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Datasheet for the decision of 18 September 2019

Case Number: T 0767/16 - 3.2.08

Application Number: 09743477.3

Publication Number: 2273950

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Language of the proceedings: EN

Title of invention:
ASPHERIC TORIC INTRAOCULAR LENS

Patent Proprietor:
Novartis AG

Opponent:
KOWA Company, Ltd

Headword:

Relevant legal provisions:
EPC Art. 100(a), 56
RPBA Art. 13(1)

Keyword:
Inventive step - (no) - partial problems
Late-filed request - admitted (no)

Decisions cited:

Catchword:

Europäisches Patentamt
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Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 0767/16 - 3.2.08

D E C I S I O N
of Technical Board of Appeal 3.2.08
of 18 September 2019

Appellant: (Opponent)	KOWA Company, Ltd 3-4-14 Nihonbashi-Honcho Chuo-Ku Tokyo Tokyo 103-8433 (JP)
Representative:	Black, Diego Withers & Rogers LLP 4 More London Riverside London SE1 2AU (GB)
Respondent: (Patent Proprietor)	Novartis AG Lichtstrasse 35 4056 Basel (CH)
Representative:	Hanna Moore + Curley Garryard House 25/26 Earlsfort Terrace Dublin 2, D02 PX51 (IE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 1 February 2016 rejecting the opposition filed against European patent No. 2273950 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	M. Alvazzi Delfrate
Members:	C. Herberhold
	Y. Podbielski

Summary of Facts and Submissions

I. By decision posted on 1 February 2016 the Opposition Division rejected the opposition against European patent No. EP-B-2 273 950.

II. The opponent (appellant) lodged an appeal against that decision in the prescribed form and within the prescribed time limit.

III. Oral proceedings before the Board took place on 18 September 2019.

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

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

The respondent (patent proprietor) requested that the appeal be dismissed and the patent be maintained as granted or, as an auxiliary measure, that the patent be maintained on the basis of auxiliary request 1 filed with letter dated 24 October 2016, or on the basis of auxiliary request 5 filed with letter dated 16 August 2019, or on the basis of auxiliary request 8 filed during the oral proceedings before the Board.

IV. Main request:

Claim 1 of the main request, i.e. claim 1 as granted reads as follows:

"An ophthalmic device, comprising:

an ophthalmic lens (10) having an anterior surface (14) and a posterior surface (16); and
one or more haptics (20) coupled to the ophthalmic lens;
wherein one of the posterior or anterior surfaces is shaped so that the ophthalmic lens is configured as an aspheric lens and one of the posterior or anterior surfaces is shaped so that the ophthalmic lens is configured as a toric lens,
characterized in that the ophthalmic lens has a selected edge thickness at the 45 degree meridian of between 0.2 and 0.3 mm, and varies periodically around the toric lens, wherein the edge thickness varies sinusoidally".

V. Auxiliary request 1:

The subject matter of claim 1 of auxiliary request 1 defines in addition to the features of claim 1 of the main request that

"all four of the 45 degree meridian thicknesses are equal".

VI. Auxiliary request 5:

The subject matter of claim 1 of auxiliary request 5 is restricted with respect to the subject matter of claim 1 of auxiliary request 1 to a particular selected edge thickness at the 45 degree meridian of 0.21 mm. The explicit wording of the feature is as follows:

"**characterized in that** the ophthalmic lens has a selected edge thickness at the 45 degree meridian of ~~between 0.2 and 0.3~~ 0.21 mm...".

VII. Auxiliary request 8

Claim 1 of auxiliary request 8 combines the subject-matter of claims 1 and 3 of auxiliary request 1, i.e. in addition to the features of claim 1 (see point V above), the following is defined:

"wherein a single surface is shaped with toricity and asphericity, the single surface defined by:

$$sag = toric(r,\theta),$$

wherein

$$toric(R_{avg},r,\theta) = \frac{(c_x\cos^2\theta + c_y\sin^2\theta)r^2}{1+\sqrt{1-(1+k_x)c_x^2r^2\cos^2\theta-(1+k_y)c_y^2r^2\sin^2\theta}},$$

wherein

$$c_x = \frac{1}{R_x}, c_y = \frac{1}{R_y},$$

and for toric surfaces, k_X and k_Y should not be 0, and

$$asph(R_{avg},r) = \frac{cr^2}{1+\sqrt{1-(1+k)c^2r^2}}, c = \frac{1}{R_{avg}}$$

".

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

D1: WO 2006/060477;
D17: Tetsuro Oshika: "Acrylic Foldable Intraocular Lens (Alcon)", Japanese Journal of Ophthalmic Surgery, vol. 15, Medical-Aoi Publications, Inc., 2002, page 311-316;
D17a: English language translation of parts of D17;
D19: "The Acrysof Toric IOL's FDA Trial Results - A look at the clinical data", Cataract & Refractive Surgery Today, pages 66 - 68, Stephen S. Lane, MD; May 2006;

D19a: "Accurate correction of preoperative astigmatism with the AcrySof® Toric IOL, Edgardo Carreño, M.D., New Phaco and IOL Technology, in association with Ophthalmology Times, October 2007.

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

Admittance of D19a

It could not be denied that document D19a was late filed. However, it had a short, non-complex disclosure which essentially only helped to illustrate the sinusoidal variation of the edge thickness which had already been disclosed in document D19 for exactly the same prior art intraocular lenses. Moreover, the document had been submitted as soon as possible, well in advance of the deadline mentioned in the Board's communication dated 23 April 2019. For these reasons, it should be admitted into the appeal proceedings.

Inventive step – Claim 1, main request

The AcrySof IOL as disclosed in D19 and D19a comprised all features of the pre-characterising portion. In particular, following the definition in paragraph [0005] of the patent as granted, its toric profile exhibited deviations from a spherical surface such that its toric surface also qualified as aspheric. As could be further appreciated in Figure 1 of D19a the lens comprised a periodically sinusoidally varying edge thickness. The only difference was thus the selected edge thickness at the 45 degree meridian of between 0.2 and 0.3 mm. The definition of a single point thickness of a sinusoidally varying edge, wherein it was not even clear whether said value defined a maximum, a minimum

or an intermediate thickness, could not have any technical effect. Even assuming that foldability was somehow linked to the features of the characterising portion, the selected thickness was entirely conventional for lenses as the one disclosed in D19, D19a. This was evidenced by document D17 which related to foldable lenses made from the very same material and which disclosed the typical edge thicknesses of such lenses to be in the claimed range. The subject-matter of claim 1 was thus not inventive.

This analysis was not changed if one considered the toric lens of D19, D19a not to comprise an aspheric lens surface. Indeed, whereas the selected thickness value related to the mechanical problem of folding the lens, the asphericity of the lens surface corrected for corneal spherical aberration and thus related to an optical problem. Both technical problems were entirely unrelated, without there being any synergy between the two, such that it was appropriate to formulate two partial problems. It was, however, well established in the prior art - see in this respect e.g. D1, the paragraph bridging pages 14 and 15 - that for improving lens performance in eyes with corneal spherical aberration, a selected degree of asphericity could be imparted to the toric surface of a toric intraocular lens. Consequently, also the solution of the second partial problem was obvious and the subject-matter of claim 1 of the main request did not involve an inventive step.

Inventive step – Claim 1, auxiliary requests 1 and 5

Claim 1 of auxiliary requests 1 was not inventive for the reasons already discussed with respect to the main request. The toric lens of D19/D19a had equal thickness

of the edge at all four 45 degree meridians because of its symmetry with respect to the principal meridians. This did not change when asphericity was imparted to one of its surfaces as according to D1 the asphericity imposed for a certain radial distance from the lens center was the same for all meridians and thus affected the thickness of all 45 degree meridians in the same way.

Likewise further restricting the edge thickness at the 45 degree meridian to 0.21 mm did not involve an inventive step. When trying to improve foldability without detriment to mechanical resilience, the skilled person would consider the values typically used for foldable lenses of that material. As evidenced by D17a, Tables 6 and 7, the value of 0.21 mm was just one of the conventionally applied edge thicknesses without any surprising technical effect.

Admittance of auxiliary request 8

Auxiliary request 8 was filed unacceptably late. It was furthermore not *prima facie* allowable in that it was already known from D1, page 14, last paragraph, that - in order to correct for corneal aspheric aberration - asphericity could be imparted to the toric surface, the non-toric surface or both. The request should thus not be admitted into the appeal proceedings.

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

Admittance of D19a

Document D19a had been filed many years after the opposition without any good reason. It was not clear,

how the document was to be treated, i.e. whether it formed a prior art on its own, or was somehow to be seen in mosaic with D19. Moreover its Figure 1 was at best of schematic nature and did not allow deriving a certain form of the lens's edge therefrom. Thus, the document should not be admitted into the appeal proceedings.

Inventive step – Claim 1, main request

The lens disclosed in D19/D19a was a toric lens without asphericity. Such a lens did not qualify as aspheric in the understanding of the person skilled in the art. Furthermore, even if D19 mentioned slight variations in the edge's thickness around the circumference of the optic, there was no disclosure of a periodic, let alone of a sinusoidal variation. In this context, Figure 1 of D19a was of no help in that the drawing was of schematic nature, not to scale and only showed a single side of the edge. Moreover, the edge shown was sigmoidal but not sinusoidal. There was also no disclosure of a selected edge thickness at the 45 degree meridian of between 0.2 and 0.3 mm.

Starting from the lens disclosed in D19/D19a, the skilled person had no reason to provide said lens with a periodically, sinusoidally varying edge with a selected thickness at the 45 degree meridian of between 0.2 and 0.3 mm. Indeed, documents D17 invoked by the appellant in this context exhibited a smooth continuous constant thickness edge, which was an assured edge design from which the skilled person would not deviate. Furthermore, the edge thickness values disclosed in D17 applied to plane lenses and could thus not simply be transferred to the toric and aspheric lens design of the present invention.

Consequently, the subject matter of claim 1 of the main request involved an inventive step.

Inventive step – Claim 1, auxiliary requests 1 and 5

Claim 1 of auxiliary request 1 further defined that all four of the 45 degree meridian thicknesses were equal. This feature helped foldability of the lens. It could not be derived from the lens disclosed in D19/D19a because imparting asphericity changed the volume distribution of the lens and thereby the edge form. Thus claim 1 of auxiliary request 1 was inventive.

Claim 1 of auxiliary request 5 further defined the thickness at the 45 degree meridian to be 0.21 mm. This value was the lowest of all those provided in D17a and it was surprising that the lens would be made that thin. There was no reason why the skilled person for a toric and aspheric lens would select a thickness corresponding to the thinnest value known for conventional non-toric, non-aspheric lenses.
Thus, at least claim 1 of auxiliary request 5 should be considered inventive.

Admittance of auxiliary request 8

Auxiliary request 8 had been filed as a reaction to the interpretation of newly admitted document D19a during oral proceedings, which came as a surprise to the respondent. The amendment was based on granted claim 3 and thus was neither complex nor could it be surprising. The request should thus be admitted into the proceedings.

Reasons for the Decision

1. Admittance of D19a

Document D19a was submitted with appellant's letter dated 8 July 2019, and thus well after the expiry of the time limit for filing the statement setting out the grounds of appeal. Its admission into the proceedings is thus subject to the discretion of the Board in accordance with Article 13(1) RPBA.

The disclosure of D19a relates to exactly the same AcrySof Toric IOLs (IOL = Intra Ocular Lens) discussed in prior art D19, which had already been admitted into the opposition proceedings (see point 2.5 of the impugned decision) and which have been relied upon in the grounds of appeal. Indeed, D19 and D19a both refer to lenses with the identical identification numbers SN60T3, SN60T4, and SN60T5 (see D19, page 66, first paragraph and D19a, page 2, left column, first paragraph). D19a additionally comprises Figure 1 which does not contain new technical information but merely provides - notwithstanding its schematic nature - an illustration of what is meant by the "slight variations in the edge's thickness around the circumference of the optic due to different curvature of the principal meridians" discussed in D19 (see page 68, left column, last paragraph). Figure 1 further illustrates the fact (which is mentioned in the consecutive sentence of D19) that the variation between the principal meridians changes as the cylindrical power changes from model to model.

D19a thus does not introduce into the proceedings a new line of attack or new technical information, but merely

renders the information already contained in D19 more intuitively accessible. It is furthermore a short (2,5 pages) document of low complexity which has been filed more than 2 months before the oral proceedings.

The Board thus found it appropriate to admit document D19a into the appeal proceedings.

2. Inventive step – Claim 1, main request

2.1 Closest prior art

The AcrySof Toric IOL as disclosed in documents D19 and D19a forms a suitable closest prior art. This was common ground between the parties. In particular it addresses foldability of the lens for insertion into the eye with existing surgical equipment (D19, page 66, left column, penultimate paragraph, last sentence), the technical problem which in the patent (paragraph [0015]) has been associated with the features of the characterising portion.

2.2 Differentiating features

2.2.1 It is common ground between the parties that the AcrySof Toric IOL as disclosed in documents D19 and D19a is:

An ophthalmic device, comprising:
an ophthalmic lens having an anterior surface and a posterior surface; and one or more haptics (D19, Figure 1; D19a, abstract: "modified L haptics") coupled to the ophthalmic lens;
wherein one of the posterior or anterior surfaces is shaped so that the ophthalmic lens is configured as a toric lens.

It is also common ground that neither D19 nor D19a discloses a selected edge thickness at the 45 degree meridian of between 0.2 and 0.3 mm.

2.2.2 The appellant further argued that because of the AcrySof lens being a toric lens, it was *per definition* aspheric in that it had a radial profile of a surface that exhibits deviations from a spherical surface, see the definition in paragraph [0005] of the patent specification. However, in each of the principal meridians, the toric AcrySof lens has the radial profile of a sphere. In view of the sag equation typically used in the field to describe an aspheric surface (see e.g. the patent page 3, line 15; D1, page 4, lines 3, 4), which results in an asphericity of the meridians independent of the angular position and thus also in the principal meridians, the Board comes to the conclusion that for the person skilled in the art in the particular field an aspheric surface implies that each and every meridian needs to deviate from the meridians of a spherical surface.

It is noted that asphericity can be imparted on a toric lens (see e.g. D1, page 14, last paragraph) which results in a toric and aspheric surface. However, while the term toric does not exclude an aspherical component being imparted on the toric surface (which is also in accordance with the equation given in paragraph [0013] of the patent), in the understanding of the skilled person, a toric surface is not necessarily aspheric in that the principal meridians may be the meridians of a sphere.

With this understanding of the skilled person, the AcrySof lens disclosed in D19/D19a does not have an aspheric surface.

2.2.3 Conversely, the respondent was of the opinion that the AcrySof IOL as disclosed in D19/D19a did not exhibit an edge thickness that varies periodically around the toric lens, wherein the edge thickness varies sinusoidally.

In particular, D19a, Figure 1 did not show a sinusoidal form but rather a sigmoid one. The Figure was furthermore only of schematic nature and did only show a single side aspect of the lens edge without any information about the form of the hidden edge.

The Board notes, however, that a toric surface is axially symmetric with respect to its principal meridians. Although not explicitly shown in Figure 1, it is thus clear how the edge looks on the backside. The wavy form with two minima and maxima resembles the wave-like course of the sinus function and as such has to be considered periodical and sinusoidal. The same conclusion follows from the fact that D19 discloses the slight variations in the edge's thickness around the circumference of the optic to be a consequence of the different curvature of the principal meridians.

Therefore, the AcrySof Lens as disclosed in D19/D19a exhibits an edge thickness that varies periodically around the toric lens, wherein the edge thickness varies sinusoidally.

2.2.4 To conclude, the subject-matter of claim 1 of the main request differs from the AcrySof lens in the following features:

a) the ophthalmic lens has a selected edge thickness at the 45 degree meridian of between 0.2 and 0.3 mm,

b) one of the posterior or anterior surfaces is shaped so that the ophthalmic lens is configured as an aspheric lens.

2.3 Technical effect and problem to be solved

According to paragraph [0015] of the patent, the features under 2.2.4 a) allow the lens to be shaped so that it can fit in and be implanted with existing surgical equipment. They thus solve the problem to allow lens implantation with a technique familiar to the surgeon (patent, paragraph [0019]), a technique which requires the lens to fold in half.

On the other hand, the aspheric shape of either the anterior or posterior surface corrects for corneal spherical aberration (patent, paragraph [0003]), solving the problem of providing excellent vision across a range of object distances and to substantially reduce the shortcomings of prior art systems for improving vision (patent, paragraph [0006]).

The invention thus addresses the rather mechanical problem of lens implantation and the optical problem of improving optical lens performance. Both are unrelated.

2.4 Obviousness

With respect to the optical problem, the skilled person would consider the teaching of document D1 which likewise relates to IOLs and to the problem of providing excellent vision and reducing the

shortcomings of the prior art (D1, page 1, lines 12-37). In particular, in the context of astigmatic eyes for which toric lenses such as the AcrySof lens disclosed in D19/D19a are used, it is taught to impart a selected degree of asphericity to the toric surface, to the non-toric surface or to both (D1, page 14, last paragraph). Following that teaching, the person skilled in the art arrives at a lens with one of the posterior or anterior surfaces being shaped so that the ophthalmic lens is configured as an aspheric lens.

As to the problem of lens insertion and foldability it has to be noted that also the AcrySof Lens according to D19/D19a is to be inserted with a technique already known to the surgeon: the lens easily folds in half and may be inserted through an incision measuring less than 3 mm using the Monarch II injector (D19, page 66, first column, penultimate paragraph, last sentence).

Every IOL inevitably has some thickness at the 45° meridian, the particular value being, however, not disclosed in D19 and D19a. Still, when manufacturing the AcrySof lens with the aspheric modification of one of the surfaces as discussed, the person skilled in the art has to provide a certain thickness, a choice which implies a selected thickness at the 45° meridian. The criteria for selecting the lens thickness (and thus the edge thickness) are known to the skilled person: the lens needs to be thin enough for folding in half, such that insertion as before remains possible. It furthermore needs to be sufficiently thick to be mechanically robust. This optimisation of a single parameter according to known criteria is a typical routine task of the skilled person. The claimed thickness range largely overlaps with the thicknesses being typically used in acrylic foldable IOLs (see D17/

D17a, Tables 2, 4-7) and thus cannot be considered surprising.

To conclude, the person skilled in the art would arrive at the claimed subject-matter without involving an inventive activity.

3. Inventive step – Claim 1, auxiliary request 1

Claim 1 of auxiliary request 1 defines additionally (with respect to the main request) that all four of the 45 degree meridian thicknesses are equal.

For a toric lens this is, however, an inherent property due to the lens being symmetric with respect to the axes of the principal meridians (typically at 0/180 and 90/270 degrees).

With the asphericity imparted to the toric surface being only dependent on the radial position on the surface (see the formula in D1, page 10, line 17), the four 45 degree meridian thicknesses remain equal also with the asphericity imparted on the lens as discussed in point 2 above.

Therefore, the subject-matter of claim 1 of auxiliary request 1 does not involve an inventive step.

4. Inventive step – Claim 1, auxiliary request 5

Auxiliary request 5 defines that the ophthalmic lens has a selected edge thickness at the 45 degree meridian of ~~between 0.2 and 0.3~~ 0.21 mm.

Although a thickness of 0.21 mm at the 45 degree meridian has been disclosed as "preferably" in the

application as filed and the patent (see page 5, lines 2-4 of the application as filed and paragraph [0015] of the patent), there is no evidence that at this particular value a surprising technical effect occurs. Selecting a particular value within an obvious range does not involve an inventive step.

The respondent argued that 0.21 mm was the thinnest edge value disclosed in D17/D17a and that it was indeed surprising that the claimed lens could be made that thin. However, as pointed out in point 2.4 above, the skilled person selects a lens thickness (and thus a thickness at the 45° meridians) according to known criteria. A thinner lens folds more easily and can be inserted through a smaller incision. Thus, making the lens as thin as possible, while maintaining sufficient mechanical resilience amounts to a routine optimization for the skilled person, in particular as the claimed result remains within the range known for IOLs made from the same material.

5. Admittance of auxiliary request 8

Auxiliary request 8 was submitted at the latest possible moment in appeal proceedings, after the Board had already formed and communicated its negative opinion about the allowability of the main request, auxiliary request 1 and auxiliary request 5. Its admission is thus subject to the Board's discretion according to Articles 13(1) and (3) RPBA.

The respondent argued that the late filing of auxiliary request 8 was a reaction to the Board's interpretation of late filed document D19a. However, firstly, document D19a was filed more than 2 months before the oral proceedings and thus cannot justify the filing of an

additional request at such a late point in time. Secondly, inventiveness had been put into doubt starting from D19 as closest prior art already in the statement of grounds of appeal (point 7.1.3 of the statement of grounds). Thirdly, the Board's communication dated 23 April 2019 likewise mentioned that D19 appeared to be the closest prior art in that it related to foldability of the lens and explicitly mentioned slight variations in the edge's thickness around the circumference of the optic. There is thus nothing surprising in the course of the proceedings which can justify the late filing of auxiliary request 8.

Furthermore, it is not *prima facie* apparent in what way the single surface shaped with toricity and asphericity according to claim 1 of auxiliary request 8 differs from the toric surface of the AcrySof lens according to D19/D19a on which a selected degree of asphericity has been imparted following the formula in D1, page 10, lines 17, 18 with the higher order coefficients set to zero. The subject-matter of claim 1 of auxiliary requests 8 is thus not *prima facie* allowable.

Therefore, auxiliary request 8 was not admitted into the appeal proceedings.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

D. Magliano M. Alvazzi Delfrate

Decision electronically authenticated