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**Datasheet for the decision  
of 1 October 2013**

**Case Number:** T 0239/11 - 3.2.08

**Application Number:** 07001027.7

**Publication Number:** 1785106

**IPC:** A61F2/16

**Language of the proceedings:** EN

**Title of invention:**

Multi-zonal monofocal intraocular lens

**Applicant:**

Abbott Medical Optics Inc.

**Headword:**

**Relevant legal provisions:**

EPC Art. 123(2)

**Keyword:**

Amendments - added subject-matter (yes)  
-- Main Request, First and Second Auxiliary Request  
Amendments - added subject-matter (no)  
-- Third Auxiliary Request

**Decisions cited:**

G 0002/10

**Catchword:**



**Beschwerdekammern  
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Case Number: T 0239/11 - 3.2.08

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.08**  
**of 1 October 2013**

**Appellant:** Abbott Medical Optics Inc.  
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**Representative:** HOFFMANN EITLE  
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**Decision under appeal:** **Decision of the Examining Division of the European Patent Office posted on 10 September 2010 refusing European patent application No. 07001027.7 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairwoman:** P. Acton  
**Members:** C. Herberhold  
D. T. Keeling

## **Summary of Facts and Submissions**

I. The appellant (applicant) lodged an appeal received on 26 October 2010 against the decision of the Examining Division, posted on 10 September 2010, on the refusal of European patent application No. 07001027.7. The appeal fee was paid on the same day and the statement of grounds was received on 10 January 2011.

II. After oral proceedings the Examining Division had issued a communication under Rule 71(3) EPC based on an auxiliary request filed during the oral proceedings. In reply the appellant submitted a new request, which replaced all previously submitted requests.

In a communication the Examining Division raised objections under Article 76(1) and Article 123(2) EPC. After a further reply from the appellant dated 15 June 2010 the Examining Division did not give its consent to the amendment in accordance with Rule 137(3) EPC and refused the application under Article 113(2) EPC for lack of a text agreed by the appellant.

III. Oral proceedings took place before the Board of Appeal on 1 October 2013.

IV. At the end of the oral proceedings the requests of the appellant were as follows:

To set aside the decision of the Examining Division and to grant a patent in accordance with the Main Request or the First, Second or Third Auxiliary Request, all filed with the grounds of appeal.

V. Claim 1 according to the Main Request reads:

"A multi-zonal monofocal intraocular lens (60) having an optic (62) with two discrete concentric optical zones (70, 72) centered on the optical axis (OA), the zones adapted to focus incoming light rays to form an image from an object, comprising:

a first lens surface (68a); and  
a second lens surface (68b) disposed opposite the first lens surface;

the first lens surface (68a) comprising:

a first zone (70) overlapping the optical axis of the lens for producing an image when the intraocular lens is centered on the optical axis of the human eye; and

a second zone (72) concentric about the first zone,

wherein the first zone comprises a spherical surface and the second zone comprises an aspherical surface,

the zones being configured to focus light entering the zones from a distant point source to substantially a single point such that the light substantially falls within the range of the depth-of-focus of a spherical lens having an equivalent focal length."

Claim 1 according to the First Auxiliary Request differs from claim 1 according to the Main Request in that it further requires the second zone to be

"adapted to compensate for optical aberrations in the image resulting from one or more non-optimal states of the lens".

Claim 1 according to the Second Auxiliary Request differs from claim 1 of the Main Request in that it further defines the second zone to be

"adapted to compensate for optical aberrations in the image resulting from implanted intraocular lens decentration of greater than at least about 0.1 mm or adapted to compensate for optical aberrations in the image resulting from implanted intraocular lens tilt of greater than at least about 1 degree".

Claim 1 according to the Third Auxiliary Request differs from claim 1 of the Main Request in that it further defines the second zone to be

"adapted to compensate for optical aberrations in the image resulting from implanted intraocular lens decentration of greater than at least about 0.1 mm" (Feature A).

The designation "Feature A" has been introduced by the Board.

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

The basis of independent claim 1 of all requests was to be found in items 12 and 19 (see paragraph [0068]) in combination with paragraphs [0029] (lines 44 to 46) and [0030] of the description.

While claim 1 of the Third Auxiliary Request comprised all features of item 12, Feature A had been omitted in the Main Request and replaced by other features in the First and Second Auxiliary Requests. This was allowable for the following reasons:

In view of the general problem of "compensating for non-optimal states" (see e.g. paragraphs [0013], [0014], [0015], [0032], [0060], [0065]) Feature A was not indispensable for the function of the invention.

It was true that the last sentence of paragraph [0017] disclosed that the first surrounding zone "is adapted to compensate for optical aberrations resulting from implanted intraocular lens decentration of greater than at least about 0.1 mm" (Feature A). However, this did not imply that the first surrounding zone must be necessarily designed to compensate for this kind of aberration. In particular in view of the first two sentences of paragraph [0018] it was clear that the compensation for aberrations resulting from IOL decentration was only facultative ("may be") and that the first surrounding zone might alternatively compensate for optical aberrations resulting from implanted IOL tilt of greater than at least about 1 degree. In this context the word "also" should not be interpreted to mean "in addition to" but rather "alternatively".

Various passages in the application (see paragraphs [0014], [0018], [0032], [0042], [0043], [0054], [0055], [0066]) demonstrated that the present invention addressed and solved not only the problem of decentration of an implanted intraocular lens (IOL), but that it equally related to other non-optimal implant positions (e.g. lens tilt, lens rotation, lens dislocation due to capsular shrinkage), as well as spherical aberration or problems due to varying lighting conditions. The problem of lens decentration being only one example of these non-optimal states, Feature A could not be considered as essential for the invention.

Finally, the modification of item 12 was limited to the second zone and thus did not require modification of other features to compensate for the change.

Furthermore, the compensation for other non-optimal states was not functionally linked to the compensation for decentration. It was also not inextricably linked to the existence of three zones. Although it was correct that the specific embodiment described in paragraphs [0040] to [0052] related to a lens having three zones, paragraph [0050] third sentence clarified that the example was not limited to a lens having at least three zones. Since the sentence stated that it was preferable to have at least three zones, it was disclosed that less than 3 zones were - although less preferably - conceivable as well, which in the context of a lens with "a plurality of zones" was equivalent to a specific disclosure of a lens having two zones.

Consequently, all requests on file fulfilled the requirements of Article 123(2) EPC.

## Reasons for the Decision

### 1. Admissibility

The appeal is admissible.

### 2. Allowability of the amendments - Main Request - First and Second Auxiliary Request

#### 2.1 Claim 1 of all pending requests defines a multi-zonal monofocal IOL having a first lens surface comprising a first zone with a spherical surface and a second zone with an aspherical surface.

The application as originally filed does not comprise any claim relating to a multi-zonal monofocal IOL of this type.

As pointed out by the appellant, a basis for such an IOL could be found almost literally in paragraph [0068] under item 12 in combination with item 19. In this paragraph, the second zone of the IOL is defined as being "adapted to compensate for optical aberrations in the image resulting from implanted intraocular lens decentration of greater than at least about 0.1 mm" (Feature A).

However, claim 1 according to the Main Request or according to the First or Second Auxiliary Requests (second alternative) does not comprise this feature.

Thus it needs to be established, whether a multi-zonal monofocal IOL comprising two zones, whereby the second zone does not have the properties of Feature A can be derived directly and unambiguously, using common



general knowledge, from the application as filed (G2/10, reasons 4.5.1).

2.2 The only disclosure in the application as filed relating explicitly to an IOL with a first lens surface comprising only two zones is in paragraph [0068] (items 12 to 19) and in paragraphs [0017] and [0018].

2.2.1 Paragraph [0068], items 12 to 19 discloses an IOL comprising Feature A and nothing suggests to the skilled person that the first surrounding zone may in fact not have the properties of Feature A.

Moreover, paragraph [0017] (last sentence) clearly states that the first surrounding zone (which corresponds to the "second zone") "is" adapted to compensate for aberrations resulting from IOL decentration, i.e. that it has to show the properties of Feature A.

It is true that the first sentence of paragraph [0018] - which refers to the same aspects of the invention as paragraph [0017] - states that the first surrounding zone "may be" configured to compensate for aberrations resulting from IOL decentration. However, since the two sentences contradict each other, the first sentence of paragraph [0018] cannot be considered clear and unambiguous information that Feature A was only facultative in the inventive IOL.

The situation remains the same when considering the second sentence of paragraph [0018]. The appellant argued that in the present context the word "also" had the meaning of "alternatively" rather than of "in addition to". Therefore, the IOL could be adapted to either compensate for lens decentration or tilt. Even

accepting this interpretation, the second sentence of paragraph [0018] remains in contradiction with the last sentence of paragraph [0017] which requires the IOL to be adapted to compensate for lens decentration. Due to this contradiction, these paragraphs do not disclose clearly and unambiguously that Feature A is a facultative property of the first surrounding zone.

2.2.2 Furthermore, if - as in the Main Request - Feature A is omitted, the second zone is only defined as "comprising an aspherical surface", "concentric about the first zone", "the zones being configured to focus light entering the zones from a distant point source to substantially a single point such that the light substantially falls within the range of the depth-of-focus of a spherical lens having an equivalent focal length." These remaining features do not define a lens "less sensitive to non-optimal states such as decentration and tilt of the IOL". In fact, the remaining functional definition is nothing more than the definition of a "monofocal lens" as given in paragraph [0030] of the description. The aspheric design of the second zone alone does not necessarily result in a lens "less sensitive to nonoptimal states such as decentration and tilt of the IOL". For example the TECNIS Z9000 monofocal lens - which has an aspheric surface - is explicitly disclosed as particularly "sensitive" to slight errors in decentration or tilt of the lens, especially in lowlight conditions" (paragraph [0013]).

Consequently the omission of Feature A means that the very feature indispensable for providing a lens "less sensitive to non-optimal states such as decentration and tilt of the IOL" (paragraph [0014]) is absent from claim 1 of the Main Request.

2.3 The appellant has further pointed to several passages in the description to demonstrate that the correction for non-optimal states achieved by the inventive IOL was not restricted to decentration but in fact may address every non-optimal state of implantation, including in particular errors in tilt. However, none of these disclosures is made in the context of a lens with a first lens surface comprising only two zones.

2.3.1 Paragraphs [0042] and [0043] relate to an IOL having an intermediate zone "at least designed to help correct aberrations of the IOL when it is decentered, tilted or otherwise in a non-optimal state" (paragraph [0042], second sentence).

Since the term "intermediate zone" inherently implies the existence of adjacent inner and outer zones, the IOL referred to in paragraph [0042] has to be a lens with a first lens surface comprising three zones. To put it differently: an "intermediate zone" inevitably has a clearly recognizable structural relationship with its neighbouring zones.

Furthermore, paragraph [0042] explicitly discusses the design and function of the inner and outer zones in relation to the intermediate zone. While the intermediate zone has the function to correct aberrations when the IOL is in a nonoptimal state, it is the outer zone which is designed to minimise the spherical aberrations natural to spherical monofocal IOLs (paragraph [0042], last sentence). In view of the problem posed in paragraph [0014], which formulates a need for a correction for the spherical aberrations as well as for a reduction of the sensitivity to non-optimal states, the intermediate and the outer zones in fact coact to solve the problem posed. Consequently,

there is also a clearly recognisable functional relationship between the intermediate zone and the inner and outer zones. This stresses again the fact that paragraphs [0042] and [0043] relate to an IOL with a first lens surface comprising three zones and hence do not disclose an IOL with a first lens zone comprising two zones only, with a second zone adapted to correct for a non-optimal state without correcting for lens decentration.

It also shows that it is not justified to extract the feature of an intermediate zone being adapted to compensate for a non-optimal state other than lens decentration from its originally disclosed context, i.e. by omitting the third zone from the disclosed three zone IOL. Consequently, said extracted feature cannot replace feature A in the disclosure of paragraphs [0068] (items 12 to 19), [0017] and [0018]. The subject-matter defined in claim 1 of the First and Second Auxiliary Requests thus amounts to an intermediate generalization.

The appellant argued that the second zone claimed could comprise a first, inner part adapted to correct for aberrations resulting from non-optimal states and a second, outer part adapted to correct for spherical aberrations, such a lens solving the problem posed without a third outer zone being required. However, such an interpretation of the claim language is not in line with the use of the word "zone" throughout the application: a zone is defined by its predominant function; thus an outer part of the second zone having a different predominant functionality would be called a third zone (which is missing from the claim).

2.3.2 Nor can the above analysis be changed by taking into account the third sentence in paragraph [0050], which states that there are "preferably at least three zones ( $i \geq 3$ ) to achieve enhanced performance for a 6 mm diameter pupil size".

The appellant reasoned that the feature "preferably at least three", in the context of a multi-zonal lens (i.e. a lens having at least two zones), implicitly disclosed a lens having two zones.

Firstly, this reasoning could only apply to the particular situation in which enhanced performance for a 6 mm diameter pupil size is to be achieved. However, the independent claims of the pending requests are not restricted to this particular situation.

Secondly, paragraph [0050] refers to the lens shown in Figure 5A (see the first sentence of paragraph [0050]), which is a multi-zonal lens having three zones. The person skilled in the art has no reason to give the term "preferably" so much weight as to omit one of the zones shown in Figure 5A. This is even more so since - as discussed above - the third zone is "designed to minimize the spherical aberrations natural to spherical monofocal IOLs", i.e. it addresses the first part of the problem underlying the invention (see paragraph [0014]). Moreover, since the three zones are in close functional and structural relationship, omitting one of them would require a modification of the other features to compensate for the change.

2.3.3 Paragraph [0013] discusses problems arising in the TECNIS prior art IOL, not the IOL of the present invention, and thus cannot be the basis for amending the claim.

2.3.4 Paragraphs [0014], [0032] (first sentence) and [0066] (first sentence) define the problem to be solved by the present invention in general, not whether it is solved by a particular two or three zone IOL. Because of Feature A, the two zone lens is less sensitive to decentration and outperforms the prior art IOLs in a decentered implant position, thus solving the problem posed by the invention. However, paragraphs [0014], [0032] and [0066] do not clearly and unambiguously disclose a two zone IOL which is less sensitive to and provides enhanced performance in a non-optimal state different from decentration. As shown above, being sensitive to and providing enhanced performance for such a non-optimal state (thus also solving the problem posed) is only disclosed in the context of an IOL having three zones.

2.3.5 The first sentence of paragraph [0015] relates to a multi-zonal IOL adapted to reduce aberrations over a range of decentration. Apart from being only a general disclosure, i.e. without any link to a particular two zone or three zone lens design, the only non-optimal state explicitly addressed is "lens decentration". The same arguments set out under point 2.2.1 above with respect to paragraphs [0017] and [0018] apply to the second sentence of paragraph [0015].

2.3.6 Paragraphs [0053] and [0054] as well as Figures 6A and 6B illustrate the IOL performance of the multi-zonal monofocal lens shown in Table 1, i.e. of a three zone IOL. Figure 7 compares the efficiency of three lenses in a Monte Carlo simulation of a clinical population. The very same identifiers as in Figures 6A and 6B have been assigned to these three lenses. It has thus to be concluded from the context that the multi-zonal lens

used in the Monte Carlo simulation is the same as the one which was discussed in paragraphs [0053] and [0054], i.e. the IOL shown in Table 1. The randomly selected "over 100 different eyes" used in the Monte Carlo simulation may have had varying conditions of corneal aberrations, IOL decentration and IOL tilt, the efficiency of the IOL defined in Table 1 being determined for each of these eyes and then averaged. However, the only conclusion that can be drawn is that the IOL of Table 1 is not only efficient when decentred by 0.5 mm but also for "averaged" clinical conditions. This does not warrant the conclusion that Feature A may be missing in the lens of Table 1. On the contrary, Figure 6B shows that the multi-zonal lens tested is indeed adapted to compensate for lens decentration of 0.5 mm. Moreover, there is clearly no unambiguous disclosure that paragraph [0055] related to a two zone IOL design.

2.3.7 Paragraphs [0060] to [0065] all relate to methods of designing a three zone lens: paragraph [0059], first sentence, refers to the provision of an optical model of a lens comprising an inner zone, an intermediate zone, an outer zone and zonal design parameters, i.e. the very zonal design parameters to which the sentence in paragraph [0060] refers. Analogous reasoning applies to the disclosure in paragraphs [0019] and [0020], both relating to the same aspect of the invention.

2.4 Therefore, an IOL comprising only two zones and having a second zone which does not have the properties of Feature A presents the skilled person with new technical information which cannot be derived directly and unambiguously, using the common general knowledge, from the application as originally filed.

Hence claim 1 according to the Main Request and according to the First and Second Auxiliary Requests do not comply with the requirements of Article 123(2) EPC.

3. Allowability of the amendments - Third Auxiliary Request

3.1 It is undisputed that claim 1 of the Third Auxiliary Request (which comprises Feature A) can be based on paragraph [0068], items 12 and 19 of the description as originally filed, with the further claim features being disclosed in paragraphs [0029] and [0030]. Thus claim 1 of the Third Auxiliary Request fulfills the requirements of Article 123(2) EPC.



## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the Examining Division for further prosecution on the basis of:

Claims: 1 to 6,  
Description: pages 1 to 21 and  
Figures: 1 to 7,

in accordance with the Third Auxiliary Request filed with the grounds of appeal and corresponding to the text as enclosed with the communication under Rule 71(3) EPC of 27 July 2009.

The Registrar:

The Chairwoman:



V. Commare

P. Acton