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Datasheet for the decision of 5 May 2014

Case Number: T 0832/09 - 3.2.02

Application Number: 03009955.0

Publication Number: 1352623

IPC: A61F9/01

Language of the proceedings: EN

Title of invention:
Apparatus for customized refractive surgery

Applicant:
IVIS TECHNOLOGIES S.r.l

Headword:

Relevant legal provisions:
EPC Art. 54, 56, 76(1), 84, 123(2)

Keyword:
Amendments - added subject-matter (no)
Claims - clarity after amendment (yes)
Novelty - after amendment (yes)
Inventive step - after amendment (yes)

Decisions cited:
R 0015/11

Catchword:

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Case Number: T 0832/09 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 5 May 2014

Appellant: (Applicant)	IVIS TECHNOLOGIES S.r.l Via Luigi Corsi 50 74100 Taranto (IT)
Representative:	Wegner, Hans Bardehle Pagenberg Partnerschaft mbB Patentanwälte, Rechtsanwälte Prinzregentenplatz 7 81675 München (DE)
Decision under appeal:	**Decision of the Examining Division of the European Patent Office posted on 25 November 2008 refusing European patent application No. 03009955.0 pursuant to Article 97(2) EPC.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	C. Körber
	D. Ceccarelli

Summary of Facts and Submissions

I. On 25 November 2008 the Examining Division posted its decision to refuse European patent application No. 03009955.0 for lack of inventive step.

II. An appeal was lodged against this decision by the applicant by notice received on 30 January 2009. The appeal fee was received on 28 January 2009. The statement setting out the grounds of appeal was received on 3 April 2009.

III. Oral proceedings were held on 14 April 2011 at the end of which the Board announced its decision to dismiss the appeal.

IV. In petition for review proceedings (R 15/11), the Enlarged Board of Appeal decided to set aside the decision mentioned under point III and to reopen the proceedings before Board 3.2.02.

V. In response to the present Board's communication dated 20 February 2014, the appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of its main request filed with letter dated 22 April 2014, or, in the alternative, auxiliary requests II or III filed with letter dated 3 August 2013.

VI. The following documents are of importance for the present decision:

D1: WO-A-98/42291;
D2: US-A-5 571 107;
D3: US-A-4 721 379;
D4: DE-A-43 37 842;

D5: US-A-5 740 815.

VII. Claim 1 of the main request reads:

"An apparatus for determining and ablating a corneal tissue volume necessary for correcting a visual ametropia, comprising:

a. a control unit (1) operatively connected to an excimer laser (5) or solid state laser (5), and to a corneal topographer (2), for morphologically determining a corneal front surface of an eye;

b. the apparatus being configured to:

b.1 determine an aconic surface adapted to approximate the corneal front surface of the eye;

b.2 determine a corneal ideal aconic surface from a vectorial summation of a refraction related to the determined aconic surface and of the subjective refraction of the eye; and

b.3 determine an ablating volume by a crossing of the corneal front surface of the eye and of the corneal ideal aconic surface."

Claims 2 to 10 are dependent claims.

VIII. The appellant's arguments are in essence those on which the following Reasons of the Decision are based.

Reasons for the Decision

1. The appeal is admissible.

2. Amendments

Claim 1 of the main request is based on page 1, lines 3 to 6, page 3, lines 4 to 12 and lines 27 to 28, page 4, lines 1 to 8, page 5, line 28 to page 6, line 7 and page 6, lines 15 to 21 of the application as originally filed (with corresponding passages being present in the parent application as published (WO-A-01/03621)).

The description filed with letter dated 22 April 2014 has been adapted to the amended set of claims, with document D1 being acknowledged as closest prior art.

The Board is satisfied that the requirements of Articles 123(2) and 76(1) EPC are fulfilled.

3. Clarity

3.1 As credibly stated by the appellant, the "aconic surface" referred to in feature b.1 of claim 1 of the main request designates a surface that cannot generally be described by a rotation of a conic section such as a circle, ellipse or parabola around its axis of symmetry (a simple aconic surface being constituted, for instance, by a torus). An approximation to the corneal front surface of the eye as defined in feature b.1 can be performed by standard fitting algorithms known to the skilled person.

3.2 From page 5, line 28 to page 6, line 21 it may be understood that the "subjective refraction of the eye" in feature b.2 is determined subjectively, e.g. by an

ophthalmologist getting a patient to look through lenses with varying refraction at a row of characters with diminishing size, and is characterised by a number of conventionally employed parameters such as "sphere", "cylinder" and "axis", as appropriate. They relate to the visual correction required for optimised vision. Similarly, the "aconic surface" in feature b.1 may be characterised by a corresponding set of parameters, extracted from respective mathematical models known to the skilled person. The subjective refraction parameters are then summed vectorially with the refraction parameters derived from the fitted aconic surface, yielding ideal refractive parameters from which "the corneal ideal aconic surface" can be reconstructed using known algorithms. The summation of refraction is of "vectorial" nature since in general not only one-dimensional diopter values are summed, but further values such as "cylinder" and "axis" are involved, i.e. a multi-dimensional calculation is carried out.

3.3 The Board is satisfied that requirements of Article 84 EPC are fulfilled.

4. Novelty

Document D1 discloses a method for determining data for treating a cornea (claim 1 of D1) by means of a laser (claim 10) of a kind not further specified in D1. The locations of a plurality of points of the cornea are determined via topometry (claim 2). The locations of the plurality of points may be graphically displayed to the eye surgeon, e.g. by means of a mesh representation (page 3, lines 8 to 11). These "locations of a plurality of points of the cornea" in D1 may be seen as corresponding to the morphologically determined

"corneal front surface of an eye" as defined in feature a of claim 1. However, even if the mesh representation is regarded as some kind of approximation, there is no disclosure in D1 that an aconic surface is used for this approximation as defined in feature b.2 of claim 1.

D1 further teaches that a control surface ("Sollfläche") of the cornea may be determined subjectively by the surgeon based on his clinical experience (page 4, lines 4 to 8). This may be seen as corresponding to the "subjective refraction" referred to in feature b.2 of claim 1. For the plurality of points of the cornea, the distance to the control surface is calculated (claim 1), and the location and the distance of the plurality of points are output by a computer for laser treatment of the cornea (claim 1). Before the actual treatment is carried out, the treatment is simulated and the expected result is displayed to the surgeon (page 4, lines 14 to 19). If the result is not satisfactory, the treatment method is altered or the control surface is varied (page 5, lines 2 to 4). In varying the control surface, graphically displaying the distances of the plurality of points from the control surface may help the surgeon (page 4, lines 4 to 8). The computer allows different treatment methods and control surfaces to be simulated, so that the optimised treatment method can then be carried out (page 5, lines 4 to 7). After simulating the different control surfaces and/or treatment methods, the surgeon selects those which provide the best result (page 7, lines 2 to 13) before the laser treatment is actually carried out. This may be seen as corresponding to determining "an ablating volume by a crossing of the corneal front surface of the eye" (feature b.3 of claim 1) and of the control surface disclosed in D1. However, D1 merely discloses

that the control surface is spherical (page 3, line 11), which is different from an aconical surface according to the definition given in point 3.1 above. From nowhere in D1 can it be derived that the control surface is a "corneal ideal aconic surface", determined as defined in feature b.2 of claim 1.

Accordingly, D1 fails to disclose that the laser is an **excimer** laser or **solid state** laser as defined in feature a of claim 1, that the "surface adapted to approximate the corneal front surface" referred to in feature b.1 is **aconic**, and that the apparatus is configured to determine a corneal ideal **aconic** surface **from a vectorial summation of a refraction related to the determined aconic surface and of the subjective refraction of the eye** and to determine an ablating volume by a crossing of the corneal front surface of the eye and of the corneal ideal **aconic** surface as defined in features b.2 and b.3.

Nor do the other cited documents disclose in combination the features of claim 1.

Accordingly, the subject-matter of claim 1 of the main request is novel within the meaning of Article 54 EPC.

5. Inventive step

Document D1 represents the closest prior art.

The approximation of the corneal front surface by an aconic surface as defined in the above-mentioned distinguishing feature b.1 provides a realistic fit, especially to an astigmatic cornea, thus reducing the volume to be ablated in such situations. The determination of a corneal ideal aconic surface from a

vectorial summation as defined in feature b.2 permits a correlation with parameters conventionally used to characterise subjective refraction (as mentioned above in point 3.2), particularly in cases of astigmatism. In such situations, the patient's vision can thus be corrected more accurately with minimised ablation.

The objective technical problem is to provide an ablation apparatus that allows a more accurate correction of different individual kinds of visual ametropia with minimal removal of corneal structure (page 1, lines 3 to 6 and 13 to 24 of the description of the application).

Document D1 itself gives no hint towards the above-mentioned distinguishing features and the underlying problem.

Document D2 relates to laser surgery of corneas and addresses the inadequacy of corrective surgery in aspheric, irregularly astigmatic corneal surfaces (column 1, lines 41 to 45) thus giving a hint in the direction of the above-mentioned problem. However, the approach taken in D2 by using a diffractive optical element (DOE) to manipulate and modify the irradiated flux density profile over the entire area to be treated (column 2, lines 24 to 33) is quite different from that of the present invention as defined in features b.1 to b.3.

From claim 3 of D3 one may derive that an "idealized cornea" is defined (yet not an ideal **aconic** surface) and used in a laser sculpting means (Modules E and G in Figure 1 and column 5, lines 37 to 66). However, D3 does not disclose or suggest that the idealised cornea is determined from a vectorial summation as defined by

feature b.2 of claim 1, involving an aconic surface determined as defined in feature b.1.

D4 discloses a corneal ablation apparatus and suggests (page 2, lines 8 to 10) an excimer laser or solid state laser as mentioned in feature a of claim 1. D4 is mainly concerned with avoiding extreme changes in curvature arising in the transition zone between ablated and non-ablated areas and smoothing this transition (page 2, lines 39 to 43). The surface adapted to approximate the corneal front surface is not aconic. Nor does D4 disclose or suggest the specific vectorial summation according to feature b.2. The "post-ablation curve" is described by its radius of curvature (R2), and there is no suggestion in D4 that it could correspond to an aconic surface.

D5, likewise cited in the European Search Report, also discloses an apparatus for determining and ablating corneal tissue volume with an excimer laser (column 10, lines 49 to 51) as mentioned in feature a of claim 1. The document teaches to determine a target induced astigmatism from a subtraction of refractive and topographic astigmatisms which may be induced on the cornea. However, it also fails to disclose the determination of a corneal ideal aconic surface, let alone from a vectorial summation of refraction related to the determined aconic surface and of the subjective refraction of the eye (features b.1 and b.2 of claim 1).

Accordingly none of the teachings of the cited documents renders obvious the features of claim 1 of the main request. Its subject-matter is based on an inventive step within the meaning of Article 56 EPC. The same

applies to claims 2 to 10 which relate to preferred embodiments of the invention as defined in claim 1.

6. As the main request is allowable, it is not necessary for the Board to deal with the auxiliary requests.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to grant a patent on the basis of the following documents:

claims 1 to 10 of the main request filed with letter dated 22 April 2014;

description pages 1, 1a and 2 to 8 filed with letter dated 22 April 2014;

drawing sheets 1/2 and 2/2 as originally filed.

The Registrar: The Chairman:

I. Aperribay E. Dufrasne

Decision electronically authenticated