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D E C I S I O N
of 30 March 1999

Case Number: T 0063/96 - 3.2.2

Application Number: 86304097.8

Publication Number: 0247260

IPC: A61B 3/10

Language of the proceedings: EN

Title of invention:
Apparatus for analysis and correction of abnormal refractive errors of the eye

Patentee:
Visx Incorporated

Opponent:
01: Firma Carl Zeiss
02: Summit Technology, Inc.

Headword:
-

Relevant legal provisions:
EPC Art. 54(2), (3), 56

Keyword:
"Novelty (main request) - yes"
"Inventive step (main request) - no"
"Remittal to the first instance (auxiliary request)"

Decisions cited:
-

Catchword:

-

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Case Number: T 0063/96 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 30 March 1999

Appellant: (Proprietor of the patent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 3 November 1995 revoking European patent No. 0 247 260 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: W. D. Weiß
Members: M. G. Noël
J. C. M. De Preter

Summary of Facts and Submissions

I. European patent No. 0 247 260 was granted on 28 July 1993.

II. In consequence of two oppositions filed by the respondents against the grant of the patent, the Opposition Division decided on 3 November 1995 to revoke the European patent for lack of novelty of its subject-matter with respect to document:

(3) EP-A-0 224 322 in connection with priority document

(3b) GB-8 604 405 filed 21 February 1986

and/or for lack of inventive step having regard, in particular, to the combination of documents:

(1) "Photoablative reprofiling of the cornea using an excimer laser: Photorefractive keratectomy" by J. Marshall et al., Lasers in Ophtalmology, volume 1, No. 1, May 1986, pages 21 to 48; and

(2) WO-A-86/02249

III. The appellant (proprietor of the patent) lodged an appeal against the first instance's decision on 12 January 1996. A statement of grounds was filed on 13 March 1996 to support the maintenance of claim 1 as granted (main request).

The respondent 1 (opponent 1) decided not to reply to the appellant's statement.

The respondent 2 (opponent 2) replied by letter dated 19 September 1996 and requested that oral proceedings be arranged.

IV. Following a first communication by the Board issued on 15 May 1998 the appellant on 25 September 1998, filed an auxiliary request comprising three new independent claims 1, 9 and 13, the patent as granted being maintained as main request.

V. In a second communication sent on 29 December 1998 and annexed to the summons to attend oral proceedings, the provisional opinion of the Board was that claim 1 according to the main request lacked novelty with respect to document (3) within the meaning of Article 54(3) EPC. Instead, claim 1 according to the auxiliary request appeared to be novel. Subject to some formal amendments to be made in the other independent claims of the auxiliary request, it was the Board's intention to remit the case back to the first instance for further examination of the new independent claims, the subject-matter of which had been removed substantially. In that view, oral proceedings could be avoided provided that the respondent's request for oral proceedings be abandoned.

VI. In response to the second communication of the Board, the respondent 2 decided to withdraw its request for oral proceedings and the respondent 1 informed the Board that it would not attend the oral proceedings. The appellant replied by maintaining its view as to the novelty of claim 1 according to the main request.

VII. Oral proceedings were held on 30 March 1999 in the

presence of the appellant only. At the oral proceedings and in their written submissions the parties argued as follows:

(i) the appellant:

- Document (3) is a state of the art within the meaning of Article 54(3) EPC. There is disclosed "a display" in the paragraph at the bottom of column 24, but said paragraph has no counterpart in the respective priority document (3b). Therefore, the display disclosed in document (3) with reference to Figure 24 is not entitled to the priority date of document (3b) and, consequently, not opposable to the novelty of claim 1.

- In priority document (3b)(cf. in particular page 17, lines 17 to 21) there is no mention of any "display" or of any "monitor" as a noun, i.e. used as a visual control device. Instead, a control and monitoring unit is provided in order "to monitor" (as a verb) the operation, using a microcomputer, whereby reprofiling of the cornea is effected between measurement operations. However, a microcomputer does not require a display to perform these operations and to obtain the desired corneal profile. Further, Figure 14 of document (3b) has very little in common with Figure 22 of document (3), which may illustrate a subsequent development of document (3b) but without the benefit of the priority date. And even if document (3b) was held to disclose a display, both the actually and

desired topographies of the anterior surface of the cornea would not be displayed as required by feature (e) of Claim 1 in suit.

Since neither document (3) nor document (3b) directly and unambiguously disclose the provision of a display, feature (e) of Claim 1 according to the main request must be regarded as novel.

- Document (1) describes the clinical procedure of photorefractive keratectomy (PRK) as being premature. This document is speculative and actually contains no enabling disclosure but a list of prerequisites, most of which were unobtainable at the time the document was published. Therefore, the Opposition Division failed to consider the teaching of document (1) at the filing date of the opposed patent, which results in an inadmissible ex-post-facto analysis.

- Document (2) discloses a scanning keratometer provided with display means for displaying measurements of the actual topography of the eye. To adapt such display means to additionally display the desired topography of the cornea and to incorporate such topography determining means into the reprofiling system according to document (1) must be regarded as a further ex-post-facto reasoning. It results that claim 1 cannot be derived from a combination of the precited documents and, therefore, involves an inventive step.

(ii) The respondent 2:

- The clear teaching in document (3) of monitoring parameters which indicate the progress of a reprofiling operation, implies the display of such parameters in a visual display, the more because said monitoring is done using a computer which operates in dependence on the actual and ideal topography data of the corneal shape. Therefore, the subject-matter of claim 1 lacks novelty with respect to the disclosure of document (3).

- Document (1) only differs from the subject-matter of claim 1 according to the main request by feature (e), that is by display means for displaying the actual and desired topograhies. Since document (2) discloses the provision of display means in a scanning keratometer for measuring and monitoring the condition of the cornea during PRK operation, this technique is also relevant to other ophtalmo procedures, including that proposed in document (1) or in the contested patent as well. Therefore, the subject-matter of claim 1 is rendered obvious by the consideration of documents (1) and (2).

VIII. The appellant, at the end of the oral proceedings, requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or on the basis of claims 1 to 13 as submitted by letter of 25 September 1998 (auxiliary request).

The respondent 2, in its written submissions, requested

that the appeal be dismissed.

IX. Claim 1 according to the main request reads as follows:

"Ophtalmological apparatus for correctively improving optical properties of an eye by sculpturing the optically used central area of the anterior surface of the cornea to achieve a requisite change in the curvature thereof, said apparatus comprising:

(a) a digital computer; and

(b) computer controlled automatic lasersculpturing means for directing laser radiation to the optically used central area of the anterior surface of the cornea, the laser radiation being such as to be capable of selectively ablating the anterior surface of the cornea by photodecomposition with penetration into the stroma and volumetric removal of corneal tissue;

and said apparatus being **characterized** by the provision of:

(c) means connected to said computer for determining the actual topography of the anterior surface of the cornea and for entering corresponding digitized actual topography data into storage in said computer;

(d) means connected to said computer for enabling digitized output data corresponding to a desired topography of the anterior surface of the cornea to be entered into storage in said computer; and

(e) display means connected to said computer and arranged to provide a computer-aided and coordinated display of the actual and desired topographies;

and by virtue of the arrangement being such that in operation of the apparatus the laser radiation of said laser-sculpturing means is automatically controlled by said computer in dependence upon the actual and desired topography data in said computer storage so as to effect a sculpturing volumetric removal of tissue from the optically used central area of the anterior surface of the cornea in order to achieve a change in the curvature thereof away from its actual topography and towards its desired topography."

Reasons for the Decision

1. The appeal is admissible.

2. *Novelty (main request)*

2.1 With respect to novelty documents (3) and (3b) have to be considered as a state of the art under the provision of Article 54(3) EPC.

The Board has been convinced by the arguments submitted by the appellant during the oral proceedings and summarised in above point VII(i). The term "monitor" mentioned at several occasions in document (3) and associated priority document (3b) always refers to the function of controlling or checking the operation of the system by maintaining a regular surveillance of the

same. This function generally expressed by the verb "to monitor" or "monitoring" (see document (3), column 5, line 33 and column 10, line 47; document (3b), page 5, line 7 and page 17, line 15) is performed by the computer but does not necessarily imply the provision of a display device as such, whereas feature (e) of claim 1 in suit refers specifically to a display used as a visual control device ("a monitor" as a noun) for performing the function. Therefore, feature (e) is not directly or unambiguously derived from, i.e. not implicitly disclosed by document (3). Consequently, the subject-matter of claim 1 is novel within the meaning of Article 54(3) EPC.

2.2 Document (1) relates to photorefractive keratectomy and discloses (cf. in particular right-hand columns of pages 23 and 46) an ophtalmological apparatus having all features recited in claim 1, excepted feature (e), as was accepted by the appellant too. As a matter of fact, document (1) does not describe any display, still less "display means for providing a computer-aided display of the actual and desired topographies of the cornea" so that, again, the subject-matter of claim 1 is novel also within the meaning of Article 54(2) EPC.

3. *Inventive step (main request)*

3.1 Document (3) being irrelevant for the assessment of inventive step of the subject-matter of claim 1 in the meaning of Article 56, second sentence EPC, document (1) is regarded as the closest prior art.

With respect to document (1), the only distinguishing feature (e) of claim 1 represents the contribution to

the solution of the problem addressed in the patent (cf. column 4, lines 5 to 9) of providing a computer-aided means for determining the nature and extent of refraction-corrective corneal surgery required to achieve emmetropia of an eye to be corrected.

According to feature (e) display means are connected to the computer and arranged to provide a display of the actual and desired topographies. According to Figure 1 of the patent, these means correspond to an additional CAD/CAM display referred to in module D for receiving, from module A, digitized measurement data of the actual topography of the corneal surface and, from module E, digitized data of the desired or idealized topography of the same (cf. column 6, lines 47 to 55). Therefore, feature (e) allows for a direct visual comparison between the idealized and the measured eye along the meridian selected for profile display (cf. column 7, lines 20 to 29).

3.2 Document (1) recommends to exploit the extremely promising potential of photorefractive keratectomy (PRK), in particular in terms of accuracy for controlling corneal tissue removal, although the introduction of PRK as a clinical procedure was regarded as still premature at this time.

However, document (1) discloses all the prerequisites which are necessary for performing said procedure, in particular all essential means the ophtalmological apparatus should incorporate, some of which are measuring and computing means for appropriately calculating the desired correction, starting from preoperative measurements. It is of minor importance

that the means proposed in document (1) are generally disclosed in terms of their functions since claim 1 is not more specific either ("means for"). Consequently, the subject-matter of claim 1 under appeal only differs from the disclosure of document (1) by the provision of display means according to feature (e)(see also point 2.2).

3.3 Document (2) discloses (cf. Figure 1) a scanning keratometer comprising a microcomputer and having display means 22 for the display of data and control information (cf. page 5, lines 1 to 8). Most commercially available keratometers are criticized in document (1) as not being sufficiently precise when measuring corneal refraction errors. This criticism, however does not apply to the keratometer disclosed in document (2) which has the advantages of speed, ease of use, accuracy and low cost, and therefore allows for rapid and accurate measurement and mapping of the corneal curvature. This known keratometer may not only be used during a number of ophtalmic surgical procedures for the purpose of monitoring the condition of the cornea but also for other purposes such as, for example, for measuring and/or monitoring width and depth of incisions made in the cornea, e.g. during radial keratotomy lasering (cf. page 16, second paragraph).

It is true that the scanning keratometer according to document (2) is suggested to be used mainly for displaying a topographic representation of the eye from measurement values. However, whenever the eye measurements remain within a set range, a number of scan are made and points of any successive scan may be

compared with the corresponding point on the previous scan (cf. bottom of page 13 and top of page 14). In such cases, the displayed topography can be said to correspond to desired values. In the Board's view, it is close at hand for a person skilled in the art to make use of the display means at disposal in document (2), in the most appropriate way, in particular to display both the actual and the desired topographies of the cornea from measured and desired values provided by the procedure recommended in document (1).

3.4 For these reasons the Board is satisfied that the subject-matter of claim 1 according to the main request is rendered obvious having regard to the teachings of documents (1) and (2) in combination. As a consequence, the provisions of Article 56 EPC are not fulfilled.

4. *Auxiliary request*

Independent claims 1, 9 and 13 according to the auxiliary request are formed by combining different features taken from the dependent claims of the main request. In particular, independent claims 1 and 13 incorporate previous claims 6 and 8 relating respectively to thickness means connected to the computer for determining the thickness of the cornea at different locations (module B) and for storing the corresponding data into the computer (module C) as well as means for providing a comparative display of the measured topography and thickness data in relation to a corresponding integrated data-bank experience (module F).

By the submission of these new claims, the subject-matter of the present invention has now been moved towards new combinations of features which have not yet been examined by the first instance. Therefore, the Board considers it appropriate to make use of its power conferred by Article 111(1) EPC to remit the case to the Opposition Division for further prosecution on the basis of the claims according to the auxiliary request.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the Opposition Division for further prosecution on the basis of claims 1 to 13 submitted by letter of 25 September 1998.

The Registrar: The Chairman:

S. Fabiani W. D. Weiß