neither evidence of it being publicly available, nor could an FDA approved package insert be considered proof of the common general knowledge. Moreover, A7 did not relate to the specific procedure described in the patent. Document A7 was thus irrelevant to the question of original disclosure and should not be admitted into the procedure.

*Article 100(c) EPC - Main request*

The earlier application mentioned input of corneal topography data into program 32 and calculation of the power of the toric lens and the axis orientation in paragraph [0016]. However, the axis orientation mentioned in that paragraph was the orientation of the axis of the toric lens and not of the cornea. This was explicitly stated in paragraph [0017], which referred to the "image of the eye with the ... overlaid steep axis of the toric lens...". In this context, also paragraph [0022], which likewise mentions an axis orientation or an image of the eye including an axis

overlaid, could only be understood to refer to the steep axis of the toric lens.

Furthermore, the disclosure in the earlier application concerned only the output of the program and not its input, whereas the claim defined the uploading, i.e. the input. Even from A7, which could not be considered common general knowledge anyway, it could not be derived that corneal measurements including a steep axis were to be uploaded.

Indeed, for correction of astigmatism it was necessary to align the steep axis of the toric lens with the flat axis of the cornea. Thus if anything was needed to determine a guiding overlay of the steep axis of the toric lens, it was the flat axis of the cornea and not its steep axis.

Last but not least, although paragraph [0016] disclosed the use of a corneal topographer to produce a surface profile, this was no disclosure of corneal topography measurements including a steep axis. As could be seen from A9, page 62, corneal topography measurements *per se* did not comprise any axis. Even if an axis was to be determined, this could be done later, i.e. after uploading to the system.

There was thus no clear and unambiguous disclosure of uploading corneal topography measurements including a steep axis in the earlier application as originally filed.

*Auxiliary requests 1-9*

The subject-matter claimed in auxiliary requests 1 to 9 extended beyond the disclosure of the earlier

application as filed for the same reasons as discussed with respect to the main request.

*Auxiliary requests 10, 11*

Despite of the chair's statement during oral proceedings in the opposition proceedings that auxiliary requests 10 and 11 did not comprise undisclosed features A and A' and therefore had to be discussed, the appellant explicitly withdrew these requests. It was thus evident that these requests could and should have been discussed in the opposition proceedings. Therefore, the Board should exercise its discretion not to admit auxiliary requests 10 and 11 into the appeal proceedings.

**Reasons for the Decision**

1. No substantial procedural violation

It is clear from the corrected minutes of oral proceedings before the opposition division, point 6.4, that the appellant offered to provide further evidence of IOLs being commercially available at the priority date and of alignment of the IOL with the steep axis being standard practice at the time. According to the corrected minutes, "the chairman did not think that this was necessary".

However, the opposition division's decision is based on it not being clearly and unambiguously disclosed in the earlier application as filed that the topography measurements include a steep axis (decision point 13.3, last sentence).

From the decision, there is thus no indication that the opposition division's decision was based on any doubts about IOLs being commercially available at the priority date or about alignment of the IOL with a steep axis being standard practice at the time. Therefore, the chair's statement that further evidence on this point was not necessary was correct.

Furthermore, even if the appellant had provided evidence of IOLs being commercially available at the priority date or of alignment of the IOL with the steep axis being standard practice at the time, this would not have overcome the argument on which the decision is based.

Even assuming in the appellant's favour a violation of the right to be heard from the opposition division's side in misleading the appellant into not filing the further evidence, this would thus not have been causal for the decision taken, i.e. such a procedural violation would not be substantial.

Consequently, there is no fundamental deficiency justifying a remittal to the first instance and a reimbursement of the appeal fee in accordance with Rule 103(1)(a) is not equitable by reason of a substantial procedural violation.

2. Admission of A7 into the proceedings

A7 has been filed at the earliest possible moment in appeal proceedings, in reaction to the reasoning in the decision, in order to support appellant's arguments based on the common general knowledge. While the opposition division rejected the document as late filed, the Board notes that it relates to the aligned

placement of a toric IOL lens with the steep corneal meridian and can thus be considered *prima facie* relevant. In this context, the Board judges the doubts raised by the respondent about the document's public availability, about its suitability as evidence of the common general knowledge and about its relevance as not sufficient to justify it being rejected upfront for procedural reasons.

Therefore, the document is admitted into the appeal proceedings (Article 12(4) RPBA).

3. Article 100(c) EPC - Main request

The decisive question in the present case is whether Features A and A' can be considered originally disclosed, i.e. whether there is clear and unambiguous disclosure in the earlier application as originally filed of "pre-operative corneal topography measurement including a steep axis" being uploaded / received.

3.1 Paragraph [0016] of the earlier application discloses a corneal topographer to produce a surface profile. The data from the topographer are input into program 32 to calculate the power of the toric lens and the axis orientation. There is no disclosure of said "corneal topography measurements including a steep axis".

The appellant was of the view that paragraphs [0016], [0017] and [0022] disclosed the output of the image of the eye with the steep axis of the cornea overlaid, thus inherently disclosing the uploading of corneal topographer data including a steep axis.

However, as both the astigmatic cornea and the (toric) IOL are toric lenses, both comprise a steep and a flat



axis. The paragraphs cited do not clearly and unambiguously refer to the steep axis of the cornea. On the contrary, paragraph [0017] explicitly refers to the steep axis of the toric lens being used to generate reference diagrams. Paragraph [0022] concerns the second way of producing such reference diagrams (the first way being mentioned at the end of paragraph [0017]) and thus must be understood to likewise refer to an image of the eye including the steep axis of the toric lens. This is further in accordance with paragraph [0016], lines 46-49, stating that from the topographer data the program calculates the power of the toric lens and the axis orientation, a statement which - from its context - must be read to refer to the axis orientation of the toric lens rather than to the axis orientation of the cornea. Consequently, the output of the program according to paragraph [0016], lines 55, 56, must be understood to be the image of the eye with the axis of the toric lens being overlaid.

It should also be noted that - if the sentence in paragraph [0016], lines 46-49 were to refer to a calculation of the steep axis of the cornea (as put forward by the appellant) - this would be evidence for uploading corneal topography measurements not including a steep axis, with said axis being calculated only after uploading.

Furthermore, the output of the image of the eye with the vessels, overlaid steep axis of the toric lens and the centre of the eye (as disclosed in paragraph [0017]) is well suitable to guide the surgeon during the placement and correct orientation of an IOL on the eye. For example, the lens might comprise marks indicating its steep meridian which is to be aligned with a target steep meridian of the toric lens which is

overlaid on the image of the eye. That O2 and A7 disclose alignment of marks on the lens with a representation of the steep axis of the cornea does not change the above analysis as the documents do not provide evidence that their alignment method was the one applied in the earlier application as filed.

Even if the steep axis of the cornea was used / determined in the earlier application in an intermediate procedural step, i.e. during calculation of the axis orientation of the toric lens and of the steep axis of the toric lens (which was then to be overlaid on the image of the eye), this would not necessarily mean that it was uploaded / received in the method / by the console. It could well be determined only after uploading of the topography data.

To conclude, there is no clear and unambiguous disclosure in the earlier application as filed of corneal topography measurement including a steep axis, let alone of uploading such measurements including a steep axis.

### 3.2 Common general knowledge

Even assuming in the appellant's favour that documents A3-A5, A7, A9 and O2 were publicly available and representative of the skilled person's general knowledge, this does not change the above analysis.

As can be seen from A4, Step 1 or from the Figures in A9, page 62, corneal topography read-outs *per se* do not inherently comprise a steep axis of the cornea. The axis is determined in a consecutive step, which could be done before or after uploading. Determination of the steep axis of the cornea before uploading / reception

as claimed in the patent is thus not the only possible way of carrying out the method of generating a placement guide derivable from the prior art mentioned, in particular not from A7 which is silent on uploading of the corneal topography data.

Such a step is hence not implicit in the disclosure of the earlier application as originally filed, even assuming that documents A3-A5, A7, A9 and O2 were representative of the common general knowledge.

3.3 Therefore, features A and A' cannot be considered clearly and unambiguously disclosed. Consequently, the ground of opposition according to Article 100(c) EPC prejudices the maintenance of the patent based on the main request.

4. Auxiliary requests 1-9

As agreed by both parties, the argumentation under point 3 above applies *mutatis mutandis* to auxiliary requests 1-9, which each have at least one independent claim comprising feature A or A'. Article 100(c) EPC thus likewise prejudices the maintenance of the patent based on these requests.

5. Auxiliary requests 10, 11

Auxiliary requests 10 and 11 had been on file during oral proceedings before the opposition division. According to point 10 of the corrected minutes, during said proceedings, the chair announced that the feature extending beyond the disclosure of the earlier application as filed was not present in said requests, which thus had to be discussed. Following that

statement, the appellant withdrew its requests 10 and 11.

Therefore, due to the procedural step taken by the appellant, the opposition division did not and could not discuss and decide on auxiliary requests 10 and 11. Re-admitting these requests in the appeal proceedings would result in a procedural circumvention of the opposition division (commonly referred to as "forum shopping"), forcing the Board to decide on the requests in a first and final manner, contrary to the main purpose of opposition appeal proceedings. On the other hand admitting the requests and remitting the case to the opposition division would be unacceptable as it would be contrary to the principle of procedural economy.

The Board, in exercising its discretion under Article 12(4) RPBA, thus decided not to admit auxiliary requests 10 and 11 into the proceedings.

**Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairwoman:



C. Moser

P. Acton

Decision electronically authenticated