

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte RICHARD A. HOFER, STEPHEN J. KOONS, and
JOHN KARL SHIMMICK

Appeal 2008-2331
Application 09/950,563
Technology Center 3700

Decided: September 22, 2008

Before DONALD E. ADAMS, ERIC GRIMES, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to methods and systems of performing laser vision correction. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

BACKGROUND

Laser vision correction “procedures generally employ an ultraviolet or infrared laser to remove a microscopic layer of an anterior stromal tissue from the cornea to alter its refractive power” (Spec. 1). The Specification discloses that correcting hyperopia or astigmatism (or both in the same eye) using laser correction procedures presents difficulties because the required ablation creates “steep walls” or “sharp transitions” on the surface of the cornea (*id.* at 2-3).

What is needed in the field of ophthalmological surgery, therefore, are systems and methods for correcting both hyperopia and astigmatism of the eye by laser removal of the corneal surface. It would be particularly desirable to perform such hyperopia and astigmatism corrections without generating steep walls in the region between the outer boundary of the optical zone and the adjacent untreated anterior surface portion of the cornea.

(*Id.* at 3.)

The Specification discloses

systems, methods and apparatus for performing selective ablation of a corneal surface of an eye to effect a desired corneal shape, such as for correcting a hyperopic condition by laser sculpting the corneal surface to increase its curvature. The present invention is particularly useful for correcting hyperopic conditions with a cylindrical component of curvature (i.e., astigmatism).

(*Id.*)

DISCUSSION

1. CLAIMS

Claims 1-14 are on appeal. Claims 1, 5, 9 and 13 are representative and read as follows:

Claim 1: A method of performing selective ablation of a corneal surface of an eye to effect a desired corneal shape, wherein the desired corneal shape includes a first section having a first depth of tissue removal and a second section having a second depth of tissue removal less than the first depth, the method comprising:

- establishing an optical correction zone on a corneal surface of an eye;
- directing a laser beam through an aperture to produce a profiled beam having substantially rectangular shape and a cross-sectional area smaller than the optical correction zone; and

- displacing the laser beam to a plurality of selected locations on the optical correction zone to effect the desired corneal shape, wherein at least a portion of a substantial amount of the selected locations covers the first section of the optical correction zone to remove corneal tissue to the first depth at the first section, and at least a portion of a lesser amount of the selected locations cover the second section to remove corneal tissue to the second depth at the second section that is less than the first depth.

Claim 5: The method of claim 1 further comprising the step of allowing the laser beam to pass through a variable diameter diaphragm and a variable width slit.

Claim 9: A system for performing selective ablation of a corneal surface of an eye to effect a desired corneal shape, the system comprising:

- a laser that generates a laser beam;
- delivery optics coupled to the laser that directs the laser beam onto a corneal surface of an eye;

- a variable aperture element that profiles the laser beam to perform cylindrical corrections on the cornea; and

- a laser beam direction system that displaces the laser beam across the cornea, wherein the laser beam direction system and the variable aperture element operate in conjunction to change the corneal surface from an initial

curvature having hyperopic and astigmatic optical properties to a subsequent curvature having correctively improved optical properties.

Claim 13: The system of claim 9 wherein the laser beam direction system comprises
an imaging lens positioned between the variable aperture element and the eye, and
a translational motor for translating the imaging lens along a linear direction so as to translate an image of the variable aperture element across the corneal surface.

2. OBVIOUSNESS

Claims 1-14 stand rejected under 35 U.S.C. § 103(a) as obvious in view of Seiler¹ and L'Esperance.² The claims are argued in five groups: claims 1-4 (group 1), claims 5 and 6 (group 2), claims 7 and 8 (group 3), claims 9-12 (group 4), and claim 13 (group 5). The claims in each group stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii).

With regard to claim 1, the Examiner relies on Seiler as disclosing “scanning a beam across a variable aperture to produce refractive correction” (Answer 3). The Examiner relies on L'Esperance as disclosing that “selective ablation such as for correcting myopia; hyperopia, astigmatism, and transition zones can be formed by selective exposure through appropriately configured variable apertures” (*id.*).

The Examiner concludes that it would have been obvious “to provide the corrective combinations (e.g. myopic and astigmatic) taught by

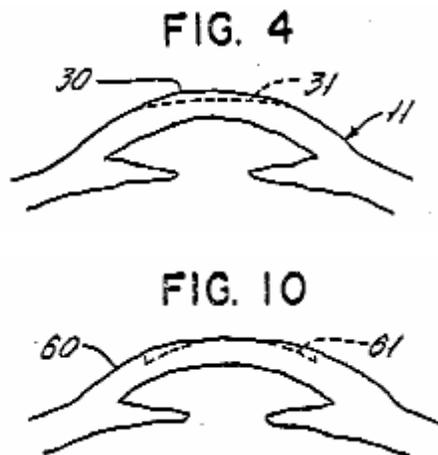
¹ Theo Seiler, *Photorefractive Keratectomy: European Experience*, Color Atlas/Text of Excimer Laser Surgery 53-54, (Igaku-Shoin Medical Publishers, Inc., New York, New York 1993).

² L'Esperance, Jr., US 4,732,148, Mar. 22, 1988.

[L'Esperance], since these are common refractive corrections; and to define a second zone which is covered by less than two of the selected locations and/or in a central zone, since this would provide a hyperopic correction and leave the maximum amount of corneal tissue" (*id.*).

We conclude that the Examiner has set forth a prima facie case that claim 1 would have been obvious to the ordinary artisan. Seiler discloses that there are two different approaches to photorefractive keratectomy: the scanning slit technique and the large-area technique (Seiler 53). Seiler also discloses that the scanning slit technique "creates a large-area photoablation by scanning a slitlike exposure area of $7 \times 1 \text{ mm}^2$ " (*id.* at 54) and that the technique can be used to correct either myopia or hyperopia (*id.*).

L'Esperance discloses the "controlled ablation of the cornea, using ultraviolet laser radiation, wherein irradiated flux density and exposure time are so controlled as to achieve [the] desired depth of the ablation" (L'Esperance, abstract). Figures 4 and 10 of L'Esperance are shown below:



Figures 4 and 10 are said to show simplified diagrams to illustrate "the nature of ablative corneal sculpture ... for the case of correcting a myopia

condition” and “for the case of correcting a hyperopia condition,” respectively (*id.* at col. 2, ll. 51-66).

L’Esperance discloses that the dashed line 31 in Fig. 4 “represents the ultimate curvature to which the anterior surface of the cornea should be modified” for myopia correction and that to “achieve the curve **31**, the minimum desired photodecomposition is at the outer boundary **29**, and the maximum is at the center” (*id.* at col. 4, ll. 49-60).

L’Esperance discloses that Fig. 10 illustrates that “the anterior curvature is to be increased, as to achieve a new profile **61**” for hyperopia correction (*id.* at col. 6, ll. 53-57) and that laser pulses are allocated so that “greatest cumulative ablative penetration of the cornea is at larger radii, while least penetration is at smaller radii, resulting in the corrected ultimate profile **61** of decreased radius” (*id.* at col. 7, ll. 9-13).

We agree with the Examiner that it would have been *prima facie* obvious to one of skill in the art at the time the invention was made to combine the teachings of Seiler and L’Esperance and thereby arrive at the invention of claim 1. Seiler discloses the use of a laser for corneal laser ablation to correct both myopia and hyperopia by scanning a slitlike exposure area of $7 \times 1 \text{ mm}^2$ (i.e., a profiled beam having substantially rectangular shape) over the area of cornea to be corrected. L’Esperance discloses that correction of either myopia or hyperopia by laser ablation entails the ablation of corneal tissue to at least two different depths to achieve shaping of the cornea. Thus, in view of the references, one of skill in the art would understand that correcting myopia or hyperopia using the scanning method of Seiler would entail corneal tissue removal to a first

depth at a first section and corneal tissue removal at a second depth, which is less than the first depth, at a second section.

Appellants argue that the references do not disclose displacing a laser beam to a plurality of selected locations to achieve first and second tissue depths and that the combined references do not suggest a pattern of substantially rectangular ablations, as required by claim 1 (Appeal Br. 8-9).

We are not persuaded by this argument. It is well settled that “claims in an application are to be given their broadest reasonable interpretation consistent with the specification and that claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art.” *In re Sneed*, 710 F.2d 1544, 1548 (Fed. Cir. 1983) (citation omitted). “Absent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification or prosecution history when those sources expressly disclaim the broader definition.” *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004).

Here, claim 1 does not recite “a pattern of substantially rectangular ablations”; it only requires that the laser beam be a profiled beam with a substantially rectangular shape. Although the Specification discloses rectangular ablations on the surface of the cornea, the Specification also discloses that the profiled beam shape that is imaged onto the surface of the eye may be generated by variety of techniques, including masks (Spec. 7, ll. 20-23). Thus, it would be improper to limit claim 1 only to methods wherein the profiled rectangular beam forms rectangular ablations directly.

In addition, Seiler reasonably appears to describe a pattern of rectangular ablations. Seiler discloses photoablation by scanning a laser

having a slit-like exposure area of $7 \times 1 \text{ mm}^2$ (Seiler 54). Seiler states that the laser works at a repetition rate of 25 Hz and that usually “a field of $7 \times 10 \text{ mm}^2$ is scanned with a sweep time of 2 seconds” (*id.*). In our view, these disclosures would reasonably be understood to describe a process of moving a laser to achieve ablation to different tissue depths. Seiler’s description of a $7 \times 1 \text{ mm}^2$ exposure area being scanned at a repetition rate of 25 Hz across a field of $7 \times 10 \text{ mm}^2$ also reasonably appears to describe a pattern of substantially rectangular ablations.

Appellants also argue that there is no motivation or suggestion in the art to combine the references to arrive at the method of claim 1 and that L’Esperance “teaches away from the combination of the two references” in that the L’Esperance system “uses a non-scanning laser and ... the objects of the L’Esperance patent are achieved without the use of scanning techniques” (Appeal Br. 10). Appellants further argue that there is no motivation or suggestion to combine Seiler and L’Esperance because “Seiler contemplates masks mounted on suction rings adjusted and fixed to the patient's eye” and the masks of L’Esperance “are designed to be positioned in front of the laser” (*id.*).

We are not persuaded by this argument. Seiler discloses that using a scanning laser in conjunction with masks was a conventional method of correcting myopia or hyperopia by laser photoablation. The Examiner relies on the disclosure of L’Esperance only to show that corneal ablation to correct for myopia or hyperopia is known to involve ablation at different depths at different locations. The Examiner’s rejection does not depend on the masks of L’Esperance being physically incorporated into the method of

Seiler, but only to indicate the pattern of ablation that is to be generated on the surface of the cornea.

With regard to claims 5 and 7, Appellants argue that the cited references do not teach or suggest the step of “allowing the laser beam to pass through a variable diameter diaphragm and a variable width slit” (Appeal Br. 11).

The Examiner reasons that L’Esperance discloses “a surgery wherein both an astigmatic procedure and a cylindrical procedure are performed ... requiring the passage of the beam first through the variable width slit (e.g. as shown in Fig. 19) and then through a variable iris” (Answer 8). The Examiner concludes that the claims read on the “surgery described by L’Esperance” (Answer 9). Thus, as we understand it, the Examiner’s reasoning is that performing the procedures sequentially (i.e. an astigmatism correction procedure with passage of the beam through a variable slit and then a myopia correction procedure with passage of the beam through a variable diameter diaphragm, or vice versa) would meet the limitations of the claims.

We agree with Appellants that the Examiner has not adequately explained how the references would have suggested “the step of allowing the laser beam to pass through a variable diameter diaphragm and a variable width slit” (claim 5) or a method comprising “allowing the laser beam to pass through a variable diameter diaphragm and a variable width slit” (claim 7).

The Examiner has interpreted the claims as reading on performing two different procedures to constitute allowing the laser beam pass through both

(i) a variable diameter diaphragm and (ii) a variable width slit. This reading of the claim language is broader than would be considered reasonable by a person of ordinary skill in the surgical art. Claim 5 states that “the laser beam” used in “[a] method of performing selective ablation” (claim 1) is allowed to pass through both a variable diameter diaphragm and a variable width slit. Claim 7 recites the same limitations. The claim language therefore indicates that the laser beam passes through both the diaphragm and the slit in the same procedure.

Consistent with the claim language, the Specification states that “[i]n a preferred implementation of the method, the laser beam passes through a variable width slit and a variable diameter diaphragm to create a profiled beam that is imaged onto the corneal surface” (Spec. 4). Given this description in the Specification and the specific language of the claims, those of skill in the art would interpret the claims to require that the same laser beam be allowed to pass through a variable diameter diaphragm and a variable width slit in the same procedure.

Thus, we agree with Appellants that the Examiner has not established a prima facie case of obviousness with regard to claims 5 and 7 in view of Seiler and L’Esperance. Claims 6 and 8 depend on claims 5 and 7, respectively, and therefore incorporate their limitations. The rejection of claims 5-8 under 35 U.S.C. § 103(a) is reversed.

With regard to claim 9, Appellants argue that the cited references do not “teach or suggest a laser beam direction system that displaces the laser beam across the cornea” and do not “teach or suggest a system for performing selective ablation of a corneal surface in which a laser beam

direction system and a variable aperture element *operate in conjunction* to change the corneal surface from an initial curvature having hyperopic and astigmatic optical properties to a subsequent curvature having correctively improved optical properties” (Appeal Br. 14).

We do not find this argument to be persuasive. Seiler discloses a scanning laser, as set forth above, and that myopia is corrected using “a standard iris diaphragm driven by a stepper motor, whereas hyperopia is corrected by means of a rotating diaphragm with spirallike perforations” (Seiler 54). This disclosure reasonably appears to describe a “laser beam direction system that displaces the laser beam across the cornea,” as recited in claim 9.

In addition, L’Esperance discloses that both hyperopic and astigmatic optical properties may be present in a single eye (L’Esperance, col. 8, ll. 37-41) and that a variable aperture may be used to correct for astigmatism (*id.* at col. 8, ll. 1-7; col. 10, ll. 15-26; and Fig. 19). Thus, given that Seiler discloses a system for selective ablation to change corneal shape using a laser beam direction system that displaces the laser beam across the cornea and masks to control the shape, and given that L’Esperance discloses a variable aperture element to correct astigmatism, the references would have suggested to one of skill in the art the combination of a displaceable laser beam direction system and a variable aperture element to correct astigmatism.

With regard to claim 13, Appellants argue that the cited references do not teach or suggest “an imaging lens and translational motor as recited in claim 13” (Appeal Br. 14-15).

The Examiner cites L'Esperance's Figure 31 as "demonstrat[ing] a variable aperture (elements 171, 172, and 173) with a zoom lens interposed [between] the aperture and the cornea (element 174) with a drive (element 176) that actuates a motor (element 175)" (Answer 10). The Examiner reasons that the "motor causes the zoom lens to translate linearly back and forth, in the manner of standard zoom lenses in the art," and this "linear motion will, in turn, cause the image to expand (or contract) on the cornea, thereby translating it across the corneal surface" (*id.*).

We agree with Appellants that the Examiner has not adequately explained how the references would have suggested "a translational motor for translating the imaging-lens along a linear direction so as to translate an image of the variable aperture element across the corneal surface," as required by claim 13.

Here, the Examiner has interpreted the claims as reading on a motor that causes a zoom lens to operate in the manner of standard zoom lenses in the art, i.e., to cause the image to expand or contract.

However, the claim specifies that the translational motor translates "the imaging-lens along a linear direction *so as to translate an image of the variable aperture element across the corneal surface.*" The Specification describes the function of the translational motor as follows:

The image lens motor 12 is used to translate the lens 51 relative to the central axis.... Displacing lens 51 by translating the lens in a radial direction off the central axis . . . displaces the image of the aperture in a related manner. As discussed in more detail below, lens 51 may be displaced such that the image of the aperture is displaced across the optical correction zone to effect a series of rectangular ablations (i.e., cylindrical corrections) across the optical correction zone.

(Spec. 7, l. 31 through 8, l. 3.)

Thus, the claim specifies that the purpose of the translational motor is to translate an image of the variable aperture across the corneal surface, and the Specification provides that the lens motor translates the lens relative to the central axis, so as to effect a series of ablations across the optical correction zone.

When the claim is read in light of the Specification, those of skill in the art would recognize that a standard zoom lens that operates to move the lens in a direction along a central axis would not meet the limitation of the claim because it would not displace an image across the optical correction zone of a corneal surface. Thus, we agree with Appellants that the Examiner has not established a prima facie case of obviousness with regard to claim 13 in view of Seiler and L'Esperance, and the rejection of claim 13 under 35 U.S.C. § 103(a) is reversed.

SUMMARY

We affirm the rejection of claims 1-4, 9-12, and 14 under 35 U.S.C. § 103(a), but reverse the rejection with respect to claims 5-8 and 13.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

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