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Datasheet for the decision of 5 February 2026

Case Number: T 0452/23 - 3.4.01

Application Number: 18208644.7

Publication Number: 3505145

IPC: A61F9/008

Language of the proceedings: EN

Title of invention:
LASER FIDUCIALS FOR AXIS ALIGNMENT IN CATARACT SURGERY

Patent Proprietor:
AMO Development, LLC

Opponent:
Aechter, Bernd

Headword:
Laser fiducials for cataract surgery / AMD Development

Relevant legal provisions:
EPC Art. 76, 123(2)
RPBA 2020 Art. 12(4)

Keyword:
Divisional application - added subject-matter (yes)
Amendment to case - reasons for submitting amendment in appeal proceedings (no) - amendment admitted (no)

Decisions cited:
T 0096/12, T 0410/96

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Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0

Case Number: T 0452/23 - 3.4.01

D E C I S I O N
of Technical Board of Appeal 3.4.01
of 5 February 2026

Appellant: (Patent Proprietor)	AMO Development, LLC 1700 E. St. Andrew Place Santa Ana, CA 92705 (US)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Appellant: (Opponent)	Aechter, Bernd Ter Meer Steinmeister & Partner Patentanwälte mbB Nymphenburgerstrasse 4 80335 München (DE)
Representative:	Ter Meer Steinmeister & Partner Patentanwälte mbB Nymphenburger Straße 4 80335 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 22 December 2022 concerning maintenance of the European Patent No. 3505145 in amended form.**

Composition of the Board:

Chair	P. Scriven
Members:	P. Fontenay
	L. Bühler

Summary of Facts and Submissions

I. The patent in suit is based on a divisional application of the earlier ("parent") application 14725337.

II. The Opposition Division decided that the patent could be maintained in amended form, according to the then auxiliary request 1D.

III. Both the opponent and the proprietor appealed this interlocutory decision.

IV. The opposition relied on grounds under Article 100(a) EPC in conjunction with Articles 54 (lack of novelty) and 56 EPC (lack of an inventive step), under Article 100(b) EPC (sufficiency of disclosure), and under Article 100(c) EPC (extension of subject-matter).

V. The Opposition Division held that the grounds of opposition regarding added subject-matter prejudiced the maintenance of the patent. Concretely, the Opposition Division considered that the subject-matter of claim 1 of the main request defined a non-allowable intermediate generalisation of the disclosed subject-matter, since the claim did not specify that the *treatment axis* it refers to was originally disclosed in the context of astigmatism and was input by the user of the apparatus.

VI. The same finding regarding added subject-matter applied to claim 1 of auxiliary requests 1A and 1B, which failed to specify both that the treatment axis was input by a user and was linked to astigmatism. Claim 1 of auxiliary request 1C defined both limitations but was unclear in view of dependent claims 8 and 9. Claim 1 of auxiliary request 1D, which defined both limitations and did not include claims 8 and 9, was considered to meet the requirements of the EPC.

VII. The Opposition Division further considered that the subject-matter of claim 1 of auxiliary request 1D was new and inventive over document

D1: US provisional application 60/906 944.

VIII. On appeal, the proprietor requested that the impugned decision be set aside and the opposition rejected. In the alternative, they requested that the patent be maintained on the basis of one of 44 auxiliary requests, labelled 1A, 1B, 1C, 1E, 2, 2A, 2B, 2C, 2E, 3, 3A, 3B, 3C, 3E, 4, 4A, 4B, 4C, 4D, 4E, 5, 5A, 5B, 5C, 5D, 5E, 6, 6A, 6B, 6C, 6D, 6E, 7, 7A, 7B, 7C, 7D, 7E, 8, 8A, 8B, 8C, 8D and 8E. Auxiliary request 1C corresponds to auxiliary request 1D, which was considered allowable by the Opposition Division. Auxiliary requests 4, 4A to 4D, 5, 5A to 5D, 6, 6A to 6D, 7D, 8, 8A to 8D were new requests, that were filed for the first time with the statement of grounds.

IX. The opponent requested that the impugned decision be set aside and the patent be revoked.

X. The parties were summoned to oral proceedings, in accordance with their respective requests.

XI. In a communication setting out its provisional opinion (Articles 15(1) and 17(2) RPBA), the Board indicated that it shared the view of the Opposition Division that claim 1 of the main request contained added subject-matter. With regard to the objection of lack of novelty on the basis of D1, and contrary to the finding of the Opposition Division, the Board had no doubt that the surgical incisions that contributed, in D1, to the creation of the various indents in the eye were performed with the assistance of the appropriately controlled processor.

XII. In their reply to the Board's preliminary opinion, the proprietor contested the Board's view. They emphasised, regarding the issue of added matter, that the recited feature of claim 1 regarding the treatment axis was not inextricably linked to astigmatism and to the fact that it was input by a user. They referred to originally filed claims 1, 4, and 11, and paragraphs [0014], [0017], [0022], and [0122] of the application as filed, which provided a basis for omitting these features in the claim definition.

XIII. They also referred, regarding novelty, to the claim language which defined first and second fiducials generated on an internal anatomical structure of the eye. This confirmed, they argued, that the fiducials were not three-dimensional, cut-out sections but defined mere reference marks. This excluded these marks

contributed to any locking function, as was the case for the three-dimensional indents disclosed in D1. Moreover, the locking function in D1 resulted from the association of the bumps in the intraocular lens with complementary indents in the anatomical portion present within the eye, so that the position of the two axes relative to each other was pre-set. This excluded that the user was able to determine the alignment of the two axes.

XIV. At oral proceedings before the Board, the proprietor reiterated their position that the feature of a treatment axis in claim 1 of the patent was not inextricably linked to astigmatism and to it being input by a user. They further elaborated on the differences of the claimed subject-matter from the apparatus of D1. While the fiducials according to the invention implied some engraving of the anatomical tissue and involved cutting, this was not to be compared with the indents of D1, which were intended for locking purposes and were not located on the surface of the anatomical area but extended over the entire thickness of the tissue, or a substantial portion of it.

XV. After the Board had decided on the issue of added matter, concluding that the omission, in claim 1, of the features regarding the treatment axis and the absence of its input by a user defined a non-allowable intermediate generalisation of the claimed subject-matter, the proprietor maintained auxiliary requests 1C, 4C, 5C, 6C, and 8C but withdrew all the other auxiliary requests. The proprietor's final requests were, consequently, that the opposition be rejected

(main request) or, in the alternative, that the patent be maintained on the basis of the claims according to one of auxiliary requests 1C, 4C, 5C, 6C, and 8C.

XVI. The proprietor argued that auxiliary requests 4C, 5C, 6C and 8C, which had been filed for the first time with the statement of grounds, were to be admitted. These new requests did nor raise any new issues and did not even add features that were not already present in the auxiliary requests that had been filed during the opposition proceedings. This applied, more specifically, to auxiliary request 4C and 5C, which differed from corresponding earlier requests 4C and 5C filed during opposition proceedings, respectively, only in that the alternative of an arc for the shape of the fiducials and that of the capsule lens for the anatomical structure had been deleted.

XVII. The opponent confirmed their request that the decision under appeal be set aside and the patent revoked.

XVIII. Claim 1 of the main request (claim 1 of the patent) reads:

An apparatus (2), the apparatus (2) comprising:
a laser (44) to generate a laser beam;
a scanner (62) to scan the laser beam;
an implantable device, such as an intraocular lens (IOL), having a vision correcting axis and a marker (600a, 600b);
a processor (54) operatively coupled to the laser (44) and the scanner (62), wherein the

processor (54) is configured to cause said apparatus (2) to generate a fiducial (500d1, 500d2) on an anatomical structure of an eye (EY) of a patient to enable the marker (600a, 600b) of the implantable device to be placed in a positional relationship relative to the fiducial (500d1, 500d2) to align the vision correcting axis of the implantable device with an aberration axis of the eye, wherein the processor (54) is configured to cause said apparatus (2) to generate at least two fiducials (500d1, 500d2) on the anatomical structure of the eye; characterized in that a first fiducial (500d1) and a second fiducial (500d2) are generated on an internal anatomical structure of the eye to define the treatment axis extending across a pupil of the eye and wherein the marker comprises a first marker (600a) and a second marker (600b) placed on opposite sides of the implantable device to define the vision correcting axis of the implantable device and wherein the marker (600a, 600b) and the fiducial (500d1, 500d2) are visible to a user to determine an alignment of the aberration axis with the vision correcting axis.

XIX. Claim 1 of auxiliary request 1C differs from claim 1 of the main request in that the charactering portion of the claim specifies that the treatment axis is

... the treatment axis of an astigmatism of the eye, which axis is input by a user....

XX. Claim 1 of auxiliary request 4C differs from claim 1 of the main request in that it specifies that the treatment axis is

> *... the treatment axis of an astigmatism of the eye, which axis is input by a user [...] wherein the fiducials (500d1, 500d2) have the shape of one or more of a dot, a line, a rectangle, an arrow, a cross, a trapezoid, a square, a chevron, a pentagon, a hexagon, a circle or an ellipse ....*

XXI. Claim 1 of auxiliary request 5C differs from claim 1 of the main request in that the preamble of the claim specifies that

> *... the anatomical structure is one of the limbus, the cornea, the sclera, the iris or the stroma ...*

and in that the characterising portion of the claim specifies that the treatment axis is

> *... the treatment axis of an astigmatism of the eye, which axis is input by a user ...*

XXII. Auxiliary request 6C combines the amendments to claim 1 of auxiliary requests 4C and 5C.

XXIII. Claim 1 of auxiliary request 8C differs from claim 1 of auxiliary request 6C in that the anatomical structure is limited to the stroma.

Reasons for the Decision

Main request - added subject-matter

1. The patent is derived from a divisional application. Its original description is identical to that of the parent application but additionally includes a final section in which claims 1-32 of the parent are presented as a list of "embodiments". The original application documents further contain the drawings of the parent as well as new claims 1-13.

2. Claim 1 of the patent was amended during the examination procedure of the underlying application to recite that *a first fiducial and a second fiducial are generated on an internal anatomical structure of the eye to define the treatment axis extending across a pupil of the eye*.

3. The opponent objected to this amended wording, arguing that it defined added subject-matter. This was because the claim failed to specify that the treatment axis referred to astigmatism and that it was input by a user.

4. In the proprietor's opinion, the skilled person would have readily recognised, from the original disclosure of the application and of the parent, that the notion of treatment axis was not inextricably linked to astigmatism but was disclosed for both lower order aberrations such as astigmatism and higher order aberrations such as trefoil. In this context, they referred in particular to paragraphs [0017] and [0122] of the original application, in which these other forms

of treatment are explicitly mentioned. Furthermore, they emphasised that originally filed claims 1, 4, and 11, in combination with paragraphs [0014] and [0022] of the application as filed, provided a direct and unambiguous basis for claim 1 of the patent. These sections of the description disclosed that the feature of the treatment axis being input by a user reflected a mere option.

5. Paragraph [0017] of the original application discloses that the aberration axis of the eye may comprise *an astigmatic axis or an axis of a higher order aberration*. The paragraph further refers to higher order aberration of the eye such as coma, trefoil, and spherical aberration. This is confirmed by paragraph [0122] of the original application, which states that the corrected aberration may include a lower-order aberration such as astigmatism or a higher-order aberration such as trefoil. Although these statements in the description suggest that the aberration axis is not limited to astigmatism, they do not contain a clear and unambiguous indication that the treatment axis is equivalent to the aberration axis of the eye.

6. Regarding the feature of the treatment axis being input by a user, the Board concurs with the Opposition Division that the use of the modal verb "can" in paragraphs [0014] and [0022] of the original application is not sufficient to establish that the feature is optional in the context of the claim definition.

7. First, the use of the modal verb "can" in paragraph [0014] does not necessarily convey that there is a version of the invention in which the user inputs the axis and another in which they do not. It might just as

well convey that the invention affords the user the ability to input the axis. Paragraph [0014] associates the notion of treatment axis with that of astigmatism and of a user input. It follows that the statements in paragraph [0014] do not establish beyond ambiguity that the treatment axis can be dissociated from its input by a user. Second, paragraph [0022] discloses various options concerning the apparatus. In particular, it envisages an option for the apparatus which *can further comprise a user input for inputting a treatment axis of an astigmatism of an eye.* The modal verb is used there with a different meaning. The option mentioned in this paragraph however links the notion of treatment axis with both astigmatism and the input of its axis by a user and does not provide a basis for omitting the latter feature.

8. Notwithstanding the fact that claims 1, 4, and 11 in the original application associate the features of a treatment axis with that of an astigmatism and its input by a user (claim 4) and is thus not sufficient to constitute a basis for omitting the features of an astigmatism axis and its input by a user in claim 1 of the patent under Article 100(c) EPC, said claims, which were filed with the divisional application and were not part of the parent, also cannot serve, on their own, as a basis under Article 100(c) EPC.

9. The footnote at the bottom of page 10 of the proprietor's submissions of 5 January 2026, in response to the Board's preliminary opinion, however, suggests that the reference to these claims refer to the claims of the parent. Claim 4 of the parent (listed as "embodiment" 4 in the original application), relates to the method of claim 1 (listed as "embodiment" 1, in the original application), wherein *a user inputs a*

treatment axis of an astigmatism of the eye. Contrary to the proprietor's view, claim 4 of the earlier application confirms the previous analysis that, in the context of the earlier application as filed, the notion of treatment axis is linked to the input of the astigmatism axis by a user, and cannot, therefore, justify the omission in claim 1 of the features of the treatment axis being an astigmatism axis and its input by a user.

10. In conclusion, the feature of the treatment axis is disclosed in the original and earlier applications only in combination with the feature of an astigmatism of the eye and the feature of the treatment axis being input by the user. A clear and unambiguous basis for omitting either of these two aspects is lacking in both original and earlier applications.

11. Claim 1 of the main request defines added subject-matter (Article 100(c) EPC).

Auxiliary request 1C - Novelty

12. Document D1 is a copy of US provisional application 60/906,944, submitted as priority document for international patent application WO-A-2008/112294, published on 18 September 2008. D1 was thus made available to the public on that date, and forms part of the prior art under Article 54(2) EPC.

13. D1 discloses an apparatus comprising a laser to generate a laser beam, a scanner to scan the laser beam (page 8, lines 24-31; page 10, line 27 - page 11, line 3) and a user input (page 20, lines 18-20). The apparatus can be used with an intraocular lens (IOL),

having a vision correcting axis and marks to be positioned on an anatomical structure of an eye (page 27, lines 12-14). The apparatus of D1 comprises a controller operatively coupled to the laser and the scanner, which controls the apparatus to generate these marks on the anatomical structure of an eye in a patient (page 20, lines 23-25) to enable corresponding marks on the IOL to be placed in a defined relationship to the anatomical structure. The apparatus may contribute in creating capsulorhexis incisions tailored for astigmatism-correcting IOLs, as disclosed on page 27, lines 12-22.

14. In an embodiment of such treatment, the controller contributes to the creation of indents on a lens capsule of an eye, to enable corresponding bumps on the IOL to be locked in a positional relationship with them (page 27, lines 12-23; Figure 25A). The bumps that are provided on the IOL permit its proper orientation and locking with the corresponding indents on the lens capsule.

15. In the proprietor's opinion, the indents disclosed in D1 are not fiducials within the meaning of the present invention. In their view, the term "fiducial" had a specific meaning in ophthalmology that distinguished them from incisions and cuttings in anatomical structures. While the proprietor conceded that the fiducials according to the invention were not just two-dimensional structures on an anatomical structure of the eye, but implied some engraving and cutting in a thin layer of tissue, they argued that this nevertheless precluded the presence of incisions extending through a significant thickness of the lens capsule. Such fiducials were therefore not comparable to the indents of D1, which were intended for locking

purposes and were not located on the surface of the anatomical structure.

16. Moreover, D1 did not disclose the creation of structures that could serve as orientation aids. The indents of D1, combined with the bumps of the intraocular lens, served as a locking function. This configuration defined a pre-set alignment for the indents and bumps, thus preventing alignment of the vision correction axis of the implantable device with the aberration axis of the eye.

17. The argument did not persuade the Board.

18. In the absence of evidence that the term "fiducial" has a specific meaning in the field of ophthalmology which excludes three-dimensional structures of the kind shown in D1, the indents disclosed therein do constitute fiducials within the meaning of the present invention. The reference, in claim 1, to a fiducial on an anatomical structure of an eye is not conclusive and merely implies, in the context of the invention, the presence of a reference resulting from a change in the structure of ocular tissue. This corresponds to a three-dimensional structure present within the anatomical structure and visible to the user. This is confirmed by the patent specification, according to which the fiducials correspond to precise incisions produced by the laser, for example, in the cornea, in the lens capsule, or in the crystalline lens nucleus (paragraph [0022] of the patent specification). The claim language does not distinguish between engravings on a surface of an anatomical structure and indents extending over a significant depth of the tissue structures.

19. The locking function that is achieved by the association of the indents in the anatomical structure and the corresponding bumps of the intraocular lens, in D1, is independent of the fact that the indents are visible and serve correctly to align the IOL. In effect, it is precisely this locking of the two interacting elements that ensures, in the context of D1, the alignment of the correction axis of the implantable device with the aberration axis of the eye. The claim language does not preclude the possibility that the required alignment between fiducials and markers can be achieved by such a locking effect between the anatomical structure and the IOL.

20. Contrary to the proprietor's view, the Board thus considers that the term "fiducial" in claim 1 merely requires the presence of a visible reference which can be used for aligning an intracular lens.

21. The proprietor further emphasised that D1 did not disclose a processor configured to generate at least two fiducials on an anatomical structure of an eye to enable the markers of the implantable device to be placed in a positional relationship relative to the fiducials. They referred to the decisions of the boards of appeal in cases T 96/12 and T 410/96, which emphasise that a means-plus-function construction, applied to a controller in a medical device, implied that the controller of the medical device, as programmed, was adapted to carry out the recited functions. The proprietor further underlined that the prior art controllers were programmed differently and were thus unsuitable, and certainly not configured, for causing the apparatus to generate a fiducial on an anatomical structure of an eye.

22. In contrast to the Opposition Division, the Board finds that the control electronics disclosed in D1 do meet the definition, in claim 1, regarding the processor. This follows, firstly, from the wording of the claim, which refers to a *processor to cause the apparatus to generate a fiducial on an anatomical structure of an eye,* which is too vague for the skilled person to infer any concrete functionalities of the claimed processor. Secondly, the patent specification is not helpful in this regard. The feature in question was included in claim 1 during the examination procedure and has no literal basis in the application, or in the earlier application as filed (Article 100(c) EPC), thus making it impossible to infer any concrete limitation regarding the way the processor was programmed extending beyond the fact that the processor somehow contributes to the generation of fiducials on the anatomical structure. It would not be consistent with decisions T 96/12 or T 410/96 to ascribe, under the circumstances, any concrete functionality to the processor.

23. The provision of indents in D1 (page 27, lines 18-23; Figure 25A) necessarily implies the assistance of the control electronics, which may be a computer or microcontroller (page 8, lines 25-28; page 18, lines 26-27). Even if D1 is silent as to the precise functionalities of the control electronics, the eye surgery which consists in the creation of indents in the anatomical structure requires a precise control of the laser settings such as its position, its energy, and its focusing depth. This also applies to the settings and control of the scanner which determines the treatment location and progress. All these surgical steps require a control of some sort, and necessarily involve control electronics.

24. The proprietor's argument that a laser system, which creates a fiducial instead of an indent, would not be able to contribute to the intended mechanical locking function expected from the indents, is certainly correct, but it is irrelevant under the given circumstances. The question is rather, whether a laser system which creates indents contributes to the functionality expected from fiducials, namely the provision of reference marks on the eye structure. This is true of all indent structures insofar as they are visible, as is the case of the indents disclosed in in Figure 25A of D1.

25. The claim language, effectively, only requires the provision of fiducials on an eye. The remaining indications in the claim merely specify one aspect of the underlying surgical process, namely that the markers of the implantable device can be positioned in a positional relationship relative to the fiducials. They do not add to the functionality of the processor itself, which does not go beyond the generation of fiducials on the anatomical structure of the eye.

26. The goal of the surgical treatment, in D1, is to correct astigmatism. This implicitly means that the axis of the detected aberration and the axis of the IOL must be selected accordingly (D1: page 4, lines 5-28).

27. The subject-matter of claim 1 of auxiliary request 1C, therefore, is not new (Article 54 EPC).

Auxiliary request 4C - Admissibility - Allowability

28. Claim 1 of auxiliary request 4C differs from claim 1 of auxiliary request 1C in that it additionally defines a

list of possible shapes for the fiducials. Specifically, they can have the shape of one or more of a dot, a line, a rectangle, an arrow, a cross, a trapezoid, a square, a chevron, a pentagon, a hexagon, a circle, or an ellipse. This version of claim 1 differs from claim 1 of corresponding request 4C before the Opposition Division in that the alternative shape of an "arc" has been deleted from the list.

29. Although new request 4C is a reaction to the objection of lack of novelty or inventive step raised in the opposition proceedings, and could and should have been filed before the Opposition Division, the amendment is straightforward and does not affect procedural economy. For this reason, the Board exercised its discretion in favour of the proprietor and admitted auxiliary request 4C into the proceedings (Article 12(4) RPBA).

30. The amendment in claim 1 of auxiliary request 4C does not affect the Board's conclusion that the claimed subject-matter is not new, within the meaning of Article 54 EPC, taking into account the teaching of D1. This follows from the Board's finding that the indents of D1, as shown in Figure 25A, have the shape of a line. The claim language places no restriction regarding the shape of such a line, which is not limited to a straight lines of the kind illustrated in Figure 6 of the patent.

31. The subject-matter of claim 1 of auxiliary request 4C is not new (Article 54 EPC).

Auxiliary request 5C, 6C and 8C - Admissibility

32. Auxiliary requests 5C, 6C, and 8C were filed together with the statement of grounds. They represent a response to the objections of lack of novelty and inventive step, raised in the opposition proceedings. Compared to claim 1 of auxiliary request 1C, claim 1 specifies the anatomical structure on which the fiducials are generated (auxiliary request 5C, 6C, 8C) and includes, insofar as claim 1 of auxiliary requests 6C and 8C are concerned, a list of shapes for the fiducials. Claim 1 of auxiliary request 5C differs from claim 1 of corresponding auxiliary request 5C before the Opposition Division in that the recited list of anatomical structures no longer includes a lens capsule.

33. The proprietor has not explained why the amendments, which could and should have been filed before the Opposition Division, were filed only with the statement of grounds of appeal. Although claim 1 of auxiliary request 5C differs from claim 1 of the corresponding request 5C previously filed in the opposition proceedings only by the deletion of one alternative, the amendment raises new questions regarding novelty and inventive step, which affects the procedural economy of appeal proceedings.

34. As a consequence, the Board did not admit auxiliary requests 5C, 6C, and 8C into the appeal proceedings (Article 12(4) RPBA).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chair:

D. Meyfarth P. Scriven

Decision electronically authenticated