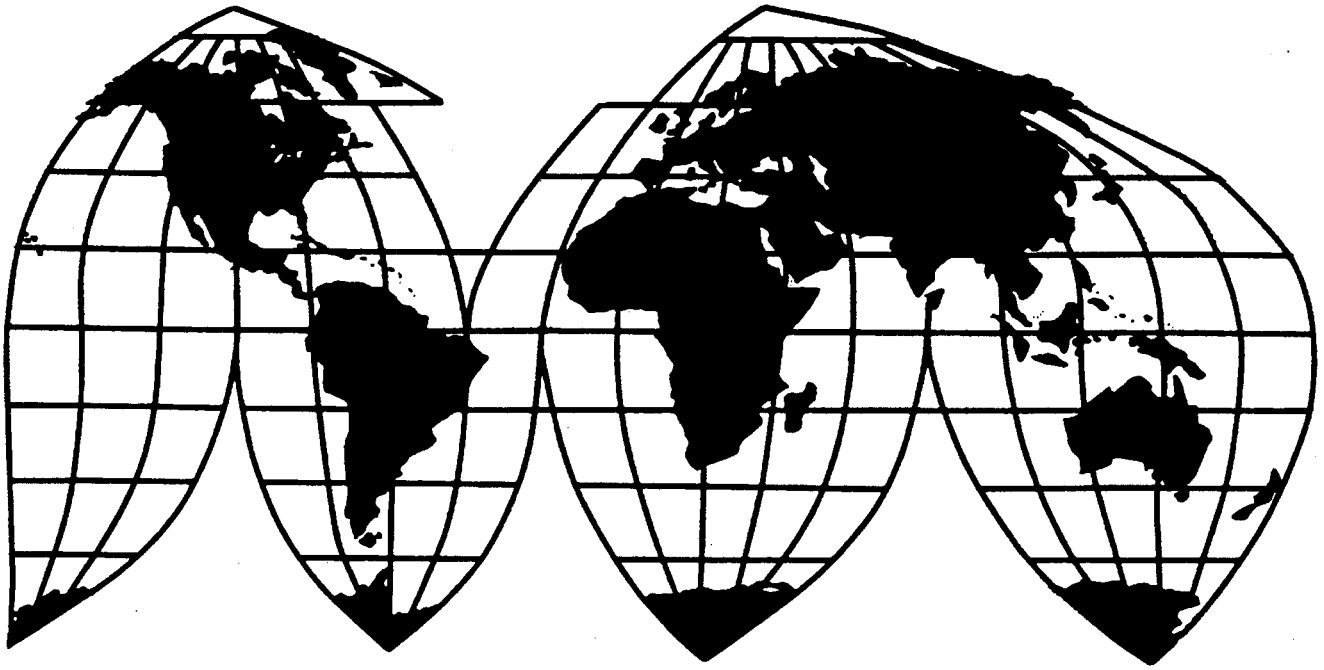
In the Matter of

Certain Excimer Laser Systems for Vision Correction Surgery and Components Thereof and Methods for Performing Such Surgery

Investigation No. 337-TA-419

Publication 3299 **May 2000**

U.S. International Trade Commission



Washington, DC 20436

U.S. International Trade Commission

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Marcia E. Miller, Vice Chairman
Jennifer A. Hillman
Stephen Koplan
Thelma J. Askey
Deanna Tanner Okun

Address all communications to
Secretary to the Commission
United States International Trade Commission
Washington, DC 20436

U.S. International Trade Commission

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In the Matter of

Certain Excimer Laser Systems for Vision Correction Surgery and Components Thereof and Methods for Performing Such Surgery

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UNITED STATES INTERNATIONAL TRADE COMMISSION
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In the Matter of

CERTAIN EXCIMER LASER SYSTEMS FOR VISION CORRECTION SURGERY AND COMPONENTS THEREOF AND METHODS FOR PERFORMING SUCH SURGERY

Inv. No. 337-TA-419

'00 MAR -6 P2:14

NOTICE OF FINAL DETERMINATION

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has found no violation of section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, in the above-referenced investigation.

FOR FURTHER INFORMATION CONTACT: Timothy P. Monaghan, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone 202-205-3152. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202-205-1810.

SUPPLEMENTARY INFORMATION: This investigation was instituted on March 1, 1999, based on a complaint by VISX, Inc. ("VISX"), 64 Fed. Reg. 10016-17. The respondents named in the investigation are Nidek Co., Ltd., Nidek Inc., and Nidek Technologies, Inc (herein collectively "Nidek"). Complainant alleges importation and sale of certain excimer laser systems for vision correction surgery that infringe claims of U.S. Letters Patents Nos. 4,718,418 ("the '418 patent") and 5,711,762 ("the '762 patent"). An evidentiary hearing was held from August 18, 1999, to August 27, 1999.

On December 6, 1999, the presiding administrative law judge ("ALJ") issued her final initial determination ("ID") finding that complainant VISX failed to establish the required

domestic industry, that there was no infringement of any claim at issue, and that the '762 patent was invalid and unenforceable.

VISX, Nidek, and the Commission investigative attorneys filed petitions for review of the ID on December 17, 1999, and on December 27, 1999, all parties responded to each other's petitions for review of the ID. On February 2, 2000, the Commission determined not to review the ID's findings with respect to the '418 patent and determined to review all the ID's findings with respect to the '762 patent.

Having examined the record in this investigation, including the briefs and the responses thereto, the Commission determined that there is no violation of section 337. More specifically, the Commission found no infringement of any claim at issue of the '762 patent and no domestic industry with respect to the '762 patent. The Commission determined to take no position on the issues of the validity and enforceability of the '762 patent.

This action is taken under the authority of section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, and sections 210.45-210.51 of the Commission's Rules of Practice and Procedure, 19 C.F.R. §§ 210.45-210.51.

Copies of the public versions of the Commission order and the Commission opinion in support thereof are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street S.W., Washington, D.C. 20436, telephone 202-205-2000.

By order of the Commission.

Donna R. Koehnke
Secretary

Issued: March 6, 2000

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C. 20436

In the Matter of

CERTAIN EXCIMER LASER SYSTEMS FOR VISION CORRECTION SURGERY AND COMPONENTS THEREOF AND METHODS FOR PERFORMING SUCH SURGERY

Inv. No. 337-TA-419

ORDER

This investigation was instituted on March 1, 1999, based on a complaint by VISX, Inc. ("VISX"), 64 Fed. Reg. 10016-17. The respondents named in the investigation are Nidek Co., Ltd., Nidek Inc., and Nidek Technologies, Inc (herein collectively "Nidek"). Complainant alleges importation and sale of certain excimer laser systems for vision correction surgery that infringe claims of U.S. Letters Patents Nos. 4,718,418 ("the '418 patent") and 5,711,762 ("the '762 patent"). An evidentiary hearing was held from August 18, 1999, to August 27, 1999.

On December 6, 1999, the presiding administrative law judge ("ALJ") issued her final initial determination ("ID") finding that complainant VISX failed to establish the required domestic industry, that there is no infringement of any claim at issue, and that the '762 patent is invalid and unenforceable.

VISX, Nidek, and the Commission investigative attorneys filed petitions for review of the

ID on December 17, 1999, and on December 27, 1999, all parties responded to each other's petitions for review of the ID.

On February 2, 2000, the Commission determined not to review the ID's findings with respect to the '418 patent and determined to review all the ID's findings with respect to the '762 patent.

Having examined the record in this investigation, including the briefs and the responses thereto, it is hereby ORDERED THAT:

1. The investigation is terminated with a finding of no violation of section 337 of the Tariff Act of 1930 (19 U.S.C. §1337).

2. The Commission finds that the claims in issue of the '762 patent are not infringed by the accused imported Nidek EC-5000 laser systems for vision correction surgery.

3. The Commission finds that no domestic industry exists with respect to the '762 patent.

4. The Commission takes no position with regard to the validity and enforceability of the '762 patent.

5. The Secretary shall serve copies of this Order, and the forthcoming Commission Opinion in support thereof, on the parties of record and on the Department of Health and Human Services, the Department of Justice, and the Federal Trade Commission, and publish notice thereof in the *Federal Register*.

By order of the Commission.

Donna R. Koehnke

Secretary

Issued: March 6, 2000

CERTAIN EXCIMER LASER SYSTEMS FOR VISION CORRECTION SURGERY AND COMPONENTS THEREOF AND METHODS FOR PERFORMING SUCH SURGERY

337-TA-419

CERTIFICATE OF SERVICE

I Donna R. Koehnke, hereby certify that the attached **Notice of Final Determination and Order**, was served upon the following parties via first class mail and air mail where necessary, on March 6, 2000.

Donna R. Koehnke, Secretary
U.S. International Trade Commission
500 E Street, S.W., Room 112
Washington, D.C. 20436

ON BEHALF OF COMPLAINANT VISX INCORPORATED:

Harold J. McElhinny, Esq.
Morrison and Foerster LLP
425 Market Street
San Francisco, CA 94105

Alan Cope Johnson, Esq.
Morrison and Foerster LLP
755 Page Mill Road
Palo Alto, CA 94304

G. Brian Busey, Esq.
Morrison and Foerster LLP
2000 Pennsylvania Avenue, N.W.
Washington, D.C. 20006

ON BEHALF OF RESPONDENTS NIDEK COMPANY LIMITED, NIDEK INCORPORATED, AND NIDEK TECHNOLOGIES INCORPORATED:

Neil B. Siegel, Esq.
Robert M. Masters, Esq.
Sughrue, Mion, Zinn, Macpeak
and Seas, PLLC
2100 Pennsylvania Avenue, N.W.
Suite 800
Washington, D.C. 20037-3213

F. David Foster, Esq.
Sturgis M. Sobin, Esq.
Ablondi, Foster, Sobin and Davidow
1150 Eighteenth Street, N.W.
Suite 900
Washington, D.C. 20036

ON BEHALF OF RESPONDENTS NIDEK COMPANY LIMITED, NIDEK INCORPORATED, AND NIDEK TECHNOLOGIES INCORPORATED-CONT.:

Joseph F. Tringali, Esq.
Simpson Thacher and Bartlett
425 Lexington Avenue
New York, NY 10017

ON BEHALF OF COMMISSION:

Steven A. Glazer, Esq.
Office of Unfair Import Investigations
U.S. International Trade Commission
500 E Street, S.W., Room 401-K
Washington, D.C. 20436

Juan S. Cockburn, Esq.
Office of Unfair Import Investigations
U.S. International Trade Commission
500 E Street, S.W. Room 401-Q
Washington, D.C. 20436

Timothy P. Monaghan, Esq.
Office of the General Counsel
U.S. International Trade Commission
500 E Street, S.W. Room 707-U
Washington, D.C. 20436

PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C. 20436

In the Matter of CERTAIN EXCIMER LASER SYSTEMS FOR VISION CORRECTION SURGERY AND COMPONENTS THEREOF AND METHODS FOR PERFORMING SUCH SURGERY	Inv. No. 337-TA-419

COMMISSION OPINION

This section 337 investigation is before the Commission for final disposition of the issues under review and, if necessary, for determinations on remedy, the public interest, and bonding. We find no violation of section 337 of the Tariff Act of 1930. We therefore need not consider the issues of remedy, the public interest, and bonding.

I. BACKGROUND

The Commission instituted this investigation based on a complaint filed on January 22, 1999 by VISX, Incorporated ("VISX"), a Delaware corporation headquartered in California. The complaint alleged a violation of section 337 by Nidek Co., Ltd., Nidek Inc., and Nidek Technologies, Inc. (collectively "Nidek") in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain excimer laser

systems for vision correction surgery and components thereof that allegedly infringed claims 26 and 27 of U. S. Letters Patent 4,718,418 ("the '418 patent"), claim 30 of U. S. Letters Patent 4,732,148 ("the '148 patent"), and claims 1, 7, 10, and 12 of U. S. Letters Patent 5, 711, 762 ("the '762 patent"), all owned by VISX. The Commission issued its notice of investigation on February 23, 1999. On May 12, 1999, VISX moved to amend the notice of investigation to add independent claim 1 and dependent claims 6 and 8 of U.S. Letters Patent 5,735,843 ("the '843 patent") and to delete claim 30, the only claim at issue of the '148 patent. That motion was denied by an administrative law judge ("ALJ") order issued on May 27, 1999, with leave granted to VISX to refile a motion withdrawing claim 30 of the '148 patent (Order No. 13). Such a motion was filed on June 8, 1999, and was unopposed. The ALJ granted the motion on June 9, 1999, in an initial determination ("ID") which the Commission determined not to review. The evidentiary hearing in this matter began on August 18, 1999, and concluded on August 27, 1999.

On December 6, 1999, the ALJ issued her final ID finding that there was no violation of section 337. The ALJ found that there was no infringement of any claim at issue in the proceeding. She further found that the complainant failed to demonstrate satisfaction of the domestic industry requirement of section 337 for either the '418 patent or the '762 patent and also found that the '762 patent was invalid under 35 U.S.C. § 102 (f) because of improper inventorship and unenforceable because of inequitable conduct before the U.S. Patent and Trademark Office.

VISX, Nidek, and the Commission investigative attorneys ("IAs") filed petitions for review of the ID, and all filed responses to each other's petitions for review.

On February 2, 2000, the Commission determined not to review the ID's findings with respect to the '418 patent and determined to review all the ID's findings with respect to the '762 patent. The parties were asked to respond to a series of questions, as well as provide written submissions on remedy, the public interest, and bonding. In accordance with the Commission's instructions, the parties filed their main briefs on February 14, 2000, and their reply briefs on February 18, 2000.

Having examined the record in this investigation, including the briefs and the responses thereto, we determine that there is no violation of section 337. In determining not to review the ALJ's findings that the '418 patent was not infringed and that there was no domestic industry practicing that patent, we adopted her findings as our own.[1] Therefore, we do not further discuss the '418 patent. Upon review of the ALJ's findings with respect to the '762 patent, we find no infringement of any claim at issue of the '762 patent, and no domestic industry practicing the claims of the '762 patent. We take no position on the issues of validity and enforceability of the '762 patent. *Beloit Corp. v. Valmet Oy*, 742 F.2d 1421 (Fed. Cir. 1984).

II. NO VIOLATION OF SECTION 337

The Products and Patent at Issue

A. The Products at Issue

The products at issue are excimer laser systems for vision correction surgery and components thereof. Such systems are used for the purpose of changing the shape of a patient's cornea so that images are properly focused on the retina, which reduces or eliminates the need for

[1] *See* 65 Fed. Reg. 6625-28.

corrective eyewear. Excimer laser systems emit laser pulses to remove (ablate) very thin layers of tissue from the front (anterior) surface of the cornea in a pattern so as to reshape the cornea. The term "excimer" is short for "excited dimer," and in this investigation refers to lasers that use mixtures of argon and fluorine gas to generate laser light at a desired wavelength of invisible ultraviolet light. VISX's excimer laser systems, the domestically-produced 20/20A, 20/20B, STAR, and STAR S2 systems, and respondents' imported excimer laser system, the Nidek EC-5000, all use an excimer laser beam at a wavelength of 193 nanometers to ablate corneal tissue to correct vision problems.

B. The Patent at Issue

The `762 patent, entitled "Laser Surgery Apparatus and Method," was issued on January 27, 1998, and expires on January 26, 2015. The named inventor is Dr. Stephen Trokel. The `762 patent has been assigned to VISX. The `762 patent stems from a series of continuation applications and divisional applications that emanated from original Application Serial No. 561,804, which was filed with the U.S. Patent and Trademark Office ("PTO") on December 15, 1983. The '762 patent did not issue until 14 years later.

VISX contends that respondents' imported laser systems infringe independent claim 1 and dependent claims 7, 10, and 12 of the `762 patent. VISX also contends that its domestic laser systems practice claims 1, 10, and 12 of the patent.

a. Claim Construction

The analysis of infringement involves a two-step process: first, construction of the claims asserted to determine their meaning and scope, and second, comparison of the properly construed

claims to the accused products. In construing the claims of a patent, the meaning and scope of the patent claims must be determined by reference to intrinsic evidence, *viz.*, the claim language, the patent specification, and the prosecution history. Extrinsic evidence, such as expert testimony about how those skilled in the art would interpret certain language in the claim, may also be considered when appropriate as an aid in arriving at the proper construction of the claim. *Tanabe Seiyaku Co. v. U.S. Int'l Trade Comm'n*, 109 F.3d 726, 732 (Fed. Cir. 1997), *cert. denied*, 118 S.Ct. 624 (1997); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Claim language should be construed according to its usual meaning to one of ordinary skill in the art where such construction is consistent with the specification. *Multiform Dessicants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998).

With respect to "means-plus-function" claim elements, the statute provides that:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

35 U.S.C. § 112, paragraph 6. The Federal Circuit has stated that "[t]he plain and unambiguous meaning of paragraph six is that one construing means-plus-function language in a claim must look to the specification and interpret that language in light of the corresponding structure, material, or acts described therein, and equivalents thereof, to the extent that the specification provides such disclosure." *In re Donaldson*, 16 F.3d 1189, 1193 (Fed. Cir. 1994).

Thus, by statutory mandate, the functional language of a means-plus-function claim is

interpreted by reference to the "corresponding structure" disclosed in the specification. Therefore, a threshold issue in claim construction is determining whether the claim at issue is a means-plus-function claim. If the claim is found to be a means-plus-function claim, then it "must be limited to only those means that are "equivalent" to the actual means shown in the patent specification. This is an application of the doctrine of equivalents in a restrictive role, narrowing the application of broad literal claim elements."[2]

1. Claim 1

Claim 1 of the '762 patent reads as follows:

> A system for use in a laser source surgical method for removing corneal tissue, said system comprising:
>
> (a) a laser that produces a beam of radiation at a wavelength of about 193 nanometers in a series of pulses;
>
> (b) *a laser delivery system means* for receiving said radiation from said laser and delivering a fraction of said radiation to a cornea; and
>
> (c) wherein said radiation produces a depth of ablation of *approximately 1 micron* for each accumulation of one joule per square centimeter of energy applied.

CX-967, col. 6, lines 39-49 (the '762 patent) (emphasis added).

We agree with the ALJ's finding that the preamble's limitation to an apparatus for procedures only on corneal tissue is necessary for proper definition and construction of the scope of claim 1. ID at 41, *citing Gerber Garment Tech. Inc v. Lectra Systems, Inc.*, 916 F.2d 683 (Fed. Cir. 1990) ("Where words in the preamble 'are necessary to give meaning to the claim and properly define the invention,' they are deemed limitations of the claim"); *Perkin Elmer Corp. v.*

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[2] *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 28 (1997)

Computervision Corp., 732 F.2d 888 (Fed. Cir.), *cert. denied*, 469 U.S. 857 (1984) (finding claim limitations in the preamble where ". . . it is necessary to give meaning to the claim and properly define the invention).

Clauses (b) and (c) contain the claim elements in dispute. Each of these will be discussed below.

a. Laser Delivery System Means

The "laser delivery system means" described in clause (b) of claim 1 of the '762 patent is a means-plus-function element that requires examination of the specification for the structure(s) performing the function of "receiving said radiation from said laser and delivering a fraction of said radiation to a cornea." Before the ALJ, VISX and the IAs argued that Figures 2 and 3 of the '762 patent depict laser delivery systems that are the corresponding structures disclosed in the specification. ID at 41. Nidek contended that the '762 patent required that the specific delivery systems of Figures 2 and 3 be incorporated into Figure 1 as examples of the laser delivery system. Consequently, Nidek argued that the laser delivery system of claim 1 requires the use of a proximity mask as depicted in Figure 1. ID at 41-42.

The ALJ construed the laser delivery system of claim 1 of the '762 patent as requiring the use of a "proximity mask." She based her claim construction on a finding that the apparatuses shown in Figure 3 and Figure 2 must be used with the system shown in Figure 1 due to the labeling of those figures and sentences in the patent that state: "FIG 2 is a schematic illustration of a laser delivery system for use with the apparatus and system of FIG 1" and that "FIG 3 is a schematic illustration of an ophthalmic delivery system for use with the apparatus and system of

FIG 1." ID at 44, *citing* RX 3, col. 2, lines 62-67 (the '762 patent). Consequently, she found that the laser delivery system of claim 1 required the use of a proximity mask as set forth in Figure 1 of the patent. ID at 46.

While we agree with the ALJ that these sentences are unambiguous descriptions set forth in the patent itself, we find that there are statements in the patent and its prosecution history that more fully explain the intended function of Figure 3 which indicate that it is intended to be an alternative embodiment of element (b) of claim 1. We find that Figure 1 and Figure 3 both depict complete alternative structures for claim element (b). In other words, Figures 1 and Figure 3 each separately depict the laser delivery system of claim 1 of the '762 patent that "receiv[es]" laser radiation from the excimer laser source and "deliver[s] a fraction of said radiation to a cornea." Accordingly, this construction does not require that a "proximity mask," as disclosed in Figure 1, be used in conjunction with the apparatus of Figure 3 in order for the apparatus of Figure 3 to perform the function claimed by element (b) of claim 1. This construction is most consistent with the terms of claims 1, 10, and 12 of the '762 patent, the specification, and the prosecution history. First, the portion of the '762 specification describing Figure 3 describes a complete system for receiving laser radiation and delivering it all the way to the eye. The Figure 3 apparatus is described as "an ophthalmic delivery system" that directs "laser beam 82 through variable slit 84 to and through lens 86, through an aperture 88, through another lens 90, and onto an area, such as an eye 92, upon which a surgical procedure is to be performed." RX-3, col. 4, lines 5-10. Moreover, Figure 3 and the accompanying description in the patent do not teach the use of a proximity or contact mask. Figure 2, on the other hand, is described in the specification

as a "laser delivery system 50," but no mention is made of the laser beam reaching the cornea and there is no apparent means set forth in Figure 2 for delivering a fraction of the laser radiation to the cornea unless a proximity or contact mask is used. RX-3, col. 3 line 66- col. 4, line 4. Given this, we believe that the patent teaches that Figure 2 was intended to fit into item 22 of Figure 1 (the laser delivery system), which requires a proximity or contact mask and which shows the laser beam being delivered to the eye through the mask. We find that Figure 3, on the other hand, does not readily fit into item 22 of Figure 1 because Figure 3 shows a complete delivery system reaching the cornea, as does the apparatus shown in Figure 1. In this regard, Figure 3 also has a means for delivering a fraction of the radiation to the cornea without a proximity contact mask.

The prosecution history supports this claim construction. In June 1996, the PTO examiner rejected certain claims in the application that led to the '762 patent on various grounds, one of which was that the specification failed to provide an enabling disclosure under 35 U.S.C. § 112 for forming, among other things, a mask that would "provide a graded intensity from center to edge." (CX-710 at 82354 (June 18, 1996 Office Action).) After an interview with VISX, the Examiner withdrew the nonenablement rejections, stating that "changing the area of the variable slit (element 84, Figure 3) changes the area of the ablation spot of the eye (element 92, Figure 3)." (*Id.* at 82361 (August 16, 1996, Examiner Interview Summary Record).) The examiner also found that the specification "would imply to one having ordinary skill in the art, the use of multiple apertures (either circular or slit) to provide a given configuration and/or depth to the ablated area." *Id.* In further support of this interpretation, the examiner agreed to have

double-headed arrows added to slit 84, further emphasizing that slit's ability to open and close. Additionally, an examination of the file wrapper reveals that this clarification of the operation of variable slit 84 was one of the primary reasons for allowance of the '762 patent. Notice of Allowability, CX-710 at 082477, referencing the amendment filed September 18, 1996.

We believe these statements support VISX's construction of claim 1, *viz.*, that variable slit 84 has the capability to influence or determine the size and ablation pattern on the cornea, and that Figure 3 is an alternate embodiment of element (b) of claim 1 that fulfills the "delivering radiation while reducing intensity" function of the laser delivery system means without the use of a proximity mask. Statements in the prosecution history are highly relevant in construing claims and are often of critical significance in determining the meaning of the claims. *Vitronics, 90 F.3d at 1582; accord Intel Corp. v. United States ITC*, 946 F.2d 821, 843 (Fed. Cir. 1991). Indeed, we note that the examiner, under M.P.E.P 1302.10, chose Figure 3 as the pictorial embodiment of the invention, to be shown on the first page of the '762 patent.

For these reasons, we find that Figure 3 is a separate embodiment of element (b), the laser delivery system means, of claim 1 of the '762 patent, and that the laser means does not require that the proximity mask of Figure 1 be used in conjunction with the apparatus of Figure 3 in order for the Figure 3 apparatus to perform the claimed function of element (b) of claim 1.

b. Ablation Rate

The ALJ found that the ablation rate term of "approximately 1 micron," set forth in clause (c) of claim 1, should be construed literally to cover between 0.7 and 1.3 microns, *i.e.*, a range of $\pm$ 0.3 microns or a 30 percent variation. We believe that the ALJ's interpretation of this

claim term is correct and adopt it as our own.[3]

The ALJ found that, in light of the ordinary meaning of the claim terms, the illustration in the specification (the only example offered in the specification comports with 1 micron for each Joule/cm^2), and the evidence regarding this technology, "approximately 1" literally covers between 0.7 and 1.3 microns, *i.e.*, a range of $\pm$ 0.3 microns or a 30 percent variation. She noted that in common parlance "approximately" is used to refer to something that is near to or close to whatever it modifies. ID at 49. She found it appropriate under the circumstances, given the inherent flexibility in such a term, to consider testimony by those of skill in the art, and she found that the most credible expert testimony supported a more narrow range, such as that proposed by Nidek and the IAs, rather than the broad range proposed by VISX. ID at 49.

VISX's primary witness on this issue, Dr. Motamedi, testified that his interpretation of "approximately 1" as extending to "3" comports with the ordinary meaning of "approximately," a conclusion with which the ALJ did not agree. ID at 50. Given the weight of testimony about the acceptable range of deviation, the ALJ stated that she could not accept Dr. Motamedi's and VISX's assertion that such a large range (up to 3 microns) should be allowed within the scope of "approximately 1 micron." ID at 50. [

[3] Before the ALJ, VISX argued that "approximately 1 micron" should be construed to cover up to 3 microns, while Nidek contends that only a 0.25 micron variation above and below 1 micron should be permitted under the "approximately" language, and the IAs take the position that the "conservative" covered range should be "no less than 1 micron $\pm$ 0.3 microns." ID at 46.

] Therefore, she found that "approximately 1 micron" literally covers a range of 0.7 microns to 1.3 microns. ID at 50-51.

We find that the ALJ's interpretation of the ablation rate claim element was reasonable. Accordingly, we adopt her finding that "approximately 1 micron" literally covers a range of 0.7 microns to 1.3 microns.

2. Claim 7

Claim 7, which depends from claim 1, defines a system of claim 1 which can produce pulses at the cornea which have between 100 and 200 milijoules of energy per square centimeter. The ALJ construed the claim as merely requiring the system to produce pulses within the range of intensity described in the claim. ID at 51. We agree with that construction of the claim.

3. Claim 10

Claim 10 depends from claim 1, and adds a means-plus-function limitation (a means for controlling the volume of tissue removed during a procedure), and further specifies that the means should include a mask.

In the specification of the '762 patent, the structures identified as controlling the volume of corneal tissue removed are the laser power supply and control system 24 and, as explicitly set forth in the claim language, a mask. RX 3, col. 4, lines 53-57. The control system allows for controlling the pulse energy density and the pulse repetition rate, which determine in part the volume of tissue ablated. RX 3, col. 3, lines 60-65. As to the mask, the specification teaches that "[d]efined volumes of tissue can be removed by masking to control the area ablating the tissue to a predetermined depth." RX 3, col. 5, lines 21-23. We adopt a construction of claim 10 whereby the mask disclosed in the specification is the contact or proximity mask 30 shown in Figure 1 of the patent, or any of the masks in Figures 4, 5, 6, 7, and 8, referred to in the specification as masks "useable with the apparatus and system of FIG. 1." RX 3, col. 3, lines 1-11. This is consistent with the ALJ's interpretation of the claim. ID at 54.

4. Claim 12

Claim 12, which depends from claim 1, recites an additional means-plus-function limitation, "means for selectively shaping a surface of the cornea," as part of the laser delivery system means. We adopt a construction of claim 12 whereby the corresponding structures in the specification that selectively shape the surface of a cornea are the power supply and control 24, along with the masks shown in the patent figures as 30, 110, 120, 130, and 140. We believe that the masks disclosed in the specification are clearly linked with this means-plus-function element "means for selectively shaping a surface of the cornea":

> In fact, the laser light of the described method and apparatus can be applied to a circular mask of graded intensity center to edge. This would take away more tissue either centrally or peripherally

> depending on the distribution of light. The net effect would be either to steepen or flatten the cornea. The ability to make controlled radial incisions, *or to selectively shape the corneal surface*, allows modification of the refractive status of the eye.

RX 3, Col. 5, lines 56-65 (emphasis added).

This interpretation is supported by the specification, which explains that the power supply and control determine the pulse repetition rate and the laser output. Since the ablation of tissue is determined in large part by the fluence and pulse repetition rate, these structures, along with the masks, perform the function of selective re-shaping of the cornea. ID at RX 3, col. 4, lines 53-64.

B. Infringement of the '762 Patent

The asserted claims, as properly construed, must be compared to the accused product, Nidek's EC-5000 system, to determine whether the patent claims are infringed. *Tanabe Seiyaku Co. v. U.S. Int'l Trade Comm'n*, 109 F.3d 726, 732 (Fed Cir.), *cert. denied*, 118 S.Ct. 624 (1997); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). The burden rests on the patent owner to establish infringement by a preponderance of the evidence. *Rohm & Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1092 (Fed. Cir. 1997); *SmithKline Diagnostics Inc. v. Helena Lab. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988). The patent owner must show that, for each claim asserted, the accused product satisfies every claim limitation, either literally or under the doctrine of equivalents. *Id.* To prove literal infringement of a means-plus-function limitation, the patent owner must demonstrate that a structure on the accused product performs the same function as, and is structurally identical or

equivalent to, the structure identified in the patent specification as corresponding to the means-plus-function limitation. *Odetics, Inc. v. Storage Tech. Corp.*; 185 F.3d 1259 (Fed. Cir. 1999). To prove infringement under the doctrine of equivalents, the patentee must show that the accused product contains elements equivalent to each claimed element of the patented invention. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 40 (1997).

VISX alleges infringement by Nidek's imported EC 5000 laser system of claims 1, 7, 10, and 12 of the '762 patent either literally under 35 U.S.C. § 112, ¶ 6 or under the doctrine of equivalents. Specifically, VISX argues that the functions performed by the EC-5000 are identical to those set forth in claim 1 of the '762 patent (*i.e.*, to receive radiation from a laser and deliver a fraction of this radiation to the eye) and that the EC-5000 infringes the laser delivery means of claim 1, both literally and under the doctrine of equivalents. VISX's Written Submission of the Issues Under Review, pp. 74-77.

We agree with the ALJ that the Nidek device does not infringe any of the claims of the '762 patent. Although we do not adopt the ALJ's finding that claim 1 of the '762 patent requires a proximity mask,[4] we note that the ALJ found that regardless of the absence of a proximity mask, the delivery system in the EC-5000 is not the structural equivalent of that shown in Figure 3, on which VISX bases its infringement argument. ID at 70. Consequently, we agree with her conclusion that the Nidek device does not infringe any of the claims of the '762 patent because the imported Nidek EC-5000 laser system does not satisfy the "laser delivery system means" and

[4] We adopt the ALJ's finding of no infringement of a laser delivery system means that requires a proximity mask. ID at 70.

ablation rate limitations of claim 1 of that patent, either literally or under the doctrine of equivalents. Although we do not adopt the ALJ's finding that claim 1 of the '762 patent requires a proximity mask, we note that she found that regardless of the absence of a proximity mask, the delivery system in the EC-5000 is not the structural equivalent of that shown in Figure 3, on which VISX bases its infringement argument. ID at 70.

At the outset, we note that VISX seeks broad patent protection based on the alleged pioneering nature of Dr. Trokel's invention. However, the ALJ rejected VISX's arguments for a broad and liberal construction, as well as a broad range of equivalents, for the '762 patent based on its alleged status as a "pioneer patent." The ALJ noted that the '762 patent did not pass through the PTO quickly. Rather, its issuance was significantly delayed because of the need to make arguments and amendments to overcome prior art in the rapidly evolving field of laser surgery. Moreover, citing *Augustine Medical Inc. v. Gaymar Indus. Inc.*, 181 F.3d 1291, 1302 (Fed. Cir. 1999), the ALJ found that the wide breadth of claims and equivalency accorded to pioneer patents comes about naturally through application of the usual precepts and rules, rather than by applying a special or different standard for such patents. We agree with the ALJ's conclusion that the '762 patent is not a pioneer patent.[5]

1. Laser Delivery System

VISX argues that the EC-5000 infringes claim 1 of the '762 patent either literally or

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[5] We note that the '762 patent, which issued on January 27, 1998, is based on an application filed 14 years earlier on December 15, 1983. The issued patent resulted from a series of continuation and divisional applications that added no new matter to the initial disclosure.

under the doctrine of equivalents because the functions performed by the EC-5000 are identical to those set forth in claim 1 of the '762 patent, (*i.e.*, to receive radiation from a laser and deliver a fraction of this radiation to the eye). However, *functional equivalence* is not our sole consideration in an analysis of literal or doctrine of equivalents infringement under 35 U.S.C. § 112, ¶ 6. The statute states that "such claim[s] shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." As noted above, "[t]he plain and unambiguous meaning of paragraph six is that one construing means-plus-function language in a claim must look to the specification and interpret that language in light of the corresponding structure, material, or acts described therein, and equivalents thereof, to the extent that the specification provides such disclosure." *Donaldson*, 16 F.3d at 1193.

VISX bases its arguments for literal infringement of the laser delivery means element of claim 1 on the structure disclosed in Figure 3 of the '762 patent. Eden Tr. 810:9-14. CPX 33C. However, as the ALJ found, Nidek's EC-5000 device does not employ the same or a structurally equivalent optical system as that disclosed in the '762 patent. She found that, although both systems perform the function set forth in the means-plus-function claim of the patent, the Nidek EC-5000 laser delivery system also lacks other significant optical components such that one skilled in the art would not deem the systems structurally equivalent. ID at 71. We agree with her finding that although both systems perform the function set forth in the means-plus-function claim of the patent, the EC-5000 laser delivery system lacks certain significant optical components. Moreover, as she found, VISX has not offered a credible explanation for its

position that such a different configuration of optical components functioning in such a different way can qualify as "equivalent." ID at 72.

For example, at the hearing, VISX proffered expert testimony by Dr. Eden, who testified that Nidek's EC-5000 delivery system was equivalent to the laser delivery system in Figure 3 of the '762 patent. In that testimony, Dr. Eden used hearing Exhibit CPX-33C and redrew the laser rays of Figure 3, moved the treatment plane (the cornea being operated on) closer to the laser delivery system in order to remove one of the lenses, and then removed aperture 88. Exhibit CPX-33C is reproduced below:

Nidek's Optical Delivery System is Equivalent to Fig. 3 in the '762 Patent

visx

FIG. 3

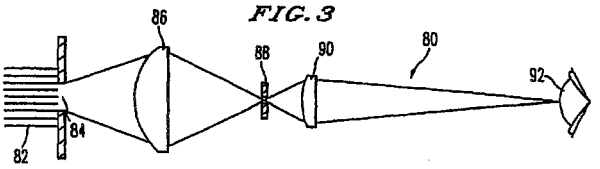
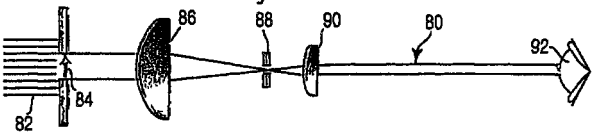
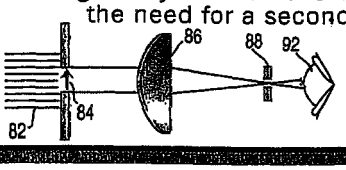


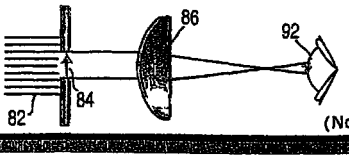
FIG. 3 with rays redrawn



Placing the eye nearer lens 86 eliminates the need for a second lens

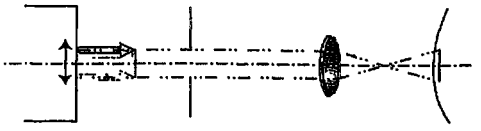


Aperture (88) can be eliminated



(Note: This is a single lens imaging system)

EC – 5000 as pictured in Nidek brochure



(Lines darkened and color added)

CPX 33 C

We agree with the ALJ that Dr. Eden's attempt to simplify Figure 3 in order to arrive at something not disclosed in the '762 patent is not credible:

> I do not accept as credible Dr. Eden's testimony regarding the functionality of the Fig. 3 system, and for the same reasons do not find his opinion on equivalency sufficient to carry VISX's burden. VISX has not offered a credible explanation for its position that such a different configuration of optical components functioning in such a different way can qualify as "equivalent".

ID at 71.

In this regard, we find that Dr. Eden's equivalence analysis is based on a number of incorrect assumptions. First, Dr. Eden redrew the ultraviolet light rays so that the chief rays travel through the aperture, but these redrawn rays contradict what is shown and taught by the patent itself, as Dr. Eden himself conceded.[6] Dr. Sowada testified that Dr. Eden's redrawn rays were incorrect because the chief rays cannot cross the optical axis at the same place that the diverging or marginal rays cross the optical axis. *Compare* RX-823 and RX-825. Sowada Tr. 1464-1466. Thus, it appears that the chief rays, as shown by Dr. Eden in his figure labeled "Fig. 3 with rays redrawn," would cross the optical axis at a point prior to reaching the aperture 88 (Sowada Tr. 1464-1466), and Dr. Eden's redrawn rays are therefore technically incorrect. However, regardless of whether Dr. Eden or Dr. Sowada is correct on this point, Dr. Eden's redrawn rays are not what is taught or shown in the '762 patent.

Dr. Eden next removed the lens 90 and brought the eye closer to the aperture 88, which reduced the working distance (*i.e.*, the distance between the delivery system and the cornea)

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[6] Q Well, draw them -- draw them as they are in figure 3, please.
A They will -- oh -- well, in figure 3, they are incorrect. That's the problem.
Eden Tr. 814-815

taught by the patent. Eden Tr. 804. This alteration is required because the EC-5000 does not use a pair of lenses, such as lens 86 and 90 in Figure 3, but rather uses a single lens to project the image of the iris onto the cornea. RX-751; Ohtsuki Tr. 1325-1326; Sowada Tr. 1474. In fact, the EC-5000 does not have any structure comparable to the aperture having a fixed opening, such as aperture 88, positioned between the lenses to block the chief rays or any rays. RX-510; Sowada Tr. 1475; Eden Tr. 809. Thus, in order to address the fact that the EC-5000 has no structure that performs the function of aperture 88 (Eden Tr. 825), Dr. Eden discarded aperture 88, despite the fact that he testified himself that aperture 88 performs a beneficial function in the system of the '762 patent. Eden Tr. 802-805; RX-818. Dr. Eden testified that aperture 88 in concert with the two lenses and the variable slit function as an imaging system as taught by the patent. Additionally, in 1989, Dr. Munnerlyn, VISX's founder and former president, represented to the PTO under oath that aperture 88 was imaged onto the cornea. RX-249, 11. ("The lens 90 is used to magnify the image at the aperture 88 onto the eye 92.") It would appear, therefore, that VISX's founder as well as its own expert witness believe that aperture 88 and lens 90 serve a useful function as taught by the '762 patent. We agree with the ALJ that VISX has not offered a credible explanation for its position that such a different configuration of optical components functioning in such a different way can qualify as equivalent.

In addition, we find that the EC-5000 uses an iris diaphragm for correcting myopia (Ohtsuki Tr. 1323), not a variable slit like element 84 of the '762 patent. Although VISX argues that the term "variable slit" used in the '762 patent can be a circular opening (VISX Reply Brief, p. 43), and therefore equivalent to the iris diaphragm of the EC-5000 device, we note that the

common usage of the term "slit" implies a rectangular opening ("a long narrow cut or opening," American Heritage Dictionary). Moreover, the '762 patent itself distinguishes between a slit and a circular opening ("[t]he masks are formed with a slit, circular, crescent or other openings," (line 8 of the abstract of the '762 patent)). Although iris diaphragms were well known before 1983 (*see, e.g.*, IBM notebook RX-59C, 00515), Dr. Trokel does not use the term iris diaphragm in the '762 patent. We therefore conclude that the term "variable slit" (CX 967, col. 4, line 7) used in the patent refers to a *rectangular* opening of varying size. In contrast, the EC-5000 images a *non-rectangular* iris onto the eye, thereby forming a rounded ablation pattern on the round, optically-used area of the cornea. The result achieved by an iris diaphragm are not the same as or similar to that achieved by a variable slit.

In this regard, we note that the iris diaphragm of the accused Nidek device is used to perform myopic corrections. The standard procedure for myopic correction is to start the iris diameter at a small opening (*i.e.*, small relative to the area being corrected) and progressively increase the opening during the procedure between laser pulses. Munnerlyn, Tr. 252. If the EC-5000 used a variable slit, which was fixed prior to surgery, as taught by the '762 patent, it would not be able to perform a myopic correction, which is the only procedure for which the EC-5000 was approved in the United States as of the time of the evidentiary hearing. Ohtsuki Tr. 1389. Rather, the accused device employs a microprocessor to vary the diameter of the iris opening during the surgical procedure to perform myopic corrections. Ohtsuki Tr. 1332, 1342-1347, RX 650C.

The proper focus of a section 112, ¶ 6, means-plus-function equivalence analysis is on the

insubstantiality of any differences in structure. "Section 112, paragraph 6, rules out the possibility that any and every means which performs the function specified in the claim literally satisfies that limitation.' The proper test is whether the differences between the structure in the accused device and any disclosed in the specification are insubstantial." *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus.*, Inc., 145 F. 3d 1303, 1309 (Fed. Cir. 1998) (citations omitted). We find that VISX has not met its burden in proving by a preponderance of the evidence that the differences between the structure in the Nidek device and those of the '762 patent are insubstantial.

VISX and the IAs argue that the ALJ's section 112, ¶ 6 analysis is flawed because it performs a component-by-component comparison of Figure 3 to the EC-5000 delivery system contrary to the Federal Circuit's holding in *Odetics, Inc. v. Storage Tech. Corp.*, 185 F.3d 1259 (Fed. Cir. 1999). The *Odetics* Court states that the individual components of an overall structure are not claim limitations. "Rather, the claim limitation is the overall structure corresponding to the claimed function. This is why structures with different numbers of parts may still be equivalent under section 112, ¶ 6, thereby meeting the claim limitation." *Odetics*, 185 F.3d at 1268. We conclude that the ALJ's conclusion is not based on a "component-by-component" analysis but rather is predicated on an understanding of the individual components, their effect on the functionality of the overall laser delivery system, and how the system affects delivering the laser beam to the cornea. The individual elements of Figure 3 operate in concert to produce the laser delivery system as taught by the '762 patent. In her infringement analysis, the ALJ examined the entire structure of the EC-5000 laser delivery system which required an

understanding of how the individual elements of the system interact with each other to deliver the laser beam to the cornea. The focus of a section 112, ¶ 6 equivalency analysis is structural equivalence. After determining the structure corresponding to the claimed means, the analysis proceeds to the differences between the claimed structure, and the accused structure and literal infringement is found if those differences are insubstantial. *Odetics*, 185 F.3d at 1268-1268. We believe that the ALJ's infringement analysis was proper in view of *Odetics*.

The ALJ analyzed the overall laser delivery *structure* of Figure 3 and concluded that it was not equivalent to the overall laser delivery structure of the EC-5000. FF 127-131; ID at 70-72; Sowada Tr. 1464-1466; 1474-1475. In contrast, as discussed above, we believe that VISX and Dr. Eden improperly based their infringement argument on a comparison of only of few components of the laser delivery system means disclosed in Figure 3 with two components of the EC-5000. We believe that the ALJ's conclusion is consistent with *Odetics* and that there are significant differences in the overall structure of the delivery system of the EC-5000 and that disclosed in the '762 patent that preclude a finding of literal infringement under the 112, ¶ 6.

Once section 112, ¶ 6 literal non-infringement is established, doctrine of equivalents infringement is precluded unless the accused structure is shown to be a later-developed structure that was not available at the date of invention.

> Thus, a finding of a lack of literal infringement for lack of equivalent structure under a means-plus-function limitation may preclude a finding of equivalence under the doctrine of equivalents.
>
> * * *
>
> [G]iven the prior knowledge of the technology asserted to be equivalent, it could readily have been disclosed in the patent. There is no policy-based reason why a patentee should

> get two bites at the apple. If he or she could have included in the patent what is now alleged to be equivalent, and did not, leading to a conclusion that an accused device lacks an equivalent to the disclosed structure, why should the issue of equivalence have to be litigated a second time?"

Chiuminatta, at 1310-11. (emphasis added)

The record is clear that the accused structure in the EC-5000 delivery system consisting of a single lens imaging system with an iris diaphragm existed well before 1983. Sowada Tr. 1474; Eden Tr. 824. We therefore conclude that, since Dr. Trokel does not mention an iris diaphragm or a single lens alternative to the dual lens system disclosed in the '762 patent, the iris diaphragm and a single lens cannot be equivalent to the variable slit 84 and the dual lens system of the '762 patent under the doctrine of equivalents.

Moreover, as to the doctrine of equivalents, for all the reasons discussed above, we find substantial differences between the structures disclosed in the '762 patent and the accused Nidek device. Additionally, when the complete delivery systems are compared, we find that the result achieved by the EC-5000 delivery system is substantially different from that of the '762 delivery systems, and it is achieved in a substantially different manner from that of the '762 delivery systems. Unlike the systems disclosed in the '762 patent, the EC-5000 slit scanning system takes pulses and scans them across the treatment plane. In the EC-5000, the entire scan pattern is rotated so that beam intensity variations are minimized and the pulses themselves partially overlap during the scanning process. This technique for delivering the beam from the laser to the cornea is not disclosed in the '762 patent. The '762 patent discloses a fixed beam delivery system for "receiving said radiation from said laser and delivering a fraction of said radiation to a

cornea." ID at 69, 71; RX-3, Figs. 1-3. This type of delivery system creates a very specific result when applied to corneal tissue. Because the profile of an excimer pulse is highly non-uniform (Trokel Tr. 344) the ablations discussed in the '762 patent are narrow incision-like ablations, using the variable slit (Fig. 3) or masks with openings between 100 and 800 microns wide. RX-3, col. 4, lines 11-21 (the '762 patent). These narrow ablations are performed by selecting a small, uniform subset of the beam, and the resulting ablated surface is nearly uniform (RX-3, Figure 11), with no "central island" phenomenon occurring. Munnerlyn Tr. 280-281. However, as Nidek argues, if the fixed beam delivery system of the '762 patent was used for wide area ablation, it would create non-uniform bottom surfaces and central islands. *Id.*

Finally, the iris diaphragm and microprocessor control enable the accused device to perform myopic corrections which cannot be accomplished by the variable slit fixed prior to surgery as taught by the '762 patent.

Based on the foregoing, we find that the EC-5000 does not infringe the '762 patent under the doctrine of equivalents because the EC-5000 employs a substantially different laser delivery system that achieves a different result, in a different way, than the laser delivery system disclosed in the '762 patent. The microprocessor controlled iris diaphragm of the Nidek EC-5000 is a substantially different laser delivery system than variable slit 84 of the laser delivery system disclosed in the '762 patent. The EC-5000 scanning system achieves a different result than the fixed beam delivery system of the '762 patent. The overall single lens, iris diaphragm laser delivery structure of the EC-5000 achieves this result in a different way than the overall variable slit and fixed opening aperture between two lens laser delivery structure of Figure 3 of the '762

patent.

2. Ablation Rate

To establish infringement of the ablation rate element of claim 1 of the '762 patent, VISX has the burden of proof to establish by a preponderance of the evidence that the accused Nidek EC-5000 ablates at a rate of approximately 1 micron per J/cm^2. As discussed earlier, we agree with the ALJ's analysis that the ablation rate of approximately 1 micron per J/cm^2 recited in claim 1 of the '762 patent covers a range of 0.7 to 1.3 microns (*i.e.*, $\pm$ 30 percent).

The ALJ concluded that the EC-5000 ablates at a rate of 1.6 to 1.7 microns per J/cm^2 and thus fails literally to satisfy the patent's ablation rate limitation. After an examination of the voluminous and sometimes conflicting record evidence proffered by each party regarding the rate at which Nidek device ablates, the ALJ found that a commercial EC-5000, as approved by the FDA and currently sold in the United States, ablates at a rate of approximately 1.6 to 1.7 microns. Her finding was based on Nidek's interrogatory responses and on FDA data which the ALJ deemed reliable, both because the data was not created and presented for purposes of litigation and because of the serious obligation of accuracy associated with submissions to the FDA. ID at 78, *citing* CX 476C at 151-53; CX 1103C; CX 821C; CX 808C; CX 803C; CX 950C at 17. We find that her analysis is reasonable, and we therefore adopt her finding. Thus, we agree with the ALJ's finding that the ablation rate of the Nidek device does not literally infringe the ablation rate of claim 1 of the '762 patent, which was construed to be between .7 and 1.3 microns.

We do not find that VISX has established by a preponderance of the evidence that the 1.6

to 1.7 microns ablation rate of the EC-5000 is equivalent to the upper limit of 1.3 micron of the '762 patent. As the ALJ found, while it seems possible that an ablation rate higher than 1.3 microns *might* be viewed by one of ordinary skill in the art as equivalent to "approximately 1," we agree with the her that VISX produced no evidence to that effect. Rather, in support of its equivalency arguments, VISX cites only testimony regarding alleged error ranges and acceptable deviations to be considered in connection with the literal meaning of "approximately." Having considered this testimony and argument in connection with her claim construction of "approximately 1," the ALJ found that it would not be appropriate to rely on the very same evidence to extend the 0.7 to 1.3 microns range even further. Rather, as the ALJ found, expert testimony regarding the insubstantiality of a certain difference or differences in ablation rate beyond the upper limit for literal infringement, as viewed by one of ordinary skill in the art, would be appropriate for an equivalency analysis. VISX did not produce such testimony. ID at 79. Thus, we agree with the ALJ's finding that VISX failed to meet its burden of establishing infringement by a preponderance of the evidence and adopt the ID on infringement of this claim element.

We note that the IAs argued that there was only an insubstantial difference between the 1.6 to 1.7 microns ablation rate of the EC-5000 and the top-of-the range ablation rate of 1.3 microns of the '762 patent because ophthalmologic surgeons generally tolerate being within $\pm$ 0.5 diopters of accuracy. ID at 79, *citing* McDonnell, Tr. 1055-56, 1058-60.[7] The IAs

[7] A diopter equates to roughly 12 microns of corneal ablation depth. Munnerlyn, Tr. 133-34; McDonnell, Tr. 1055.

contended that the difference between the EC-5000's ablation rate and the ablation rate disclosed in the '762 patent should be deemed insubstantial, presumably because a surgeon would not be concerned about the difference. ID at 79. However, as the ALJ found, whether an ablation rate produces an outcome acceptable to a surgeon depends on the degree of correction being made, differing, for example, for a 5-diopter myopic correction and a 10-diopter myopic correction. ID at 79. We agree with that analysis. Moreover, we note that element (c) of claim 1 claims an ablation rate and ablation *depth* does not equal ablation *rate*. The IAs have not explained how an ablation rate delivered by a laser delivery system during surgery can be equivalent to a total depth of ablation measured after surgery.

As discussed above, we conclude that there is no infringement of claim 1 of the '762 patent by Nidek's EC-5000 laser system, either literally or under the doctrine of equivalents, because it has not been shown by a preponderance of the evidence that the Nidek EC-5000 satisfies the "laser delivery system means" or the ablation rate elements of the'762 patent.

Claim 7, 10, and 12

Claims 7, 10, and 12 depend from claim 1. Because the EC-5000 does not infringe claim 1, we find that the EC-5000 also does not infringe claims 7, 10, or 12.

III. Validity of the '762 Patent

Inasmuch as there are other grounds (*viz.*, no infringement of any claims at issue and no domestic industry for any of the VISX systems, as discussed below) for a finding of no violation of section 337, we take no position on the issue of inventorship.

IV Enforceability of the '762 Patent

Inasmuch as there are other grounds for a finding of no violation of section 337, we take no position on the issue of inequitable conduct.

V. Domestic Industry

As a prerequisite to finding a violation of section 337, VISX must establish that "an industry in the United States, relating to the articles protected by the patent ... concerned, exists or is in the process of being established." 19 U.S.C. § 1337(a)(3). Typically, the domestic industry requirement of section 337 is viewed as consisting of two prongs: the economic prong and the technical prong. *Certain Variable Speed Wind Turbines and Components Thereof,* Inv. No. 337-TA-376, Comm'n Opinion at 14-17 (1996). The economic prong concerns the investment in a domestic industry, while the technical prong involves whether complainant (or its licensees) practices its own patent. To satisfy the economic prong, the domestic industry must involve: (1) significant investment in plant and equipment; (2) significant employment of labor or capital; or (3) substantial investment in its exploitation, including engineering, research and development, or licensing. 19 U.S.C. § 1337(a)(3).

VISX relies on four products for its domestic industry showing: the STAR, the STAR S2, the 20/20A, and the 20/20B systems.

A. Technical Prong

We find that VISX's STAR, STAR S2, 20/20A, and 20/20B systems do not practice claims 1, 10, or 12 of the '762 patent. We conclude that the VISX systems do not practice claim 1 of the '762 patent, either literally or under the doctrine of equivalents, for the same reasons set forth in the section on non-infringement by the EC-5000, which reasons are incorporated here by

reference. Moreover, our own analysis of the technical prong of the domestic industry requirement confirms this finding.

To prevail on the technical prong of section 337, VISX must show that its products were within the scope of the claims, properly construed. Given that clause (b) of claim 1 is drafted in means-plus-function format, VISX must establish that its products perform the identical function set forth in the "means" clause, and do so with structure which is the same as or equivalent to structure disclosed in the '762 patent specification. *Serrano v. Telular Corp.*, 111 F.3d 1578 (Fed. Cir. 1997).

VISX contends that its systems practice claims 1, 10, and 12 both literally and under the doctrine of equivalents. Regarding the "laser delivery means" identified in the '762 patent, VISX draws a parallel only to Figure 3 as the corresponding structure for the laser delivery means. [

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As with infringement, the focus of VISX's arguments concerning the technical prong is based on the alleged equivalence between the structure disclosed in the '762 patent and the laser delivery means of its systems. VISX relies on Figure 3 as the structure corresponding to that portion of the claim. By statutory mandate, the functional language of a means-plus-function claim is interpreted by reference to the "corresponding structure" disclosed in the specification. ("An element in a claim for a combination may be expressed as a means or step for performing a

specified function ... and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." 35 U.S.C. § 112, ¶ 6.) VISX has failed to prove equivalency and instead relies on broad conclusory statements that fall short of the particularized evidence of structural equivalence required to show equivalence.

[

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Moreover, as to the doctrine of equivalents, for all the reasons discussed above we find substantial differences between the structures disclosed in the '762 patent and the VISX systems. Additionally, when the complete delivery systems are compared, we find that the result achieved by the VISX systems is different from that of the '762 delivery system, and it is achieved in a different manner. [

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We also note that, although VISX now attempts to disavow this admission, VISX compared the single lens and aperture systems of the Nidek EC-5000 to VISX's optical system twice in its post-hearing brief, and both times argued that they were identical. (VISX Post Hrg Br. p. 220. "The optical system of the [VISX system] is identical to the system shown for the Nidek system.") If Nidek's EC-5000 system does not infringe the '762 patent, and the optical systems of the VISX systems are "identical" to the EC-5000, then VISX's systems do not practice the '762 patent for the same reasons that the EC-5000 does not infringe. We therefore find that VISX's systems do not practice claims 1, 10, or 12 of the '762 patent.

There is a second, independent reason why the VISX systems do not practice claim 1 of the '762 patent, *viz.*, the VISX systems do not practice the ablation rate of claim 1, since the ablation rates of the VISX systems are outside the ablation rate of claim 1, as properly construed. As discussed above, the ALJ found the outer range the ablation rate of claim 1, to be 1.3 microns per joule of applied energy. We adopted this finding.

[

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As to claims 10 and 12, these claims depend from claim 1 and if VISX does not practice claim 1, then it cannot practice claims 10 or 12.

Based on the foregoing, we find that VISX has not demonstrated that its products practice claim 1, 10, or 12 of the '762 patent because it failed to establish that its products have the requisite "laser delivery system means" or the requisite ablation rate.

B. Economic Prong

The ALJ previously concluded in an ID (Order No. 9) that the economic prong of domestic industry was met for VISX's STAR and STAR S2 systems. The Commission determined not to review that ID. The Commission finds that no reason exists to perform a separate analysis of the economic prong for the remaining VISX products, the 20/20A and the 20/20B, since we find that these systems do not meet the technical prong of domestic industry.

PUBLIC VERSION

Conclusion

In conclusion, we find (1) the claims in issue of the '762 patent are not infringed by the accused imported Nidek EC-5000 laser systems for vision correction surgery, and (2) no domestic industry exists with respect to the '762 patent. We have taken no position on the issues of the validity and enforceability of the '762 patent. We have determined that there is no violation of section 337 of the Tariff Act of 1930 in this investigation.

FINAL PUBLIC VERSION
UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of **Certain Excimer Laser Systems for Vision Correction Surgery and Components Thereof and Methods for Performing Such Surgery**

Inv. No. 337-TA-419

Initial Determination

Appearances

Harold J. McElhinny, Alan Cope Johnston, Barry E. Bretschneider, G. Brian Busey, Eric Elliff, Sunil R. Kulkarni, Paul J. Riley, Bryan A. Schwartz, and Rowena A. W. Yeung, of Morrison & Foerster on behalf of Complainant VISX, Incorporated

Neil B. Siegel, Robert M. Masters, Carl J. Pellegrini, John F. Rabena and Abraham J. Rosner of Sughrue, Mion, Zinn, Macpeak & Seas ; and Sturgis M. Sobin and F. David Foster of Ablondi, Foster, Sobin & Davidow on behalf of Respondents Nidek Co., Ltd., Nidek Technologies, Inc. and Nidek Inc.

Steven A. Glazer, Juan Cockburn, T. Spence Chubb, and Lynn I. Levine on behalf of the Office of Unfair Import Investigations, U.S. International Trade Commission

Debra Morriss, Presiding Administrative Law Judge:

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I. Procedural Background

VISX, Incorporated ("VISX"), a Delaware corporation headquartered in California, filed a complaint on January 22, 1999, supplemented on February 9, 1999, under 19 U.S.C. § 1337 ("Section 337") requesting relief in the form of permanent exclusion as well as cease and desist orders, based on the alleged importation into the United States, the sale for importation, and the sale within the United States after importation of certain excimer laser systems for vision correction surgery and components thereof by Nidek Co., Ltd., Nidek Inc. and Nidek Technologies, Inc. (collectively "Nidek"). The Commission issued its Notice of Investigation on February 23, 1999, instituting this Section 337 investigation concerning VISX's allegations of infringement of Claims 26 and 27 of United States Patent 4,718,418 ("the '418 Patent"), Claim 30 of United States Patent 4,732,148 ("the '148 Patent") and Claims 1, 7, 10, and 12 of United States Patent 5,711,762 ("the '762 Patent") all owned by VISX, as well as VISX's claim of the requisite domestic industry. The Commission named VISX as the Complainant and the three above referenced Nidek entities as the Respondents. Subsequently, VISX, on May 12, 1999, filed a motion to amend the Notice of Investigation to add independent Claim 1 and dependent Claims 6 and 8 of U.S. Patent No. 5,735,843 ("the '843 Patent") and to delete Claim 30 of the '148 Patent. The motion was denied by order issued on May 27, 1999, with leave granted to VISX to refile a motion withdrawing Claim 30 of the '148 Patent (Order No. 13). Such a motion was filed on June 8, 1999, which was unopposed, and was granted by a June 9, 1999 Initial Determination which the Commission, on July 2, 1999, decided not to review.

By Order No. 3, issued March 22, 1999, a target date of March 1, 2000, for completion of the investigation was established. Order No. 62 extended the target date to March 6, 2000. All

parties made appearances at a Preliminary Conference on April 8, 1999, at which time a procedural schedule was set. During the prehearing phase of the investigation, several motions for summary determination were timely filed by the parties. The first of these was a motion filed by VISX on April 26, 1999, requesting summary determination that the economic prong of the domestic industry requirement of Section 337 was met based on its Star and Star S2 products. The motion, which was unopposed, was granted by an Initial Determination issued on May 7, 1999, which the Commission, on June 7, 1999, determined not to review. Subsequently, VISX filed separate motions on May 26, 1999, June 29, 1999 and July 15, 1999, requesting summary determination rejecting certain affirmative defenses associated with the '418 and '762 Patents as well as Patent Application Serial No. 746,330 ("the '330 Application"), each of which was denied in separate orders issued on July 9, 1999, July 15, 1999, and July 29, 1999, (Orders Nos. 35, 37, and 42). Also denied by an order issued July 30, 1999, was a motion filed by the Respondents on July 16, 1999, for summary determination of no domestic industry for the '418 Patent (Order No. 43). Subsequently, the Respondents, on August 2, 1999, filed a notice withdrawing from the investigation several affirmative defenses they had previously raised in their response to the Complaint. The Notice of Withdrawal was accepted in Order No. 44, issued on August 3, 1999.

The hearing in this matter commenced on August 18, 1999 and concluded on August 27, 1999. All parties were represented at the hearing. Subsequent to the hearing, initial and reply briefs, proposed initial and reply Findings of Facts and Conclusions of Law, comments to the initial Findings and Conclusions, and statements regarding key factual issues were filed by the parties. These submissions have been fully considered in reaching this decision and any omission

of a discussion of an issue raised by the parties or of a portion of the record does not indicate that it has not been considered. Rather, such issues and/or portions of the record were found to be irrelevant, immaterial and/or without merit. Additionally, any objections which may not have been ruled on to date and which may remain outstanding are hereby denied.

II. Jurisdiction

A. Importation[1]

Section 337 requires an "importation" or a "sale for importation" as a condition of the Commission's exercise of subject matter jurisdiction. Enercon GmbH v. Int'l Trade Comm'n, 151 F.3d 1376 (Fed. Cir.), cert. denied, 119 S.Ct. 1803 (1999) Nidek does not contest the importation of its accused products for commercial sale. Nidek Initial Post-Hearing Brief at 2-3. This stipulation satisfies the importation requirement in Section 337.

B. Personal Jurisdiction

Each of the Nidek entities concedes that it is properly subject to the exercise of personal jurisdiction by the Commission in this investigation. Nidek Initial Post-Hearing Brief at 3.

III. Claim Construction

The analysis of infringement allegations involves a two-step process: first, construction of the claims asserted to determine their meaning and scope, and second, comparison of the properly construed claims to the accused products. See Tanabe Seiyaku Co. v. U.S. Int'l Trade Comm'n, 109 F.3d 726 (Fed Cir.), cert. denied, 118 S.Ct. 624 (1997); Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). In performing claim construction, the meaning and scope of patent claims should be determined with reference

[1]The domestic industry component of jurisdiction is separately addressed, *infra*.

to the claim language, the specification, and the prosecution history. Extrinsic evidence outside the record before the Patent and Trademark Office ("PTO"), such as expert testimony about how those skilled in the art would interpret certain language in the claim, may also be considered when appropriate as an inherent part of the process of claim construction and as an aid in arriving at the proper construction of the claim. Tanabe, 109 F.3d at 732; Markman, 52 F.3d at 979. Claim language should be construed according to its usual meaning to one of ordinary skill in the art where such construction is consistent with the specification. Multiform Dessicants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1477 (Fed. Cir. 1998). A patentee, however, acting as "his own lexicographer," may give terms an unusual meaning so long as the specification or prosecution history clearly conveys the atypical definition. Hoechst Celanese Corp. v. BP Chem. Ltd., 78 F.3d 1575, 1578 (Fed. Cir. 1996).

As a threshold matter, VISX argues for "broad and liberal construction as well as a broad range of equivalents" for the '762 Patent and the '418 Patent, given their alleged status as *pioneer patents*. VISX cites Westinghouse v. Boyden Power Brake Co., 170 U.S. 537, 561-62 (1898) for its definition of a *pioneer patent* as one disclosing "a function never before performed, a wholly novel device, or one of such novelty and importance as to mark a distinct step in the progress of the art." Nidek disputes the status of these patents as *pioneers* and disagrees with VISX's argument about special latitude for *pioneer patents*, criticizing VISX's citation of "out-dated cases", and citing in response a June 1999 opinion by the Federal Circuit stating that "... no objective legal test separates pioneers from non-pioneers ... The peripheral claiming system itself, however, makes the best distinction between pioneers and non-pioneers." Augustine Medical Inc. v. Gaymar Indus. Inc., 181 F.3d 1291, 1301 (Fed. Cir. 1999). VISX, in turn, contends that its

cited cases represent good law and that its position on *pioneer patents* is consistent with Augustine Medical's explanation that:

> Pioneers enjoy the benefits of their contribution to the art in the form of broader claims. Without extensive prior art to confine and cabin their claims, pioneers acquire broader claims than non-pioneers who must craft narrow claims to evade the strictures of a crowded art field. Thus, claim scope itself generally supplies broader exclusive entitlements to the pioneer. Moreover, a pioneer generally need not fear traditional limits on the application of the doctrine of equivalents such as prior art or prosecution history estoppel ....

Id. at 1301-02. The Staff takes no position on the issue.

Initially, I do not believe the record supports a characterization of the '418 Patent and the '762 Patent as true *pioneer patents*, in light of the Augustine Medical court's statement that "... amendments or arguments to overcome the prior art are generally unnecessary in true pioneer applications." Id. at 1302. As Nidek points out, the prosecution histories of these patents reflect that they did not sail quickly through the PTO to issuance, but instead were significantly delayed, in part because of the need to make arguments and amendments to overcome prior art. See RX 2; RX 4; RX 10; RX 11; RX 12. Furthermore, regardless of their true status, I conclude that in light of the authority cited by VISX and in light of Augustine Medical, the wide breadth of claims and equivalency accorded to *pioneer patents* comes about naturally through application of the usual precepts and rules, rather than by applying a special or different standard for such patents. Accordingly, the established doctrines underlying claim construction and equivalency apply to the '418 Patent and the '762 Patent.

A. U.S. Patent No. 4,718,418 – Claims 26, 27, 30 and 32

The '418 Patent, titled "Apparatus for Ophthalmological Surgery", issued on January 12,

1998 with Dr. Francis A. L'Esperance, Jr. named as the sole inventor. The patent is directed toward a laser surgical device for use in vision correction effected by reshaping the surface of the cornea. The patent was subsequently assigned to VISX. VISX asserts that Nidek's accused devices infringe Claims 26 and 27 of the patent, and VISX relies on Claims 30 and 32 for the technical prong of domestic industry.

1. Claim 26

Claim 26 in its entirety, and with disputed claim terms underlined, reads:

- Apparatus for performing ophthalmological surgery by selective ablation of the anterior surface of the cornea with penetration into the stroma to achieve a volumetric removal of corneal tissue,
- said apparatus comprising laser means producing an output beam in the ultraviolet portion of the electromagnetic spectrum,
- and characterized by a spot which at cornea impingement is small in relation to the cornea to be operated upon,
- said laser means including means for adjusting beam-exposure flux to a level at which resultant corneal-tissue ablation per unit time is to an ascertained elemental depth which is but a fraction of a predetermined maximum depth of ablation into the stroma,
- scan-deflection means positioned for deflection of said beam in a limited field about a central axis, said scan deflection means having two coordinates of deflection for area coverage within the perimeter of said limited field,
- and control means with coordinating control connections to said scan-deflection means and to said laser for varying the perimeter of successive area scans within said field wherein said area scans are symmetrical about the central axis,
- whereby said scan-deflection means may perform one area scan within one perimeter limit before performing another area scan with another perimeter limit, whereby to effect a controlled sculpturing action upon the cornea to alter the optical properties thereof.

CX-427, Col. 16, lines 12-17 (emphasis added).

a. Anterior Surface of the Cornea

In Order No. 49 in this investigation, as a sanction against the Respondents for violation of an order compelling the production of certain documents, I entered a rebuttable factual inference "... that one of ordinary skill in the art understands the phrase 'anterior surface of the cornea' to mean the surface of the eye presented to the doctor at the time of surgery and can, depending on the procedure being performed, comprise the epithelium, the Bowman's membrane if the epithelium has been mechanically removed, or the stroma in the case of a LASIK procedure". Order 49 at 9; see also Order No. 59 (denying reconsideration of the sanction). VISX and the Staff argue that the evidence of record is consistent with this definition, and that the Respondents failed to rebut this inference. VISX cites the testimony of its own expert, Dr. Neal Sher, as well as articles by Nidek's expert, Dr. Peter McDonnell in support of this definition. See Sher, Tr. at 460-462, 465; McDonnell, Tr. at 1117-1124; CX 762 at 822-23; CX 763 at 1201-02, 1204-05. VISX further asserts that the '418 Patent's specification, with references to the "front surface of the cornea" and the "outer surface of the cornea", and prosecution history, reflecting the addition of the "anterior surface" limitation in order to overcome prior art involving corneal tissue removal from the posterior surface of a removed cornea, indicate that the "anterior surface" refers to the surface of the eye presented to the doctor at the time of surgery.

As a threshold matter, Nidek argues that the 1983 filing date of the patent application constitutes the appropriate time period from which to measure the understanding in the art of the claim terms. Nidek criticizes VISX's references to post-1983 articles and other documents as irrelevant given their time frame. Nidek, however, never points to any evidence indicating that the meaning of this term changed over time. In fact, as VISX notes, the only expert testimony at

the hearing on this point offered clarification that the meaning of "anterior surface of the cornea" has *not* evolved since 1983, such that its definition at that time remains consistent with its definition today. See Sher, Tr. at 447.

Nidek insists that the proper construction of "anterior surface of the cornea" necessitates restricting its application exclusively to the epithelium, which, under normal conditions, is the outermost layer of the cornea. Nidek argues the factual inference has been rebutted because textbooks and the ophthalmic experts for both Nidek and VISX agreed that *normally*, the epithelium is the outermost layer of the cornea, such that intrinsic evidence – the alleged plain meaning of the term -- therefore supports adopting Nidek's proposed construction of "anterior surface". Nidek criticizes VISX's proposed construction as involving an abnormal situation where the epithelium is missing from the eye, and according to Nidek, in the examples cited by VISX of patients having lost their epitheliums through some trauma, these patients would not qualify for refractive surgery.

Nidek also argues that because, according to Nidek, the general practice in the field of corneal laser surgery in 1983 involved ablation of the epithelium with the laser, the general understanding of the claim term would have been that it referred to ablation through the epithelium. To buttress this position, Nidek asserts that the reference in the claim to "with penetration into the stroma" means that the ablation of the cornea must begin outside the stroma, rendering implausible VISX's proposed claim construction, where the ablation *could* start *with* the stroma, in an eye lacking an epithelium and Bowman's membrane. Nidek also cites the patent specification, referring to "... controlled ablative photodecomposition of the cornea, namely, of the epithelium, Bowman's membrane, and stroma levels of the cornea" for its interpretation,

maintaining that the patent thereby identified the epithelium as a layer ablated by the laser. Nidek contends that the applicant's statement in the prosecution history that the penetration into the stroma occurred "*via* the anterior surface of the cornea" must mean *through* the anterior surface, which, in an unaltered eye, is the epithelium.

The Staff agrees with VISX's proposed construction, that "anterior surface of the cornea" merely connotes the direction from which the ablation is performed, rather than referring to a specific layer of corneal tissue. The Staff contends that Nidek failed to rebut the factual presumption entered in Order No. 49, and that even apart from the presumption, the weight of the evidence supports construing the term only to mean the surface of the cornea facing the surgeon at the time of the procedure. According to the Staff, the patent specification's reference to the ability of the apparatus to ablate the epithelium, Bowman's membrane and stroma, and the file history, where an amendment was made to distinguish the claimed invention's removal of corneal tissue from the *anterior* surface rather than the *posterior* surface, as claimed by certain prior art, lend credence to its proposed construction. See CX 427, Col. 2, lines 20-26 (patent specification); CX 211 (patent file history); SX 4 (prior art treatise). Furthermore, the Staff cites testimony consistent with its position from VISX's expert, Dr. Sher, as to the understanding of the term by one of ordinary skill in the art. See Sher, Tr. at 445-51. Finally, pointing to several examples, the Staff maintains that articles by those in the field, including by Nidek's expert, Dr. McDonnell, indicate that the term "anterior surface" of the cornea can and often does refer to the stroma, in instances where the epithelium and Bowman's membrane have been removed.

I conclude that Nidek failed to rebut the presumption that one of ordinary skill in the art understands the phrase 'anterior surface of the cornea' to mean the surface of the eye presented to

the doctor at the time of surgery which, depending on the procedure being performed, may comprise the epithelium, the Bowman's membrane if the epithelium has been mechanically removed, or the stroma in the case of a LASIK procedure. Notably, within the '418 Patent, there are references to the epithelium, distinct from the references to the "anterior surface of the cornea". See CX 427, Col. 15, line 60; Col. 2, line 25. This distinction in terminology casts doubt on Nidek's contention that "anterior surface of the cornea" can mean only "epithelium", as the references in the patent suggest that if the intent were to limit the reference exclusively to the epithelium, that term would have been used instead of the broader term "anterior surface of the cornea". Nidek's argument and citation of testimony that *normally*, in an unaltered eye, the "anterior surface" is, in fact, the epithelium does not overcome the presumption, because the argument and testimony are not inconsistent with the presumption.[2] The fact that in many cases, the anterior surface of a cornea is the epithelium does not lead to the conclusion that "anterior surface" can never refer to anything other than the epithelium, such as in those cases where the epithelium has been removed or where the eye has otherwise been altered. Nor does the prosecution history serve to rebut the presumption, instead suggesting that the "anterior surface" term was added to overcome prior art involving corneal surgery on the posterior surface of the cornea, indicating a directional meaning of the term rather than a reference to a specific layer of

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[2]Even Nidek's own expert, Dr. McDonnell, has used the term "anterior corneal surface" in reference to the front surface of the cornea remaining after manual removal of the epithelium. See McDonnell, Tr. at 1117-24; CX 762 at 822; see also CX 763 at 1201-02, 1204-05. Furthermore, Nidek itself and its personnel have used the term in this same manner. See e.g. CX 794C at 20142, 20203-04; CX 818C at 40038A-41; CX 558C at 6, 39.

the cornea[3]. See CX 700 at 84515-25, 84579; see also Sher, Tr. at 447 (stating that a person of ordinary skill in the art in 1983 would have understood the epithelium as a *layer* of the cornea, not a *surface*). Ultimately, the evidence remains insufficient to overcome the presumption entered in Order No. 49, and in keeping with the tenet that claim language should be construed in accordance with its meaning to one of ordinary skill in the art, the construction of "anterior surface of the cornea" set forth in Order No. 49 is adopted.

b. Laser Means

This claim element bears the means-plus-function form, such that the patentee obtains patent protection for the specific means disclosed in the specification and structural equivalents therefor. See 35 U.S.C. § 112, ¶ 6; Chiuminatta Concrete Concepts, Inc. v. Cardinal Ind., Inc., 145 F.3d 1303, 1308 (Fed. Cir. 1998). VISX argues that the "laser means" refers simply to an ultraviolet laser, either continuous wave ("CW") or pulsed (excimer), and its associated power supply. Nidek argues that the laser means can only refer to a CW laser because of Claim 26's teaching that the "laser means" includes "means for adjusting beam-exposure flux to a level at which resultant corneal-tissue ablation per unit time is to an ascertained elemental depth." See CX 427, Col. 15, lines 12-15. According to Nidek, "beam-exposure flux" is mentioned in the specification only in connection with a CW laser. See CX 427, Col. 7, lines 24-27. Nidek also contends that because Claim 26's laser means is said to produce "an output beam in the ultraviolet portion of the electromagnetic spectrum and characterized by a spot which at cornea impingement is small in relation to the cornea to be operated upon", optical components must be included to

[3]I disagree with Nidek's strained contention that the word "via" in the phrase "via the anterior surface of the cornea" supports its construction, and instead I conclude that "via" supports a finding that the claim element connotes direction.

change the size of the laser beam. See Sowada, Tr. at 1432-33; Eden, Tr. at 732-33, 849-50. Specifically, Nidek maintains that lens element 26 is the only structure disclosed in the specification to reduce the laser beam to the size of the spot sizes disclosed in the '418 Patent, and that this must therefore be part of the "laser means". The specification describes lens elements 26 as including a cylindrical element and a spherical element, but Nidek highlights Dr. Sowada's testimony that a CW laser needs only the spherical lens to reduce the beam size, while a pulsed laser needs the cylindrical lens as well. See Sowada, Tr. at 1428-29.

In response, VISX first contends that the only function associated with the laser means is the "producing an output beam in the ultraviolet portion of the electromagnetic spectrum" clause, and that attributing a sizing function to the laser means is inappropriate. Second, VISX complains that the portion of the specification relied on by Nidek as describing the laser means actually describes the corresponding structure to the "means for shaping, focusing" the beam as set forth in Claims 30 and 32, not in Claims 26 and 27. See CX 427, Col. 4, lines 13-20. Third, VISX argues that Nidek's proposed interpretation conflicts with other '418 Patent claims' references to "laser means", particularly as Claim 8 teaches a "laser means" in language similar to Claim 26's, and its dependent Claim 13 then adds the additional limitation of a means for reducing the beam's cross-section to a particular spot size. According to VISX, then, the similarly defined "laser means" of Claim 8 cannot include a structure which reduces or sizes the output beam, and thus, Claim 26's "laser means" should be consistently construed. Nidek replies, citing C.R. Bard Inc. v. M3 Systems, Inc., 157 F.3d 1340, 1364 (Fed. Cir.), cert. denied, 119 S.Ct. 1804 (1999), that if claim differentiation presents a problem here, the statutory means-plus-function analysis should take precedence.

The Staff disputes Nidek's argument, noting that the '418 Patent clearly applies to both CW and pulsed lasers, and criticizes Nidek's reasoning stemming from the term "beam-exposure flux", maintaining that the term does not apply exclusively to CW lasers, but can also be used in connection with pulsed lasers. In support thereof, the Staff points out that Claim 8 includes a reference to "beam-exposure flux" even though its dependent, Claim 10, explicitly teaches that the "laser means is an excimer [pulsed] laser". See CX 427. The Staff also argues that Nidek attempts to read restrictive limitations into this element which are not properly included therein. Even if the function of the "laser means" were deemed to include reducing the spot size, the Staff maintains that the Respondents' position on the narrow range of available equivalents should be rejected.

Given the means-plus-function form of the "laser means" claim element, the specification of the '418 Patent should be the source for identifying the structure serving this function. Based on a review of the specification, I conclude as an initial matter that the "laser means" can include either a CW or pulsed laser device, and its power supply. The specification initially refers to the "laser device" with no indication of a particular type of laser. Next, in describing the laser for the preferred embodiment, the specification makes quite clear that any laser emitting in the UV spectrum should satisfactorily meet the claim requirements. The specification refers to gas lasers and crystal lasers as acceptable, and mentions a specific model of a Lambda Physik excimer laser as a commercially available example suitable for use in the invention. See CX 427, Col. 3, line 59 - Col. 4, line 4. The specification also explicitly states, at Column 7, lines 3 through 9:

> In the discussion thus far, an excimer laser has been the illustrative source of an ablating beam, and it has been generally indicated that other lasers are available as alternative sources in the desired

> ultraviolet region and at presently suitable energy levels, and these other lasers will emit continuously for periods of controlled duration.

Ultimately, the specification makes plain that Claim 26's "laser means" should not be limited to CW lasers, as urged by Nidek.

According to Claim 26, the laser means produces "an output beam in the ultraviolet portion of the electromagnetic spectrum, and characterized by a spot which at cornea impingement is small in relation to the cornea to be operated upon". Turning to the parties' dispute as to the laser means and the beam sizing function, I conclude that a review of Claim 26 in its entirety indicates that the phrase "characterized by a spot which at cornea impingement is small ..." modifies and describes the "output beam" said to be produced by the laser means. As a result, all the other disputed terms included in the entire "laser means ..." clause should be addressed and considered together.

The parties disagree as to the meaning of "the cornea to be operated upon", which is the reference point for the size of the laser spot. Citing supporting testimony by its expert, Dr. Sher, as to the understanding of this term in 1983 by an ophthalmologist of ordinary skill, VISX contends that, by its plain and ordinary meaning, this phrase refers to the entire cornea of the eye undergoing the surgery.

Nidek, on the other hand, contends that considering the claims and specification of the '418 Patent, the "cornea to be operated upon" must refer to the area over which the laser spot will be scanned. According to Nidek, the area of the varying concentric circles such as the circular area shown in Figure 3 of the Patent constitute the "cornea to be operated upon". See CX 427. VISX disagrees, and points to other claims of the '418 Patent that it maintains support its

position, specifically references in Claims 30 and 32 to "the optically functioning area of the cornea".

According to VISX, use of the term "optically functioning area of the cornea" in another claim indicates that "cornea to be operated upon" should not be construed to mean the same thing, so as to improperly import limitations from another claim. VISX also cites Dr. L'Esperance's related U.S. Patent No. 4,665,913 ("'913 Patent"), which refers to laser spot sizes that are "but a small fraction of the area of the cornea to be subjected to ablation". CX 292, Col. 10, lines 12-13. VISX relies on the fact that Claim 26 of the '418 Patent does not refer to "*area* of the cornea" as evidence that "cornea to be operated upon" should be construed as the entire cornea. In addition, looking to the prosecution history of the '418 Patent, VISX maintains that the claim language in other claims was broadened by amendment from "small relative to [the central area of the external surface of the cornea]" to "small in relation to the cornea to be operated upon", such that the latter terminology necessarily signifies the entire cornea, in order to give meaning to the amendment. See CX 702 at 084229-31. VISX concludes, then, that because terms should be construed consistently throughout a patent, the same claim term in Claim 26 must also necessarily refer to the entire cornea.

The Staff agrees with VISX's proposed construction of this term, and also cites expert witness testimony and the prosecution history in support. The Staff and VISX also add that in the embodiments, the spot size is small relative to *both* the entire cornea and the portion to be ablated.

Nidek turns to the patent specification's illustrative embodiments for a sense of the "small" spot size. Under Nidek's proposed interpretation, the spot sizes are small in relation to the

portion of the cornea being ablated in each example. Nidek contends that adopting VISX's view strips the claim element of any meaning since the patent then offers no concrete instruction on the size of the spot. Citing Dr. Sher's testimony, Nidek asserts that the precise definition of "small" is ambiguous, and argues the propriety of looking to the specification for guidance, ultimately concluding that the construction of the spot size should be limited to a maximum of .5 mm by .5 mm, the largest explicitly disclosed in the specification. Nidek also argues that based on the prosecution history of the patent, wherein the applicant argued to overcome an objection by the examiner by calling the spot size disclosed in the Taboada articles[4] "irrelevant", the spot size should not be construed to reach dimensions around 6 mm x 1.9 mm. In summary, Nidek insists that all the intrinsic evidence in the form of the claims, specification and the prosecution history supports finding a maximum of .5 mm by .5 mm.

While Nidek argues extrinsic evidence should not be considered given the allegedly clear conclusion from the intrinsic evidence, Nidek nonetheless takes the position that even if extrinsic evidence is considered, it cannot support an interpretation allowing a spot size larger than 1 mm in diameter. Nidek relies on Dr. McDonnell's testimony for this proposition, since he identified that size as the maximum practical diameter for the purpose described in the '418 Patent. See McDonnell, Tr. at 1035-36. Nidek discounts VISX's expert testimony on this issue, arguing that Dr. Eden relied on allegedly irrelevant literature pertaining to the Microscan 771, ignoring that the spot sizes discussed therein were in connection with a CO_2 laser having a much longer wavelength than the excimer laser that Nidek contends is required by Claim 26. VISX insists that the spots

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[4]While the applicant stated that .1 cm^2 was the spot size disclosed in both Taboada articles, one of the articles actually disclosed a spot size of 6 mm x 1.9 mm. See CX 117; CX 213.

produced by the Microscan 771 can overlap, such that for practical purposes, a large beam spot can still produce a sufficiently smooth surface. See Munnerlyn, Tr. at 186-87. VISX also relies on testimony that the EC-5000 and other excimer laser systems obtain clinically acceptable results using beams larger than 1 mm in diameter to support its position.

VISX criticizes the use of the illustrative examples disclosed in the specification to determine the scope of the "small" spot, noting that the specification cautions that "[w]hile the invention has been described in detail for various illustrative embodiments and modes, it will be understood that modifications may be made without departing from the scope of the invention." CX 427, Col. 9, lines 9-12. VISX further maintains that the importation of these numerical figures from the specification into the claim violates claim construction principles, and that it ignores the specification's identification of the Microscan 771 as a suitable scanner, since that scanner furnishes variable spot sizes ranging from .45 mm to 7.5 mm in diameter. See Munnerlyn, Tr. at 185-86; Eden, Tr. at 732-33; CX 206 at 00720061; RX 77 at 00001057. Relying on testimony by VISX's Dr. Munnerlyn, Nidek replies that the Microscan 771 does not itself size down the beam, and its variable spot sizes depend on what lens is used with the Microscan 771. See Munnerlyn, Tr. at 278.

VISX takes issue with Nidek's characterization of the significance of the irrelevancy statement in the prosecution history, pointing out that the applicant never explained exactly *why* he deemed the Taboada spots irrelevant, and arguing that there are many reasons, other than difference in the size of the laser spots, that the applicant might have made that statement. VISX insists that the irrelevancy statement does not evidence a "deliberate, unmistakeable, [sic] and unequivocal intent to give up coverage over spot sizes equal to or larger than 10 mm^2 to 11.4

mm^2." VISX Initial Post-Hearing Brief at 23. Nidek replies that VISX offers no hard evidence that the applicant's statement is for any reason other than a distinction in the sizes of the spots. The Staff agrees that the applicant distinguished the Taboada articles based on spot size. Nidek next then criticizes VISX's contentions that at the very least, the prosecution history would only limit it to a smaller spot size than the Taboada spots, instead contending that Claim 26's spot must be much smaller, based on the prosecution history and the evidence of the practical functionality of the '418 Patent apparatus. See McDonnell, Tr. at 1035, 1040-41.

The Staff maintains that "small" refers to "a spot that in absolute size reflects the inventor's concept of a small laser beam that scans in raster fashion within a perimeter of the cornea, and is therefore small enough to create a plurality of scan lines such as those shown in Figures 3 and 4 of the '418 Patent." Staff Initial Post-Hearing Brief at 25. In response to VISX's argument against importation from the illustrative embodiments in the specification, the Staff notes that the embodiments must be considered probative since the specification offers little other guidance. As to VISX's argument that the identification of the Microscan 771 indicates allowance for a larger beam, the Staff agrees with Nidek that such was not the intent of the applicant, in part because the Microscan 771 was designed for use with a larger beam CO_2 laser rather than an excimer laser.

Nidek makes an additional argument that the small spot taught by Claim 26 cannot vary in size during the ablation procedure, but VISX and the Staff disagree. Nidek maintains that when the claim describes "said beam" being deflected to cover the desired perimeter, it refers back to the "output beam ..." having the characteristics previously described, including the small spot. Based on this and the asserted lack of any contradictory indication in the patent, Nidek claims that

the spot size must remain unchanged during the procedure. In further support thereof, Nidek cites another patent of Dr. L'Esperance's in which he states, "As distinguished from the scanning procedure described in [the application leading to the '418 Patent], a sculpting action results from controlled change of projected laser spot size, in the course of a given treatment ...." RX 5, Col. 2, lines 21-28. VISX maintains that because Claim 26 sets forth no requirement that the spot remain a uniform size, the claim should not be construed to include such a requirement.

Considering the entire "laser means" claim element, I conclude that a UV laser is required that through the use of optical components can produce an output beam that creates the requisitely small laser spot. The parties remain sharply divided over the size of the "small" spot. The claim language lacks specificity as to the range of acceptable dimensions, merely teaching its size as small in comparison to the "cornea to be operated upon". As an initial matter, I agree with VISX and the Staff that by its plain meaning, the "cornea to be operated upon" refers to the entire cornea, rather than just a particular region of the cornea being ablated during a scan. The references in Claims 30 and 32 to the "optically functioning area of the cornea" reflect the drafter's indication of a more specific area or region of the cornea where intended, and the drafter made no such indication in Claim 26. This construction is consistent with the prosecution history, where in other, earlier claims, the language describing the point of comparison for the small spot size was broadened by amendment from referring to a specific region of the cornea to "the cornea to be operated upon". See CX 702 at 084229-31; CX 700 at 84487; CX 427.

Turning then, to the requisite spot size, I note that the output beams produced by such lasers are too large to function properly for the stated purposes in the '418 Patent, so that some

accommodation must be made to shrink the beam spot down to an appropriately small size.[5] See Sowada, Tr. at 1429, Eden, Tr. at 840. When it comes to determining what constitutes an appropriately small size, VISX diverges from Nidek and the Staff, with VISX insisting that "[t]here is no specific numerical limitation as to the laser spot size". VISX Post-Hearing Brief at 19. I cannot accept VISX's proposed interpretation of this claim element, because the proposed interpretation would fail to offer sufficient notice to the public of the subject matter claimed in the patent, and could also fail to provide adequate guidance to one skilled in the art on how to construct the invention without undue experimentation. See In re Morris, 127 F.3d 1048, 1054 (Fed. Cir. 1997) (noting the principle that claims must provide fair notice to the public). Because beams of commercially available lasers at that time, unaltered, did not produce a spot small enough to perform the necessary ablation scanning patterns, the patent should inform the public about how small the spot should be to accomplish the purpose of the invention and about how to reduce the spot created by the beam. VISX's proposed interpretation ignores such patent disclosure requirements, instead opting for a vague and overly broad reach.

The specification offers some guidance on the size of the spot in the form of "an illustratively useful rounded-square spot size of 0.5 mm by 0.5 mm" and in the form of an even smaller spot size of 30 microns. See CX 427, Col.4, lines 13-15, Col. 6, lines 59-67. While given that these references in the specification are the only indication what specific size range of spot might be contemplated under Claim 26, they nevertheless purport to be just examples, such that I

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[5]VISX makes the argument that the scan patterns set forth in the patent are merely exemplary and should not be considered in connection with the determination of the spot size, but I note that the specification teaches that the scan pattern figures depict scan patterns taught by the patent, and therefore should be considered in connection with the construction of this claim limitation.

find that some ambiguity remains as to the proper interpretation of "small."[6] Extrinsic evidence in the form of expert testimony can therefore be useful to shed light on the understanding of the claim term in the context of the described procedure by one of ordinary skill in the art. Nidek's expert, Dr. McDonnell, offered credible testimony that from the standpoint of one of ordinary skill in the art, taking into consideration the goal to achieve as smooth a surface as possible in the shortest time possible, a 1 mm spot size would be most practical. See McDonnell, Tr. at 1032-37; see also RX 757 - RX 761. VISX's expert, Dr. Eden, testified in favor of construing the term to include much larger spot sizes based on the disclosure of larger spots by CO_2 lasers in literature for the Microscan 771. See Eden, Tr. at 732; see also Munnerlyn, Tr. at 164. However, as Nidek points out, VISX's own witness, Dr. Munnerlyn, testified that the spot size produced with a laser in conjunction with the Microscan 771 depends on the wavelength of the laser, and also depends on the selection of lenses used therewith. Munnerlyn, Tr. at 277-79. In addition, the CO_2 laser produces a wavelength much longer and well beyond the UV spectrum. See Munnerlyn, Tr. at 164-65. Since Claim 26 teaches a UV laser, and since the selection of lenses can affect size, the spot size produced with a CO_2 laser producing a longer wavelength and an unspecified selection of lenses should not serve as guidance. Also, while VISX points to Nidek's EC-5000 as exemplary of laser vision correction products using larger laser spot sizes for surgical procedures, I note that the EC-5000 does not employ the same type of scanning patterns as taught by the patent. Accordingly, I conclude that the laser means described in Claim 26 must output a beam with a diameter no larger than 1 mm in order to satisfy the "small in relation ..." element.

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[6]I agree with Nidek and the Staff that Dr. L'Esperance's prosecution history statement distinguishing his spot size from that in the Taboada articles indicated that the Taboada articles showed irrelevantly large spot *sizes*. See CX 211 at 7-8.

Furthermore, I agree with Nidek's position that the output beam produced should consistently be characterized by the requisitely small spot. The language of Claim 26 supports this conclusion. The claim language simply indicates that the beam produced is "characterized by a spot which at cornea impingement is small in relation to the cornea to be operated upon." I note that there is no indication in the patent that the size of the spot created on the cornea should become larger at any point during the surgery. As Nidek points out, the subsequent reference in the claim to "said beam" refers back to the beam with the aforementioned characteristic. See CX 427, Col. 16, line 4. Furthermore, to the extent the claim could be deemed ambiguous on this issue, extrinsic evidence in the form of another patent of the inventor, Dr. L'Esperance, demonstrates that the spot size in Claim 1 of the '418 Patent should remain "small" throughout the procedure. Specifically, Dr. L'Esperance's '148 Patent entitled "Method for Performing Ophthalmic Laser Surgery", contains a statement distinguishing its disclosure from that of the application leading to the '418 Patent based on the former using a varying spot size for the treatment procedure, indicating that the '418 Patent discloses a spot whose size does not vary. See RX 5, Col. 2, lines 21-28.

Claim 26 next teaches that the laser means additionally includes "means for adjusting beam-exposure flux to a level at which resultant corneal-tissue ablation per unit time is to an ascertained elemental depth which is but a fraction of a predetermined maximum depth of ablation into the stroma." CX 427, Col. 15, line 67 - Col. 16, line 3. All the parties concede that the claim term "beam-exposure flux" has no ordinary meaning in the art, and, in fact, the term appears to be unique to the patents of Dr. L'Esperance. See Sowada, Tr. at 1433; Eden, Tr. at 736; see also CX 427, CX 545. VISX asserts, however, that because the '418 Patent uses the terms "beam-

exposure flux" and "irradiated flux density" interchangeably, one skilled in the art would understand the terms as referring to energy fluence per unit time. See Eden, Tr. at 736. According to VISX, "flux" is a common term referring to the rate at which particles pass through a given area, and in the context of the '418 Patent, "flux" involves controlling laser energy to achieve a particular depth of ablation. See SX 10; CX 427, Col. 2, lines 26-28. The broader context of Claim 26 and the specification describe reshaping in part by adjusting characteristics of the laser beam such as the energy density or beam flux, such that VISX maintains "beam-exposure flux" should be defined as "the amount of energy delivered to an area of the cornea over a given period of time." VISX Post-Hearing Brief at 24.

Nidek introduces its claim construction by emphasizing that "means for adjusting beam-exposure flux" should be interpreted as a means-plus-function claim element pursuant to 35 U.S.C. § 112, ¶ 6. As a result, Nidek contends that the specification must serve as the source for the meaning of this claim element, and therefore argues that it necessarily refers to a structure used exclusively in conjunction with a CW laser as described in Column 7, lines 24-27. Nidek also points to a dictionary definition of "flux" offered by the Staff as an indication that "flux" involves a continuous stream, thereby connoting a CW laser. See SX 10. Nidek points out that Dr. L'Esperance's patent attorney, Mr. Hopgood, coined the term "beam-exposure flux", and maintains that the claim itself does not convey the special meaning of the term. Under proper principles of patent construction, then, Nidek argues that the specification serves as the best guide and that the only section of the specification pertaining to "beam-exposure flux" only discusses use of a CW laser. To bolster its proposed construction, Nidek also cites Claim 26's combination of "beam-exposure flux" with ablation "per unit time" as an indication to those skilled in the art of

lasers that the claim concerns a CW laser, and points out by contrast that the patent refers to "energy *per pulse*" in reference to excimer lasers. See Sowada, Tr. at 1435-36. Nidek criticizes VISX's and the Staff's reliance on other patent claims to construe this element, maintaining that such reliance flies in the face of the proper, statutorily mandated means-plus-function analysis.

The Staff agrees with VISX that "beam-exposure flux" is synonymous with "irradiated flux density" and applies to excimer as well as CW lasers, referring to "the laser energy delivered per unit area, expressed in millijoules per square centimeter". Staff Post-Hearing Brief at 28. While the Staff acknowledges the means-plus-function context, it argues that the "means for adjusting beam-exposure flux" is identified as the power supply and programmable exposure and scan control unit of Figure 1 in the patent, such that the claim element covers that structure and its equivalents.

The phrase "means for adjusting beam-exposure flux" is in means-plus-function form, but contrary to Nidek's suggestion, that does not mean that the specification serves as the exclusive source for determining the *definition* of the term "beam-exposure flux". Rather, the means-plus-function form simply dictates that, using the proper definition of the term, the *identification of the structure* performing the function of adjusting beam-exposure flux should be derived from the specification. For this reason and for the reasons set forth above in connection with my conclusion that the laser means need not be limited to a CW laser, I reject Nidek's argument that the inclusion in the specification of the term "beam-exposure flux" in connection with a CW laser mandates that the laser means be construed to refer only to a CW laser. Based on a review of the patent in its entirety, I agree with VISX and the Staff that the claim term can apply to either pulsed or CW lasers. The context in which the term is used throughout the '418 Patent suggests

it refers to adjustment in the amount of laser energy applied to particular areas of the cornea over a particular period of time during the surgical procedure. For example, the specification includes the following passage:

> The showing of FIGS. 1 to 5 will thus be understood to illustrate the further case wherein ultraviolet laser radiation on axis 12 is of continuous-wave nature, for programmed exposure and scan control at 15, such that the *per-unit time exposure* of a given element of scanned area on a given scan-deflected pass of the elemental area *involves beam-exposure flux at a level at which resultant corneal-tissue ablation per scan is to an ascertained elemental depth* which is but a fraction of the desired maximum ablation into the stroma region of the cornea.

CX-427, Col. 7, lines18-27 (emphasis added).

While the specification refers to beam-exposure flux in connection with a discussion of use of a CW laser at Column 7, I note that the same passage refers to the "per-unit time exposure", and that a later passage in Column 9 dealing with the invention generally, with no restriction to CW lasers, also refers to the "unit-time exposure". CX-427, Col. 9, lines 3-4. Furthermore, as VISX points out, another claim of the '418 Patent specifies use of a pulsed laser but also includes the term "beam-exposure flux". See e.g. Claim 10. While Nidek argues the impropriety of looking to other claims, I find the argument unpersuasive, and deem it appropriate to examine the patent in its entirety and to establish a construction allowing for consistency in the definition of terms. See Fonar Corp. v. Johnson & Johnson, 821 F.2d 627, 632 (Fed. Cir.1987), cert. denied, 484 U.S. 1027 (1988) (holding that same term should be given a consistent meaning throughout the patent). The means for adjusting beam-exposure flux disclosed in the specification is the power supply - programmable exposure & scan control unit shown as 15 in Figure 1 of the patent. See CX 427, Fig. 1; see also CX 427, Col. 7, lines 18-27, Col. 9, lines 1-4.

Turning to the entire "laser means" claim term, then, because of the means-plus-function form of the claim element, the specification serves as the source from which to identify the structure or structures performing the functions set out in the claim, as previously construed. As stated above, the specification makes clear that the laser means includes a laser device that can be CW or pulsed and its associated power supply. Furthermore, for the function of producing the requisite small spot, I note that the lens elements are the only structures for such purpose disclosed in the specification:

> To bring this [beam] down to an illustratively useful rounded-square spot size of 0.5 mm by 0.5 mm at the eye 11, corrective lens elements at 26, as of quartz, calcium fluoride, or magnesium fluoride, will be understood to include a cylindrical element and a spherical element whereby beam size is reduced while the rectangular section is compressed to substantially square section.

CX 427, Col. 4, lines 13-20. Thus, each of these structures constitute part of the "laser means". Under the mandatory means-plus-function analysis, then, the patentee is entitled to protection for the laser device, associated power supply, the corrective lens elements disclosed in the specification and, as set forth, *infra,* the Microscan 771 as the "scan-deflection means" included therein, and structural equivalents thereof.

c. Scan-Deflection Means

Claim 26 also recites a scan-deflection means to deflect the laser beam "in a limited field about a central axis" as part of the laser means. VISX describes these means as "those elements that determine the scan pattern and the scan limits of the laser beam as it impinges on the cornea. VISX Initial Post-Hearing Brief at 25. According to VISX, the patent identifies those elements of scanner means 14 under microprocessor control as the scan-deflection means. See CX 427 at

Figures 1, 13, and Column 4, lines 4-13, 44-48, 66-Column 5, line 2, Column 3, lines 14-22. VISX notes that the patent offers the Microscan 771 as an example of a commercially available scan-deflection means that turned the laser on or off as appropriate for the ablation pattern in a procedure. See Munnerlyn, Tr. at 185-88; Sowada, Tr. at 1439; CX 206. However, VISX insists that the Microscan 771 serves only an illustrative purpose, and that any device with the same elements under microprocessor control as are found in scanner means 14 should qualify as scan-deflection means under Claim 26.

Whereas Nidek agrees that scanner 14 performs the function of the scan-deflection means, Nidek contends that due to the means-plus-function form of this claim element, it must be limited to the Microscan 771, the structure to perform this function disclosed in the specification. Nidek again criticizes VISX for allegedly deviating from the statutory means-plus-function analysis and for taking the position that an iris[7] can perform the function of the scan-defection means. In opposition, Nidek emphasizes that the specification contains no disclosure of an iris as the corresponding structure to the scan-deflection means.

The Staff takes the position that a means-plus-function analysis should apply, and notes that the specification discloses the Microscan 771 as performing the disclosed function without describing the precise structure by which the Microscan 771 actually deflects the beam. Based, thereon, the Staff proposes that "scan-deflection means" should be construed "to encompass scanners that can deflect a laser beam to scan 'in a limited field about a central axis,' including the Microscan 771 scanner and equivalents thereof." Staff Post-Hearing Brief at 30.

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[7]An "iris", or "iris diaphragm" refers to an essentially circular, variable opening through which the laser beam passes, and by which a portion of the beam may be blocked. See Eden, Tr. at 682.

The scan-deflection means taught by Claim 26 is also described as "having two coordinates of deflection for area coverage within the perimeter of said limited field". According to VISX, this claim element describes the scan-deflection means' ability to divert the laser beam in two coordinates. Citing Dr. Munnerlyn's explanatory testimony, Nidek focuses on the capacity of the Microscan 771 disclosed in the specification to deflect the beam over a limited rectangular area, firing the laser only when the value stored in the corresponding memory map indicates an area to be exposed to the laser. Nidek contends that in order to cover the area to be ablated, the small laser spot must be deflected in two directions. The Staff maintains that the claim element refers to scanning either rectilinearly, rotationally, or a combination of both, such that the scan-deflection means can create scan patterns such as those in Figures 3 and 4 of the patent. The Staff, unlike Nidek, seems to find no absolute limitation to the Microscan 771 in this claim limitation.

As the parties all concur, the scanner 14, the Microscan 771 is identified in the specification as the means for scan deflection: "For this purpose, a suitable scanner, known as 'Microscan 771' is commercially available from Laser Industries, International, Hendon, England and therefore need not be here described in detail." CX 427, Col. 4, lines 29-33. Thus, under the means-plus-function analysis, the Microscan 771 and its structural equivalents should receive protection under Claim 26. Claim 26 further describes the scan-deflection means as having "two coordinates of deflection for area coverage", apparently describing the Microscan 771, the only "scan-deflection means" identified in the specification, and any proffered equivalents must also satisfy this claim limitation. See Symbol Tech., Inc. v. Opticon, Inc., 935 F.2d 1569, 1575 (Fed. Cir. 1991) ("[T]he scope of [a means-plus-function] claim is not limitless, but is confined to

structures expressly disclosed in the specification and corresponding equivalents ..."). The scan-deflection means uses the two coordinates of deflection to facilitate deflecting the laser so as to accomplish scanning patterns such as those identified in Figures 3 and 4 of the patent.

d. Control Means ...

The parties next address the proper construction of that portion of the claim describing another part of the laser means, "control means with coordinating control connections to said scan-deflection means and to said laser for varying the perimeter of successive area scans within said field wherein said area scans are symmetrical about the central axis". According to VISX, which relies on the specification at Column 3, lines 17-22 and Column 4, lines 33-36, the "control means" set forth in Claim 26 merely refers to a microprocessor. VISX emphasizes that the microprocessor need not operate to turn the laser on and off during the ablation process, as in the Microscan 771, since VISX insists that the Microscan 771 merely serves as an illustrative embodiment.

Nidek, again stressing the means-plus-function form of the claim element, contends that the identified function is "varying the perimeter of successive area scans ...", and that the corresponding structure disclosed in the specification is the "programmable exposure & scan control" unit 15 depicted in Figure 3 of the patent. Nidek maintains that this unit disclosed in the specification is part of the Microscan 771 and includes a microprocessor. Nidek explains that the Microscan 771's memory map and ability to turn the laser on or off to correspond to the pre-programmed area of ablation, essentially a software control system, represents the control functionality taught by Claim 26. Nidek further notes the coordinating control connections between the control means and the laser, and between the control means and the scanner.

Ultimately, Nidek concludes that the control means "requires a microprocessor having a memory storing a memory map, with operative connections to a laser and a scanner." Nidek Post-Hearing Brief at 39. Nidek criticizes VISX's proposed construction as incomplete, ignoring the specific programmable functions the microprocessor must perform, and Nidek insists that the '418 Patent discloses a specifically programmed microprocessor. The Staff agrees that the specification discloses that the control means can be found in the Microscan 771's microprocessor, and thus concludes that the claim term "should be construed to encompass ... a programmable microprocessor with memory such as that in the Microscan 771 and structural equivalents thereof." Staff Post-Hearing Brief at 32. The Staff notes its disagreement with Nidek's position on the specifically programmed microprocessor, calling it an improper attempt to unduly restrict claim language to particular embodiments discussed in the specification. According to the Staff, citing Dr. Eden's testimony, equivalent control means to the Microscan 771's microprocessor include those that may not have a memory map and may not turn the laser on or off based on information in the memory map. See Eden, Tr. at 902-05.

The '418 Patent specification explains that the "control means" is included in the scanner, and subsequently sets forth that "... the control means 16 associated with [the Microscan 771] includes a microprocessor with memory for delineated boundary limits of scan, such as the limiting circle 30. The delineation can be to the surgeon's desired boundary contours and the scan speed and direction may be programmed or manually controlled." CX 427, Col. 4, lines 33-39; see also Col. 3, lines 18-22. Thus, because of the means-plus-function form of this claim term, the control means covered by this claim are those found in the microprocessor of the Microscan 771, identified in the specification, and structural equivalents thereof. According to the manufacturer's

literature on the Microscan 771, it was a "microprocessor-controlled microsurgery unit" and included an electronic control box and a control console. CX 206 at NC00720058-59. The literature makes clear that these controls allow the operator to control the area or line to be scanned as well as its size and the scanning speed. CX 206. As to Nidek's arguments for the microprocessor to be specifically programmed, I conclude that such determinations should not be made in connection with claim construction. Having identified the structure corresponding to the means set forth in the claim, additional specifics such as those proffered by Nidek should more appropriately be considered in connection with decisions about whether specific structures constitute structural equivalents to the identified means.

e. To Alter the Optical Properties Thereof

Claim 26 sets forth that the apparatus described operates "whereby to effect a controlled sculpturing action upon the cornea to alter the optical properties thereof". According to VISX, this merely teaches the result of using the claimed apparatus, and applies to all types of procedures reaching this result. See CX 427, Abstract, Col. 4, line 57 - Col. 5, line 32, Col. 6, line 29 - Col. 9, line 20. Citing Israel v. Cresswell, 166 F.2d 153, 156 (C.C.P.A 1948), VISX contends that such a "whereby" clause does not constitute a substantive claim limitation, but instead just describes the result of the preceding claim limitation. While the Staff views this clause as a substantive claim limitation, rather than a mere description of an expected result, the Staff maintains that the claim should not be limited in application to particular types of procedures using the apparatus. Nidek emphasizes that because the change in curvature of the cornea, producing the change in its optical properties, comes about through repetitive scanning by a small laser spot, those limitations must also be inherent in this claim element.

I conclude that the "whereby" clause does have substantive meaning for the claim, as it goes beyond merely stating an expected result. See Texas Instruments Inc. v. U.S. Int'l Trade Comm., 988 F.2d 1165, 1172 (Fed. Cir. 1993). This claim term requires that the apparatus effect scanning so as to sculpt or reshape the cornea and thereby change its optical properties. The specification and other claims of the patent refer to specific vision defects that can be corrected through controlled use of the apparatus,[8] but I find that Claim 26 contains no limitation as to particular types of changes to the optical properties of the cornea. Accordingly, this claim element merely requires that operation of the apparatus taught by Claim 26 must produce some modification to the optical properties of the cornea.

2. Claim 27

Claim 27, in its entirety, reads:

- Apparatus for performing ophthalmological surgery by selective ablation of the anterior surface of the cornea with penetration into the stroma to achieve a volumetric removal of corneal tissue,
- said apparatus comprising laser means producing an output beam in the ultraviolet portion of the electromagnetic spectrum and characterized by a spot which at cornea impingement is small in relation to the cornea to be operated upon,
- said laser means including means for adjusting beam-exposure flux to a level at which resultant corneal-tissue ablation per unit time is to an ascertained elemental depth which is but a fraction of a predetermined maximum depth of ablation into the stroma,
- scan-deflection means positioned for deflection of said beam in a limited circular field of maximum radius about a central axis, said scan-deflection means having two coordinates of deflection for area coverage within the circumference of said circular field,
- and control means with coordinating control connections to said scan-deflection means and to said laser for varying the radius from one to another area scan within said circular field,

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[8] See e.g. CX 427, Col. 4, lines 58-62 ("... the external surface of a cornea 32 may be modified to achieve a change in optical properties of the involved eye, here illustratively a myopic eye ....").

- whereby successive area scans may be circular and at different radii about the central axis, whereby to effect a controlled sculpturing action upon the cornea to effect a myopia-reducing alteration of the optical properties thereof.

CX-427, Col. 16, lines 18-43.

The parties stipulate that a finding of infringement or non-infringement of Claim 26 likewise determines infringement or non-infringement of Claim 27, and therefore no separate claim construction or infringement analysis of Claim 27 need be performed.

3. Claim 30 and Claim 32

Claim 30 in its entirety, and with disputed elements underlined, reads:

- Apparatus for performing ophthalmological surgery by selective ablation of the anterior surface of the cornea with varied penetration up to a predetermined maximum penetration into the stroma to achieve an anterior-curvature change by volumetric removal of tissue within the optically functioning area of the cornea,
- said apparatus comprising: a laser producing a pulsed laser beam in the ultraviolet region of the electromagnetic spectrum,
- means for shaping, focusing and directing the beam toward the cornea with an intensity to produce tissue penetration to a depth per pulsed exposure which is but a fraction of said predetermined maximum,
- said means including means for selectively (a) determining and controlling one circular area of exposure to the extent of at least said fractional depth and (b) determining and controlling a different circular area of exposure to the extent of at least said fractional depth,
- each of said circular areas being within the optically functioning area of the cornea and concentrically disposed with respect to the optical axis of the cornea,
- whereby the cumulative penetration of the cornea for both said areas of exposure can effect a myopia-reducing corrective change in the curvature of the cornea.

CX-427, Col. 17, lines 29-51.

Claim 32 in its entirety, and with disputed claim terms underlined, reads:

- Apparatus for performing ophthalmological surgery by selective ablation of the anterior surface of the cornea with varied penetration up to a predetermined maximum penetration into the stroma to achieve an anterior-curvature change by volumetric removal of tissue within the optically functioning area of the cornea,
- said apparatus comprising: a laser producing a pulsed laser beam in the ultraviolet region of

the electromagnetic spectrum;

- means for shaping, focusing and directing the beam toward the cornea with an intensity to produce tissue penetration to a depth per pulsed exposure which is but a fraction of said predetermined maximum;
- said means including means for selectively (a) determining and controlling one circularly annular area of exposure to the extent of at least said fractional depth and (b) determining and controlling a different circularly annular area of exposure to the extent of at least said fractional depth,
- each of said circularly annular areas being within the optically functioning circular area of the cornea and concentrically disposed with respect to the optical axis of the cornea;
- said areas having overlapping relation at least to the outer diameter of the optically functioning area,
- and one of said annular areas having a lesser inner diameter than the other of said annular areas;
- whereby the cumulative penetration of the cornea for both said annular areas of exposure can effect a hyperopia-reducing corrective change in the curvature of the cornea.

CX-427, Col. 18, lines 7-34.

The construction of these claims arises only in connection with VISX's domestic industry allegations, as VISX does not accuse Nidek's devices of infringing Claim 30 or Claim 32 of the '418 Patent. The two claims are quite similar, but Claim 30 pertains to myopia treatment while Claim 32 pertains to hyperopia treatment. The parties essentially focus their dispute around two means-plus-function elements found in both claims, the "means for shaping, focusing and directing the beam ..." which includes "means for selectively ... determining and controlling ..." different circular areas of exposure to a particular depth.

As to the first means-plus-function element, VISX maintains that the patent teaches a single means to perform the three articulated functions – shaping, focusing and directing – in no particular order. VISX maintains that the specification identifies the means as "an optical delivery system consisting of lens elements 26, scanner 14, and the unnumbered mirror located between the lens elements 26 and scanner 14." See CX 427 at Figure 1, Figure 13, Col. 3, lines 14-22, Col.

4, lines 4-20; and Col. 7, lines 47-57. VISX stresses, however, that while the patent identifies a scanner as one of the components making up this means, the claim term should not be construed to require a structure that performs a scanning function, since the claim term refers to "directing" rather than "scanning". The Staff generally agrees with VISX's position, and takes issue with Nidek's more narrow interpretation of the claim term.

Nidek argues that the means for shaping, focusing and directing involves three distinct functions to be performed in that precise order, such that "... the equivalent structure must practice those functions and in the same order." Nidek Post-Hearing Brief at 44. According to Nidek, the '418 Patent specification identifies the first of the lens pair 26 as performing the "shaping", while the second lens performs the "focusing", and the scanner 14 accomplishes the "directing" function. Nidek goes on to note that the scanner 14 is defined specifically as a Microscan 771.

Turning to the means for "determining and controlling" included in the means for shaping, focusing and directing, VISX argues that the disclosed structure performing this function "includes components in scanner 14, which are under microprocessor control." See VISX Post-Hearing Brief at 38 (citing CX 427 at Figure 1).[9]

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[9]VISX's expert, Dr. Eden testified as follows:

> What are the -- in the '418 patent, what are the means for selectively determining and controlling one circular area of exposure?
>
> A The means for that is the microprocessor-controlled scanner, and there are optical structures and elements within that scanner that respond to commands from the microprocessor. That's what determines those areas of exposure.

Eden, Tr. at 774.

The Staff approaches construction of this claim element without explicitly identifying the structure in the '418 Patent specification it contends performs the function in question. However, the Staff implicitly suggests that the identified structure is part of the Microscan 771 scanner. The Staff jumps directly to the scope of equivalents covered by this claim element, and argues that a controller, such as a microprocessor, "... that issues commands to the optical elements in order to change the area of exposure according to a particular set of instructions" should qualify. Staff Post-Hearing Brief at 46. The Staff further specifies its position that an acceptable equivalent could include use of an iris diaphragm due to its "substantial[] interchangeab[ility]" with the structures disclosed in the patent specification.

Nidek maintains that the structures for performing the functions taught by this claim element "... can either be the programmable exposure and scan control of the beam contained in module 15 which is used to drive the scanner 14 or an internal memory or processor in the scanner 14 itself." Nidek Post-Hearing Brief at 46. Nidek here emphasizes that either alternative allows for active control over the "means for ... directing", which Nidek contends is required by the claim.[10] Nidek cites the specification as indicating that the scanner, even with a microprocessor, must somehow be controlled, such that the means must include a structure for a point of information input, either to directly control the scanner or to provide parameters for programming. See CX 427, Col. 4, lines 35-39. Finally, Nidek disputes VISX's and the Staff's positions on the acceptable range of equivalents.

The parties all stand in agreement as to the structures identified in the '418 Patent

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[10]VISX cautions that the patent does not teach any such direct microprocessor connection to the structure that "directs" the laser beam, and contends that such an interpretation improperly imports teachings in the specification that relate only to an illustrative embodiment.

specification that perform the "shaping, focusing and directing" function – lens elements 26, the unnumbered mirror and the scanner 14. Accordingly, under the applicable means-plus-function analysis, these identified structures and any structural equivalents receive protection under the patent. As to Nidek's assertions that the functions should be split and linked to particular components, and that any equivalents must perform the three functions in the particular order identified, I find nothing in the patent to support such an interpretation. As the Staff and VISX point out, a single means is identified for performing the three functions, and the claim and specification place no significance on the order in which the shaping, focusing and directing is accomplished. The parties' arguments regarding a scanning function essentially involve determining what constitutes an acceptable equivalent under the applicable analysis, and is more properly addressed, as necessary, in connection with the technical prong of domestic industry.

The patent teaches that the "means for selectively (a) determining and controlling one circularly annular area of exposure to the extent of at least said fractional depth and (b) determining and controlling a different circularly annular area of exposure to the extent of at least said fractional depth" is included within the means for shaping, focusing and directing. The specification of the '418 Patent indicates that the means for determining and controlling can be found within the scanner 14, a suitable example of which the specification identifies as the Microscan 771. The specification further sets forth that a microprocessor with memory in the Microscan 771 delineates the boundary limits of scanning, such as in the circular scanning patterns shown in Figures 3 and 4. CX 427, Col. 4, lines 33-43; Col. 9, lines 1-8; see also Col. 5, lines 20-23 (myopia). The specification goes on to note that such functions may be manually controlled or programmed. Id. Ultimately, then, the microprocessor with memory and the manual control

features of the Microscan 771 are the structures corresponding to the determining and controlling function, such that these and their structural equivalents receive protection under the patent.

B. U.S. Patent No. 5,711,762 – Claims 1, 7, 10 and 12

The '762 Patent, titled "Laser Surgery Apparatus and Method" issued on January 27, 1998, with Dr. Stephen Trokel named as the sole inventor. The patent was assigned to VISX, who now asserts that Nidek's accused devices infringe its Claims 1, 7, 10 and 12. Claims 7, 10 and 12 depend on Claim 1.

1. Claim 1

Claim 1 of the '762 patent, with the claim elements in dispute underlined, reads as follows:

A system for use in a laser source surgical method for removing corneal tissue, said system comprising:

- a laser that produces a beam of radiation at a wavelength of about 193 nanometers in a series of pulses;
- a laser delivery system means for receiving said radiation from said laser and delivering a fraction of said radiation to a cornea; and
- wherein said radiation produces a depth of ablation of approximately 1 micron for each accumulation of one joule per square centimeter of energy applied.

CX-967, Col. 6, lines 39-49.

a. A System for Use in a Laser Source Surgical Method for Removing Corneal Tissue

The parties initially dispute the significance of the preamble of Claim 1, set forth above. According to VISX and the Staff, the reference in the preamble to removal of corneal tissue takes this preamble outside the general rule that a preamble does not serve to limit a claim. See e.g. DeGeorge v. Bernier, 768 F.2d 1318 (Fed. Cir. 1985). Citing Federal Circuit authority, VISX and the Staff argue that in this instance, because the preamble is essential to the meaning of the claim, the preamble should be deemed to limit the claim. See Pitney Bowes, Inc. v. Hewlett-

Packard Co., 182 F.3d 1298 (Fed. Cir. 1999) (noting that where, in the context of the claim as a whole, the preamble seems to recite limitations or is necessary for the "life, meaning, and vitality" of the claim, no distinction should be drawn between the preamble and the remainder of the claim).

The Staff points out that in its view, the prosecution history suggests that the applicant amended this claim to add "removing corneal tissue" in order to overcome the examiner's rejection over an article by Dr. Srinivasan.[11] See CX 706, tab 21. The article, entitled "Far UV Photoetching of Organic Material", generally corresponds to the subject matter of the '135 Patent, but does not explicitly refer to corneal tissue. See CX 706, tab 5. The Staff argues that by amending this and other claims to pertain exclusively to devices for the ablation of corneal tissue, Dr. Trokel convinced the examiner that the '762 Patent invention was sufficiently distinct from Dr. Srinivasan's disclosure. Accordingly, the Staff contends that this preamble should be construed as a substantive claim limitation.

I accept the Staff's and VISX's arguments in favor of deviating from the general rule that the preamble of a claim does not serve as a limitation. Under the circumstances, the prosecution history, as set forth above, strongly supports construing the preamble as a limitation. Although the description of the preferred embodiment includes references to use of the apparatus on other biological matter (e.g. RX 3, Col. 3, lines 43-47), the prosecution history shows that proposed claims directed to use of the laser apparatus on dental caries and skin lesions were canceled to overcome the examiner's objections. See CX 706, tab 21; RX 4. Furthermore, Claim 1 also

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[11]Dr. Trokel's and Dr. Srinivasan's joint experimental work is discussed, *infra*, in connection with inventorship of the '762 Patent.

includes as a limitation an ablation rate specifically for *corneal tissue*. As the record reflects that ablation rates vary with different materials, the preamble's limitation to an apparatus for procedures only on corneal tissue is necessary for proper definition and construction of the scope of Claim 1. See Gerber Garment Tech. Inc. v. Lectra Systems Inc., 916 F.2d 683 (Fed. Cir. 1990) ("Where words in the preamble 'are necessary to give meaning to the claim and properly define the invention,' they are deemed limitations of the claim"); Perkin Elmer Corp. v. Computervision Corp., 732 F.2d 888 (Fed. Cir.), cert. denied, 469 U.S. 857 (1984) (finding claim limitations in the preamble where "...necessary to give meaning to the claim and properly define the invention").

b. Laser Delivery System Means ...

This means-plus-function claim element necessitates searching the specification for the structure(s) performing the functions "receiving said radiation from said laser" and "delivering a fraction of said radiation to a cornea". According to VISX, Figures 2 and 3 of the '762 Patent show laser delivery systems that are the corresponding structures disclosed in the specification. VISX argues that this is apparent from the patent, and also cites supporting testimony by Dr. Eden. See Eden, Tr. at 888-89.

VISX maintains that the system of Figure 3 allows for the delivery of a fraction of the laser radiation to facilitate ablation at the appropriate depth *without* the use of a mask such as that shown as 30 in Figure 1. According to VISX, the ability to adjust variable slit 84 permits the accomplishment of this result. With regard to Figure 3, VISX insists that it operates to image variable slit 84 onto the cornea, rather than imaging aperture 88 onto the cornea, as Nidek's Dr.

Sowada testified.[12] See Sowada, Tr. at 1458. VISX contends that Dr. Sowada's position conflicts with the description in the patent that Figure 3's apparatus "would take away more tissue either centrally or peripherally", since Dr. Sowada's point-to-point imaging system would not allow for varied ablation during the procedure to remove more tissue centrally or peripherally. VISX also cites the prosecution history in support of its position on variable ablation during the procedure. See CX 710 at 82361.

Nidek contends that the Patent requires that the specific delivery systems of Figures 2 and 3 must be incorporated into Figure 1 as examples of the laser delivery system 22. Nidek goes on to note that Figure 1 shows a contact or proximity mask because of the proximity of the mask 30 to the cornea and because of the absence of any optical components between the mask and the cornea. Although the space between the mask and the cornea is not specified in Figure 1, Nidek asserts that the practical necessity of replicating patterns onto the cornea dictates that the distance be no more than approximately one millimeter. See Sowada, Tr. at 1453-54. Nidek further cites supporting testimony both by Dr. Sowada and by Dr. Trokel, the latter in the context of an interference proceeding. See id.; RX 214 at 143 (Dr. Trokel referring to the mask in a similar figure as a contact mask). Nidek goes on to argue that because the patent specification sets forth that the apparatuses and systems in Figures 2 and 3 be used with the apparatus and system in Figure 1, and because of all of the masks shown in the '762 Patent could serve as proximity masks, this means-plus-function element necessarily requires that the means include a proximity

[12]This is significant because aperture 88 represents a fixed opening, unlike variable slit 84, which represents an adjustable opening.

mask[13]. See RX 3, Col. 2, lines 62-67. Nidek also points to testimony by Dr. Sowada that a proximity mask could function and serve a useful purpose with the systems shown in Figures 2 and 3. Sowada, Tr. at 1455-57, 1466-67.

As to this dispute about the interrelationship between Figures 1, 2 and 3, the Staff initially notes that Figure 1 depicts a box 22 identified as a laser delivery system directing the laser through "openings 28 formed in a mask 30" and onto the cornea. RX 3, Col. 3, line 52. The Staff goes on to explain that the patent's description refers to Figure 2 as a laser delivery system and Figure 3 as an ophthalmic delivery system. Focusing on Figure 3, the Staff turns to the prosecution history, particularly an initial rejection, amendment, then allowance of claim language relating to this subject, for support in arguing that the figure reflects a system capable of delivering a variable spot size of laser light to the cornea. See CX 710. The Staff also cites Ms. Braren's IBM lab notebook entries as supporting its interpretation of Figure 3 as showing the projection of variable slit 84 through aperture 88 and onto the cornea. See CX 24 at 08514-15. Under this interpretation of Figure 3, according to the Staff, changing the intensity of laser light at the cornea is possible by varying the size of the opening 84. See Eden, Tr. at 682-83. Focusing on Figure 3, the Staff asserts that one of ordinary skill in the art would recognize it as an ophthalmic imaging system. See Eden, Tr. at 693, 818-19, 886-87. The Staff then concludes that the corresponding structures to the laser delivery system means are the apparatus in Figure 2 or the apparatus in Figure 3, and that these structures and their equivalents should receive patent protection.

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[13]Nidek does concede that the specification sets forth one example, not relevant here, where no mask would be used for the laser delivery system means: "a fiber-optic pipe and rod delivery system may be utilized without masks". RX 3, Col. 3, lines 43-44.

Under the means-plus-function analysis, I conclude that the structures identified in the specification that perform the receipt and delivery function set forth in Claim 1 are the apparatuses shown in Figure 2 and Figure 3 of the patent, explicitly described in the specification as "a laser delivery system" and "an ophthalmic delivery system", respectively, and the fiber-optic pipe and rod delivery system. However, as explicitly taught by the patent, the systems in Figures 2 and 3 must be used in conjunction with the system and apparatus shown in Figure 1. One of the components of Figure 1 is specifically labeled as a laser delivery system, such that the systems of Figures 2 and 3 are said to fit into and be used with the overarching system and apparatus shown in Figure 1. See RX 3, Figure 1, component 22. Also, the patent explicitly states that "FIG 2 is a schematic illustration of a laser delivery system for use with the apparatus and system of FIG 1" and that "FIG 3 is a schematic illustration of an ophthalmic delivery system for use with the apparatus and system of FIG 1". RX 3, Col. 2, lines 62-67.[14]

Furthermore, the apparatus and system of Figure 1 includes a depiction of a contact or proximity mask, and I conclude that the patent therefore teaches that the systems and apparatuses of Figures 2 and 3 should be used with a proximity mask such as that set forth in Figure 1. See Sowada, Tr. at 1455, 1467. VISX and the Staff maintain that the system of Figure 3 can accomplish the desired purpose without use of a proximity mask, such that none should be required in connection with this claim. According to VISX and the Staff, no proximity mask should be required in part because of prosecution history statements that the variable slit aperture

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[14]I also note that on cross-examination VISX's expert, Dr. Eden, admitted that "it is clear that Figure 3 is to be used in conjunction with Figure 1" and is in fact "a part of Figure 1", Eden, Tr. at 795.

84 (rather than a proximity mask) allowed for application of a variable intensity across the ablated area over time. See CX 710 at 082361. However, I do not believe that these statements are determinative. These statement do not directly indicate that the aperture 84 determines the area or pattern of ablation on the cornea, and may only indicate that the size of the aperture 84 can be varied to affect the *fluence* delivered in the course of a procedure. Additionally, VISX's current position in this regard is inconsistent with other statements made to the PTO and with other testimony regarding the functionality of the system of Figure 3. For example, according to Dr. Munnerlyn's representations to the PTO during an interference proceeding, the laser light passes from aperture 84 through a lens and on to the "pinhole" aperture 88, through another lens, and that the image from 88 is ultimately imaged onto the cornea. See RX 249 at 4-11. In that proceeding, Dr. Munnerlyn of VISX submitted a declaration including the statement that the image at the aperture 88 is magnified onto the eye. Id. at 11. Accordingly, the size and pattern of the projection onto the cornea cannot be exclusively and directly determined by varying the slit aperture 84, such that the use of a proximity mask would be inappropriate. Dr. Srinivasan testified with regard to Figure 3 that the pattern projected onto the target cornea would be a pattern of the aperture 88. Srinivasan, Tr. at 1217. Dr. Trokel admitted that Figure 3 is an adaptation of a drawing of Figure 3 that Dr. Srinivasan gave him (Trokel, Tr. at 403), lending credibility to Dr. Srinivasan's statements about how it works.[15] This functionality of the apparatus of Figure 3 was attested to by Dr. Sowada, by Dr. Srinivasan, and by Dr. Munnerlyn himself in the interference document. See RX 249; Sowada, Tr. at 1458-59; Srinivasan, Tr. at

[15] In correspondence dated October 20, 1983, Dr. Trokel referred to Dr. Srinivasan's "knowledge and skills in ... preparing the difficult delivery system" as "essential to this project". CX 231.

1217.[16] VISX's criticism of Dr. Sowada's testimony is unfounded, as his description of the overall functionality of the system of Figure 3 comports with VISX's description to the PTO in the aforementioned interference proceeding.

Ultimately, I find VISX's and the Staff's arguments unavailing in their attempt to overcome the explicit and plain teaching of the patent that the structures identified as laser delivery systems be used with the apparatus in Figure 1 of the patent, which includes a proximity mask. I conclude that the use of a proximity mask with the apparatuses and systems of Figures 2 and 3 can serve a useful purpose, and should not be rejected as a nonsensical notion. The most credible testimony on this issue supports my conclusion, and I find Dr. Eden's testimony on this issue, including his testimony that aperture 84, rather than aperture 88, is imaged onto the cornea, is lacking in credibility in light of all the other conflicting evidence and testimony.

c. Wherein Said Radiation Produces a Depth of Ablation of Approximately 1 Micron for Each Accumulation of One Joule per Square Centimeter of Energy Applied

As VISX succinctly states, "[t]he dispute regarding this element centers on the construction of 'approximately 1 micron.'" VISX Post-Hearing Brief at 56. VISX maintains that "approximately 1 micron" should be construed as anywhere up to 3 microns, while Nidek contends that only a .25 micron variation from "1 micron" should be permitted under the "approximately language", and the Staff takes the position that the "conservative" covered range should be "no less than 1 micron $\pm$ 0.3 microns".

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[16] While VISX at one point attempts to rely on Dr. Munnerlyn's representations to the PTO as supporting its interpretation of Figure 3, VISX's own expert, Dr. Eden testified that Dr. Munnerlyn's statement to the PTO did in fact indicate that Dr. Munnerlyn believed aperture 88 is imaged onto the cornea. Eden, Tr. at 1648.

VISX argues that Dr. Trokel used the "approximately 1 micron" terminology in the patent to protect his invention from those who might make insignificant changes in the ablation rate and design around his system. VISX maintains that the term of degree, "approximately", allows for flexibility dependent on the technological facts in this case. As additional evidence of flexibility, VISX notes the use of only a single numerical figure, "1", instead of "1.0", which additional figure might indicate an intention to express the number with greater precision. Looking to the specification and prosecution history, VISX points out that the exemplary figures are in similarly round single-figure numbers and that the rough estimate status of "approximately 1" is confirmed by a statement that "about 1 micron" is removed for each joule per square centimeter of energy density. See RX 3, Col. 4, lines 57-58; CX 706, Tab 12 at 9. Next, VISX cites the testimony of its experts that "approximately 1" indicates a broad range rather than a specific number. See Motamedi, Tr. at 505, 490. Dr. Motamedi testified that in 1983, the known range of error in measurement accounted for many variables such as the type of tissue being ablated, the level of hydration of the tissue, the corneal layer being ablated, technical difficulties in measuring the depth of ablation, the energy output of the laser and the size of the area being ablated. Motamedi, Tr. at 490-503. Dr. Eden confirmed that the standard deviation of a measurement in the early era of a new field can be quite large. Eden, Tr. at 711-12. VISX criticizes expert testimony from Nidek's Dr. Sowada and Dr. McDonnell as not well-reasoned and as failing to take account of the 1983 date of the patent. VISX concludes with the assertion that Dr. Trokel's language should be liberally construed in light of his allegedly pioneering work.

Nidek emphasizes that the claim language describing this element is plain and unambiguous, and further points out that the only example offered in the specification comports with precisely 1

micron for each Joule/cm^2. See RX 3, Col. 4, lines 57-58 ("in forming a 200 micron deep groove, for example, 200 joules per cm^2 would be required"). According to Nidek, VISX's position on the acceptable claim would totally vitiate the claim element, and would result in a failure by the patent to provide the public with sufficient notice of the scope of the claim. Nidek maintains that "approximately" means "reasonably close to; nearly; almost; about" so as to allow only for relatively slight variations. Although Nidek opposes looking to extrinsic evidence under the circumstances, it argues that even if such evidence is considered, expert testimony supports an allowance of only a 10-15% range, because in 1983, a 10-15% margin of error in depth precision was the standard for radial keratotomy ("RK") cuts, an analogous procedure for vision correction[17]. See McDonnell, Tr. at 1046, 1051; Trokel, Tr. at 313, 377-78. Using another analogy, Dr. McDonnell testified that in 1983 and today, the accuracy of prescription glasses ranges $\pm$ .25 diopters. McDonnell, Tr. at 1054. For laser surgery today, $\pm$ .5 diopters is considered reasonable accuracy. Sher, Tr. at 1535. Nidek cites testimony indicating that because one diopter equates to around 12 microns of ablation, for a five diopter correction requiring a 60-micron depth of ablation, to be within the $\pm$ .5 diopter range, an accuracy of $\pm$ 6 microns would be required, constituting a 10% variance from the intended depth. See McDonnell, Tr. at 1054-58; Trokel, Tr. at 415-17. Ultimately Nidek concludes that even taking into account VISX's position regarding measurement uncertainties, the interpretation of "approximately 1" should not extend beyond "about a 25% variation".

In support of its position, the Staff cites authority for the proposition that terms such as

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[17]Both VISX and the Staff criticize this analogy to RK as inappropriate on the grounds that no tissue was being ablated and that surgical expectations for this different type of procedure should not be carried over to the patent.

"approximately" should be accorded "reasonable scope" within the context of the field of the invention. See Modine, 75 F.3d at 1554. The Staff argues that the evidence supports its proposed range of ± .3 microns, greater than the range proposed by Nidek but smaller than that proposed by VISX. First, the Staff points to Dr. Trokel's 30-40% error rate in measuring the degree of ablation during the 1983 experiments. See Trokel, Tr. at 349-53. Second, the Staff cites Dr. Grundfest's statement that using what he believed to be the most accurate method of measuring ablation depth, he experienced a variation factor of approximately 15%. See Grundfest, Tr. at 949. Third, the Staff notes that Dr. Sowada testified that energy meters in 1983 offered precision of ± 25-30%. See Sowada, Tr. at 1469, 1488. Finally, the Staff points out that its 30% figure comes within the ambit of the claim element in the view of Dr. Motamedi. See Motamedi, Tr. at 555-56. Taking account of the foregoing, the Staff opines that its 30% variation range offers the best synthesis of the evidence relating to the understanding of "approximately 1 micron" by one skilled in the art at the relevant time.

As to the construction of "approximately 1 micron", I conclude that in light of the ordinary meaning of the claim terms, the illustration in the specification, and the evidence regarding this technology, "approximately 1" literally covers between .7 and 1.3 microns, a range of ± .3 microns, or a 30% variation. I note that in common parlance, "approximately" is used to refer to something that is near to or close to whatever it modifies. While I deem it appropriate under the circumstances, given the inherent flexibility in such a term, to consider testimony by those of skill in the art, the most credible expert testimony supports a more narrow range such as that proposed by Nidek and the Staff, rather than the extremely broad range proposed by VISX. VISX's primary witness on this issue, Dr. Motamedi, testified that his interpretation of "approximately 1"

as extending to "3" comports with the ordinary meaning of "approximately,"[18] a conclusion with which I do not agree. See Motamedi, Tr. at 546. He further testified that his precise proposed definition of the term in the context of the patent is "an inexact result adequate for a given purpose", and that the given purpose in the patent is corneal and refractive surgery. Motamedi, Tr. at 547-48.

Given the weight of testimony about the acceptable range of deviation, I cannot accept Dr. Motamedi's and VISX's assertion that such a vast range should be allowed within the scope of "approximately 1 micron". In connection with Dr. Motamedi's credibility on this point, I note that on cross-examination, he conceded that at his deposition, he offered an even broader range, stating that the range could extend at least up to 6. Motamedi, Tr. at 553-54. However, Dr. Motamedi also confirmed on cross-examination that in another proceeding, he testified that a 30% variation would be "pretty close to the range" taught by this element. Motamedi, Tr. at 555. Under questioning on his evolving position on the acceptable range, Dr. Motamedi stated that "... I have gone back and looked at the data *that is available to me from Nidek*, and from the literature, and as I said earlier today, I have more confidence in 2 than I would in 6." Motamedi, Tr. at 554-55 (emphasis added). Dr. Motamedi's testimony gives a clear indication that he manipulated his construction of this term in this investigation to accommodate the infringement analysis of Nidek's accused products, thus undermining his credibility on this issue. See Scripps v. Genentech, 927 F.2d 1565, 1580 (Fed. Cir. 1991) ("[T]he words of the claims are construed independent of the accused product"). Notably, Dr. Motamedi's admission of his earlier

[18]On cross-examination, Dr. Motamedi conceded agreement with the common definitions of "approximately" as acceptable in the context of Claim 1 of the '762 Patent: "reasonably close to, nearly, almost, about". Motamedi, Tr. at 551.

acquiescence to a 30% range is consistent with testimony by Nidek's Dr. Sowada, and conforms to the ordinary meaning of "approximately". In light of the foregoing, "approximately 1 micron" literally covers a range of .7 microns to 1.3 microns.[19]

2. Claim 7

Claim 7 of the '762 patent reads as follows:

> A system according to claim 1, which can produce pulses at said cornea which have between 100 and 200 milijoules of energy per square centimeter.

Claim 7 depends on Claim 1, and adds the limitation on the fluence level range – from 100 to 200 milijoules of energy per square centimeter. VISX and the Staff maintain that this limitation merely requires the system to produce pulses within the range of intensity described, but Nidek argues that "... the entire area (i.e., cross-section) of the pulse that is exposed to the tissue ..." must have a single, consistent fluence level to facilitate uniform ablation. VISX and the Staff argue first, that nothing in the claim language, specification or prosecution history supports Nidek's proposed interpretation, and second, that such a construction defies the inherent non-uniformity of an excimer laser pulse. See Motamedi, Tr. at 523; see also Trokel, Tr. at 344.

I find nothing in the claim language to support imposing the limitation advocated by Nidek. Nidek also fails to point to any indication that its proposal would be consistent with the understanding of one of ordinary skill in the art, and in fact, the only expert testimony cited by any party on this issue directly conflicts with Nidek's proposed interpretation of Claim 7.

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[19]VISX makes an argument that various margins of error were allegedly associated with the different parameters affecting the ablation rate, and cites testimony from numerous different witnesses. However, the only cited evidence synthesizing the interplay among these various alleged error margins and parameters comes in the form of testimony by Dr. Motamedi, whose testimony regarding the ablation rate, as I noted previously, cannot be relied on.

3. Claim 10

Claim 10 of the '762 Patent reads as follows:

> A system according to claim 1, further comprising means, including a mask, for controlling a volume of corneal tissue removed by said system during corneal laser surgery.

Claim 10 is dependent from Claim 1, and adds a means-plus-function limitation – means for controlling the volume of tissue removed during a procedure, further specifying that the means should include a mask. According to VISX, citing Column 4, lines 53-64 of the patent, the structures identified in the specification for performing this function are the power supply and control 24 along with a mask. VISX explains its position that control 24 regulates the energy output, and therefore largely determines the fluence level that helps determine the volume of tissue removed. As for the mask, VISX suggests that the specification identifies variable slit 84 of Figure 3 as a corresponding structure, and notes its view that the mask could also be an iris diaphragm. VISX maintains that these structures would be understood by one of ordinary skill in the art to constitute masks, and cites testimony by Dr. Sowada that a variable slit and an iris diaphragm are generally both considered to be masks. See Sowada, Tr. at 1491-92.

Nidek agrees with the inclusion of control 24 as part of the corresponding structure, but disagrees that aperture 84 can be part of the corresponding structure, arguing that the '762 Patent consistently uses "mask" to refer to "a curved, fixed opening contact/proximity mask", citing Figures 1, 4-8, Column 3 at line 51, and Column 4, lines 11-51. Nidek emphasizes that the other terminology reserved for variable slit 84 distinguishes it from a "mask" in the context of the patent. VISX responds that Nidek's position that an iris diaphragm cannot constitute the mask referred to in this claim is indirectly inconsistent with positions Nidek took in responding to

discovery.[20]

The Staff maintains that the "further comprising" language of the claim indicates the addition of an element to the laser delivery system structure of Claim 1. The Staff cites the discussion in the patent's written description of a mask as "formed from particular material and with one or more slit or circular openings to impinge upon an area of the cornea of an eye to form therein a groove of predetermined peripheral configuration and depth." See RX 3, Col. 3, lines 35-39. The Staff cites other descriptive statements from the specification regarding the masks as well as statements in the prosecution history to counter Nidek's position. The Staff takes the position that the means should be identified as: the mask 30 in Figure 1, the variable slit 84 in Figure 3, aperture 88 in Figure 3, the mask 30 in Figure 4, the mask 110 in Figure 5, the mask 120 in Figure 6, the mask 130 in Figure 7, and the mask 140 in Figure 8, and that structural equivalents thereof should also be covered.

In the specification of the '762 Patent, the structures identified as controlling the volume of corneal tissue removed are the laser power supply and control system 24 and, as explicitly set forth in the claim language, a mask. As to the power supply and control system, the specification teaches that:

> The output of laser 20 is delivered in a series of pulses under control of laser delivery system 22 and laser power supply and control system 24. For each micron depth of corneal tissue to be ablated, one joule per square centimeter was applied.

RX 3, Col. 4, lines 53-57. The control system allows for controlling of the pulse energy density

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[20]VISX contends that in providing information on Nidek's invalidity contentions as to the '148 patent, since withdrawn from this investigation, "Nidek argued that Figure 3 of the '762 patent discloses variable slit 84, which could also be an iris diaphragm." VISX Reply Brief at 19 (citing CX 895C at 52).

and the pulse repetition rate, which determine in part the volume of tissue ablated. See RX 3, Col. 3, lines 60-65. As to the mask, the specification teaches that "[d]efined volumes of tissue can be removed by masking to control the area ablating the tissue to a predetermined depth." RX 3, Col. 5, lines 21-23. The mask for this purpose disclosed in the specification is the contact or proximity mask 30 shown in Figure 1 of the patent, or any of the masks in Figures 4, 5, 6, 7 and 8, referred to as masks "useable with the apparatus and system of FIG. 1". RX 3, Col. 3, lines 1-11. Because the structures performing this function include the control system in addition to the mask, I conclude that no problem exists stemming from claim differentiation between Claim 1 and Claim 10. Accordingly, this claim limitation literally covers these identified structures and their structural equivalents performing the same function.

4. Claim 12

Claim 12 of the '762 Patent reads as follows:

> A system according to claim 1, wherein said laser delivery system means comprises means for selectively shaping a surface of the cornea.

Claim 12 of the patent depends on Claim 1, but adds the means-plus-function limitation set forth above as part of the laser delivery system means. VISX maintains that the corresponding structures that selectively shape the surface of a cornea are the power supply and control 24, along with variable slit 84. VISX explains that the power supply and control determine the pulse repetition rate and the laser output, and since the ablation of tissue is determined in large part by the fluence and pulse repetition rate, these structures, along with the variable slit 84, perform the function of selective re-shaping of the cornea. See RX 3, Col. 4, lines 53-64.

The Staff takes a different position, relying on the prosecution history. Although the Staff

acknowledges no direct discussion of the meaning of this claim during prosecution, it contends that the applicant's amendatory remarks concerning Figure 3 of the patent encompass Claim 12, such that the means identified are the apparatus and system of Figure 3.

Nidek gives another proposed construction, arguing that the corresponding structure identified in the patent specification can only be "a fixed opening curved contact mask, such as mask 30 with slits 100 ranging in width from 150-800 microns, mask 110 with holes 112 ranging in diameter from 100-750 microns, and masks 120, 130, 140." See RX 3, Col. 4, lines 13-23. This type of mask, according to Nidek, is the only structure disclosed in the patent allowing for selective shaping. See Sowada, Tr. at 1471-72. VISX again criticizes Nidek's refusal to acknowledge that an iris diaphragm could be the "means" in question.

As a threshold matter, I find VISX's proposed construction problematic, because while VISX acknowledges that this means-plus-function term is included in the "laser delivery system means" of Claim 1, VISX nonetheless proposes corresponding structures that were not part of the structures VISX previously identified as the "laser delivery system means". This inconsistency significantly undermines VISX's position on the interpretation of this claim limitation, as VISX never identified the power supply and control system 24 as part of the "laser delivery system means", and as these two components are separately labeled and discussed in the patent. See e.g. RX 3, Figure 1; Col. 3, lines 49-51, 60-62. Additionally, the Staff's proposed interpretation does not comport with my construction of the "laser delivery system means" of Claim 1.

Based on a review of the specification, I conclude that the structure disclosed for selectively shaping the surface of a cornea must be the proximity mask shown in use in Figure 1 that can shape the corneal surface. The specification describes the mask as having openings "of any

convenient peripheral configuration". RX 3, Col. 3, lines 42-43. The masks are shown in the patent figures as 30, 110, 120, 130, and 140. The specification also states in part:

> In fact, the laser light of the described method and apparatus can be applied to a circular mask of graded intensity center to edge. This would take away more tissue either centrally or peripherally depending on the distribution of light. The net effect would be either to steepen or flatten the cornea. The ability to make controlled radial incisions, *or to selectively shape the corneal surface*, allows modification of the refractive status of the eye.

RX 3, Col. 5, lines 56-65 (emphasis added).

Although I am aware that in light of the inclusion of a proximity mask in the laser delivery system means of Claim 1, the identification of a proximity mask as the "means for selectively shaping" could arguably raise a claim differentiation issue for this dependent Claim 12, I nonetheless deem this construction appropriate, as the claim language and specification support this construction, as does the prosecution history . See Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 1269 n.4 (Fed. Cir.), cert. denied, 479 U.S. 1030 (1987) (upholding construction of independent claim that rendered dependent claim redundant, where the patent in its entirety supported the construction); Texas Co. v. Globe Oil & Refining Co., 112 F. Supp. 455, 467 (N.D. Ill.), aff'd, 225 F.2d 725 (7th Cir. 1955) (holding claim differentiation inapplicable where resulting construction would "measure an invention different and contrary to that disclosed in the specifications").

IV. Infringement

The asserted claims, as properly construed, must be compared to the accused product, Nidek's EC 5000 system, to determine whether the patent claims are infringed. Tanabe Seiyaku Co. v. U.S. Int'l Trade Comm'n, 109 F.3d 726, 732 (Fed Cir.), cert. denied, 118 S.Ct. 624

(1997); Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). The burden rests on the patent owner to establish infringement by a preponderance of the evidence. Rohm & Haas Co. v. Brotech Corp., 127 F.3d 1089, 1092 (Fed. Cir. 1997); SmithKline Diagnostics Inc. v. Helena Lab. Corp., 859 F.2d 878, 889 (Fed. Cir. 1988). The patent owner must show that for each claim asserted, the accused product satisfies every claim limitation, either literally or under the doctrine of equivalents. Id. As for the numerous means-plus-function limitations at issue in this investigation, to prove literal infringement, the patent owner must demonstrate that a structure on the accused product performs the same function as, and is structurally identical or equivalent to, the structure identified in the patent specification as corresponding to the means-plus-function limitation. Odetics, Inc. v. Storage Tech. Corp., 185 F.3d 1259 (Fed. Cir. 1999). To prove infringement under the doctrine of equivalents, the patentee must show that the accused product contains elements identical or equivalent to each claimed element of the patented invention. See Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co., 520 U.S. 17, 40 (1997).

A. '418 Patent

VISX alleges infringement by Nidek's EC 5000 of Claims 26 and 27 of the '418 Patent. The parties stipulate that any finding of infringement or non-infringement of Claim 26 can also be applied to Claim 27 without separate consideration of the latter.

In light of my construction of "anterior surface of the cornea" as referring to the surface of the eye presented to the surgeon, no dispute remains over the EC-5000 meeting the first portion of Claim 26 disclosing an "[a]pparatus for performing ophthalmological surgery by selective ablation of the anterior surface of the cornea with penetration into the stroma to achieve a

volumetric removal of corneal tissue." Although Nidek argues that the EC-5000 approved for use in the United States cannot ablate an epithelium and therefore does not ablate the "anterior surface", because I concluded in the claim construction section, *supra*, that "anterior surface" does not necessarily refer only to the epithelium, this argument is rejected.

Turning to consideration of the described "laser means" taught by Claim 26, I previously found that the identified structures were a pulsed or CW laser device, its associated power supply, lens elements 26 shown in the patent, and the Microscan 771 comprising the included scan-deflection means and control means. No party disputes that the EC-5000 employs a pulsed laser with its associated power supply. See Sowada, Tr. at 1436-37; Eden, Tr. at 738; Ohtsuki, Tr. at 1321; see also Staff Post-Hearing Brief at 84. The parties agree that the EC-5000 does not have a structure identical to lens element 26 in the '418 Patent, but while VISX and the Staff argue that the single spherical lens on the EC-5000 is an equivalent to the spherical lens-cylindrical lens combination in the patent, Nidek disagrees.

The parties focus much of their dispute on whether the EC-5000 has *any* structure that performs the requisite function, disagreeing over whether the particular size beam produced by the EC-5000 is "small in relation to the cornea to be operated upon", as required by Claim 26. As set forth in the claim construction section, *supra*, this aspect of Claim 26 may be satisfied where the spot produced by the laser beam on the cornea remains 1 mm or less in diameter. VISX argues that even assuming such an interpretation of the claim, the EC-5000 infringes, because at least briefly during the course of a myopia correction procedure, the EC-5000 beam forms a .5 mm spot on the cornea. See CX 386C at 132; Ohtsuki, Tr. at 1382-83. Although VISX concedes that throughout *most* of the procedure, the beam is significantly larger, VISX insists that where all

elements of a claim are met during a portion, but not all, of a procedure, infringement should still be found. See Bell Comm. Research, Inc. v. Vitalink Comm. Corp., 55 F.3d 615, 622-23 (Fed. Cir. 1995) ("...an accused product that sometimes, but not always, embodies a claimed method nonetheless infringes"); Interspiro USA, Inc. v. Figgie Int'l, Inc., 815 F. Supp. 1488, 1512 (D. Del.), aff'd, 18 F.3d 927 (Fed. Cir. 1994). Nidek argues that the EC-5000 generally uses a large spot - even larger than the Taboada spot that the patentee called "irrelevant" in the prosecution history. See McDonnell, Tr. at 1043. Nidek admits that for a small portion of a surgical procedure, when the iris aperture on the EC-5000 is set at its minimum opening, it results in a spot size of .5 mm in diameter. See Ohtsuki, Tr. at 1326. Nidek argues that this should not be deemed to satisfy the claim, relying on its narrow proposed construction of "cornea to be operated upon", but based on my broader construction of the term as referring to the entire cornea, Nidek's argument in this regard fails. Alternatively, Nidek contends that the minimal use of the .5 mm spot size by the EC-5000 does not establish infringement because VISX fails to prove that the small spot sculpts the cornea to "alter the optical properties thereof", as required by Claim 26. The Staff supports this position, asserting that the evidence does not support finding that the very minimal use of the requisitely small spot in the EC-5000 procedure involves alteration of the optical properties of the cornea. The Staff maintains that the EC-5000 therefore does not infringe Claim 26 as "[t]his aspect of the EC-5000's operation is clearly not equivalent to the method of performing myopia correction described in the '418 patent ...." Staff Initial Post-Hearing Brief at 87.

In the EC-5000, the optical properties of the cornea are altered by the laser device performing a series of scans behind an iris diaphragm. Eden, Tr. at 733-35. Ten partially

overlapping laser pulses[21] make up each scan, and the pulses begin with the laser being deflected as far as possible in one direction, then sweeping in a line and becoming less deflected until passage through the central axis, and then continuing its sweep, deflecting gradually in the other direction, ending deflected as far as possible toward the opposite end of the line from its starting point of deflection. Ohtsuki, Tr. at 1329-31; Eden, Tr. at 733-35. The iris diaphragm, depending on the degree to which it is open, allows a portion of the laser beam to pass through it to the cornea, and with the changing deflection, larger portions of the beam pass through the closer the beam comes to the center axis. Ohtsuki, Tr. at 1326, 1332; RX 724C. Upon completion of a scan, the laser beam is rotated 120 degrees, another scan is performed, and this continues until the surgery is complete. Ohtsuki, Tr. at 1326-27, 1332, 1382-83; McDonnell, Tr. at 1131-32. I conclude that the EC-5000, throughout most of a surgical procedure, produces a laser spot on the cornea much larger than the "small" spot taught by Claim 26. See Eden, Tr. at 733-36; Ohtsuki, Tr. at 1329-31; RX 724C. I find that because of the deflection of the beam in the EC-5000 being passed through a sometimes very small opening in the iris diaphragm during its scan at the beginning of a procedure, the EC-5000 briefly produces a spot of the requisitely "small" size. However, because this "small" spot is not used consistently throughout the surgical procedure to alter the optical properties of the cornea, the EC-5000 does not literally infringe Claim 26. See Eden, Tr. at 735; Ohtsuki, Tr. at 1329-31; McDonnell, Tr. at 1043-44. Claim 26 of the patent teaches using a particularly small spot rastered in particular scan patterns on the cornea to reshape it and thereby alter its optical properties. The EC-5000 reshapes the cornea to alter its optical

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[21]The pulses partially overlap to accommodate for the inherently uneven energy distribution of the laser beam, where the energy is strongest at the center of the beam, and weaker at the edges. See Eden, Tr. at 825; Grundfest, Tr. at 955, 1010.

properties, but accomplishes this by using a large laser spot that is *not* rastered as in the '418 Patent. I note that the situation presented here is distinct from that in the case law cited by VISX, Bell Comm. Research, Inc. v. Vitalink Comm. Corp., 55 F.3d 615 (Fed. Cir. 1995) and Interspiro USA, Inc. v. Figgie Int'l, Inc., 815 F. Supp. 1488 (D. Del.), aff'd, 18 F.3d 927 (Fed. Cir. 1994). In those cases, the courts indicated that to infringe a patent claim, the method or device need only meet all the claim elements *at some point* or *in some mode*. See Id. at 1512; Bell Comm., 55 F.3d at 622-23. In this case, the claim itself requires that the laser consistently produce a small spot on the cornea in order to effect certain results, such that if the small spot is *not* consistently produced, the accused device does not practice the claim – at any time or in any mode. Under these circumstances, the consistency requirement is inherent in the claim, not in the law.

Given that the EC-5000 has no structure performing the function identical to the function of the "laser means" of the '418 Patent, and therefore does not literally infringe Claim 26, it is necessary to address the alternative argument advanced by VISX of infringement under the doctrine of equivalents. VISX contends that "Claim 26 contemplates a spot which is small enough to be moved around the cornea for purposes of altering the optical properties of the eye", and that the varying spot sizes, up to 10 mm^2, can be used to obtain substantially the same results as the consistent use of Claim 26's "small" spot. VISX Post-Hearing Brief at 77. In support of its argument under the doctrine of equivalents, VISX cites only minimal, conclusory testimony from Dr. Eden. See Eden, Tr. at 733, 744, 852.

The Staff, which maintains that all elements of Claim 26 *except* the small spot size are satisfied by the EC-5000, takes a divergent view from VISX's. Citing prosecution history estoppel, the Staff points out that the larger of the EC-5000 spot sizes, with a maximum size of

2 mm x 8 mm at cornea impingement, are larger than the prior art Taboada spot characterized by the '418 Patent inventor as "irrelevant" to distinguish his own invention from the Taboada article. See CX 211 at 7-8. Accordingly, the Staff contends that as to any spot size at or larger than the 6 mm x 1.9 mm dimensions of the "irrelevant" Taboada spot, no infringement under the doctrine of equivalents should be found. Turning to the smaller of the EC-5000 spot sizes, the Staff asserts that because VISX has failed to show that they sculpt the cornea to alter its optical properties, and because the EC-5000 sculpts the cornea with large beams in hundreds of scans, the EC-5000 structures are not substantially interchangeable with Claim 26's "laser means" for purposes of the doctrine of equivalents.

Nidek sharply criticizes VISX's doctrine of equivalents argument on this claim element, noting that VISX's only cited supporting evidence comes from its optics expert, Dr. Eden, rather than its ophthalmic expert. Nidek contends that Dr. Eden is not competent to provide testimony on this issue, and points out contradictory testimony by its own expert, Dr. McDonnell, who testified that a larger spot size than the 1 mm diameter construed could not practically be substituted in Claim 26. See McDonnell, Tr. at 1035-36, 1040; RX 757 - RX 762. Nidek therefore insists that the differences in the function and structures are substantial. See id..

As an initial matter, I note that no party raises any objection to the application of the doctrine of equivalents to this means-plus-function claim. I conclude, however, that as contended by Nidek and the Staff, VISX fails to establish infringement of Claim 26 under the doctrine of equivalents. Applying an element-specific approach to the doctrine of equivalents, and considering my finding that the laser means producing an output beam with the requisitely small spot cannot be found in the EC-5000, I find that the EC-5000 lacks a "laser means" that performs

substantially the same function in substantially the same way. See Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co., 520 U.S. 17, 29 (1997) (noting that the doctrine of equivalents should be applied to individual claim elements and stating that "[i]t is important to ensure that the application of the doctrine, even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety"). The differences between the subject matter of Claim 26 and the EC-5000 are substantial. As set forth above, the proffered equivalent structures on the EC-5000 do not produce the consistently small spot for corneal sculpting to alter optical properties, as taught by the patent. The only evidence cited by VISX in support of infringement of this element under the doctrine of equivalents is conclusory testimony by its expert, Dr. Eden, and I find that the approach taken by Dr. Eden and by VISX seeks to read this claim element out of Claim 26, as cautioned against in Hilton-Davis. See id. Ultimately, while the EC-5000 laser means may accomplish the same result, sculpting of the cornea to alter its optical properties, as Claim 26's "laser means", the EC-5000's "laser means" functions in a substantially different manner, and does not infringe under the doctrine of equivalents. See McDonnell, Tr. at 1033-36, 1041-44.

Furthermore, turning to the scan-deflection means that are included as part of the laser means, the parties all acknowledge that the EC-5000 does not employ the Microscan 771, the structure disclosed in the '418 Patent specification as performing the function of the "scan-deflection means". As to structural equivalency, VISX points to the structures in the EC-5000 allegedly performing the same function as a scanning mirror, an image rotator, and a microprocessor-controlled iris diaphragm. VISX seems, however, to bypass a true inquiry into structural equivalency, focusing primarily on the identity or similarity of function. Citing to

minimal supporting evidence and testimony, VISX offers its own description of the way the Microscan 771 allegedly functions, and cites an expert opinion by Dr. Eden that it is the substantial equivalent of the aforementioned components in the EC-5000. VISX concludes that because both the Microscan 771 and the EC-5000 use computer controls to set the size and location of the boundary lines for each scan, and because both "always travel[] the same distance" and cause the laser to irradiate a predetermined area of the cornea, they should be deemed equivalents. VISX Initial Post-Hearing Brief at 80-82.

I must conclude that VISX's arguments do not meet its burden of showing *structural* equivalency for the means-plus-function analysis or equivalency under the doctrine of equivalents. Dr. Munnerlyn of VISX testified as follows about the Microscan 771:

> Q What was the purpose of the Microscan 771?
> A It was a programmable system that allowed the doctor to preprogram an irregular area of -- on the tissue, so that within that area it would ablate a uniform ablation.
> Q And how did it work?
> A It consisted of a control panel and what was referred to as an optomechanical or electro-optical scanning micromanipulator. And one could preprogram a shape using a joy stick. And there was a memory component in it, I believe it was 128 element by 128 element array, and the software determined whether a particular point in the array was outside of the area that had been designated or whether it was inside.
>
> Then as the system scanned over the area determined by the array, it made a decision as to whether to expose the laser light or not to expose the laser light, depending upon whether it was within this defined aperture.
>
> ***
>
> Q Dr. Munnerlyn, is it your understanding that this Microscan operator, by having the operator first draw in the area in which he wanted the beam to be deflected --
> A He drew in the area that he wanted to be exposed.
> Q The operator would draw in the area to be exposed,

and then would a memory map be created in the system of that area?

A That is correct.

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Q Is it your understanding after the area had been drawn in, a memory map would be created in the system which has this oval depicted digitally by ones and zeros?

A Yes.

Q The memory map was basically a rectangle, I think you said 128 by 128?

A That is correct.

Q So we could just theoretically draw a rectangle around that oval, couldn't we?

A That is correct.

***

Q Dr. Munnerlyn, was it your understanding this Microscan had a series of mirrors inside of it?

A It was referred to as an electro-optical scanner. From my personal knowledge, I believe it did have mirrors, but the operator's manual does not specify what it does have.

Q Based on your personal knowledge, were these mirrors inside this Microscan moved so that the beam which came in would be deflected to a different position as a function of the orientation of the mirrors?

A That is correct.

Q And in the case of the Microscan, would the Microscan then start at the top of the memory map and then just proceed to move across in one direction and back in the other direction?

A That is correct.

Q Okay.

A I'm not -- yes. It essentially covered the space outside the area that's designated.

Q And then when the -- when the area to be exposed fell within the memory map, would there be a signal sent back to fire the laser so that the beam would then be directed to that point where it was to be exposed?

A That is correct.

Munnerlyn, Tr. at 185, 267-69. Other than Dr. Munnerlyn's testimony based on personal familiarity with the Microscan 771, VISX points only to the relatively limited information in the

Microscan 771 owner's manual, CX 206, for evidence of its structure and functionality.

As a threshold matter, then, I find the lack and nature of evidence on the Microscan 771 troubling, in light of VISX's burden to provide the information necessary for an equivalency determination. Dr. Munnerlyn himself notes one instance of the lack of corroboration in the Microscan 771 owner's manual for Dr. Munnerlyn's statements about the structure and functionality of the Microscan 771. Furthermore, given his status as an employee and founder of VISX, corroboration of Dr. Munnerlyn's testimony is particularly desirable. Even if Dr. Munnerlyn's testimony is relied upon, however, I nonetheless find failure to prove equivalency here under the means-plus-function analysis or under the doctrine of equivalents.

As to the EC-5000 components cited by VISX, Mr. Ohtsuki of Nidek explained that the laser light is:

> ... sent over to the scanning mirror, and this scanning mirror is such that it moves up and down, back and forth. Then the laser beam which is scanned is sent over to the image rotator. The image rotator is made up of this mirror, and that which appears to be triangular in shape. These are designed in such a way that they rotate together. The light that comes out then goes through the iris aperture. Then the light goes through the -- through the round -- elliptical lens and then is sent to the cornea.

Ohtsuki, Tr. at 1325. He further testified that the purpose of the iris diaphragm is "... to determine the area to be subject to the beam, the area on the cornea which is to be subject to the beam." Id. at 1326.

These components do *not* operate to turn the laser on and off in order to vary the perimeter of scans for the appropriate area of ablation, and in fact the EC-5000 has no such mechanism. See Ohtsuki, Tr. at 1331; RX 724C. Rather, the laser continues to operate with the scanning mirror

deflecting the beam, but the iris diaphragm may block the beam from passing through to the cornea. Ohtsuki, Tr. at 1328, 1341-42. VISX recognizes this distinction when it states "[i]n the Microscan 771 the computer controls the area to be irradiated by turning off the laser when the scanner is outside the predetermined boundary lines, whereas in the Nidek EC-5000, an iris diaphragm blocks the laser beam from ablating tissue outside the predetermined area on the cornea." VISX Initial Post-Hearing Brief at 81.

In addition, the scan-deflection means of the '418 Patent rasters, in non-overlapping pulses, its small laser spot, turning the laser on and off where appropriate, to create the scanning patterns identified in the patent figures. The EC-5000's components, by contrast, scan the relatively larger laser spot in overlapping pulses, turning a 120 degree rotation after each scan, and its scanning patterns do not resemble those of the '418 Patent.

Dr. Sowada also offers an extensive discussion of his opinion that these components in the EC-5000 are not equivalent to the Microscan 771, and I find his testimony persuasive. See Sowada, Tr. at 1439-43. Ultimately, a review of this evidence yields the conclusion that the EC-5000's scanning mirror, image rotator, and iris diaphragm do not constitute structural equivalents of, and function in a substantially different way than, the Microscan 771.

As to the "control means with coordinating connections to the scan-deflection means", I previously identified the corresponding structure as the microprocessor of the Microscan 771. Nidek argues that to satisfy this limitation, the microprocessor must have a memory map and operate to turn the laser on and off. Nidek also contends that the microprocessor in the EC-5000 does not control the linear scanning mirror or the image rotator *once a surgical procedure has begun*. VISX and the Staff disagree.

In Order No. 49 in this investigation, I entered a factual finding that "... in the Nidek EC-5000, the iris diaphragm, linear scanner, and laser are all controlled by an interconnected set of microprocessors." See also Ohtsuki, Tr. at 1340-41; Sowada, Tr. at 1445. The EC-5000's microprocessor controls the components that ultimately determine the scanning and ablation areas. Although I found that the EC-5000 does not have the scan-deflection means of the '418 Patent, or its equivalent, I see no compelling argument that the microprocessor in the EC-5000 is not at least equivalent to the Microscan 771's microprocessor, as a means of controlling the structures determining scanning and ablation.

In conclusion, because the EC-5000 does not meet all the limitations of Claim 26, I find no infringement of this claim. Furthermore, in light of the parties' stipulation, I similarly find no infringement of Claim 27.

B. '762 Patent

VISX alleges infringement by Nidek's EC 5000 of Claims 1, 7, 10 and 12 of the '762 Patent. Claims 7, 10 and 12 are dependent on Claim 1.

1. Claim 1

The EC-5000 is a corneal laser surgery system, and no party disputes that the system includes a 193 nm excimer laser as taught by Claim 1. However, the parties disagree as to whether the EC-5000 meets the "laser delivery system means" and the ablation rate elements of Claim 1.

As to the "laser delivery system means" element of Claim 1, VISX argues that the EC-5000 has a structural equivalent of Figure 3 of the '762 Patent, on the grounds that the EC-5000 delivery system uses lenses and apertures, performs the same function and operates in

substantially the same way to achieve substantially the same result as the delivery system in Figure 3. The Staff maintains that Nidek's delivery system should be compared to Figures 1, 2 and 3 of the patent, and concludes both that the EC-5000 delivery system performs a function identical to that set forth in this means-plus-function term, and that the EC-5000 is structurally equivalent to a conglomeration of the various delivery systems the Staff contends are shown in Figures 1, 2 and 3 of the patent.

Nidek asserts that because the delivery systems disclosed by the patent in Figures 2 and 3 require use of a proximity mask such as that shown in Figure 1, and the EC-5000 uses no such proximity mask, no infringement of this claim limitation can be established. See Sowada, Tr. at 1474; Ohtsuki, Tr. at 1325-26; RX 751. Nidek further contends that because the patent teaches a fixed beam delivery system, while the EC-5000 uses a slit scanning system, no equivalence can be found. See Figures 1-3; RX 751; RX 724C. Nidek also asserts that as to Figure 2, the EC-5000 does not include the use of nitrogen to blow over the surface being treated and does not focus the laser rays to a point as shown in the figure.

As to Figure 3, Nidek notes other differences between the EC-5000 delivery system and the optical path shown in the figure, specifically: the EC-5000's use of an iris diaphragm with a circular opening for correcting myopia rather than a variable slit aperture as in Figure 3 (see Ohtsuki, Tr. at 1323, 1325-27, 1364-65); the EC-5000's single lens imaging rather than the dual lens imaging shown in Figure 3 (see RX 751; Ohtsuki, Tr. at 1325-26; Sowada, Tr. at 1474); and the EC-5000's lack of an aperture with a fixed opening such as component 88 shown in Figure 3 (see RX 510; Sowada, Tr. at 1475; Eden, Tr. at 809). In criticizing VISX's equivalency arguments, Nidek extensively details its position that Dr. Eden's testimony on this issue shows

serious technical and legal flaws in an alleged attempt to alter and "redesign" Figure 3 so as to transform it into something never disclosed. Nidek concludes that once Dr. Eden's "transformation" of Figure 3 was completed, this "major contribution", as VISX characterized Figure 3, was reduced to a single lens system well known in the art for 300 years. See Eden, Tr. at 824; RX 818; Sowada, Tr. at 1474.

As set forth in the claim construction section, *supra*, the "laser delivery system means" teaches the use of a proximity mask in connection with the systems shown in Figures 2 and 3. Accordingly, although the EC-5000 has a means for receiving radiation from the laser and delivering a fraction thereof to the cornea, because its means does not include use of a proximity mask, I find no literal infringement of this claim. Furthermore, I agree that even regardless of the absence of a proximity mask (see Sowada, Tr. at 1473), the delivery system in the EC-5000 is not the structural equivalent of that shown in Figure 3, on which VISX bases its infringement contention.

VISX's argument relies on the removal of certain optical components from Figure 3 to pare down that system until its structure resembles the EC-5000 delivery system. According to VISX, citing Dr. Eden's testimony, the removal of these optical components, such as aperture 88 and lens 90, leaving a system more akin to the EC-5000's, does not really change the structure. VISX contends that these components are unnecessary and would serve no purpose in a system such as Nidek's since the EC-5000 employs a disk-shaped aperture, thus having no need to be inverted because a non-inverted disk appears the same as an inverted one. VISX Post-Hearing Brief at 87. Nidek disputes VISX's allegations about the functionality of the system of Figure 3, pointing out that the patent teaches a rectangular slit, and that it too would appear the same inverted as non-

inverted. Nidek concludes that these optical components apparently perform other purposes in the system of Figure 3 such that a system omitting them should not be deemed structurally equivalent. Nidek also points out that even VISX's Dr. Eden admits that lens 90 performs at least the beneficial function of allowing an adequate working distance between the apparatus and the patient in order to operate, and that aperture 88 also has a beneficial effect. See Eden, Tr. at 804-05. Finally, Nidek cites testimony from Dr. Sowada for the proposition that one skilled in the art would not consider the systems equivalent because the Figure 3 delivery system does not image a variable aperture onto the cornea, as in the EC-5000. See Sowada, Tr. at 1464, 1466, 1474-75.

I do not find the requisite equivalence between the "laser delivery system means" disclosed in the '762 Patent and the laser delivery system in the EC-5000. Although both systems perform the function set forth in the means-plus-function claim of the patent, in addition to the absence of a proximity mask on the EC-5000, the delivery system also lacks other significant optical components, such that one skilled in the art would not deem the systems structurally equivalent. For example, comparing the EC-5000 to Figure 3 of the patent, on which VISX's equivalency argument relies, the EC-5000 lacks the aperture 88, or anything analogous, and constitutes a single-lens imaging system rather than the dual lens plus aperture system of Figure 3. See Sowada, Tr. at 1473-74; See also Eden, Tr. at 800, 803, 806 (admitting that aperture 88 and the lens 90 form a core part of the laser delivery system means of Figure 3 and that the EC-5000 lacks those elements). I find Dr. Sowada's testimony on this issue credible, while I believe that Nidek offers compelling arguments to undermine Dr. Eden's testimony on the equivalency issue. In addition, as I set forth in the claim construction section, *supra*, I do not accept as credible Dr. Eden's testimony regarding the functionality of the Figure 3 system, and for the same reasons do not find

his opinion on equivalency sufficient to carry VISX's burden. VISX has not offered a credible explanation for its position that such a different configuration of optical components functioning in such a different way can qualify as "equivalent."

Turning next to the ablation rate limitation of Claim 1, VISX argues that the limitation is satisfied by the EC-5000, and cites a variety of evidence. VISX notes that in response to interrogatories, Nidek stated that the EC-5000 ablates approximately 0.6 microns per scan and operates at a fluence in the range of 300 - 600 mJ/cm²/scan, which VISX translates to an ablation rate of between 1 and 2 microns per accumulation of 1 J/cm². See CX 950C, # 157, 158. VISX also points out that Nidek submitted data to the FDA indicating that the EC-5000 ablates at an approximate rate range of 0.91 microns to 1.37 microns for each accumulation of 1 J/cm². VISX also asserts that other data supplied by Nidek to the FDA suggests that at 283 mJ/cm², the fluence per scan measured by Nidek's expert, Dr. Grundfest, the EC-5000 ablates at a rate ranging from 0.94 to 1.1 microns for each accumulation of 1 J/cm². See CX 821C at 12; Motamedi, Tr. at 516-20; Grundfest, Tr. at 993-98. Next, VISX cites Dr. Grundfest's scan measurements, but translates them to the full-width, half-maximum ("FWHM") measurement method, alleging that once translated, they indicate an ablation rate range of 0.9 microns to 1.7 microns for each accumulation of 1 J/cm² in a pulse mode, and that if adjustments are made "for the uncertainties associated with measuring ablation depth and fluence", the range expands to 0.8 to 3.6 microns for each accumulation of 1 J/cm² in a scan mode, with 95% certainty. See Grundfest, Tr. at 974-91; CX 1103; RDX 60C; RDX 59C. VISX acknowledges, however, that Dr. Grundfest himself, testifying for Nidek, concludes that in the scanning mode, the EC-5000 ablates tissue at a range of 2.2 ± 0.3 microns per J/cm². VISX criticizes Dr. Grundfest's method and results, but maintains

that even if this conclusion of Dr. Grundfest is accepted, infringement of this element under the doctrine of equivalents is shown because the difference in ablation rates is insubstantial.

Nidek contends that the EC-5000 ablation rate is in the range of 2 microns per J/cm², relying on testing conducted by its expert, Dr. Grundfest. See RX 764C; RX 662C; Grundfest, Tr. at 926. Nidek argues that Dr. Grundfest's qualifications are excellent, insists that VISX has not met its burden of proving infringement, and asserts that VISX relies on "junk science" to support its position. Nidek maintains that Dr. Grundfest's per scan ablation rate measurements represent the most accurate figures, superior in accuracy to those figures from per pulse FWHM measurements that Nidek relied on itself prior to this litigation. Nidek criticizes VISX for not offering any test data of its own, and attacks Dr. Motamedi's expert opinion of an ablation rate of 1.2 - 1.7 microns per J/cm² as based on estimates where no correlation exists between the depth achieved and the fluence used to create that depth. See Motamedi, Tr. at 507-08.

Nidek maintains that Dr. Motamedi used improper assumptions for his calculations, including that a uniform fluence level was used for certain measurements, and that the fluence per scan is three times the fluence per pulse in an EC-5000 (although this assumption came from Nidek's own estimate used for internal purposes pre-litigation).[22] Nidek goes on to attempt to undermine Dr. Motamedi's reliance on Nidek's own documentation on the EC-5000,[23] characterizing the information in the documentation as outdated, unrepresentative or inaccurate. As to its

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[22]However, Nidek acknowledges that even using the 2.2 factor it now deems accurate to convert fluence per pulse to fluence per scan, the ablation rate range comes to 1.64 - 2.32 microns per J/cm². Nidek Post-Hearing Brief at 97.

[23]According to Dr. Motamedi, CX 821C, a 1993 Nidek document, contains data showing that the EC-5000 ablates in the range of 0.5 - 1.7 microns per J/cm². See Motamedi, Tr. at 520.

interrogatory responses, stating that EC-5000s are calibrated to 0.6 microns per scan on corneal tissue with a typical fluence in the range of 300 - 600 mJ/cm²/scan, also relied on by Dr. Motamedi, Nidek insists that the numbers depend on the situation, and that "Dr. Motamedi uses the most favorable numbers from the ranges without considering whether the EC-5000 would ever match up performance-wise in actuality." Nidek Post-Hearing Brief at 98. Next, Nidek criticizes Dr. Motamedi's reliance on a 1998 article from an issue of the Journal of Refractive Surgery dedicated to the proceedings of the Nidek International Excimer Laser Users Meeting in which the authors report an ablation rate for the EC-5000. See CX 581C-Q. Nidek cites a statement by the authors that they used not only their own data but also published data, and because the published data cited includes data pre-dating the EC-5000, Nidek argues that Dr. Motamedi should not rely on the information in the article. Nidek claims VISX's translation of Dr. Grundfest's per scan measurements to FWHM is inappropriate in the context of this litigation, asserting that FWHM is not the industry standard, does not accurately represent the entire pulse area ablating tissue, and has no applicability to the clinically used scanning mode of the EC-5000. See Kirkham, Tr. at 1161-62; Grundfest, Tr. at 924. With regard to VISX's adjustment of Dr. Grundfest's data to account for a $\pm$ 3.6 error factor, Nidek insists the expansion of the standard deviation is based on unsubstantiated assumptions and ignores fundamental principles associated with determining standard deviation. See Grundfest, Tr. at 1004, 961.

In its reply brief, VISX returns fire against Nidek for its criticisms of VISX's position. In response to Nidek's contention that CX 821C dates from 1993, VISX points out that Nidek provided the same information to the FDA in 1999 and 1997, and VISX thus suggests that Nidek thereby vouched for its current accuracy. See CX 808C at 50960; CX 803C at 21365-66, 21649.

VISX undermines Nidek's assertions that improper assumptions were made in reaching VISX's position, and that proper correspondence was made between evidence used for its calculations. VISX attacks Nidek for abandoning its own admissions regarding the EC-5000 having an ablation rate of 1.6 - 1.7 microns per J/cm²/scan made in interrogatory responses and through its corporate designee witness. According to VISX, some of the same evidence relied on for these earlier admissions is now relied on by Nidek to support its current claim of a higher ablation rate of 2.2 microns per J/cm². See CX 476C at 151-54. VISX next criticizes Dr. Grundfest's analysis for not using acceptable methodology in the scientific community. See Eden, Tr. at 1603, 1609-10, 1612.

Next, Nidek addresses the contention that the EC-5000 infringes the ablation rate limitation under the doctrine of equivalents. According to Nidek, the difference in the ablation rate taught by the patent and the ablation rate of the EC-5000 is substantial, and the two rates cannot be deemed equivalent. Citing testimony by Dr. McDonnell, Nidek maintains that the maximum acceptable deviation in depth precision has never exceeded $\pm$ 20 - 25%[24], and Nidek asserts that the EC-5000's rate represents a 100% deviation from the rate disclosed in Claim 1. See McDonnell, Tr. at 1050-66. Nidek highlights an alleged practical importance of a higher ablation rate in the EC-5000 to compensate for the additional time inherent in the EC-5000's linear scan and rotate method, since minimizing the duration of refractive surgery is important to minimize dehydration of the eye and ensure the best possible result. See McDonnell, Tr. at 1034-35. In

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[24]Nidek complains that VISX characterizes the "result" under the doctrine of equivalents analysis as an acceptable surgical result rather than as the ablation rate itself. Nidek argues that an acceptable variance for a refractive surgery result should not be equated to the variation from the ablation rate in the patent by the EC-5000.

response to case law cited by VISX for the proposition that numerical deviations analogous to that of the EC-5000 ablation rate from the rate disclosed in the patent infringe under the doctrine of equivalents, Nidek computes the percentage of the deviation in those cases and argues that a 33% variance was the highest variance deemed infringing under the doctrine of equivalents. See Pall Corp. v. Micron Separations,Inc., 792 F. Supp. 1298, 1325, 1327-28 (D. Mass.), aff'd in part, rev'd in part, 66 F.3d 1211 (Fed. Cir. 1995) (20% difference); Phillip Morris v. Brown & Williamson Tobacco Corp., 641 F. Supp. 1438, 1456, 1483-84 (N.D. Ga. 1986) (33% variation); In the Matter of Certain N.I.B. Magnets, Inv. No. 337-TA-372 (Dec. 11, 1995) (8.4% difference).

VISX responds that Nidek's position on the substantiality of the difference between Claim 1 and the EC-5000 depends on a "red herring" – a comparison of the EC-5000 ablation *depth* with the ablation *rate* taught by the patent. VISX insists that Nidek's claim that a surgeon would consider substantially different an EC-5000 that uses 1 joule/cm^2 to ablate one micron from a system that uses 0.5 joules/cm^2 to ablate 1 micron is actually inconsistent with the testimony of Nidek's own expert, Dr. McDonnell. VISX characterizes Dr. McDonnell's testimony as indicating that a surgeon would be unconcerned with the fluence level needed to achieve the correct ablation depth, caring only that the correct ablation depth is achieved. See McDonnell, Tr. at 1099-1100. VISX states that this testimony supports the conclusion that the range of ablation rate from 1.46 to 4.0 microns, for example, must then represent an insubstantial difference providing the ablation depth remains constant.

The Staff takes the position that this claim element is literally infringed by the EC-5000. The Staff supports heavy reliance on the figures Nidek submitted to the FDA rather than on the test

results from Dr. Grundfest, conducted specifically for this litigation. The Staff also points out Dr. Grundfest's admission that if his results were used in connection with the information Nidek provided to the FDA, the EC-5000 ablation rate comes to "approximately 1". See Grundfest, Tr. at 997-98. Alternatively, the Staff maintains that the EC-5000 infringes under the doctrine of equivalents, on the grounds that Nidek's deviation from the claimed rate falls within the rate variation that eye surgeons deem acceptable. See Motamedi, Tr. at 513-15; RX 764C. Accordingly, the Staff concludes that the difference even between a 2.2 rate and an "approximately 1" rate is insubstantial.

The weight of the evidence supports finding no infringement of this claim limitation by the EC-5000. Although I conclude that the EC-5000 ablates at a rate of 1.6 to 1.7 microns per J/cm^2, this fails to literally satisfy the patent's ablation rate limitation, and VISX fails to meet its burden of showing equivalency. First, I turn to Nidek's contention that the EC-5000's ablation rate is approximately 2.2 microns per J/cm^2. As an initial matter, I reject Nidek's arguments against its own previously used per pulse to per scan conversion rate, against using FWHM, and against relying on data measured in pulse mode and converted. As to measuring ablation rate based on per pulse data converted with a factor of three pulses per scan, Nidek considered such data and the conversion rate therefor sufficiently reliable for its own internal use prior to this litigation. See Ohtsuki, Tr. at 1353-54; 1369. Thus, I deem it sufficiently reliable for litigation purposes as well. As to FWHM, I further note that Nidek's witness, Mr. Ohtsuki, admitted that until this litigation arose, Nidek itself always used FWHM for measurement, such that I find Nidek's current arguments about the inaccuracy of this form of measurement too convenient for this litigation and therefore unpersuasive. See Ohtsuki, Tr. at 1382.

Turning to the evidence, then, the information submitted by Nidek to the FDA regarding the EC-5000 ablation rate, and Nidek's own admissions in interrogatory responses and through its corporate designee witness, Mr. Suzuki, all point to a conclusion that the EC-5000 ablates at a rate of approximately 1.6 - 1.7 microns per J/cm². CX 476C at 151-53; CX 1103C; CX 821C; CX 808C; CX 803C; CX 950C at 17. I deem the FDA data reliable both because it was not created and presented for purposes of infringement litigation, and because of the serious obligation of accuracy associated with submissions to the FDA. See e.g. 18 U.S.C. § 1001. The reasons for considering Nidek's own earlier admissions to a 1.6 - 1.7 ablation rate reliable need no explanation, and I accord little to no weight to Nidek's present attempts to "back pedal" out of these admissions. Additionally telling is that Dr. Sowada, one of Nidek's expert witnesses testified that he was told by Nidek lawyers that the EC-5000 ablates corneal tissue at a rate of between 1.6 and 1.7 microns per J/cm². Sowada, Tr. at 1501. Under the circumstances, I am not persuaded to permit all of the foregoing evidence to be overcome by Dr. Grundfest's test results, reached using a single EC-5000 machine, and produced specifically for use in this litigation.

As to the equivalency of the 1.6 - 1.7 ablation rate to the upper range of 1.3 microns per J/cm², I found in the claim construction section, *supra*, that VISX has not built an adequate record for such a finding. While it seems quite possible that at least to some extent, a higher ablation rate than 1.3 *might* be viewed by one of ordinary skill in the art as equivalent to "approximately 1", VISX unfortunately points to no evidence to this effect. Rather, in support of equivalency arguments, VISX cites only testimony regarding alleged error ranges and acceptable deviations to be considered in connection with the literal meaning of "approximately". Having considered this testimony and argument in connection with my construction of "approximately 1", it would not be

appropriate to somehow rely on the very same evidence to extend the range even further. Rather, expert testimony regarding the insubstantiality of a certain difference or differences in ablation rate would be appropriate for this equivalency analysis, but VISX makes no reference to such testimony. Furthermore, as noted above, I do not find credible the testimony of VISX's expert on the ablation rate issue, Dr. Motamedi.

The Staff makes the argument for the insubstantiality of the difference, but to support it, relies on an argument that ophthalmologic surgeons generally tolerate being within $\pm$ .5 diopters of accuracy. See McDonnell, Tr. at 1055-56, 1058-60. A half diopter equates to roughly 6 microns of corneal ablation depth. See Munnerlyn, Tr. at 133-34; McDonnell, Tr. at 1055. The Staff then argues that the difference in the EC-5000's ablation rate from the ablation rate disclosed in the patent should be deemed insubstantial presumably because a surgeon would not be concerned about the difference. However, as Nidek points out in its Post-Hearing Reply Brief, the variation of ablation rate for the EC-5000 should not be equated in this way. As explained by Dr. McDonnell, Tr. at 1055-65, whether a variation in ablation rate produces an outcome acceptable to a surgeon depends on the degree of correction being made, differing for a 5-diopter myopic correction and a 10-diopter myopic correction, for example. Accordingly, I do not accept the Staff's analogy as an appropriate way to determine equivalency for this claim limitation.[25]

While the parties take divergent views in analyzing case law surrounding numerical ranges and words of approximation in patents, the cases make clear that the equivalency analysis must be technology-specific, such that the percentage deviations allowed or disallowed in other cases concerning other

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[25]The Staff also cites to RX 764C as support for their equivalency argument. The numbers in those tables, however, do not reflect ablation rates of machines as they would be used by doctors in surgery, thereby undermining the Staff's argument. Ohtsuki, Tr. 1361.

technology are not dispositive here. See Eiselstein v. Frank, 52 F.3d 1035, 1040 (Fed. Cir. 1995) ("the meaning of the word 'about' is dependent on the facts of a case, the nature of the invention, and the knowledge imparted by the totality of the earlier disclosure to those skilled in the art"); Modine Mfg. Co. v. U.S. Int'l Trade Comm'n, 75 F.3d 1545, 1554 (Fed. Cir.), cert. denied, 518 U.S. 1005 (1996) ("Precedent illustrates the fact-dependency of the technologic scope of 'about' and similar terms, depending on their contexts and the precision or significance of the measurement used"). Based on my assessment of the record, I conclude that VISX does not meet its burden of showing infringement of this claim limitation, either literally or under the doctrine of equivalents.

1. 2. Claim 7

In support of its infringement contentions as to Claim 7, VISX cites Nidek's statement in The Excimer Manual, CX 977 at 325, that "[t]he average energy density of the EC-5000 is 140 mJ/cm^2", a Nidek internal memorandum on the EC-5000, CX 355C at 2, stating that "[t]he fluence/shot is about 140-200 mJ/cm^2", and testimony by Dr. Grundfest at 985-86 in the trial transcript. The Staff concurs that the EC-5000 meets this claim limitation on energy density. Nidek relies on its proposed interpretation of the claim limitation as requiring a uniform fluence to counter the infringement allegation. Based on my construction of the claim, the EC-5000 satisfies the energy density range taught by Claim 7, and therefore infringes this limitation. Because the claim depends on Claim 1, however, and because the EC-5000 does not meet all elements of Claim 1, it follows that the EC-5000 therefore does not infringe Claim 7 either.

3. Claim 10

In connection with the construction of this claim, *supra*, I held that the structures identified

as controlling the volume of corneal tissue removed are the laser power supply and control system 24 and, as explicitly set forth in the claim language, a mask. VISX argues that the EC-5000 has a laser power supply allowing for control to produce a predetermined depth of ablation and an iris diaphragm serving as the mask. See CX 480C; Eden, Tr. at 718-19. The Staff argues that the EC-5000's iris diaphragm and slit aperture structure acts as a mask so as to perform the identical function set forth in the means-plus-function term. See Eden, Tr. at 716-18. The Staff further argues its structural equivalency to variable slit 84 of Figure 3 of the patent, so as to literally infringe this claim limitation. See CX 710 at 6-7, 10-11.

Nidek insists that the EC-5000 lacks the mask required by Claim 10, on the grounds that the mask referred to in the patent is not an iris or an aperture, but must be a proximity mask. Thus, although the EC-5000 has an iris diaphragm and a slit aperture, Nidek contends these do not satisfy the claim limitation. Nidek also argues that the EC-5000 iris is not equivalent to the mask disclosed in Claim 10. At the reply stage, Nidek suggests that if the control system for the laser is considered part of the means, the EC-5000's should be deemed substantially different because its pulse repetition rate is significantly higher than the 25 Hertz maximum taught by the '762 Patent. See RX 3, Col. 4, line 62 - Col. 5, line 1; Ohtsuki, Tr. at 1331.

I agree that the laser power supply and iris diaphragm and slit aperture features of the EC-5000 do not qualify as structural equivalents to the laser power supply and mask taught by Claim 10 of the '762 Patent. Nidek makes a very convincing argument, based on distinctions in terminology used in the '762 Patent, that when the inventor referred to a "mask" rather than to an "iris" or an "aperture", he intended a proximity mask such as that shown at 30 in Figure 1 of the patent, or such as those appearing as Figures 4 - 8. See RX 3, Col. 4, lines 5-52. The inventor

himself testified that he referred to a contact mask in the patent, and in that same testimony used distinct terminology for an "aperture". See RX 214 at 143. Accordingly, allowing the patentee to be his own lexicographer, in light of the patentee's apparent distinction between the proximity mask in the patent, on the one hand, and an iris or aperture, on the other hand, I believe no structural equivalency between these elements should be found. See also Sowada, Tr. at 1499 (testifying as to the absence of a proximity mask precluding satisfaction of this claim limitation). No party offers an argument for infringement of this claim limitation under the doctrine of equivalents.

For the foregoing reasons, then, and because the EC-5000 does not meet all elements of Claim 1, from which Claim 10 depends, I find no infringement of this claim.

4. Claim 12

I construed the means-plus-function claim limitation found in Claim 12 to refer to a proximity mask able to selectively shape the cornea and structural equivalents thereof. VISX's argument for infringement of the "means for selectively shaping" limitation depends primarily on the adoption of its proposed interpretation of the claim limitation, which interpretation I rejected. VISX maintains that in the EC-5000, the means for selectively shaping a corneal surface consists of the laser power supply and an iris diaphragm. See CX 480C; Eden, Tr. at 723-25.

Nidek argues that the EC-5000 includes no proximity mask whatsoever, and therefore does not meet this claim limitation. Nidek contends that the structure performing selective shaping in the EC-5000 is the linear scanning and rotating structure within the delivery system, which Nidek insists is not structurally equivalent to the means of Claim 12. See RX 751; RX 724C. As to infringement under the doctrine of equivalents, Nidek maintains that even if the EC-5000's iris is

compared to the proximity masks of the '762 Patent, they cannot be deemed equivalent because of the substantial difference that in the EC-5000, the iris provides motorized control for various sized openings while the fixed proximity masks of the '762 Patent would require manual replacement by the surgeon during the procedure to change to a different size opening.

The Staff concludes that the iris diaphragm and slit aperture features of the EC-5000 perform the selective shaping function set forth in Claim 12, and that this structure is not identical to the corresponding structures in the '762 Patent specification. According to the Staff, however, citing testimony by VISX's Dr. Eden, the EC-5000's iris diaphragm and slit aperture features are substantially interchangeable with the "optical train structure of Figure 3". See Eden, Tr. at 693, 818-19, 886-87.

Considering the EC-5000's iris diaphragm and slit aperture as structures allowing for selective shaping of the corneal surface, I note that these structures are not proximity masks, such that they are not structurally equivalent to Claim 12's "means for selectively shaping". See Sowada, Tr. at 1499. Turning to whether these features may be deemed equivalent to the proximity mask for purposes of the doctrine of equivalents, I find that VISX has not met its burden of proof to establish such equivalence. VISX offers no direct argument on this issue, and the Staff relies on testimony by Dr. Eden, who offered a proposed construction of "means for selectively shaping" that differed from the construction I adopted, thus undermining his testimony on equivalency as to this limitation. Furthermore, to the extent his testimony involves the laser delivery system in Figure 3 of the patent, I previously noted that I do not find his testimony on the nature and functionality of the system credible. Dr. Sowada testified that given the absence of the proximity mask, no infringement finding should be made. See Sowada, Tr. at 1499. Under the

circumstances, I cannot conclude that this means-plus-function element is infringed under the doctrine of equivalents. For the foregoing reasons, then, and because the EC-5000 does not meet all elements of Claim 1, from which Claim 12 depends, I find no infringement of this claim.

V. Invalidity

A. Anticipation – '762 Patent

Nidek argues that Claims 1, 7, 10 and 12 of the '762 Patent were anticipated by U.S. Patent No. 4,784,135 ("'135 Patent"), entitled "Far Ultraviolet Surgical and Dental Procedures", issued to Blum, Srinivasan[26], and Wynne. No party disputes the prior art status of the '135 Patent. Anticipation exists when a prior art reference discloses every limitation of a patent claim. Celeritas Tech., Ltd. v. Rockwell Int'l Corp., 150 F.3d 1354, 1361 (Fed. Cir.), cert. denied, 119 S.Ct. 874 (1999). The disclosure of each limitation may be express or inherent. Continental Can Co. USA Inc. v. Monsanto Co.., 948 F.2d 1264, 1268 (Fed. Cir. 1991).

As an initial matter, the parties dispute whether for purposes of determining the applicable burden of proof on anticipation, the '135 Patent should be deemed "new" prior art that was not considered by the '762 Patent examiner, or should instead be deemed prior art previously considered by the examiner during prosecution of the '762 Patent. See Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1359 (Fed. Cir.), cert. denied, 469 U.S. 821 (1984) (noting the higher burden for proving anticipation where prior art was considered by the examiner during prosecution because of the "... deference that is due to a qualified government agency presumed to have properly done its job"). Nidek points out that in 1997, after all of the '762 Patent's claims

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[26]Dr. Trokel, the named inventor of the '762 Patent, did research and experimental work underlying the '762 Patent with Dr. Srinivasan at Dr. Srinivasan's IBM laboratory, as set forth in greater detail in the section on inventorship of the '762 Patent, *infra*.

had already been allowed, VISX twice attempted to submit the '135 Patent in an Information Disclosure Statement ("IDS"), but the PTO expressly denied the submission as untimely. RX 4 at NC00050628, NC00050638-39. Nidek notes that VISX again tried to have the PTO consider the '135 Patent in January 1998, but the PTO again denied the submission. RX 4 at NC00050718-19. VISX, on the other hand, maintains that because the '135 Patent was cited as a reference in at least one parent application of the '762 Patent, it therefore should be deemed considered by the examiner in the prosecution of the '762 Patent. See CX 967 at face page; M.P.E.P. §§ 904, 707.05 (instructing an examiner to check parents of continuation and divisional applications for pertinent prior art); Am. Hoist, 725 F.2d at 1359 (citing presumption that PTO correctly did its job). The Staff asserts that "[t]he '135 patent is listed as a prior art reference on the face of the '762 patent, indicating that the PTO considered the reference before issuing the patent." Staff Initial Post-Hearing Brief at 107.

Even assuming without deciding, for purposes of argument, that Nidek is correct that the '135 Patent qualifies as "new" prior art, such that Nidek's burden of proof is not heightened, I nonetheless conclude, as set forth below, that the '135 Patent does not anticipate the claims in question. Accordingly, in light of this conclusion, I need not rule on the applicable burden, as Nidek cannot meet either the lessened or the heightened burden.

According to Nidek, the '135 Patent establishes that the '762 Patent teaches nothing more than a new use of an old device – the same device disclosed in the '135 Patent, which claims an excimer laser system as a surgical tool for use on biological tissue. See RX 7. Citing In re Schreiber, 128 F.3d 1473 (Fed. Cir. 1997), Nidek maintains that because the '762 Patent's "... functional recitation directed to corneal tissue or ablation rate of corneal tissue does not add

any additional structure and does not require any structure different from what is disclosed in the prior art '135 patent", the '762 Patent should be invalidated as anticipated. Nidek Initial Post-Hearing Brief at 106. VISX insists that because the '135 Patent is not directed to corneal surgery, this distinction alone can prevent an anticipation finding.

1. Claim 1

The parties agree that the '135 Patent teaches use of a 193 nm pulsed laser, thereby meeting Claim 1's limitation of "a laser that produces a beam of radiation at a wavelength of about 193 nanometers in a series of pulses." See RX 7, Col. 3, lines 14-17, 31-33, 58-65. I note, however, that the limitation in Claim 1's preamble is not satisfied by the '135 Patent which does not refer to corneal tissue. See RX 7. Additionally, the parties disagree as to whether the '135 Patent satisfies the "laser delivery system means" and the ablation rate claim limitations.

Turning to the laser delivery system, Nidek relies on testimony by Dr. Sowada indicating that the '135 Patent discloses a delivery system with the same structures taught by the '762 Patent's Figures 1 and 2, including the contact or proximity mask. See Sowada, Tr. at 1478-79; see also RX 7, Col. 4, lines 11-14, Col. 3, line 67 - Col. 4, line 2. Nidek points out that none of VISX's experts rebutted this testimony by Dr. Sowada, as VISX's expert, Dr. Eden, concentrated on comparing the '135 Patent delivery system only to Figure 3 of the '762 Patent. See Eden, Tr. at 1617-18. The Staff agrees with Nidek that the '135 Patent shows a structurally identical or equivalent laser delivery system to the one in Figure 2 of the '762 Patent, thereby meeting this claim limitation.

VISX contends that Figure 3 of the '762 Patent shows a two-lens imaging system with a variable slit, while Figure 2 shows a single-lens imaging system. See Eden, Tr. at 679-80, 885.

VISX then cites Dr. Sowada's testimony that the system in the '135 Patent is neither an imaging nor a focusing system, concluding that the systems are not identical or equivalent. See Sowada, Tr. at 1518. VISX also maintains that the '135 Patent does not teach use of a variable slit, and does not teach delivery of laser radiation *to a cornea*, as in the '762 Patent's Claim 1.

I agree that the '135 Patent teaches a laser delivery system that meets the "laser delivery system means" limitation of Claim 1. The '135 Patent's figure shows a single-lens system used with a proximity mask, akin to the system of Figure 2 of the '762 Patent used with the proximity mask, as shown in Figure 1. See RX 7 figure; see also RX 7, Col. 6, lines 46-64 (describing the contact mask). I also find Dr. Sowada's testimony on the equivalency of these systems convincing. As to VISX's citation of his testimony that the '135 Patent does not show a focusing or imaging system, I note that he explained that it showed a "contact mask system", which is entirely consistent with the '762 Patent's delivery system. See Sowada, Tr. at 1518. As to VISX's characterization of Dr. Sowada's testimony that nothing in the '762 Patent shows mask 30 as a contact mask, I note that Dr. Sowada testified that one skilled in the art would recognize mask 30 as a contact or proximity mask even though it is not explicitly so stated in the patent. See Sowada, Tr. at 1490.

Next, turning to the ablation rate limitation of Claim 1, Nidek acknowledges that this is not explicitly disclosed in the '135 Patent, but, again citing Schreiber, argues that the limitation does not add any further structural element to Claim 1 and should not preclude anticipation. Alternatively, Nidek maintains that because the ablation rate set forth in Claim 1 would always be met, given a fluence level between 100 and 200 mJ/cm^2, and because the '135 Patent gives fluence level examples that fall in that range, the requisite ablation rate is inherently present in the '135

Patent. See RX 44C; see also RX 7, Col. 4, lines 53-54, 65-66, Col. 6, lines 51-53. In other words, according to Nidek, if the apparatus in the '135 Patent were set to the appropriate fluence level and a cornea were placed in the target area, the "approximately 1 micron" ablation rate would be achieved. See Sowada, Tr. at 1480.

As to the ablation rate limitation, VISX cites the testimony of Nidek's expert, Dr. Sowada, conceding that the '135 Patent does not disclose this claim element because the '135 Patent "... has not dealt with corneal tissue." Sowada, Tr. at 1517-18. The Staff sides with VISX on this limitation, taking the position that the '135 Patent does not inherently disclose this ablation rate. VISX points to testimony by Nidek's expert, Dr. McDonnell, that the only two ways a person of ordinary skill in the art in 1983 could determine the ablation rate for corneal tissue would be to experiment and measure or to read the article authored by Dr. Trokel, Dr. Srinivasan and Ms. Braren summarizing the results of their experiments. See McDonnell, Tr. at 1092-93. Citing Finnigan Corp. v. U.S. Int'l Trade Comm'n, 180 F.3d 1354, 1365 (Fed. Cir. 1999) and Continental Can, 948 F.2d at 1269, VISX argues that this defeats any inherency finding which requires that the inherent disclosure be readily recognized by those of ordinary skill in the art. According to the Staff, the examples of ablation depths achieved on different materials using different fluences indicate, if anything, "... that there is no consistency in ablation rate from one type of material to the next ...", such that the ablation rate for corneal tissue cannot be inherently disclosed. See RX 7, Col. 4, lines 55-68, Col. 6, lines 46-54.

I conclude that the '135 Patent does not anticipate the ablation rate limitation of Claim 1. The parties correctly note that the '135 Patent gives no express teaching of this ablation rate, as it never addresses corneal tissue. See RX 7. As to an inherent teaching, I am persuaded against

finding one by the admission of Nidek's expert that even upon reading the '135 Patent, experimentation would be required on the part of one skilled in the art to determine the "approximately 1 micron" ablation rate for corneal tissue disclosed in the '762 Patent. See McDonnell, Tr. at 1092-93. The Staff also notes that the examples of ablation results on different materials provided in the '135 Patent suggest that ablation rate varies according to the type of material, again suggesting that experimentation would be required. See Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1569 (Fed. Cir.), cert. denied, 488 U.S. 892 (1988) (noting that the disclosure in allegedly anticipating prior art must be enabling).

I reject Nidek's argument that the ablation rate taught by Claim 1 merely provides a result such that it should not be construed as a structural limitation. I note that while Nidek argues that the laser device would naturally produce this ablation rate at a given fluence level, that fluence level is not disclosed in Claim 1. Rather Claim 1 indicates that the laser system is structured to produce that ablation rate, indeed teaching a limitation. Furthermore, as to Nidek's contention that because the requisite fluence level can be found in the '135 Patent, the ablation rate limitation should be deemed satisfied, I note that while the ranges in the '135 Patent may encompass that taught by Claim 1, they are not as specific, such that trial and error would necessarily be involved to reach the ablation depth specified.

Based on the failure to satisfy Claim 1's preamble and on the absence in the '135 Patent of any explicit or inherent teaching of the ablation rate limitation of Claim 1,[27] I conclude that this

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[27]My conclusion here dovetails with my findings, *infra*, regarding Dr. Srinivasan's role in the inventorship of the '762 Patent device. While I find that Dr. Srinivasan made a significant contribution to the ablation rate limitation, I also find that the ultimate conclusion as to the rate stemmed from the joint experiments Dr. Trokel and Dr. Srinivasan performed together. The '135 (continued...)

claim is not anticipated.

2. Claim 7

This dependent claim cannot be anticipated, based on my conclusion that Claim 1 is not anticipated. Wahpeton Canvas Co. v. Frontier, Inc., 870 F.2d 1546, 1553 (Fed. Cir. 1989). However, I note that the additional limitation taught by Claim 7, the ability to produce pulses having between 100 and 200 millijoules of energy per square centimeter, is met by the '135 Patent. Nidek and the Staff both take this position. The '135 Patent discloses use of the excimer laser at fluences ranging from 10 to 300 mJ/cm^2. See RX 7, Col. 4, lines 53-54. Thus, as Dr. Sowada testified, the apparatus described in the '135 Patent has the ability to produce pulses in the requisite fluence range. See Sowada, Tr. at 1480. Based on the language of Claim 7, I am not persuaded by VISX's argument that no anticipation of this limitation should be found because "... nothing in the '135 patent enables persons of ordinary skill in the art to use the fluence levels in claim 7 on corneal tissue." VISX Reply Brief at 34.

3. Claim 10

This dependent claim cannot be anticipated, based on my conclusion that Claim 1 is not anticipated. Wahpeton Canvas Co. v. Frontier, Inc., 870 F.2d 1546, 1553 (Fed. Cir. 1989). As to the additional limitation set forth in Claim 10, however, the "means, including a mask, for controlling a volume of corneal tissue removed", I found the corresponding structures in the '762 specification to be the laser power supply and control system 24 and a proximity mask. The '135 Patent proposes using a Lambda Physik laser, having a power supply and a control system, as

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[27](...continued)
Patent naturally does not reflect the results of Dr. Trokel's and Dr. Srinivasan's joint experimental work.

evidenced by the direction to set particular levels, apparently through use of the control system. See RX 7. Furthermore, all parties acknowledge that the '135 Patent discloses use of a proximity mask. See RX 7, Col. 6, lines 46-64. VISX's arguments against this claim limitation being satisfied rest on its proposed claim construction, which I rejected, *supra*.

4. Claim 12

This dependent claim cannot be anticipated based on my conclusion that Claim 1 is not anticipated. Wahpeton Canvas Co. v. Frontier, Inc., 870 F.2d 1546, 1553 (Fed. Cir. 1989). However, the additional limitation of a "means for selectively shaping a surface of the cornea" is satisfied by the '135 Patent. The means-plus-function limitation in the '762 Patent claims the corresponding structure of a proximity mask, and, as set forth above, no dispute exists that the '135 Patent teaches use of a proximity mask. While VISX cites testimony by Dr. Eden that the '135 Patent system could not shape the surface of a cornea, in fact he merely testified that it would be "awkward" to use it, or that it was a "poor" system for this purpose, primarily because of the use of proximity masks, which he incorrectly concluded were not taught by the '762 Patent. Eden, Tr. at 1618-19.

B. Obviousness – '762 Patent

Nidek contends that Claims 1, 7, 10 and 12 of the '762 Patent should be invalidated as obvious based on the '135 Patent together with Beckman et al., "Limbectomies, Keratectamies, and Keratostomies Performed with a Rapid Pulsed Carbon Dioxide Laser", American Journal of Ophthalmology, 1971, Volume 71, page 1277 (RX 92) ("Beckman Article") or Keates et al., "Carbon Dioxide Laser Beam Control for Corneal Surgery", Ophthalmic Surgery, 1981, Volume 12, page 117 (RX 91) ("Keates Article"). Section 103 sets forth the requirement that the subject

matter of a patent be non-obvious. The patent should not be obtained if:

> ...the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

35 U.S.C. § 103(a) (1998).

An obviousness determination involves an analysis of the prior art from the perspective of one of ordinary skill in that art at the time of the patent in question, including consideration of whether there existed an explicit or implicit suggestion to combine particular pieces or features of the prior art. Graham v. John Deere Co., 383 U.S. 1, 17 (1966); Env. Instruments, Inc. v. Sutron Corp., 877 F.2d 1561, 1568 (Fed. Cir. 1989). The obviousness challenger must show some teaching or suggestion in the prior art to make any combination or substitution of features on which the challenger relies. Fromson v. Anitec Printing Plates, Inc., 132 F.3d 1437, 1447 (Fed. Cir.), cert. denied, 119 S.Ct. 56 (1998). To make the determination regarding such a teaching or suggestion, the following factors may be considered for a motivation to combine or substitute: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art. In re Rouffet, 149 F.3d 1350, 1355-56 (Fed. Cir. 1998).

As set forth in connection with the preceding section on anticipation, I concluded that the '135 Patent discloses all the limitations of Claims 1, 7, 10 and 12 *except* the preamble's limitation which teaches use of the device for removal of corneal tissue, and the ablation rate limitation set forth in Claim 1, from which the other three claims depend. Thus, the only considerations that need be reached in this obviousness analysis, involving the '135 Patent combined with other prior art, are whether the other prior art discloses these limitations and whether there exists some

teaching or suggestion to combine the disclosures in such pieces of prior art. However, Nidek makes no assertion that the Beckman Article or the Keates Article discloses or teaches the ablation rate limitation of Claim 1 of the '762 Patent.[28] In light of my findings as to no anticipation by the '135 Patent, and in light of Nidek's failure to offer any prior art teaching the ablation rate limitation absent from the '135 Patent, the obviousness defense must be rejected.

C. Inventorship – '762 Patent

Section 102(f) provides that "[a] person shall be entitled to a patent unless – (f) he did not himself invent the subject matter sought to be patented ...." 35 U.S.C. § 102(f). Section 102(f) thus mandates as a condition of patentability "that a patent accurately list the correct inventors of a claimed invention." Pannu v. Iolab Corp., 155 F.3d 1344, 1348-49 (Fed. Cir. 1998). Section 116 sets forth the parameters of joint inventorship and joint application for a patent, including, in pertinent part:

> When an invention is made by two or more persons jointly, they shall apply for patent jointly .... Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.
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35 U.S.C. § 116. The Federal Circuit has recently addressed this statute noting that:

> All that is required of a joint inventor is that he or she (1) contribute in some significant manner to the conception or

[28]Rather, Nidek offers this combination of prior art to address a possible construction of Claim 1 where the preamble, referencing removing corneal tissue, was the only absent limitation. Under such a construction, Nidek argues that the Beckman Article and/or the Keates Article teach the use of lasers for corneal surgery, such that their combination with the '135 Patent, which does not explicitly reference corneal tissue, but instead just references human biological tissue generally, would render the '762 Patent claims in question obvious.

> reduction to practice of the invention, (2) make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art.

Pannu, 155 F.3d at 1351.

Although Section 116 and Section 256 make provisions for the correction through the PTO of inadvertent mistakes in the naming of inventors in patent applications, all parties concede that the Commission lacks authority to make such a correction, such that if an incorrect statement of inventorship is found, the Commission cannot grant relief based on the patent unless the PTO or a court makes the necessary correction. Certain Eprom, Eeprom, Flash Memory and Flash Microcontroller Devices and Products Containing Same, Inv. No. 337-TA-395, Comm'n Op. at 9-10 (October 13, 1998).

Patentees receive a presumption that the named inventor on the issued patent is the true and only inventor. Ethicon, Inc. v. U.S. Surgical Corp., 135 F. 3d 1456, 1460 (Fed. Cir.), cert. denied, 119 S.Ct. 278 (1998). Proof of incorrect inventorship must be by clear and convincing evidence. Ethicon at 1461.

In this investigation, Nidek asserts an improper inventorship defense, citing Claims 1, 7, 8, 10, 12 and 15 of the '762 Patent as invented or co-invented by others. Nidek argues that clear and convincing evidence demonstrates that Dr. Stephen Trokel was not the inventor of these claims, although he is the only named inventor on the '762 Patent. Although Dr. Trokel acknowledges that Dr. Rangaswamy Srinivasan and Ms. Bodil Braren, both of IBM, provided him his introduction to and some use of an excimer laser, and assisted him in conducting the experiments on which the '762 Patent is largely based, Dr. Trokel maintains that they made no

significant contribution to the inventive work. Dr. Srinivasan has since retired from IBM, while Ms. Braren continues her employment with the company.

According to Nidek, Dr. Srinivasan and Ms. Braren, rather than Dr. Trokel, were the true inventors of the claimed subject matter. Nidek points out that Dr. Srinivasan, along with Dr. Barbara Garrison, is credited with developing the theory of ablative photodecomposition, explaining the revolutionary discovery by Dr. Srinivasan and colleagues at IBM that excimer laser light produces extraordinary effects in solid organic material. See Srinivasan, Tr. at 1177-78, 1184. [

] In contrast, Nidek insists that Dr. Trokel and VISX have not brought forward records or documentation to support Dr. Trokel's independent conception claim. Nidek contends that Dr. Srinivasan shared the fruits of this prior work with Dr. Trokel, including giving him as yet unpublished articles, and that based on their IBM experience, Dr. Srinivasan and Ms. Braren determined all of the critical parameters of the July 20, 1983 and July 28, 1983

experiments on which Dr. Trokel relied, at least in part, to develop the patent claims at issue. See Srinivasan, Tr. at 1197-98, 1200, 1238-40; Braren, Tr. at 1282-86.

As further support for the improper inventorship defense, Nidek emphasizes the co-authorship of the December 1983 seminal article published in the American Journal of Ophthalmology on excimer laser surgery on the cornea authored by Dr. Trokel, Dr. Srinivasan and Ms. Braren ("AJO Article"). See RX 186. While Nidek acknowledges testimony by Dr. Srinivasan and Ms. Braren in the 1990 interference proceeding between Dr. Trokel and Dr. L'Esperance allegedly supporting Dr. Trokel's inventorship, Nidek notes that at that time, neither was aware of the specifics or scope of Dr. Trokel's patent claims. See Srinivasan, Tr. at 1249; Braren, Tr. at 1297. In fact, Dr. Srinivasan testified that he remained in the dark as to Dr. Trokel's claims regarding the precise scope of his invention until December 1995, which was after the issuance of the '388 Patent, a method patent related to the '762 Patent. Srinivasan, Tr. at 1253.

Nidek further includes in their briefing a claim-by-claim analysis of the inventorship issue, offering specific arguments against Dr. Trokel's independent conception and in favor of deeming Dr. Srinivasan and/or Ms. Braren the true inventors of the subject matter. Nidek highlights the ablation rate, the laser delivery system means, the fluence level, the mask, and the pulse rate as elements of these claims for which Dr. Srinivasan and/or Ms. Braren should be fully credited.

VISX argues to the contrary, that Dr. Trokel had expertise with lasers, albeit not excimer lasers, before ever meeting Dr. Srinivasan. Citing Dr. Trokel's testimony, VISX maintains that Dr. Trokel conceived of the experiments performed in the IBM laboratory, including the basic parameters of the laser setting and operation. See Trokel, Tr. at 333-35, 338-40, 383-84. VISX

points out that for the second set of experiments, Dr. Trokel prepared the masks, and that after October 1983, Dr. Trokel conducted experiments at his own laboratory rather than at IBM's. VISX also stresses that Dr. Trokel studied the ablation depth of the corneal cuts himself – at a location other than the IBM laboratory. See Trokel, Tr. at 349.

To bolster its opposition to the inventorship defense, VISX further contends that Dr. Srinivasan's and Ms. Braren's conduct indicates their belief that they were not the inventors of the subject matter claimed in the '762 Patent. VISX emphasizes that they did not treat information surrounding the experiments as IBM confidential information, [

] VISX next argues that Dr. Srinivasan's testimony was not consistent with Ms. Braren's, and in some cases, their testimony was inconsistent with that previously given in connection with a Trokel vs. L'Esperance interference proceeding. VISX goes on to claim, citing to Dr. Trokel's testimony, that Dr. Trokel spoke to Dr. Srinivasan about a patent application, and that Dr. Srinivasan declined to be named as a joint inventor because of his belief that Dr. Trokel was the sole inventor. See Trokel, Tr. at 361-62, 421.[29] VISX also argues that the PTO has already decided the inventorship issue and that its determination is entitled to deference.

In its claim-by-claim analysis, VISX addresses the same elements cited by Nidek, and asserts that Nidek cannot show by clear and convincing evidence that Dr. Srinivasan or Ms. Braren contributed to the conception of the claimed inventions. VISX argues that with respect to the

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[29]In the same passage of testimony, Dr. Trokel states that when Dr. Srinivasan allegedly declined on his and IBM's behalf any inventorship claim to the invention as to corneal surgery, "[h]e said, besides, I have to tell you that IBM has filed a patent on medical applications and surgical applications of this technology." Trokel, Tr. at 362.

claim elements in dispute, insufficient evidence was offered to corroborate the testimony of the proposed co-inventors.

The Staff sides with VISX, concurring that Dr. Srinivasan and Ms. Braren should not be deemed co-inventors of any of the claimed matter in the '762 Patent. In support thereof, the Staff argues that Dr. Srinivasan's and Ms. Braren's prior testimony and conduct are inconsistent with Dr. Srinivasan's inventorship, and further points out that the PTO, in connection with Dr. Trokel's '843 Patent, considered joint inventorship, in light of the AJO Article, but accepted Dr. Trokel's sole inventorship claim based on transcripts of the interference deposition testimony of Dr. Srinivasan and Ms. Braren.

Considering all the pertinent evidence of record, including the testimony at the hearing, I find that clear and convincing evidence establishes that Dr. Srinivasan should properly have been named a co-inventor, along with Dr. Trokel, of the '762 Patent. The record reflects that the fruit of Dr. Srinivasan's research and development work on delivery systems, as well as the pulse rates and ablation rates for ablative photodecomposition by excimer lasers on biological tissue contributed significantly to numerous '762 Patent claim elements.

As an initial matter, I note that the testimony of Dr. Srinivasan and Ms. Braren supports a finding that the '762 Patent suffers from an improper identification of inventor. While for the reasons set forth below, Dr. Trokel's testimony on the inventorship issue was lacking in credibility, both Dr. Srinivasan and Ms. Braren, by contrast, presented credible, compelling testimony. Dr. Srinivasan spoke quite knowledgeably about the invention and the inventive work, and demonstrated a keen understanding of the thought process and experimentation behind certain claim elements. Dr. Trokel, on the other hand, lacked these qualities, and admitted to a

lack of knowledge surrounding how at least some key claim elements were determined. See e.g., Trokel, Tr. at 420. (Dr. Trokel stating that he had no information on whether certain research performed by Dr. Trokel's lab assistant who conferred with Dr. Srinivasan affected his patent claims); see also Trokel, Tr. at 389 (where despite the patent's statement that more rapid pulse rates than 25 Hertz created tissue heating distortion from gas pressure backup in the irradiated area, Dr. Trokel testified that he did not know whether the limit of 25 Hertz was in any way related to the problem of gas pressure that was discussed with Dr. Srinivasan; see '762 Patent, Column 4, line 62 - Column 5, line 2). The lack of knowledge Dr. Trokel displayed at the hearing is further reflected in the Patent itself in which, for example, the rays in Figure 3, which Dr. Trokel is presumed to have drawn, were filled in improperly, evidencing a disturbing lack of understanding of fundamental elements of the patent which VISX claims constituted a major contribution by Dr. Trokel to the state of the art. See Eden, Tr. at 812, 815, 1645-1647.

As to financial interest in this proceeding, under the terms of their employment by IBM during the time of the experiments at the IBM lab, neither Dr. Srinivasan nor Ms. Braren could retain ownership of any intellectual property developed therefrom. Thus, although Dr. Srinivasan was employed as a consultant by Nidek in connection with this investigation, Ms. Braren, who received no compensation from any party to this investigation, lacks a financial interest in the outcome of the inventorship question. Braren, Tr. at 1263. Although Dr. Trokel assigned his patent rights to VISX, he remains a major shareholder in VISX[30], and has a financial interest in the outcome of this investigation. Trokel, Tr. at 374-75; RX 243. Finally, contrary to VISX's

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claims, the testimony of Dr. Srinivasan and Ms. Braren regarding Dr. Srinivasan's contribution to the invention in question is corroborated by documentary evidence including but not limited to laboratory notebooks and scientific papers. See e.g., RX 58C; RX 59C; RX 154; RX 222; RX 247. In fact, the evidence corroborating Dr. Srinivasan's inventive work far outweighs evidence reflecting inventive work by Dr. Trokel.

In addition to my reliance on the manner in which Dr. Trokel presented himself at the hearing, I also find that the content of Dr. Trokel's testimony contributes to my determination regarding his lack of credibility. For example, in an attempt to minimize the contributions of Dr. Srinivasan and Ms. Braren, Dr. Trokel states that despite never before having seen or operated an excimer laser, upon his first visit to the IBM lab:

> [w]ell, if [Dr. Srinivasan] gave me the instruction book to that laser and gave me the keys to the lab, those experiments would have been done in July. The reason that he was there made it easier and made it a lot less work, but I promise you, give me the instruction book, give me a few hours, that thing would have been up and running, and I would have done those experiments *** Again, I can say that they served to run the instrument for me, but I was perfectly capable of running it myself, and had they not been there, and had I had access to it, I would have run it.

Trokel, Tr. at 382, 383.

These statements by Dr. Trokel that he could have done the experiments himself had he only been given the instruction manual for the laser, a few hours, and the keys to the lab are undercut by the fact that in the fall of 1983, when Dr. Trokel obtained his own excimer laser, Dr. Srinivasan and Ms. Braren went to Dr. Trokel's office and set up the optical system for him. This action indicates, contrary to Dr. Trokel's testimony, that he did need assistance in performing his experimental work and reflects negatively on the credibility of Dr. Trokel. Braren Tr. at 1292;

Trokel, Tr. at 396-97, 1581-82; RX 234. Of particular importance, moreover, is that these statements contradict Dr. Trokel's own statements near the time of the inventive work, indicating that Dr. Srinivasan played an important role in the development of the invention claimed in the '762 Patent. See e.g. RX 234 (12/7/83 letter requesting an academic appointment at Columbia University for Dr. Srinivasan because his "*continued role* in helping develop different *ophthalmic surgical applications* will require that this relationship extend over a minimum of at least the next year"); RX 228C [

] RX 229 (10/19/83 letter stating that he and Dr. Srinivasan intended to work together on perfecting a delivery system for clinical applications); RX 235C [

] While, at the hearing, Dr. Trokel downplayed those more contemporaneous statements largely as "puffery", I find it more likely that those statements represent a more truthful account of Dr. Srinivasan's role in the '762 Patent invention. See Trokel, Tr. at 393-400. Also, despite characterizing Dr. Srinivasan's role as essentially having provided a facility and some very basic knowledge, as set forth above, Dr. Trokel admitted at the hearing that he consulted Dr. Srinivasan about the draft of the AJO Article they eventually co-authored with Ms. Braren, and "would have accepted" any changes made by Dr. Srinivasan. Trokel, Tr. at 354. Such a willingness to accept without question any revisions by a co-author suggests a more significant role than Dr. Trokel is now willing to admit. Furthermore, in describing the response to the AJO Article, Dr. Trokel noted "[w]ell, I was pleased, Dr. Srinivasan was pleased. *We* held a press conference at the Presbyterian Hospital to announce this work." Trokel, Tr. at 361 (emphasis added). Again, the

inclusion of Dr. Srinivasan in the press conference announcing this work suggests a more significant role than Dr. Trokel is now willing to admit. The record also includes an article by Dr. Trokel where he states that:

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] Finally, although not dispositive, the prosecution history of the '762 Patent bears negatively on Dr. Trokel's credibility, revealing his early attempt, despite his visits to the IBM lab and acquisition of much of the pertinent information from Dr. Srinivasan's and IBM's research and development in this area, to broadly claim, for himself as sole inventor, a laser source surgical apparatus, directed specifically at dental caries and skin lesions which he now freely admits was Dr. Srinivasan's and IBM's creation.[31] See RX 4 at NC 00050458.

While VISX attacks Dr. Srinivasan's credibility on several grounds, I find them unavailing. As for Dr. Srinivasan's delay in asserting co-inventorship, Dr. Srinivasan explained in his testimony that he remained unaware of the scope of the invention claimed in Dr. Trokel's application(s), and promptly asserted his part in the '762 and '388 Patent inventions upon becoming aware of their contents.[32] Srinivasan, Tr. at 1249; see CX 460; Srinivasan, Tr. at 1252-

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[31]Subsequently during the prosecution, the application was amended, because of a rejection based on the '135 Patent issued to Dr. Srinivasan *et al*, to delete all 33 of the original claims and to substitute claims limited to systems for use in a laser source surgical method for removing corneal tissue.

[32]The '762 and '388 Patents ultimately resulted by continuation and/or division from the (continued...)

56.[33] Also, while VISX alleges that Dr. Srinivasan stated in the 1990 interference deposition that he believed Dr. Trokel to be the inventor of the subject matter at issue therein, in fact his testimony referring to Dr. Trokel as "inventor" and to his own "secondary contribution" was in response to a question about the order of authorship of the AJO Article, with Dr. Srinivasan explaining why he was comfortable with being second to Dr. Trokel on the list of authors. Not only was the patent not being discussed at that point in the deposition, but VISX points to no evidence even indicating that Dr. Srinivasan knew the precise scope of Dr. Trokel's claimed invention at that time,[34] and, as set forth above, Dr. Srinivasan affirmatively states that he was not aware of the breadth of the claimed invention at that time. Dr. Srinivasan's supportive interference testimony may have resulted from misplaced trust in Dr. Trokel or a mistaken impression about what Dr. Trokel claimed as his invention. Dr. Srinivasan, stated at the hearing that he misspoke in calling Dr. Trokel the inventor "of the discovery" at issue at that deposition, essentially using a poor choice of words that did not accurately convey his thoughts. Srinivasan, Tr. at 1243-44. In addition, in the deposition, Dr. Srinivasan did state that he believed he made a

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[32](...continued)
same original application, Serial Number 561,804, abandoned.

[33] [

] While VISX relies on this as proof that Dr. Srinivasan was properly not named as a co-inventor, I note that, as argued by Nidek, the letter does not state that IBM had determined there was no legal basis for a claim of co-inventorship and that [

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[34]VISX also argues that because Dr. Srinivasan served as a consultant to VISX in 1992 and again from 1995-1996, he was familiar with the scope of the application for the '762 Patent, but VISX points to no evidence that Dr. Srinivasan's consulting responsibilities would have brought him in contact with the patent application.

"secondary" contribution to the inventive work, indicating that collaboration had occurred.

Ms. Braren also offered credible testimony regarding the experimentation leading to the '762 Patent, and presented herself as both a truthful witness and a witness lacking a stake in the proceedings. While she makes no direct inventorship claim for herself, she described Dr. Trokel as relatively lacking in expertise in excimer lasers, and explained the role Dr. Srinivasan played, and the role she played under Dr. Srinivasan's direction, in determining important parameters in the work, as much more substantial than Dr. Trokel's characterization. She confirms that the determinations regarding many of the significant elements of the experiments from which the AJO Article, and in turn, the '762 Patent stemmed, were not made by Dr. Trokel. See e.g. Braren, Tr. at 1282-90; see also RX 219C at 087627.

VISX, in attempting to undermine the credibility of the testimony of Dr. Srinivasan and Ms. Braren, points to alleged inconsistencies between their testimony regarding "their respective roles in the July 20, 1983 experiments", specifically as to whether Dr. Srinivasan instructed Ms. Braren on the laser and optics set-up for the experiments, or whether Ms. Braren herself made decisions about where to place the lenses or the different iterations of exposure. VISX Initial Post-Hearing Brief at 146 (citing Srinivasan, Tr. at 1238; Braren, Tr. at 1285). I find, upon reviewing their testimony in its entirety, however, that their accounts are essentially *consistent* except for minor, insignificant variations likely resulting more from a difference in perspective than from divergent accounts of the facts.[35]

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[35]The Staff contends that at Ms. Braren's deposition during the interference proceedings in 1990, she testified she had no recollection of the facts surrounding the experiments on July 20 and 28, 1983 other than what was specifically recorded in her notes. The Staff argues that in contrast at the hearing in this investigation she recalled many details, thereby affecting negatively her (continued...)

The argument against the inventorship defense based on the '843 Patent examiner's consideration and acceptance of the naming of Dr. Trokel as the sole inventor on that patent, which shares the same specification as the '762 Patent, is also rejected. See CX 712, Tab 12 at 2. VISX asserts that the examiner initially rejected the '843 Patent claims based on improper inventorship in light of the AJO Article, but subsequently allowed them to go forward with Dr. Trokel as the only inventor after reviewing Dr. Srinivasan's and Ms. Braren's 1990 interference deposition transcripts. See CX 712, Tabs 19 & 22. According to VISX, then, citing American Hoist & Derrick Co v. Sowa & Sons, Inc., 725 F.2d 1350, 1359-60 (Fed. Cir.), cert. denied, 469 U.S. 821 (1984), the examiner's determination as to inventorship should be granted "the deference owed to administrative agency decisions". See VISX Post-Hearing Brief at 145. However, I do not believe American Hoist can carry VISX's position in this case, as that court noted that with respect to a court's assessment of evidence *not* considered by the PTO in a patent validity determination, no reason for deference to the PTO's determination exists. Id. The court noted:

> When an attacker simply goes over the same ground travelled by the PTO, part of the *burden* is to show that the PTO was wrong in its decision to grant the patent. When new evidence touching (the) validity of the patent not considered by the PTO is relied on, the

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[35](...continued)
overall credibility. In advancing its contention, the Staff does not identify any specific instances where Ms. Braren's hearing testimony is any more detailed than the statements given in her deposition. Additionally, a review of the portion of the deposition transcript cited by the Staff discloses that Ms. Braren's statement that she had no recollection that she did anything other than what she put in her notebook, related to a question about one part of the experiments "i.e., the experiment reported there for the holes." CX 26C, Braren deposition at 22-23. Under the circumstances, the Staff's contention is an overgeneralization of Ms. Braren's statement in her deposition and I do not find that it serves to undermine the credibility of her testimony in this proceeding.

> tribunal considering it is not faced with having to *disagree* with the PTO or with *deferring* to its judgment or with taking its expertise into account.

Id. at 1360. Just such a situation exists with the '762 Patent. First, it is notable that the PTO determination on which VISX relies pertains to a different, albeit related, patent. Second, VISX itself admits that the examiner's allowance of the claims was based on the interference deposition transcripts, while an abundance of other evidence regarding inventorship has been considered and relied on here. Thus, I conclude that American Hoist in no way precludes or even suggests any impropriety in finding an inventorship misstatement in the '762 Patent despite the PTO's action with regard to the '843 Patent.

I note several specific claim elements to the invention of which Dr. Srinivasan significantly contributed, so as to qualify him as a co-inventor of the '762 Patent. For example, Claim 1 recites, *inter alia*, "a laser that produces a beam of radiation at a wavelength of about 193 nanometers in a series of pulses", and clear and convincing evidence supports a finding that Dr. Srinivasan was at least in substantial part responsible for the determination of that wavelength. Prior to June 1983, Dr. Srinivasan and his colleagues at IBM had conducted research and experimentation to determine the optimal wavelength for ablative photodecomposition of biological tissue, and had already reached the conclusion that 193 nanometers was the optimal wavelength. See RX 222 at 577 (Dr. Srinivasan's 1982 article explaining the distinct properties of and beneficial results from 193 nm laser use on PMMA). Both Dr. Srinivasan and Ms. Braren testified that they set this parameter for the first two sets of experiments with Dr. Trokel, and Dr. Srinivasan also testified that he and Dr. Trokel discussed the appropriate wavelength during the course of the inventive work, during which time Dr. Srinivasan communicated the substance of

IBM's findings on this issue and recommended against using a 248 nanometer wavelength, as Dr. Trokel wished to try. See Braren, Tr. at 1271, 1283-86; Srinivasan, Tr. at 1198, 1208-09, 1238-40; RX 58C at 622, 636. Also, Ms. Braren testified that she provided the 193 nanometer figure to Dr. Trokel in connection with the AJO Article, indicating that this was not information determined by or even known with certainty by Dr. Trokel. See Braren, Tr. at 1294. While Dr. Trokel did not offer an explanation at the hearing of how he allegedly conceived of the 193 nanometer provision, there has been some suggestion that he relied on the two Taboada articles, which refer to 193 nanometer and 248 nanometer excimer lasers. See CX 117; CX 213. However, the Taboada articles do not address tissue removal for a therapeutic purpose and so are not directly analogous. See Trokel, Tr. at 323-24; CX 117, CX 213. The AJO Article in contrast states "[w]e found that the excimer laser produced an optimal biologic effect in the far-ultraviolet at 193 nm." RX 186 at NC00200205.

A second example of Dr. Srinivasan's significant contribution to the invention involves the "laser delivery system means for receiving said radiation from said laser and delivering a fraction of said radiation to a cornea" recited in Claim 1. Nidek argues, citing Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456, 1460 (Fed. Cir. 1998), that because Dr. Srinivasan conceived of the embodiment of such means shown in figures of the '762 Patent, this alone qualifies him as a co-inventor. According to Ethicon, "[t]he contributor of any disclosed means of a means-plus-function claim element is a joint inventor as to that claim, unless one asserting sole inventorship can show that the contribution of that means was simply a reduction to practice of the sole inventor's broader concept." Id. at 1463. Except for minor adaptations, Figure 1 of the '762 Patent is identical to a schematic created by Dr. Srinivasan and published in his 1983 article

"Kinetics of the Ablative Photodecomposition of Organic Polymers in the Far-Ultraviolet (193nm)". See RX 154; Trokel, Tr. at 355, 403. As to Figure 3, representing an optical delivery system that is intended to be incorporated into Figure 1 as element 22, [

] [36] Braren, Tr. at 1280-84, 1288-89. Moreover, contrary to VISX's claims in its brief, Ms. Braren testified that she did, indeed, show Dr. Trokel her drawing of a two-lens system. Braren, Tr. at 1300-01. [

] Though some differences exist, the IBM drawing was obviously the genesis of Dr. Trokel's Patent drawing. See RX 229 (10/19/83 letter stating that he and Dr. Srinivasan intended to work together on perfecting a delivery system for clinical applications). See also Trokel, Tr. at 403; Srinivasan, Tr. at 1217.

As a third example, clear and convincing evidence demonstrates Dr. Srinivasan's co-invention of the ablation rate claim element. Claim 1 teaches "a depth of ablation of approximately 1 micron for each accumulation of one joule per square centimeter of energy applied". This ablation rate was included in the AJO Article, and was calculated from the July 1983 experiments' settings and data. See RX 186 at 00200206; Braren, Tr. at 1294-95. I note that Dr. Trokel, in response to a question concerning the contribution Dr. Srinivasan made to the

[36]I note, however, that Dr. Trokel designed and prepared the proximity masks used in the experiment on July 28, 1993, which are disclosed in the '762 Patent. See Srinivasan, Tr. at 1217-18; Trokel, Tr. at 346.

determination of the ablation rate, testified:

> Well, the framing it in terms of microns per millijoule, I believe was -- microns per joule was, I believe, his suggestion. I wanted to put it in terms of microns per pulse, but he used different units, but he never measured it in the cornea, and he never had any suggestion about what the corneal rates would be.

Trokel, Tr. at 373. The record as a whole, however, convincingly demonstrates that while the ablation rate is determined from a formula incorporating energy density and the depth of ablation, and Dr. Trokel performed the mechanical calculations, other information and considerations necessary to reach the ablation rate can be traced back to Dr. Srinivasan's input. First, Ms. Braren credibly testified as follows about the ablation rate disclosed in the AJO Article:

> Q Did you supply any information with respect to the indications here about the rate of ablation?
> A That was a calculation that was made.
> Q It was made from the numbers you supplied Dr. Trokel?
> A Yes. And the depth that was measured from the photographs.
> Q Did he have to do anything other than pull out the calculator and make the calculations?
> A No.

Braren, Tr. at 1295. Additionally, Dr. Srinivasan and IBM colleagues had previously done extensive work analyzing ablation rates, including on human tissues such as the aorta. See RX 247. Dr. Srinivasan provided Dr. Trokel with then-unpublished articles setting forth information on the predictable relationship between energy density and ablation rate. See e.g. RX 247; RX 154 at 053226-27. Dr. Srinivasan also worked with Dr. Trokel to determine the fluence level instrumental in determining ablation depth -- Dr. Srinivasan contributed information from his prior experimental work on the aorta, while Dr. Trokel contributed his relatively greater expertise on

the relevant characteristics of the cornea. See Srinivasan, Tr. at 1206. Thus, while Dr. Trokel may have by himself performed rote calculations to arrive at the ablation rate number, Dr. Srinivasan played an important role in its determination. Even in 1984 and 1985, Dr. Trokel continued to seek the input and insight of Dr. Srinivasan regarding ablation rate measurements, as demonstrated by exhibits RX 236, RX 237 and RX 238.

Other related examples of Dr. Srinivasan's significant input into the '762 Patent arise in connection with Claim 7's fluence range of "between 100 and 200 millijoules of energy per square centimeter", Claim 8's pulse rate of "between 1 and 20 Hertz", and Claim 15's pulse rate of "from 1 Hertz to 25 Hertz". Dr. Srinivasan and Ms. Braren both testified that they selected the appropriate fluence range of 100 - 200 millijoules for the cornea experiments based on IBM's prior research, particularly on the artery. Srinivasan, Tr. at 1198, 1206; Braren, Tr. at 1283-85, 1288-89. As to the pulse rate, the '762 Patent specification notes that pulse rates exceeding 25 Hertz "... create tissue heating distortion from gas pressure backup in the irradiated area." RX 3, Col. 4, line 66 - Col. 5, line 1. At the hearing, Dr. Trokel did not explain the source of this maximum pulse rate in the patent, and even when prodded about whether heating distortion from gas pressure backup in the irradiated area factored into these limitations, Dr. Trokel testified that he did not know whether the limit of 25 Hertz was in any way related to the problem of gas pressure that was discussed with Dr. Srinivasan. Trokel, Tr. at 389. Dr. Srinivasan testified that based on his prior experimental work, he informed Dr. Trokel about the gas pressure backup problem and the upper limit on the pulse rate to avoid the problem. See Srinivasan, Tr. at 1208, 1218-20. The record includes documentary evidence lending credence to Dr. Srinivasan's testimony. See e.g. RX 58C, RX 59C, RX 62C and RX 237. I note that while in his trial

testimony, Dr. Trokel stated that he didn't think Dr. Srinivasan had any sense of the clinical implications of the pulse rate (Trokel, Tr. at 372-73), even if, as a surgeon, Dr. Trokel had more of a "sense" of the clinical implications of the pulse rate, he still benefitted from Dr. Srinivasan's prior research work and conclusions regarding the effect of various pulse rates. In other words, even if Dr. Trokel provided the input on the ultimate desired effect on the cornea, the record indicates that, Dr. Srinivasan developed the knowledge as to the optimal pulse rate to achieve this desired effect. Dr. Trokel himself confirmed Dr. Srinivasan's input on these claim elements in the previously referenced article where Dr. Trokel stated that [

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As to Ms. Braren, I do not find clear and convincing evidence to attribute co-inventorship to her. While she apparently played a part in the experiments leading up to the AJO Article and, in turn, the patent, the evidence supporting Dr. Srinivasan's actual inventive contribution is much greater than for Ms. Braren. She worked as a lab technician under Dr. Srinivasan and, while she certainly exercised some judgment about some parts of the work with Dr. Trokel, she acted primarily under Dr. Srinivasan's direction. See e.g. Srinivasan, Tr. at 1238; Braren, Tr. at 1285, 1291, 1304-05. Although Ms. Braren had knowledge of the results of the prior IBM excimer laser research and development work on biological tissue, and apparently applied that knowledge in assisting with the experiments with Dr. Trokel, the evidence regarding her alleged inventive role does not rise to the clear and convincing standard. She may have been familiar with which

settings were most appropriate, but she was supervised by Dr. Srinivasan, and the record does not clearly indicate that Dr. Srinivasan had not previously instructed Ms. Braren in developing this knowledge or familiarity. See Srinivasan, Tr. at 1190; Braren, Tr. at 1285, 1289 (noting that she made decisions in setting up the equipment for the experiments with Trokel based on her "prior work and knowledge"). Also, both prior to and after the experiments with Dr. Trokel, Dr. Srinivasan and Dr. Trokel substantively conferred on the inventive work outside the presence and without the participation of Ms. Braren. See Srinivasan, Tr. at 1196-97, 1199-2000; Braren, Tr. at 1290; Trokel, Tr. at 333-35, 342, 348, 350, 1574. While she is a co-author of the AJO Article, both Dr. Trokel and Dr. Srinivasan indicate that this was largely nominal, in deference to a standard practice at IBM of giving co-author credit to lab technicians as a sign of appreciation where possible. See Trokel, Tr. at 355; CX 712, Tab 19 at 27-28. Finally, in contrast to Dr. Srinivasan, I note that at the hearing, Ms. Braren offered no assertion of being an inventor of the '762 Patent. Ultimately, I deem the evidence surrounding her alleged contribution insufficient to find her a co-inventor.

D. Derivation – '762 Patent

"To show derivation, the party asserting invalidity must prove both prior conception of the invention by another and communication of that conception to the patentee." Gambro Lundia AB v. Baxter Healthcare Corp., 110 F.3d 1573, 1576 (Fed. Cir. 1997). "A claim that a patentee derived an invention addresses originality -- who invented the subject matter of the count?" Price v. Symsek, 988 F.2d 1187, 1190 (Fed. Cir. 1993). In connection with the derivation defense, the parties rely on their respective versions of the factual background underlying the inventorship defense and many of the same arguments, discussed *supra*. Nidek contends that Dr. Trokel

derived the invention set forth in Claims 1, 7, 8, 10, 12 and 15 of the '762 Patent from Dr. Srinivasan and "potentially Ms. Braren". VISX and the Staff dispute Nidek's assertion, with the Staff arguing that at least the ablation rate limitation of Claim 1 was not derived from Dr. Srinivasan, such that neither Claim 1 nor any of the other dependent claims should be invalidated based on the derivation defense.

In the preceding section on the inventorship defense, I held that while Dr. Srinivasan made significant contributions to the same '762 Patent claims as are at issue here, I further held that Dr. Trokel also contributed to the claims and should properly have been named a co-inventor. My factual findings in that section are equally applicable here, and are incorporated here by reference. I noted in particular that the ablation rate limitation found in Claim 1 resulted in part from the joint experimental work of Dr. Srinivasan and Dr. Trokel, and although I deemed Dr. Srinivasan's contribution more significant, I conclude that each of them is properly credited with inventing the subject matter of Claim 1. I noted that the two men worked together to determine the fluence level instrumental in determining ablation rate -- Dr. Srinivasan providing input from his prior experimental work on the aorta, while Dr. Trokel contributed his relatively greater expertise on the relevant characteristics of the cornea. See Srinivasan, Tr. at 1206. Accordingly, because I deem Dr. Trokel a co-inventor of the subject matter claimed in the '762 Patent's Claim 1, I cannot conclude that he derived it entirely from Dr. Srinivasan or Ms. Braren. Thus, given that the other claims asserted by Nidek are all dependent on Claim 1, I similarly cannot conclude that Claim 7, 8, 10 or 12 should be invalidated under the derivation defense.

VI. Unenforceability[37]

A. '418 Patent

Nidek argues the unenforceability of the '418 Patent on several grounds. First, Nidek alleges inequitable conduct arising from a misrepresentation by the named inventor to the patent examiner during prosecution. Second, Nidek asserts that Dr. L'Esperance committed fraud in connection with certain interferences involving patents that Nidek characterizes as related to the '418 Patent, so as to taint the '418 Patent with the fraud. Third, according to Nidek, the subsequent failure by VISX and by Dr. Trokel to inform the PTO of Dr. L'Esperance's fraud upon learning of it in the course of the interferences should render the '418 Patent unenforceable. Fourth and finally, Nidek relies on these same underlying facts to argue that the equitable doctrine of unclean hands renders the '418 Patent unenforceable.

1. Inequitable Conduct

"Inequitable conduct is ... the submission of false material information, during the prosecution of a patent with an intent to deceive." Gambro Lundia AB v. Baxter Healthcare Corp., 110 F.3d 1573, 1580 (Fed. Cir. 1997). In this regard, Nidek maintains that during prosecution of application 746,330 ("'330 Application"), Dr. L'Esperance falsely informed the patent examiner that he used his invention on human eyes for a myopia correction in order to overcome a rejection based on non-enablement. Particularly, the source of the examiner's

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[37]While VISX states in a footnote in its brief that it objects to Nidek's reliance on any activity in connection with interferences other than the '026 Interference as outside the scope of the affirmative defenses set forth in Nidek's Response to the Complaint and Notice of Investigation, I note that Nidek raised these arguments in the Joint Narrative Statement of Issues and in its Prehearing Brief without VISX making any motion *in limine* for their exclusion. At this stage in the investigation, I do not believe VISX raises its objection in a timely manner, and it is therefore rejected.

enablement concern in rejecting certain claims was the language pertaining to microprocessors and their programming. RX 13 at 175340. The '418 Patent at issue in this investigation resulted from application 916,646 ("'646 Application"), but contains one claim from the '330 Application which was transferred to the '646 Application after its allowance in the '330 Application. Both the '646 Application and the '330 Application are continuations in part of application 552,983 ("'983 Application").

On June 19, 1986, Dr. L'Esperance and his patent attorney held a personal interview with the examiner, and submitted an affidavit by David E. Hardt in response to the rejection, wherein Dr. Hardt opined that the specification meets the enablement requirement. See id. at 175345, 175364-94. The examiner nonetheless issued a final Office Action on September 16, 1986, rejecting claims for non-enablement, noting with respect to the Hardt affidavit that "[w]hile one of ordinary skill in the art may be capable of performing such a programming task, it is still not clear that the task could be performed without undue experimentation on the part of the programmer." Id. at 175396. Dr. L'Esperance and his patent attorney conducted a second personal interview with the examiner on April 16, 1987, at which meeting Nidek asserts Dr. L'Esperance personally stated that he had recently used his invention on human eyes to make a myopia change.[38] See RX 83C at 008217. [

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[38]However, Nidek's basis for this assertion consists only of a follow-up letter by Dr. L'Esperance's patent attorney wherein he states, "[a]t the conference, Dr. L'Esperance mentioned that the first two human eyes had recently been the subject of laser-sculpturing of the visually used part of the cornea...", and further notes the enclosure of representative photographs with an explanation thereof. RX 83C at 008217-18. The examiner's interview summary record contains no mention of the human trials, instead merely indicating: "agreed that the affidavit overcomes the rejection on the basis of 35 USC 112 1st paragraph and that the rejection under 35 USC 103 is not sufficient to anticipate the claimed invention." CX 1076.

] Dr. L'Esperance's patent attorney followed up the April 16 interview with a paper submission dated April 27, 1987, in which he made reference to the interview and included two pictures of the human trials. RX 83C at 008217-20.

On May 15, 1987, the examiner issued a Notice of Allowability for the '330 Application, allowing the previously rejected claims. RX 13 at 175419. In that notice, the examiner stated that he dropped the non-enablement rejections based on the applicant's comments and submissions in connection with the '983 Application. RX 79 at SUG000001261-62. In order to support its position that the examiner relied on the alleged misrepresentation by Dr. L'Esperance in the interview, Nidek first argues that the examiner's description of the comments and submissions does not mesh with the record on the '983 Application, the parent case, and "[t]he reasonable conclusion is that the Examiner was referring to the '330 application (the continuation) and not to Application No. 552,983 because L'Esperance's comments and submission of brochures were made in the '330 application and not in Application No. 552,983." Nidek Initial Post-Hearing Brief at 172. Second, Nidek points to an answer by the examiner to an appeal brief filed by Dr. L'Esperance in connection with another application, 327,988 ("'988 Application") wherein the examiner stated "[Dr. L'Esperance's] arguments that he was the first person to so apply a laser beam was instrumental to the allowance of the claims in the original application." RX 17 at 011798. According to Nidek, no such argument by Dr. L'Esperance can be found in the record of the '983 Application, such that Nidek again argues that the examiner meant to refer to the alleged interview comments of Dr. L'Esperance in connection with the '330 Application rather

than to the '983 Application.[39]

Both VISX and the Staff dispute Nidek's contentions on this issue, maintaining that clear and convincing evidence does not support finding that the statement by Dr. L'Esperance about the human trials constitutes a misrepresentation, that any such statement was material to the non-enablement issue, or that the examiner relied on any such statement. See Halliburton Co. v. Schlumberger Tech. Corp., 925 F.2d 1435, 1440 (Fed. Cir. 1991) (applying the legal standard for materiality in existence at the time in question, whether "a reasonable examiner" would rely).

I conclude that Nidek has not met its burden of proving inequitable conduct here by clear and convincing evidence. See Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 872 (Fed Cir.), cert. denied, 490 U.S. 1067 (1989) (noting the burden to prove materiality and intent by clear and convincing evidence in the context of inequitable conduct). As an initial matter, the only indication offered by Nidek of the alleged misrepresentation by Dr. L'Esperance in the interview comes from the paper submitted by his patent attorney, which does not directly indicate that Dr. L'Esperance referred to the use in human trials of the scanning element of the invention at issue in the '330 Application. See RX 83C. Furthermore, I agree that under the "reasonable examiner" standard, or in inquiring as to any actual reliance by this examiner, the evidence of materiality also fails to rise to the level of clear and convincing. The inventor's reduction to practice of his own invention should hardly sway an examiner that the disclosure in the inventor's specification is sufficiently enabling to one of ordinary skill in the art. See Stewart-Warner Corp. v. City of Pontiac, 767 F.2d 1563, 1569-70 (Fed. Cir. 1985) (in the context of the person of

[39]However, the '330 Application is not the parent of the '988 Application, and VISX maintains that other references in the same document indicate that the examiner referred to the application that issued as the '913 Patent.

ordinary skill for an obviousness determination, noting that "section 103 is not concerned with the actual skill of the inventors — whose skill may be extraordinary — but rather with the level of ordinary skill in the art"). Similarly, because the human trials in question were conducted in 1987, their timing, four years after 1983 when the '330 Application was filed, suggests they should not be dispositive of whether the specification enabled one skilled in the art to practice the invention in 1983. See In re Wright, 999 F.2d 1557, 1563 n.8 (Fed. Cir. 1993) ("[T]he issue is not what the state of the art is today or what a skilled artisan today would believe, but rather what the state of the art was on [the filing date of the application] and what a skilled artisan would have believed at that time"). Under the circumstances, a reasonable examiner should not have relied on Dr. L'Esperance's use of the claimed invention for human trials as grounds to overcome a non-enablement rejection. Furthermore, as to any actual reliance by this examiner, the evidence does not support any such finding. As set forth above, Nidek's attempts to show actual reliance rest on making assumptions regarding, and correction of, statements made by the examiner that reflect no reliance, and this type of second guessing cannot serve as clear and convincing evidence. Accordingly, for the foregoing reasons, the inequitable conduct defense as to the '418 Patent is rejected.

2. Fraud in Interferences and Failure to Inform the PTO

Nidek rests its argument for the unenforceability of the '418 Patent for fraud in connection with interferences largely on analogy to the facts of Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co., 324 U.S. 806 (1945). Taunton Technologies, Inc. ("Taunton") at one time owned U.S. Patent Nos. 4,770,172; 4,773,414; 4,798,204 and 4,665,913 (the '172, '414, '204 and '913 Patents, respectively), each of which issued naming Dr. L'Esperance as the

inventor. RX 210 at VISX 0003844. A predecessor of VISX ("VISX California") owned U.S. Patent Application Serial No. 081,986 ("the '986 Application"), naming Dr. Munnerlyn as the inventor, and U.S. Patent Application Serial No. 109,812 ("the '812 Application"), naming Dr. Trokel as the inventor. RX 16 at NC00051874; RX 548 at 86. VISX California, owner of the Munnerlyn '986 and Trokel '812 Applications, provoked four patent interferences against L'Esperance's '913, '172, '414, and '204 Patents, then owned by Taunton. RX 210 at VISX 0003844. The four interferences included: (a) Interference No. 102,026 ("the 026 Interference") between Dr. L'Esperance's '913 Patent and Dr. Trokel's '812 Application; (b) Interference No. 102,073 ("the 073 Interference") between Dr. L'Esperance's '204 Patent and Dr. Munnerlyn's '986 Application; (c) Interference No. 102,182 ("the 182 Interference") between Dr. L'Esperance's '172 Patent and Dr. Munnerlyn's '986 Application; and (d) Interference No. 102,183 ("the 183 Interference") between Dr. L'Esperance's '414 Patent and Dr. Munnerlyn's '986 Application. RX 455 at VISX/FTC 091712; RX 457 at VISX/FTC 056850; RX 462 at VISX/FTC 055837; RX 466C at VISX/FTC 094591.

According to Nidek, Dr. L'Esperance intentionally submitted false information to the PTO, in the form of a forged diary page backdated to January 22, 1983, in Preliminary Statements submitted in the '073, '182 and '183 Interferences. See RX 451 at 090985-86, 1015; RX 807 at 317; Nathan, Tr. at 82-83. Nidek also argues that Dr. L'Esperance forged and backdated other technical documents, which pertained in part to the invention at issue in the '026 Interference, that he approved for examination by VISX California in the interest of settling the interferences. See RX 205C at 250661; RX 193C at 154213; see also RX 205C at 250661-62; RX 807 at 321-22. Then, Nidek contends, Taunton's attorneys and the opposing parties in the interference, including

VISX California, [ ] entered into a settlement among themselves of this and the other interferences. See RX 205C at 250664-65; RX 210 at 0003844. Nidek asserts that this behavior renders unenforceable the patents involved in all four interferences, and all related patents as well, including Dr. L'Esperance's '418 Patent.

In fact, it should be noted here that upon discovering the forgery of the diary page submitted with the Preliminary Statements in the '073, '182 and '183 Interferences, Taunton's patent counsel withdrew the diary page, and moved to submit Corrected Preliminary Statements, stating that the diary page submitted with the original Preliminary Statements contained "a material error" and could not be relied upon. See RX 335; RX 357. While Dr. L'Esperance's and Taunton's counsel cited and quoted from Rohm & Haas v. Crystal Chem. Co., 722 F.2d 1556, 1572 (Fed. Cir. 1983), cert. denied, 469 U.S. 851, a case dealing with misrepresentation to the PTO, the motion also represented that "... the error was made as the result of mistake or inadvertence on the part of the undersigned attorneys who signed the Preliminary Statement, who were unaware when the Preliminary Statement was filed that the diary entry in question could not be relied upon." RX 357 at 2.

Nidek argues that under analogous facts in Precision Instrument, the Court upheld a trial court's reliance on the equitable principle of "unclean hands" as a bar to enforcement of several patents. In that case, in the context of an interference, the first applicant filed a Preliminary Statement containing false information, and when the second applicant learned of it, he made no report whatsoever to the PTO. Id. at 809-12. Instead, the two applicants settled the interference proceeding on terms including that the first applicant concede priority to the second, and that the first applicant's patent application be assigned to the second applicant and his employer. Id. at

812-14. Ultimately, both applications matured into patents, and when the same parties became embroiled in patent infringement and breach of settlement contract litigation based on these same patents and a related reissue patent not directly involved in the interference, the trial court refused to enforce the patents and contracts, noting:

> Those who have applications pending with the Patent Office or who are parties to Patent Office proceedings have an uncompromising duty to report to it all facts concerning possible fraud or inequitableness underlying the applications in issue.
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> ***
>
> Outside settlements of interference proceedings are not ordinarily illegal. But where, as here, the settlement is grounded upon knowledge or reasonable belief of perjury which is not revealed to the Patent Office or to any other public representative, the settlement lacks that equitable nature which entitles it to be enforced and protected in a court of equity.

Id. at 818-19.

Factually, VISX points to evidence that no fraudulent material was submitted to the PTO in connection with the '026 Interference. See Bailey, Tr. at 1588; McCabe, Tr. at 100-02, 110-11; Nathan, Tr. at 84, 88. VISX also insists, as to the other three interferences, that Taunton was the exclusive licensee and subsequent assignee of Dr. L'Esperance's patents, and that Taunton acted forthrightly upon learning of the misrepresentation in the Preliminary Statements, such that no inequitable conduct finding should apply to it or its successors. Furthermore, VISX contends that the settlement of the interferences was not fraudulent in any way, and was not precipitated by the discovery of the forgery. See Munnerlyn, Tr. at 144-46, 149.

In addition, VISX maintains that under the applicable standard for the disclosure obligation, set forth in the 1991 version of 37 C.F.R. § 1.56, the obligation applies only to information adverse to the patentability of an applicant's own application, not to information adverse to claims

of priority by an opponent. See CX 658. VISX then argues that VISX California had no disclosure obligation, as the information discovered did not pertain to the pending applications naming Dr. Munnerlyn as inventor. Also, because the priority of the '418 Patent was never at issue, VISX concludes that the information could not be deemed material to this patent.

VISX further contends that all of the alleged wrongful conduct is immaterial to the '418 Patent, both because the conduct occurred after the issuance of the '418 Patent, and because the conduct lacks the "immediate and necessary" relation to the '418 Patent for tainting of that patent. VISX maintains that case law such as SSIH Equipment S.A. v. U.S. Int'l Trade Comm'n, 718 F.2d 365, 378-79 (Fed. Cir. 1983), supports an absolute rule that improper conduct cannot be material to a patent that issued *before* the conduct took place. See also Ristvedt-Johnson, Inc. v. Brandt, Inc., 805 F. Supp. 549, 556 (N.D. Ill. 1992); Boots Labs., Inc. v. Burroughs Wellcome Co., 223 U.S.P.Q. 840, 850 (E.D. Va. 1984); Plantronics, Inc. v. Roanwell Corp., 185 U.S.P.Q. 505, 506 (S.D.N.Y. 1975). VISX then concludes that since the '418 Patent issued prior to the alleged inequitable conduct, it should not be deemed unenforceable on the basis thereof. See CX 427; RX 547 at 1884; RX 457 at 56844; RX 462 at 55836; RX 466C at 94590.

As to the argument for "infectious" inequitable conduct reaching the '418 Patent, VISX cites the standard from Keystone Driller Co. v. Gen. Excavator Co., 290 U.S. 240, 245 (1933) that for "infection" to occur, the conduct must have an "immediate and necessary relation" to the allegedly infected patent. VISX insists that the '418 Patent lacks the immediate and necessary relation to the alleged conduct. VISX argues initially, citing Baxter Int'l, Inc. v. McGaw, Inc., 149 F.3d 1321 (Fed. Cir. 1998), that all patents stemming from the same parent application are not automatically "infected" by inequitable conduct committed in the prosecution of the parent

application, and are not "infected" if the omission was "in no way material" to their claimed subject matter. Accordingly, VISX contends that Baxter supports a conclusion that any misconduct in connection with these interferences cannot "infect" the '418 Patent. Even as to the '026 Interference, in which no forgery was submitted to the PTO, but which was settled with the other three interferences, VISX argues a lack of the necessary relatedness as the '418 Patent was "based on a separate, divisional patent application" from the '913 Patent at issue in the '026 Interference, thus constituting a "separate invention". VISX notes that the PTO issued both the '913 Patent and the '418 Patent without requiring a terminal disclaimer, confirming their "separate" nature.

The Staff takes the position that the conduct in connection with the four interferences lacks an "immediate and necessary relation" to the '418 Patent, such that the asserted defense should be denied. The Staff cites FMC Corp v. Hennessy Ind., Inc., 836 F.2d 521, 524 (Fed. Cir. 1987) and Black and Decker, Inc. v. Hoover Service Center, 765 F. Supp. 1129, 1138 (D. Conn. 1991) for the proposition that inequitable conduct during prosecution of a patent not asserted in an infringement suit cannot be used to prevent enforcement of the asserted patent. As to the failure to inform the PTO, the Staff notes that Taunton's counsel did make a disclosure to the PTO, and again opines that regardless, the '418 Patent is not sufficiently related to the patents at issue in the interferences to qualify for "infectious" inequitable conduct.

I reject this inequitable conduct defense as to the '418 Patent, as I conclude that the circumstances at issue do not meet the standard for "infectious" inequitable conduct. In Keystone Driller, on an unclean hands defense, the Court found sufficient relatedness between inequitable conduct in connection with the enforcement of one patent in a first suit and the other patents

asserted in a second enforcement suit where the plaintiff relied in part on the decree in the first suit wherein the inequitable conduct occurred and where "... the devices covered by the five patents [were] important, if not essential, parts of the same machine."[40] Keystone Driller, 290 U.S. 240. In Consolidated Aluminum Corp. v. Foseco Int'l Ltd., 910 F.2d 804, 810 (Fed. Cir. 1990), the court found "infectious" inequitable conduct, specifically finding "more than mere relatedness of subject matter". In that case, the patentee intentionally concealed the best mode in a first patent, thereby enabling it to include that disclosure in a second patent and use it "as a basis for its successful arguments in prosecuting the applications that became the other patents-in-suit [the third and fourth patents which were continuations-in-part of the second patent]." Id. at 811-12. The Consolidated court concluded that the inequitable conduct in prosecuting the first patent thereby "... permeated the prosecution of the other patents-in-suit and renders them unenforceable." Id. at 812.

Nidek's arguments for the "immediate and necessary" relationship focus on the relationship among the patents themselves. Other than noting that the patents at issue in the interferences, like the '418 Patent, relate to corneal laser surgery and were all ultimately acquired by VISX, Nidek's only argument for relatedness focuses on the '913 Patent that was at issue in the '026 Interference. See Nidek Initial Post-Hearing Brief at 190-91.[41] I cannot accept this argument,

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[40]In that case, the plaintiff maintained that the unclean hands defense would not apply "... unless the wrongful conduct is directly connected with and material to the matter in litigation ..." such that if the plaintiff came with unclean hands as to an infringement claim on one patent, it should not result in the dismissal of other infringement claims on other related patents. Id. at 243.

[41] As an initial matter, I remain unconvinced that clear and convincing evidence was introduced of fraud on the PTO in the '026 Interference, as the record does not reflect submission (continued...)

though, as I conclude that the applicable case law suggests that the courts look not for an "immediate and necessary" relationship between the *patents*, but rather, an "immediate and necessary" relationship between the *inequitable conduct* and the *relief being sought* in connection with the allegedly "infected" patent. See e.g. Keystone Driller, 290 U.S. at 245. In Baxter Int'l, Inc. v. McGaw, Inc., 149 F.3d 1321, 1331-32 (Fed. Cir. 1998), for example, the court held that although inequitable conduct, intentionally omitting a material prior art reference, was committed in the prosecution of two patents, a third patent that issued as a divisional from the same initial application was not "infected" because the omitted prior art reference bore no relevance to the invention claimed in the third patent. The Baxter court concluded:

> It is also settled law that inequitable conduct with respect to one claim renders the entire patent unenforceable. [citations omitted] However, where the claims are subsequently separated from those tainted by inequitable conduct through a divisional application, and where the issued claims have no relation to the omitted prior art, the patent issued from the divisional application will not also be unenforceable due to inequitable conduct committed in the parent application.

Id. at 1332. Similarly, in SSIH Equipment S.A. v. U.S. Int'l Trade Comm'n, 718 F.2d 365, 378 (Fed. Cir. 1983), the court rejected allegations of "infectious" inequitable conduct (intentional non-disclosure of possible on-sale bar for other patents) where "[t]he acts which are alleged to have taken place all occurred after the '762 patent issued and do not deal with the invention claimed in the '762 patent."

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[41](...continued)
of a forged or falsified document in that interference, as distinguished from the other three. Nidek also argues, however, that the alleged failure to inform the PTO of the intentional misrepresentation in the other interferences prior to settlement of all the interferences affects the '913 Patent directly and thus "infects" the '418 Patent.

The false submission to the PTO cited by Nidek pertained to the priority date of Dr. L'Esperance's inventions at issue in the four interferences. The '418 Patent was not directly involved in any of the four interference proceedings. Furthermore, the invention date of the '418 Patent was never at issue before the PTO, and was never challenged in an interference proceeding. The '418 Patent does not rely on any of Dr. L'Esperance's patents at issue in the interference proceedings for its invention date. See RX 14; RX 15; RX 183; RX 565. The '418 Patent issued prior to the alleged inequitable conduct including the settlement of the four interferences. Based on the foregoing, and in light of the case law, I cannot conclude that the fraudulent submission of a document to establish priority in the '073, '182 and '183 Interferences, or the failure to inform the PTO more fully of the fraudulent submission prior to settling all four interferences, bears a sufficiently close relationship to the '418 Patent to satisfy the "immediate and necessary" relationship requirement. Therefore, the inequitable conduct defense alleged here by Nidek is denied.

3. Unclean Hands

Nidek relies on the identical facts and arguments set forth in connection with its inequitable conduct defense, arising out of fraud in the interferences and failure to inform the PTO, for its unclean hands defense to enforcement of the '418 Patent. VISX correctly points to the statement in Consolidated that "[i]ndeed, what we have termed 'inequitable conduct' is no more than the unclean hands doctrine applied to particular conduct before the PTO" as an indication that the ruling on inequitable conduct should also apply to the unclean hands defense here alleged by Nidek. The Staff similarly relies on its position on inequitable conduct as identical to its position on the unclean hands defense. Staff Initial Post-Hearing Brief at 165-66. Nidek makes no

argument in reply that any different standard should apply to its unclean hands defense. Accordingly, based on the same factual findings and for the same reasons set forth in connection with the preceding section, which are incorporated here by reference, Nidek's unclean hands defense to enforcement of the '418 Patent is rejected.

B. '762 Patent

Nidek asserts the unenforceability of the '762 Patent based on: (1) Dr. Trokel's and VISX California's failure to inform the PTO of Dr. L'Esperance's fraudulent submission in the three interferences, as set forth above; (2) an allegedly intentional misstatement of inventorship; and (3) application of the unclean hands doctrine in light of the failure to inform the PTO.

1. Failure to Inform PTO

Nidek asserts that because an application by Dr. Trokel (for a patent other than the '762 Patent) was at issue in the '026 Interference, and because Dr. Trokel and VISX learned that Dr. L'Esperance allowed them to be shown allegedly falsified documents for settlement purposes, but did not inform the PTO of this, the '762 Patent should not be enforced. Nidek contends that Dr. Trokel and VISX had an obligation to disclose this information to the PTO as pertinent to the resolution of the '026 Interference. See CX 658 (1991 version of 37 C.F.R. § 1.56(a)). Other than a parenthetical statement that the '762 Patent is "progeny of" the '388 Patent that was involved in the '026 Interference, Nidek offers no explanation or argument as to the requisite "immediate and necessary" relation between the failure to inform the PTO and the enforcement of the '762 Patent.

I reject this defense by Nidek for several reasons. First, there is no indication of a fraudulent representation or submission by Dr. L'Esperance *to the PTO* in connection with the '026

Interference,[42] and Nidek cites no case law supporting its interpretation that an alleged misrepresentation by Dr. L'Esperance, directly to his opponents for settlement purposes, gives rise to a duty of disclosure to the PTO. Second, even assuming such information were material and such a duty of disclosure existed under the 1991 version of 37 C.F.R. § 1.56, I note that the regulation also provides that, for persons other than the inventor, inventor's attorney, or inventor's agent, disclosure "... may be made to the Office through an attorney or agent having responsibility for the preparation or prosecution of the application or through an inventor who is acting in his or her own behalf." CX 658 (37 C.F.R. § 1.56(b) (1991)). Accordingly, the regulation indicates that Dr. Trokel and VISX could satisfy their duty by disclosing the information at issue to Taunton's patent counsel, who were responsible for prosecuting the patent and the interference. In fact, Dr. Trokel and VISX learned of the alleged inequitable conduct from Taunton's patent counsel, such that this information was already known by the persons referred to in 37 C.F.R. § 1.56(b) (1991). See Bailey, Tr. at 1590. Third, under the standards for "infectious" inequitable conduct outlined in the preceding section, Nidek fails to establish the requisite "immediate and necessary" relationship between the failure to inform the PTO alleged here, and the enforcement of the '762 Patent, which was not at issue in the '026 Interference.

2. Inventorship

Relying on the same factual background underlying its inventorship defense, as set forth *supra*, Nidek further argues the unenforceability of the '762 Patent for alleged inequitable conduct

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[42]I note that, contrary to Nidek's contention, fraudulent material was submitted to the PTO in the Precision Instrument case on which Nidek relies as support for its unenforceability argument. Specifically, a Preliminary Statement which included false dates as to the conception, disclosure, drawing, description and reduction to practice of a claimed invention was filed. Precision Instrument, 324 U.S. at 809.

before the PTO in intentionally making a false statement of inventorship. Nidek contends that at least as to the omission of Dr. Srinivasan as a named co-inventor on the '762 Patent, Dr. Trokel's intent to deceive the PTO should be found. Nidek cites Stark v. Advanced Magnetics, Inc., 119 F.3d 1551, 1555 (Fed. Cir. 1997) as indicating that filing a false inventorship oath under 35 U.S.C. § 115 could constitute inequitable conduct so as to render the patent unenforceable.

Noting the Federal Circuit's instruction that "[t]he more material the omission or the misrepresentation, the lower the level of intent required to establish inequitable conduct", Nidek argues the material nature of Dr. Trokel's oath of sole inventorship. See Critikon v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1256 (Fed. Cir.), cert. denied, 118 S.Ct. 1510 (1998); see also Nobelpharma AB v. Implant Innovations, Inc., 129 F.3d 1463, 1474 (Fed. Cir.), cert. denied, 119 S.Ct. 178 (1998). According to Nidek, a false statement to the PTO in an affidavit or oath qualifies as material as a matter of law. See Refac Int'l, Ltd. v. Lotus Dev. Corp., 81 F.3d 1576, 1583 (Fed. Cir. 1996); Paragon Podiatry Lab., Inc. v. KLM Lab., Inc., 984 F.2d 1182, 1191 (Fed. Cir. 1993). As to deceptive intent, Nidek points to a variety of facts indicating such intent, including the following: Dr. Trokel's ongoing failure to apprise Dr. Srinivasan or Ms. Braren of the scope of his patent application, even when he sought their testimony on his behalf in an interference proceeding (e.g. Srinivasan, Tr. at 1240; Braren, Tr. at 1297); his unauthorized use of information from unpublished papers and IBM research shared with him by Dr. Srinivasan (RX 154, RX 153; RX 247; RX 499; Srinivasan, Tr. at 1200-04; Trokel, Tr. at 331-32, 338, 403); Dr. Trokel's refusal to sign the IBM confidentiality agreement given to him by Dr. Srinivasan (Srinivasan, Tr. at 1234); Dr. Trokel's inclusion in his original patent application of a discussion on ablating dental caries and skin lesions with a fiberoptic delivery system despite never

having done any experiments relating thereto, while IBM performed such experiments and included disclosures relating thereto in the '135 Patent (Trokel, Tr. at 405, 408); Dr. Trokel's denial that he saw the application for the '135 Patent before that patent issued [

] (RX 242C; Trokel, Tr. at 408); Dr. Trokel's admission at the hearing that although he was concerned about the original version of his patent application covering IBM's prior work, he signed and submitted a sworn statement of first and sole inventorship on the original version of his application (including dental caries and skin lesions) (Trokel, Tr. at 407-10); an alleged lack of even good faith mistaken belief that he was the sole inventor, apparent from Dr. Trokel's lack of knowledge or ability to testify as to certain significant aspects of the '762 Patent invention (Trokel, Tr. at 389, 420; see also Eden, Tr. at 812, 815, 1645-1647); the striking and unexplained similarity between figures of Dr. Srinivasan and/or Ms. Braren and those appearing in the '762 Patent (RX 59C at 515; Braren, Tr. at 1300-01).

VISX offers factual arguments against this defense, maintaining, as with the inventorship invalidity defense, that Dr. Trokel indeed is the sole inventor of the '762 Patent invention. Furthermore, VISX maintains that even if the inventorship is incorrect on the patent, Dr. Trokel did not act with an intent to deceive the PTO. VISX does not dispute the materiality of a sworn inventorship statement, nor that an intentionally false inventorship oath would constitute inequitable conduct. The Staff takes the position that Dr. Trokel was the sole inventor, and that therefore no misrepresentation as to inventorship was made.

"Inequitable conduct is ... the submission of false material information, during the prosecution of a patent with an intent to deceive." Gambro Lundia, 110 F.3d at 1580. My factual

findings and conclusions set forth in connection with the inventorship invalidity defense, *supra*, are applicable to this defense also, and are incorporated here by reference. I previously found an incorrect statement of inventorship on the '762 Patent, in that Dr. Srinivasan should have been named as a co-inventor along with Dr. Trokel. None of the parties dispute that a sworn statement in a patent application inaccurately stating inventorship qualifies as material. Based on my previous findings, and based on the aforementioned arguments for finding such intent offered by Nidek, which I deem persuasive, I conclude that Dr. Trokel acted with deceptive intent in submitting his oath of sole inventorship. The record clearly demonstrates that Dr. Trokel could not possibly have in good faith believed himself to be the sole inventor of the claims in the issued '762 Patent or in the application therefor. While VISX argues that Dr. Srinivasan declined to be named as an inventor, I note that VISX cites only supporting testimony by Dr. Trokel, who I did not find to be a credible witness, and I further note that the record indicates that Dr. Trokel was suspiciously secretive with Dr. Srinivasan about the '762 Patent application, such that as Dr. Srinivasan testified, until the patent issued, he was not familiar with its scope. See Srinivasan, Tr. at 1249, 1252-56; see CX 460. I find evidence that Dr. Trokel intentionally appropriated for use in his patent application material and information from Dr. Srinivasan and/or IBM without authorization. See RX 186; RX 154; RX 742; Srinivasan, Tr. at 1209-10; Braren, Tr. at 1287, 1291-96; Trokel, Tr. at 355-56, 402-03; CX 438C. Given the materiality of the inventorship misrepresentation and the deceptive intent of Dr. Trokel, I conclude that the false inventorship statement rises to the level of inequitable conduct, rendering the '762 Patent unenforceable.

3. Unclean Hands

Nidek relies exclusively on the identical facts and arguments set forth in connection with its

inequitable conduct defense, arising out of failure to inform the PTO, for its unclean hands defense to enforcement of the '762 Patent. As set forth previously, and as indicated by the Federal Circuit in Consolidated, "[i]ndeed, what we have termed 'inequitable conduct' is no more than the unclean hands doctrine applied to particular conduct before the PTO". Accordingly, based on my findings and ruling denying Nidek's inequitable conduct defense based on Dr. Trokel's and VISX's failure to inform the PTO of alleged fraud by Dr. L'Esperance in the '026 interference proceeding, which findings and ruling are incorporated here by reference, Nidek's unclean hands defense is also rejected.

VII. Domestic Industry

As a prerequisite to reliance on Section 337(a)(1)(B), VISX must establish that "...an industry in the United States, relating to the articles protected by the patent ... concerned, exists or is in the process of being established." 19 U.S.C. § 1337(a)(3). Typically, the domestic industry requirement of Section 337 is interpreted as consisting of two prongs: economic and technical. E.g., Certain Variable Speed Wind Turbines and Components Thereof, Inv. No. 337-TA-376, Comm'n Opinion at 14-17 (1996). The economic prong concerns the investment in a domestic industry, while the technical prong involves whether the claimed investment pertains to material protected by the patent. The domestic industry for articles protected by the '418 Patent and the '762 Patent must involve: (1) significant investment in plant and equipment; (2) significant employment of labor or capital; or (3) substantial investment in its exploitation, including engineering, research and development, or licensing. 19 U.S.C. § 1337(a)(3).

VISX relies on four products for its domestic industry showing: the STAR, the STAR S2, the 20/20A and the 20/20B. In Order No. 9, which the Commission declined to review, I found

satisfaction of the economic prong of domestic industry by the VISX systems for which VISX submitted evidence in connection with its motion for summary determination on this issue. The parties now dispute whether that ruling covers only the STAR and the STAR S2, or whether it also covers the 20/20A and the 20/20B. This issue is addressed, *infra*, in the section on the economic prong.

A. Technical Prong

1. '418 Patent

VISX asserts a domestic industry in the STAR, the STAR S2, the 20/20A and the 20/20B practicing Claim 30 and the STAR S2 practicing Claim 32 of the '418 Patent. I interpreted the disputed limitations of these claims in the claim construction section, *supra*.

a. Claim 30

As to Claim 30, the parties' dispute over the practice of this claim boils down to whether VISX's products have the "means for shaping focusing and directing" including the "determining and controlling" means.[43] I concluded that the corresponding structures for shaping, focusing and directing identified in the patent consisted of the lens element 26, the unnumbered mirror and the scanner 14, with the microprocessor with memory and the manual control features of the scanner serving as the "determining and controlling" means.

VISX maintains that in the STAR, the STAR S2, the 20/20A and the 20/20B, their optical delivery systems perform the "shaping, focusing and directing" function. VISX argues that the collection of lenses, prisms and an iris diaphragm in its products is the same as or equivalent to

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[43]In light of my construction of "anterior surface of the cornea", there remains no question that the VISX products practice this claim limitation.

the structures taught by the '418 Patent for performing this function. Although VISX nominally maintains an argument for structural identity, it essentially acknowledges that the structures are different – [

] See VISX Post-Hearing Brief at 203-05.

VISX's expert, Dr. Eden, is relied upon by VISX to assert the equivalence of the structures at issue, as he characterizes them as "very similar", "quite similar", or "for all intents and purposes, the same". See Eden, Tr. at 768-72.

Nidek contends that VISX cannot satisfy the technical prong, as its products do not meet all of the limitations of either Claim 30 or Claim 32. Addressing Claim 30, Nidek asserts that the absence of a Microscan 771 scanner or any equivalent thereof from all of VISX's domestic industry products takes them outside the scope of this claim. Nidek points out that the Microscan 771 disclosed in the patent is programmed to fire the laser only when the beam is directed at the area designated for ablation and that the domestic industry products [

] See Munnerlyn, Tr. at 268-70, 251-52; Eden, Tr. at 904-05. According to Nidek, [

] Although Nidek acknowledges [

] See Texas Instruments Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558 (Fed. Cir. 1996) (requiring particularized testimony).

As to the "determining and controlling" means of Claim 30, VISX argues [

[44]

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Nidek contends that [

[44][

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The Staff takes the position that VISX's domestic industry products practice this claim of the patent, and disagrees with Nidek's contentions on this issue. However, the Staff offers little in the way of explanation of its position.

I conclude that VISX has not satisfied its burden of proving that the STAR, the STAR S2, the 20/20A or the 20/20B practices this claim of the '418 Patent. Although the products have structures performing "shaping, focusing and directing" of a beam, including some means for "determining and controlling", the structures performing these functions differ significantly from the identified structures in the specification of the '418 Patent. While I do not accept Nidek's approach to construction of this claim by splitting the functions, and linking the split functions to particular components, I find that Nidek nonetheless raises valid issues about the differences in components identified in the patent from those performing the same function in VISX's domestic industry products, particularly regarding [ ] The structures for comparison differ markedly, and reach the specified result in substantially different ways. For example, [

] To support its equivalency claims, VISX relies heavily on testimony by Dr. Eden. However, I accord little weight to this testimony as I find it too conclusory, and lacking in any meaningful explanations for the equivalency opinions he offers. See Eden, Tr. at 765, 768-72, 904-05. While

VISX minimally cites to testimony on equivalency by Dr. Munnerlyn, I cannot give such opinion testimony any weight because Dr. Munnerlyn was not designated as an expert witness and because, given his position at VISX, he cannot be considered an impartial witness. Furthermore, although VISX argues [

[45]

] [46]

b. Claim 32

Turning to Claim 32, directed explicitly to hyperopia treatment, VISX relies exclusively on the STAR S2, its only product approved by the FDA for hyperopia correction in the United States. See VISX Initial Post-Hearing Brief at 210.[47] The disputed terms of Claim 32 parallel those of Claim 30, and VISX again maintains that the "means for shaping, focusing and directing"

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[45]See VISX Reply Brief at 66 n.89.

[46]In footnote 89 of its Reply Brief, VISX cites Al-Site Corp. v. VSI Int'l, Inc., 174 F.3d 1308, 1320 (Fed. Cir. 1999) for the proposition that "[a]lthough known in the art in 1983, the iris diaphragm is not precluded from being an equivalent structure *under § 112, ¶ 6* equivalence." While this may be true, the case still cites with approval Chiuminatta's principle that if a proposed equivalent was known in the art at the time of a patent, and the proposed equivalent is deemed *not* to qualify as a structural equivalent under § 112, ¶ 6, it cannot then qualify as an equivalent under the doctrine of equivalents. Id.

[47]Although the Staff initially argued that the STAR, the STAR S2, the 20/20A and the 20/20B all practiced Claim 32, it subsequently revised its position as limited only to the STAR S2 given its status as the only one of the products with FDA approval for hyperopia treatment in the United States.

is satisfied by the optical delivery system in the STAR S2, which includes mirrors, lenses, prisms, an iris diaphragm and a slit aperture. See Munnerlyn, Tr. at 177-78. VISX contends that the "determining and controlling" means are [

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In addition to Nidek's already-rejected argument regarding the "anterior surface of the cornea" limitation, Nidek asserts that the absence of a scanner dooms VISX's position that the STAR S2 practices Claim 32. Nidek argues that VISX failed to present sufficient evidence even regarding what structures in the STAR S2 practice "shaping, focusing and directing", and the "determining and controlling" functions. As to the technical aspects of the functions and the possible proposed structures practicing them in the STAR S2, Nidek makes many of the same arguments as for Claim 30, regarding the absence of a scanner, and the use of [ ] again citing Chiuminatta. However, Nidek makes one distinction with regard to Claim 32 and its direction specifically to hyperopia and the ablation pattern necessary for correction of this condition. Nidek asserts that [

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As with Claim 30, I find a failure by VISX to satisfy its burden of proving practice of Claim 32 of the patent by the STAR S2 system. For the reasons set forth above in connection with the

common means-plus-function claim terms shared with Claim 30, which reasons are incorporated herein by reference, I find insufficient evidence of structural equivalency of the proposed equivalents in the STAR S2 to those structures disclosed in the specification of the '418 Patent. See World Wide, Inc. v. Nike, Inc., 38 F.3d 1192, 1196 (Fed. Cir. 1994) (noting the patentee's burden at trial to establish equivalence). Furthermore, although VISX maintains that it satisfies its burden through testimony by Dr. Eden, I find his testimony on the practice of this claim particularly problematic. [

] Thus, I conclude that for the reasons previously stated and in light of this omission, I cannot give sufficient credence to Dr. Eden's testimony on this issue to deem it adequate to carry VISX's burden of proof. See generally Texas Instruments, 90 F.3d at 1567-68. I find that VISX has not demonstrated practice of Claim 32 literally or under the doctrine of equivalents.

VISX has not met its burden of proving a domestic industry in the practice of Claim 30 or Claim 32 of the '418 Patent.

2. '762 Patent

VISX asserts a domestic industry in the STAR, the STAR S2, the 20/20A and the 20/20B practicing Claims 1, 10 and 12 of the '762 Patent. I interpreted these claims in the claim construction section, *supra*.

a. Claim 1

VISX maintains that its domestic industry products practice Claim 1, and the Staff maintains that practice of the claim is demonstrated under the doctrine of equivalents. Nidek contends that VISX's products do not meet the "laser delivery system means" and the ablation rate limitations set forth in this claim. For the "laser delivery system means", Nidek contends that the evidence does not support finding literal practice of this element, and that VISX never alleged or offered evidence as to the doctrine of equivalents and should therefore be precluded from arguing it. VISX contends it did both allege and offer proof relating to the doctrine of equivalents, such that the doctrine of equivalents should be considered in the domestic industry analysis of this claim limitation.[48] In its prehearing and post-hearing briefing, VISX makes arguments relating to the doctrine of equivalents. Whether VISX offered adequate proof to support its arguments is, like the other issues in this case, disputed by the parties. I see no reason, however, to preclude consideration of the doctrine of equivalents under the particular circumstances of this case.

VISX contends that each of the products at issue [

] Tacitly acknowledging that the delivery systems in its products are not identical to that of the patent, VISX's first line of argument is that they "... perform the same function, achieve the same result and operate in substantially the same way as the embodiment illustrated in Figure 3 of the '762 Patent." VISX Initial Post-Hearing Brief at

[48]I note that in VISX's Prehearing Brief, it made the allegation that the delivery system in its domestic industry products "... serve[s] the same function as [sic] in substantially the same way to produce the same result", an obvious reference to practice under the doctrine of equivalents. VISX Prehearing Brief at 159.

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The Staff opines that the "laser delivery system means" claim limitation is met by structural

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[49][

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equivalents in VISX's domestic industry products. In support thereof, the Staff states [

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] I conclude that the domestic industry products do not practice Claim 1 of the '762 Patent either literally or under the doctrine of equivalents for the same reasons set forth in the section on non-infringement by the EC-5000, *supra*, which reasons are incorporated here by reference. In patent infringement cases, the accused products must always be compared to the patent, rather than to any product made by the patent-holder, because infringement is judged against the claims of the patent, as properly construed. See Zenith Lab., Inc. v. Bristol-Myers Squibb Co., 19 F.3d 1418, 1423 (Fed. Cir.), cert. denied, 513 U.S. 995 (1994) ("As we have repeatedly said, it is error for a court to compare in its infringement analysis the accused product or process with the patentee's commercial embodiment or other version of the product or process; the only proper comparison is with the claims of the patent"). In this investigation, having previously compared the accused product to Claim 1, and having concluded that it does not practice this claim of the patent, [

] I also note that while Nidek raised significant issues

regarding allegedly substantial differences in the "way" in which the laser delivery systems in the domestic industry products function, as confirmed both by Dr. Munnerlyn and Dr. Eden, VISX failed to respond in its reply brief. See Munnerlyn, Tr. at 236-37, 245; Eden, Tr. at 806, 826-28, 831-34, 880. Nidek's criticism of VISX for ignoring the role of numerous optical elements in its systems that do not appear in the '762 Patent in analyzing the manner or way in which the delivery systems reach the desired result is justified.

The claim limitation on ablation rate has been previously construed in the claim construction section, *supra*, and has been previously applied under the doctrine of equivalents in the infringement section, *supra*. [

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[

] The figure falls outside the literal range of ablation rates I found for Claim 1 of this patent. As to practice under the doctrine of equivalents, as noted in the section on non-infringement of this limitation in the EC-5000, *supra*, VISX fails to point to expert testimony or evidence to meet its burden of proof

on equivalency. I therefore conclude that the domestic industry products do not practice this element, either literally, or under the doctrine of equivalents.

Based on the foregoing, I find that VISX has not demonstrated that its domestic industry products practice Claim 1 of the '762 Patent for failure to establish that the products have the requisite "laser delivery system means" or the requisite ablation rate.

b. Claim 10

VISX argues that its domestic industry products satisfy Claim 10's limitation of "means, including a mask, for controlling a volume of corneal tissue removed by said system during corneal laser surgery" with [

] Nidek argues that in addition to the problems stemming from Claim 10's dependency on Claim 1, because none of the domestic industry products has a proximity mask such as that required by Claim 10, no practice of Claim 10 should be found. Nidek criticizes VISX's position by pointing out that [

]

Having previously held that the structures identified as controlling the volume of corneal tissue removed are the laser power supply and control system 24 and, as explicitly set forth in the claim language, a mask, and having previously held that the EC-5000's iris diaphragm and slit aperture did not qualify as structural equivalents, [

] As I noted in the section on non-infringement of this claim by the EC-5000, the mask disclosed in this claim limitation [

]

c. Claim 12

VISX maintains that Claim 12's limitation that the laser delivery system means includes "means for selectively shaping a surface of the cornea" is satisfied by [

] Nidek, in addition to relying on its arguments under Claim 1, also asserts that the domestic industry products lack the type of proximity mask required by Claim 12's means-plus-function limitation. Nidek again criticizes VISX for [ ] I note, however, that in *this* claim, as distinguished from Claim 10, the additional means-plus-function limitation is described as being included in the laser delivery system means previously taught by Claim 1. Thus, for Claim 12, Nidek's argument against "double inclusion" is not necessarily appropriate since, by definition, the "means for selectively shaping a surface of the cornea" must be part of the "laser delivery system means". The Staff asserts satisfaction of this limitation literally, but gives no explanation and cites no evidence in support thereof.

I concluded in the construction of the means-plus-function claim limitation found in Claim 12 that the corresponding structure disclosed in the specification is a proximity mask used for selective shaping of the cornea. No party offers evidence that this type of mask, or any equivalent

thereof, is found in any of the domestic industry products. Accordingly, I find that VISX does not meet its burden of proving practice of Claim 12 of the '472 Patent.

VISX fails to establish the technical prong of domestic industry in the practice of Claims 1, 10 or 12 of the '762 Patent.

B. Economic Prong

As set forth in the introduction to this section on domestic industry, I noted the parties' divergent contentions as to the proper scope of products covered by the summary determination granted in Order No. 9. My review of the parties' submissions in connection with VISX's motion for summary determination indicates that VISX only submitted supporting evidence concerning the STAR and the STAR S2, and that Nidek conceded that it did not dispute a finding of satisfaction of the economic prong only as to those products on which VISX offered supporting evidence, the STAR and the STAR S2. Accordingly, the summary determination does not apply to VISX's 20/20A and 20/20B products.

However, although VISX points to evidence and offers argument in support of a finding that the 20/20A and 20/20B satisfy the economic prong of domestic industry, I conclude that this issue need not be reached in light of the parties' contentions and my findings on the technical nature of the four domestic industry products. Specifically, although VISX acknowledges, as testified to by Dr. Munnerlyn, certain differences between these four products, no party places any significance on these differences in regard to practice of any claim limitation at issue here. No party raises arguments in this investigation suggesting that the different aspects of the 20/20A or 20/20B might result in their practicing a claim limitation not practiced by the STAR or the STAR S2. Rather, with the exception of the STAR S2 being the only product to be considered in connection

with Claim 32, for all other claims, the parties discussed the features and functionality of the four domestic industry products generally, such that they rise or fall together. Under the circumstances, then, no reason exists to perform a separate analysis of the economic prong for the 20/20A and the 20/20B. Although VISX meets its burden as to the economic aspects of domestic industry, its failure to prove that the domestic industry products practice the two patents at issue is fatal to satisfying the statutory requirement.

Conclusion

Accordingly, for the foregoing reasons, I determine that the importation and sale of Nidek's accused devices does not violate Section 337 by reason of infringement of the '418 or '762 Patents. VISX fails to establish the required domestic industry, and further fails to prove infringement of the asserted claims of these Patents by the Nidek devices. The evidence of record also demonstrates the invalidity and unenforceability of the '762 Patent.

INITIAL DETERMINATION AND ORDER

Based on the foregoing opinion, findings of fact, conclusions of law, and the record as a whole, and having considered all pleadings and arguments as well as proposed findings of fact and conclusions of law, it is my Initial Determination ("ID") that no violation of Section 337 exists in the importation into the United States, sale for importation, or sale within the United States of certain excimer laser systems for vision correction surgery and components thereof and methods for performing such surgery.

I hereby certify to the Commission this ID, together with the record of the hearing in this investigation consisting of the following:

a. The transcript of the prehearing conference held on April 8, 1999, and the transcript of the hearing held from August 18, 1999 to August 27, 1999,

b. The exhibits accepted into evidence in this investigation as listed in the attached exhibit lists, and

c. All orders entered in this investigation as well as all pleadings, briefs and other documents and things filed with the Secretary.

In accordance with 19 C.F.R. § 210.39(c), all confidential material under 19 C.F.R. § 210.5 is to be given *in camera* treatment.

The Secretary shall serve a public version of this ID upon all parties of record and the confidential version upon counsel who are signatories to the Protective Order (Order No. 1) issued in this investigation, and the Commission investigative attorney. To expedite service of the public version, counsel are hereby Ordered to serve on my office no later than December 13, 1999, a copy of this ID with those sections considered by the party to be confidential bracketed in

red.

Pursuant to 19 C.F.R. § 210.42(h), this ID shall become the determination of the Commission unless a party files a petition for review pursuant to § 210.43(a) or the Commission, pursuant to § 210.44, orders on its own motion a review of the ID or certain issues herein.

Debra Morriss
Administrative Law Judge

Issued: December 6, 1999

FINDINGS OF FACT and CONCLUSIONS OF LAW
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FINDINGS OF FACT

I. Background

1. All findings of fact set forth in the Initial Determination are incorporated herein by reference.

2. The Complainant, VISX, Incorporated ("VISX") is incorporated under the laws of Delaware and is headquartered in Santa Clara, California. Order No. 9.

3. The named Respondents in this investigation are Nidek Co., Ltd., Nidek Inc. and Nidek Technologies, Inc. (collectively "Nidek"). Notice of Investigation (February 23, 1999).

4. U.S. Patent No. 4,718,418 ("'418 Patent"), entitled "Apparatus for Ophthalmological Surgery", issued on January 12, 1988 to Dr. Francis A. L'Esperance, Jr. Order No. 35.

5. The '418 Patent has been assigned to VISX. Order No. 35.

6. U.S. Patent No. 4,665,913 ("'913 Patent") issued on May 19, 1987 to Dr. Francis A. L'Esperance, Jr. Order No. 35.

7. The '913 Patent has been assigned to VISX. Order No. 35.

8. U.S. Patent No. 5,711,762 ("'762 Patent"), entitled "Laser Surgery Apparatus and Method", issued in January 1998 from Patent Application Serial No. 474,243, which was a division of Patent Application Serial No. 341,207, which was a division of Patent Application Serial No. 893,841, which was a continuation of Patent Application Serial No. 673,541, which was a continuation of Patent Application Serial No. 109,812, which was the patent application that issued as the '388 Patent. Order No. 37.

9. The '762 Patent has been assigned to VISX. Complaint, Pg. 11, ¶ 24.

II. Jurisdiction

10. Nidek does not contest the importation for commercial sale of its accused products. Nidek Initial Post-Hearing Brief at 2-3.

11. Each of the Nidek entities acknowledges being subject to personal jurisdiction in this investigation by the Commission. Nidek Initial Post-Hearing Brief at 3.

III. Claim Construction

A. '418 Patent

12. A rebuttable inference exists "... that one of ordinary skill in the art understands the phrase 'anterior surface of the cornea' to mean the surface of the eye presented to the doctor at the time of surgery and can, depending on the procedure being performed, comprise the epithelium, the Bowman's membrane if the epithelium has been mechanically removed, or the stroma in the case of a LASIK procedure." Order No. 49; see also Order No. 59.

13. Dr. Sher testified as follows:

[

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Sher, Tr. at 447.

14. The meaning in the art of the term "anterior surface of the cornea" has not changed since 1983. See Sher, Tr. at 447.

15. Dr. McDonnell qualified as an expert in refractive surgery, in particular, as an active clinician having extensive medical school teaching, laboratory experience, and as an expert in the evaluation and use of excimer lasers for refractive purposes. Tr. at 1013.

16. Dr. McDonnell testified as follows:

Q Doctor, would you turn to tab '762 in your binder, please. This is another article that you wrote.

A Yes. With Dr. Trokel and Dr. Campos.

Q Published in 1993; is that correct? Down in the right-hand corner of the front page.

A It is cut off in my copy. I think it is a 3, yes.

Q If somebody wants reprints, they write to you; is that right?

A Right.

Q Sir, if you look at the first sentence under the bar in the second column, do you see that?

A Yes.

Q That says, "Excimer laser photorefractive keratectomy involves ablation of the anterior surface of the central cornea to change its radius of curvature"; do you see that?

A Yes.

Q That uses almost exactly the same language as the patent; is that correct?

A Very similar.

Q Does this article discuss laser ablation of the epithelium, Doctor?

A In this article, I'm not --

Q Does it --

A -- that that references. In this article the epithelium was removed.

Q The epithelium was removed in the article you're talking about here; is that right?

A In this article, the epithelium was removed manually.

Q So if you look at page 823 in the left-hand corner, it talks about removing the epithelia using a blunt spatula, right?

A Yes. I think that's how we did it.

Q And then in the right-hand column, last full paragraph, it says if the anterior surface is completely smooth –

A Yes.

Q I won't take you through it, but will you take my word that the word "anterior surface" is used four or five times throughout this article to describe the surface of the

cornea after the epithelium was removed?

A Yes, it is.

Q If you go back, sir, to the first page, the sentence I read which defines excimer laser photorefractive keratectomy, the sentence says, "Excimer laser photorefractive keratectomy involves ablation of the anterior surface of the central cornea to change its radius of curvature"; that sentence is correct, isn't it?

A Yes.

McDonnell, Tr. at 1117-1124.

17. Dr. Sher testified as follows:

[

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Sher, Tr. at 445-51.

18. In the '418 Patent, the terms "anterior surface of the cornea" and "epithelium" are used distinctly. CX 427, Col. 15, line 60; Col. 2, line 25.

19. CX 762, a 1993 article co-authored by Dr. McDonnell, at 822-23, states in pertinent part

that "[e]xcimer laser photorefractive keratectomy involves ablation of the anterior surface of the central cornea to change its radius of curvature....", and "anterior surface" does not refer exclusively to the epithelium.

20. CX 763, a 1992 article co-authored by Dr. McDonnell, at 1201-02, 1204-05, refers to the "anterior corneal surface" without intending an exclusive reference to the epithelium.

21. Nidek's FDA submissions, CX 794C at 20142, 20203-04, and CX 818C at 40038A-41, refer to performing optical correction by recontouring or removing tissue from the "anterior surface of the cornea" or the "anterior corneal surface" where more than the epithelium is to be ablated.

22. The prosecution history of the '418 Patent indicates that the "anterior surface" term connotes a direction rather than a specific layer of the cornea. See CX 700 at 84515-25, 84579 (showing modification of claim language including "anterior surface", changed from "external surface"); CX 702 at 084229-31 (amending claim language including "anterior surface").

23. Claims 30 and 32 of the '418 Patent refer to the "optically functioning area of the cornea". CX 427, Col. 17, lines 34-35, Col. 18, line 12.

24. The '418 Patent specification refers to many types of lasers, including non-continuous wave lasers, as acceptable for use in the invention. CX 427, Col. 3, line 59 - Col. 4, line 4; Col. 7, lines 3-9.

25. Dr. Munnerlyn currently serves as a science and technology advisor to VISX's R&D group. Munnerlyn, Tr. at 120.

26. Dr. Munnerlyn was one of the founders of VISX. Munnerlyn, Tr. at 125.

27. Dr. Sowada qualified as an expert in lasers and particularly, beam delivery systems using an optical proponent. Tr. at 1421.

28. Dr. Sowada testified as follows:

[

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Sowada, Tr. at 1428-33.

29. Dr. Eden qualified as an expert in lasers and optics. Tr. at 669.

30. Dr. Eden testified as follows:

[

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Eden, Tr. at 732-33.

31. Dr. Eden testified as follows:

Q And in the context of Dr. L'Esperance's examples, the size of the spot impinging on the eye 11 would either be 30 microns or one-half by one-half millimeter, correct?

A In those two examples, that's correct.

Q That presumably could be done by the scanner 14?

A Presumably.

Q And would the scanner 14 also have to have within it then some lenses to reduce the size of the 193-nanometer excimer laser pulse emitted from laser 13?

A Unless the laser being produced by the laser would -- well, there would have to be some focusing.

Q So at some point, you would agree with me whether it is the box 13, or figure 13, or scanner 14, there must be some lensed system to reduce the size of the beam before it leaves the scanner and directly onto the eye?

A What I was objecting to earlier was you wanted to include them in box 13. You wanted to include it in the laser means. Now you're saying now you want to connect it to the scanner; is that right?

Q Would you agree with that interpretation?

A I'm saying there clearly is a lens in scanner – excuse me, in 14, because we are told the spot size can be as large as 7.5 millimeters.

Q To reduce it in size, to reduce it in size as L'Esperance discloses, there would also have to be some objects in the scanner 14 to reduce the beam in size before it was output from the scanner and directed onto the eye 11?

A We need to be careful. My understanding of the Microscan 771, which is given as the only example of a suitable scanner, was not capable of producing 30 micron spot sizes. So I think we need to be a bit careful.

Q In that sense, Dr. L'Esperance made an error in his patent?

A I think he's implying there must be an additional lens somewhere if it's to do that.

Again, I would interpret that, simply, Mr. Siegel, by saying one skilled in the art would know there's a wide range of possibilities. One of them is to produce much larger spots than you suggested.

Q The claim in -- the claim, in fact, doesn't define a large spot. The claim requires a small spot, doesn't it?

A It does. It is a relative term, yes.

Eden, Tr. at 849-50.

32. Dr. Munnerlyn testified as follows:

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Munnerlyn, Tr. at 185-188.

33. Dr. Munnerlyn testified as follows:

[

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Munnerlyn, Tr. at 277-79.

34. The lens, rather than the scanner, disclosed is responsible for sizing the beam. See Munnerlyn, Tr. at 277-79.

35. Dr. McDonnell testified as follows:

> Q Would the 3-millimeter spot provide acceptable smoothness?
>
> A No. As can be seen, it would leave these very large jagged treatments, so it would not be smooth.
>
> Q Let's go to the next one, RX-760, the 2-millimeter spot.
>
> A This next is using a 2-millimeter spot. So one can squeeze in many more now, stay within the 6 millimeter diameter, and if one then makes a cross-section of how this might look -- we are dividing it into three, and then there would be two, and then a single treatment in the center, and that would result in each one of these steps having 20 microns, about 20 microns of depth from the edge of the ablation zone to the center of the ablation zone.
>
> Q Let's look at the next one, the 1-millimeter spot.
>
> A This shows again how as this surface area of the -- as the diameter area decreases the surface area of these spots, these circles, very much decreases, and one can stick a lot more of these circles in that area. I think one can appreciate how the spots or the steps associated with this become smaller and smaller.
>
> So at the bottom in the cross-sectional area, you can see now that to achieve approximately a 60-micron deep ablation, each of the steps is now reduced down to about 10 microns in vertical distance.
>
> Q Doctor, do these spot sizes then demonstrate a

correlation between spot size and ultimate smoothness which is obtained?

A Yes. As the spots become smaller and smaller in diameter, the overall smoothness of the surface dramatically improves and comes closer and closer to resembling the smoothness one would expect of a lens.

Q Is that what this Exhibit RX-762 shows?

A Yes. My goal here is to try to show visually by comparison what would be the difference, let's say, at the top between a rough ablation that would be done with the 3-millimeter spot, where each of these steps is 30 microns deep compared to the very small 30-micron spot illustrated by L'Esperance, where at this scale it comes close to resembling a smooth line.

McDonnell, Tr. at 1040-41.

36. Dr. McDonnell testified as follows:

Q And with respect to this half millimeter by half millimeter spot size, Dr. McDonnell, is there a relationship between the size of the spot which ablates the ultimate smoothness which is ultimately obtained?

A Yes. Because the way it works is, because it is breaking it up into little areas, each of successive ablations, the smaller the spot, the smoother the end result because it is broken up over -- with a larger number of spots, that the little separation from one spot to the next and the steps that we call -- we call them steps, the steps down will become less and less.

Q And what's the significance of smoothness in the context of the refractive procedures that we're talking about here?

A Well, the ablation needs to be smooth for two reasons. If the corneal surface is left rough and irregular, then that will degrade the vision just as a pair of glasses that are scratched or contacts that are scratched or have debris on them. So it very much affects the quality of vision.

Second, we understand the way the cornea heals, that a very rough or irregular cut or shaving of the cornea will stimulate a more intense healing response, which would be more likely to result in a scarred, cloudy, irregular

cornea.

Q Dr. L'Esperance's patent provides a second example of a 30 micron spot. This is Exhibit RX-757. Let me place that up on the screen here.

Explain to the Court, if you can, Dr. McDonnell, exactly what's the relationship of this 30 micron spot to the issue of smoothness.

A Well, one can see just on inspection that by using the small spots, you can -- you could put a lot of spots in there. There are almost no areas where you can't put a spot without going outside the perimeter.

And because it is so many spots, it is broken up into such a gradation that the corneal looks very, very smooth. On this scale, one hardly can appreciate in the cross-section any irregularity with these steps that would result.

Q So conceptually, conceptually, if you had your choice of spot size, would you make it larger to smaller to achieve the necessary smoothness?

A Well, to achieve -- you know -- just a perfectly smooth result, one would ideally have an infinitely large number of infinitely small spots to use -- to do this procedure with.

Q Would the result be that it would make an infinitely long amount of time to do it?

A Yes. That's been the problem or the issue with scan lasers has been in general with this spot size. If it is small, it takes longer to transverse across the cornea, fill in these areas, and therefore, it can be -- take a lot longer than so-called broad beam lasers.

Q Let's just digress for a second. Let's talk about this issue of time since it has come up. To what extent is the time of the procedure that you perform on the eye significant, in terms of procedures which may result in the same overall result to the eye, but take much longer for you as a refractive surgeon to perform, as opposed one which can be done in a relatively short time frame?

A There really are two issues with length of the procedure. One is that the way that we know and line everything up according to the optically useful part of the cornea is that there's a blinking target light that the patient is asked to maintain fixation on during the procedure. And patients have a tendency to have what are

called saccades or microsaccades, where the eye will move essentially almost involuntarily. The longer the procedure takes, the more likely the eye is to move during the procedure, which obviously would result in ablation of the wrong part of the cornea until the surgeon could stop the procedure.

So that would lead to a less optimal result.

The second part of the time issue is the fact that once the lid speculum is placed in the eye so the patient can't blink and the light is under the eye of the operating microscope, the cornea begins to thin, begins to dehydrate. And so not only is there the issue of knowing at what rate the cornea bleeds, but if the procedure took a long time, the ablation rate within that tissue might actually be changing even as the surgery is being performed.

So our goal as surgeons is not to dally at all when performing this procedure, but to move fairly quickly once we get going. And so a procedure that took a long period of time would result in greater uncertainty in terms of this variation in hydration of the cornea and variation in the ablation rate.

Q We'll talk about spot size again. Excuse me for the digression.

From your perspective as a refractive surgeon, is there a practical maximum spot size in the scanning lasers that provides a degree of smoothness, taking into account the time constraints that you need to address?

A Practical maximum is between -- is close to 1 millimeter spot or slightly smaller.

Q Why is that?

A The -- I believe -- well, it is a number of issues that you looked at. There are several companies working on this issue, a lot of people working on it over the years, and the -- about 1 millimeter seems to be the way to go in terms of the smoothness, in terms of achieving some compromise between the smoothness of the ablation.

I have some other drawings showing what happens if you try to go larger. The steps become very large, and it becomes uneven. The time required for the procedure, because if a spot was made much smaller than 1 millimeter, it would take much longer to complete the surgery.

McDonnell, Tr. at 1032-36.

37. RDX 119 shows a comparison of various spot sizes relevant to this claim construction issue. See McDonnell, Tr. at 1037.

38. The unaltered beams of commercially available lasers in 1983 did not produce a spot size small enough to perform the ablation scanning patterns taught by the '418 Patent. See Sowada, Tr. at 1429; Eden, Tr. at 840.

39. The '418 Patent specification provides examples of spot sizes of 0.5 mm by 0.5 mm, and of 30 microns. CX 427, Col. 4, lines 13-15, Col. 6, lines 59-67.

40. U.S. Patent No. 4,732,148, entitled "Method for Performing Ophthalmic Laser Surgery", issued to Dr. L'Esperance, contains a statement distinguishing its disclosure from that of the application leading to the '418 Patent based on the former using a varying spot size for the treatment procedure, indicating that the '418 Patent discloses a spot whose size does not vary. See RX 5, Col. 2, lines 21-28.

41. Dr. Eden testified as follows:

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Eden, Tr. at 736.

42. Dr. Sowada testified as follows:

[

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Sowada, Tr. at 1433.

43. Dr. Sowada testified as follows:

[

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Sowada Tr. at 1435-36.

44. Dr. Eden testified as follows:

[

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Eden, Tr. at 902.

45. Dr. Sowada testified as follows:

[

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Sowada, Tr. at 1439.

46. Dr. Eden testified as follows:

[

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Eden, Tr. at 902-05.

47. According to the manufacturer's literature on the Microscan 771, it was a "microprocessor-controlled microsurgery unit" and included an electronic control box and

a control console. CX 206 at NC00720058-59. The literature makes clear that these controls allow the operator to control the area or line to be scanned as well as its size and the scanning speed. CX 206.

48. The '418 Patent specification states in part:

> The laser device 13 is served by a suitable power supply 15, and the scanner means 14 includes selectively operable control means, suggested by legend, for determining scan pattern, effective limits of scan action, and, if desired, the time-varying profile of one or more dimensional components of scan action.

CX 427, Col. 3, lines 17-22.

49. The '418 patent specification teaches that lens element 26 can "bring [the beam dimension] down to an illustratively useful rounded-square spot size" by reducing and compressing the beam. CX 427, Col. 4, lines 13-20.

50. The '418 Patent specification states in part, "[f]or the indicated Lambda Physik [laser] equipment, spot-size reduction is feasible via means 26 [corrective lens element 26]". CX 427, Col. 6, lines 61-63.

51. The '418 Patent specification teaches that the Microscan 771 includes a programmable microprocessor that can be programmed for the scan speed and direction, and to delineate boundary limits of scanning. The specification further teaches that these may be manually controlled. CX 427, Col. 4, lines 33-39.

B. '762 Patent

52. The prosecution history of the '762 patent reflects the cancellation of claims directed to dental caries and skin lesions. CX 706, tab 21; RX 4.

53. Dr. Sowada testified as follows:

Everything before the cornea -- between the cornea and the laser itself which emits the beam is the so-called beam delivery system. And the whole thing is considered to be a surgical device for performing ophthalmological surgery.

Q Doctor, is it important for the shape that hits the cornea to have the same shape of the mask 30?

A It is important in order to achieve reproducible results or predictable results. When you want to irradiate certain pentam of the cornea so that you can predict what it will be, it will be like in a stencil, in so-called mask number 30.

Q And how would you characterize this mask 30?

A This mask 30 is a so-called "contact mask."

Q Can you explain what you mean by contact mask?

A Contact masks have been used in semiconductor manufacturing since the early '70s. The word implies that the mask is in contact with the object which receives the image -- which receives the irradiation beam. However, it has been found out that upon separating the mask from the wafer in producing semiconductor species, that the wafer can be damaged. And therefore, the so-called proximity mask has been used quite frequently. As far as the application goes, "proximity mask" and "contact mask" mean the same thing.

Q In an example such as that shown on figure 1, what is the relative distance between the 32 and mask 30?

A Due to the properties of the excimer laser beam, this distance should not be larger than about 1 millimeter. If it would become larger, the area defined on the cornea will become blurred and have an uncertain surrounding which would not allow it to have reproducible ablation going on on the cornea, which we must try to strive for.

Q What causes this blurred image if the mask is not close enough to the tissue?

A This is the point which is difficult to understand from this picture, because someone, just looking at this picture, has the imagination that laser rays are all parallel with each other. With an excimer laser, this is not true. An excimer laser is almost like an ordinary light bulb or like the sun, so that if we go away a little bit from the window, the edge of the window frame will become uncertain. And the same thing will happen when you make the separation between the mask and the cornea larger.

Sowada, Tr. at 1453-54.

54. In interference deposition testimony, Dr. Trokel described a figure showing a mask similar to the mask 30 in Figure 1 of the '762 Patent as a contact mask. RX 214 at 142-43.

55. Dr. Sowada testified as follows:

> Q What's figure 2 show, Doctor?
> A Figure 2, according to the patent, shows possible laser beam delivery system to be inserted as a laser beam delivery system in figure 1. However, we note that there's no contact mask shown, and as I have said earlier, laser beam delivery means in the description of figure 1 should include the mask. But one can, of course, imagine that the mask be placed to the right side of this laser beam delivery system.
>
> This delivery system consists mainly of single lens, number 54, which focuses the parallel incoming beam, number 52, to a smaller diameter. It is housed in a casing, which is normally done in order to allow safe operation with the laser beam, and it has some means that are openings, 60 and 62, to allow streaming flow of nitrogen gas through it. In the patent, it is said that one should apply stream -- the streaming nitrogen gas from number 60 and let it flow out at 62.
>
> I would not recommend this because this would tend to bring debris which is produced on ablation at the surface of the cornea towards the lens, number 54, which then could be burnt in in a sense and make the lens eventually opaque. Optical engineering, usually the stream of the gas is the other way around, but I think this is a minor point concerning the description of this picture.
>
> Q Just briefly, Doctor, what does the flow of nitrogen do?
> A Flow the nitrogen is very helpful in order to maintain the intensity of the beam and avoid reduction of ozone, which is typical for the fact if you transmit a beam from an excimer laser at 193 millimeter to air containing oxygen, and this ozone is toxic.

Q Is the use of nitrogen unique to an excimer laser?

A No, it is not unique to laser beam.

Q Doctor, how do you know that figure 2 is to be used in the apparatus of figure 1?

A I think I have seen in the description where it says so.

Q Column 2 of the patent?

A Yes. There at line 64 it says figure 2 is a schematic illustration of the laser delivery system for use with the apparatus and system of figure 1. So one could take this and plug it into figure 1.

Q Would you characterize figure 2 as an imaging system?

A Never.

Q And please explain.

A There's no mask which is going to be imaged, and these lines which are shown to go through from the left side to the right side are meant to represent rays. These rays should show that an image is going to be constructed. That is not shown in this picture.

Q Please explain to the court what figure 3 shows.

A Figure 3 is, according to the patent, a so-called ophthalmic delivery system. I have thought about this figure for a long time to understand it, and the first thing is why it is ophthalmic. It shows on the right side an eye symbolized by item number 92, and this may be the reason. We see in the figure above figure 2, from the left side parallel rays coming, and they impinge on number 84, which is called "variable slit." The variability is demonstrated by the down arrows.

From there on, the lines number 82 are not continuing, but two new lines which are not parallel to the previous ones are emerging, coming onto a lens number 86. From there on, these lines are combined and crossing each other at item 88, which is called an "aperture." Going on to item 90, which is another lens, and then eventually being combined in one spot on the cornea. In order to understand an optical memory system, you can either start from the left side and develop the understanding of the propagation of the rays to the right side or do it the opposite way.

For me, it is easier to start on the cornea. If we see where the rays are combining on the cornea, then this is going to be the image point of an object from which these

two rays have commonly started. And that is the center point of aperture 88. Therefore, this picture shows that lens number 90 produces an image of 88 onto 92. There are other components in this figure, like lens 86 and the variable slit number 84.

What do they do? This is very difficult to understand, and the best explanation I can come up with is that number 84 produces an intensity distribution upon 88. The intensity of it can be modified by changing the separation of the variable bars. By opening up, more of the laser beam will be transmitted. By closing them down, less will be transmitted. So 84 will be something like very good attenuator of the beam, but the image, if it is supposed to image, then the object which is image 88.

Sowada, Tr. at 1455-57.

56. Dr. Sowada testified as follows:

Q Are you saying, Dr. Sowada, then, to make this work, you would have to move aperture 88 closer to lens 86 to allow the chief rays to pass through?

A That's exactly the right position, yes.

Q Dr. Eden has testified that aperture 88 could play the role of blocking some of the marginal rays, and if you move aperture 88 closer to 86, would it block some of the marginal rays?

A Yes. Right now, it has the function of blocking the chief rays. If you move it closer to lens 86, it will block marginal rays. But the question is whether we want to have the marginal rays in an imaging system where we want to reproduce the object intensity at the mask on to the cornea. Whatever rays we block will be missing on the cornea and will not allow faithful reproduction.

Q Now, does this patent explain how figure 3 is to be used?

A Excuse me. Can you explain that?

Q Sure. If we look at column 2 of the patent.

A Yes, it says it is an ophthalmic delivery system for use with the apparatus and system of figure 1. Therefore, because I do not believe that aperture 88 -- I'm sorry, aperture variable slit 84 is onto the cornea, it may be used in connection with a contact mask.

Sowada, Tr. at 1466-67.

57. Dr. Eden testified as follows:

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Eden, Tr. at 682-683.

58. Dr. Eden testified as follows:

Q And the lens 90, however, is a part of Dr. Trokel's major accomplishment; it is the second lens in his two-lens system, isn't it?

A As I said earlier, my statement in my expert report, and I stand by that, is, it is the combination of an

imaging system with the opening diaphragm that I consider to be a really clever development, Mr. Siegel.

Whether it is one lens or two lens imaging system is not the major point.

Q In your expert report, Dr. Eden, you weren't quite that general. You said one of the major contributions made by Dr. Trokel in the '762 patent was to take a conventional two -- lens plus aperture imaging system and combine them with a variable aperture at the object plane. That's what you said, didn't you?

A Which someone skilled in the art would understand would be similar to a single lens imaging system or a five lens imaging system, Mr. Siegel.

Q But, in fact, in your third panel you have eliminated one of the lenses, haven't you?

A That is correct, because for a corneal system, a corneal surgical system, the inversion of the image that is accomplished by the second stage of the imaging system is not crucial.

Eden, Tr. 818-19.

59. In the '762 Patent specification, Figure 1 is described as "a schematic illustration of a photoablation apparatus and system incorporating the instant invention". RX 3, Col. 2, lines 62-63.

60. In the '762 Patent specification, Figure 2 is described as "a schematic illustration of a laser delivery system for use with the apparatus and system of FIG. 1". RX 3 Col. 2, lines 64-65.

61. In the '762 Patent specification, Figure 3 is described as "a schematic illustration of an ophthalmic delivery system for use with the apparatus and system of FIG. 1". RX 3, Col. 2, lines 66-67.

62. In the prosecution history of the '762 Patent, an interview summary record by the examiner includes the following statements:

> The disclosure relating to Figure 3, discusses a variable slit (element 84). The slit as described would enable one having ordinary skill in the art to apply a variable intensity [footnote] across the ablated area over time. That is, changing the area of the variable slit (element 84, Figure 3) changes the area of the ablation spot of the eye (element 92, Figure 3).
>
> [footnote reads: "The meaning of the term "intensity" as used here is intended to be the same as that ascribed to this term in the originally filed specification: energy per unit area ....]

CX 710 at 082361.

63. In a declaration submitted in the '026 Interference, Dr. Munnerlyn of VISX, referring to the same figure as Figure 3 of the '762 Patent, stated that:

> With specific reference to Figure 3 of the Trokel patent applications, the laser beam incident upon the aperture 84 has an illustrated divergence which is collected by the lens 86 and focused through the secondary aperture 88.
>
> ***
>
> The lens 90 is used to magnify the image at the aperture 88 onto the eye 92.

RX 249 at 10-11.

64. Dr. Eden testified that he agreed that Dr. Munnerlyn's interference declaration indicated that the lens 90 is used to magnify the image at aperture 88 onto the eye of 92. Eden, Tr. at 1648.

65. Dr. Srinivasan testified as follows regarding Figure 3 of the '762 Patent:

> [

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Srinivasan, Tr. at 1217.

66. Dr. Trokel testified as follows:

> Q Was figure 3 an adaptation of a drawing that Dr. Srinivasan had given to you?
> A Yes.

Trokel, Tr. at 403.

67. In correspondence dated October 20, 1983, Dr. Trokel referred to Dr. Srinivasan's "knowledge and skills in ... preparing the difficult delivery system" as "essential to this project". CX 231.

68. Dr. Motamedi qualified as an expert in lasers and laser tissue interaction. Motamedi, Tr. at 483.

69. Dr. Motamedi testified as follows:

> Q But based on the studies that had been done subsequently, and the errors that had been found in those studies, have you been able to quantify at all what you mean by a multiple?
> A It's -- as I said during my deposition -- you know -- it would be a multiple. One, two, three, four. I would feel very comfortable repeating what I stated in my deposition. Two and three would be very comfortable. If you go further down to that, my confidence in that would be less.
> Q To make sure I understand what you're saying, you're saying that approximately 1 micron --
> A Right.
> Q -- would be understood in 1983 to be how much?

A 2 micron, 3 microns.

Motamedi, Tr. at 505.

70. Dr. Motamedi testified as follows:

Q Right. If you could maybe list the types of [depth measurement] errors that you were just referring to.

A The errors that I am referring to can be characterized into three categories.

One is the effect of the tissue on any measurements, that is, any type of alteration or any changes that the tissue may have, and its effect on the response that we will assess to measure the depth of ablation.

The other one is the error, the source of errors that are associated with the measurements of the final effect, ultimate effect of the laser; that is, how we measure the depth and size of the crater that is induced by the laser radiation in the tissue.

The third one, the errors that are associated with the -- with measuring the parameters of the lasers that - describing the configuration of the beam, the energy the beam carries.

Each one of those steps will have certain errors associated with them.

Motamedi, Tr. at 490-91.

71. Dr. Eden testified as follows:

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Eden, Tr. at 711-12.

72. Dr. McDonnell testified as follows:

> Q If we refer to column 5, beginning at line 55, and I will project that up, if I can. Let me read it. It says, "Radial incisions as well as concentric rings in crescents can be accomplished with the described apparatus and method."
>
> Do you see that?
>
> A Yes.
>
> Q What would you understand radial incisions to be in 1983?
>
> A Radial incisions, the reason that that was of great interest in 1983 was the common refractive surgical procedure at that time was radial keratotomy, in which a series of radial incisions were made in the cornea to treat nearsightedness.
>
> Q Do you, Doctor, have a specific experience in performing RK procedures?

A Yes. I was trained to do RK in my fellowship and performed it after my fellowship; and at USC we were one of the centers in the nationwide trial radial keratotomy called the Perk study.

Q Was RK a known procedure in 1983?

A It is an operation developed in Russia that came to this country in 1978.

McDonnell, Tr. at 1046.

73. Dr. McDonnell testified as follows:

Q If the range of precision, shall we say, was more than 10 percent, extrapolated out to 20 percent, and the result was a cut that was too deep, would you cut all the way through the cornea then?

A Yes.

Q I take it that would not be considered a successful outcome, would it?

A No. That would be a significant complication.

Q If the range of precision resulted in a depth of cut that was an undercut by 20 percent, the successful outcome have resulted in that case?

A No. If you went only, let's say, 70 percent depth, it would be not very useful as a correction for the nearsightedness.

McDonnell, at Tr. 1051.

74. Dr. Trokel testified as follows:

Q Finally, Doctor, would you explain to the Court what -- I heard you mention RK before. Is that radial keratotomy?

A RK is the commonly used description for the surgical procedure known as radial keratotomy, which describes the operation.

As you can see, a series of radial incisions in the periphery of the cornea allow the center of the cornea to flatten, which changes the optics of the eye.

This has been -- prior to the advent of the excimer laser was probably the largest, most commonly used refractive surgical procedure.

Trokel, Tr. at 313.

75. Dr. Trokel testified as follows:

Q And if the clinician for some reason made a depth of incision that was too great, say 10 percent too great, so that he cut 500 microns deep, would that have yielded a successful result?

A You mean cutting with a knife, sir?

Q Yes.

A It could be. Micro perforations were not uncommon. They were an unhappy result.

Q If he undercut by 10 percent, or overcut by 10 percent in the case of RK, I take it the result would not have been one of a satisfactory result for the patient?

A No. I didn't say that. I said small overcorrections were clinically acceptable. Undercorrections didn't work. If you didn't cut deeply enough, it wasn't effective. Small overcorrections were – produced a small leakage, which was reasonably acceptable to the surgeons.

Q And if he overcut by 15 percent through the cornea, would that have been successful?

A If he paid a complete incision through the cornea, that would have been unsuccessful, that's correct.

Q And I take it when you were conceptualizing the use of this excimer laser and its use, for example, in an RK environment, you would expect to achieve at least this precision of 90 to 95 percent depth of incision?

A Yes.

Trokel, Tr. at 377-78.

76. Dr. Sher testified as follows:

Q Dr. Sher, could you estimate for the Court how many laser refractive cases you have done over the course of your career?

A Over 1000.

Q And are your nomograms based on your clinical experience?

A My nomograms are based on my clinical experience and are constantly changing.

Q And today, what kind of accuracy do you receive on the results that you get?

A The accuracy was quite similar to what Dr. McDonald said. It really depends -- I'd like to be plus or minus 10 percent. Meaning if you're within .3 or .5 diopters you're quite acceptable. A 10 diopter myopic patient, your accuracy would be a diopter off each way or more. So these results are constantly changing, constantly improving, as Dr. McDonald [sic -- McDonnell] pointed out yesterday.

Sher, Tr. at 1535.

77. Dr. McDonnell testified as follows:

Q Half a diopter. Just to put it in perspective, if we can give the Court an example at least that I'm familiar with, when we go to the ophthalmologist and get fitted for new lens and you get down to the end and the ophthalmologist flips that glass, and says, is it better this way or better that way -- in my case it is never better -- but can that be quantified in terms of diopters?

A The which-is-better-1-or-2 question, the smallest increment we usually measure refractive correction is 0.25 diopters, or one quarter of a diopter.

So the goal with glasses is to get accuracy within about one quarter of a diopter.

Q For glasses?

A For glasses.

Q Let's, if we can, consider the range of acceptable levels of ablation using a laser procedure in terms of diopters. And using some examples that I think we've already set forth in your report, but let's just go through them in the math. If we consider first a 12 -- excuse me, a 5 diopter myopic procedure, 5 myopic, and assume if we can the numbers used in this investigation to date, it takes approximately 12 microns to ablate to 1 diopter.

May I use the paper there, Your Honor?

JUDGE MORRISS: Yes.

MR. SIEGEL: Thank you.

BY MR. SIEGEL:

Q Can you get it? Let's start with that 5 diopter myopic. At 12 microns for 1 diopter, how many microns would

you then have to ablate to get to the 5 diopter?

A The formula is actually somewhat complicated. The rule of thumb is 12 microns per diopter, so that would be for 5-diopter correction, using D as the abbreviation, that would be about 6 microns of removal of the tissue right in the very center, because it is sloping. So there's very little tissue removed toward the edge and maximally in the center. The maximal center removal would be 60 microns.

Q Then if half a diopter was the desired range, how would that translate into microns at 12 microns per diopter?

A One-half diopter equals 6 microns.

Q In the case, then, of a 5 diopter myopic change, what does a half a diopter represent in terms of percentage of the total material to be ablated?

A That would be, half a diopter would be 10 percent of the total of 60 microns.

Q Would that be considered an acceptable range of accuracy in the context of these laser procedures that are being used today?

A Yes. I think patients who say that -- they'll only be happy if they have perfect 20-20 or 20-15 vision, we try to discourage from doing it, because we can't promise that, because there's also the issue of how people heal, which is different among people.

But a 10 percent in this situation, you get people -- to get this person to -- in the 20-20 to 20-25 range would be, I think, considered by most patients to be acceptable.

Q Would that be also within the range of correction that you could do or a ophthalmologist could do for my glasses, get me within half a diopter?

A Almost -- almost certainly. With glasses, most people, unless they have some disease, should definitely be 20-20, which is either half a diopter or quarter diopter.

Q Let's consider a second example. Let's consider a 10 diopter myopic change. And to effectuate a 10 diopter myopic change, how much corneal tissue would then have to be ablated?

A Take twice that. 10 diopters would mean that in the very center of the ablated area, 120 microns out of a central thickness of 500 or so, about 120 microns would be removed.

Q And if we wanted to have again this -- a 10 percent error rate, what would a 10 percent error equate to in terms of the number of microns permitted in that procedure?

A Well, 10 percent would equal a 12 micron, which is essentially equal to 1 diopter. Difference in terms of refraction.

Q And if we wanted to get down to the 5 -- excuse me, the half a diopter target, the ideal target -- what would be the range of variability there?

A To get half a diopter correction, the variability could only be 5 percent of 6 microns.

Q Doctor, to put it in perspective, is 10 diopter myopic change considered to be a rather extreme procedure performed using this equipment?

A Yes. Well, the laser -- lasers have different approval limits. I think VISX's lasers are approved to treat up to 12. Nidek, I think, is approved to treat 13 or 13 and a half. In this country, 90 percent of all nearsighted people are 5 diopters or less. To get above 5 diopters is relatively severe.

MR. SIEGEL: If I can hand the witness the eye chart for a second, Your Honor.

BY MR. SIEGEL:

Q If you can explain to the Court, then, in the context of these two procedures, the 5 diopter and the -- how does that correlate to the ability of the refractive surgeon to get a person down to a level that he could -- he can read that chart without glasses after he has the procedure?

A Well, if a person is 5 diopters or 10 diopters nearsighted and sitting in the exam chair, they probably do not see the E at all.

Q Cannot read the E?

A Cannot read the E.

Q Okay.

A If they get -- if we get a 5 -- if we get a 10 percent, so that they're within 5 diopter -- within half a diopter of the final desired correction zero, then that patient could probably see either the 20-20 or 20-25 line.

Q That 10 percent variation down to half a diopter would give a very -- I take it, it would be an acceptable result for a person that comes in and can't read the E.

A You have to be careful with certain patients who are very perfectionistic. Engineers, for example, will have --

Q Be careful?

A -- will have trouble if they don't get perfect. They are used to seeing perfectly. But for most people, studies show they are highly satisfied with vision in this range.

Q And in the 10 diopter correction, which you indicated was somewhat extreme, what would be the level of precision you would expect in terms of the ability of a patient to be satisfied after he has a procedure done?

A The more extremely hyeropic patients are often satisfied with less than perfect vision because they feel disabled to start off with. So if we got a 10 percent variability, we are within 12 microns. That would be 1 diopter, which would be about 20-40 on the eye chart, which would let them drive without glasses, although they still might wear glasses at least part of the time for activities where they feel they need 20-20 or 20-25 vision.

So it would make them, we think, functional. So we try to only do patients at that high level that feel that this would be an acceptable outcome.

McDonnell, Tr. at 1054-58.

78. Dr. Trokel testified as follows:

Q . . . Dr. Trokel, you have performed excimer laser surgery on patients in your practice; is that correct?

A Yes.

Q To your knowledge, what is the acceptable level of variation from a surgeon's standpoint in refractive corrections?

A Probably 10 percent.

Q Can you explain that a little bit more specifically? 10 percent of what?

A Laser manufacturers and surgeons have one goal in mind with these systems. They constantly strive to make that number smaller, to improve the results. And while initially a fairly substantial error or standard deviation perhaps was acceptable, that has -- the answer to your question has been a target which has changed over the

years.

I remember the very first studies we did, the standard deviation was 2 diopters. After some changes, the standard deviation was down to 1 diopter. Now the standard deviation is down to perhaps half a diopter, a little bit less.

The standard deviation of our ability to measure the refractive state of the eye is perhaps half a diopter, three-eighths of a diopter.

So we progress on several fronts. We improve refractive technology. We improve our ability to analyze the eye. We improve the ability to make the laser more stable. We improve the techniques for calibrating the laser so that we can assure its output.

So the -- it is a reasonable question that sounds like it has an easy answer, but the number has been getting smaller, and happily so, which explains the broad acceptance of the technology.

Q When you use the percentage of 10 percent, are you thinking in terms of microns of ablation or diopters?

A That was a rough estimate of a 5 diopter average myopic refraction. A half a diopter might be the kind of standard deviation you get -- you know -- this has been a reasonable working number, although I think we are probably better than that today.

Trokel, Tr. at 415-17.

79. Dr. Trokel testified as follows:

Q At either the first or second session at IBM, did anybody measure the depth to which the corneas were be ablated?

A Not when we were at IBM, no.

Q Now, did you, Dr. Trokel, measure ablation depths?

A Yes, I did.

Q Why did you do that?

A Because it was critical to understand the precision of this. And the precision of this was really based on how much or really, rather, how little tissue could be removed with each pulse of laser light. And I was astonished to find out even in my first preliminary measurements that I was removing roughly a quarter of a

micron of tissue, because that was roughly half a wavelength of light.

***

Q Now, did you have a sense back in 1983 as to how accurate your measurements of ablation department were?

A Oh, I knew there were a lot of problems with the ablation depth measurements, yes.

***

Q Now, in your mind in 1983, was the ablation rate significant as part of your work?

A Absolutely, yes.

Q What was the significance to you at that time of the ablation rate?

A Because if you are going to reshape the eye in a manner similar to that prescribed by Professor Barraquer, you had to know in advance how much tissue you were going to remove. If you wanted to take out one diopter of corneal power, you had to be able to calculate exactly how much tissue you were going to remove.

Turns out, for a 6 millimeter area, it is about 12 or 13 microns of tissue.

And the accuracy is based on the amount of tissue you can remove with each little pulse of light.

And the fact that ultimately it turned out to be a fifth or even less of a micron per diopter meant that each diopter had about 70 or 80 or a hundred successive layers of tissue that were removed, which means you increased the accuracy about a hundred times over what Professor Barraquer had, which means that you can do precise machining of the cornea.

So we had to get some estimate of those numbers. Our estimate was that it was a fraction of a micron per pulse; and that, I thought, was really showed for the first time you had a new kind of surgical approach to the eye.

Trokel, Tr. at 349-53.

80. Dr. Sowada testified as follows:

You cannot say exactly, because at the time of 1983 in the laboratory, he did not have a measurement device which would give completely, 100 percent reliable readings. The energy meters available in 1983 had a precision of roughly

25 to 30 percent. Therefore, I believe this claim 1C, especially the approximately, must be interpreted in terms of plus or minus 25 to 30 percent.

Sowada, Tr. at 1469.

81. Dr. Sowada testified as follows:

Q And now you have changed your opinion to say that the approximately 1 micron must take into account the difficulty of measuring energy; correct?

A Not completely correct. What I meant in the claim 1C of the '762 patent is that in the meantime, I have reached the understanding that this is helping hint for the man or woman who designs such a device in order to achieve a result which is acceptable to an ophthalmologist.

Q So in your view, 1 micron -- the 1, approximately 1 micron could be plus or minus 25 to 30 percent; correct?

A This is the goal that the skilled person that I envision would strive for, yes.

Sowada, Tr. at 1488.

82. Dr. Motamedi testified as follows:

Q I take it then, Doctor, you would agree with me that a 30 percent variation would fall within the range of element C?

A Obviously. That would clearly be --

Q .97 to 1.3 would clearly be within the range of element C, correct?

A Very much so.

Q Do you recall in the FTC investigation you testified that a 30 percent variation would be pretty close to the range of element C?

A Yes.

Q And in your FTC deposition -- I'm sorry, trial testimony -- you didn't say it was obviously within the range of element C, did you?

A No, I didn't. But I wasn't asked where the range would stop. I said it's pretty close, but I was never asked what the range would be.

Q I have your FTC testimony here.

And beginning at page 5175, line 1, the question is, "And in your opinion within the meaning of the '762 patent claim would 1.28 be approximately the same as 1?"

Then your answer is set forth below. Do you see that?

A Yes, I see that.

Q I highlighted you said, "I would say this is pretty close."

A I still believe that today.

Q I believe you also said the bottom portions where I highlighted, "A 30 percent error difference, I would think, is not out of range of what is stated in this claim."

Do you see that?

A Yes. And it is in agreement with what I said today.

Q But you didn't say it was obviously within the range; is that correct?

A It is a matter of choice of words. I don't think what I'm saying today is any different than what I said there.

Q Okay. Let's look at the next page of 5177.

The question is, does Dr. Trokel – sorry.

Does Dr. Trokel in the '762 patent define what "approximately" means?

The portion highlighted. So I would think that approximate would be a reasonable -- cover that range that we are talking about. I mean, if this turns out to be a hundred microns or 10 microns, or even 5 microns, then I would say, oh, well, the therapeutic outcome may be quite different.

But then the question is, let's say if it is done with 30 percent more or less, what is the consequence of that from the end point. And I would say that in any of these procedures, that kind of variation could occur.

Do you recall that testimony?

A Yes. I believe this is in complete agreement with what I'm saying today.

Q In this testimony you said that 5 microns was out of the range; do you recall that?

A Where did I say out of the range?

Q Line 23.

A I would say it is -- outcome may be quite different. It is out of the therapeutic range. I'm not

talking about the therapeutic approach. We are talking about measurements, error that could be associated with the depth of ablation.

I'm not here to opine myself as an ophthalmologist. I'm talking about measurement error associated with ablation depth. That is what you said in here.

Motamedi, Tr. at 555-57.

83. Dr. Motamedi testified as follows:

Q Let's look at RX-414, which is in your binder.

On page 3, left-hand column, do you see the definition of "approximately"? Reasonably close to, nearly, almost, about?

Do you see that?

A Yes, I do.

Q Would you agree with that definition in the context of claim 1?

A Yes, I do.

Motamedi, Tr. at 551.

84. Dr. Motamedi testified as follows:

Q Okay. Doctor, I believe you have stated at least in your expert report that the term "approximately" should be given its ordinary meaning; is that correct?

A That's right.

Q And in your opinion, to somebody of ordinary skill in the art in 1983, there would have -- they would have understood the word "approximately" to mean approximation; is that correct?

A It would be approximately or approximation, right.

Q Well, turn to page 6 of your expert report, paragraph 17.

A Yes, sir.

Q In the first sentence, do you see that?

A Yes, sir.

Q And you state that somebody of ordinary -- I'm sorry, thus one of ordinary skill in the field of laser-tissue interaction in 1983 would have understood the

word "approximately" as used in claim one of the '762 patent to have meant an approximation or "an inexact result adequate for a given purpose."

Do you see that?

A Yes, I do.

Q And is it your testimony that's how approximately should be construed?

A In the essence of this patent, yes. Considering that the intention of this patent is to teach someone to develop a system, and this is supposed to be serving as a guideline, yes.

Q Using this inexact result adequate for a given purpose, would you agree that the inexact result means that there is a certain tolerance that's acceptable for a given purpose?

A Inexact results mean that there is a certain degree of variation that you could -- you can tolerate and still achieve the given purpose, yes.

Q And in the context of claim 1, isn't the given purpose as we see here laser source surgical method for removing corneal tissue?

A I don't believe that's quite right. As I understand it, a system for use --

Q Right.

A -- of surgical methods, it is the system that is an apparatus that is supposed to be teaching -- is supposed to be taught in this patent.

Q The system is to be used in corneal surgery, correct?

A Of course.

Q It could include refractive surgery; is that correct?

A Of course.

Motamedi, Tr. at 546-48.

85. Motamedi testified as follows:

Q Sure.

Element C does not require exactly 1 micron of tissue to be ablated per 1 joule centimeter squared?

A Right.

Q Doctor, I believe you testified earlier today that

you think the range of ablation depth could cover a multiple of 1 micron, such as 2 or 3; is that correct?

A Yes, I did.

Q Do you recall in your deposition when you indicated that the range could cover 2, 3, 4, 5 or even 6 microns per each accumulation of 1 joule?

A Well, if I have said that, maybe you can show it to me. I did recall that I said it would be 2, 3, 4. It all depends on what studies you would conduct under controlled conditions to provide that range.

But I did -- I do remember saying 2, 3, 4. Maybe I said 5 and 6. I don't remember. Maybe I have.

Q Well, do you recall in your deposition saying or testifying that it would be a multiple of 1?

A Obviously.

Q But it would not be an order of magnitude?

A Exactly.

Q All right. An order of magnitude would be 10, for example?

A That's right.

Q Or .1?

A That's right.

Q But anywhere in between was your testimony?

A But as I said, it would be 2, 3, 4, and that's what I said in my deposition, and that's what I restated today.

Q Reading from your deposition, page 136, line 15: "But in your opinion, is there any range that you will say will definitely be within that limitation element C?

"Answer: As I said, it's a multiple. Whether it is 3, it is 5, it is 6 or 5, I don't know. But it's not -- I can't say that it's not going to be order of magnitude, because I don't think it would happen from the governing processes that are involved."

Do you recall that testimony?

A Yes, I do.

Q And in that testimony, you said it could be 6 or 5; is that correct?

A Yes. As I said earlier today, after you pressed me to come up with a more confined number to define what multiple is, I have gone back and looked at the data that is available to me from Nidek, and from the literature, and as I said earlier today, I have more confidence in 2 than I

would in 6.

Motamedi, Tr. at 553-54.

86. Dr. Motamedi's testimony in this and other proceedings reflects his manipulation of the construction of "approximately 1" to accommodate the infringement analysis of the EC-5000. Motamedi, Tr. at 553-57.

87. "Approximately 1 micron" literally covers a range of .7 microns to 1.3 microns. Sowada, Tr. at 1469, 1488; Motamedi, Tr. at 555-56.

88. Dr. Motamedi testified as follows:

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Motamedi, Tr. at 523.

89. Dr.Trokel testified as follows:

> Q According to entries in your notebook, if there are any, what day did you visit Lamdba [sic] Physik?
>
> A On July 26 of 1983.
>
> Q What did you discuss at Lamdba [sic] Physik when you went there?
>
> A We discussed excimer laser physics, excimer laser operation, and the commercial products that were available. We discussed optics that could be used to move excimer laser light around.
>
> I -- we discussed how to create uniform excimer beams from a rather uneven original beam. And I did not tell them the purpose of this, but they were impressed that I had come to visit them, and they spent a lot of time reviewing this with me.

Trokel, Tr. at 344.

90. Dr. Sowada testified as follows:

> Q You agree with me, don't you, Dr. Sowada, that an iris diaphragm is a mask?
> A Sure.
> Q And that a variable slit is a mask?
> A Yes.
> Q Now, it's correct, isn't it, that using an iris diaphragm or a slit aperture, they don't have to be close to a target to restrict the area of irradiation on that target?
> A I would assume that your question has to be answered by you are incorrect.

Sowada, Tr. 1491-92.

91. The '762 Patent specification identifies the means for controlling of Claim 10 as the laser power supply and control system 24 and a mask. See RX 3, Col. 4, lines 53-57, Col. 3, lines 1-11, 60-65, Col. 5, lines 21-23, Figs. 4, 5, 6, 7 and 8.

92. As to the power supply and control system, the specification teaches that:

> The output of laser 20 is delivered in a series of pulses under control of laser delivery system 22 and laser power supply and control system 24. For each micron depth of corneal tissue to be ablated, one joule per square centimeter was applied.

RX 3, Col. 4, lines 53-57.

93. The control system allows for controlling of the pulse energy density and the pulse repetition rate, which determine in part the volume of tissue ablated. See RX 3, Col. 3, lines 60-65.

94. As to the mask, the specification teaches that "[d]efined volumes of tissue can be removed by masking to control the area ablating the tissue to a predetermined depth." RX 3, Col. 5, lines 21-23.

95. Dr. Sowada testified as follows:

> A Claim 12, a system, according to claim 1, wherein said laser delivery system means comprises means for selectively shaping a surface of the cornea. This specifically addresses itself to the way that the laser beam delivery system in connection with the mask is ending the protection of the cornea where it should not be operated upon and where no shaping should occur and select those portions of the cornea which should be operated upon by placing the mask correctly.
>
> Q When you referred to "a mask," were you referring to something like that shown in figures 5 and 4?
>
> A Exactly.

Sowada, Tr. at 1471-72.

96. The '762 Patent's Figure 1 shows the power supply and control system 24 as a separate component from the laser delivery system. RX 3, Fig. 1; Col. 3, lines 49-51, 60-62.

97. The masks are shown in the patent figures as 30, 110, 120, 130 and 140. The specification also states in part:

> In fact, the laser light of the described method and apparatus can be applied to a circular mask of graded intensity center to edge. This would take away more tissue either centrally or peripherally depending on the distribution of light. The net effect would be either to steepen or flatten the cornea. The ability to make controlled radial incisions, *or to selectively shape the corneal surface*, allows modification of the refractive status of the eye.

RX 3, Col. 5, lines 56-65 (emphasis added).

IV. Infringement

98. RX 765 represents the overall configuration of the EC-5000. Ohtsuki, Tr. at 1321.

A. '418 Patent

99. The parties stipulate that any finding of infringement or non-infringement of Claim 26

can also be applied to Claim 27 without separate consideration of the latter. Tr. at 760.

100. Given my construction of "anterior surface", no party disputes that the EC-5000 is an apparatus for performing ophthalmological surgery by selective ablation of the anterior surface of the cornea with penetration into the stroma to achieve a volumetric removal of corneal tissue.

101. Dr. Sowada testified as follows:

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Sowada, Tr. at 1436-37.

102. Dr. Eden testified as follows:

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Eden, Tr. at 738.

103. Mr. Ohtsuki, an employee of Nidek Co., Ltd., was primarily responsible for the design and development of the EC-5000. Ohtsuki, Tr. at 1317, 1320.

104. Mr. Ohtsuki testified as follows:

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Ohtsuki, Tr. at 1321.

105. Mr. Ohtsuki testified as follows:

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Ohtsuki, Tr. at 1325.

106. Mr. Ozawa is the general manager of R & D medical instruments for Nidek, Ltd., and is also the general manager of excimer lasers. CX 385C at 14.

107. Mr. Ozawa testified in deposition that when the aperture of the iris diaphragm in the EC-5000 is at its smallest, the diameter of irradiation on the cornea is approximately 0.5 millimeters. CX 386C at 132.

108. Mr. Ohtsuki testified as follows:

Q Prior to this litigation, Mr. Ohtsuki, it's true, isn't it, that Nidek always used full width half max to measure the average fluence of a pulse?

A In calculating the average pulse fluence, that was the case, yes.

Q It's correct, isn't it, Mr. Ohtsuki, that during a myopic correction procedure using EC-5000, the aperture starts out at minimum size and projects a spot of .5 millimeters in diameter onto the cornea?

A .5 millimeters is the size of the cornea, the smallest size of the cornea using the iris aperture. However, depending on the conditions of the surgery, it may be larger than 0.5 millimeters. It can be larger than 1 millimeter, depending on the circumstances.

Q Do you know, Mr. Ohtsuki, for the 5 diopter correction that you and Mr. Masters talked about yesterday, for a 5 diopter correction using a 5-1/2 millimeter treatment zone, the iris would start at minimum aperture and project a spot of no more than half a millimeter in diameter; right?

A I do not have the precise calculation data available with me now, so I'm not sure, but I suspect that it starts at 0.5 millimeters.

Q You testified yesterday that for a 5 diopter correction, there would be a hundred scans; correct?

A Whether or not it would be precisely 100, I don't know. It would depend on other circumstances. I would say approximately 100.

Q Approximately 100. The iris will open an increment for each one of those 100 scans; correct?

A That is correct.

Q So if there's a total change in the diameter of the iris from .5 millimeters to 5.5 millimeters, that would be a total change in the aperture of 5 millimeters; correct?

A Yes, if you're talking about the difference between the starting size and ending size, yes, you're talking about 5 millimeters.

Q And the aperture will change in diameter by .05 millimeters with each scan?

A That's not the case.

Q It changes it in different amounts?

A It changes. It varies.

Ohtsuki, Tr. at 1382-83.

109. Dr. McDonnell testified as follows:

Q Dr. McDonnell, if the green rectangle, Dr. Taboada's spot, was considered to be irrelevant to L'Esperance, what conclusion do you reach relative to the Nidek spot shown in blue?

A Well, the Nidek spot dwarfs all the other spots by comparison, not only in common issuance but in cross-sectional area. It would be more dramatic. So if the Taboada spot is irrelevant because it is so large, then the Nidek spot is much more dramatically so.

Q And you projected this now on a 6-millimeter corneal ablation area?

A Yes.

Q Doctor, then, with your understanding of what the history and the patent prosecution was leading up to this phrase "small in relation to the cornea to be operated on," have you formed an opinion as to whether this Nidek spot would be small in relationship to the cornea to be operated on?

A Yes. I think it very clearly would not be small in relation to the area to be operated on.

McDonnell, Tr. at 1043.

110. Dr. Eden testified as follows:

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Eden, Tr. at 733-36.

111. Mr. Ohtsuki testified as follows:

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Ohtsuki, Tr. at 1329-31.

112. Mr. Ohtsuki testified as follows:

[

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Ohtsuki, Tr. at 1326-27.

113. Mr. Ohtsuki testified as follows:

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Ohtsuki, Tr. at 1332.

114. The EC-5000 reshapes the cornea using primarily a relatively large laser spot that is successively overlapped, rather than using a small spot that is rastered without overlap. See Ohtsuki, Tr. at 1329-32.

115. In the prosecution history of the '762 Patent, Dr. L'Esperance distinguished the spot size produced in his invention from the spot size referenced in prior art articles by Dr. Taboada, characterizing the Taboada spots as "irrelevant". CX 211 at 7-8. The context reflects that his characterization was based on the size of the spots. See CX 211.

116. Dr. McDonnell testified as follows:

> Q Doctor, then, with your understanding of what the history and the patent prosecution was leading up to this phrase "small in relation to the cornea to be operated on," have you formed an opinion as to whether this Nidek spot would be small in relationship to the cornea to be operated on?
>
> A Yes. I think it very clearly would not be small in relation to the area to be operated on.
>
> Q Let me ask you one question before we break for lunch. Is it your understanding this spot was scanned across the aperture?
>
> A Yes. The way the Nidek works is it is scanning in one direction across the -- across the surface of the cornea that's exposed by the iris diaphragm.

Q So am I correct that at periods of time, you might see a piece of this pulse being exposed through the aperture?

A Yes.

Q Would that fact change your opinion in any way with respect to the size of the spot in relation to the cornea to be --

A No.

McDonnell, Tr. at 1043-44.

117. The EC-5000's laser means does not consistently produce a small spot throughout a procedure. See Eden, Tr. at 735; Ohtsuki, Tr. at 1329-31; McDonnell, Tr. at 1043-44.

118. Other than Dr. Munnerlyn's testimony based on personal familiarity with the Microscan 771, VISX points only to the relatively limited information in the Microscan 771 owner's manual, CX 206, for evidence of its structure and functionality. See CX 206; Munnerlyn, Tr. at 185, 267-69.

119. The EC-5000's scanning mirror, image rotator, and microprocessor-controlled iris diaphragm do *not* operate to turn the laser on and off in order to vary the perimeter of scans for the appropriate area of ablation, and in fact the EC-5000 has no such mechanism. See Ohtsuki, Tr. at 1331; RX 724C. Rather, the laser continues to operate with the scanning mirror deflecting the beam, but the iris diaphragm may block the beam from passing through to the cornea. Ohtsuki, Tr. at 1328, 1341-42.

120. The scan deflection means of the '418 Patent rasters in non-overlapping pulses, its small laser spot, turning the laser on and off where appropriate, to create the scanning patterns identified in the patent figures. The EC-5000's components, by contrast, scan the relatively larger laser spot in overlapping pulses, turning a 120 degree rotation after each

scan, and its scanning patterns do not resemble those of the '418 Patent. See Ohtsuki, Tr. at 1325-26.

121. I find credible and persuasive Dr. Sowada's testimony on the lack of equivalency between the patent's scan-deflection means and the EC-5000's scanning mirror, image rotator, and microprocessor-controlled iris diaphragm. See Sowada, Tr. at 1439-43.

122. In the Nidek EC-5000, the iris diaphragm, linear scanner, and laser are all controlled by an interconnected set of microprocessors. Order No. 49; Order No. 59; see also Ohtsuki, Tr. at 1340-41; Sowada, Tr. at 1445.

B. '762 Patent

123. The laser delivery system in the EC-5000 does not include a proximity mask. See Sowada, Tr. at 1474; Ohtsuki, Tr. at 1325-26; RX 751; Eden, Tr. at 806.

124. Dr. Sowada testified as follows:

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Sowada, Tr. at 1474.

125. Mr. Ohtsuki testified to the components of the EC-5000's laser delivery system, and no contact or proximity mask is included as a component. See Ohtsuki, Tr. at 1325-26.

126. Dr. Sowada testified that "The EC-5000 does not have a contact mask in its delivery system." Sowada, Tr. at 1473.

127. The laser delivery system in the EC-5000 is not structurally equivalent to the system shown in Figure 3 of the '762 Patent. See Sowada, Tr. at 1464, 1466, 1473-75.

128. Dr. Sowada testified as follows:

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Sowada, Tr. at 1473-75.

129. The EC-5000 laser delivery system, as compared to Figure 3 of the patent, lacks aperture 88 and the lens 90. See Sowada, Tr. at 1473-74; See also Eden, Tr. at 800, 803, 806.

130. I do not find Dr. Eden's testimony on the EC-5000 delivery system as equivalent to the Figure 3 laser delivery system for use with Figure 1 credible.

131. I find Dr. Sowada's testimony on the lack of equivalency between the EC-5000 delivery system and the Figure 3 laser delivery system for use with Figure 1 credible. See Sowada, Tr. at 1473-75.

132. In response to interrogatories, Nidek stated that the EC-5000 ablates approximately 0.6 microns per scan and operates at a fluence in the range of 300 - 600 mJ/cm²/scan. See CX 950C, # 157, 158.

133. Dr. Grundfest qualified as an expert in excimer laser applications in medicine and biology, and in particular as an expert in the laser tissue interactions and the effects of excimer lasers on biological tissue and specifically including the cornea. Grundfest, Tr. at 923.

134. Dr. Grundfest performed experiments using one EC-5000 machine, for purposes of this investigation, to determine the ablation rate of corneal tissue by the EC-5000. Grundfest, Tr. at 923.

135. Dr. Grundfest testified as follows:

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Grundfest, Tr. at 949.

136. Dr. Motamedi testified as follows:

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Motamedi, Tr. at 516-20.

137. Dr. Grundfest testified as follows:

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Grundfest, Tr. at 993-98.

138. Mr. Ohtsuki testified as follows:

> Q Prior to this litigation, Mr. Ohtsuki, it's true, isn't it, that Nidek always used full width half max to measure the average fluence of a pulse?
> A In calculating the average pulse fluence, that was the case, yes.

Ohtsuki, Tr. at 1382.

139. CX 821C represents a 1994 FDA submission by Nidek reflecting a corneal ablation rate for the EC-5000 of 0.5 - 1.7 microns per J/cm^2. CX 821C; see also Motamedi, Tr. at 520.

140. CX 808C at 50960 and CX 803C at 21365-66, 21649 reflect Nidek's submission to the FDA in 1999 and 1997 of the same ablation rate information contained in CX 821C.

141. Mr. Suzuki, Nidek Co., Ltd's manager of the legal affairs section of the legal and regulatory affairs division, served as Nidek's corporate designee witness. CX 475C at 5, 15-16.

142. Mr. Suzuki testified that the EC-5000 ablates corneal tissue at a rate of approximately 1.6 or 1.7 microns per one joule per square centimeter on a per scan basis. CX 476C at 151-53.

143. In interrogatory answers in this investigation, Nidek represented that the EC-5000 has an ablation rate of 1.6 - 1.7 microns per J/cm^2/scan. CX 950C at 17.

144. The EC-5000 can produce pulses having between 100 and 200 millijoules of energy per

square centimeter. CX 977 at 325 (publication noting that "[t]he average energy density of the EC-5000 is 140 mJ/cm²"); CX 355C at 2 (a Nidek internal memorandum on the EC-5000 stating that "[t]he fluence/shot is about 140-200 mJ/cm²"); Grundfest, Tr. at 985-86.

145. The '762 Patent uses distinct terminology to refer to an iris diaphragm or aperture, as distinguished from a "mask" (proximity mask). See RX 3, Col. 4, lines 5-52.

146. In deposition testimony prior to the onset of this investigation, Dr. Trokel testified that he referred to a contact mask in the '762 Patent, and in that same testimony used distinct terminology for an "aperture". See RX 214 at 143.

147. Dr. Sowada testified as follows:

> Q ***
> Doctor, I'm correct, aren't I,
> that your opinion that the EC-5000 does not infringe claim 10 of the '762 patent is based solely on the absence of a contact mask?
> A For me, not being trained in legal terms is sufficient to find a very grave error or difference between two things. Since it does not have contact mask, which is basic element in the patent '762, I believe to be not infringement proven.

Sowada, Tr. at 1499.

148. Dr. Sowada testified that the EC-5000's lack of a proximity mask precludes a finding of infringement of Claim 12. Sowada, Tr. at 1499.

V. Invalidity

A. Anticipation – '762 Patent

149. U.S. Patent No. 4,784,135 ("'135 Patent"), entitled "Far Ultraviolet Surgical and Dental

Procedures", issued to Blum, Srinivasan, and Wynne, and qualifies as prior art to the '762 Patent. RX 7.

150. The '135 Patent was filed on December 9, 1982. Order No. 48.

151. The '135 Patent teaches use of a 193 nm pulsed laser. See RX 7, Col. 3, lines 14-17, 31-33, 58-65.

152. Dr. Sowada testified that the '135 Patent discloses a delivery system with the same structures taught by the '762 Patent's Figures 1 and 2, including the contact or proximity mask. See Sowada, Tr. at 1478-79; see also RX 7, Col. 4, lines 11-14; Col. 3, line 67 - Col. 4, line 2.

153. Dr. Eden's testimony regarding anticipation of the "laser delivery system means" claim element by the '135 Patent focused on comparing the '135 Patent's delivery system to Figure 3 of the '762 Patent. See Eden, Tr. at 1617-18.

154. The '135 Patent's figure shows a single-lens system used with a proximity mask, akin to the system of Figure 2 of the '762 Patent used with the proximity mask, as shown in Figure 1. See RX 7; see also RX 7, Col. 6, lines 46-64 (describing the proximity mask).

155. I deem Dr. Sowada's testimony on the equivalency of the delivery systems in Figure 2 of the '762 Patent and in the '135 Patent credible and convincing. See Sowada, Tr. at 1478-79.

156. One skilled in the art would recognize the mask 30 in Figure 1 of the '762 Patent as a proximity mask. See Sowada, Tr. at 1490.

157. Dr. Sowada testified that the '135 Patent does not disclose the ablation rate limitation of Claim 1 because the '135 Patent "... has not dealt with corneal tissue." Sowada, Tr. at

1517-18.

158. Dr. McDonnell testified as follows:

Q Doctor, in your view, the Blum patent does not explicitly disclose the ablation rate that would be achieved with 193 nanometer light on corneal tissue, does it?
A No, I don't see disclosure like that.
Q In fact, in your view, in 1983, a person of ordinary skill who wanted to learn that ablation rate had only two ways to get it; isn't that right? Didn't you say they could measure it?
A Yes, they could measure it.
Q And the other way they could get it was to read Dr. Trokel's article; isn't that what you said?
A Dr. Trokel did perform some measurements on that, and -- but the alternative would have been to measure it yourself.
Q In your deposition you said if you wanted that information in 1983, there were only two sources, measuring it and Dr. Trokel's article; that's your testimony, correct?
A I don't recall that discussion in the deposition, but that sounds like I might have said that.
Q That's what you believe as you're sitting here today?
A Right. Unless somewhere somebody else had published it that I don't know about.
Q And as I think you mentioned on your direct, the Blum patent doesn't even mention using an excimer laser on the cornea, does it?
A I think it does not.

McDonnell, Tr. at 1092-93.

159. The '135 Patent does not explicitly or inherently disclose the ablation rate for corneal tissue or the specific settings necessary to achieve it. RX 7.

160. Experimentation and research would have been required by one of ordinary skill in the art in 1983 to determine the ablation rate for corneal tissue using the device taught by the

'135 Patent. See McDonnell, Tr. at 1092-93; RX 7, Col. 4, lines 55-68, Col. 6, lines 46-54 (reflecting variance of ablation rate depending on the material being ablated).

161. The '135 Patent discloses use of the excimer laser at fluences ranging from 10 to 300 mJ/cm^2. See RX 7, Col. 4, lines 53-54; Sowada, Tr. at 1480.

162. The '135 Patent proposes using a Lambda Physik laser, having a power supply and a control system, as evidenced by the direction to set particular levels, apparently through use of the control system. See RX 7.

163. The '135 Patent discloses use of a proximity mask. See RX 7, Col. 6, lines 46-64.

164. Dr. Eden testified that it would be "awkward" to use the '135 patent device to shape the cornea, or that it was a "poor" system for this purpose, primarily because of the use of proximity masks, which he incorrectly concluded were not taught by the '762 Patent, but did not testify that the '135 Patent device could not shape the cornea. See Eden, Tr. at 1618-19.

B. Obviousness -- '762 Patent

165. Beckman et al., "Limbectomies, Keratectamies, and Keratostomies Performed with a Rapid Pulsed Carbon Dioxide Laser", American Journal of Ophthalmology, 1971, Volume 71, page 1277 (RX 92) ("Beckman Article") constitutes prior art to the '762 Patent. See RX 92; RX 3.

166. Keates et al., "Carbon Dioxide Laser Beam Control for Corneal Surgery", Ophthalmic Surgery, 1981, Volume 12, page 117 (RX 91) ("Keates Article") constitutes prior art to the '762 Patent. See RX 91; RX 3.

167. The Beckman Article and the Keates Article do not disclose an ablation rate for corneal

tissue. See RX 91; RX 92.

C. Inventorship – '762 Patent

168. Dr. Srinivasan was employed by IBM Corporation from 1961 until his retirement in 1990, doing research in the field of photochemistry, including lasers, and is known as the "father" of ablative photodecomposition. Srinivasan, Tr. at 1176; Trokel, Tr. at 391-92.

169. Ms. Bodil Braren began working at IBM in 1982, and was employed by IBM at the time of the evidentiary hearing. Braren, Tr. at 1263.

170. Ms. Braren lacks any financial interest in the outcome of this investigation, and has received nothing of value from any party in this investigation. Braren, Tr. at 1263.

171. Dr. Srinivasan testified knowledgeably about the '762 Patent invention and the inventive work, and demonstrated a keen understanding of the thought process and experimentation behind certain claim elements. Srinivasan, Tr. at 1170-1262.

172. Dr. Srinivasan testified as follows:

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Srinivasan, Tr. at 1177-78.

173. [

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174. Dr. Srinivasan testified as follows regarding RX 123C:

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Srinivasan, Tr. at 1184.

175. Dr. Trokel admitted to a lack of knowledge surrounding how at least some key claim elements were determined. See e.g., Trokel, Tr. at 420 (Dr. Trokel stating that he had no information on whether certain research performed by Dr. Trokel's lab assistant who conferred with Dr. Srinivasan affected his patent claims); see also Trokel, Tr. at 389 (where despite the Patent's statement that more rapid pulse rates than 25 Hertz created tissue heating distortion from gas pressure backup in the irradiated area, Dr. Trokel testified that he did not know whether the limit of 25 Hertz was in any way related to the problem of gas pressure that was discussed with Dr. Srinivasan; see '762 Patent, Column 4, line 62 - Column 5 line 2).

176. Dr. Trokel testified as follows:

> Q Did the research that is shown in RX-238 affect your patent claims in any way, to your knowledge?
> A I have no information about that, Mr. Glazer.

Trokel, Tr. at 420.

177. Dr. Sowada testified as follows:

For me, it is easier to start on the cornea. If we see where the rays are combining on the cornea, then this is going to be the image point of an object from which these two rays have commonly started. And that is the center point of aperture 88. Therefore, this picture shows that lens number 90 produces an image of 88 onto 92. There are other components in this figure, like lens 86 and the variable slit number 84.

What do they do? This is very difficult to understand, and the best explanation I can come up with is that number 84 produces an intensity distribution upon 88. The intensity of it can be modified by changing the separation of the variable bars. By opening up, more of the laser beam will be transmitted. By closing them down, less will be transmitted. So 84 will be something like very good attenuator of the beam, but the image, if it is supposed to image, then the object which is image 88.

Q So to summarize, Doctor, are you saying that the aperture 88 is being imaged onto the cornea?

A That's what I say and what I believe.

Q Were you present when Dr. Eden testified to the fact that the variable slit 84 is imaged onto the cornea?

A I have no explanation and no understanding for this statement.

Q And you do not agree with Dr. Eden?

A I completely disagree.

Q Can you explain why?

A In order to show that the point is being imaged, we have to follow the construction and details as given in the art, and this art is not very young. Optical engineering is probably one of the more older types of engineering. The oldest lens that has been reported comes from 1000 BC in a level where Troy was destroyed. In 1704 Sir Isaac Newton published a book on fiberoptics, and his third figure in this book on optics shows how to construct an image if imaging is performed by a lens, and this is done by following the rays which originate at one point on the object and travel along different paths through the lens and are reconfigured at one point, which will then be the image of the object point.

Sowada, Tr. at 1458-59.

178. Dr. Eden testified as follows:

> Q If you were to have this chart CPX-38 up, and then Trokel's figure 3, wouldn't you agree with -- wouldn't you agree with me that your students would conclude from this figure that Trokel is showing focusing the rays with a lens?
>
> A I guess I don't understand your question. First of all, I would not show figure 3 to my students as it is currently drawn, because early in their education, they need to have the rays drawn properly so that they acquire the skill to be able to interpret a diagram such as figure 3.

Eden, Tr. at 812.

179. Dr. Eden testified that in Figure 3 of the '762 Patent, the rays "... are incorrect. That's the problem". Eden, Tr. at 815.

180. The rays shown in Figure 3 of the '762 Patent are drawn inaccurately, and evidence a disturbing lack of understanding of fundamental elements of the laser delivery system which VISX claims constituted a major contribution by Dr. Trokel to the state of the art. See Eden, Tr. at 812, 815, 1645-1647.

181. Dr. Trokel is a major shareholder in VISX, and has a financial interest in the outcome of this investigation. Trokel, Tr. at 374-75; RX 243.

182. Corroborating documentary evidence exists of Dr. Srinivasan's contribution to the '762 Patent invention. See e.g., RX 58C; RX 59C; RX 154; RX 222; RX 247.

183. Ms. Braren testified as follows:

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Braren. Tr. at 1277-79.

184. RX 58C is the [

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185. RX 59C is the [

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186. RX 62C [

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187. Dr. Srinivasan testified as follows:

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Srinivasan, Tr. at 1190.

188. Dr. Srinivasan testified as follows:

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Srinivasan, Tr. at 1197-98.

189. [

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190. Dr. Srinivasan testified as follows:

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Srinivasan, Tr. at 1200 .

191. Dr. Srinivasan testified as follows:

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Srinivasan, Tr. at 1238-39.

192. Ms. Braren testified as follows:

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Braren, Tr. at 1282-86.

193. Dr. Srinivasan testified as follows:

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Srinivasan, Tr. at 1249.

194. Ms. Braren testified as follows:

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Braren, Tr. at 1297.

195. Dr. Trokel testified as follows:

Q And at this particular time, were there choices to be made concerning pulse repetition rate of the laser?

A Yes.

Q Who made those choices?

A I did.

Q Did Dr. Srinivasan have any input whatsoever concerning the pulse repetition rate of the laser to be used on July 20?

A You know, Srini was terrific. He welcomed me to his lab. I gave him my ideas. I suggested this. To suggest that he did not talk with me about this is just wrong. We were discussing this. But the operational parameters were mine, and he generally -- he said, yes, that's a good idea. He generally approved what I said.

Q Sitting here today, Dr. Trokel, can you separate out in your mind the fact that Dr. Srinivasan had no input whatsoever in that experiment on July 20 concerning the pulse rate of the laser?

A I was -- wanted to start with a low pulse rate. In fact, I think that he wanted -- no. I just would have to make it up. I don't want to speculate on this. All I can do is remember the operational parameters were very close to what I came into that room with.

Trokel, Tr. at 383-84.

196. Dr. Trokel testified as follows:

Q After this paper was published in December of 1983, did you become aware of public reaction to this paper?

A Oh, yes. Yes. Yes. Indeed. There was a great deal of excitement about the material in this paper.

Q What -- would you describe for me a little bit more fully what this excitement consisted of.

A Well, I was pleased, Dr. Srinivasan was pleased. We held a press conference at the Presbyterian Hospital to announce this work.

We -- I received phone calls over the next month from eye doctors saying, can we use this; what do we have to do to get one of these instruments to use.

The laser companies invited me to California to give a presentation of this material and what I thought it could be used for. It was well-received.

Q In the period from July of 1983 to the end of 1983, did you and Dr. Srinivasan have any discussion regarding patents or inventions regarding what you had done with him at IBM?

A Yes.

Q What did you discuss?

A Sometime in August I was talking to him when the paper was in its final stages of preparation, and I told him that I thought that there was patentable material in this, in this -- in this paper, and I discussed this. I said, look, does IBM have any ownership claims on this, because, after all, it was done in their laboratory.

He said, oh, no. No. No. This is all your idea.

I said, well, what about you, do you think that you had some inventive input -- you know -- into this? Again, for the same reason.

He said, Stephen, this is about corneal surgery. He said, besides, I have to tell you that IBM has filed a patent on medical applications and surgical applications of this technology.

I said, well -- you know -- does it discuss the eye? He said, look, I can't tell you anything about what's in this patent, this is highly confidential material. And he became a little nervous and evasive. He said, but try

it -- you know -- place a patent. It is a good idea. You'll get a lot of interest. And he was right.

Q Around this time in August of 1983, did Dr. Srinivasan give you any IBM documents?

A He gave me the reprints some of which had IBM document identifiers, yes.

Trokel, Tr. at 361-62.

197. Dr. Trokel testified as follows:

Would it be fair to conclude, Dr. Trokel, that without Dr. Srinivasan and Dr. Braren present, those experiments would not have been conducted by you in July?

A Well, if he gave me the instruction book to that laser and gave me the keys to the lab, those experiments would have been done in July.

The reason that he was there made it easier and made it a lot less work, but I promise you, give me the instruction book, give me a few hours, that thing would have been up and running, and I would have done those experiments.

Q Well, my question to you was, at the time, Dr. Trokel, if Ms. Braren and Dr. Srinivasan were not present, those experiments would not have been conducted, would they have?

A Again, I can say that they served to run the instrument for me, but I was perfectly capable of running it myself, and had they not been there, and had I had access to it, I would have run it. You know, if they were not there and if I did not have access to the laser, they'd not have been done; that is correct.

Trokel, Tr. at 382.

198. I deem Dr. Trokel's testimony regarding his ability, with the requisite facilities, to perform the corneal tissue excimer laser experiments in July 1983 without any assistance from Dr. Srinivasan not credible. See Trokel, Tr. at 382, 383.

199. In the fall of 1983, when Dr. Trokel obtained his own Lambda Physik excimer laser, Dr.

Srinivasan and Ms. Braren went to Dr. Trokel's office and set up the optical system for him, indicating that Dr. Trokel did need assistance in performing his experimental work. See Braren Tr. at 1292; Trokel, Tr. at 396-97, 1581-82.

200. Ms. Braren testified as follows:

[

]

Braren, Tr. at 1292.

201. In a 12/7/83 letter requesting an academic appointment at Columbia University for Dr. Srinivasan, Dr. Trokel stated that Dr. Srinivasan's "*continued role* in helping develop different *ophthalmic surgical applications* will require that this relationship extend over a minimum of at least the next year." RX 234.

202. [

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203. In a 10/19/83 letter, Dr. Trokel stated that he and Dr. Srinivasan intended to work together on perfecting a delivery system for clinical applications. RX 229.

204. [

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205. While, at the hearing, Dr. Trokel downplayed the statements in RX 228C, RX 229, RX 234, and RX 235C as "puffery", I find it more likely that those statements represent a more truthful account of Dr. Srinivasan's role in the '762 Patent invention. See Trokel, Tr. at 393-400.

206. Dr. Trokel admitted at the hearing that he consulted Dr. Srinivasan about the draft of the AJO Article they eventually co-authored with Ms. Braren, and "would have accepted" any changes made by Dr. Srinivasan. Trokel, Tr. at 354.

207. The joint press conference with Dr. Trokel and Dr. Srinivasan announcing the '762 Patent work suggests a significant role played by Dr. Srinivasan. Trokel, Tr. at 361.

208. [

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209. When originally applying for his patent, Dr. Trokel attempted to claim the laser apparatus for use on dental carries and on skin lesions. See RX 4 at NC 00050458.

210. Dr. Trokel testified as follows:

> Q I'd like to refer you to Exhibit CX-455.
> A Yes.
> Q Do you recognize this, Dr. Trokel?
> A Yes.
> Q What is it, sir?
> A This appears to be a photocopy of the initial version of the paper that I sent to the American Journal of Ophthalmology.
> Q I see. Who wrote Exhibit CX-455?
> A I did.
> Q What did Dr. Srinivasan do to help write CX-455?
> A I gave him a version of this, prior to my mailing it, for his approval and comments.
> Q Did he approve it?
> A Yes, he did. I don't recall if he made any comments or indicated any changes. If he did, I would have accepted them.
> Q Did Ms. Braren have any input into CX-455?
> A No.

Trokel, Tr. at 354.

211. Dr. Srinivasan testified as follows:

> [
>
>]

Srinivasan, Tr. at 1252.

212. Dr. Srinivasan gave credible testimony that he remained unaware of the scope of the invention claimed in Dr. Trokel's application(s), and promptly asserted his part in the

'762 and '388 Patents invention upon becoming aware of their contents. Srinivasan, Tr. at 1249; see CX 460; Srinivasan, Tr. at 1252-56.

213. In the '026 Interference deposition, Dr. Srinivasan stated that he believed he made a "secondary" contribution to the inventive work, indicating that collaboration had occurred. See CX 712, Tab 19 at 27.

214. Ms. Braren also offered credible testimony regarding the experimentation leading to the '762 Patent, and presented herself as both a truthful witness and a witness lacking a stake in the proceedings. Braren, Tr. at 1262-1305.

215. Ms. Braren confirmed in her testimony that the determinations regarding many of the significant elements of the experiments from which the AJO Article, and in turn, the '762 Patent stemmed, were not made by Dr. Trokel, but instead were made by Dr. Srinivasan or by her. See e.g. Braren, Tr. at 1282-90; see also RX 219C at 087627.

216. Considering the totality of the testimony of Dr. Srinivasan and Ms. Braren, I find their accounts of the experiments performed with Dr. Trokel essentially *consistent* except for minor, insignificant variations likely resulting more from a difference in perspective than from divergent accounts of the facts. See Srinivasan, Tr. at 1160-1262; Braren, Tr. at 1282-90.

217. Prior to June 1983, Dr. Srinivasan and his colleagues at IBM had conducted extensive research and experimentation to determine the optimal wavelength for ablative photodecomposition of biological tissue, and had already reached the conclusion that 193 nanometers was the optimal wavelength. See RX 222 at 577 (Dr. Srinivasan's 1982 article explaining the distinct properties of and beneficial results from 193 nm laser use

on PMMA).

218. Dr. Srinivasan and Ms. Braren were responsible for the laser wavelength parameter for the first two sets of experiments with Dr. Trokel, and Dr. Srinivasan counseled Dr. Trokel as to other wavelengths. See Braren, Tr. at 1271, 1283-86; Srinivasan, Tr. at 1198, 1208-09, 1238-40; RX 58C at 622, 636.

219. Ms. Braren testified that she provided the 193 nanometer figure to Dr. Trokel in connection with the AJO Article. Braren, Tr. at 1294.

220. The Taboada articles, although they refer to 193 nanometer and 248 nanometer excimer lasers, do not address tissue removal for a therapeutic purpose and so are not directly analogous to the experiments by Dr. Srinivasan and Dr. Trokel. See Trokel, Tr. at 323-24; CX 117, CX 213.

221. Except for minor adaptations, Figure 1 of the '762 Patent is identical to a schematic created by Dr. Srinivasan and published in his 1983 article "Kinetics of the Ablative Photodecomposition of Organic Polymers in the Far-Ultraviolet (193nm)". See RX 154; Trokel, Tr. at 355, 403.

222. [

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223. The ablation rate of Claim 1 of the '762 Patent was included in the AJO Article, and was calculated from the July 1983 experiments' settings and data. See RX 186 at 00200206;

Braren, Tr. at 1294-95.

224. Ms. Braren testified as follows regarding the July 28, 1983 experiments:

[

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Braren, Tr. 1288-89.

225. Ms. Braren testified as follows:

[

]

Braren, Tr. at 1295.

226. Dr. Srinivasan provided Dr. Trokel with then-unpublished articles setting forth information on the predictable relationship between energy density and ablation rate. See e.g. RX 247; RX 154 at 053226-27.

227. Dr. Srinivasan testified as follows:

[

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Srinivasan, Tr. at 1206.

228. Even in 1984 and 1985, Dr. Trokel continued to seek the input and insight of Dr. Srinivasan regarding ablation rate measurements. See RX 236, 237 and 238.

229. Ms. Braren testified as follows:

[

]

Braren, Tr. at 1290-91.

D. Derivation – '762 Patent

230. Dr. Trokel and Dr. Srinivasan worked together to determine the fluence level

instrumental in determining ablation depth -- Dr. Srinivasan providing input from his prior experimental work on the aorta, while Dr. Trokel contributed his relatively greater expertise on the relevant characteristics of the cornea. See Srinivasan, Tr. at 1206.

VI. Unenforceability

A. '418 Patent

231. The '418 Patent at issue in this investigation resulted from application 916,646 ("'646 Application"), but contains one claim from the '330 Application which was transferred to the '646 Application after its allowance in the '330 Application.

232. Both the '646 Application and the '330 Application are continuations in part of application 552,983 ("'983 Application").

233. The two divisions that occurred during the prosecution of the '762 Patent arose from restriction requirements issued by the Patent Office in 1993 and 1995. Order No. 37.

234. The examiner rejected certain claims of the '330 Application for non-enablement, focusing on language pertaining to microprocessors and their programming. RX 13 at 175340.

235. On June 19, 1986, Dr. L'Esperance and his patent attorney held a personal interview with the examiner, and submitted an affidavit by David E. Hardt in response to the rejection, wherein Dr. Hardt opined that the specification meets the enablement requirement. See RX 13 at 175345, 175364-94.

236. The examiner issued a final Office Action on September 16, 1986, rejecting claims for non-enablement, noting with respect to the Hardt affidavit that "[w]hile one of ordinary skill in the art may be capable of performing such a programming task, it is still not clear

that the task could be performed without undue experimentation on the part of the programmer." Id. at 175396.

237. Dr. L'Esperance and his patent attorney conducted a second personal interview with the examiner on April 16, 1987. See RX 83C; Order No. 42.

238. Dr. L'Esperance's patent attorney followed up the April 16 interview with a paper submission dated April 27, 1987, in which he made reference to the interview and included two pictures of human corneal laser surgery trials discussed at the interview. RX 83C at 008217-20.

239. [

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240. The examiner's interview summary record contains no mention of the human trials, instead merely indicating: "agreed that the affidavit overcomes the rejection on the basis of 35 USC 112 1st paragraph and that the rejection under 35 USC 103 is not sufficient to anticipate the claimed invention." CX 1076.

241. On May 15, 1987, the examiner issued a Notice of Allowability for the '330 Application, allowing the previously rejected claims. RX 13 at 175419. In that notice, the examiner stated that he dropped the non-enablement rejections based on the applicant's comments and submissions in connection with the '983 Application. RX 79 at SUG000001261-62.

242. Taunton Technologies, Inc. ("Taunton") at one time owned U.S. Patent Nos. 4,770,172; 4,773,414; 4,798,204 and 4,665,913 (the '172, '414, '204 and '913 Patents, respectively), each of which issued naming Dr. L'Esperance as the inventor. RX 210 at VISX 0003844.

243. A predecessor of VISX ("VISX California") owned U.S. Patent Application Serial No. 081,986 ("the '986 Application"), naming Dr. Munnerlyn as the inventor, and U.S. Patent Application Serial No. 109,812 ("the '812 Application"), naming Dr. Trokel as the inventor. RX 16 at NC00051874; RX 548 at 86.

244. VISX California, owner of the Munnerlyn '986 and Trokel '812 Applications, provoked four patent interferences against L'Esperance's '913, '172, '414, and '204 Patents, then owned by Taunton. RX 210 at VISX 0003844. The four interferences included: (a) Interference No. 102,026 ("the 026 Interference") between L'Esperance's '913 Patent and Trokel's '812 Application; (b) Interference No. 102,073 ("the 073 Interference") between L'Esperance's '204 Patent and Munnerlyn's '986 Application; (c) Interference No. 102,182 ("the 182 Interference") between L'Esperance's '172 Patent and Munnerlyn's '986 Application; and (d) Interference No. 102,183 ("the 183 Interference") between L'Esperance's '414 Patent and Munnerlyn's '986 Application. RX 455 at VISX/FTC 091712; RX 457 at VISX/FTC 056850; RX 462 at VISX/FTC 055837; RX 466C at VISX/FTC 094591.

245. According to Nidek, Dr. L'Esperance intentionally submitted false information to the PTO, in the form of a forged diary page backdated to January 22, 1983, in Preliminary Statements submitted in the '073, '182 and '183 Interferences. The false information was intended to secure an earlier priority date. See RX 451 at 090985-86, 1015; RX 807 at 317; Nathan, Tr. at 82-83.

246. Upon discovering the forgery of the diary page submitted with the Preliminary Statements in the '073, '182 and '183 Interferences, Taunton's patent counsel withdrew

the diary page, and moved to submit Corrected Preliminary Statements, stating that the diary page submitted with the original Preliminary Statements contained "a material error" and could not be relied upon. See RX 335; RX 357.

247. As to the '026 Interference, the record does not reflect submission of a forged or falsified document in that interference, as distinguished from the other three interferences.

248. The '418 Patent does not rely on any of Dr. L'Esperance's patents at issue in the interference proceedings for its invention date. See RX 14; RX 15; RX 183; RX 565.

B. '762 Patent

249. The findings of fact in connection with the invalidity defense based on improper inventorship apply to the unenforceability defense based on improper inventorship as well.

250. Under the 1991 version of 37 C.F.R. § 1.56, for persons other than the inventor, inventor's attorney, or inventor's agent, the required disclosure "... may be made to the Office through an attorney or agent having responsibility for the preparation or prosecution of the application or through an inventor who is acting in his or her own behalf." CX 658 (37 C.F.R. § 1.56(b) (1991)).

251. Dr. Trokel and VISX learned of the alleged inequitable conduct by Dr. L'Esperance from Taunton's patent counsel, such that this information was already known by the persons referred to in 37 C.F.R. § 1.56(b) (1991). See Bailey, Tr. at 1590.

252. None of the parties dispute that a sworn statement in a patent application inaccurately stating inventorship qualifies as material.

253. Dr. Trokel acted with deceptive intent in submitting his oath of sole inventorship in the

application for the '762 Patent.

254. Dr. Trokel refused to sign the IBM confidentiality agreement given to him by Dr. Srinivasan. Srinivasan, Tr. at 1234.

255. Dr. Trokel denied that he saw the application for the '135 Patent before that patent issued [

] I find Dr. Trokel's denial not credible.

256. Dr. Trokel admitted at the hearing that although he was concerned about the original version of his patent application covering IBM's prior work, he signed and submitted a sworn statement of first and sole inventorship on the original version of his application (including claims directed to dental caries and skin lesions). Trokel, Tr. at 407-10.

257. Dr. Trokel intentionally appropriated for use in his patent application material and information from Dr. Srinivasan and/or IBM without authorization. See RX 186; RX 154; RX 742; Srinivasan, Tr. at 1209-10; Braren, Tr. at 1287, 1291-96; Trokel, Tr. at 355-56, 402-03; CX 438C.

VII. Domestic Industry

A. Technical Prong

1. '418 Patent

258. Dr. Munnerlyn testified as follows regarding the Microscan 771:

[

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Munnerlyn, Tr. at 268-70.

259. [

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Munnerlyn, Tr. at 251-52.

260. Dr. Eden testified as follows:

[

]

Eden, Tr. at 904-05.

261. I find Dr. Eden's equivalency opinions on Claim 30 for domestic industry too conclusory, and lacking in any meaningful explanations for the equivalency opinions he offers. See Eden, Tr. at 765, 768-72, 904-05.

262. Dr. Munnerlyn was not designated as an expert witness and, given his position as a founder and employee of VISX, his testimony on equivalency cannot be considered impartial.

263. Dr. Sowada testified as follows:

[

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Sowada, Tr. at 1445.

264. [

]

265. [

]

266. VISX admits that the iris diaphragm was known in the art in 1983. VISX Post-Hearing Reply Brief at 66 n.89.

267. U.S. Patent 4,732,148, entitled "Method for Performing Ophthalmic Laser Surgery", also issued to Dr. L'Esperance, based on a common parent application with the '418 Patent, teaches use of an iris diaphragm as part of a less complex and expensive substitute to a scanner and scanner control. RX 5, Col. 5, lines 60-61.

268. The STAR S2 is VISX's only product approved by the FDA for hyperopia correction in the United States. VISX Initial Post-Hearing Brief at 210.

269. [

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270. Dr. Munnerlyn testified as follows:

[

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271. [

] See Eden, Tr. at 780-84.

272. [

]

273. [

]

274. I do not find Dr. Eden's testimony on the practice of Claim 32 by the STAR S2 credible.

See Eden, Tr. at 780-84.

2. '762 Patent

275. [

]

276. [

]

277. Dr. Eden testified as follows:

> Q Please answer my question.
> Have they used in the EC-5000 exactly the system of a two lens plus aperture in a variable slit, those four elements?
> A No. As we discussed earlier today, they use a single lens imaging system.

Eden, Tr. at 806.

278. [

]

279. In the '762 Patent laser delivery system of Figure 3, the lens 90 images aperture 88 onto

the treatment plane. Sowada, Tr. at 1527.

280. [

]

281. [

]

282. The microprocessor-controlled iris diaphragm and/or slit aperture in the domestic industry products do not constitute structural equivalents to the laser power supply and control system and the mask.

283. [

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284. **B. Economic Prong**

285. The VISX laser systems for vision correction are VISX's only product and source of 100% of its operating revenues. Order No. 9.

286. Each VISX system is built, tested, and quality-checked at VISX's facility in Santa Clara, California. Order No. 9.

287. VISX has invested $10.3 million in property and equipment (including furniture and fixtures, machinery and equipment, and leasehold improvements), the net value of which as of December 31, 1998 was $4.318 million. Virtually all of this investment relates to the Santa Clara facility. Order No. 9.

288. Approximately 17,000 square feet of the space in the Santa Clara facility occupied by

VISX is currently devoted to manufacturing operations. Order No. 9.

289. It takes over [ ] labor hours to build, test, and quality check a single VISX STAR or STAR S2 system. Order No. 9.

290. The excimer laser in the VISX STAR or STAR S2 system is built and integrated with associated components in VISX's Santa Clara facility; it takes [ ] to build and integrate the laser and components of the laser assembly. Order No. 9.

291. As of March 31, 1999, VISX employed [ ] people in operations relating to the manufacture of the STAR S2™ system. Order No. 9.

292. Aggregate wages and benefits for the employees in VISX's Operations group (the manufacturing operations) was [ ] million in 1998. Order No. 9.

293. VISX produced [ ] STAR™ systems in 1998. Order No. 9.

294. VISX built [ ] STAR S2™ systems in the first quarter of 1999. Order No. 9.

295. The list price of a STAR S2™ system is $525,000. Order No. 9.

Conclusions of Law

1. All conclusions of law set forth in the opinion are incorporated herein by reference.

2. The U. S. International Trade Commission has personal jurisdiction over the parties and subject matter jurisdiction over this investigation.

3. Nidek has imported and sold the accused products.

4. The evidence offered by VISX fails to demonstrate satisfaction of the domestic industry requirement of Section 337 for either the '418 Patent or the '762 Patent.

5. The evidence of record does not demonstrate the accused Nidek products infringe the asserted claims of the '418 Patent.

6. The evidence of record demonstrates the invalidity and unenforceability of the '762 Patent based on improper inventorship.

7. Even assuming *arguendo*, the validity and enforceability of the '762 Patent, the evidence of record does not demonstrate that the accused Nidek products infringe the asserted claims of the '762 patent.

8. There is no violation of Section 337 with respect to the accused Nidek devices as to either the '418 Patent or the '762 Patent.

CERTAIN EXCIMER LASER SYSTEMS FOR VISION CORRECTION SURGERY AND COMPONENTS THEREOF AND METHODS FOR PERFORMING SUCH SURGERY

337-TA-419

CERTIFICATE OF SERVICE

I, Donna R. Koehnke, hereby certify that the attached INITIAL DETERMINATION was served upon Stephen A. Glazer, Esq. and Juan Cockburn, Esq., Commission Investigative Attorneys, and the following parties via first class mail and air mail where necessary on **March 28**, 2000.

Donna R. Koehnke, Secretary
U.S. International Trade Commission
500 E Street, S.W., Room 112A
Washington, D.C. 20436

FOR COMPLAINANT VISX, INCORPORATED:

Harold J. McElhinny, Esq.
MORRISON & FOERSTER, LLP
425 Market Street
San Francisco, CA 94105-2482

Alan Cope Johnson, Esq.
MORRISON & FOERSTER, LLP
755 Page Mill Road
Palo Alto, CA 94304

G. Brian Busey, Esq.
MORRISON & FOERSTER LLP
2000 Pennsylvania Avenue, N.W.
Washington, D.C. 20006-1888

CERTAIN EXCIMER LASER SYSTEMS FOR VISION CORRECTION SURGERY AND COMPONENTS THEREOF AND METHODS FOR PERFORMING SUCH SURGERY

337-TA-419

FOR RESPONDENTS NIDEK CO., LTD., NIDEK INCORPORATED AND NIDEK TECHNOLOGIES INC.:

Neil B. Siegel, Esq.
Robert M. Masters, Esq.
SUGHRUE, MION, ZINN, MACPEAK & SEAS, PLLC
2100 Pennsylvania Avenue, NW, Suite 800
Washington, D.C. 20037-3213

F. David Foster, Esq.
Sturgis M. Sobin, Esq.
ABLONDI, FOSTER, SOBIN & DAVIDOW
1150 Eighteenth Street, N.W., Suite 900
Washington, D.C. 20036

Joseph F. Tringali, Esq.
Henry B. Gutman, Esq.
Jeremy S. Pitcock, Esq.
Randall R. Rainer, Esq.
SIMPSON THACHER & BARTLETT
425 Lexington Avenue
New York, NY 10017

PUBLIC MAILING LIST

Donna Wirt
LEXIS - NEXIS
1150 18th Street, N.W.
Suite 600
Washington, D.C. 20036

Ronnita Green
West Group
Suite 1010
901 Fifteenth Street, N.W.
Washington, D.C. 20005