UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of	)	
	)	**Docket No. 9286**
VISX, Incorporated,	)	
a Corporation	)	Filed: May 27, 1999
	)	(*Public*)

Before: Stuart A. Levin
Administrative Law Judge

For: The Federal Trade Commission.
Veronica G. Kayne, Assistant Director; *Michael D. McNeely,* Senior Litigation Counsel, *Barry Costilo, Dana Abrahamson, Kent Cox, Joshua Newberg Chul Pak, Martin Dajani, Jeremy Cubert, Jacqueline Berman,* and *Jeffrey Goodman;* Bureau of Competition, FTC

For: Respondent VISX, Inc.
Susan A. Creighton, Ron E. Shulman, Mark D. Flanagan, Roger J. Chin, and *Andrew Leibnitz;* Wilson Sonsini Goodrich & Rosati, Palo Alto, California, and *Joseph J. Simons;* Rogers & Wells, Washington, D.C.

INITIAL DECISION

In a three count complaint issued March 24, 1998, the Commission alleged, *inter alia,* that Summit Technology and VISX, Inc., combined and conspired to fix prices and monopolize the lease and sale of medical equipment and surgical technology used by doctors to correct vision disorders such as nearsightedness (myopia), farsightedness (hyperopia), and astigmatism (an asymetrically curved refractive surface of the cornea which produces blurred or fuzzy vision). Counts 1 and 2 of the complaint challenged a patent pooling partnership formed in 1992 by Summit and VISX, known as Pillar Point Partners (hereinafter, P^3), which allegedly eliminated competition between the partners in the sale and lease of laser equipment used to perform a surgical procedure called photorefractive keratectomy (hereinafter, PRK). The P^3 agreement also required Summit and VISX to pay P^3 a fee each time one of their lasers was used on each eye of every patient. The per-procedure fee was, in most instances, billed to doctors or other sublicensees of VISX or Summit.

Shortly after the complaint issued, VISX, Summit, and the Commission negotiated a settlement of all charges stemming from the P^3 arrangement, and Counts 1 and 2 of the complaint were withdrawn from adjudication. On June 4, 1998, Summit and VISX agreed to dissolve P^3,

and final consent orders were entered by the Commission on February 23, 1999, following a period of public comment.

As a result of the settlement, only Count 3 of the complaint charging VISX, alone, with acts and practices constituting inequitable conduct and fraud on the United States Patent and Trademark Office (hereinafter, PTO) remained unresolved.[1] Count 3 alleges two types of fraud. Paragraphs 17 and 18 allege fraud by deliberate falsification of records. Paragraph 16 alleges fraud by omission of material facts.[2]

Specifically, Paragraph 17 of the complaint alleges that Dr. Francis A. L'Esperance obtained three patents covering method claims for preparing the cornea of the human eye for photorefractive keratectomy (PRK). The patents were held by Taunton Technologies. On August 5, 1987, Dr. Charles Munnerlyn filed an application for a patent related to PRK and assigned it to Old VISX, Respondent's predecessor. Two years later, on August 1, 1989, the PTO declared the Munnerlyn-L'Esperance interferences. Thereafter, the parties sparred for priority until Taunton and Old VISX merged, forming Respondent, VISX, Inc. As the common owner of the patents and the application at issue in the interferences, VISX then advised the PTO that it would make a factual and legal determination identifying the inventor pursuant to 37 CFR 1.78(c) and 37 CFR 1.602(a). In partial reliance upon VISX's subsequent submissions, the PTO issued Patent 5,163,934 to Munnerlyn, and resolved the two other interferences in favor of L'Esperance.

The focus of the alleged fraud which tainted the L'Esperance/Munnerlyn interference is set forth in three subparagraphs of complaint Paragraph 18. Allegedly, L'Esperance "fabricated, back-dated and falsified his scientific records," which he and his adult son signed and falsely dated (Subpara. (a)), "fabricated, back-dated, and falsified a diary page" regarding the date he allegedly conceived of the intervention (Subpara. (c)), and then, through attorneys, made misleading statements to the PTO about the authenticity of his scientific records and diary (Subpara. (b) and (c)). Complaint Paragraph 19 ties Respondent to the fraud by alleging that, in resolving the interferences after the merger, it knew what L'Esperance had done: willfully misled

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[1] Summit was not a party to the allegations and charges in Count 3 of the complaint, and as a result of the settlement, it no longer was a party in interest in the proceeding. Thus, it neither appeared nor participated at the hearing. Accordingly, I have amended the case caption to delete Summit as a party to the litigation of this matter within the scope of Count 3 of the Complaint in accordance with Rule 3.15 (a)(1).

[2] Pursuant to Rule 3.51(a), the Initial Decision must issue within one year from the date the complaint issued unless extraordinary circumstances justify 60-day extensions. The complaint issued March 24, 1998. On August 15, 1998, an order issued which declared this an extraordinary matter involving complex antitrust/patent issues warranting extensions in the discovery timetable, and a corresponding extension, until May 24, 1999, for the Initial Decision. The hearing convened on December 14, 1998, and concluded on February 24, 1999. The *In Camera* Decision in this matter was filed on May 21, 1999. Post-hearing, both parties moved to reopen the record: Complaint Counsel on April 8, 1999; Respondent on April 20 and May 11, 1999. These motions are herein addressed in footnotes 5, 6, and 7 respectively.

the PTO about L'Esperance's fraudulent conduct, and deceived the PTO about the basis for its resolution of the interferences and the true inventors of the inventions at issue. The complaint in Paragraph 19 then charges that the conduct described constituted willful fraud and inequitable conduct before the PTO.

Respondent moved for summary decision with respect to the fraud alleged in Paragraphs 17-19, and Complaint Counsel, having decided not to pursue these matters, did not substantively respond to the motion in accordance with Rule 3.24(a) 3. Consequently, on December 14, 1998, an order issued dismissing Paragraphs 17-19 of the complaint and all charges related to allegations set forth in those paragraphs.

The remaining dispute between the parties involves the alleged inequitable conduct or fraud by omission perpetrated by VISX. The complaint at Paragraph 16, alleges that during the prosecution of U.S. Patent No. 5,108,388 (hereinafter, Trokel '388 or '388 patent), which contains claims covering methods for performing PRK, VISX and others, on behalf of Dr. Stephen Trokel, the named inventor of the '388 patent technology, willfully withheld from the PTO articles, patents, and patent applications which they knew were material prior art. Complaint Counsel contend that had this prior art been disclosed to the PTO, Trokel '388 would not have issued. Thus, Paragraph 20 alleges that such withholding of prior art constitutes inequitable conduct and fraud on the PTO, and Paragraph 25 charges that the acquisition of a patent by such conduct is an unfair method of competition in violation of Section 5 of the Federal Trade Commission Act.

Shortly after the complaint issued, the Examiner at the PTO granted a request, filed by a third party, for reexamination of Trokel '388. During the pre-trial proceedings in this matter, and at times during the trial, the implications of the pending reexamination were explored. (*See*, Pre-Trial Hearing, December 9, 1998, Tr. at 176-177). Although the record shows that such requests are routinely granted, and when granted, they often result in rejection or modification of the patent claims, neither party sought a stay of these proceedings pending the outcome of the reexamination. Thus, on March 31, 1999, five weeks after the final day of hearing in this matter, the Examiner, on reexamination, issued an office action rejecting the '388 Patent in its entirety. He first rejected claims 1-3 of the '388 patent as obvious in light of a 1971 article by Beckman, et. al., and U.S. Patent No. 4,784,135 (the Blum patent), then rejected claims 4 and 5 as unpatentable over a 1981 article by Keates, et. al., in light of *Beckman* and *Blum*, and finally rejected all of the claims for obviousness type double patenting over U.S. Patents 5,711,762 and 5,735,843. The *Beckman* reference the Examiner relied upon is a new reference not involved in the allegations of witholding alleged in the Commission's complaint. *Blum* and *Keates*, however, are prior art references allegedly withhheld during the prosecution of the '388 patent.[3]

By motion filed April 8, 1999, Complaint Counsel seek to reopen the record to admit these recent PTO actions. While acknowledging that the motion is timely, Respondent opposes the admission of these office actions as devoid of probative value. Respondent emphasizes that it was not required to respond to the requests for reexamination, and it elected, as is customary in

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[3] In a separate decision, the Examiner also rejected the claims of the (LASIK) '695 patent.

such proceedings, not to respond. Consequently, the Examiner has not yet had an opportunity to consider VISX's comments on issues under reexamination. Indeed, the Examiner, on April 16, 1999, afforded VISX 30 days to respond to his determinations. If, after hearing from VISX, he issues a second rejection, VISX can appeal to the Board of Patent Appeals and Interferences. Until the appeal is decided, the PTO cannot issue certificates of unpatentabilty, and accordingly, the patents must be presumed valid pursuant to 35 U.S.C. Section 282.[4] Nevertheless, the Examiner's action is a significant development.

While this record leaves little doubt the Examiner will have much to consider once VISX becomes a more active participant in the reexamination proceeding, I am, nevertheless, unpersuaded that the office actions taken thus far lack probative value in this proceeding. The issues of fraud and inequitable conduct are not before the Examiner, and the validity of the patent, absent fraud or inequitable conduct, is not before the FTC. As such, cases like *Hoechst Celanese Corp.* v. *BP Chemicals Ltd*, 78 F3d 1575 (Fed. Cir. 1996), and *Acoustical Design, Inc.*, v. *Control Electronics Co.*, 932 F.2d 939 (Fed. Cir. 1991), are not applicable. While the grant of reexamination and even preliminary rejection may not be probative in "assessing patentability" or the liklihood of patent invalidity, such actions by the PTO are "surely evidence that the criteria for reexamination have been met (i.e., that a substantial new issue of patentability has been raised)." *Hoechst*, at 1578. Furthermore, the Examiner's reliance on *Keates* and *Blum,* either as old or new references, is a factor to consider in assessing their materiality. As the Court in *Glaverbel Societe Anonyme* v. *Northlake Marketing & Supply*, Inc., 45 F.3d 1550 (Fed. Cir. 1995), noted, reduction in claim scope during reexamination, "is not itself probative" of a material withholding with intent to deceive, but must be considered in context with, "[A]ll evidence, including evidence tending to show good faith." *Glaverbel Societe*, at 1558.

As such, these office actions may not, alone, be probative of material withholding, but the fact that the Examiner cited and relied upon *Keates* and *Blum* is a factor, among others, which must be considered in evaluating their materiality as references, which in turn, is probative in determining whether or not the elements of inequitable conduct have been established. Although the holding in *Molins PLC* v. *Textron, Inc.*, 48 F.3d 1172 (Fed. Cir. 1995) involved a reissue rather than reexamination, the Court's observation is equally applicable here: "[T]he result of a PTO proceeding that assesses patentability in light of information not originally

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[4] Were it otherwise, and the claims of the '388 patent were regarded as invalid based on the Examiner's rejection of the claims, the existence of any fraud or inequitable conduct, alone, might not be sufficient to sustain the allegations in the complaint. Dr. Levy, Complaint Counsels' economic expert, testified, for example, that if the '388 patent is invalid, it cannot constitute a relevant technology market, and it could not contribute to VISX's alleged market power. (Tr. 1666-1667). Under such circumstances, the Commission's observation in *American Cyanamid* would seem instructive: "We are not holding that every misrepresentation of fact or withholding of material information before the Patent Office necessarily constitutes *per se* an unfair method of competition under the Federal Trade Commission Act. Some patents may be commercially worthless or have no adverse effects on competition." *American Cyanamid*, 63 F.T.C. at 1862, *vacated on other grounds*, *American Cyanamid Co.* v. *FTC*, 363 F.2d 757 (6th Cir. 1966). *See also*, Case No. 74, 1 FTC 560 (1915-1919).

disclosed can be of strong probative value in determining whether the undisclosed information was material." *Molins PLC*, at 1179. Indeed, it would not necessarily matter whether the Examiner ultimately allowed or rejected the claims over combinations of prior art which included *Keates* and *Blum*. The fact that he assessed patentability in light of those references is a probative factor in determining whether these references are material. *Id.* Accordingly, in the Findings and Conclusions which follow, these recent office actions are considered in context in light of the record as a whole.[5]

FINDINGS OF FACT

1. "VISX" refers to VISX, Incorporated, a Delaware corporation. VISX was formed by the merger of two companies: VISX, Incorporated, a California corporation (VISX "California") and Taunton Technologies, Inc., ("Taunton"). (Stipulation Nos. 15-18). Taunton, founded in 1986, was one of the first companies to attempt to develop the equipment and surgical techniques necessary to use an excimer laser for therapeutic and refractive corneal surgery. CX 148 at 17; Tr.3661-3663. VISX California, founded in 1987, was also trying to develop the equipment and surgical techniques necessary to use an excimer laser for therapeutic and refractive corneal surgery. CX 148 at 17.

2. VISX California was incorporated in 1987 by Dr. Charles Ray Munnerlyn. Dr. Munnerlyn is a physicist specializing in optical engineering. (Tr. 3633-3634). He is founder of VISX California and served on its Board with Dr. Trokel, who was then medical advisor to the company. (Tr.3663-3664). Dr. Munnerlyn originated the term photorefractive kerotectomony. (Tr. 3670). Following the merger of Taunton and VISX California, Munnerlyn took over the operations of VISX as CEO (Tr. 3702) until

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[5] In its Oppostion to the Motion to Reopen, Respondent's Counsel states, "VISX is mindful that the general rule in these proceedings has been that even marginally relevant evidence may be admitted for 'what it is worth'." Resp. Opp. at pg. 3. Respondent's counsel uncharacteristically mischaracterize the record to the extent they contend that it reflects some "general rule" that evidence was admitted for "what it is worth." Respondent was advised at the outset of the hearing that its general hearsay objections would be overruled, consistent with administrative practice and procedure, generally, and Supreme Court precedent, specifically, to the extent Respondent was afforded a fair opportunity to take depositions or otherwise develop responsive evidence in pretrial discovery in preparation for the hearing, *See, Richardson* v. *Perales*, 402 U.S. 389 (1971). Respondent's other objections, however, were considered on their merits and, when well-founded, were sustained (*See, eg.*, Tr. 1842-1845), unless, of course, counsel, upon reflection, elected to withdraw an objection. *See, eg.*, Tr. 1750-1751.

Respondent argues further that the admission of these office actions is an invitation to error. To the contrary, however, any evaluation of the alleged fraud and inequitable conduct involved in this matter cannot ignore this new, probative, and timely proffered evidence of the Examiner's decision to reject the '388 patent claims based, in part, on *Keates* and *Blum*. Complaint Counsels' motion to reopen and admit CX 539 and 540 is, hereby, granted pursuant to 37 CFR Section 3.51(e).

July, 1994,, (Tr. 3718) when he became a technical consultant to the company. (Tr. 3720).

3. Dr. Munnerlyn is a former employee of Cooper Vision, Inc. VISX, California bought Cooper Vision's excimer laser business in 1988. (CX 39). In 1996, VISX received FDA approval for its 2020-B excimer laser system. Since then, it received approval for its Star system and the current model, the Star-S-2. (Tr. 3378- 33790; Stipulation No. 7).

4. Today, approximately 250 excimer lasers used for vision correction in the U.S. are VISX systems. VISX lasers account for the majority of laser vision correction surgery in the United States. (CX-354 at 5, 11). The VISX laser system uses an iris diaphragm delivery system. The iris diaphragm is a mechanical device that opens or closes to permit the proper amount of laser energy to reach the cornea. This technique is known as wide-area ablation. Tr. 3114 - 3116; CX398; RX 1462 at 29; RX 1482 at 205834; Tr. 390; CX 157 at 228.

5. VISX's laser systems have, through multiple FDA approvals, been approved to perform a broader range of procedures than any other manufacturer. VISX has FDA approval for up to 12 diopters of myopia, up to 6 diopters of astigmatism and up to 4 diopters of hyperopia. Tr. 1262-1263, 1267; CX 42 at 33-34; Tr. 3138 - 3139; Tr. 3377-3378, Tr. 3445; CX 354 at 6-7; CX 529 at 8.

The Cornea

6. Dr. Steven Schallhorn was called to testify by Complaint Counsel. Dr. Schallhorn, Ophthalmologist Commander, Medical Corp, U.S. Navy, explained that the cornea is the transparent tissue in front of the eyeball which is partially responsible for the eye's focusing function. It is about the size of a dime and only one half millimeter thick. The three outer layers of the cornea are the epithelium (the outermost layer), Bowman's membrane, and the stroma. Tr. 262-373; CX 42 at 5; Stipulation No. 1.

7. The cornea, like other tissue, is subject to injury and a variety of pathological conditions. (Tr. 1786-1787). When it forms an incorrect curvature, a refractive disorder results. If the curvature is too steep, too flat, or too uneven, the cornea cannot properly focus light onto the retina. (CX 42 at 5). Refractive disorders account for the vast majority of vision problems and result from the eye's inability to properly focus light on the retina. Refractive disorders include myopia, hyperopia, and astigmatism. (CX 42 at 4-5). Myopia (i.e., nearsightedness) refers to difficulty seeing distant objects. It occurs when light focuses in front of, rather than on, the retina. Hyperopia (i.e., farsightedness) refers to difficulty seeing nearby objects. It occurs when light focuses behind, rather than on, the retina. Astigmatism refers to blurred vision caused by an asymmetrically curved refractive surface of the eye. Stipulation Nos. 2, 3, 4; CX 350.

8. The severity of refractive disorders is usually measured in diopters, which are units of measurement of the refractive power of lenses. (Stipulation No. 5). Negative diopters correct nearsightedness, while positive diopters correct farsightedness. Tr. 271.

9. Laser surgery is available today to remove tissue from the cornea to give it the proper curvature. This form of surgery is called laser vision correction. Currently, there are two methods of commercially available laser vision correction. They are known as"PRK" ("photorefractive keratectomy") and "LASIK," (Laser In Situ Keratomileusis). Dr. Stephen Trokel is a Professor of Ophthalmology, Columbia University, New York City. He is a Founding Director of VISX, California, a consultant, and major stockholder in Respondent VISX. (Tr. 701-1002). Dr. Trokel is the inventor of PRK.

10. Both PRK and LASIK use a laser to precisely remove a small, predetermined volume of corneal tissue. This removal alters the eye's curvature to improve vision. (Tr. 1142-1143; Tr. 273-279; CX 342 at 3; Tr. 447; CX 342 at 3; CX 354). In addition to PRK and LASIK, laser thermokeratoplasty ("LTK" or "collagen-shrinking" technology) uses a pulsed infrared laser to heat up the collagen in the corneal stroma, thereby causing the corneal stroma to tighten. This technology has been under development since at least 1992 by Sunrise Technologies, a publicly traded company. Tr.1196; 3449; 3159.

11. PRK is performed as follows: the doctor removes the epithelium layer of the cornea and then proceeds with the ablation of Bowman's membrane and the stroma. Following the procedure, the doctor places a disposable soft contact lens onto the surface of the eye. The lens is left in place for a period of three to five days until the epithelium has recovered. Tr. 3108-3109; Tr. 3383; CX 42 at 6; CX 352; CX 148.

12. The other form of laser vision correction is LASIK ("Laser In Situ Keratomileusis"). It is performed as follows: the doctor positions the patient under the laser and then places a cutting device called a microkeratome on the eye. The eye is pressurized until it is firm, and the microkeratome passes across the cornea, and cutting a flap by slicing nearly all the way through the cornea, creating a flap which is still attached by a small bit of tissue. Occasionally, the flap becomes detached, creating a cap which is separated from the top layer of tissue. The doctor then removes the microkeratome and performs the laser treatment on the exposed surface of the stroma. At the end of the procedure, the doctor repositions the flap or cap. Tr. 3109-3110; Tr. 3383; CX 42 (1997 VISX 10-K) at 6.

13. In the past, the preferred way to do LASIK was to cut a flap rather than a cap. The flap was preferable because it helped hold the tissue on the eye following the surgery, and it helped the surgeon replace the tissue on the eye in the proper alignment. A new technique allows the surgeon to create a cap. With this method, the surgeon makes marks on the cornea with dye so that the cap can be reoriented properly, and makes a recessed circular cut in the cornea before using the microkeratome. This recessed cut allows the cap to stay on the cornea after the procedure is over because the cap is recessed rather than sitting on the surface of the eye. Tr. 3123-3126. LASIK is currently more popular than PRK. LASIK is surgery that involves manual cutting of corneal tissue and thus entails risks.

14. The laser used to perform laser vision correction currently commercially available is known as an excimer laser. First developed in 1975, the excimer laser is used industrially to etch a variety of materials. The particular excimer laser used for PRK or

LASIK produces its beam in a cylinder containing argon fluoride gas. When a high-voltage electrical current is run through the gas, it emits ultraviolet ("UV") light. The light's wavelength is determined by the gas or gas mixture used; the shorter the wavelength, the more energetic the light emitted. An argon fluoride mixture emits ultraviolet radiation at a wavelength of 193 nanometers. (RX 1482 at VISX/FTC 205811, 205815 (gas mixture); Tr. 1875- 1877) . Laser thermokeratoplasty ("LTK") uses an infrared laser to perform laser vision correction. Tr. 3159-60.

15. The excimer laser is highly accurate in removing corneal tissue. Each pulse of laser beam radiation removes about one-quarter of a micron of tissue. (Tr. 279; CX 354). The excimer laser is the only commercially available laser capable of removing very small and very precise amounts of tissue without thermal damage to surrounding tissue. CX 39 at 3; Tr. 279, 281- 282; Tr.4631- 4632; CX 148 at 6.

16. Laser vision correction apparatus is considered a medical device under the United States Food, Drug and Cosmetic Act, and must go through the Food and Drug Administration ("FDA") approval process. CX 296 at 8; CX 42 at 5; CX 39 at 5-6.

17. In March, 1998, when the Complaint issued in this matter, two firms marketed excimer lasers to perform laser vision correction in the United States. In October, 1995, Summit Technology, Inc.'s ("Summit") excimer laser was approved by the FDA. (CX 296). In March, 1996, VISX's excimer laser was approved by the FDA. Prior to these dates, Summit and VISX had obtained FDA approval to market their excimer lasers in the United States for therapeutic (non-refractive) uses. *(See,* Tr. 3377; Tr. 3404).

18. Summit manufactures and sells two excimer lasers used to perform laser vision correction. Each Summit laser uses a wide area ablation technique. One of Summit's lasers uses an iris diaphragm to control the ablation of the cornea. Summit also has a laser model that uses an ablatable mask. When using an ablatable mask, the ablation is controlled by the thickness of the mask itself. Stipulation No. 6; Tr. 3131; Tr. 390; Stipulation No. 58; Tr. 3130-3133; CX 145; CX 146 (S 22 007003); CX 147 (S 22 006956-62).

19. In October, 1995, Summit's iris excimer laser was approved by the FDA for the treatment of myopia between 1.5 and 7 diopters. Summit recently received approval for its ablatable mask system, which corrects for myopia, but has not yet received approval to correct for myopic astigmatism or hyperopia. RX 1312 at 8; Tr. 3131-3134; Tr. 5071; RX-1566 at 259.

Historical Background of the '388 Patent

20. Physicians have known for centuries that "volumetric removal" of corneal tissue alters the cornea's optical properties. Until recently, corneal surgery was performed mechanically, using scalpels, lathes and burrs. (CX-198-A; Tr.1811, 1850-1851; Tr. 4714). More recently, lasers have been added to the surgeon's toolbox.

21. On November 17, 1983, Dr. Francis L'Esperance, an ophthalmologist involved in the formation of Taunton, filed patent application No. 552,983 relating to the use of ultraviolet laser radiation in corneal surgery. (CX 211-A; CX 23, at 0003869, 0003908). Subsequently, Dr. L'Esperance received a number of patents covering methods and apparatus involving laser vision correction. One of these U.S. Patents, No. 4,665,913 ('913 patent), issued on May 19, 1987. The '913 patent was owned by Taunton, and traces its priority date of November 17, 1983, back to Patent Application No. 552,983. That application was continued in part on June 24, 1985, by patent Application No. 748,358, which matured into the issued patent. CX 21 A-K; CX 342 (VISX/FTC10804483) at 11-12); Tr.2493; Tr. 2620; Stipulation Nos. 26, 27; CX 211-A, RX 1441.

22. In 1987, VISX California owned no patents, and Dr. Munnerlyn had one patent application pending. The next year, VISX California became the assignee of a U.S. Patent Application No. 561,804, filed on December 15, 1983, by Dr. Trokel. Tr. 3695--3696; CX 342 at 11; RX 1064.

23. Dr. Trokel's application concerned the use of an argon-fluoride excimer laser or other source capable of generating pulsed far-ultraviolet radiation through a mask to remove tissue, peripherally or centrally, from the optical area to steepen or flatten the cornea. (Tr. 2081-2082; RX-1507 at 152415). Seventeen claims in the application were apparatus claims, and sixteen were method claims. Of 33 claims total, only two, claims 15 and 32, referred specifically to the eye or cornea. The other claims related to "tissue or other biological matter," teeth caries (claims 16 and 33) or skin lesions (claim 17). CX 117, pp.152419-152421; RX-1507; Tr. 702-16, 852, 855.

24. Dr. Trokel's application was reviewed at the PTO by the same examiner, David Shay, who, as an Assistant Examiner, reviewed the L'Esperance application which matured into the '913 patent. CX 211-A; CX-327-A; Tr.2468-2469, 2472, 2493; Tr.4760. VISX and Complaint Counsel agreed, pursuant to PTO policy, that neither would attempt to call Examiner Shay (hereinafter, Examiner) as a witness in this proceeding.

25. Dr. Trokel's Application No. 561,804 was continued on May, 2, 1986, with Application No. 859,212. That application was continued again, with Application No. 109,812, filed on October 16, 1987. CX-327-A; Tr. 2490.

26. Dr. Trokel copied claims 1 and 2 of U.S. Patent No. 4,665,913 into Patent Application No. 109,812 in order to provoke an interference with Patent No. 4,665,913. Stipulation 42; CX-212.

27. On September 30, 1988, the PTO declared Interference Proceeding 102,026 between Dr. Trokel (on U.S. Patent Application No. 109,812) and Dr. L'Esperance (on his issued patent, U.S. Patent No. 4,665,913). Dr. L'Esperance was the "senior party" in the interference proceeding and Dr. Trokel was the "junior party." Examiner-in-Chief James Boler (hereinafter, Examiner-in-Chief) was assigned to preside over the preliminary stages of the interference. Stipulations 22, 23, 43; Tr. 255; Tr. 4909-4910.

28. An interference is a proceeding instituted in the PTO before the Board of Patent Appeals and Interferences, (hereinafter the Board), to determine any question of patentability and priority of invention between two or more parties claiming the same patentable invention. When declaring an interference, the PTO formulates an interference count which sets forth the interfering subject matter. The PTO designates claims from each party's application or patent as corresponding to the interference count it has formulated. 37 C.F.R. §1.601(i); Stipulations 44-46.

29. In the Trokel/L'Esperance interference, the PTO did not formulate a new interference count, but designated claim 41 from the Trokel application and claim 1 from the L'Esperance '913 patent, which were identically worded, as the count. In addition, claims 42 to 50 of the Trokel application, and claims 2 and 15-38 of the L'Esperance '913 patent were designated as corresponding to the count which means that they were either exactly the same as, or obvious in view of, what was in the count. RX 1; CX 392; Tr.4896-4897, 4898.

30. On August 30, 1988, Dr. Trokel assigned the rights to his patent application to VISX California. Dr. Trokel associated himself with VISX to secure the financial backing needed to challenge Dr. L'Esperance in an interference proceeding. VISX acquired the Trokel application with the intent to pursue the interference with L'Esperance's '913 patent. CX 23, p. 0003857; Tr. 3671-3673; Tr. 844-847, 852-853.

31. The record shows that Dr. Munnerlyn also copied claims from three patents issued to Dr. L'Esperance for the purpose of provoking interferences with those patents. The PTO declared three interferences on August 1, 1989: interference number 102,073 involved U. S. Patent No. 4,770,172, which had issued on September 13, 1988; interference number 102,182 involved U. S. Patent No. 4,773,414, which had issued on September 27, 1988; and interference number 102,183 involved U. S. Patent No. 4,798,204, which had issued on January 17, 1989. Stipulation 28; CX 342; VISX/FTC 108044-83); CX 37 (Table, dated 11/4/92).

32. None of the four interferences proceeded to a litigated conclusion. During the interference proceedings, VISX California and Taunton opened merger negotiations, and on April 6, 1990, VISX California and Taunton signed a letter of intent to merge. CX 23, (VISX 0003818-918) at 27-28; Stipulation No. 29.

33. On November 27, 1990, Taunton consummated its acquisition of VISX California. After the merger of Taunton and VISX California, Taunton renamed itself VISX, Inc., and became the common owner of the L'Esperance patents and the Munnerlyn and Trokel patent applications involved in the interferences. Stipulation No. 31; CX 23 (VISX 0003818-918) at 20.

34. Under patent office rules, VISX, as the common owner of the patents and applications in the interferences, was obligated to resolve the interferences. An official of the merged firm, Dr. Munnerlyn, determined which inventor should be awarded priority in each interference and advised the PTO, which then issued orders implementing the decisions. The Trokel Interference was resolved in favor of Dr. Trokel. Stipulation No.

32; CX 63 (PTO Judgment and Termination of Proceeding, dated 1/16/91, for Interference 102,026 (VISX 0014813-14)); 37 C.F.R. § 1.78 (c); CX 23 (Amendment No. 3 to the Sec Form S-4 Registration Statement of Taunton Technologies, dated 10/3/90 (VISX 0003818-918)) at VISX 0003855.

35. VISX continued the prosecution of the Trokel 109,812 application after it emerged from the interference. This application matured into U.S. Patent No. 5,108,388 ('388 patent) on April 28, 1992. Claims 4 and 5 of the '388 patent correspond to claims 41 and 50, which had been awarded priority over the L'Esperance claims involved in the interference and had formerly been in the '913 patent. Stipulations 33, 48; Tr. 2559.

Pillar Point Partners (hereinafter P^3)

36. Following the merger of VISX and Taunton, VISX entered into a patent pool with its other potential rival, Summit. P^3 was formed on June 3, 1992. Summit and VISX each created wholly owned subsidiaries (Summit Partner, Inc., and VISX Partner, Inc.), which became partners in Pillar Point. In forming the partnership, VISX and Summit pooled their laser vision correction and laser vision correction-related patents, including the '388 patent. Stipulation No. 54; CX 47 (VISX 036412-24) at 36419; CX 45 P3 agreement) at VISX 002102; CX 296 at 5-6.

37. Under the terms of the P^3 agreement, the partners set a fee that each firm would pay into the partnership each time either firm's machine performed a laser vision correction procedure. The fee is known as a per-procedure fee. The P^3 agreement called for VISX and Summit to each submit a proposed level for the fee between $30 and $250, and the highest proposal determined the level of the fee. In 1995, VISX and Summit each submitted a proposed level for the fee: VISX proposed $175 and Summit proposed $250. The fee was therefore set at $250. CX 45 at VISX 002171; CX 233-A; CX 157 at 68; Tr. 3180.

38. During the time the pool was in existence, each firm collected a per-procedure fee from its customers and paid that fee into the pool. Under the agreement, P^3 passed the fee revenue back to VISX and Summit. VISX's share of the revenue was $140 and Summit's share was $110. CX 296 at 10; Tr. 3402; CX 45 at VISX 002164; CX 53 at 6-7; RX 1312 at 25946-7; CX 233-A; CX 297 at 7; CX 296 at 5-6; CX 157 at 76 - 83; CX 43 at 43; Tr. 1277-1279.

39. VISX enforces the per-procedure fee by requiring a keycard to operate its laser. In order to operate a VISX excimer laser, a VISX keycard must be inserted into the machine. The price of a VISX keycard is $260. According to VISX, $250 constitutes a payment for intellectual property rights that is paid to VISX each time its excimer laser is used, and $10 is for the card. (Tr. 3181; 446-447; 3380; 3389.). The procedure fee represents the means by which VISX seeks to recover its $100 million investment in research, development, and clinical trials. Absent the per-procedure fee, VISX would have had to charge approximately $3-4 million per machine to recover its investment. At that price, it is unlikely that many doctors would have purchased machines. Tr. 3418-3419.

40. VISX and Summit entered into a consent decree with the Commission, (CX 344 (Agreement Containing Consent Order to Cease and Desist in the Matter of Summit Technology, Inc., & VISX, Inc.); CX 291), pursuant to which P^3 was dissolved in June, 1998. The Consent Order does not preclude Summit or VISX from separately establishing and independently imposing per-procedure fees.

Duty of Candor

41. Patent applicants, their attorneys, and others substantively involved in the application process have a continuing duty of candor and good faith, including an obligation to bring material prior art to the attention of the examiner during the course of a patent prosecution. CX 376 (37 C.F.R. § 1.56); Tr. 2461; Tr. 800-807, 796-797; Tr. 4225, 4386-4387; 4168, 4177-4178.

42. This duty to bring material prior art to the attention of the examiner applied to Dr. Trokel. He reviewed the application and the prior art search made before the application was filed, commented on the language of the claims, and suggested changes incorporated into the claims by his attorney. Tr. 800-805.

43. This duty to bring material prior art to the attention of the examiner also applied to Dr. Munnerlyn, the Chief Executive Officer of the assignee of the patent application, by virtue of his substantive involvement in the application process. (Tr. 4225, 4386-4387), to Charles Gholz, an attorney and member of the patent bar who represented VISX during the interference and prosecution of the application, (Tr.4168, 4177-4178), and to two patent attorneys, Feldman and Berger, who represented Dr. Trokel in the prosecution of his patent application before the PTO. Tr. 796-797, 805-807.

44. A duty of candor and good faith is imposed upon applicants and their representatives before the PTO, because the PTO staff, while highly capable and qualified, is nevertheless faced with a vast amount of material. As a consequence, the PTO staff requires the candid and honest assistance of applicants. Tr. 2460-2461.

45. Patent Examiners are subject to work production quotas, (Tr. 2485-2487; Tr. 4979), and are limited not only by the fact that they often are not as familiar with a given technology as the applicant, but by the amount of time it takes to read and understand the application. In general, an examiner's research for prior art references does not relieve the applicant of, or in any way diminish, the duty of candor and honesty in dealing with the PTO. Tr. 2487-2489.

46. A patent applicant should not assume that an examiner will necessarily remember, when examining a particular application, other applications which the examiner is examining or has examined in the past. (MPEP § 2004 (1989); Tr. 2571; MPEP § 2001.06(b) (1989); Tr. 2573). However, neither MPEP § 2001.06 (CX 276) nor MPEP § 2004 (CX 376) state that an applicant cannot rely on the examiner of a particular application to be aware of applications belonging to the same applicant or assignee.

47. Complaint Counsel called Joseph V. Colaianni as an expert witness in this proceeding. Colaianni is an attorney and head of the Intellectual Property Group at the law firm of Patton Boggs. From 1970 until 1984, he was a Judge on the U.S. Court of Claims. Since leaving the Court, he has specialized in a variety of patent matters, including litigation, patent prosecution, and inequitable conduct. Although his personal experience in handling patent interference proceedings, in particular, is limited, (Tr. 2444, Tr. 2436-3056), he was qualified to testify as an expert witness. Colaianni explained that § 2004 of the MPEP contains suggestions, not requirements. (Tr. 3019-3020, 3026-3028, 3030-3035). He also explained that MPEP § 2001.06 does not specifically apply to interferences, but provides general guidelines. (Tr. 3019-3020).

48. Colaianni further testified, in confirmation of testimony he had previously given in a state court proceeding, that if two applications are pending before the same examiner at the same time and involve similar subject matter or technology, it is not necessary to cite the references from either application in the other application, because the examiner has both applications before him, and will be aware of the content in both applications. Tr. 3030-3035; RX 1512.

Prior Art

49. Prior art consists of (a) articles, speeches, or other information available before the filing of a patent application or before the date of invention, and (b) U.S. Patents filed before the filing of the application at issue. A U.S. patent is available as prior art after it is granted. 35 U.S.C. § 102 (1995); Tr. 2455-2456.

50. An invention is not novel and is said to be "anticipated" if it is disclosed in a single prior art reference before the applicant's date of invention or more than a year before the applicant's filing date. (35 U.S.C. § 102 (1995); Tr. 2454; Tr. 4763-4764). The parties in this proceeding agree that none of the prior art references at issue in this case anticipates any of the claims of the '388 patent. *See e.g.* Tr. 2063-2065; Tr. 2972.

51. An invention is not patentable if it (a) is disclosed through the combined teachings of two or more prior art references before the applicant's date of invention or more than one year before the applicant's filing date, and (b) there is a suggestion in the prior art to combine the teachings of two or more prior art references. Prior art teachings cannot be combined with hindsight, and objective evidence of non-obviousness must be considered. 35 U.S.C.§103(1995); Tr. 2454-2455; 4764.

52. The Manual of Patent Examining Procedures ("MPEP") is an authoritative source detailing the patent examination process. It is primarily a set of instructions from the Commissioner to the examining corps of the Patent Office. It sets forth the details of PTO examinations, is made available to the public, and describes procedures on which the public can rely. It is, however, advisory in nature. Tr. 2458.

53. A patent applicant can bring prior art to the attention of the examiner even if the reference, in the applicant's view, does not affect the patentability of the claims. (CX

377). There is no duty to cite to the examiner prior art which the applicant believes does not affect the patentability of the claims. Section 2004, paragraph 13 of the MPEP suggests that applicants not disclose prior art which, they believe, does not affect the patentability of the claims. Tr. 3029.

54. Prior art that would impair the patentability of the applicant's claims or cause the claims to be limited must be disclosed if the applicant is aware of it. CX 375 at Sec. 1.56(a); Tr. 2464.

55. If doubt exists regarding the materiality of prior art, the desirable and safest course is to submit the information to the examiner so that the examiner may determine its relevance. MPEP § 2004 (1989); Tr. 2462-2464, Tr. 2470 -2471; CX 377; Tr. 2571-2572; Tr. 3026-3028.

56. Not all prior art references cited to or considered by the examiner will appear on the cover of the patent. Of the four prior art patents cited by Dr. Trokel in column one of the '388 patent, three of them were not listed by Examiner Shay on the face of the '388 patent. Tr. 2763-2767.

57. Methods of bringing prior art to the attention of the examiner include filing an Information Disclosure Statement (IDS), citing it in the specifications of the application or in conference, and by way of amendments or supplemental IDS filings. Tr. 2465-2467; 37 C.F.R. § 1.56 (1989); 37 C.F.R. §§ 1.97(b)-(d), 1.98 (1989).

58. An IDS should, among other things, identify the prior art to be considered by the examiner, state the relevance of the prior art, and attach a copy of the prior art. (Tr. 2465 - 2467; 37 CFR 1.97, 1.98). A patent applicant is permitted to submit multiple IDS's, including supplements after the initial filing, to bring additional prior art references to the examiner's attention. (Tr. 2468-77). The rule at 37 C.F.R. §1.98 only concerns IDSs pursuant to 37 C.F.R. §§ 1.97 and 1.99. In reviewing an IDS, an examiner must note, in writing, prior art submitted by the applicant but not considered by the examiner. Tr. 2473-2474.

59. Prior art may also be brought to the attention of the examiner during an interview. While the MPEP does not have the force of law, it provides, as a matter of policy, that the applicant or the examiner, following an Examiner Interview, is expected to provide a written record of the interview and identify the specific prior art discussed. (MPEP §713.04 (1990); Tr. 2467). Applicants are given the opportunity to correct the examiner interview summary record, (Tr. 2627, 2630-2631), but the examiner would not necessarily write down references that were not applicable. Tr. 4857-4858.

60. The MPEP contains very specific instructions to examiners to make a record of their process of finding and analyzing prior art during the course of an examination. For example, in MPEP Section 717.05, examiners are told to record their searches in the PTO reference classification system, their consideration of periodicals such as *Popular Mechanics* and sources, such as the Sears Roebuck catalogue, and to note even cursory searches. Under MPEP Section 717.05, an examiner is supposed to record a consultation

with another examiner discussing where he or she might search. On an IDS form received from an applicant, the examiner is required to initial a citation if considered, and to draw a line through it if it is not considered. Tr. 4939- 4940; MPEP Section 717.05; Tr. 2473-2474.

Prior Art Allegedly Withheld

61. The Complaint alleges that four material prior art references were not disclosed to the examiner in connection with the prosecution of Trokel '388. These four prior art references are:

(1) Richard H. Keates, Leno S. Pedrotti, Hugo Weichel, William H. Possel, *Carbon Dioxide Laser Beam Control for Corneal Surgery,* 12 Ophthalmic Surgery 117 (1981) *(Keates) CX* 30;

(2) U.S. Patent Number 4, 784,135 ('135 or IBM patent or Blum patent) CX 184;

(3) Dr. Manfred Karp's German Patent Application DE 3,148,748, dated December 1981 *(Karp) CX* 190; CX 357; and

(4) L. Girard, *Advanced Techniques in Ophthalmic Microsurgery,* Corneal Surgery (1981) *(Girard) CX* 359.

62. For the purpose of providing a brief introduction, *Keates* discloses the use of a C02 laser in corneal surgery to make incisions for RK and to reshape corneal tissue. The reference disclosed that the CO2 laser produced residual thermal damage. Dr. Keates worked to minimize the thermal damage and thought the CO2 laser could be an ideal surgical tool, but it never achieved clinical success as a refractive surgical instrument. (Tr. 539, 596, 604-605). Dr. Keates appeared as a witness called by Complaint Counsel. He is a Professor of Ophthalmology at New York Medical College, and Director Consultant to Autonomous Technologies of Orlando, Florida, and author of the allegedly withheld *Keates* reference. Tr.483-692

63. The ' 135 patent discloses the use of a 193nm excimer laser to produce a unique laser-tissue interaction known as photoablative decomposition when laser light photons with energy of at least 5ev are absorbed by protein molecules in tissue, and rather than heat up, the energy is sufficient to break the chemical bonds of the tissue molecules causing tiny fragments of tissue to explode away from the surface. (CX 184 (the '135 patent at colt 3, lines 14-16, 54-63, colt 7, lines 9-17, 23-37); Tr. 1875-1877). As the fragments of tissue are "disconnected" from the substrate, they leave the surface at high velocity and can carry with them any energy beyond that which was needed to break the bonds. If they carry all the excess energy with them, the process does not cause thermal damage to the remaining tissue. If too much energy is applied initially, the fragmenting process may not carry off excess energy, and heating or thermal damage can occur. CX 184 (the '135 patent); Tr. 1877-1878; Tr. 4630).

64. *Karp* discloses an apparatus combining a laser scalpel and a computer. *Karp* teaches directing a undisclosed type of laser at the cornea for the purpose of making incisions according to a predetermined pattern, using the laser as a surgical tool to form scars. *Karp* specifically discloses the use of this apparatus to perform operations such as radial keratotomy as described by Dr. Fyodorov. Such procedures necessarily result in depth penetration into the stroma. (CX 189; CX 190; CX 357 (Karp); Tr 1862-1863; 1939-1939; Tr. 2537-2538; Tr. 3895-3896, 3952). The record indicates, however, that *Karp* misapprehends how to perform radial keratotomy to the extent that RK requires relaxing cuts while *Karp* discloses scarring which may contract the cornea. (Tr. 4539-4540).

65. *Girard* discloses a broad range of therapeutic and refractive surgical techniques. These techniques include superficial keratectomy, keratoabrasion, radial keratotomy, and keratomileusis. *Girard* describes the pioneering work of Dr. Jose Barraquer on fundamental refractive surgery techniques to correct nearsightedness, farsightedness and astigmatism. It discloses a technique to correct myopia and hyperopia, called keratomileusis, which entails reshaping the cornea through volumetric removal of corneal tissue from the posterior surface of a lenticle cut from the cornea. CX 359 *(Girard);* Tr. 1871-1875, 1955-1958. The removal of tissue from the anterior surface of the cornea (such as in superficial keratectomy) is described in a chapter devoted to therapeutic, not refractive techniques, and there is no suggestion that it should be used for refractive purposes. CX 359.

66. An IDS was not submitted for these references in connection with the prosecution of the Trokel '388. (Tr. 2477-2478). It is also undisputed that, in connection with the '388 patent prosecution, no examiner's interview report listed *Karp, Blum,* or *Girard* as having been discussed in connection with the prosecution of Trokel '388. (Tr.2478). The *Keates* article was discussed with the Examiner on September 24, 1991, in connection with two L'Esperance applications and two pending Trokel applications, one of which included the application which matured into the '388 patent. RX 1515, 1516, 1517; Tr. 3702-3705; Tr. 4339; 4345; Tr. 2834-2835, 2838.

67. None of these references are listed on the cover page of the '388 patent. The listing of a reference on the first page of the patent demonstrates that the examiner considered the reference. (CX 327 A; Tr. 2585, 2569, 2491). As previously mentioned, however, not all prior art references cited to or considered by the examiner will appear on the front of the patent, and of the four prior art patents cited by Dr. Trokel in column one of the '388 patent, three of them were not listed by the Examiner on the face of the '388 patent. Tr. 2763 - 2767.

68. The '388 patent file wrapper does not indicate that the Examiner specifically considered the four prior art references. Likewise, there is no evidence in the '388 patent file wrapper that the Examiner affirmatively noted that he chose not to consider the four prior art references. Tr. 2478-2479.

69. References in a particular class in the PTO classification system are found in file drawers sometimes referred to as "shoes". The cover sheet of the '388 patent and the file

history reveal that the Examiner conducted several prior art searches in the "shoes" where the '135 patent and *Karp* are ordinarily filed. Of course, the fact that the Examiner searched in those shoes does not necessarily mean that he considered those references. The examiner might have overlooked a document in the shoe or material may have been removed from a shoe. The fact that examiners do their own searches does not abrogate the duty of candor because examiners may miss or overlook art. Colaianni thus opined that he would not have declined to bring the Blum patent or the *Karp* reference to the attention of the examiner even if he knew that the examiner had searched in the shoes containing those references. Tr. 2624-2625, 2771-2784, 2786; Tr. 4904-4905.

70. Citation of a reference during an interference proceeding may be sufficient to bring the reference to the attention of the examiner during the course of patent prosecution. Colaianni testified during cross-examination that the interference was part of the prosecution process of the '388 application. Tr. 3005 - 3006.

71. Respondent called Saul I. Serota as an expert witness in this proceeding. Serota is a patent consultant and was formerly Chief Administrative Patent Judge, U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences. (Tr. 4738-4989). As a qualified patent expert, Serota testified that once a reference is cited to the examiner for any purpose, the reference is considered to be before the examiner for all purposes, (Tr. 4987-4988), and Colaianni acknowledged that if a reference is before an examiner, it may be assumed that the examiner read it. Tr. 2837.

The L'Esperance '913 Patent

72. The '913 patent claimed the use of ultraviolet radiation to achieve controlled ablative photo decomposition of portions of the cornea in order to change the optical properties of the eye. (Order No. 1 para. 6). Prior art references in the '913 patent included the *Karp* reference, the *Girard* reference, and the European counterpart to the Blum patent. (Order No. 1 para. 10.). As previously noted, Examiner Shay was the Assistant Examiner on the '913 patent.

The '026 Interference

73. In October 1987, Dr. Trokel filed an amendment to his patent application, which added claims 41 through 50. (Order No. 1 Para.8). Four of these claims were copied directly from L'Esperance's '913 patent in order to provoke an interference with the '913 patent. In particular, claim 1 of the '913 patent is identical to claim 41, which became claim 4 of the '388 patent. Dr. Trokel informed the examiner that the six other claims were drawn to the same invention. (Stip.Para. 42; Order No. 1 Para. 9.)

74. At the time of his deposition on November 23-24, 1998, Colaianni had not formed any conclusions about what went on during the Trokel/L'Esperance interference, (Tr. 2643), he did not know the procedural steps the PTO followed to determine whether or not to declare an interference (Tr. 2644), nor did he know whether or not before

deciding to declare an interference, the PTO is required to make a determination that the claims in the application which correspond to the count are patentable to the applicant. Tr. 2644-2645.

75. To institute an interference, a Primary Examiner fills out a Form 850, and forwards it to the Board, which has exclusive jurisdiction over the interference. (Tr. 2669-2670). On July 22, 1988, Examiner Lee Cohen, assisted by Examiner Shay, completed an initial interference memorandum on Form PTO-850. (RX-1). In the Form 850, Examiner Cohen found Dr. Trokel's claims 41-43 and 45-50 to be allowable to Dr. Trokel. Examiner Cohen found that Dr. Trokel's claims 3-5, 34-40 and 44 were non-allowable. RX-1; Order No. 1 Para. 11.

76. Prior to completion of Form-850 (RX-1), Examiner Shay and Primary Examiner Cohen had before them the L'Esperance '913 Patent application files and the Trokel application files (including parent applications). (Tr. 4761-4762). In preparing Form 850 and deciding whether or not the *Trokel* claims were allowable for purposes of Form-850 (RX-1), the Examiners were expected to review the prior art references contained in the '913 Patent application files, (Tr. 4767), including the *Karp* and *Girard* references which were cited in the '913 file history, (Tr. 4767-4768; RX-1561), the "Background of the Invention" section of the L'Esperance '913 Patent which disclosed that carbon dioxide lasers had been used to perform surgery on the eye, (Tr. 4768-4769; RX-1561), and the *Laser Focus* article, which was cited in the Trokel patent application prosecution history. Tr. 4770-4771; RX-1561.

77. The term "allowable" in Form 850 encompasses all of the statutory requirements of Title 35, U.S.C. Sections 101, 102, 103 and 112. (Tr. 4763). The determination that claims are "allowable" for purposes of Form 850 indicates that the examiner reviewed the prior art references contained within the application files for the interfering patent and patent application, (Tr. 4764-4765), and determined that some of Trokel's claims were allowable over prior art and some were nonallowable. Tr. 4765-4766; *See also,* § 2307.02 of the MPEP (RX-1513); Tr. 2739-2744.

78. The Examiner-in-Chief verifies that the claims of the interfering patent and patent application are patentable. If they are not patentable, there is no reason to set up an interference. (Tr. 4758). On September 30, 1988, the Examiner-in-Chief declared Interference Proceeding No. 102,026 (the "'026 interference") between Dr. Trokel's U.S. patent application No. 109,812 and the '913 patent. (CX 10; Order Specifying Undisputed Facts Regarding VISX's Summary Decision Motion No. 1 ~ 12; Stip. ll 43). By annotating the Form-850 (RX 1) with "OK, JRB," the Examiner-in-Chief found, in this instance, the interference in a condition to be declared. (Tr. 4771-4772; RX 1561). The Examiner-in-Chief thereafter presided over the '026 interference. Order No. 1 Para. 13.

79. At the commencement of an interference, the Board receives copies of the application files of the interfering patent and patent application including the files of parent applications, and any references that were cited therein. (Tr. 4756-4757). As a matter of practice, copies of prior art references applied during the course of the prosecution are kept in the back of the application for the convenience of the examiner.

(Tr. 4753-4754, 4974). A copy of the *Karp* reference is contained in the file history of the '913 Patent. Tr. 4975-4976; CX 396 at Z-239.

80. In 1988, Dr. Trokel assigned his patent application to VISX California. (Order No. 1 Para. 14; Tr. 3671). VISX intended to pursue the '026 interference when it acquired these rights. (Tr. 3673). Dr. Munnerlyn retained Charles L. Gholz, a partner in the law firm of Oblon, Fisher, Spivak, McClelland & Maier to represent VISX California in the '026 interference. Tr. 3673-3674.

81. For the past 15-17 years, Gholz, has been employed as an attorney with the law firm of Oblon, Spivak, McClelland,Maier,& Neustadt. He is chairman of the patent interference section of his firm. (Tr. 4171-4172). He has represented VISX since 1988, and appeared on its behalf before the PTO in both the '026 interference proceeding and the subsequent prosecution of the '388 patent. (Tr. 4178). Gholz is an experienced lawyer in the area of patent interference proceedings, and has published numerous articles on patent issues in leading intellectual property journals, including an annual article in the Journal of the Patent and Trademark Society analyzing recent Federal Circuit opinions in the area of patent interferences. (Tr. 4182-4184). One of his articles, in the APLA Quarterly Journal, addressed the serious criminal and disciplinary consequences for lawyers found to have committed inequitable conduct. (Tr. 4192-4195). Respondent called Gholz to testify in this proceeding. Tr. 4167-4480.

82. Dr. Munnerlyn looked to Gholz to guide VISX through the interference process. (Tr. 3687). It was Gholz's responsibility to communicate with the PTO on VISX's behalf and to determine what to disclose to the PTO. (Tr. 3676). It also was Gholz's responsibility to decide what types of motions to file and how to respond to motions by the party L'Esperance. Dr. Munnerlyn's role was to provide technical assistance to Gholz. Tr. 3675, 3687.

83. On January 30, 1989, VISX filed the Party Trokel's Motion No. 4, which sought to designate certain L'Esperance claims as corresponding to the court in interference. (CX-126; RX-1536, Tab 6). In this motion, VISX expressly cited the Blum patent and the *Keates* article, among other references, and also submitted copies of the references in support of the motion. (CX 135; RX 1536 at Tab 11; RX 1536 at Tab 14; Tr. 4257-4259). In filing Motion 4, Gholz expected that the Examiner-in-Chief would see and review the references. Tr. 4256-4257; 4259-4260.

84. On January 30, 1989, VISX filed The Party Trokel's Motion No. 5, for judgment pursuant to 37 C.F.R. § 1.633(a). (RX-1536, Tab 7; Tr. 4241). In this motion, VISX claimed that L'Esperance had committed fraud by failing to cite the *Karp* reference to the Patent Office during the prosecution of the '913 patent. (RX 1536, Tab 7.) In that motion and in its subsequent reply brief, VISX claimed that the *Karp* reference was more material to certain L'Esperance claims (18-24, 55 and 56) that were not part of the interference than any other prior art before the PTO. *(Id.;* RX 1536, Tab 23; CX 143.)

85. In Motion No. 5, VISX specifically noted that it was not claiming that the *Karp* reference was pertinent to any of L'Esperance's sculpting claims that were part of the interference. (RX 1536, Tab 23 at 5 n.9; CX 143 at 5 n.9.) At the time Motion No. 5 was filed, Dr. Munnerlyn understood that L'Esperance claims 18-24, 55 and 56 pertained to the use of a computer-controlled laser to scan RK-like incisions into the cornea. The '388 Patent does not disclose scanning. (Tr. 4799-4800). Dr. Munnerlyn believed that the *Karp* reference was material to the L'Esperance claims because the *Karp* reference described control of a laser beam with a computer. Tr. 3744; 3803-3804; 3811-3812.

86. If Motion No. 5 had succeeded, judgment would have been entered against the Party L'Esperance; the '388 application would have gone back into *ex parte* prosecution; and the Examiner would have had to review Motion No 5, (Tr. 4241-4242), which included the *Karp* reference as a prior art reference. Tr. 4242-4243.

87. Gholz submitted an exhibit list to the PTO which contained the *Karp* reference, the Blum patent, and the *Keates* article. Tr. 4260-4261.

88. On November 24, 1989, the Examiner-in-Chief issued his decision on preliminary motions in the interference. The decision: (a.) denied Trokel's Motion 4, and in so doing, the Examiner-in-Chief expressly discussed the Blum patent and the *Keates* article, (RX 114 at 146352); and (b.) denied Trokel's Motion 5, (RX 114 at 146351). The decision also found Trokel's claims 41-50 claims, "are broad enough to read on merely providing incisions in the cornea by means of ultraviolet radiation...such incisions result in the removal of some corneal tissue as called for in claim 41 or redefinition of the anterior surface of the cornea as set forth in claim 50." *Id.* at 146355.

89. In rendering his decision on the preliminary motions (RX 114), the Blum patent, the *Keates* article, and the *Karp* reference were before the Examiner-in-Chief. (Tr. 4818, 4820). The parties to the interference could reasonably expect the Examiner-in-Chief to consider patentability with respect to *Blum, Keates,* and *Karp.* Tr. 4823-4825.

90. In a December 1, 1989 letter, Gholz wrote to Dr. Munnerlyn concerning the Examiner-in-Chief's decision on preliminary motions and *Trokel* claims not in the interference. (CX-197.) He discussed the fact that the *Laser Focus* article was antedateable, but a *Taboada* article was not. Gholz stated that the outlook for allowance of those claims was "fairly bleak," particularly in light of the issuance of the Blum patent, because the Blum patent was not antedateable under 35 U.S.C. §102(e). (Tr. 4268- 4273). Dr. Trokel subsequently overcame these references by limiting his claims to corneal tissue. Tr. 4275.

91. In deciding L'Esperance's Motion for Reconsideration (RX-118), filed December 9, 1989, the Examiner-in-Chief had before him the L'Esperance '913 Patent file history which included the *Girard* reference. Tr. 4838.

92. On January 16, 1990, Dr. Srinivasan testified in the '026 interference, pursuant to VISX's subpoena. (RX 152; RX-543; Tr. 3682). Dr. Srinivasan was an IBM employee who participated in the development of IBM's Blum patent, and who worked with Dr.

Trokel at the IBM laboratory in July, 1983. (CX-168 at 204314; Tr. 4230-4232; Tr. 3680-3682). Gholz expected that the Examiner-in-Chief would read Dr. Srinivasan's testimony. Tr. 4232-4233.

93. Dr. Srinivasan's testimony substantiated Dr. Trokel's testimony about his July, 1983 experiments. (Tr. 3682; Tr.4237-4239). Gholz testified that he had no concern about the Examiner-in-Chief reading Dr. Srinivasan's testimony and concluding that Dr. Trokel's invention was not patentable in light of Dr. Srinivasan's prior work with the excimer laser on biological tissue. Tr. 4236.

94. On January 3, 1990, the Party L'Esperance filed a motion for a special testimony period which requested that a period be set to take testimony regarding the meaning of claims 41 and 50 at the '388 application and the patentability of those claims if given the meaning attributed to it by the Examiner-in-Chief in his decision on preliminary motions. (RX-143 at 147461). L'Esperance's motion for a special testimony period on the question of patentability of Trokel's claims 41 and 50 over the prior art was granted, because the Examiner-in-Chief gave those claims 41 and 50 a broader interpretation than either party. (RX-1490; Order No. 1 Para. 21).

95. Colaianni testified that upon granting the motion to set aside a special testimony period in the Trokel/L'Esperance interference, the Examiner-in-Chief was aware of the patentability issue. Tr.2897-2898.

96. The issue of patentability is always before an Examiner-in-Chief during an interference proceeding. If any prior art references come to their attention which may suggest unpatentability, they have a duty to take action to address those issues. (Tr. 4821). The record also shows that it would be inappropriate for the Board to ignore patentability questions arising during an interference matter pending before it. Tr. 4842-4843.

97. During the period between April 4 and 6, 1990, VISX, California and Taunton Technologies, Inc. agreed to merge. (Stip.1t 29; Order No. 1 Para. 22). Following the announcement of the impending merger of VISX California and Taunton, the PTO, on April 16, 1990, granted a motion for a one-month suspension of the '026 interference. The one-month suspension was later extended several times until judgment was entered on the issue of priority against Dr. L'Esperance in the '026 interference. Stip. Para. 30; Stip. 32; RX-202; Order No. 1 Para. 23.

98. Although as a result of the merger of VISX California and Taunton, no special testimony was taken concerning the patentability of the claims over the prior art, (Tr. 4294-4296), the Examiner-in-Chief, on January 10, 1991, issued an order to show cause why judgment should not be entered against claims 42 through 49 of the '388 application. (RX-204; Order No. 1 Para. 24; Tr. 2919-2922). Had the Examiner-in-Chief also concluded that Trokel claims 41 and 50 were unpatentable, he was required to so state in an order to show cause. (Tr. 2925). In response to the January 10, 1991, order to show cause, VISX submitted a statement of non-opposition with respect to claims 42-49. (Order No. 1 Para. 25; RX-205.)

99. Colaianni testified that even after the parties to the Trokel/L'Esperance interference resolved the issue of priority, the Examiner-in-Chief was statutorily obligated to reject the Trokel claims if he believed they were unpatentable. (Tr. 2937). Colaianni provided two possible explanations for the fact that claims 41 and 50 of the Trokel application were not rejected. First, he suggested that the Examiner-in-Chief simply did not consider the issue of whether claims 41 and 50 were patentable. Second, he suggested that the issue of patentability was squarely in the Examiner-in-Chief's mind because he had raised the issue in January 1990, and granted the special testimony period, but, after thinking about the matter for a year, concluded only that claims 42 through 49 were unpatentable. (Tr. 2937). Colaianni thought that either explanation was plausible, 50/50, (Tr. 2937-2938), but he believed the Examiner-in-Chief never reached the question of patentability of claims 41 and 50 over the prior art. (Tr. 2937-2938). He testified:

Q: Don't you know that he's statutorily obligated to reject the claims as unpatentable, even if the parties agree who should get priority?

A: Yes

Q: But he didn't do that?

A: He didn't do it, but I'm not sure he considered it. But he didn't do it, so I'll grant you that.

Q: So, he failed on his duty, is that your testimony?

A: No, I'm just saying that wasn't an issue before him.

Q: Or maybe it was squarely an issue because [Mr. Boler's] the one who raised it, and after thinking about it for a year, all he concluded was 42 through 49 are unpatentable."

A: I think either might be plausible, but I think it's equally plausible that he didn't reach it. Tr.2937.

At trial, Colaianni changed his testimony from his prior testimony: a 50% chance became a 0% chance. He sought to explain this change as follows:

Q: Okay. So, it's 50/50.

A: No, I don't think so. I think, as I reflect on it and as I look at it now, there is no way that he reached the question of patentability of 41 and 50 on the prior art.

Q: Okay, but at your deposition, it was 50/50.

A: No, I -- I -- that's what it says, but I think, you know, you just wore me down, Mr.

Shulman. You wore me down then but you're not going to wear me down today. Tr. 2937-2938.

Colaianni acknowledged at trial that 50/50 is not clear and convincing evidence. Tr. 2937-2938.

100. On January 16, 1991, a three judge panel of the Board, including Examiner-in-Chief Boler, entered final judgment. The Board held: "Based on the record before us, Stephen L. Trokel is entitled to a patent on his claims 41 and 50 but is not entitled to a patent on his claims 42 through 49 corresponding to the count." (RX-206; Order No. 1 para. 26.). The phrase "record before us" in the Board's decision, RX-206, included all the documentation generated throughout the interference, as well as everything that was in the patent application files. That record included *Keates, Blum, Karp,* and *Girard.*

101. At the outset of his deposition on November 23-24, 1998, Colaianni was unaware that the Board had issued a final decision in which it concluded that Trokel was entitled to a patent on claims 41 and 50 in his application. (Tr. 2892-2893). After he was shown the Board's Final Decision, Colaianni testified that the "record" before the Board mentioned in the Final Decision included all four prior art references at issue in this case: *Blum, Girard, Karp,* and *Keates.* (Tr. 2908). After the lunch break, however, Colaianni changed his testimony and opined that the record before the Board did not include any of the four references, but rather was limited to three documents (referenced in this record as RX-202, RX-204 and RX-205), which the Board specifically mentioned. (Tr. 2915-2918). Consistent with Colaianni's original testimony on this issue, Serota and Gholz testified that the "record before" the Board included all references on Trokel's exhibit list, on L'Esperance's exhibit list, and in the file histories of the '388 application and the '913 patent. (Tr. 4302.)

102. The settlement of the interference did not affect the Board's ability to address the issue of a special testimony period established by the Examiner-in-Chief during the interference or its consideration of patentability raised during the interference proceeding by the Examiner-in-Chief. Tr. 4841-4845.

103. The Examiner-in-Chief raised the issue of patentability during the interference proceeding based on a record which included copious citations to *Karp, Blum,* and *Keates,* and a clear, unambiguous disclosure of *Girard.* (Tr. 4746). That same record was before the Board, consisting of a three member panel including Examiner-in-Chief Boler, when the Board decided the patentability issue in favor of Dr. Trokel. (Tr. 4747-4748). The record before the Examiner-in-Chief and the Board included the prior art references cited in Findings 72, *supra,* and 105-139, *infra.* The Board's final judgment was a judgment on the merits.

Prior Art References Cited During The '026 Interference

1. The *Karp* Reference

104. VISX cited *Karp* on pages 2 and 5-8 of The Party Trokel's Motion No. 5 on January 30, 1989. (RX-1536 at Tab 7.)

105. VISX identified *Karp* as Exhibit 7 in The Party Trokel's List of Exhibits Submitted with its Preliminary Motions on January 30, 1989. (RX-1536 at Tab 10; Order Specifying Undisputed Facts Regarding VISX's Summary Decision Motion No. 1 para. 15.)

106. VISX submitted a copy of *Karp* marked as Exhibit 7 on January 30, 1989. (RX 1536 at Tab 12.)

107. VISX identified a certified translation of *Karp* as Exhibit 8 in The Party Trokel's List of Exhibits Submitted with its Preliminary Motions on January 30, 1989. (RX-1536 at Tab 10.)

108. VISX submitted a copy of a certified translation of *Karp* marked as Exhibit 8 on January 30, 1989. (RX-1536 at Tab 13; Order Specifying Undisputed Facts Regarding VISX's Summary Decision Motion No. 1 para 19.).

109. Taunton cited *Karp* on pages 3 and 6-8 of Senior Party L'Esperance's Opposition to Junior Party Trokel's Motion No. 5 on February 21, 1989. (RX-1536 at Tab 17.)

110. Taunton cited *Karp* on pages 3-7 of Affidavit of Roy C. Hopgood in Support of Senior Party L'Esperance's Opposition to Junior Party Trokel's Motion No. 5 on February 21, 1989. (RX- 1536 at Tab 18.)

111. Taunton submitted a copy of *Karp* as Exhibit 2 to Affidavit of Roy C. Hopgood in Support of Senior Party L'Esperance's Opposition to Junior Party Trokel's Motion No. 5 on February 21, 1989. (RX-1536 at Tab 19.)

112. Taunton submitted a copy of a translation of *Karp* as Exhibit 5 to Affidavit of Roy C. Hopgood in Support of Senior Party L'Esperance's Opposition to Junior Party Trokel's Motion No. 5 on February 21, 1989. (RX-1536 at Tab 20.)

113. VISX cited *Karp* on pages 5-9 of The Party Trokel's Reply to The Party L'Esperance's Opposition to The Party Trokel's Motion No. 5 on March 8, 1989. (RX1536 at Tab 23; CX-143.).

114. The *Karp* reference was before the Examiner-in-Chief on at least ten occasions in the '026 interference. (RX-1564 at 2-5; ***see generally*** Stip. Para. 52.). The Examiner-in-Chief was aware of the *Karp* reference.

2. The *Girard* Reference

115. The *Girard* reference was before the Examiner-in-Chief during the '026 interference. (RX-1564 at 2-5; *see generally* Stip. Al 53.). Specifically, Taunton cited *Girard* on page 5 of Senior Party L'Esperance's Motion Under 37 C.F.R. § 1.633(c)(4) on February 12, 1990. (RX-1536 at Tab 27; Order No. 1 para. 27.).

116. The *Girard* reference in the L'Esperance '913 Patent file history was pertinent to the Examiner-in-Chief's decision on L'Esperance's motion for reconsideration (RX 118), filed December 9, 1989. Tr. 4838.

3. The '135 (Blum) Patent

117. VISX cited *Blum* on pages 4 and 8 of The Party Trokel's Motion No. 4 on January 30, 1989. (RX-1536 at Tab 6; Order No. 1 para. 16.) Footnote 5 of Motion 4 states that the *Blum* et al. patent discloses apparatus that can be used to scan the radiation beam over a portion of the organic material to be etched.'" (Order No. 1 para 16.)

118. VISX cited *Blum* on pages 5-6 of The Party Trokel's Motion No. 13 on January 30, 1989. (RX-1536 at Tab 8.)

119. VISX cited *Blum* on page 3 of the Declaration of Roger F. Steinert on January 30, 1989. (RX-1536 at Tab 9.)

120. VISX identified *Blum* as Exhibit 5 in The Party Trokel's List of Exhibits Submitted with its Preliminary Motions on January 30, 1989. (RX-1536 at Tab 10; Order No. 1 para.15.)

121. VISX submitted a copy of *Blum* marked as Exhibit 5 on January 30, 1989. (RX1536 at Tab 11; Order No. 1 para. 18.)

122. Taunton cited *Blum* on page 4 of Senior Party L'Esperance's Opposition to Junior Party Trokel's Motion No. 4 on February 21, 1989. (RX-1536 at Tab 15.)

123. Taunton cited *Blum* on pages 2-4 of the Declaration of Myron L. Wolbarsht in Support of Senior Party L'Esperance's Opposition to Junior Party Trokel's Motions Nos. 4 and 13 on February 21, 1989. (RX-1536 at Tab 16.).

124. Taunton cited *Blum* on page 3 of Senior Party L'Esperance's Opposition to Junior Party Trokel's Contingent Motion No. 13 on February 21, 1989. (RX-1536 at Tab 21.)

125. The Examiner-in-Chief cited *Blum* on pages 2-3 of his Decision on Preliminary Motions on November 24, 1989. (RX-1536 at Tab 26; Order No. 1 para 32.)

126. The *Blum* patent was before the Examiner-in-Chief on at least nine occasions in the '026 interference. (RX-1564 at 2-5; *see generally* Stip. Para. 49.).

4. The *Keates* Article

127. VISX cited *Keates* on page 6 of The Party Trokel's Motion No. 4 on January 30, 1989. (RX-1536 at Tab 6; Order No. 1 para 16.)

128. VISX cited *Keates* on pages 3 and 5 of The Party Trokel's Motion No. 13 on January 30, 1989. (RX-1536 at Tab 8.)

129. VISX identified *Keates* as Exhibit 17 in The Party Trokel's List of Exhibits Submitted with its Preliminary Motions, and submitted a copy of *Keates to* Examiner-in Chief Boler on January 30, 1989. (RX-1536 et Tab 10; Order No. 1 Para. 15.)

130. VISX submitted a copy of *Keates* marked as Exhibit 17 on January 30, 1989. (RX-1536 at Tab 14; Order No. 1 Para. 20.)

131. Taunton cited *Keates* on pages 4-5 of Senior Party L'Esperance's Opposition to Junior Party Trokel's Motion No. 4 on February 21, 1989. (RX-1536 at Tab 15.)

132. Taunton cited *Keates* on pages 2 and 4-5 of the Declaration of Myron L. Wolbarsht in Support of Senior Party L'Esperance's Opposition to Junior Party Trokel's Motions Nos. 4 and 13 on February 21, 1989. (RX-1536 at Tab 16.)

133. Taunton cited *Keates* on pages 2-3 of Senior Party L'Esperance's Opposition to Junior Party Trokel's Contingent Motion No. 13 on February 21, 1989. (RX- 1536 at Tab 21:)

134. VISX cited *Keates* on page 2 of The Party Trokel's Reply to The Party L'Esperance's Opposition to The Party Trokel's Motion No. 4 on March 8, 1989. (RX 1536 at Tab 22.)

135. VISX cited *Keates* on page 2 of The Party Trokel's Reply to The Party L'Esperance's Opposition to The Party Trokel's Motion No. 13 on March 8, 1989. (RX 1536 at Tab 24.)

136. VISX cited *Keates* on page 1 of Second Declaration of Roger F. Steinert Submitted by the Party Trokel on March 8, 1989. (RX-1536 at Tab 108.)

137. The Examiner-in-Chief cited *Keates* on page 2 of his Decision on Preliminary Motions on November 24, 1989. (RX-1536 at Tab 26; Order Specifying Undisputed Facts Regarding VISX's Summary Decision Motion No. 1 para 32.)

138. The *Keates* article was before the Examiner-in-Chief on at least eleven occasions during the '026 interference proceedings. (RX-1564 at 2-5; ***see generally*** Stip. Para. 51.)

'388 Prosecution/ Post-Interference

139. After the '026 interference terminated, the prosecution of Trokel's patent application resumed, (Stip.para. 33; Order No. 1 para. 30), with respect to claims not involved in the '026 interference. (Order No. 1 para. 29). Gholz's law firm handled the post-interference prosecution of the '388 application. Tr. 3701-3702.

140. Upon resumption of the *ex parte* prosecution, the matter was returned to Examiner Shay, (Order No. 1 para.31), along with the interference files. (Tr. 4302-4303). The examiner received those files, and, pursuant to MPEP 1302.12, at a minimum, reviewed the decision on preliminary motions, (Tr. 4303, 4304; 4452-4453; 4471-4472). and when he was finished with the file, he returned it to the Service Branch of the Board. MPEP 2363.

141. While they are adjudicated before different decision makers, the interference proceeding is part of the prosecution of a patent application not something entirely separate from the *ex parte* prosecution. (Tr. 4850-4852, 4984, 4988). Claims 4 and 5 of the '388 Patent, previously Trokel's claims 41 and 50 in the interference, were found by the Board to be patentable to Trokel. (Stip. 48). Tr. 4845-4846.

142. The MPEP instructs *ex parte* examiners to review those portions of decisions on preliminary motions that relate to "motions to dissolve," (MPEP Section 1302.12), which now constitute any Rule 633(a) motions raising issues of patentability. (Tr. 2580). Complaint Counsel cite no statute, rule, or regulation that states that a reference disclosed during an interference must be resubmitted.

143. Colaianni testified that references cited in an interference are "a perfect example of" things which should, pursuant to Sections 2001.06 (b) and (c) of the MPEP (CX-276), be cited during an *ex parte* prosecution, (Tr.3021). Sections 2001.06(b) and (c) of the MPEP, create no specific duty to re-cite references. Colaianni testified:

Q: But you'd agree that in the language there [of MPEP sections 2001.06(b) and (c)], it doesn't clearly and unambiguously say anything about duties to recite references cited in the interference, would you not?

A: I think that it doesn't say that, but in my estimation, that's a perfect example of where you should cite it. Tr. 3021.

144. It was Gholz's practice at the conclusion of an interference to fill out an IDS identifying all the references cited during the interference so that the references would be printed on the front of the patent. (Tr. 4304-4305; 4307-4308). Gholz testified that he did not believe he was obligated to provide such a list, (Tr. 4306), and, in this instance, he testified that he forgot to submit an IDS upon completion of the '026 interference. (Tr. 4306-4307).

145. On May 14, 1991, VISX filed preliminary amendments for L'Esperance application numbers 708,744 and 701,467. The two documents cross-referenced each other and a co-pending application for a Trokel patent other than the '388. VISX requested an interview with the Examiner to consider all three applications jointly in order to determine whether there might be any double-patenting concerns raised by the three co-pending applications. Order No. 1 para. 36; RX-1421; Tr. 4320-4323.

146. On June 11, 1991, VISX submitted a response to an office action in the '388 prosecution. (RX-1544). In this response, VISX amended claims 38-40 to add a limitation to corneal tissue. (Tr. 4312-4313). VISX added the corneal limitation to overcome the *Laser Focus* disclosure. Tr. 4313.

147. In September 1991, the Examiner rejected claims 38-40 of the Trokel application as being anticipated by *Taboada, et al.* (Order No. 1 para. 37.)

148. The prosecution history of the '913 patent shows that L'Esperance agreed to limit his claims to cover only the removal of tissue from the *anterior surface* of the eye to overcome the Examiner's rejection over *Girard.* CPF 153-154, 209. *Girard* discloses techniques for operating on the anterior portion of the eye, and a technique, keratomileusis, pioneered by Dr. Barraquer that involved removal of a button of corneal tissue, freezing it, then removing tissue from the posterior side of the button and reattaching it. (Tr. 4835). The *Trokel* article, which was cited in the October, 1985 office action discloses keratomileusis. Tr. 4835.

149. On September 24, 1991, Gholz, Dr. Munnerlyn and Roy Hopgood, the attorney handling L'Esperance applications, met with the Examiner in the Examiner's office at the PTO to discuss L'Esperance Application Nos. 708,744 and 701,467 and the Trokel applications. (RX 1515-1517; Tr. 3702-3705; 4339; 4345). The meeting lasted over an hour. (Tr. 3704; 4340). During the meeting, the applications were discussed in series, beginning with the Trokel application. (Tr.4341-4342). VISX discussed potential double-patenting issues among the applications pending with the Examiner. (Tr. 4345-4346). The Examiner determined that there was no double patenting problem between the L'Esperance applications and either of the then-pending Trokel applications, one of which was the '388 application. RX-1515, 1516; Tr. 4396-4397.

150. At the September 24, 1991 meeting, VISX's representatives discussed the *Keates* article with the Examiner. (RX 1515, 1516; Tr. 3705-3707). Those discussions are noted in CX 393 and 394. (Tr. 2830-2831). VISX's representatives also discussed changing certain claims in the '388 application to add the limitation "depth penetration into the stroma," (CX 346), which made allowable claims 1-3 of the '388 patent.

151. At trial, Colaianni testified that he could not read the Examiner's handwritten notes on CX 393 or CX 394, and that he had been unable to obtain better copies of those exhibits to ascertain what the Examiner had written. (Tr. 2831-2833). Colaianni agreed that the Examiner's handwritten notes might be of considerable interest, particularly if the Examiner had indicated that he had considered the claims of the '388 patent application during the portion of the interview devoted to the L'Esperance applications where the

Keates reference was disclosed and discussed. (Tr. 2833-2834). Colaianni was then shown legible copies of CX 393 and CX 394, which are VISX's exhibits, RX 1488 and RX 1489, as well as blow-ups of those exhibits, RX 1515 and RX 1516. Tr. 2834-2835.

Compliant Counsel contend that illegible copies of the examiner interviews had been provided to Complaint Counsel by VISX; however, there is no evidence that VISX purposely produced illegible documents to mislead Complaint Counsel, and Complaint Counsel does not contend otherwise. Moreover, at a pre-trial hearing, I noted that documents related to the meeting were illegible, (*See*, Pre-trial hearing Transcript of December 9, 1998, at 181-182), and, at the outset of the hearing, I again advised Complaint Counsel that many of their documents were illegible, and steps should be taken timely to secure legible documents if they expected to rely upon them in this proceeding. Tr. 16-20.

152. Colaianni testified that if a reference is before an examiner, an applicant is entitled to assume that the examiner read it and drew conclusions about its pertinence to the claims that were before him. (Tr. 2837). Colaianni then reviewed, for the first time, the legible copies of CX 393 and CX 394, in which the Examiner had written that, during the interview, he had "discussed the fact that since any forthcoming allowance would be due to subject matter drawn to the feature of providing different diopter corrections by varying time exposure, there would be no double-patenting issue with the Trokel applications." (Tr. 2838). In determining whether there would be a double-patenting issue between the claims of the L'Esperance applications and the claims of the Trokel applications, the Examiner would have to compare the L'Esperance claims to those in the *Trokel* applications, because "there is no other way to do it." (Tr. 2839-2841). Although he insisted that the Examiner never considered *Keates* in connection with the '388 patent, it was demonstrated to Colaianni that the Examiner was aware of *Keates*. (Tr.2842, 2855). He testified that: "Q....[Mr. Shay] plainly knew about the reference. A. Yes." (Tr. 2836). Colaianni continued to assert, however, that *Keates* was only considered by the Examiner in connection with his double-patenting analysis, not with respect to any prior art analysis involving '388 claims, (Tr. 2846, 2855), but conceded that he had previously testified that if you know the examiner and you file, for example, an Information Disclosure Statement in one application and it's before the same examiner [as a co-pending application], it's not necessary to file it again since "the same examiner has the applications and will be aware of what's going on in the two applications." Tr. at 3034-3035.

153. During the September 24, 1991 interview, the VISX representatives told the Examiner that they believed the *Keates* reference was not germane to the disclosure of *Trokel,* because *Keates* discusses procedures that result in scarring. (Tr. 2848). Colaianni testified that Dr. Trokel made the same comment in his discussion of the carbon dioxide laser prior art set forth in column one of the '388 patent. Tr. 2848-2849.

154. Colaianni testified that during the course of the interview on September 24, 1991, VISX did nothing to prevent the Examiner from comparing the *Keates* reference to the claims of the '388 patent application, (Tr. 2849), and he did not "mean to imply" that

during this interview on September 24, 1991, VISX did anything " to hide the ball" from the Examiner. Tr. 2849-2851.

155. The only Trokel applications pending in the PTO as of September 24, 1991 were the applications for the '388 patent, and Serial No. 673,541. (RX-1084 (Related U.S. Application Data).) Both of these applications were assigned to the Examiner. (RX-1084 (Primary Examiner); RX-1074 (Primary Examiner).)

156. On April 28, 1992, the '388 patent issued. (Order No. 1 para 38; Stip. Para. 48.)

The Examiner Prior Art Searches During The '388 Prosecution

157. During the prosecution of the application for the '388 patent, the Examiner searched for material prior art in class 128, subclass 303.1 where *Karp is* located in the PTO (Tr. 2773-2774; RX-1074). The dates on which he conducted his searches for material prior art, and the number of times he searched for such prior art in class 128, subclass 303.1, are revealed in the file history of the '388 patent application. Tr. 2774-2775; RX-1507.

158. The Examiner conducted a search in class 128/303.1, (1) in U.S. Patent App. Ser. No. 561,804 (Trokel) on January 30, 1985. RX-1536 at Tab 1; (2) in U.S. Patent App. Ser. No. 859,212 (Trokel) on September 17, 1986. RX-1536 at Tab 2; (3) in U. S. Patent App. Ser. No. 109,812 (Trokel) on July 7, 1988. RX-1536 at Tab 25; and (4) in U.S. Patent App. Ser. No. 109,812 (Trokel) on September 12, 1991. RX-1536 at Tab 25. While the Examiner searched in the classes and subclasses containing the *Karp* reference on at least four occasions in the course of the prosecution of the Trokel '388 Patent, (RX-1564 at 12-13), he may not have considered those references.

159. The Examiner searched in the classes and subclasses where the Blum patent is archived at the PTO on at least four occasions in the course of the prosecution of the Trokel '388 Patent. RX-1564 at 12-13. He conducted searches in class 606/3 where *Blum* is archived, (1) in connection with U.S. Patent App. Ser. No. 109,812 On January 23, 1990, (RX-1536 at Tab 25); (2) in class 128/303.1 in U.S. Patent App. Ser. No. 109,812 on September 12, 1991, (RX-1536 at Tab 25); (3) in class 128/395, in U.S. Patent App. Ser. No. 109,812) on September 12, 1991, (RX-1536 at Tab 25.); and (4) in class 606/3 where *Blum* is archived, in U.S. Patent App. Ser. No. 109,812 on September 12, 1991. RX-1536 at Tab 25. It is possible that a copy of a particular patent may not be available at the particular time the examiner conducts his search.

Citations To Prior Art References in Co-Pending Applications

160. VISX cited *Keates, Karp, Girard,* and *Blum* to the Examiner on numerous occasions during the prosecution of co-pending applications.

1. The *Karp* Reference

161. The *Karp* reference was before the Examiner on at least sixteen occasions in VISX's (or VISX's predecessor-in-interest, Taunton) co-pending patent applications during the prosecution of the Trokel '388 Patent. RX-1564 at 6-11.

162. Examiner Shay and Taunton discussed *Karp* in an Examiner Interview for Patent App. Ser. No. 691,923 (L'Esperance) on September 16,1986. RX-1536 at Tab 45.

163. Examiner Shay considered *Karp,* which is cited in Form PTO-892 in Patent App. Ser. No. 691,923 (L'Esperance) on November 3,1986.RX-1536 at Tab 46.

164. Examiner Shay considered *Karp,* which is cited in Form PTO-892 in Patent App.Ser. No. 748,358 (L'Esperance) on November 4,1986.RX-1536 at Tab 47.

165. Examiner Shay cited *Karp* on pages 2-4 of Examiner's Action in Patent App.Ser. No. 748,358 (L'Esperance) on November 14, 1986. RX-1536 at Tab 48.

166. The Examiner cited *Karp* on pages 2-3 of Examiner's Action in Patent App. Ser. No. 691,923 (L'Esperance) on November 14, 1986.RX-1536 at Tab 49.

167. Taunton cited *Karp* on pages 2-3 and 5-6 of Amendment in Patent App. Ser. No. 691,923 (L'Esperance) on December 5, 1986. RX-1536 at Tab 50.

168. Taunton cited *Karp* on pages 2-3,5-7 and 9 of Amendment in Patent App. Ser. No.748,358 (L'Esperance) on December 8,1986. RX-1536 at Tab 51.

169. Taunton cited *Karp* on pages 1-3 of Supplement to Summary of Interview, Involving Examiner David Shay, and Applicant's Attorneys, Roy C. Hopgood and Stephen Banker in Patent App. Ser. No. 748,358 (L'Esperance) on December 8,1986. RX-1536 at Tab 52.

170. Examiner Shay and Taunton discussed *Karp* in an Examiner Interview for Patent App. Ser. No. 691,923 (L'Esperance) on January 20, 1987.RX-1536 at Tab 53.

171. The Examiner considered *Karp,* which is cited in Form PTO-1449 in Patent App. Ser. No.748,358 (L'Esperance) on January 20, 1987.RX-1536 at Tab 54.

172. The Examiner considered *Karp,* which is cited in Form PTO-892 in Patent App. Ser. No. 691,923 (L'Esperance) on January 27, 1987. RX-1536 at Tab 55.

173. The Examiner considered *Karp,* which is cited in Form PTO-892 in Patent App. Ser. No. 916,646 (L'Esperance) on February 11, 1987.RX-1536 at Tab 56.

174. The Examiner cited *Karp* on page 4 of Examiner's Action in Patent App. Ser. No. 916,646 (L'Esperance) on February 20, 1987.RX-1536 at Tab 57.

175. The Examiner allowed Taunton's U.S. Patent No. 4,665,913 (L'Esperance) to issue over *Karp* on May 19, 1987. RX-1536 at Tab 3.

176. The Examiner allowed Taunton's U.S. Patent No. 4,669,466 (L'Esperance) to issue over *Karp* on June 2, 1987. RX-1536 at Tab 59.

177. The Examiner allowed Taunton's U.S. Patent No. 4,718,418 (L'Esperance) to issue over *Karp* on January 12, 1988. RX-1536 at Tab 65.

178. The *Karp* reference was cited in patents issued by the Examiner on at least four occasions during the prosecution of the Trokel '388 Patent. RX-1564 at 12-13.

179. The Examiner allowed U.S. Patent No. 4,856,513 (Muller) to issue over *Karp* on August 15, 1989. RX-1536 at Tab 102.

180. The Examiner allowed U.S. Patent No. 4,994,058 (Raven) to issue over *Karp* on February 19, 1991. RX-1536 at Tab 105.

181. The Examiner allowed U.S. Patent No. 5,019,074 (Muller) to issue over *Karp* on May 28, 1991. RX-1536 at Tab 106.

182. The Examiner allowed U.S. Patent No. 5,102,409 (Balgorod) to issue over *Karp* on April 7, 1992. RX-1536 at Tab 107.

2. The *Girard* Reference

183. The *Girard* reference was before the Examiner on at least fifty occasions in VISX's (or VISX's predecessor-in-interest, Taunton) co-pending patent applications during the prosecution of the Trokel '388 Patent. RX- 1564 at 6- 11.

184. The Examiner considered *Girard,* which is cited in Form PTO-892 in Patent App. Ser. No. 552,983 (L'Esperance) on January 9, 1985. RX-1536 at Tab 32.

185. The Examiner cited *Girard* on pages 5-6 of Examiner's Action in Patent App. Ser. No. 552,983 (L'Esperance) on March 1, 1985. RX-1536 at Tab 33.

186. The Examiner and Taunton discussed *Girard* in an Examiner Interview for Patent App. Ser. No. 552,983 (L'Esperance) on March 20, 1985. RX-1536 at Tab 34.

187. Taunton cited *Girard* on pages 6-7 of Amendment in Patent App. Ser. No. 552,983 (L'Esperance) on March 22, 1985. RX-1536 at Tab 35.

188. The Examiner and Taunton discussed *Girard* in an Examiner Interview for Patent App. Ser. N o. 552,983 (L'Esperance) on March 28, 1985. RX-1536 at Tab 36.

189. The Examiner considered *Girard,* which is cited in Form PTO-892 in Patent App. Ser. No. 748,358 (L'Esperance) on September 10, 1985. RX-1536 at Tab 37.

190. The Examiner considered Girard, which is cited in Form PTO-892 in Patent App. Ser. No. 740,276 (L'Esperance) on September 10, 1985. RX-1536 at Tab 38.

191. The Examiner considered Girard, which is cited in Form PTO-892 in Patent App. Ser. No. 691,923 (L'Esperance) on September 12, 1985. RX-1536 at Tab 39.

192. The Examiner cited Girard on pages 4-5 of Examiner's Action in Patent App. Ser. No. 691,923 (L'Esperance) on October 1, 1985. RX-1536 at Tab 40.

193. The Examiner cited Girard on pages 2-3 of Examiner's Action in Patent App. Ser. No. 748,358 (L'Esperance) on October 1, 1985. RX-1536 at Tab 41.

194. The Examiner cited Girard on pages 3-4 of Examiner's Action in Patent App. Ser. No. 740,276 (L'Esperance) on October 15, 1985. RX-1536 at Tab 42.

195. The Examiner and Taunton discussed Girard in an Examiner Interview for Patent App. Ser. No. 748,358 (L'Esperance) on October 17, 1985. RX-1536 at Tab 109.

196. Taunton cited *Girard* on page 11 of Amendment in Patent App. Ser. No. 740,276 (L'Esperance) on November 20, 1985. RX- 1536 at Tab 43.

197. The Examiner cited *Girard* on pages 3-4 of Examiner's Action in Patent App. Ser. No. 794,444 (L'Esperance) on April 11, 1986. RX-1536 at Tab 44.

198. The Examiner cited *Girard* on pages 2-4 of Examiner's Action in Patent App. Ser. No. 748,358 (L'Esperance) on November 14, 1986. RX-1536 at Tab 48.

199. The Examiner cited *Girard* on page 3 of Examiner's Action in Patent App. Ser. No. 691,923 (L'Esperance) on November 14, 1986. RX-1536 at Tab 49.

200. Taunton cited *Girard* on page 7 of Amendment in Patent App. Ser. No. 691,923 (L'Esperance) on December 5, 1986. RX-1536 at Tab 50.

201. Taunton cited *Girard* on pages 5 and 8-9 of Amendment in Patent App. Ser. No. 748,358 (L'Esperance) on December 5, 1986. RX-1536 at Tab 51.

202. The Examiner and Taunton discussed Girard in an Examiner Interview for Patent App. Ser. No. 746,330 on April 16, 1987. RX-1536 at Tab 58.

203. The Examiner allowed Taunton's U.S. Patent No. 4,665,913 (L'Esperance) to issue over Girardon May 19, 1987. RX-1536 at Tab3.

204. The Examiner allowed Taunton's U.S. Patent No. 4,669,466 (L'Esperance) to issue over *Girard* on June 2, 1987. RX-1536 at Tab 59.

205. Taunton cited *Girard* on pages 7-8 of Amendment in Patent App. Ser. No. 891,169 (L'Esperance) on June 3, 1987. RX-1536 at Tab 60.

206. The Examiner cited *Girard* on pages 3-5 of Examiner's Action in Patent App. Ser. No. 891,169 (L'Esperance) on August 26, 1987. RX-1536 at Tab 61.

207. The Examiner considered *Girard,* which is cited in Form PTO-892 in Patent App. Ser. No. 891,285 (L'Esperance) on September 10, 1987. RX-1536 at Tab 62.

208. The Examiner cited *Girard* on page 3 of Examiner's Action in Patent App. Ser. No. 891,285 (L'Esperance) on September 16, 1987. RX-1536 at Tab 63.

209. Taunton cited *Girard* on pages 2 and 8 of Affidavit of Louis J. Girard in Patent App. Ser. No. 891,169 (L'Esperance) on December 2, 1987. RX-1536 at Tab 64.

210. The Examiner allowed Taunton's U.S. Patent No. 4,732,148 (L'Esperance) to issue over *Girard* on March 22, 1988. RX-1536 at Tab 66.

211. Taunton cited *Girard* on pages 7 and 9 of Applicant's Brief on Appeal in Patent App. Ser. No. 891,169 (L'Esperance) on March 30, 1988. RX-1536 at Tab 67.

212. The Examiner cited *Girard* on page 5 of Examiner's Action in Patent App. Ser. No. 060,164 (L'Esperance) on March 31, 1988. RX-1536 at Tab 68.

213. Taunton cited *Girard* on pages 6-7 of Amendment in Response to Final Rejection in Patent App. Ser. No. 060,164 (L'Esperance) on April 12, 1988. RX-1536 at Tab 69.

214. The Examiner considered Girard, which is cited in Form PTO-892 in VISX's co-pending Patent App. Ser. No. 081,986 (Munnerlyn) on June 3, 1988. RX-1536 at Tab 70.

215. The Examiner cited Girard on pages 2-4 of Examiner's Action in VISX's co-pending Patent App. Ser. No. 081,986 (Munnerlyn) on June 29, 1988. RX-1536 at Tab 71.

216. The Examiner cited *Girard* on page 11 of Examiner's Answer in Patent App. Ser. No. 891,169 (L'Esperance) on July 13, 1988. RX-1536 at Tab 72.

217. VISX cited *Girard* on pages 1-4 of Response to Office Action in VISX's co-pending Patent App. Ser. No. 081,986 (Munnerlyn) on August 23, 1988. RX-1536 at Tab 73.

218. VISX cited *Girard* on pages 3-4 of Declaration by Applicant on Objective Evidence of Non-obviousness in VISX's co-pending Patent App. Ser. No. 081,986 (Munnerlyn) on August 23, 1988. RX-1536 at Tab 74.

219. Examiners Shay and Cohen cited Girard on pages 3-5 of Examiner's Action in Patent App. Ser. No. 165,535 (Bennett) on October 4, 1988. RX-1536 at Tab 75.

220. The Examiner cited *Girard* on page 3 of Examiner's Action in VISX's co-pending Patent App. Ser. No. 081,986 (Munnerlyn) on November 18, 1988. RX-1536 at Tab 76.

221. Taunton cited *Girard* on page 6 of Applicant's Brief on Appeal in Patent App. Ser. No. 060,164 (L'Esperance) on December 29, 1988. RX-1536 at Tab 77.

222. Taunton cited *Girard* on page 6 of Amendment Under 37 C.F.R. 1.115 in Patent App. Ser. No. 165,535 (Bennett) on February 3, 1989. RX-1536 at Tab 78.

223. The Examiner considered *Girard*, which is cited in Form PTO-892 in Patent App. Ser. No. 278,272 (Warner) on May 16, 1989. RX-1536 at Tab 79.

224. The Examiner cited *Girard* on pages 2-3 of Examiner's Action in Patent App. Ser. No. 278,272 (Warner) on May 30, 1989. RX-1536 at Tab 80.

225. Taunton cited *Girard* on page 5 of Amendment and Submission of Formal Drawing in Patent App. Ser. No. 278,272 (Warner) on June 20, 1989. RX-1536 at Tab 81.

226. Taunton cited *Girard* on page 7 of Applicant's Brief on Appeal in Patent App. Ser. No. 327,988 (L'Esperance) on January 31, 1990. RX-1536 at Tab 84.

227. Taunton cited *Girard* on page 1 of Appendix Binder in Patent App. Ser. No. 327,988 (L'Esperance), and submitted a copy of Girard on January 31, 1990. RX-1536 at Tab 85.

228. The Examiner allowed Taunton's U.S. Patent No. 4,903,695 (Warner) to issue over *Girard* on February 27, 1990. RX-1536 at Tab 86.

229. The Examiner allowed Taunton's U.S. Patent No. 4,905,711 (Bennett) to issue over *Girard* on March 6, 1990. RX-1536 at Tab 87.

230. The Examiner considered *Girard,* which is cited in Form PTO-892 in Patent App. Ser. No.493,337 (L'Esperance) on July 26, 1990. RX-1536 at Tab 88.

231. The Examiner cited *Girard* on page 3 of Examiner's Action in Patent App. Ser. No. 493,337 (L'Esperance) on August 8, 1990. RX-1536 at Tab 89.

232. Taunton cited *Girard* on pages 5-7 of Amendment in Patent App. Ser. No. 493,337 (L'Esperance) on November 5, 1990. RX-1536 at Tab 90.

233. The Examiner cited *Girard* on pages 2, 4 and 9 of Examiner's Action in VISX's co-pending Patent App. Ser. No. 493,337 (L'Esperance) on April 30, 1991. RX-1536 at Tab 94; Order No. 1 para. 34.

234. The *Girard* reference was cited in patents issued by Examiner Shay on at least six occasions during the prosecution of the Trokel '388 Patent. RX-1564 at 12-13.

235. The Examiner allowed U.S. Patent No. 4,838,266 (Koziol) to issue over *Girard* on June 13, 1989. RX-1536 at Tab 100.

236. The Examiner allowed U.S. Patent No. 4,840,175 (Peyman) to issue over *Girard* on June 20, 1989. RX-1536 at Tab 101.

237. The Examiner allowed U.S. Patent No. 4,856,513 (Muller) to issue over *Girard* on August 15, 1989. RX-1536 at Tab 102.

238. The Examiner allowed U.S. Patent No. 4,994,058 (Raven) to issue over *Girard* on February 19, 1991. RX-1536 at Tab 105.

239. The Examiner allowed U.S. Patent No. 5,019,074 (Muller) to issue over *Girard* on May 28, 1991. RX-1536 at Tab 106.

240. The Examiner allowed U.S. Patent No. 5,102,409 (Balgorod) to issue over *Girard* on April 7, 1992. RX-1536 atTab 107.

3. The Blum Patent

241. The Blum patent was before the Examiner on at least four occasions in VISX's (or VISX's predecessor-in-interest, Taunton) co-pending patent applications during the prosecution of the Trokel '388 Patent. RX-1564 at 6-11.

242. 253.Taunton cited *Blum* on pages 9-10 of Applicant's Brief on Appeal in Patent App. Ser. No. 060,164 (L'Esperance) on December 29, 1988. RX-1536 at Tab 77.

243. Taunton cited *Blum* on pages 2-3 of Supplement to Applicant's Brief on Appeal in Patent App. Ser. No. 891,169 (L'Esperance) on June 23, 1989. RX-1536 at Tab 82.

244. Taunton cited *Blum* on page 2 of Petition for Leave to File Supplement to Applicant's Brief on Appeal in Patent App. Ser. No. 891,169 (L'Esperance) on June 23, 1989. RX-1536 at Tab 83.

245. VISX cited *Blum* on page 9 of Applicant's Reply in VISX's co-pending Patent App. Ser. No. 327,988 (L'Esperance) on May 7, 1991. Order No. 1 Para. 35; RX-1536 at Tab.95.

246. The *Blum* patent was cited in patents issued by the Examiner on at least two occasions during the prosecution of the Trokel '388 Patent. RX-1564 at 12-13.

247. The Examiner allowed U.S. Patent No. 4,901,718 (Bille) to issue over *Blum* on February 20, 1990. RX-1536 at Tab 103.

248. The Examiner allowed U.S. Patent No. 4,907,586 (Bille) to issue over *Blum* on March 13, 1990. RX- 1536 at Tab 104.

4. The *Keates* Article

249. The *Keates* article was before the Examiner on at least eleven occasions in VISX's (or VISX's predecessor-in-interest, Taunton) co-pending patent applications during the prosecution of the Trokel '388 Patent. RX- 1564 at 6- 11.

250. The Examiner considered *Keates,* which is cited in Form PTO-892 in VISX's co-- pending Patent App. Ser. No. 327,988 (L'Esperance) on January 23, 1991. X-1536 at Tab 91.

251. The Examiner cited *Keates* on pages 3-6 of Examiner's Answer in VISX's co-pending Patent App. Ser. No. 327,988 (L'Esperance) on January 28, 1991. RX-1536 at Tab 92; Order No. 1 para. 33

252. The Examiner considered *Keates,* which is cited in Form PTO-892 in VISX's co-pending Patent App. Ser. No. 493,337 (L'Esperance) on April 5, 1991. X-1536 at Tab 93.

253. The Examiner cited *Keates* on pages 2 and 4 of Examiner's Action in VISX's co-- pending Patent App. Ser. No. 493,337 (L'Esperance) on April 30, 1991. X-1536 at Tab 94; Order No. 1 Para. 34

254. VISX cited *Keates* on pages 2-8 and 10-12 of Applicant's Reply in VISX's co-pending Patent App. Ser. No. 327,988 (L'Esperance) on May 7, 1991. The reply included a discussion of *Keates* and the *Trokel* article, and also cited the *Blum* patent. Order No. 1, Para. 35; RX-1536 at Tab 95.

255. VISX and the Examiner discussed *Keates* and Trokel applications in an Examiner Interview for VISX's co-pending Patent App. Ser. No. 708,744 (L'Esperance); at this same meeting, claims 1-3 of the '388 Patent were allowed in VISX's Patent App. Ser. No. 109,812 (Trokel) on September 24, 1991. RX-1536 at Tabs 29 and 31.

256. VISX and the Examiner discussed *Keates* and Trokel applications in an Examiner Interview for VISX's co-pending Patent App. Ser. No. 701,467 (L'Esperance); at this same meeting, claims 1-3 of the '388 Patent were allowed in VISX's Patent App. Ser. No. 109,812 (Trokel) on September 24, 1991. RX-1536 at Tabs 30 and 31.

257. VISX cited *Keates* on pages 17-27 and 27 of Second Preliminary Amendment in VISX's co-pending Patent App. Ser. No. 708,744 (L'Esperance) on October 2, 1991. RX 1536 at Tab 96.

258. VISX listed *Keates* as Tab 2 of Binder Accompanying Second Preliminary Amendment in VISX's co-pending Patent App. Ser. No. 708,744 (L'Esperance), and VISX submitted copy of *Keates to* the Examiner on October 2, 1991. RX-1536 at Tab 97.

259. VISX cited *Keates* on pages 5-12 and 15 of Second Preliminary Amendment in VISX's co-pending Patent App. Ser. No. 701,467 (L'Esperance) on October 2, 1991. RX-1536 at Tab 98.

260. VISX listed *Keates* as Tab 2 of Binder Accompanying Second Preliminary Amendment in VISX's co-pending Patent App. Ser. No. 701,467 (L'Esperance), and VISX submitted copy of *Keates* to the Examiner on October 2, 1991. RX-1536 at Tab 99.

261. The *Keates* article was cited in patents issued by the Examiner on at least three occasions during the prosecution of the Trokel '388 Patent. RX-1564 at 12-13.

262. The Examiner allowed U.S. Patent No. 4,856,513 to issue aver *Keates* on August 15, 1989. RX-1536 at Tab 102.

263. The Examiner allowed U.S. Patent No. 4,994,058 (Raven) to issue over *Keates* on February 19, 1991. RX-1536 at Tab 105.

264. The Examiner allowed U.S. Patent No. 5,019,074 (Muller) to issue over *Keates* on May 28, 1991. RX-1536 at Tab 106.

265. Complaint Counsels' patent expert, Colaianni, offered internally conflicted testimony in respect to the need to re-cite references previously cited to the same examiner in a co-pending patent application. While he testified on direct examination that, "I think that the practice should be" to re-cite the reference, (Tr.3031 -3032), on cross-examination it was revealed that in June, 1997, he testified in Pennsylvania state court that when a reference has been disclosed to the same examiner in a different patent application "it's not necessary to file it again since the same examiner has the applications and will be aware of what's going on in the two applications." (RX-1518; RX 1512; Tr. 3035).

266. The Examiner acquired considerable experience in reviewing applications in the field of excimer lasers and ophthalmologic methods over the course of the prosecution history of the L'Esperance and Trokel applications, and was very familiar with the content of *Girard, Keates, Karp, (See,* Complaint Counsels' Proposed Rebuttal Finding 80, filed (2/15/99), and *Blum. (See,* Findings 242-246, *supra . See also,* Tr. 4867-4868; Tr. 3034-3035.

267. In addition to the specific references to *Karp* and *Girard* and the European Blum patent considered by the Examiner during the '913 patent prosecution, (Finding 72), and by examiners Cohen and Shay in connection with the preparation of the Form 850, (Finding 76-78), and by the Examiner-in-Chief in declaring the interference, (Finding 79), the record shows that *Karp* was cited on at least 65 instances in at least ten different documents during the interference, (Findings 105-115); *Girard* was cited both in the '913 patent and L'Esperance's Section 1.633(a)(4) Motion, (Findings 116-117); *Blum* was cited at least 25 times in nine separate documents, (Findings 118- 127); and *Keates* was cited at least 19 times in at least eleven documents,(Findings 138). The record further shows that, during his consideration of co-pending applications between 1985 and 1992, and *Karp* was cited to the Examiner at least 83 times on sixteen different occasions, (Findings 164-184); *Girard* was cited to him at least 192 times on at least fifty different occasions, (Findings 185-242); *Keates* was cited to him at least 88 times on at least eleven different occasions, (Findings 251-266); and *Blum* was cited to him at least 10 times on at least four different occasions.(Findings 243-250).

268. The Examiner was aware of the Blum patent, the *Girard* reference, the *Keates* article, and the *Karp* reference when the '388 patent issued on April 28, 1992.

THE '388 PATENT

Claim 1 of the '388 Patent

269. Claim 1 of the '388 patent, including the preamble, reads as follows:

> A method for producing a surgical excision of controlled depth and shape in a cornea by ablative photochemical decomposition of corneal tissue without thermal damage to the corneal tissue, said method comprising the steps of:
>
> > (a) generating a laser beam in the far ultraviolet region of the energy spectrum and at a wavelength selected to produce ablative photochemical decomposition of corneal tissue without thermal damage to the corneal tissue and
> >
> > (b) directing said radiation in a controlled manner onto said corneal tissue to induce ablative photochemical decomposition thereof in a volumetric removal of said corneal tissue without thermal heating to create a surgical excision of controlled depth and shape with depth penetration into the stroma.

Claim 2 of the '388

270. The method of claim 1 wherein said selected wavelength is 193 nanometers.

Claim 3 of the '388 Patent

271. Claim 3 of the '388 patent states:

> A method for producing a surgical excision of controlled depth and shape in a cornea by ablative photochemical decomposition of corneal tissue without thermal damage to the corneal tissue, said method comprising the steps of:
>
> > (a) generating a laser beam at a wavelength of 193 nanometers;
> > (b) directing said laser beam onto a predetermined area of corneal tissue; and
> > (c) controlling said laser beam so as to induce ablative photochemical decomposition of said corneal tissue in a volumetric removal of said corneal tissue without thermal damage to said corneal tissue to create a surgical excision of controlled depth and shape with depth penetration into the stroma.

Claim 4 of the '388 Patent

272. Claim 4 of the '388 patent states:

> The method of changing optical properties of an eye by operating solely upon the anterior surface of the cornea of the eye, which method comprises selective ultraviolet irradiation and attendant ablative photodecomposition of the anterior surface of the cornea in a volumetric removal of corneal tissue and with depth penetration into the stroma and to a predetermined curvature profile. CX 327 (col. 7, line 18 - col. 8, line 5) ('388 patent).

Claim 5 of the '388 Patent

273. Claim 5 of the '388 patent states:

> The method of using an ultraviolet laser to change the optical properties of an eye, which method comprises adjusting the intensity of laser beam projection to a level at which laser beam projection onto the anterior surface of the cornea of the eye will result in corneal-tissue ablation per unit time which is but a fraction of a predetermined maximum ablation depth into the stroma of the cornea, and directing the laser beam at the anterior surface of the cornea in a controlled manner to create at least one excision in the anterior surface of the cornea relative to the optic axis thereof by volumetric removal of corneal tissue in the course of ablative photodecomposition of the stroma causing a redefinition of the anterior surface of the cornea.

Prior Art References Disclosed
In The '388 Patent Application

274. The *Trokel* article was cited as a reference and listed on the face of the '388 patent. (RX-1074; Tr. 325-326). The *Trokel* article expressly discusses using the laser "to remove a shaped area of cornea to any depth as would be done in a lamellar keratectomy" and "to reshape the corneal curvature in a manner similar to keratomileusis. The *Trokel* article also discloses making radial incisions. (RX-221 at 149129). The *Girard* reference disclosed the techniques for performing keratomileusis and superficial keratectomy.

275. The *Keates* article disclosed the use of C02 lasers in ophthalmology. The '388 patent does not specifically mention the *Keates* article, but a section in the '388 patent, entitled "Description of the Prior Art," discloses that thermal lasers are used in ophthalmology. (Tr. 578; Tr. 820-821). The '388 specification discloses "that the CO2 laser could be used on all types of eye tissue, including specifically the cornea." (Tr. 582). The specification also discloses that the CO2 laser may cause unwanted changes such as thermal damage. Tr. 584.

Upon reading these disclosures, Dr. Keates freely acknowledged: "Q: So you understand this passage of Dr. Trokel's patent to be referring to thermal lasers like to carbon dioxide laser, correct? A: Yes." (Tr. 578). Colaianni also noted that prior art cited by Dr. Trokel (the L'Esperance '541 patent) "plainly discloses" use of a carbon dioxide laser on the cornea. Tr. 2813-2815; Tr. 582). One skilled in the art in 1983, such as Dr. Keates, considered the generic description in the cited passage of the '388 patent sufficient to include carbon dioxide lasers. Tr. 582

276. U.S. Patent No. 3,982,541, which was cited in the '388 patent, disclosed that the CO2 laser had been used to perform surgery on the cornea. Tr. 822-823.

277. The record shows that the excimer laser, unlike the carbon dioxide laser, does not cause thermal damage. (Tr. 2805). Colaianni testified that Dr. Trokel disclosed this difference to the examiner in columns one and two of his '388 patent. Tr. 2805; 2811-2817; RX-1074; RX-1023; *See also*,Tr. 583-584; Tr. 823-824.

278. The '388 patent does not specifically mention the IBM ' 135 patent (Blum), but the "Description of the Prior Art" in the '388 patent disclosed "a new tissue interaction" and "ablative photodecomposition." (Tr. 824, 825-826). Dr. Keates testified that he understood the passage to be referring to the IBM work: "Q: So you would understand from reading this that Trokel is saying this IBM work that we have just looked at is part of the prior art, right? A: Yes, sir." (Tr. 584-586). Colaianni agreed. (Tr. 2816-2817). An article entitled *Far-UV Photoetching of Organic Material* by R.Srinivasan, *et. al.*, employees of IBM Thomas J. Watson Research Center, printed in the May, 1983 issue of the publication, *Laser Focus, (*hereinafter, *Laser Focus*), is listed on the cover of the '388 patent.

Materiality Of Prior Art References

279. The thrust of Dr. Trokel's work disclosed in the '388 patent is a description of the 193 nanometer excimer laser used as a corneal etching instrument or tool. (Tr. 1849). The invention of the '388 patent is the use of an excimer laser as a new tool to etch corneal tissue for the purpose of performing whatever surgical procedure one wants to perform. (Tr. 2156). It is not specific to a particular surgical procedure, such as keratomileusis, corneal transplants, or radial keratotomy. Tr. 2156-2157.

280. Dr. Keith P. Thompson, Associate Professor of Ophthalmology, Emory University, and Medical Director of Emory Vision Correction Center, the refractive surgery unit at Emory, was called by Complaint Counsel as an expert witness to testify concerning ophthalmology, refractive surgery, and the use of lasers and excimer lasers in refractive surgery. Tr. 1785.

281. Dr. Thompson admitted that no one reading the *Trokel* article (RX-221) or the '388 patent (RX-1074) would think that Dr. Trokel invented lamellar keratectomy, corneal transplants, refractive keratoplasty, radial incisional surgery, or keratomileusis. (Tr. 2211-2214). What a person of skill in the art would understand from reading the '388 patent or the *Trokel* article is that Dr. Trokel was suggesting that his excimer laser discovery might be used as a new way of performing these old procedures. (Tr. 2215). Dr. Trokel's article is listed on the first page of the patent. Tr. 2219-2220; RX-1074.

282. Dr. Thompson's expert report did not refer to any claims of the '388 patent because Complaint Counsel had not asked him to compare the claims to the four prior art references at issue. (Tr. 2056-2058). At the hearing, however, Dr. Thompson did compare the four references to '388 patent claims. Tr. 1944-1974.

283. Dr. Thompson testified, on cross-examination, that his report contained several errors. First, he erred in numerous references which indicate that prior art anticipated the '388 patent. He agreed that such conclusions should be stricken from his report because they are wrong. (Tr. 2063-2065; RX-1501). He also agreed he was wrong in concluding that, "minimum fluence for pulsed radiation is at least 10mj/sq.cm.,"(in Section IV of his report), is disclosed in the '135 patent, but is absent from *Laser Focus*.

Dr. Thompson further acknowledged that he was mistaken when he concluded that in the '135 patent, "A specific excimer laser model is disclosed including specific information regarding the laser necessary to carry out ablative photodecomposition," but *Laser Focus* does not contain that disclosure. (Tr. 2065-2069; RX-1501). Finally, he agreed that he was in error in concluding in his report that "a beam steering mirror is disclosed in ('135patent) which teaches scanning of the laser over the target allowing for a stationary laser system" but is not disclosed in *Laser Focus*. Tr. 2248-2250; RX-1501.

284. The record shows that Colaianni relied upon Dr. Thompson's report and direct testimony and that he neither heard nor reviewed Dr. Thompson's testimony on cross-examination at the hearing. Tr. 2697-2698, 2798.

285. Dr. Thompson opined that the Blum patent was the most material of the four prior art references, followed by *Girard, Keates,* and *Karp. Karp* was the least material reference according to Dr. Thompson. Tr. 2060-2061.

Materiality Of The Blum Patent
In Light Of The *Laser Focus* Article

286. Respondent disputes the materiality of the '135 patent *(Blum)* only to the extent it believes *Blum is* cumulative of the *Laser Focus* article. (Tr. 5719). Colaianni explained that the issue of whether the *Blum* patent is cumulative of the *Laser Focus* article must be made "vis-a-vis the claims" of the '388 patent. (Tr. 2868). The *Laser Focus* article (RX 513) was considered by the patent examiner during the prosecution of the '388 Patent. RX-1074 (References Cited); Order Specifying Undisputed Facts Regarding VISX's Summary Decision Motion No. 2 Para.18.

287. An element-by-element comparison demonstrates that the *Laser Focus* article discloses every element of the independent claims of the '388 Patent disclosed by the *Blum* patent. RX-1539, Ex. B.

288. Ablative photochemical decomposition, a term used in claim 1 of the '388 patent is disclosed in the '135 patent. The generation of a laser beam in the far ultraviolet region of the energy spectrum, including a beam at 193 nm, and the use of such laser beam on biological tissue without thermal damage is similarly disclosed several times in the '135 patent. For example, the patent states: "Accordingly, a primary object of this invention is to provide an apparatus and method for efficient removal of organic biological material without heating or adverse effects to the areas of the material surrounding the area being irradiated." CX 184 (the '135 patent at col line 37; col 2, line 10; col 4, line 44); Tr. 1940; 1941; Tr. 3883, 3887.

289. The '135 patent discloses photo etching the surface of biological material in a controlled manner. (CX 184 (the '135 patent at col 2, line 24); Tr. 1947; Tr. 3884-3885, 3891). The *Laser Focus* article contains the same disclosure. (Tr. 3888-3892; *See also, Laser Focus* (RX-513) at page 1, second paragraph, last sentence which states: "We have found that intense beams of 193-nm radiation from a pulsed argon fluoride excimer laser are very effective in photo etching the surface of biological material in a controlled manner."

290. While the Blum patent discloses generating a laser beam in the far ultraviolet region of the energy spectrum and at a wavelength selected to produce ablative photochemical decomposition (Tr. 3879), an element of claim 1 of the '388 Patent, the *Laser Focus* article, on page 64 (column 3, lines 24-26), also discloses generating a laser beam in the far ultraviolet region of the energy spectrum and at a wavelength selected to produce ablative photochemical decomposition. Tr. 3877.

291. The Blum patent discloses the use of a far ultraviolet laser as a tool to etch all tissue. (Tr. 2155). Neither the Blum patent (Tr.1976, 1942), nor the *Laser Focus* article specifically mentions ablating corneal tissue with a far ultraviolet laser, an element of claim 1 of the '388 Patent. (Tr. 3880). Dr. Thompson agreed with VISX that corneal tissue is not disclosed in the '135 patent. (Tr. 1942; 2315). He also agreed that the *Laser Focus* article, like the '135 patent, broadly discloses ablating organic biologic materials. Tr. 2315-2316; 2396-2398.

292. Both the Blum patent and the *Laser Focus* article disclose ablating various types of tissue with a far ultraviolet laser. (Tr. 3880). While the Blum patent discloses ablating tissue with a far ultraviolet laser without thermal damage (Tr. 3881-3882), an element of claim 1 of the '388 Patent, the *Laser Focus* article on page 64 (column 4, lines 13-15) also discloses ablating tissue with a far ultraviolet laser without thermal damage. Tr. 3881.

293. *Blum* discloses directing the far ultraviolet radiation to volumetrically remove tissue without thermal heating. (Tr. 3887). *Blum* does not specifically disclose an element of claim 1 of the '388 Patent which is ablating corneal tissue with a far ultraviolet laser without thermal damage. Tr. 3882.

294. The Blum patent does not disclose directing the far ultraviolet radiation in a controlled manner onto corneal tissue to induce ablative photochemical decomposition of the corneal tissue, an element of claim 1 of the '388 Patent. Tr. 3883.

295. To the extent that the Blum patent discloses directing the far ultraviolet radiation in a controlled manner onto biological tissue in general to induce ablative photochemical decomposition of the tissue, such a disclosure is also in the *Laser Focus* article, on page 62 (col.1, line 19-col. 2, line 2). Tr. 3883-3884.

296. The Blum patent does not specifically mention volumetric removal of corneal tissue without thermal heating, an element of claim 1 of the '388 Patent. (Tr. 3885). To the extent that the Blum patent discloses volumetric removal of other types of tissue without thermal heating, such a disclosure is also in the *Laser Focus* article, in Figure 2. Tr. 3885-3887.

297. Dr. Thompson identified column 2, lines 24-26, and column 7, beginning at line 9 of the Blum patent, as the passages which teach volumetric removal of tissue. He explained that the passage in column 2 teaches volumetric removal because "control or volumetric removal are really the same things," and the patent states that one of its objects is "to provide effective photo etching of the surface of biological material in a controlled manner." Dr. Thompson further explained that "volumetric removal" is taught in the passage that begins at column 7, line 9, because the "absorption of a very large proportion (95 percent) of the photons in a very -- in a thin (less than 2700 angstroms) layer of organic material" is how *Blum* achieves volumetric controlled removal. (Tr. 1947-1948). The *Laser Focus* article includes a virtually identical passage citing virtually identical data as that which appears at column 7, line 9 of the Blum patent. Tr. 2268-2275.

298. The Blum patent discloses creating a surgical excision of controlled depth and shape with a far ultraviolet laser (Tr. 3891), an element of claim 1 of the '388 Patent. The *Laser Focus* article also discloses creating a surgical excision of controlled depth and shape with a far ultraviolet laser, in Figures 1 and 2 and the accompanying text. Tr. 3888-3891.

299. The Blum patent does not disclose depth penetration into the stromal tissue with a far ultraviolet laser, an element of claim 1 of the '388 Patent. Tr. 3892-3893.

300. Dr. Thompson stated in his expert report (Section 4, bullet point 3) that another disclosure present in the Blum patent which was necessary and needed to make and use the '388 invention was that "non-homogeneities in tissue do not affect ablation rate." (RX-1501). Although *Blum* contains this teaching, Dr. Thompson acknowledged that the claims of the '388 patent which define the invention say nothing about the ablation rate of corneal tissue and say nothing about the homogeneity of corneal tissue. (Tr. 2233). Furthermore, this teaching in *Blum* is contrary to what actually happens when non-homogenous corneal tissue is ablated. (Tr. 2234-2235). For example, Dr. Thompson testified that "if you have an etching tool that is highly sensitive to variations in homogeneity or, say, water content, you may not have a very good etching tool." (Tr. 2234). He further testified, that while he did not consider tissue homogeneity to include water, the level of hydration of corneal tissue causes the ablation rate to vary considerably. (Tr. 2234, 2236-2237). Dr. Thompson acknowledged that the ablation rate of clear corneal tissue varies widely from the ablation rate of scarred corneal tissue. (Tr. 2244-2246, 2322; RX-1482). The reason the inventors of Blum patent did not know the effect of non-homogeneities on the ablation rate of corneal tissue is that the inventors of the Blum patent never worked on corneal tissue. Tr. 2247.

301. Contrary to Dr. Thompson's third bullet point in Section IV of his report, the *Laser Focus* article does disclose that non-homogeneities in tissue do not affect the ablation rate. Respondent called Dr. Massoud Motamedi as an expert witness. Dr. Motamedi, PhD., is an Associate Professor of Ophthalmology, Medicine, Surgery, and Electrical Engineering, School of Medicine and College of Engineering, the Director of the Biomedical Engineering Center, and the Director of the Biomedical Laser and Spectroscopy Program at the University of Texas Medical Branch at Galveston. (Tr. 3858). Dr. Motamedi testified that *Laser Focus* discloses that the ablation rate is constant in hair, even though hair is a non-homogeneous material with multi-layer structure and variable presence of keratin and epidermal cells. (Tr. 3997-3999). While Dr. Motamedi is not a chemist, neither is Dr. Thompson.

302. The *Laser Focus* article disclosure with respect to non-homogeneities in hair not affecting the ablation rate is based on the same experiment disclosed in the Blum patent. (Tr. 3999). Noting Dr. Thompson's opinion that the *Laser Focus* article allegedly fails to disclose that non-homogeneities in tissue do not affect the ablation rate, Colaianni, based on Dr. Thompson's testimony, noted that non-homogeneities in the tissue relate to claim elements dealing with controlled removal of tissue. Tr. 2981; Tr. 1880-1881, 1883-1884, 2247.

303. Dr. Thompson testified that a detail allegedly absent from the *Laser Focus* article was the teaching in the Blum patent (set forth in Section IV, bullet point 1 of Dr. Thompson's report) that ablative photo decomposition occurs at radiation wavelengths less than 200 nanometers. Dr. Thompson admitted at trial however, that the *Laser Focus* article does, in fact, teach that ablative photo decomposition occurs at radiation of wavelengths less than 200 nanometers. (Tr. 2230-2232). Yet, he remained unwilling to change his conclusions set forth in bullet 1. (Tr. 2231). The *Laser Focus* article disclosed that ablative photo decomposition occurs at radiation less than 200 nanometers. RX-1501; *See also,* Tr. 2976-2977; 3987-3990.

304. Another detail Dr. Thompson opined was present in the Blum patent (Section IV, bullet point 6, page 5) and necessary and needed to make and use the '388 invention was that oxygen absorbs light at 193 nanometers, and, therefore, a laser system should be designed to minimize transmission of the radiation through atmospheric oxygen. (RX - 1501). Achieving consistent, controlled volumetric removal of tissue depends on sufficient energy at the target and steady energy output. (Tr. 2257). The Blum patent, however, does not teach that it is necessary and needed to minimize transmission of 193 nanometer radiation through atmospheric oxygen in order to make and use an excimer laser system. The passage of *Blum* cited by Dr. Thompson (column 3, line 66) states that minimizing transmission through oxygen is a preferred design, not a required design. (Tr. 2254-2257; RX-1012). Dr. Thompson's suggestion in his report that the *Laser Focus* article is silent about using the excimer in oxygen as opposed to a neutral atmosphere or a vacuum also is not correct. As Dr. Thompson explained at trial, the *Laser Focus* article discloses that, if you prefer, you can use a vacuum or neutral atmosphere to minimize transmission through atmospheric oxygen or, alternatively, you can use the laser in air. Tr. 2265-2267.

305. Colaianni testified that it was his understanding that the Blum patent "deals with the use of a far ultraviolet laser to ablate materials, I should say tissue materials, and it describes the use of a laser at 193 nanometers to accomplish the ablative removal of tissue from various tissues samples ... without heating or damaging." (Tr. 2866-2867). As he understands the *Laser Focus* article, it also "deals with the use of a far ultraviolet laser to ablate tissue . . . [and] describes the use of a laser at 193 nanometers to accomplish the ablative removal of tissue from various tissue samples ....without heating." (Tr. 2867-2868). He testified, based on Dr. Thompson's opinions, that it was his understanding that the '135 patent has more relevant disclosures regarding volumetric removal of tissue without heating to create a surgical incision of controlled depth and shape, (Tr. 2868-2869), but he conceded on cross-examination that his understanding regarding the technical issues in the case was less than complete because he did not listen to or read Dr. Thompson's cross-examination (Tr. 2697-2699), and he did not read either the expert reports or the deposition testimony of any of VISX's technical experts. Tr. 2693.

306. *Blum* expresses a preference for flushing oxygen, and *Laser Focus* discloses that excimer ablation can be performed in a neutral environment or in a vacuum. (Tr. 4004-4005). Nitrogen is one such neutral environment. Tr. 2255.

307. While Dr. Thompson testified that he experienced difficulty achieving consistent results in the absence of nitrogen flushing, (Tr. 1922-1923, 2257-2258), both the '135 patent and *Laser Focus* describe excimer experiments through air. The references express a preference for nitrogen flushing, but it is not necessary or needed to design a nitrogen flush mechanism. Tr. 4002-4004.

308. Dr. Thompson's report also concluded, (Section V, bullet point 2, page 4) that the Blum patent, but not the *Laser Focus* article, teaches that "organic material is etched via a linear photochemical effect." (RX-1501.). Dr. Thompson testified that, although the descriptions are similar, the '135 patent provides more information and expressly provides a disclosure important to a surgeon, that ablation proceeds via linear photochemistry. (Tr. 2409-2410). In addition, Complaint Counsel assert that the experiment depicted in *Laser Focus,* Figure 1 is not the same as described in the '135 patent, column 4, line 55, because the experiment depicted in *Laser Focus* is on bird muscle, not bird cartilage, (attached to bone) used for the experiment described in the '135 patent. *(Compare CX* 122, Figure 1 *with* CX 184, Column 4, Lines 55-68).

309. Dr. Thompson identified the paragraph beginning at column 7, line 9 in the Blum patent as containing that teaching that organic material is etched via linear photochemical effect. (Tr. 2268). He acknowledged, however, that the same passage appears nearly verbatim in the *Laser Focus* article beginning at the top of page 2 of the article. (Tr.2270-2274). The other passage Dr. Thompson identified in the Blum patent as containing that teaching appears beginning at column 4, through column 5, line 24, where *Blum* contrasts the linear and non-linear effects he obtained on nonhomogeneous tissue when using the excimer laser and the YAG laser, respectively. (Tr. 2399-2407). Dr. Thompson acknowledged that the same teaching appears in the *Laser Focus* article. (Tr. 2407-2410). He also acknowledged that the example given in the Blum patent relating to the ablation rate of hair (column 6,) shows that the ablation rate is linear. (Tr. 2288-2291). The same passage appears nearly verbatim in the *Laser Focus* article. Tr. 2293-2295. The relevant passages from Laser Focus and the '135 patent are "almost verbatim," "quite similar," "just about identical," "very similar," and "described in a similar fashion." (Tr. 2273-2275; 2294; 2410). Nor is it significant that the experiments were conducted on bird muscle, in one instance, and bird cartilage in the other. The *Laser Focus* article disclosure, with respect to creating a surgical excision of controlled depth and shape with a far ultraviolet laser, is based on the experiment disclosed in the Blum patent. (Tr. 3892). While the *Laser Focus* disclosure, according to Dr. Motamedi, is an experiment on bird muscle tissue, and the '135 patent refers to an experiment performed on bird cartilage, (Tr. 3890, 3892; CX 184 ('135 patent, col. 4, line 55-68)), Dr. Thompson noted that the experiments are essentially the same. Tr. 2401, 2414.

310. *Laser Focus* article discloses that 95 percent of photons are absorbed in a thin top layer of material and the photolyzed material is rapidly ejected. Therefore, very few photons remain behind to affect the subsequent pulse of energy. Dr. Motamedi testified that this suggests a linear ablation effect, (Tr. 3991, 3993-3994). *Laser Focus* discloses the linear removal of tissue at a rate of 400 nm/pulse, as Drs. Keates, Trokel, and Motamedi agreed. (Tr. 677-678, 902-905, 3990-3991). Dr. Trokel, Dr. Keates, and Dr. Motamedi agreed that *Laser Focus* teaches a linear rate of ablation. Tr. 677-678; 902-05; 3990-3991; 2288-2291.

311. The Blum patent and the *Laser Focus* article reveal the same data regarding the linearity of ablation. Tr. 3995-3996.

312. The claims of the '388 patent are silent about linear or non-linear rates of ablation. Tr. 3994-3995.

313. With respect to the disclosures involving the homogeneity of tissue, linearity of ablation, volumetric removal of tissue, 0xygen purging, and others cited by Dr. Thompson, which purportedly distinguish the ' 135 patent from *Laser Focus,* the record shows that the Blum patent is no more pertinent than the *Laser Focus* article to claim 1 of the '388 Patent, (Tr. 3893). While Dr. Thompson insisted that *Blum* provides more detail, the record shows that, in fact, *Blum* and *Laser Focus* disclose the same elements of claim 1 of the '388 patent. Tr. 2307-2328; *See,* RX 1505 and RX 1506.

314. Having reviewed Dr. Thompson's testimony considered as a whole, in light of the testimony of Dr. Motamedi, Dr. Keates, and the Blum patent and *Laser Focus* article, I find that the Blum patent is no more pertinent than the *Laser Focus* article to claims 3-5 of the '388 Patent. (Tr. 3893-3894). The differences between the two references noted by Dr. Thompson, and discussed in detail above, have not, on this record, been shown to be significant. *Blum* is cumulative of *Laser Focus*.

Materiality Of The *Karp* Reference

315. *Karp* discusses the work of Dr. Fyodorov (involving radial keratotomy), discloses use of a laser to perform radial keratotomy, and volumetric removal of corneal tissue. (Tr. 3895-3896, 4024, 3952). The *Karp* reference does not disclose what type of laser to use, nor does it disclose what type of microprocessor to use in conjunction with that laser. (Tr. 4541). Respondent called Dr. Neal A. Sher as an expert witness in this proceeding. (Tr. 4494-4721). Dr. Sher is an ophthalmologist and a Clinical Associate Professor of Ophthalmology since 1979 at the University of Minnesota Medical School. (Tr. 4504; RX 1550-1551). Dr. Sher testified, without contradiction, that *Karp* misapprehends how to perform the procedure with a laser, since radial keratotomy requires relaxing cuts, but *Karp* discloses scarring which may contract the cornea. Tr. 4539-4540.

316. During the '026 interference, VISX described *Karp* was "highly relevant" to RK claims and "more material than any reference previously known" to Examiner Shay. (*See*, CX 109 and 143). Dr. Munnerlyn testified that *Karp* disclosed movement of the laser beam, which he interpreted as scanning to make the incisions, and the previously pending L'Esperance claims concerned RK with a scanning laser. The '388 Patent does not disclose scanning, and VISX specifically noted, during the interference, that it was not claiming that the *Karp* reference was pertinent to any of L'Esperance's sculpting claims. Of the four prior art references cited in the complaint, Dr. Thompson considered the *Karp* reference the least pertinent to the '388 Patent. Tr. 2060-2061.

317. Colaianni testified that the Examiner's allowance of claim 1 of the '913 patent over the *Karp* reference indicates that there is a substantial likelihood that a reasonable examiner would not consider *Karp* important in deciding whether or not to allow claim 4 to issue. (Tr. 2751-2752). Claim 1 of the 913 patent is identical to claim 4 of the '388 patent. The prosecution history of the '913 makes clear that the Examiner did not allow claims pertaining to incisions and keratotomies to issue, (CX 396 at Tab 20 ('913 patent file history); Tr. 2538-2540)); and that Claim 1 was read to mean "sculpting," at the time the patent issued. (CX 396 at Tab 3 ('913 patent file history); Tr. 2557-2560)). It was only during the interference that the Examiner-in-Chief interpreted the claim as including incisions, (Tr. 2557-2560), but subsequently, as a member of the Board panel, the Examiner-in-Chief, like the Primary Examiner before him, found the claim patentable.

318. Colaianni testified that claim 4 of the '388 patent appears to be the broadest claim in the patent. In his view, it is reasonable to believe that if claim 4 is patentable over *Karp*, then the other claims in the '388 patent, which are narrower than claim 4, are likewise patentable over *Karp*. (Tr. 2757-2760). He further testified that such a reasonable belief would militate against an inference that VISX intended to deceive the Examiner with respect to *Karp*. *(*Tr. 2762-2763). Moreover, assuming claim 4 of the '388 patent was given a broader interpretation than claim 1 of the '913 by the Examiner-in-Chief during the '026 interference, (Tr. 2761), *Karp* was clearly before both the Examiner-in-Chief and the Board when the Board determined that claim 4 was patentable to Trokel.

319. On September 16, 1986, the Examiner had an interview with attorneys for L'Esperance during the prosecution of the '913 Patent. The Examiner withdrew the case from issue in order to reopen prosecution in light of the *Karp* reference. (Tr. 4789-4791). Six days later, on September 22, 1986, the Examiner rejected some pending claims in the '388 Patent application in light of the *Baron* reference, but did not cite to *Karp*. (Tr. 4792).

The *Karp* Reference in Light of the Baron Patent

320. The Examiner understood *Karp* to teach: "the use of a microprocessor controlled laser scalpel which is used to perform kerototomies using arced or diametrical cuts." (RX 1536,Tab 48,at 2-3; *See,* CC Proposed Rubuttal Finding 80(c)). The Baron patent (RX 1010) which was cited to the Examiner during the prosecution of the 388 patent discloses RK incisions. Tr. 2344.

321. *Baron* discloses removal of the epithelium from the cornea and the application of a light-absorbing dye to the surface of the cornea, and the generation of scars on the corneal surface through use of an argon laser beam to vaporize corneal tissue containing the dye. *Karp* does not require removal of the epithelium, and does not disclose the use of dye as a mediator of the interaction of the laser and the corneal tissue. (CX 357 *(Karp);* CX 358 (Baron patent); Tr. 4040). Nevertheless, an element-by-element comparison demonstrates that the Baron patent discloses the elements of the independent claims of the '388 Patent disclosed by the *Karp* reference. (RX-1539, Ex. D.). In the Baron patent, the diffusion of the dye into the cornea must be carefully controlled to

achieve a reproducible result. If the dye's diffusion cannot be controlled, an incision of controlled depth or shape in the cornea with the laser will not achieved. (Tr. 4038-4040). Yet, the record shows that *Baron* discloses creating a surgical excision of controlled depth and shape, in column 1, line 64, through column 2, line 3, and *Karp* also discloses creating a surgical excision of controlled depth and shape. Tr. 3919.

322. Dr. Motamedi testified that, like *Karp,* the Baron patent teaches that laser energy is applied to form scar tissue, (Tr. 3908), that the *Karp* laser must have been a thermal laser, (Tr. 3910), and that *Karp* discusses using a laser in the RK procedure of Fyodorov, which necessarily results in depth penetration into the stroma. (Tr. 3895-3896; 3952). There is record evidence, however, that while both *Karp* and *Baron* disclose radial keratotomy, Dr. Sher observed that *Karp* misapprehends how to perform the procedure with a laser. Tr.4539-4540.

323. Dr. Thompson testified that the use of the dye as specified in *Baron* made it unclear whether changes in corneal shape were caused by an incision or some other mechanism. (Tr.1868). Dr. Thompson proposed that heating of the cornea by the laser in the Baron patent may change the shape of the cornea and subsequently cause tissue damage and scarring (Tr.1868); however, after reviewing the language of the Baron patent, he opined that *Baron* did, in fact, disclose making computer-controlled RK incisions. Tr. 2344.

324. The Baron patent, like the *Karp* reference, discloses a laser controlled by a computer to make incisions on the cornea. Tr. 2338, 2342-2344; RX-1010; RX-214.

325. Colaianni testified that the *Karp* reference discloses a computer controlled system where the topography of the cornea is viewed, and the best places for making cuts to the cornea are calculated by the computer. The computer then operates a laser scalpel to perform the cutting. (Tr. 2538). Similarly, Colaianni testified that the Baron patent (RX 1010) also discloses a computer-controlled system in which information about the topography of the cornea is entered into the computer, (Tr. 2794-2795), and the computer calculates and presents an output representing the number, the length, the depth, and the positions of the laser-generated incisions required to correct the corneal curvature. (Tr. 2795). The computer in the Baron patent is used to control the laser to make the laser incisions. Tr. 2795.

326. Colaianni relied upon the opinions expressed in Dr. Thompson's expert report to form his conclusions about the materiality of the four prior art references at issue in this case. (Tr. 2789). Colaianni testified that before deciding whether a prior art reference is material, one first has to determine whether that reference was or was not cumulative of prior art references that were already considered by the Examiner. (Tr. 2788-2789). Colaianni relied upon Dr. Thompson's opinion about the materiality of *Karp,* however, Dr. Thompson did not address in his report the issue of whether *Karp* was cumulative of other prior art references. Tr. 2797.

327. While the *Karp* reference discloses applying laser radiation to corneal tissue, an element of claim 1 of the '388 Patent, the Baron patent introduces other variables, such as

the use of the riboflavin dye, but also discloses applying laser radiation to corneal tissue, in column 1, lines 38, 43, 46 and 64-66, and column 2, lines 1-3. Tr. 3903-3904.

328. The *Karp* reference does not disclose ablating corneal tissue without thermal damage, (Tr. 1940-1941), or volumetric removal of corneal tissue without thermal heating, (Tr. 3918). The *Karp* reference indicates that thermal damage will occur. (Tr. 3909-3910). It teaches the purposeful formation of scars. This necessarily requires heating the cornea and creating irreversible thermal injury. (Tr. 3910-3911, 3912-3913). The technique of the Baron patent also generates thermal heating and causes the formation of scars. Tr. 3908, 3910-3911, 3918-3919.

329. *Karp* does not disclose directing the far ultraviolet radiation in a controlled manner onto corneal tissue to induce ablative photochemical decomposition of the corneal tissue, an element of claim 1 of the '388 Patent. (Tr. 3917). Both *Karp* and discloses *Baron* directing other types of radiation in a controlled manner onto corneal tissue. Tr. 3917.

330. Dr. Thompson testified that elements of claim 1 of the '388 patent, as defined by Respondent, are contained in the last box of RX 1503: "to create a surgical excision of controlled depth and shape with depth penetration into the stroma." (Tr. 2201-2203; RX-1503). Dr. Thompson noted that *Karp* discloses directing laser radiation in a controlled manner to corneal tissue to create a surgical excision of controlled depth and shape with depth penetration into the stroma. (Tr. 2201-2202). He further testified on cross examination, however, that *Karp* disclosed other elements of the '388 patent only if he ignored some claim language. *(See, e.g.* Tr. 2201-2203). With respect to these elements, as Dr. Motamedi's testimony indicates, *Karp* would be cumulative in light of *Baron* even if the claim elements were defined to ignore claim language. Tr. 4045.

331. While *Baron* introduces several variables absent from *Karp,* including application of a dye to the cornea, diffusion of the dye into the cornea and subsequent vaporization of the tissue containing the dye, the Baron patent discloses creating a surgical excision of controlled depth and shape, in column 1, line 64, through column 2, line 3. (Tr. 3919, Tr. 3896, 4036-4039). The *Karp* reference also discloses creating a surgical excision of controlled depth and shape (Tr. 3919-3920), an element of claim 1 of the '388 Patent. Depth penetration into the stromal tissue is an element of claim 1 of the '388 Patent. The Baron patent discloses depth penetration into the stromal tissue with a far ultraviolet laser, in column 2, lines 14-17. (Tr. 3923-3924). Dr. Motamedi testified that *Karp* discusses using a laser in the RK procedure of *Fyodorov,* and that RK procedures necessarily result in depth penetration into the stroma. Tr. 3895-3896, 3952.

Materiality Of The *Keates* Article

332. *Keates* disclosed applying C02 laser light to corneal tissue, directing the laser radiation in a controlled manner at the cornea, creating a surgical excision of controlled depth and shape, with depth penetration into the stroma, volumetric removal of corneal tissue, operating on the anterior surface of the eye to change the optical properties of the eye (Tr. 4680). The CO2 laser, however, did not work for the applications performed by the excimer laser. Thus, Dr. Keates did not consider his article important to mention in

seeking his own patent for use of the excimer laser on the cornea. Dr. Keates testified that he did not believe that carbon dioxide laser prior art was relevant to an invention using the excimer to perform surgery on the cornea. (Tr. 545-546).

333. *Keates* discloses applying laser light to corneal tissue; directing laser radiation in a controlled manner onto the corneal tissue; creating a surgical excision of controlled depth and shape with depth penetration into the stroma. *Keates* discloses volumetric removal of corneal tissue. Tr. 3937, 3944, 3950, 4024; CX 30 *(Keates)*. Each of these disclosures is also present in the L'Esperance '913 Background, (Tr. 3943-3944, 3948-3954), which was before the Examiner and the Examiner-in Chief. Tr. 4767-4770.

334. The L'Esperance '913 patent (RX-1441A) was considered by the Examiner during the prosecution of the '388 Patent. RX-1074.

335. An element-by-element comparison demonstrates that the Background of the Invention Section of the L'Esperance '913 patent column 1, lines 12-48 (Tr. 3930) discloses every element of the independent claims of the '388 Patent disclosed by the *Keates* article. (CX-1539, Ex. E). After the merger of VISX California and Taunton, VISX Incorporated resolved Interference Proceeding 102,026 by awarding priority of invention to Dr. Trokel over Dr. L'Esperance's '913 patent. Because priority of invention was awarded to Dr. Trokel over Dr. L'Esperance's '913 patent, the '913 patent cannot be prior art to Dr. Trokel's '388 claims. The Examiner did, however, cite the '913 patent during the prosecution of the '388 patent. The '913 patent is listed on the front of the '388 patent, and the '913 Background of the Invention Section in column 1 of the '913 describes the use of the carbon dioxide laser to perform radial keratotomies on corneal tissue, and discloses the elements of the independent claims of the '388 patent to the same extent as the *Keates* reference.

336. While the *Keates* article discloses applying laser radiation to perform radial keratotomies on corneal tissue, the L'Esperance '913 Background also discloses applying laser radiation to perform radial keratotomies on corneal tissue. (Tr. 3930, 3936-3937).

337. An element of claim 1 of the '388 Patent is the ablation of corneal tissue without thermal damage. (Tr. 3934). The *Keates* article does not disclose this element. (Tr. 3939). Dr. Keates testified that he was not, in his article, "suggesting that you want to avoid the shrinkage and the charring caused by the C0-2 laser." Tr. 604.

338. The absence of thermal damage to corneal tissue is not disclosed in the *Keates* reference. Tr. 1940.

339. Dr. Thompson testified that *Keates* disclosed controlled use of a laser on the cornea to achieve volumetric removal of corneal tissue with depth penetration into the stroma. Tr. 1847-1848, 1855 -1856, 1937-1938, 1961-1962, 2193-2196, 2199-2200.

340. The *Keates* article discloses creating a surgical excision of controlled depth and shape (Tr. 3950), an element of claim 1 of the '388 Patent. The L'Esperance '913

Background also discloses creating a surgical excision of controlled depth and shape, in column 1, lines 28-32. Tr. 3948-3950, 3951-3952.

341. While the *Keates* article discloses depth penetration into the stroma (Tr. 3954), an element of claim 1 of the '388 Patent, the L'Esperance '913 Background also discloses depth penetration into the stroma, in column 1, lines 14-17 and 28-32. Tr. 3952-3954.

342. An element of claim 1 of the '388 Patent discloses directing the far ultraviolet radiation in a controlled manner onto corneal tissue to induce ablative photochemical decomposition of the corneal tissue. The *Keates* article does not disclose this element. Tr. 3943.

343. To the extent that the *Keates* article discloses directing 10.6 micron wavelength infrared radiation in a controlled manner onto corneal tissue (Tr. 3944), which is not far ultraviolet radiation, the L'Esperance '913 Background, in column 1, lines 28-31, also discloses directing 10.6 micron wavelength infrared radiation in a controlled manner onto corneal tissue. Tr. 3935-3936, 3943-3944.

344. An element of claim 1 of the '388 Patent is volumetric removal of corneal tissue without thermal heating. The *Keates* article discloses the volumetric removal of corneal tissue, but not without thermal damage. Tr. 3945.

345. The *Keates* article indicates that the carbon dioxide laser causes charring, vaporization, and damage, but it identifies the carbon dioxide laser as an "ideal" knife and as a safe and useful tool for laser surgery. (Tr. 3939-3941). The actual language of the article's summary reads:

> The controllable penetration width and depth of the C02 laser incisions seem to make the laser an ideal "knife" for such corneal modifications as radial keratotomy and epikeratophakia. Our results indicate that the C02 laser, when successfully integrated with the standard slit lamp, may be a safe and useful tool in laser surgery of the cornea. CX 30 at 117.

Dr. Keates testified that he was "advocating the use of the carbon dioxide laser as a corneal surgical tool based on the results reported" in his article. Tr. 600, 603-605.

346. *Keates* accepts that thermal damage will be present. (Tr. 3942). Dr. Keates, testified that in his article, he was "not suggesting that you want to avoid the shrinkage and the charring caused by the C02 laser." (Tr. 604). The article indicates that thermal damage is acceptable as long as it is controlled. Tr. 604. This teaches away from the claims of the '388 patent.

Materiality Of The *Girard* Reference

347. *Girard* discloses changing the optical properties of an eye by operating solely on the anterior surface of the cornea of the eye. *Girard* discusses the performance of

superficial keratectomy by use of a diamond dental burr to smooth the corneal surface in the treatment of pterygium, a disease in which growths occur on the cornea. *Girard* notes that the depth of such superficial keratectomy can be controlled by adjusting the motor speed of the drill and the pressure on the cornea, as well as by careful observation. Pterygium and other conditions of the cornea can cause superficial opacities or irregularities that interfere with vision; the purpose of remedying these conditions is to change the optical properties of the eye. Treatment of these conditions via superficial keratectomy generally involves depth penetration into the stroma. (CX 359 (*Girard*); Tr.1956-1057; 1058-1962). Superficial keratectomy is a therapeutic procedure, not an elective vision correction procedure. Tr. 1957.

348. The general technical subject matter of the '388 Patent is directed to the use of the excimer laser as a tool to perform medical procedures on the cornea. Tr. 3971-3972; RX-1539.

349. Dr. Trokel invented a new way to perform old surgical techniques discussed in *Girard.* (Tr. 326-331; Tr. 679-680). Dr. Trokel did not invent procedures such as keratomileusis or lamellar keratectomy, and never claimed he did invent them. (Tr. 2211, 2215). He was the first to propose the new methodology to perform various operations on the cornea. (Tr. 679-680; Tr. 2000-2001).

The only passage in the *Girard* reference concerning the use of the laser as a tool to perform applications on the cornea is on page 171. In that section, *Girard* discusses the use of an infrared laser to produce controlled heating of the corneal stroma. *Girard* suggests heating the cornea to a temperature that is sufficient to coagulate and shrink tissue without vaporization. (Tr. 3972-3973). The laser suggested by *Girard* generates light at the opposite end of the electromagnetic spectrum from the excimer laser. (Tr. 891-883; Tr. 579- 582; 822-823; 2815). Complaint Counsel do not argue that *Girard* is material on the basis of its reference to lasers.

350. The Examiner, at various times, opined that *Girard* teaches reshaping the cornea through the volumetric removal of corneal tissue to create an excision of controlled depth and shape, with depth penetration into the stroma. *See* RX 1536 at Tab 48 p.2 (Nov. 6, 1986) (volumetric removal of tissue), Tab.89 p.3 (Aug. 7, 1990), 49 p.3 (Nov. 12, 1986) (amount of tissue removed must be precisely controlled), Tab 41 p.3 (Sept. 26, 1985) (depth penetration into the stroma). *(See also,* Tr. 1873-1875, 1955-1961). Upon consideration of the *Girard* reference and the independent claims of the '388 Patent, Dr. Motamedi testified that *Girard* discloses no elements of the '388 Patent. Tr. 3978-3983; RX-1539, Ex. F.

351. Dr. Thompson testified on direct examination that *Girard* disclosed several important elements of the '388 patent's claims. (Tr.1871-1873, 1955-1962). On cross-examination however, Dr. Thompson acknowledged that if the claims of the '388 patent require a laser, then *Girard* does not disclose any of the elements recited in the claims. (Tr. 2203-2208; RX-1504).

352. Dr. Thompson testified on direct examination that Dr. Barraquer's work disclosed important elements of the surgical methods claimed in the '388 patent. (Tr. 1871-1872,

1956). Barraquer's keratomileusis techniques, as of 1983, did not include generating a laser beam in the far ultraviolet region of the energy spectrum and at a wavelength selected to produce ablative photochemical decomposition of corneal tissue without thermal damage to the corneal tissue, as called for by the first element, paragraph (a) or (b) of claim 1 of the '388 patent, (Tr. 2143), claim 3 of the '388 patent. Tr. 2148-2150; RX-1500), claim 4 of the '388 patent, (Tr. 2152-2154), or claim 5 of the '388 patent. Tr. 2158-2160.

353. *Girard* discloses mechanical techniques of corneal surgery, while Dr. Trokel's invention was the use of a new laser cutting tool capable of performing these old procedures. The only "laser surgery method" disclosed by *Girard is* controlled heating with an infrared laser. (Tr. 3981-3982). Dr. Trokel invented a new way to perform old procedures. Tr. 326-331, 679-680.

354. The *Girard* reference is not pertinent to claims 3-5 of the '388 Patent. (Tr. 3981). While Dr. Thompson testified *Girard* discloses, for example, changing the optical properties of an eye by operating solely on the anterior surface of the cornea, (Tr. 1956--1960), both Dr. Motamedi and Dr. Thompson concluded that *Girard* discloses none of the elements of the '388 Patent. (Finding 397, *supra.).* Thus, the claim language of '388 calls for "photo decomposition of the anterior surface" (claim 4); "directing the laser beam at the anterior surface" (claim 5). Complaint Counsel did not offer any alternative construction of the claim language at trial which avoided striking portions of claim language.

355. Colaianni testified that the fact that the Examiner allowed claim 1 of L'Esperance suggests that the claim 1 was allowed over the *Girard* reference. (Tr. 2751-2752). Claim 1 of the '913 patent is identical to claim 4 of the '388 patent.

356. Colaianni observed that claim 4 of the '388 patent appears to be the broadest claim in the patent. He testified that "it may be true" that if claim 4 is patentable over *Girard,* it would be reasonable for an applicant to believe that "the other claims in the '388 patent which are narrower than claim 4 are likewise patentable over *Girard,* (Tr. 2757-2760), and that it "may be," but he did not think it correct, that such a belief militated against an inference that VISX intended to deceive the Examiner with respect to *Girard* and *Karp.* Tr. 2762-2763.

One of Ordinary Skill

357. The field of the invention of the '388 patent is the use of an excimer laser to perform surgery on the cornea. Tr. 1983; Tr. 2685-2686.

358. While interest in refractive surgery was intensifying in the early 1980's, the level of skill in the art was limited. RK was a well-known procedure that had been performed throughout the world since the 1940s, and the PERK study by the National Institute of Health was underway. (Tr. 1800-1801, 1809-1813, 1817-1818). Additionally, Dr. Barraquer's techniques, such as keratomileusis, were well known and published in leading treatises like *Girard.* (Tr. 500-503; 1817-1818; Tr. 3154-3156). Nevertheless, refractive

surgery was performed by only few individuals in this country, and, programs in ophthalmology did not provide training in refractive surgery. Tr. 1989-1991, 2033; Tr. 4542-4543.

359. Ophthalmologists tend to specialize within their field; these sub-specialties include oculoplastics (orbital problems), cornea (refractive surgery and corneal diseases), glaucoma, vitreal retina, and pediatric. There are no formal certifications for these sub-specialties. (Tr. 1786-1787; Tr. 2417). Ten years ago, however, there was no sub-specialty in refractive surgery. Tr. 2417-18.

360. In 1983, ophthalmic surgeons were experimenting with radial keratotomy, and a few were performing keratomileusis as developed and taught by Dr. Barraquer. (Tr. 966-967; Tr. 1800-1801, 1817-1818). Various therapeutic procedures required volumetric removal of corneal tissue. These procedures were not performed with lasers. (CX 359 at 114, 116, 126-129 *(Girard);* Tr. 1956-1959; Tr. 968-973).

361. Ophthalmic surgeons were, in 1983, experimenting with various lasers, including the carbon dioxide laser and the neodymium YAG laser, to determine if they were appropriate for various types of corneal surgery. Tr. 502, 508; CX 30.

362. Dr. Thompson and Dr. Sher agree that, at a minimum, the person of skill in the art in 1983 was an ophthalmologist. (RX 1478 at (2) (Thompson expert report); RX 1550 at 9 (Sher expert report); Tr.4623). Dr. Sher testified that the level of ordinary skill in the field of the invention in 1983 would be that possessed by a general ophthalmologist who does corneal surgery. (Tr. 4709).

363. Dr. Thompson concluded that one of skill in the art in 1983 would have knowledge of the following procedures: radial keratotomy, anterior and posterior keratomileusis, superficial keratectomy and epikeratophalia. (Tr. 1800, 1809-1811, 1817-1818, 1853). Radial keratotomy was an experimental refractive surgical procedure at the time. It had been developed by Dr. Fyodorov in Russia and was introduced in the United States in the late 1970's. (Tr. 1800- 1801). The other techniques were published in a variety of sources, including Dr. Girard's textbook. Tr. 1801; 1810-1814.

364. While ophthalmologists themselves recognize any number of sub-specialties, for which there are fellowship and other training programs, (Tr. 2416-2417), there is no Board certified specialty or sub-specialty in refractive surgery. (Tr. 2416-2418). Recognition among ophthalmologists of a sub-specialty in refractive surgery is a recent phenomena that did not exist in 1983. Tr. 2418.

365. The '135 patent notes, "[t]he use of radiation from lasers in medical and dental procedures has been known for some time, having been applied shortly after the invention of the laser in 1960." CX 184 at col 1. With regard to ophthalmic lasers, medical researchers demonstrated in 1961 that lasers could be used on the retina for therapeutic purposes. *Id.* "Such laser eye surgery for detached retinas and other disorders is now routine in eye clinics throughout the world." *Id.* Dr. Sher described how argon lasers had been used to treat corneal injuries and diseases before 1983. (Tr. 4683). Ophthalmic surgeons were experimenting with various lasers, including the carbon dioxide laser and

the neodymium YAG laser, to determine if they were appropriate for corneal surgery. CX30; Tr. 502, 508.

366. Dr. Thompson was asked at trial "is it correct that the field of the invention of the '388 patent is the use of an excimer laser to perform surgery on a cornea." He replied, "yes, that is the correct field of the '388 patent as I understand it." (Tr. 1983). He later testified that the level of ordinary skill in 1983 "in the field of using an excimer laser to perform surgery on the cornea" was "low at that time in 1983." (Tr. 1990-1991). The record does not, however, establish that an ophthalmologist, in 1983, who performed corneal surgery would confer about the surgical method using the laser with a laser physicist or a Ph.D. knowledgeable about lasers. Rather, it shows that ophthalmologists sought out physicists mainly to obtain or jury-rig a delivery system, and consulted with machinists who designed and fabricated various types of masks. *See*, Tr. 536-537; Tr. 4544-4547.

367. The person of ordinary skill in the art is an ophthalmologist who, in 1983, performed corneal surgery and was interested in refractive surgery. He would have been familiar with the techniques and theory behind RK and Dr. Barraquer's keratomileusis and other procedures. Tr. 4709; Tr. 498-500; Tr. 4709; RX 1478 at 2-4.

Obviousness

368. Refractive surgeons are motivated to have better tools to perform their operations. (Tr. 1944-1945). The excimer laser is a "surgical tool" for refractive surgery. It provided an answer for taking off large amounts of tissue in a very controlled fashion without producing thermal damage. Tr. 4632.

369. Prior to Dr. Trokel in 1983, no one had suggested in the literature that the excimer laser could be used to surgically remove corneal tissue without causing thermal damage to the surrounding tissue. (Tr. 4513-4514). In his American Journal of Ophthalmology article (RX-221), Dr. Trokel was the first to publish the suggestion to use an excimer laser for refractive surgery. (Tr. 1999). Dr. Thompson testified that the same, basic idea is disclosed in both the specifications of the '388 patent (RX-1074) and the *Trokel* article (RX-221): "using an excimer laser as a new way of performing corneal surgery by precisely removing a volume of corneal tissue without thermal damage to the tissue that remains behind." (Tr. 1992-1993). Moreover, it is undisputed on this record that the '388 Patent and the *Trokel* article are both based on the same July, 1983 research work conducted by Dr. Trokel.

Radial Keratotomy

370. In 1983, radial keratotomy was not commonly practiced in the United States, and it did not become commonplace until the late 1980s. Tr. 4501, 4508; RX-1550 11 3(b).

371. In 1983, when the excimer laser first became known to ophthalmologists, it was believed that the excimer laser could be used to perform RK because of its general ability to etch tissue in a very precise manner. (Tr. 1850-1851). This belief probably supported the Examiner-in-Chief's view that claims 4 and 5 of the '388 patent were broad enough to

read on making "incisions" with a laser. There is, however, a fundamental difference in the interaction between the excimer laser and tissue, and the action of a knife used in RK to cut tissue. (*See* , Finding 389, *infra*; Tr. 1850-1851).

372. Fyodorov's RK work would not motivate one skilled in the art to use the excimer laser. Fyodorov's RK makes narrow incisions with a knife. The *Keates* article demonstrated that the C02 laser is inappropriate for RK, since it was a failure that resulted in unacceptable side effects, and Dr. Keates admitted that he did not suggest any alternative lasers in his article.(*Supra*, Findings 345 and 346). Lasers cannot make a sufficiently thin cut to perform RK, because the width of laser ablation further weakens the cornea. As a consequence, even today, no one performs RK with a laser. Tr. 4559-4562.

Manipulation of Bowman's Layer

373. The '388 patent contemplates, elective refractive procedures *(See,* Finding 416, *infra*). In 1983, removal of Bowman's layer was thought to be incompatible with maintaining 20/20 vision. Surgeons were taught that Bowman's layer should not be disturbed or removed except to treat scars, injuries, or infections. Conventional wisdom held that removal of Bowman's layer could result in irreparable scarring. Tr. 4524-4525.

374. The concern about removing Bowman's layer vitiated the motivation to combine anterior keratectomy (a therapeutic procedure) with keratomileusis (a refractive procedure), and heightened the skepticism in the field about Dr. Trokel's idea of using the excimer laser on the central optically active area of the cornea to steepen or flatten it, particularly for the purpose of myopia and hyperopia correction. *See,* Tr. 2094-2095; 2118.

375. Ophthalmologists were taught in the 1980's that injury of Bowman's layer could produce permanent corneal opacification, loss of transparency, and irregular astigmatism. (Tr. 4534; Tr. 893). Dr. Thompson admitted that far from being established in 1983 that removing of Bowman's layer resulted in a good visual acuity as set forth in his report, he believed, as late as 1988, that removal of Bowman's layer with an excimer posed, " very significant" and "fundamental" risks of corneal scarring and dense corneal opacification. (Tr. 2090-2091). It was commonly accepted that it was anathema and repugnant for surgeons to interfere with Bowman's layer in healthy corneas. Tr. 4526-4527; Tr. 896.

376. While *Girard* taught that Bowman's layer could be penetrated or removed if certain conditions were satisfied, it was conventional wisdom in 1983 that such procedures were very risky and Bowman's layer should only be removed when there was a therapeutic necessity to do so. (Tr. 4527; Tr. 4712-4713; RX-1560 at 214562-63). Dr. Thompson agreed that, in 1983, ophthalmologists generally accepted view that one only went through Bowman's layer if there was a therapeutic necessity. Tr. 2093-2094. Dr. Schallhorn noted the even today there is concern among surgeons about disturbing Bowman's layer. Tr. 236-237.

377. Dr. Thompson, reported in his '467 Patent (filed on March 2, 1988 and issued on May 8, 1990) that he was skeptical of disrupting Bowman's layer due to unpredictable

outcomes, disruption of corneal collagen, and potential for scarring. (Tr. 4528-4530; RX-1480 at 232-45). Dr. Thompson wrote in his patent that scarring rendered the use of the excimer through Bowman's layer "clinically unacceptable."

Girard's Disclosure of Keratomileusis

378. As previously described, Dr . Barraquer's keratomileus procedure, as described in *Girard,* involves slicing a button of the cornea off the front surface of the eye, freezing the button under carbon dioxide, putting it in a lathe and milling it to precise thicknesses, defrosting it, and sewing it back on the eye. The process kills the tissue, and viable keratocyte cells are no longer present. It takes months to restore any living function in the tissue. Tr. 4521.

379. Keratomileusis was never commonly practiced in the United States. In 1983, only a few surgeons performed this procedure. (Tr. 4500; Tr. 641-642; Tr 971; Tr. 2033, 2077; RX-1476). It was never adopted as a standard procedure for treating refractive disorders of the eye. (Tr. 4519). It yielded mixed results, was extremely difficult, and required months of recovery time. Sutures remained in place for four to six months. The procedure was not successful. (Tr. 4523). It was considered highly dangerous with a high degree of risk, and it was not considered acceptable for general ophthalmic use. (Tr. 894, 971). The doctors who studied and were interested in Dr. Barraquer's refractive surgery techniques sought ways to improve his work (Tr. 4657, 4662, 4664-4665.), but keratomileusis in the early 1980's was considered a "dangerous curiosity." Tr. 333-335, 496, 500 , 641, 971; Tr. 4519, 4523.

Girard's Superficial Keratectomy

380. Superficial keratectomy is carried out to treat disease of the cornea such as scars, foreign bodies, or infection. While superficial keratectomy can change the optical properties of the eye, a superficial keratectomy is performed for the purpose of treating therapeutic disorders of the eye. (Tr. 1957-1958; 2082, 2086-2088; Tr. 4525). Superficial keratectomy is not meant for refractive purposes, (Tr. 4525), and the *Girard* reference categorizes it as a therapeutic procedure. Tr. 2087.

381. In his expert report, Dr. Thompson wrote that "it would have been obvious in 1983 to one skilled in the art of refractive surgery to combine *Girard*'s observation of corneal clarity following superficial keratectomy through Bowman's layer with Barraquer's demonstration of correcting ametropia by keratomileusis to deduce that optical reprofiling of the anterior cornea through Bowman's layer could be done, provided that an instrument was available (or a surgeon skilled enough) to achieve a sufficiently smooth surface." Tr. 2100-2101; RX-1501. Yet, this record discloses no reference in the literature to suggest combining superficial keratectomy with keratomileusis. (Tr. 2107-2113; Tr. 4548).

382. Dr. Barraquer never disclosed the use of lasers. (Tr. 4557). Dr. Sher explained that Dr. Barraquer did not talk about lasers and did not render Dr. Trokel's invention obvious. Tr. 4557.

Anterior grinding

383. Dr. Barraquer and others investigated anterior surface grinding and abandoned it because the surface it produced was too rough. These attempts caused the front surface of the cornea to cloud and scar irretrievably. Tr. 4520-4521, 4714-4715, 4718-4719; RX 1560 at 214566.

The New Method

384. Using an excimer laser, Dr. Trokel suggested a new methodology to perform surgical procedures on the cornea. (Tr. 621-622, 652-653, 679-680). Dr. Thompson does not know of anyone who thought of or did any research on the use of the excimer to perform refractive surgery prior to the time Trokel published his article, (RX-221; Tr. 2000-2001), and the PTO Board determined that Dr. Trokel had priority over Dr. L'Esperance for the claims in the interference count.

385. Dr. Thompson has published two dozen articles concerning various aspects of using excimer lasers for corneal surgery. He has cited the *Trokel* article (RX-221) as the first to suggest that the excimer laser can be used to perform refractive surgery. Dr. Thompson has never cited to the *Blum, Girard, Karp,* or *Keates* references for this proposition. Tr. 2001-2002; *See also,* Tr. 2007-2008; (RX-1470); Tr. 2012 (RX-1471); Tr. 2014-2015 (RX-1472); Tr. 2015 (RX-1473); Tr. 2015-2016 (RX-1474); Tr. 2020, 2021 (RX-1475); Tr. 2023 (RX-1476); Tr. 2042 (RX-1477).

386. In an article he wrote in 1992, Dr. Thompson explained that the work of Dr. Keates described in the *Keates* reference (RX-1423A) was not a major development in the history of refractive surgery, nor was the work of *Karp* described in the *Karp* reference (RX-214), or the work of Drs. Blum, Srinivasan and Wynne described in the Blum patent (RX-1012). The *Girard* reference (CX-130) was not a major development in the history of refractive surgery. (Tr. 2023-2026). The relative recognition of the four references in comparison to Dr. Trokel's work reflects upon the objective secondary considerations of non-obviousness.

387. Dr. Trokel's work is considered in the field to be among the 15 most significant achievements in ophthalmology in the last century and one of the three most important achievements in ophthalmology and refractive surgery (RX1498, pg 146; Tr. 2048-2050, 2053; Tr. 4514-4516). Colaianni explained that objective criteria such as this helps to gauge whether or not an invention would have been obvious. Tr. 2965-2969.

388. Dr. Trokel's 1983 American Journal of Ophthalmology article was cited 242 times through 1997. (Tr. 1995-1998; Tr. 4517). In contrast, the *Keates* article was cited 16 times. Tr. 4516.

389. The use of the excimer laser to cut corneal tissue required a new understanding of the cutting process. (Tr. 574-576, 627-628). While Dr. Keates testified that he thought the excimer was obvious to try" in light of his CO2 article, (Tr. 536-537), he further

testified that prior to the excimer all laser surgical cutting was below 5ev, and once that energy level was achieved, the cutting process itself changed. (Tr. 627). He acknowledged that he described that the excimer laser produced a photochemical reaction in tissue which, "required a new understanding of the cutting process to be able to invent this new teaching." (Tr. 628).

390. The IBM patent discloses ablative photochemical decomposition, volumetric removal, thin layer by thin layer, of biological tissue-like cartilage with compositions similar to the cornea. It described photo etching the surface of biological material in a controlled manner, the use of ultraviolet light at 193 nm, the absence of thermal damage, and it applies generally to biological tissue. (CX 184). Yet, the clean cutting lines in aortic tissue, for example, demonstrated at IBM did not suggest the same effect on the cornea. Many lasers cleanly cut aortic tissue but fail to cut corneal tissue cleanly. The cornea is singular in its structure and transparency, consisting, as Dr. Schallhorn testified, of largely a protein collagen. (Tr. 305). It is unique according to Dr. Trokel's unrefuted testimony in its "highly organized macro-molecular structure" which permits the transmission of light. (Tr. 753). Unlike tissue in blood vessels, it does not "take much to cause this macro-molecular structure to become disorganized." (Tr. 753, 755). Thus, Dr. Keates agreed with Dr. Trokel that Trokel's work was new and inventive. Tr. 574-576, 620, 627-628.

391. Dr. Thompson testified that in most non-excimer laser systems, the laser energy is absorbed by the tissue and heating occurs, causing thermal effects. The laser-tissue interaction with the excimer is very different. There is very little, if any, thermal or heating effect. Tr. 1876-1877. And there is no collagen delamination with the excimer. Tr. 753.

392. *Keates* is an example of a doctor motivated to take Dr. Barraquer's techniques and explore them using a different surgical tool, a carbon dioxide laser. (Tr. 4681). The *Keates* article revealed no improvement over Barraquer's techniques, because the reported experiment resulted in tissue damage, with edge irregularity, burning, tissue necrosis, and inflammation. (Tr. 502, 596; Tr. 714, 880, 993; Tr. 4535-4536). Using the carbon dioxide laser to make cuts on the cornea did not work. It produced burns, tissue necrosis, unacceptable scarring, and collaterial damage. The carbon dioxide laser never successfully made cuts on the cornea for refractive purposes, (Tr. 4535-4536), and was never used clinically to perform refractive surgery. Tr. 539.

393. Dr. Sher testified that ophthalmologists understood what Dr. Keates was doing and the problems with the carbon dioxide laser, such as burning and unwanted thermal effects, described in the article clearly made the carbon dioxide laser an unsuitable surgical instrument for refractive surgery. Dr. Sher explained that the failure of the carbon dioxide laser in *Keates* would have been a valuable learning experience for doctors to find an alternative instrument, but the use of the excimer laser to perform refractive surgery on the cornea was not obvious in light of what was known about CO2 lasers. (Tr. 574-576; 3649).

394. *Karp* disclosed directing a laser beam at a predetermined area, operating on the anterior surface of the cornea, and achieving a predetermined curvature profile.

Nothing in *Karp,* or *Karp* in combination with *Blum,* would lead one skilled in the art in 1983 to use an excimer laser to etch the anterior surface of the cornea with depth penetration into the stroma. (Tr. 4558). Furthermore, even if such a combination had been suggested and could be made, the combination of the *Blum* and *Karp* is the same as the combination of *Laser Focus* and *Baron,* both of which were before the Examiner.

395. There is no suggestion in the prior art to combine *Girard, Keates,* or Karp, and other references to enable one to reach Dr. Trokel's invention. (Tr. 4558-4559). Dr. Keates, for example, discussed the limitations of Dr. Barraquer's techniques and suggested that the carbon dioxide laser offered certain advantages over Dr. Barraquer's instruments, (Tr. 4681-4682, CX 30), but Dr. Keates opined that his article did not suggest an alternative laser. Tr. 605.

396. The Examiner-in-Chief's decision on preliminary motions (RX-114) demonstrates that it is not obvious to combine the disclosures of *Blum* and *Girard.* Boler discussed *Blum* as well as the *Curtin* reference, which like *Girard* discloses mechanical means to change the curvature of the eye. His decision addressed the question of motivation to combine, and indicates that there is no suggestion to combine *Blum* with mechanical techniques such as those in *Curtin* and *Girard. (*Tr. 4836-4837).

397. Doctors frequently experiment with different instruments to solve problems and learn from failed experiments to look for better ways to solve problems. (Tr. 4683). Dr. Keates, however, did not propose an alternative laser, but rather advocated the carbon dioxide laser as an "ideal tool." (Tr. 600, 602, 605; 879-880; 3939-3941). The *Keates* article did not make obvious the use of the excimer laser. Tr. 574-576; 3649; 4558.

398. Dr. Thompson concluded that Claim 1 of the '388 patent was obvious in light of the '135 patent and *Karp.* The '135 patent describes the use of far UV radiation for efficient removal of biological material without heating. *Karp* discloses directing a laser to the cornea for the purpose of etching it. (Tr. 1938, 1939-1941, 1945). However, Dr. Thompson did not address whether there was any suggestion in the prior art to combine the teachings of *Karp* and *Blum.* Furthermore, even if such a combination had been suggested and could be made, the combination of the Blum patent and *Karp is* the same as the combination of *Laser Focus* and the Baron patent, both of which were before the Examiner.

399. *Karp* discusses "carrying out a surgical procedure for the treatment of myopia of the human eye in which cuts are made in accordance with a predetermined cutting pattern in the peripheral region of the cornea of the eye," thus disclosing directing a laser beam at a predetermined area. The '135 patent and *Keates* also teach directing the laser beam at a predetermined area. The '135 patent discloses directing the laser beam to a predetermined area of interest to the surgeon, which for an opthalmologist might be the cornea. *Keates* teaches directing the laser to a predetermined area of the cornea. The stated purpose and accomplishment of the work reported in *Keates* was demonstrating laser beam control down to beam diameters of 25 microns. CX 30 at 117 (*Keates*); CX 327 A-H; CX 357 *(Karp); CX* 184 (the '135 patent at col 4, line 35); Tr. 1950-1954.

400. Dr. Thompson concluded that Claim 3 of the '388 patent was obvious in light of the '135 patent and *Karp* or *Keates* since (1) the '135 teaches generating a laser beam and 193 nm., directing the laser to a predetermined area of interest to the surgeon, and controlling the laser beam to induce ablative photochemical decomposition, (2) *Karp* discloses a laser beam, directed onto a predetermined area of the cornea, and (3) *Keates* discloses a laser beam directed at the cornea. (Tr. 1952; 1954-1955). The combination of *Blum, Karp,* and *Keates* is the same as the combination of *Laser Focus, Baron* and the Background Section of the L'Esperance '913 patent, all of which were before the Examiner.

401. Dr. Thompson concluded that Claim 1 of the '388 patent was obvious in light of the '135 patent and *Keates.* He concluded that (1) *Keates* demonstrates the controlled use of a laser on the cornea to achieve volumetric removal of corneal tissue, albeit with less than optimal results because of thermal damage and (2) the '135 patent described the non-thermal interaction of 193 nm radiation with biological tissue and the controlled use of the laser to photo etch the surface of biological material. He equated "controlled" with volumetric. (Tr. 1944-1947). However, the Blum patent and *Keates* are the same as the combination of *Laser Focus* and the Background Section of the L'Esperance '913 patent, both of which were before the Examiner.

402. *Keates* and *Karp* also discuss operating on the anterior surface of the eye with a laser in order to etch or remove tissue. (CX 30 *(Keates); CX* 357 *(Karp);* Tr. 1960). The Baron patent, like *Karp,* discusses operating on the anterior surface of the eye with a laser in order to etch or remove tissue. *(See,* RX-1010). The Background Section of the L'Esperance '913 patent, like *Keates,* also contains such a discussion. *See,* RX-1441A. *See also,* RX-1539 at Exhibit D (chart for claim 5 of the '388 patent, last box), and at Exhibit E (chart for claim 5 of the '388 patent, last box).

403. Both *Karp* and the Baron patent disclose achieving a pre-determined curvature profile. (Tr. 4031; CX 189; CX 190; *See,* RX-1010 at column 1, line 61 through column 2, line 6. *See also,* RX-1539 at Exhibit D (chart for claim 4 of the '388 patent, last box).

404. The '135 patent discloses the use of 193 nm ultraviolet radiation, irradiation, ablative photochemical decomposition, and volumetric removal of biological material. CX 184 (the '135 patent); Tr. 1959-1960). The *Laser Focus* article also discloses "the use of 193 nm ultraviolet radiation" and "ultraviolet irradiation, ablative photochemical decomposition, and volumetric removal of biological material." RX 513, column 1-3, Figs. 1&2; Tr. 3877, 3879-3887.

405. *Girard* discloses a non-laser therapeutic treatment involving the volumetric removal of corneal tissue from diseased eyes. In performing superficial keratectomy, the surgeon performs a volumetric removal of tissue and creates a smoother corneal curvature. (CX 359 (Girard); Tr.1961). *Karp, Baron, Keates,* and Background Section of the L'Esperance '913 patent all disclose the volumetric removal of corneal tissue. *See,* (RX-1539) at Exhibit D (chart for claim 4, last box, and chart for claim 5, third-to-last box), and at Exhibit E (chart for claim 4, last box, and chart for claim 5, third-to-last box).

406. *Girard* discloses a method of refractive surgery (keratomileusis) whereby mechanical instruments achieve a "volumetric removal" of tissue from the "stroma" to a "predetermined curvature profile." These terms appear in the claims of the '388 patent. (Tr. 4664). As Dr. Thompson explained, the invention of the '388 patent "is the use of an excimer laser as a new tool to etch corneal tissue for the purpose of performing whatever surgical procedure one wants to perform." Tr. 2156-2158.

407. Dr. Thompson concluded that Claim 4 of the '388 patent was obvious in light of various combinations of *Karp, Keates, Girard* and the '135 patent. He opined that the most the direct path to obviousness was to combine the teachings of the '135 patent with regard to ultraviolet laser radiation and its interaction with biological tissue with the teachings of *Girard* with regard to operating on the anterior surface of the cornea to change its optical properties. (Tr. 1962-1963). This record shows, however, that the Blum patent and *Keates* is the same as the combination of *Laser Focus* and *Baron,* both of which were before the Examiner. Furthermore, claim 4 of the '388 patent is identical to claim 1 of the L'Esperance '913 patent. The Examiner participated in the issuance of claim 1 of the '913 patent over *Girard* and the European version of the Blum patent. *See,* RX- 1441.

408. All disclosures in *Keates* and *Karp* which are pertinent to claim 5 are also present in the L'Esperance '913 Background and *Baron,* respectively. *See, CX* 30; CX 357; RX 1539, Exs. D and E; Tr. 3930; Tr. 4045.

409. Redefinition of the anterior surface of the cornea occurs whenever tissue is removed from the surface or whenever the anterior surface is cut, provided that the removal or cut involves stromal tissue. If only the epithelial layer is removed or cut, it will heal and a permanent redefinition has not occurred. Tr. 1966.

410. Dr. Thompson concluded that Claim 5 of the '388 patent is obvious in light of *Karp, Keates, Girard,* and the '135 patent. He reasoned that *Karp* and *Keates* teach directing a laser beam at the anterior surface of the eye; that *Karp, Keates* and *Girard* teach volumetric removal, which necessarily involves redefinition of the anterior surface of the cornea, and that the '135 patent teaches the use of ultraviolet laser radiation. In Dr. Thompson's opinion, the most direct path to obviousness is the combination of the '135 patent and *Girard.* (Tr.1966-1967; 1973-1974). Dr. Thompson, however, did not identify any suggestion in the prior art to combine the teachings of *Blum, Karp, Keates,* and *Girard.*

411. Dr. Thompson testified that refractive surgeons would have been motivated in 1983 to combine the disclosures of the '135 patent with *Keates.* (Tr. 1944; RX 1478 at 4). However, Complaint Counsel has not identified any evidence in the record indicating that the prior art suggested that the teachings of *Blum* and *Keates* be combined.

412. Dr. Thompson testified that refractive surgeons would have been motivated in 1983 to combine the disclosures of the '135 Patent and *Karp.* (RX 1478 at 4). However, Complaint Counsel have not identified any evidence in the record indicating that the prior art suggested that the teachings of *Blum* and *Karp* be combined.

413. Dr. Thompson testified that refractive surgeons would have been motivated in 1983 to combine the disclosures of the '135 patent and *Girard*, (Tr. 1943-1944; 1977; RX 1478 at 4), however, the evidence does not indicate the prior art suggested that the teachings of *Blum* and *Girard* be combined.

Secondary Considerations

414. To guard against the temptation of hindsight reconstruction, the patent law has developed certain objective criteria by which to gauge whether or not an invention would have been obvious. (Tr. 2968-2969). Objective evidence of non-obviousness includes:

a. evidence that there was a long-felt need for the invention;

b. evidence that others tried but failed to fill that long-felt need before the invention was made;

c. evidence that after the invention was made, it was greeted with skepticism by others in the field; and

d. evidence that the invention after it was made became a commercial success. Tr. 2969.

Skepticism/Conventional Wisdom

415. In the early 1980's, the ophthalmology establishment viewed refractive surgery with a great deal of skepticism. The concept of operating on a normal cornea to correct refractive errors was considered repugnant to most ophthalmic surgeons. (Tr. 2078; CX 130 at 147; Tr. 4531-4533). Ophthalmologists generally considered Dr. Trokel's invention foolish and thought it would never be widely accepted. The head of Columbia University's ophthalmology department, for example, scoffed at the idea and thought it would never be a successful surgical procedure. Tr. 894-895.

416. It was generally accepted in 1983 that one should avoid operating on the central area of the cornea, particularly for elective purposes, due to the risk of side effects such as scarring and opacification. (Tr. 591; Tr. 894). Dr. Schallhorn confirmed that during the 1980's there was "a lot of concern" about operating on the optically active central portion of the cornea. Tr. 236-237.

While Complaint Counsel contend, in numerous proposed findings, that the '388 patent does not contemplate "vision correction nor avoidance of scarring or opacification," their contention is not supported by the record. Dr. Thompson testified that the '388 patent specification discloses the "refractive procedure" of removing tissue to steepen or flatten the cornea (Tr. 2081-2082; RX-1057 at 152415), which treats myopia and hyperopia. (Tr. 902). The '388 patent specification states that the excimer laser can "selectively shape the cornea surface [which] allows modification of the refractive status of the eye." RX-1074 at 6:6-7.

417. In 1988, Dr. Thompson wrote that operating upon the visual axis of the cornea poses "very significant risks." (RX 1480.). Five years earlier, in his application for the '388 patent, Dr. Trokel proposed to operate on the visual axis of the cornea. Tr. 2079, 2082.

Long-felt Need and Commercial Success

418. As of 1983, there had been a long-felt need for a surgical method to permanently correct refractive errors. (Tr. 2009-2012; Tr. 2022-2023). The excimer laser had been available since the 1970's; however, Dr. Trokel was the first to use it on the cornea. As of October, 1990, it was still undergoing FDA clinical trials, (Tr. 2012), but the invention enabled the industry to pursue PRK and LASIK by suggesting the use of the excimer laser for corneal surgery. Since receiving clinical approval from the FDA, the excimer has gained widespread acceptance among refractive surgeons and achieved clinical success. Tr. 2013.

REEXAMINATION

419. An office action granting reexamination of the '388 patent issued April 4, 1998. The request upon which it was based lists four items of prior art alleged not considered during the prosecution of the '388 patent. These items include the Blum patent, *Keates*, Beckman et. al., *Limbectomies, Keratectomies, and Keratostomies Performed with a Rapid Pulse Carbon Dioxide Laser*, 71 Am J. Ophthalmology, 1277(1971); and Peyman, et. al., *Modification of Rabbit Corneal Curvature with Use of Carbon Dioxide Laser Burns*, 11 Ophthalmology Surgery 325 (1980). The request, to the extent it relies on *Keates* and the Blum patent, is based upon combinations of *Keates* and *Beckman* or *Peyman*, and the Blum patent and *Beckman* or *Peyman*. It does not rely on *Keates* alone, *Blum* alone or a combination involving just *Keates* and *Blum*.

420. Ninety percent of all requests for reexamination that are filed with the Patent Office are granted. Of the requests that are granted, only 10% result in a determination that the claims of the patent under reexamination are invalid. In 25% of the requests that are granted, the Patent Office determines that no changes of any kind need to be made to the claims of the patent under reexamination. In the remaining requests that are granted, the Patent Office determines that some type of change should be made to at least one claim of the patent under reexamination. (RX-1497; Tr. 2990-91). The statistics published by the Patent Office concerning reexaminations do not indicate whether any of the changes made to claims under reexamination was required to be made because of the prior art cited in the request itself. (Tr. 2993). Once a request for reexamination is granted, the examiner can, and does, cite additional prior art against the claims, above and beyond the prior art that was cited in the request itself. Tr. 2993.

421. In 65% of reexaminations, some changes are made to one or more claims in the patent. (Tr. 2991). If such changes were not made, those patents would be held to be invalid. (Tr. 2991-2992). In 75% of the cases in which reexamination is granted, the claims of a patent are either cancelled or changed.

422. Colaianni stated in paragraph 9 of his expert report (RX-1486) that one of the bases for his opinion that the *Blum* and *Keates* references are material is that the Patent Office granted a request for reexamination of the '388 patent based, in part, on those two references. (Tr. 2984). Colaianni acknowledged that *In re Hiniker* prevents an inference that prior art is "new" just because it is cited in a reexamination order, since re-examination can be based on a combination of old and new art. Mr. Colaianni indicated, the reexamination order states that "any or all" of the references cited present a substantial new question of patentability. Tr. 2524-2530, 2535-2536, Tr. 4865-4866.

423. The grant of reexamination (CX-154) does not suggest that the Examiner believed that either *Keates* or *Blum* are new references, because there is a proposed combination with two references not cited during prosecution of the '388 Patent. (Tr. 4862-4864). Thus, a review of the underlying request upon which the Reexamination Order was based reveals that neither *Keates* alone or *Blum* alone or *Keates* and *Blum* in combination with each other but without *Beckman* or *Peyman* were specified as grounds for reexamination.

424. The request of reexamination was based solely on a combination of the *Keates* and *Blum* references with other references not cited during the prosecution of the '388 Patent. A combination of old and new references is a proper basis to request reexamination. Tr. 4866. Moreover, neither the grant of reexamination nor the Examiner's subsequent rejection of the '388 claims on March 30, 1999, indicates that the Examiner was unaware of *Blum* and *Keates* during the prosecution of the '388 patent.

425. In respect to the '388 patent, the Examiner determined to reject claims 1-3 as being unpatentable over *Beckman* in combination with *Blum*. He ruled that *Beckman* produces a surgical excision of controlled depth and shape wherein a beam of carbon dioxide laser radiation is used to remove corneal tissue, and teaches the method claimed except for the ultraviolet radiation. He reasoned that since *Blum* teaches the use of a 193 mn light to remove tissue, it would have been obvious to the artisan of ordinary skill to use the ultraviolet wavelength of *Blum* in the method of *Beckman* because *Blum* allows a method of removing organic material without heating, which is desirable.

426. The Examiner rejected claims 4 and 5 of Trokel '388 as being unpatentable over *Keates* in view of *Beckman* and *Blum*. He ruled that *Keates* teaches the use of a carbon dioxide laser to modify the refractive properties of the eye by operating on the anterior surface of the cornea in a volumetric removal of corneal tissue and with depth penetration into the stroma, while *Beckman* teaches that reducing the heating of the remaining tissue provides superior results in corneal surgery. *Blum*, he reasoned provided the teaching that using the 193 nm laser provided the tissue removal without heating. As such, the Examiner ruled that it would have been obvious to the artisan of ordinary skill in the art to employ the wavelength *Blum* in the method of *Keates* as taught by *Beckman*.

427. The rejection of the claims 1-3 and 4 and 5 of the '388 patent was, as this record demonstrates, based on a combination of new art involving the *Beckman* reference with old art references of *Keates* and *Blum*.

428. The Examiner also rejected claims 1-5 under the doctrine of double patenting over claims 1-23 of U.S. Patent No. 5, 735, 843, and claims 1-23 of U.S. Patent No. 5,711,762, and in a separate action, he rejected the claims of the '695 patent.

Supplemental Findings

Relevant Markets

The Geographic Market

429. The relevant geographic market is the United States. Order Specifying Undisputed Facts Regarding Respondent VISX, Incorporate's Motion No. 4 for Summary Decision Regarding Relevant Market and Complaint Counsel's Motion for Summary Decision January 4, 1999, at ¶ 25.

The Product Markets

Technology Market

430. Complaint Counsel contend that a technology market comprised of the intellectual property in the '388 patent is a relevant product market in this case. Tr. 1255-1255. If, however, the '388 is ultimately found invalid on reexamination, it could not constitute a relevant technology market. Tr. 1666.

431. The technology covered by the '388 patent has been the subject of marketing activity by VISX, along with other patents, since the issuance of the '388 in 1992. This marketing activity by VISX consisted of individual agreements, offers, and negotiations, and was separate from VISX's marketing of its excimer lasers. (Tr. 1280-1281, 1284-1289; CX 45 at VISX 002227; CX 81A; CX 230; Tr. 398; CX 304; CX 107). The '388 patent has never, alone, been the subject of separate marketing activity apart from VISX other patents.

432. One of the earliest transactions in the technology market occurred on June 3, 1992, when Summit and VISX formed P^3. This pooling agreement included licenses to the '388 patent, among 18 others. Stipulation No. 54; CX 45 (VISX 8-K dated June 3, 1992) (P^3 agreement); CX 296 (VISX 1995 10-K) at 5-6; Tr. 1289.

433. Since 1992, potential competitors began making inquiries about, or attempted to negotiate for, licenses to VISX patents, including the '388 patent.
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434. The market for excimer laser vision correction devices came into existence when Summit received FDA approval in October 1995. VISX then participated in the market in an economic sense because of its pooling agreement with Summit. Six months after Summit's entry, VISX began selling its own laser systems. VISX received more than half of the revenues from per-procedure fees on Summit's laser systems and all of the 6% royalty on the purchase price of those systems. Tr. 1277-1279; CX 45, (P^3Agreement); CX 296 at 1, 6, 10 (VISX 1995 10 K).

The '388 is a Necessary Input

435. The technology embodied in the '388 patent is a necessary input to performance of PRK and LASIK procedures, and to the manufacture and sale of excimer laser systems used to perform PRK and LASIK. CX 53 at VISX 38054; Tr. 1283-1285; CX 303.

436. The claims of the '388 patent are extremely broad. According to VISX, the claims are "... broadly worded and cover any use of ultraviolet radiation to change the optical properties of any eye by photodecomposition of the anterior surface of the cornea." CX 37; CX 36; CX 34 at 40835; CX 202 (AM00380-91) at 382; Tr. 3771, 3824:20-24.

437. VISX has contended that because of the '388 patent's breadth, any ophthalmologist performing PRK in the United States without a license from VISX would infringe the patent. (Respondent VISX, Incorporated's Statement of Disputed Facts Submitted in Opposition to Complaint Counsel's Motion for Partial Summary Decision at 2-3, attached to Opposition of VISX, Incorporated, to Complaint Counsel's Motion for Partial Summary Decision or, in the alternative, an In Limine Ruling, filed December 1, 1998).

438. VISX has further contended that manufacturers of excimer laser devices for laser refractive surgery cannot sell their devices for use in performing laser refractive surgery in the United States without a license from VISX because that use would infringe the '388 patent and the firms would be liable for contributory infringement of the patent. RX 1457 at 14; Tr. 3215-3216; Tr. 1156-1157; 1159; 1162-1163; Tr. 1283.

439. VISX itself has stated that '388 covers all ways of doing laser vision correction, that the '388 patent is a very basic, fundamental patent covering excimer laser refractive vision correction, and that the '388 patent is of such a fundamental nature that no excimer laser to correct refractive vision errors could operate in the U.S. without infringing this patent. (*See*, Tr. 403-404; CX 303; Tr. 1281-1283). The VISX executive responsible for negotiating licenses to VISX patents regards the '388 as a "crown jewel." (CX 157 at 167-168, 170; Tr. 3216-3217). VISX representatives have described the '388 as one of "six or eight or more" of VISX's patents that are fundamental. (CX-157 at 168-169). The '388, along with other Trokel patents, L'Esperance patents, and the Warner patent, all have been described as among the "crown jewels" in VISX's patent portfolio. (CX-157 at 170).

440 For firms manufacturing excimer lasers for vision correction, and for the laser refractive surgery procedure itself, the '388 patent is a key input. Tr. 1289-1291; Tr. 1141, 1145; 1169-1170.

441 Another key input into the laser refractive surgery procedure end-product is intellectual property covering the methods and procedures for performing laser refractive surgery with an excimer laser. (Tr. 1283-1284). Dr. Levy concluded that there are no close substitutes for the technology embodied in the '388 patent, (Tr. 1281-1284), although he agreed that if Summit could have sold its machine in 1992 without a license to the '388 patent, the '388 patent would not constitute a proper market. (Tr. 1501). Respondent proffered in its proposed finding 946 that Complaint Counsel have contended, in response to interrogatories, that Summit did not need a license to the '388 patent because its laser did not infringe the '388 patent. Complaint Counsel did not respond to this proposed finding in their "opposition" filed February 2, 1999.

442 Dr. Levy testified that there has to be separate demand for a product for it to constitute a relevant product market. (Tr. 1595). If there is no separate demand for the '388, the '388 patent cannot constitute a market. Tr. 1596-1597.

443 There is no direct evidence in this case of separate demand for the '388. As noted previously, competitors have always sought to license the '388 as part of a bundle; in fact, it has been licensed as part of a bundle, and enforced as part of a bundle. Tr. 5286-5288.

VISX and P³ indicated they would not license a patent individually for a lesser amount than its entire portfolio price, (Tr. 3617-3618;Tr. 1157-1161; Tr. 1314; Tr. 636-639 (Meeting in Dallas where Summit President announced that no licenses to P³ patents were available)). **IN CAMERA.**

As noted previously, competitors have always sought to license the '388 as part of a bundle; in fact, it has been licensed as part of a bundle, and enforced as part of a bundle. Tr. 5286-5288.

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444 LaserSight recently purchased the Blum '135 patent from IBM for $10 million. Tr. 1657-1658). Dr. Levy testified that the Blum '135 patent may constitute a market and confer market power even though LaserSight has never made any excimer laser sales in the United States, (Tr. 1641-1643, 1654, 1657), depending on whether it constitutes a properly defined technology market. However, he distinguished this situation from the '388 in the following respects: LaserSight purchased the Blum patent rights in a situation where licenses already had been issued to several firms in the market, whereas the '388 patent has only been licensed to one competitor (Summit), which shared licensing revenues in a patent pool that had set a floor on price. Tr. 1640-1645, 1303-1304.

445 Dr. Levy did not use any price level in defining the candidate technology market under Section 1.11 of the Merger Guidelines. (Tr. 1540). Whether or not the '388 patent may, in theory, have an incremental effect on the price of a bundle of patents which

include it, it has not been demonstrated on this record, and the fact remains that Dr. Levy stated that he did not have any basis for knowing what a competitive price is or would have been for the '388. (Tr. 1544). Because the '388 patent has not traded alone, there is no evidence of price for it in the record. Tr. 5288.

446. Dr. Levy, although familiar with the pricing levels for RK, glasses, and contacts, (*See*, Tr. 1555-1556), did not evaluate the prices of downstream substitutes to determine whether there were substitutes that could constrain the '388. (Tr. 1540-1541). Nor did he determine the cost structure for those alternatives. *Id.* Such price and cost data, and evidence of separate demand, would be relevant in determining whether the '388 patent is a separate market. (Tr. 5289-5290). He agreed in theory that if the '388 was invalid, it would not represent a separate market. (Tr. 1666). In reaching his opinion that the '388 is a market, he asked to assume that there was a zero percent chance that the '388 was invalid. (Tr. 1673). His assumption did not take into account any relief the FTC might obtain in this case.

Apparatus Market

447. The Complaint alleges that the sale or lease of PRK equipment, including the licensing of patents for use in performing PRK, is a relevant line of commerce. (Para. 22). The record shows that the PRK equipment or apparatus is a unit consisting of many components, including the excimer laser, a chair for the patient to sit under the laser, a computer and terminal, a microscope, and various ancillary devices which assist the ophthalmologist and technician assistant in pointing the laser and performing the procedure. Tr. 1713-1715; *See*, CX 351.

448. VISX and Summit are the only firms which have sold excimer lasers in the United States. (Tr. 388; Tr. 403-404; 417; Tr.1219-1220; Tr. 3161).

449. Dr. Stephen M. Levy, Economist, Bureau of Economis, Federal Trade Commission, provided expert testimony at the hearing. (Tr. 1241-1750). He initially testified at his deposition that there was an emerging relevant goods market in excimer lasers in 1992, (Tr. 1340-1341; RX-1450 at 4); however, at the hearing he acknowledged a mistake to the extent that the excimer laser goods market came into existence in 1995 with the FDA's approval of the Summit excimer laser. (Tr. 1343-1344).

450. Dr. Jonathan D. Putnam, Economist, employed as a Principal at Charles River Associates, Boston, Massachusetts was called as an expert witness by Respondent. He formed no opinion in respect to the alleged apparatus market in either his expert report or his testimony. Tr. 5327-5328.

451. Neither Dr. Levy nor Dr. Putnam has previously worked on a case involving the application of the Intellectual Property Guidelines in defining a technology market. Tr. 1336; Tr. 5325-5326.

452. Under the Merger Guidelines market definition test, if a hypothetical monopolist would not raise its price or would increase its price by zero, the market has to be broadened to include additional products. If the hypothetical monopolist would not raise

price, or would raise the price by zero percent, Dr. Levy, agreed that the candidate market would not be a market. (Tr. 1629). Dr. Levy pointed out that a monopolist already charging the profit-maximizing price will be unable to raise price any higher. Tr. 1629-1634.

453. Whether the hypothetical price increase is profitable or not depends, at least in part, on the percentage of sales that the monopolist would lose in response to the price increase. Dr. Levy did not provde such a calculation in this case. Tr. 1608-1609; 1260-1261; RX 1457 at 20 n.45 (Putnam Report).

454. Dr. Levy testified that knowing the demand curve faced by a hypothetical monopolist is not sufficient to determine whether profits are being maximized, because it is also necessary to know the marginal cost curve. He stated that his failure to refer to marginal cost was an oversight. Tr. 1609-1611.

455. In theory, marginal cost can have a significant impact on market definition in situations involving high fixed or sunk costs and relatively constant marginal cost, such as industries with large sunk development costs. (RX-1466 at 116). Dr. Levy agreed that VISX's business is one characterized by large sunk development costs, (Tr. 1615-1616), but he did not know the marginal cost on VISX's excimer lasers, or have any idea whether VISX's machine prices are set at or above marginal cost. Tr. 1651.

456. If the initial percentage markup over marginal cost is substantial (at least 30 percent) and the elasticity of demand not too low (less than 4), then a hypothetical monopolist would restrict output very little or not at all. (RX-1466 at 120.). Dr. Levy agreed that the implication was that under those circumstances the hypothetical monopolist would raise price very little or not at all. Tr. 1617.

457. Based on 1996-1998 VISX sales and financial data reflected in RX-1302, Dr. Levy agreed that VISX's revenues are marked up over its estimated production cost by about 200 percent. If those numbers are correct, based on the chart shown in RX-1466, he agreed that there might be no price increase at an elasticity of two or even lower. He did not know the elasticity of demand. Tr. 1626-1627.

458. The record reveals that VISX's prices are falling, both in real and nominal terms. Dr. Levy's analysis did not take such pricing data into account. (Tr. 5291). Complaint Counsel note that depending on the cause of the falling prices, such declines are not necessarily relevant to market definition. Price is defined by the interaction of demand and cost conditions. A monopolist can lower price over time and still remain a monopolist in a relevant product market where it faces either falling demand or falling costs. Demand in this case is rising, and Complaint Counsel have not suggested that costs are falling.

459. At the time the complaint issued in this matter, VISX and Summit were the only firms whose laser equipment had FDA approval. Since then, two additional excimer laser manufacturers, Autonomous and Nidek, received FDA approval, (CX 529 (1998 3Q VISX 10-Q) at 8), and Summit has announced it proposes to acquire Autonomous.

(Tr. 3532; CX 354 at 7). It is unclear in this record whether Nidek or Autonomous have, as yet, sold any any excimer laser units in the U.S.

460. Summit's acquisition of Autonomous is likely to change the competitive landscape, because, even though VISX has a "significantly broader" FDA approval range, Autonomous' LADARvision laser may be viewed as technically superior to Summit's current laser. (CX-354 at 7-8.). Dr. Levy testified: "I don't know whether or not it is an excellent machine, but it has been characterized as a machine that people would like to buy and has, indeed, cleared FDA approval." (Tr. 1356-1357). A BancBoston report anticipated that VISX would, in 1999, face "intense competition" and "pricing pressure" and observed that: "We assume . . . that the procedural fee will stay in the $250 range until the middle of 1999. At that time, in response to the competitive environment, we expect VISX to gradually lower the procedural fee. By the end of 2000, we expect the procedural fee to fall to $220." CX 54 at 11.

POTENTIAL COMPETITORS

461. Nidek Co. Ltd. sells its EC-5000 excimer laser in international markets. (CX 354 at 8; Tr. 3127). Nidek's EC-5000 laser system has a "slit-scanning" delivery system, which uses rectangular beams that sweep across the cornea. (Tr. 3130; Tr. 390; 402). Nidek sells its laser in foreign countries without a VISX license and has prevailed in a lawsuit brought by VISX against it in England. CX 354 at 10; Tr. 401-402.

462. There is record evidence that Nidek already has begun efforts to market its lasers in the United States, (Tr. 3412-3413), but, as noted above, it is unclear whether it had, at the time of trial, actually sold any systems. It is VISX's position that Nidek, before consummating sales in the U.S., needs a license to, at least, the '388 patent. CX 157 at 167-168.

463. In addition to Nidek and Autonomous, Bausch & Lomb has announced that it expects FDA approval for its excimer laser later system this year (1999). Bausch & Lomb has annual sales of more than $2 billion. A division of Bausch & Lomb (formerly Chiron Vision, a subsidiary of Chiron Corp.), is developing an excimer laser, the Chiron 217, a scanning laser that the company markets overseas. Dr. William Link, a general partner at Brentwood Venture Capital, and formerly CEO of Chiron Vision, testified that, in December, 1997, Chiron was sold to Bausch & Lomb. Dr. Link is currently a consultant to Bausch & Lomb. (Tr.1140-1227). Chiron is likely to market its laser in the United States when it receives FDA approval. CX 354 at 8; Tr. 1145; 1164; Tr. 390; Tr. 3127, 3129.

464. A sixth excimer laser manufacturer, LaserSight, Inc., also has announced that it expects FDA approval in the near future. (Tr. 3413). LaserSight, manufactures the LS-2000 excimer laser system used for vision correction. Dr. Francis E. O'Donnell, clinical ophthalmologist, and Chairman of the Board, LaserSight, Inc., testified at the hearing that LaserSight has filed a PMA application and expects FDA approval in early 1999. LaserSight has sold approximately 200 lasers outside the United States. Tr. 3095, 3099.

465. LaserSight's laser uses a technique known as photopolishing. In this system, the laser spot size is small and rounded. The laser achieves its ablation profile by directing the radiation to locations on the cornea with a significant (80%) degree of overlap. LaserSight has a patent on its delivery system. The system is capable of correcting refractive errors in excess of -15 diopters of myopia. Tr. 3097-3098, 3116, 3118, 3140.

466. Aesculap-Meditec ("Meditec") has developed two excimer lasers for international sale. Its MEL-60 embodies a "slit-scanning" technology. William T. Kelley, General Manager for North America, Aesculap-Meditec, of Irvine, California, testified at the hearing (Tr. 383-420). Meditec's newer laser, the MEL-70, embodies a "spot-scanning" technology. Meditec has withdrawn its MEL-60 laser from the FDA approval process, but plans to seek FDA approval in the near future for its MEL-70 laser. Tr. 387-388, 390-391; 401-402.

467. LaserSight, Autonomous, Nidek, Chiron, and Meditec manufacture and sell excimer lasers for use in laser vision correction procedures abroad. CX 354 at 7,8; Tr. 1289-1290, 1299, 1332-1333; Tr. 3127-3129. There is record evidence that their scanning lasers, unlike VISX's and Summit's wide area ablation systems, do not create photoacoustic shock waves which cause "central islands" in the treated areas. As a result, these producers claim their systems achieve smoother corneal surfaces than wide area ablation systems. Tr. 389-390; Tr. 3113-3118.

468. VISX's post-employment contractual arrangements with executives like Charles Munnerlyn and Alan McMillen focused solely on firms involved in the development or manufacture of laser systems. When Munnerlyn left VISX, he executed an agreement with VISX that restricted the extent to which he could interact with VISX's "Competitors." Competitors were defined as manufacturers of laser systems for correcting the refractive optical property of an eye or for the treatment of disorders of the eye. Under this arrangement, VISX did not prohibit Munnerlyn from working for manufacturers of spectacles, contact lenses, instruments for use in performing RK, or companies that make other vision correction products such as intrastromal corneal rings or interocular lenses. CX 69 at BD 003567; 0039697); CX 156 at BD 0033037.

469. When VISX first entered the market, it priced its excimer lasers relative to the price of Summit's lasers. (Tr. 3406). VISX's CEO, Mark Logan, testified that VISX bases its excimer laser prices on the price charged by other FDA-approved excimer laser manufacturers. Tr. 3527.

470. VISX added a premium to the procedure fee charged by Summit. Summit initially charged a $250 procedure fee; VISX raised this value to $260. (Tr. 3406). Logan testified that VISX would have liked to set its prices further above those of Summit since VISX's machines outperformed those of Summit. Nevertheless, VISX decided that it could best compete in the marketplace if it set its per-procedure fee only $10 above that of Summit. Tr. 3405-3407.

471. VISX's internal strategy documents identify only other laser companies as competitors. Under the heading "Competition" in its 1988-1992 "Strategic Update," VISX lists only laser manufacturers such as Summit, Meditec and Nidek. (CX 47 at 036417). In a VISX "Survey of Potential Competitors," VISX's analysis is confined solely to firms that make excimer lasers. CX 35 (Table, dated 2/9/93); *See also*, CX 53 at 38054.

472. When he was VISX CEO, Charles Munnerlyn developed a slide presentation entitled "Competition" which lists only excimer laser manufacturers. (CX 46 at VISX 035632-70). The slide presentation is dated more than five years prior to VISX's market entry, and mentions the sizeable market for glasses and contacts, *(See* CX-46 at VISX 35651); however, when it specifically covers "Competition" only Summit and Meditech-Aesculap are mentioned. (CX 46 at 035664). In addition, in a document entitled "Marketing Presentation Outline," the "1993 Market Share" section includes only excimer laser manufacturers as making up 100% of the market. Later in the same document under the heading "Competition," VISX examines pricing and other data only for other excimer laser manufacturers. The last three pages of the document track the number of excimer lasers sold in each country around the world. (CX 68 (Marketing presentation, undated (est. 1993) (AM000190-216)) at AM000193; AM000206; AM000214-216). Similarly, in a document entitled "Domestic Market Plan," a section entitled "Market Overview," states: "The ophthalmic Excimer Laser market is defined by 193 NM Wavelength excimer lasers and disposables for corneal refractive surgery." CX 232 at 0027729.

473. Summit also viewed excimer laser manufacturers as its sole source of competition. In its 1989 10-K, six years before it entered the market, under the topic "Competition," Summit identified as its competition only companies "which are currently developing excimer laser systems for ophthalmic applications." CX 341 at 319 (1989 Summit Technology, Inc. SEC Form 10-K).

474. More recently, VISX's 1997 10-K stated that the "Company's principal international competitors are Chiron, Meditec, Schwind, and Nidek," all excimer laser manufacturers. (CX 42 (VISX 1997 10 K) at 21). The 10-K also states that excimer laser surgery competes with eyeglasses, contact lenses and RK, as well as with other technologies and surgical techniques under development such as corneal implants and surgery using different types of lasers.

Downstream Competition

475. Because demand for VISX's laser systems and intellectual property is derived from the demand for laser vision correction procedures, it is useful to consider whether other vision correction methods are good substitutes for laser vision correction procedures. Tr. 1262-1263, 1267.

476. The term "downstream competition" refers to competition in the market down the distribution chain from the market at issue. It may involve the end-use consumer or it may not. This competition is "downstream" from the perspective of a manufacturer or wholesaler of the product in question. Tr. 1262.

477. Downstream competition may affect whether a seller can exert market power, because the ability of its customer or end-use consumers to switch between different products may affect which products a retailer is willing to buy. Tr. 1262.

478. In this case, the issue of downstream competition involves whether close substitutes for refractive laser surgery procedures exist for ophthalmologists and their patients. Tr. 1262-1263.

479. The Merger Guidelines recommend that evidence from downstream buyers and sellers of the product in question be considered in relevant product market determinations.

480. VISX's economist observed that a relevant inquiry would be to ask, at the margin and at the prices at which these goods are offered, whether the prospective customer would consider them to be substitutes. The evidence adduced in this record does not address this issue. Tr. 5294.

481. Dr. Levy believes that if the price of excimer laser surgery rose 5 to 10%, some consumers would switch to other alternatives, but he did not estimate the percentage who might switch. Tr. 1606-1607. In his opinion, a small but significant non-transitory price increase in PRK would not result in enough consumers switching to make a price increase unprofitable in light of the evidence which shows that price is not a driving force in such consumer decisions and that VISX and other laser manufacturers do not price their lasers on the basis of the prices of glasses, contacts, or RK. Tr. 1606.

Dr. Putnam, in contrast, observed that the appropriate inquiry is whether the marginal prospective consumer in the downstream market perceives PRK or LASIK to be a substitute for eyeglasses and contact lenses, and at what price. No evidence was adduced on this issue. (Tr. 5299-5302). An estimate of the number of consumers likely to switch, and whether a price rise would be profitable given the remaining volume would, if available, be helpful under the Guidelines.

482. Dr. Putnam testified an upstream supplier typically is concerned principally with his horizontal competition, and he may or may not know whether his behavior is constrained by downstream competition. (Tr. 5297-5298). The record shows, however, that the laser manufacturers have reason to know if the price of downstream substitutes constrains their excimer laser pricing. *See e.g.*, CX 157 at 103-108.

Radial Keratotomy ("RK")

483. RK is a surgical procedure for correcting vision. It is a surgical procedure that corrects vision by making very deep radial incisions in the cornea with a scalpel in order to weaken the eye's structure and thereby flatten its curvature. The RK incisions go 90% of the way through the cornea, in comparison to the procedure on VISX's lasers that ablates tissue of less than half the thickness of a human hair over a six millimeter diameter area, which is "very, very small". (CX 157 at 98-99; CX 42 (1997 VISX 10 K) at 21; *See also*, Tr. 296-298; Tr. 452; Tr. 3142; Stipulation No. 11; CX 353 (RK Diagram); CX 148 at 2). Unlike PRK, RK is a manual procedure that does not involve a laser. (Order No. 4 ¶ 9.) Accordingly, RK does not fall within the coverage of the '388 patent. (Order No. 4 ¶ 10.)

484. RK became an established and widely performed procedure beginning in the late 1980s, (Tr. 4510-4511). Prior to 1995, when PRK was approved, RK had "essentially 100%" of the refractive surgery market. (CX 296 at 8; CX 529 at 8; Tr. 3412). Approximately 325,000 RK procedures were performed in 1994. Tr. 3432-3433; RX-1463-A at 62.

485. A 1993 study by Washington University in St. Louis showed that among contact lens wearers, there was no greater propensity towards PRK rather than RK. It also showed that contact lens wearers are influenced by the cost of the procedure in deciding whether to have refractive surgery performed. Tr. 1577-1579; RX-1464 at ST 011273-1274.

486. VISX and others in the industry regard RK as a medically inferior vision correction procedure. CX 157 at 96-102; Tr. 297-298, 349; Tr. 392, 455-456; Tr. 1146-1148, 1152-1153, 1185-1186.

487. The 1995 A.D. Little report showed considerable growth in the number of RK procedures between 1990 and 1994. As of that time, RK was on the upswing and gaining credibility, as a number of improvements had been made to the procedure. (RX-1463A at 65; Tr. 3433-3434). In 1995 and 1996, prior to approval of PRK, the number of RK procedures continued to grow. (Tr. 3436). With FDA approval of PRK, however, the report forecast a decrease in the growth rate of RK. (RX-1463A at 65.).

488. In 1996, after both Summit and VISX had received FDA approval to sell excimer laser system, Dr. Link, Chiron's CEO, believed that RK was still performed more frequently than PRK. (Tr. 1183-1184). Industry estimates place the number of RK procedures in the United States in 1996 at 300,000 procedures. (Tr. 409-410). The number of PRK or LASIK procedures that year was approximately 70,000. CX-294.

489. Currently, there are more PRK and LASIK procedures performed in the United States than RK. (Tr. 3433). The number of PRK and LASIK procedures surpassed the real number of RK for the first time in 1998, when approximately 400,000 PRK or LASIK procedures were performed. Tr. 3433.

490. Dr. Levy estimated that RK was being performed in early 1998 at a rate of one-fifth to one-sixth the frequency of LASIK. (Tr. 1409). Some ophthalmologists no longer perform RK. Tr. 298-299.

491. Ophthalmologists have expressed significant concerns about the safety and efficacy of RK. (Tr. 4509- 4510). RK can weaken the cornea or cause progressive farsightedness 5-10 years after surgery. (Tr. 4509-4510). In some operations, the incisions penetrate beyond the cornea, causing the aqueous humor (a clear fluid that occupies the front of the eye) to percolate out of the eye. This can require additional surgery and lead to infection. RK may also leave the patient with eyes that cannot withstand changes in atmospheric pressure. CX 42 (1997 VISX 10 K) at 21; Tr. 3143-3146.

492. Postoperatively, RK poses the risk of diurnal fluctuation in vision, in which a person has different vision at different parts of the day and may need to use several different pairs of glasses depending on the time of day. Tr. 3144-3145; CX 148 at 3.

493. Because the incisions of the RK procedure are made manually, without computer control, the procedure is difficult to standardize and highly dependent on the skill of the individual surgeon. When RK was performed by experienced surgeons, the results were unpredictable, with final results likely to lead to over and under correction. It is "more of an art than a science." Tr. 3142; CX 42; CX 157 at 98-99; Tr. 3500-3502; Tr. 4509; Tr. 3934; Tr. 3151-3153.

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495. RK surgery sometimes brings about farsightedness earlier in life than otherwise expected, (Stipulation No. 12), and sometimes leaves visible scars. In contrast, laser vision correction offers a treatment that does not have the aesthetically unattractive side effects of RK. Tr. 278-279, 281; Stipulation No. 13.

496. Some patients, given the choice between RK and PRK, choose RK. (Tr. 1184; 1223-1224; Tr. 3147-3148). Ophthalmologists today often offer three levels of refractive surgery to their patients, at three different price levels. RK is the least expensive, PRK is in the middle, and LASIK is the premium-priced product. (Tr. 3436-3437).

497. While many ophthalmologists do not perform RK because of a number of side effects and potential complications, (Tr. 3142-3145), RK has some advantages over PRK, including availability, and convenience, (Tr. 298-299), lower cost, and the fact that it has been done for more years. (Tr. 1184; Tr. 3297). While RK is declining in relation to PRK, no evidence was adduced in this record that an ophthalmologist who recommends or performs RK is, suggestions by counsel to the contrary notwithstanding, engaging in conduct in violation of the Hippocratic Oath.

498. RK is commonly used to correct up to 6 diopters of myopia, and can correct up to 10 diopters, (Tr. 3143; CX 148; RX 1462), but the vast majority of refractive procedures today are now done with a laser. Tr. 392; Tr. 455; Tr. 1146-1148, 1152-1153, 1185-1186; Tr.3502; CX 157 at 96-98, 101-102; Tr. 297-298, 349.

499. Chiron Vision, which was successful in the RK instrument business, left the RK business and shifted to the excimer laser business because the RK business was being eroded by the excimer laser. Tr. 1152-1153, 1185-1187.

500. While the *Ophthalmology Times* March 19[9]8 survey of refractive surgeons found that 3.9% of refractive surgeons surveyed believe that RK will regain the lead as the most common refractive technique to correct myopia over the next three to five years, *(See*, CX 343-J. RK), it also found that the average number of PRK and LASIK procedures that were performed per month was 5.6 times that of the RK procedures performed. (CX 343 D). The evidence in this record strongly suggests that RK is likely to continue its decline while the number of laser refractive surgeries is likely to increase. CX 296 (1995 10 K) at 3; Cx 157 at 102; Tr.297; Tr. 409-410; Tr. 1146-1148; 1152-1153; 1185-1186, 1188; 1219-1220, 1226; Tr. 455-456;Tr. 491; CX 342 at 108051; 108054 ; CX 343-J; CX 148 at 3; RX 1462.

501. Prior to Summit's commercial entry into the U.S., VISX considered the relative prices of RK and PRK in Canada as a baseline in considering VISX's possible pricing in the United States. After Summit's entry, VISX focused on Summit's pricing, (Tr. 3425-3427; 3436-3440), not the price of RK. Dr. Link testified that RK was a factor in Chiron's pricing analysis, (Tr. 1221-1224), but for VISX, it was on the "radar screen," (CX 157 at 107 -108; CX 157 at 98-101; Tr.3438- 3439; *See also*, Tr. 392, 1153), and VISX has never conducted a study or analysis concerning the extent of any competitive threat that RK presents to VISX, and does not see itself competing on a day-to-day basis with RK. Tr. 3499, 3439.

502. The record shows that RK is priced below laser vision correction in the St. Louis area, for example, where the per-eye cost of RK is between $950 - $1,250. (Tr. 3226). The per-eye cost of laser vision correction is approximately $2,000. Even with this price disparity, very few patients opt for RK over laser vision correction. Tr. 3222, 3226/13-21 Tr. 449 ; Tr. 3387 (prices varies by region but, per eye, it costs approximately $1,900 for PRK and $2,200-2,300 for LASIK).

503. Some ophthalmologists perform RK, because it is cheaper, available, and more convenient than PRK. (Tr. 298-299). Some patients chose RK, because it is cheaper than PRK, Tr. 1223-1224; but Dr. O'Donnell does not believe the price of PRK would repond to a decrease in the price of RK, although some consumers might switch to RK in response to a price decrease. Tr. 3227.

Intrastromal Corneal Rings

504. Intracorneal rings are made of plastic and are inserted into a patient's eye during surgery. The surgeon makes an incision, and creates a tunnel around the periphery of the cornea. The surgeon then feeds an alloplastic ring into an incision to create a bulge around the outside of the cornea, causing the center of the cornea to flatten and thereby changing the refractive power of the patient's eye. (Tr. 3156-3157; CX 308). The leading company in corneal ring technology is KeraVision. (Tr. 1192-1193; 1196.). A Goldman Sachs market report forecasts that KeraVision's corneal ring will provide a highly attractive alternative to excimer laser surgery for the treatment of myopia. RX-1456 at 3.

505. Intracorneal rings can be removed from the eye, and to that extent they are "reversible." Whether this will be an advantage over laser vision correction remains unclear. With laser vision correction, a second procedure can be performed if the first procedure does not achieve adequate correction. Correcting vision where a corneal ring did not initially achieve the desired result involves the surgical removal of the first ring, followed by the implantation of a second ring. (Tr. 3158-3159; CX-305 at 1; RX-1456 at 3; RX-1469 at 1; Tr. 307).

506. On January 13, 1999, the FDA Medical Devices Panel unanimously voted for pre-market approval for KeraVision to make and sell corneal rings in the United States. On April 9, 1999, the FDA announced its approval of KeraVisions Intacs for mild nearsightedness, 1 to 3 diopters of refraction, with mild astigmatism, 1 diopter or less.[6]

507. KeraVision's clinical results compare favorably to LASIK in the early recovery of corrected vision. RX-1456 at 3-4.CX 305; CX 308;CX 157 at 109-112; Tr. 307-308; Tr. 3157; Tr. 3444; RX 1469 at 1.

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[6] On April 20, 1999, Respondent moved the admission of RX 1598 through 1601, reflecting KeraVision's announcement of the FDA approval, and on April 26, 1999, Complaint Counsel agreed to the admission of these exhibits provided CX 541 representing the FDA's official statement announcing its approval is also admitted. Pursuant to Rule 3.22 and 3.51(e)(1) the proffered exhibits are admitted into the record.

508. KeraVision currently is in clinical trials to extend its range of indications to moderate myopia and hyperopia, (Tr. 3444-3445), however, the record does indicate when KeraVision's corneal rings are likely to receive approval for a broader range of refractive correction. *See*, Tr. 3444-3446.

509. KeraVision views its intracorneal rings as directly competitive with other forms of permanent refractive correction. In a recent press release, KeraVision's CEO stated that KeraVision's ring "is at least as safe and effective as other surgical treatments for nearsightedness with the unique advantage that the effect can be reversed." CX-308.

510. It has been estimated that the procedure for implanting the corneal ring would cost approximately the same as the PRK procedure for nearsightedness, $2,200 per eye. Tr. 5428-5429; Tr. 5516-5517.

511. An advantage to the intrastromal corneal ring over laser vision correction is that the size of the ring can be changed in subsequent operations to create further changes in patients' refractive capabilities. (Tr. 3158-3159). In referring to this advantage, prominent clinical investigators describe the intracorneal ring as "appearing to safely and effectively correct myopia with the added benefit that we can reverse the effect." (CX-308). In addition, corneal ring technology requires almost no capital investment for ophthalmologists. (Tr. 3447).

512. There are risks associated with these implants. During the procedure, the ophthalmic surgeon makes an incision in the cornea, "tunnels around like a cork-screw sort of thing," and then feeds the foreign implant into the cornea. (Tr. 3156). The ring can end up being extruded, (Tr. 3157-3158), or can perforate the cornea. (CX 157 115). The implant may also cause infection. (Tr. 3157-3158). Correcting a corneal ring procedure requires removal of the corneal ring, followed by another implantation of a corneal ring, thereby exposing the patient to the previously mentioned risks of the procedure for a second time. (Tr. 3158).

Since most surgical procedures involve risk, it is important to provide a context in which to evaluate potential adverse consequences of the surgery. In this instance, Dr. Thompson, generally considered the corneal ring implant procedure a safe and effective way to correct myopia. He testified;

> "Q: And it is reported here that -- if I can find it -- that the KeraVision ring appears to safely and effectively correct myopia? Do you see that? It is on the first page, slightly past the halfway point, right here (indicating).
>
> A: Yes, I see that. Q: And that's reported by Dr. Waring? A: Yes.
>
> Q: And you agree with that?
>
> A: Yes, I agree with that statement." Tr. 2331.

513. Dr. Levy believes that the target market for the intracorneal ring will be smaller than for excimer laser surgery, but he does not know how much smaller. (Tr. 1399-1401). He testified:

> Q: So the niche could be quite big, is what I am getting at. Isn't that right?
>
> A: Well, I mean, quite big relative to what? Relative to the number, to the people who have excimer laser surgery? That's not quite clear. There are millions of people who have myopia or hyperopia, and so far in the past year only about 300,000 have chosen excimer laser surgery. There is no indication that KeraVision's intracorneal ring is going to approach that number of something greater or something less, other than the descriptions that it would be part of a niche market, which I take to mean it would be a smaller market than what excimer lasers are currently serving.
>
> Q: Right. It would be smaller, but you don't know how much smaller, correct?
>
> A: Quantitatively, no. Tr. 1400-1401.

514. Intracorneal rings are not a substitute for the broad range of approved laser refractive surgery applications. VISX is not interested in acquiring intracorneal ring technology, because it believes it is an inferior procedure to PRK in terms of breadth of refractive vision problems covered, inconvenience for the physician, and adverse side effects. CX 157 at 111-116; Tr. 3504.

515. VISX is aware of the potential penetration of a portion of its market by intracornael rings. Thus, Ms. Davila testified:

> Q: These technologies that we've just mentioned, do you think that they're significant threats or any threat to VISX's business?
>
> A: Well, I think we believe that both the intracorneal ring and the intraocular lenses will have a niche market. We do not believe that they will have the potential to take over the mainstream of refractive surgery. Technologically, they won't measure up to that.
>
> Q: And so, that wouldn't really threaten VISX's business?
>
> A: Well, as I say, they will have a niche so as far as the procedure is done with those and not if the laser, it's a detraction from our business potentially and again, we are a rapidly growing market and those are not technologies that we worry about. I think there are many other factors driving that market that are more important. CX 157 at 123-124.

516. The intracorneal ring will occupy a market niche. Low to moderate myopia and low to moderate hyperopia are narrower ranges of indications than excimer laser surgery, but corneal rings potentially provide a medically effective alternative to excimer laser surgery for these indications. (*See, e.g.*, Tr. 2331; RX-1456 at 3-4). The extent to which intracorneal rings could potentially penetrate the market may be significant. *See, e.g.*, RX-1469; RX-1456 ; CX-308 ; RX-1531.

Glasses and Contact Lenses

517. Laser vision correction offers a one-time, permanent treatment of refractive disorders without continuous refinements. It reduces a person's dependence on glasses or contacts. (CX 42 (1997 VISX 10 K) at 5; CX 157 at 96-97 ; Tr. 278-279, 281; Tr. 3103; CX 39 (1990 VISX 10K) at 1-2; CX 296 (1995 VISX 10K) at 2; Tr. 391; Tr. 1148 -1149, 1180). Neither contact lenses nor eyeglasses provide permanent, maintenance-free vision correction. Stipulation No. 9.

518. A comparison of the cost of glasses and contact lenses with those for PRK over a 20-year period by A.D.Little shows that PRK costs about the same as contacts discounted with a moderate risk premium. (TR. 5298-5299; RX-1457 at Ex. 6.). These calculations, however, do not take into account several factors that may be important in consumer decisions, such as the additional convenience of not wearing corrective lenses, the risk of complications resulting from PRK, and so forth. Nor did the study take into account the fact that PRK patients, once they reach the age of about 40, will probably need glasses, at least for reading. (Tr. 306; Tr. 998-999). The older the PRK patients are when the procedure is performed, the shorter the duration they are likely to avoid the cost of glasses. Indeed, Dr. Putnam cautioned against comparing "nonpermanent" vision correction such as glasses and contact lenses to the permanent techniques of PRK and LASIK. (Tr. 5347). Notwithstanding this study, however, the direct evidence in this case, adduced from VISX itself, indicates that VISX did not take the prices of glasses or contact lenses into account when making its own pricing decisions. CX 157 at 107-108; *See also*, Tr. 3525-3526, 5297-5299.

519. Most of the persons seeking laser refractive surgery are contact lens wearers or former contact lens wearers. (Tr. 448; 3106 -3107; CX 296 at 2). For some individuals who suffer from astigmatism, laser vision correction is the only option because glasses and contacts cannot correct the problem. In some instances, there are minor amounts of astigmatism which contacts can overcome. Others are not candidates for contact lenses for medical reasons. CX 278 at 129; Stipulation No. 10.

520. Ophthalmologists who perform PRK advise their patients about glasses and contacts as alternatives to PRK, and advise their patients that they should compare the risks and benefits of all of the surgical and nonsurgical refractive options. (Tr. 299-300). One of the disadvantages of PRK as a procedure is the potential loss of "best corrected vision." Tr. 366.

521. Many people choose laser vision correction for lifestyle reasons, such as the desire to pursue hobbies or athletic activities without the inconvenience of glasses or contacts. (Tr. 3394; 3498-3499; Tr. 3106). For police, firefighters, and some in the armed forces whose jobs are incompatible with glasses or contacts, laser vision correction offers advantages that glasses and contacts cannot provide. (Tr. 285-287; Tr. 448-449; Tr. 3106). Some people have no compelling occupational or lifestyle reasons, and can tolerate contact lenses, but just want to avoid the inconvenience of contact lenses or glasses. Tr. 286-287; Tr. 448-449; Tr. 3108; Tr. 3499.

522. Ophthalmologists are raising their prices for laser vision correction even as their volume is increasing because of their patient's willingness to pay. (CX 157 at 105-106). The price of excimer laser surgery has risen, in part, because the switch from PRK to LASIK has several benefits from the point of view of consumers. For example, both eyes can usually be done at the same time; recovery is much faster; and there is less pain. Ophthalmologists accordingly have been able to charge higher prices for LASIK than for PRK. Tr. 3383-3388.

523. The testimony of LaserSight's Chairman, and LaserSight's SEC reports on Form 10-K, support the conclusion that PRK and LASIK remotely compete with eyeglasses and contact lenses. (Tr. 3287; 3300-3303; RX-1522 at 9; RX-1523 at 12; RX-1524 at 13.) In his own practice, LaserSight's Chairman instructs prospective laser vision correction consumers of the alternatives, including eyeglasses, contact lenses, RK, and corneal rings. (Tr. 3310). Similar evidence was adduced from Laservision Centers, a customer of VISX's (Tr. 457-458; 460-461), VISX's 1997 SEC report on Form 10-K (CX-42 at 20.), and Summit's 1996 SEC report on Form 10-K. (RX-1312 at 259247). Yet, this evidence does not demonstrate that glasses and contacts are close substitutes for PRK or LASIK.

524. When Chiron addressed the question of pricing in its business plans, it took into account the price of eyeglasses and contact lenses. (Tr. 1176-1179). Chiron Vision's pricing studies, however, did not show a close correlation between the cost of glasses and contact lenses and the cost of excimer laser surgery. (Tr. 1148-1149). The present value of the cost of glasses and contact lenses was approximately $1,000, (Tr. 1180), but patients have the added motivation to be able permanently to remove their glasses and contact lenses and have the laser vision correction surgery despite the greater expense. Tr. 1149, 1180.

525. VISX does not view contact lenses or spectacles as a close substitute for laser vision correction systems. (CX 157, at 96-98, 107-108). VISX has never conducted studies or analyses concerning the extent of any threat posed by glasses or contact lenses to its business. Nor has VISX ever requested its marketing department to track the prices of glasses or contact lenses. Tr. 3498.

526. Glasses and contact lenses play no role "whatsoever" in VISX's decisionmaking, including setting prices. VISX has never attempted to connect the pricing of eyeglasses and contact lens, which are a "repeat product" purchased over a lifetime, to its decision making relating to PRK, an elective, one-time only procedure. CX 157, at 96-98, 107-108.

527. When VISX was a partner in P^3, it did not consider the prices of glasses and contacts in proposing a $175 per procedure fee that the partners would pay to P^3 for each procedure performed on their respective laser machines. (CX 157 at 66-69). Instead, Summit publicly submitted a $250 bid, which meant that to some extent it did not matter what figure VISX selected, and VISX was concerned principally with simply selecting a lower number. CX 157, at 73-74; 68-70.

528. Prior to receiving FDA approval in 1996, VISX discussed the procedure fees it would charge doctors, but VISX did not take into account the prices of glasses, contacts, RK and alternative non-laser refractive surgery technologies. After receiving FDA approval to correct astigmatism in 1998, VISX again considered the procedure fees it would charge doctors, and in this context the prices of alternative products were discussed. In the end, VISX's pricing decision was not impacted by glasses and contacts. Tr. 3524-3527.

529. Excimer laser manufacturers price their systems according to what other laser manufacturers are charging. They do not respond directly to prices of vision correction alternatives such as glasses and contacts. Tr. 390-391; Tr. 451; Tr. 1149, 1154-1155; Tr. 3229-3232; 3286.

530. While there is anecdotal evidence that consumers may remotely consider the relative pricing of glasses, contacts, and PRK, (RX1467), and while contact lens wearers consider the cost of PRK in deciding whether to have refractive surgery, glasses and contacts are not close substitutes for PRK or LASIK, and there is no evidence of price sensitivity between these two types of products. (Tr. 1178-1181, Tr. 1267-1277; RX-1464 at ST 011273-1274). The decision to undergo laser vision correction is driven primarily by non-price factors. Tr. 448-449; Tr. 1148; Tr. 391.

531. Excimer laser refractive surgery competes with eyeglasses and contact lenses only in a general sense. (RX-1312 at 259256; *E.g.*, RX-1312 at 259247). VISX itself does not take the price of glasses and contact lenses into account when pricing its excimer laser or its per-procedure fee. CX 157 at 107-108.

Other Vision Correction Technology Pending FDA Approval

532. Several "alternative" technologies, including phakic interocular lenses ("phakic IOLs"), and holmium lasers, are in various stages of research and development and, in some cases, FDA clinical trials. Phakic IOLs, holmium lasers, and additional corneal rings applications, all are likely to obtain FDA approval and enter the market within the next two years. Several other technologies, such as water jet technology and the use of enzymes, also are in FDA clinical trials, but are likely to take longer to clear the FDA approval process. Tr. 3550-3551.

533. VISX believes that excimer laser refractive surgery will continue to be the most commonly performed refractive surgical procedure even if new technologies, such as those discussed below, receive FDA approval. Tr. 3440.

534. Dr. Levy testified that other refractive surgery devices could not be considered close substitutes for laser surgery by ophthalmologists because these alternative technologies have not received FDA approval. (Tr. 1263). Future entry by several of these alternatives is highly likely. Tr. 5294-5297.

Intraocular Lenses

535. A phakic interocular (Phakic IOL) lens is an artificial lens that is placed inside the eye, in front of or behind the iris. (TR. 3161). Unlike laser vision correction, which can be done in an office, these lenses must be implanted in an outpatient procedure at an ambulatory surgery center or a hospital outpatient operating room. The procedure requires a few minutes to place the implants, is suture-less, and is reported to be virtually painless. (CX-307) In that respect, it is similar to other intraocular procedures, such as cataracts (Tr. 3163), which are more common and familiar to most ophthalmologists than excimer laser refractive surgery. (Tr. 3161; 3164- 3165; Tr. 441; Tr. 1369). Phakic IOLs are under development and are not yet approved by the FDA.

536. Since 1992, Chiron (now Bausch & Lomb) has been developing a phakic IOL. Staar Surgical is also developing a product which it refers to as an "implantable contact lens." Tr. 1189; 1197-1198.

537. Companies such as Staar Surgical view their products as potentially competitive with excimer laser surgery. (CX-307). Recent results of clinical trials show that phakic IOLs perform well compared with LASIK in medium to high levels of myopia, 7 to 15 diopters. (RX-1531.) Phakic IOLs also are in trials for low myopia, astigmatism and hyperopia. (Tr. 3454; CX-307). The range of myopia for which phakic IOLs are in clinical trials is 3 to 20 diopters. VISX's range of approved myopia indications is 1 to 12 diopters. CX-307; Tr. 3455.

538. The endorsement of prominent clinical investigators, together with successful clinical results, has an important effect on market perception among the general ophthalmologist community. Tr. 3456, 3461-3462, 3446-3447.

539. While a November, 1998, strategic research study by Frost and Sullivan concluded that "many researchers and managers of leading firms strongly believe that the future of refractive surgery lies in phakic IOLs," (RX-1469 at 2, 1), Logan does not agree with that view, (TR. 3459), although it is an opinion he has " heard expressed before." (Tr. 3458-3459). Logan does, however, expect "tough competiton" from phakic IOL's. Tr. 3459.

540. Phakic IOLs offer several advantages over excimer laser refractive surgery, including the fact that recovery from implantation of phakic IOLs occurs very quickly. (Tr. 308- 310). In addition, phakic IOLs correct very high levels of refractive error, where PRK is not as effective. (Tr. 308-310). Intraocular lenses have been in use for quite some time for use in cataract surgery which is a common procedure. (Tr. 1188; 1190-1191). Accordingly, most ophthalmologists are familiar with the procedure which will be used to implant phakic IOLs. Tr. 3291-3292.

541. More than 10,000 ophthalmologists in the United States currently perform surgery which is similar to that used to implant phakic IOLs, (Tr. 454, 464-465), and the use of intraocular lenses does not require the purchase of a machine, like excimer laser, that costs several hundreds of thousands of dollars. (Tr. 454, 464-465; Tr. 1190-1191; Tr. 3169). Instead, a doctor performing surgery to implant phakic IOLs needs only existing surgical equipment. Tr. 1190-1191; *See*, Tr. 3168-3169.

542. An *Ophthalmology Times* survey suggests that phakic IOLs are used, in FDA clinical trials, by 20% of refractive surgeons to correct hyperopia. (CX-343-G.) It also suggests that phakic IOLs are expected, over the next few years, to be the most common procedure for correcting high myopia. (CX-343-J.). Although the study relied upon a small data base, and was taken a year ago before the reporting of recent clinical results for phakic IOLs in the 7 to 15 diopter range (RX-1531), approximately 9% of surveyed refractive surgeons already believed at the time of the survey that phakic IOLs were likely to become the most common procedure in that range as well. (CX-343-J.)

543. Dr. O'Donnell testified that, assuming phakic IOLs are approved by the FDA, they will not be a widely used alternative because, in his opinion, their risks are unfavorably high for an elective procedure. Like other forms of permanent refractive surgery, Phakic IOLs can cause serious medical complications. The risks associated with this procedure include hemorrhaging, infection and acute glaucoma. Long-term risks include cataract development, corneal decompensation, and inflammation. (RX-1469 at 2; Tr. 3162). The FDA is assessing these risks, and industry observers believe market entry by companies producing phakic IOLs is expected within the next two years (2001). (RX-1469; Tr. 463).

Dr. O'Donnell observed that lens implants for cataract patients have an acceptable risk profile because the patient has a visual disability that cannot be treated without invasive surgery. (Tr. 3162-3163). Since most surgical procedures involve risk,

it is important to provide a context in which to evaluate potential adverse consequences of a surgical procedure. In contrast with Dr. O'Donnell's testimony, a research study by Frost & Sullivan in November 1998 concluded that "many researchers and managers of leading firms strongly believe that the future of refractive surgery lies in phakic IOLs." (RX-1469 at 2.) In addition, Dr. David C. Brown, an ophthalmologist who is a clinical investigator for one of the makers of phakic IOLs, has stated that phakic IOLs, when approved "will be in direct competition with procedures using lasers from VISX, Summit, Autonomous and other as yet unapproved excimer laser companies." (CX-307.)

544. Before it approves these implants, the FDA is likely to require substantial follow-up studies to determine the potential for serious acute complications and for serious delayed complications. (CX 306; Tr. 3161-3162; Tr. 310; CX 157 at 116-119). Market estimates anticipate that phakic IOLs will obtain FDA approval and be on the market within the next two to three years 2001-2002. Rx-1469 at 2; CX-307 at 1.

545. Phakic IOLs have the potential to correct very high levels of myopia. These levels occur in less than one percent of the population. Lasers can also treat this level of myopia, although the current machines do not yet have FDA approval for this level of correction. (Tr. 3162; 3164; 3293-3295; Tr. 3163-3164). Phakic IOLs also can correct medium levels of myopia as well, 7 to 15 diopters, (RX-1531), and are in trials for low myopia (down to 3 diopters), astigmatism, and hyperopia. (CX-307; Tr. 3454).

546. Current clinical trials show that patients find phakic IOLs an attractive alternative to LASIK at a range of 7 to 18 diopters. (*See, e.g.*, RX-1531 (out of 14 patients with myopia in range from 7 to 18 diopters, who had phakic IOL implanted in one eye and LASIK performed on the other, all 14 patients preferred phakic IOLs to LASIK).) Phase III clinical trials at even lower levels of myopia (to 3 diopters) have also been initiated. (CX-308)

547. While Phakic IOLs are not likely to take over the mainstream of refractive surgery, and while this technology is not one that VISX "worries about" in the marketplace, (CX 157 at 123-124), the weight of the evidence in this record indicates that Phakic IOLs are likely to be approved by the FDA, and upon approval are likely to occupy a niche market in medium to very high myopia patients. (Findings 95 and 96 *supra*; *Compare* CX 157 at 123-124, *with* RX-1469 at 2.).

Holmium Lasers

548. The holmium laser is used in a procedure known as laser thermokeratoplasty (LTK), in which pulsed infrared light is used to heat and shrink the collagen around the periphery of the cornea to steepen the corneal curvature. Laser thermokeratoplasty, which is sometimes referred to as "collagen-shrinking" technology, is capable of treating farsightedness and perhaps astigmatism, but not myopia. (Tr. 3159-3161; Tr.3051;

CX159 at 119-123; Tr. 417). Holmium lasers are also in clinical trials for presbyopia. (RX-1455 at 3). The leading company in LTK, Sunrise Technologies, is publicly traded. Tr. 1196; Tr. 3449.

549. The major drawback with the holmium laser is that it has to over-correct the eye. Only after an extended period of time does the eye attain its corrected vision. (Tr. 3510; Tr. 3160; RX 1455 at 3). This feature may be unattractive to patients, (Tr. 160), however, during clinical trials, patient satisfaction was reported to be high, (RX-1455), and the procedure offers the advantages that it is performed outside the vision zone and takes less than three seconds. (RX-1455 at 2, 3)

550. A VISX official testified that another difficulty with the holmium laser procedure is that the collagen affected by the laser regenerates itself, so that there is a need to repeat the procedure and the correction never becomes permanent, (CX 157 at 119), however, clinical trial results after 18 months indicated that "the effect persists." RX-1532.

551. Doctors may be attracted to LTK for three reasons. First, Sunrise expects that LTK will require a much lower initial cost than PRK. Second, Sunrise expects to charge a much lower procedure fee than excimer laser manufacturers. Third, infrared (holmium) lasers require almost no maintenance. (Tr. 3451).

552. An analyst report from September 1998 estimates that Sunrise will obtain FDA market approval and begin marketing machines in the U.S. for the correction of hyperopia before the end of 1999. RX-1455 at 3; Tr. 1382-1383.

553. The holmium laser is not, at this stage, a competitive factor in the pricing of excimer lasers. (Tr. 416-417; Tr. 1150-1151). There are, however, ophthalmologists who believe holmium lasers are better than excimer lasers in the treatment of hyperopia. Tr. 396-397.

Potential Market Penetration

554. VISX does not currently take into account any non-approved refractive correction technologies in pricing its excimer lasers, (Tr. 3527), however, it is reasonably likely that phakic IOLs, corneal rings, and holmium lasers will be approved by the FDA within the next two years. Each would occupy a sereprate niche, but overall their initial indications potentially will compete in virtually every indication for which excimer laser surgery is approved; i.e. Phakic IOLs in mid-to high myopia; corneal rings in low to mid-myopia; and holmium lasers in hyperopia.

Market Power

555. Dr. Levy opined that the '388 patent significantly contributes to VISX's market power in the relevant markets as a consequence both of its the exclusionary ability and the absence of close substitutes. Tr. 1254-1255, 1315-1316, 1318- 1319, 1323; Tr.1345,

1347. If, however, the '388 patent were found invalid on reexamination, it could not contribute to VISX market power. Tr. 1666, 1673.

556. Dr. Levy testified that if someone could invent around the '388 or if the '388 were invalid, he could not say one way or the other whether VISX would have market power in either the technology or the goods markets. (Tr. 1508-1509; 1671-1673). Respondent's technical experts, Drs. Eden and Motamedi, testified that there is no way to design around the '388 patent, which covers PRK/LASIK. *See*, TR.5486-5487; CX 303.

557. Dr. Levy defined monopoly power as the power to control prices or exclude competitors. Although data were unavailable to determine a competitive price level against which Dr. Levy could determine whether VISX has the ability to charge a supra-competitive price, (Tr. 1295-1297), he based his opinion that VISX has market power on its ability to exclude competitors, and on its the ability to control prices. Tr. 1297-1298, 1301-1308.

558. Section 2.2 of the Intellectual Property Guidelines promulgated by the FTC and Department of Justice defines "market power" as "the ability profitably to maintain prices above, or output below, competitive levels for a significant period of time." (Tr. 5220-5221; RX-1539 at 3). If the '388 patent was obtained by fraud or inequitable conduct, its licensing price (even as part of a portfolio) could not be deemed a competitive price, and any fee that VISX receives for the '388 as part of a bundle of patents is a supra-competitive price. As VISX has indicated, the licensing fee for any subset of its patents will be the same as the fee for its portfolio of patents. Tr. 3617-3618.

Concentration

559. Approximately 75% of the laser vision correction procedures in the U.S. are performed on VISX's excimer lasers; Summit lasers account for approximately 25% of the excimer laser procedures. (CX 157 at 134-135; Tr. 3492-3493; *See also*, CX 354 at 7).

560. The record includes an industry forecast that the percentage of excimer laser procedures on VISX's machines is expected to drop from 73% in 1998 to 65% in 2000, a decline of more than 10% as a consequence of increased competition. (CX-354 at 11). VISX may, of course, still derive per-procedure fees from any new entrant which licenses its technology. (Tr.1709-1710).

561. Thus, Dr. Levy believed that the appropriate measure of concentration is excimer lasers placed, not procedures performed, (Tr. 1710), and by that measure, VISX's share is approximately 68%. Tr. 3492; RX 1457 at 34; Tr. 1299-1300 (based on CX 343 F).

562. VISX challenges the estimate of 68% on several grounds, including the small data base upon which it is based. It contends that the 55% market share estimate in the Banc Boston report is more accurate. **(IN CAMERA))**,

Dr. Putnam, VISX economic expert, reported that VISX market share is 68%. RX 1457 at 34.

563. While the market share data in this record are not without flaws, both Dr. Putnam and Dr. Levy found it sufficiently reliable to report that, based on excimers actually placed, VISX market share is approximately 68%. The remainder of placements in 1998 are attributable to Summit.

Barriers to Entry and
Ability to Exclude Competitors

564. Entry by VISX's competitors into the relevant goods and technology markets is difficult due, in significant part, to the '388 patent. Tr. 1255, 1323-1324.

565. After it entered into the P³ agreement, a stated purpose of which was to license the partnership's patents, VISX, nevertheless, retained the power to exclude entry. Under the terms of the P³ agreement, VISX and Summit agreed that none of the pooled patents could be licensed to any third-party laser manufacturer without the consent of both VISX and Summit. CX 45 at VISX 002154; 002173); CX 337, Pillar Point Partners et al. v. Dulaney et al., (D. Ariz. No. CIV. 96-2051)) at 498-502.

566. P³ effectively refused to license the technology embodied in the '388 patent. (Tr. 1157-1161; Tr. 1314; Tr. 636-639 (Meeting in Dallas where Summit President announced that no licenses to P³ patents were available)). To date, VISX has refrained from licensing the '388 patent to any laser manufacturer other than Summit.

567. Chiron, Nidek, LaserSight, Meditec, Autonomous and others all made inquiries seeking licenses to P³ patents (including the '388).
IN CAMERA.

568. Prior to October 1995, VISX representatives and representatives of would-be manufacturer-licensees met to negotiate licensing terms for P³'s patents, including the '388 patent. (Tr. 636-639 (Dallas meeting where Chiron hoped to discuss possible license to P³ patents with VISX President McMillen); Tr. 3376.

569. LaserSight specified to VISX in a letter just three patents, (including the '388 patent) for which it was particularly interested in obtaining a license. The use of the abbreviation "e.g." in the letter suggests that LaserSight may have wanted to license additional patents. CX 304 at ST 020005.

570. VISX, through its partnership P³, denied access to the technology embodied in the '388 patent by offering licenses on prohibitively expensive terms. **IN CAMERA.**

VISX, through P³, sought a 6% royalty on the selling price of the laser, plus a $250 per-procedure royalty. The proposed licensing terms also included a $2 million option agreement that was non-refundable in the event the company was unsuccessful at getting FDA approval and was not creditable toward future royalties. CX 80; CX 81 A-B; Tr. 1157-1158; Tr. 3199-3201; CX 230). No firm accepted the terms VISX offered through P³. Tr. 3194; 3201; CX 230; Tr. 1158; CX 157 at 217, 269.

571. The absence of a license from VISX did not have any impact on Chiron's development of the excimer laser system (Tr. 1171-1172), attempts to obtain FDA approval of its excimer laser system (Tr. 631), its clinical trials (Tr. 1174-1175), or marketing (Tr. 632-633). Chiron's physician investigators, however, expressed concern about P³ patents, and asked Chiron what its intentions were with respect to these patents. (Tr. 1174). Respondent describes this as mere "curiousity." Such "curiosity" by informed potential customers, however, would constitute a rational inquiry deserving of a response which satisfies a risk adverse potential customer of a machine which costs hundreds of thousands of dollars.

572. Chiron's discussions with P³ about a U.S. license sought a blanket license to all of P³'s patents. (Tr. 1214-1215). By obtaining a blanket license to all of the P³ patents, Chiron's goal was to eliminate its customers' uncertainty about infringing any of the P³ patents. Tr. 1216-1217.

573. Chiron did, in 1995, take a license under VISX's foreign patents. (Tr. 634; Tr. 1198-1199; RX-1445). In entering into a license to VISX's non-U.S. patents, Dr. Link, in a letter to Mark Logan at VISX, characterized one of the benefits of the license agreement to VISX as an endorsement by Chiron of VISX's intellectual property portfolio. Tr. 1200-1201, RX-1446.

574. While Dr. O'Donnell testified that not having a license to VISX's patents made it difficult for potential entrants to raise capital, (Tr. 3221-3222; 3273), Dr. Keates, who was a consultant and board member of Chiron, testified that the absence of a license under VISX's patents did not, at the time he was with Chiron, have an impact of any kind on Chiron's excimer laser business. Tr. 632-633, 1171-1172.

575. Members of Summit's Board of Directors stressed the importance of the '388 patent among all VISX's patents, stating that they and Summit was concerned about a number of VISX patent and "particularly concerned" with the '388 patent in the time leading up to the formation of P³. (CX 340, (Declarations of Richard F. Miller, John A. Norris, Richard Traskos, and Jeffrey Bernfield, November 4-5, 1997)).

576. An analysis for Alcon (which had members on the VISX board and marketed VISX lasers), discussing an Alcon proposal to acquire VISX, noted that VISX's patents dominate the industry and that the patents that expire in 2009 (which include the '388 patent) "are viewed as so strong as to block any infringing technologies." It further noted thereafter that a per-procedure fee might not be possible. CX 182 at 8.

577. VISX has asserted that the '388 patent gives it the ability to bar anyone from performing laser vision correction. VISX argued in a White Paper submitted to the Commission: "The invention for which Dr. Trokel ultimately received a patent was recognized at the time, and today remains, a fundamental "blocking" patent for those who wish to practice PRK." (CX 369, submitted (Sept. 19, 1997). VISX's experts, Drs. Eden and Motamedi, testified that VISX possesses a large number of patents regarding refractive surgery which can block entry to the marketplace by laser manufacturers.

578. Kelley of Meditec testified that Meditec believes no VISX patents other than the '388 will prevent its MEL-70 spot-scanning laser from being lawfully marketed in the U.S. (Tr. 403- 404). The record shows, however, that Meditec has taken a license to VISX's non-U.S. patents, even though there is no foreign counterpart to the '388 among these licensed patents. RX 935; Tr. 397-398; 414-415.

579. Herbert Schwind GmbH & Co. ("Schwind"), which manufactures and sells excimer laser systems outside the United States, has taken a license to VISX's non-U.S. patent portfolio. RX-934; CX-157 at 61.

580. Chiron (Bausch & Lomb), has not been interested in separately licensing only the '388, but wanted a license to all of VISX's patent portfolio. Tr. 1603-1606.

581. Prior to Chiron's anticipated commercialization of its excimer laser system, Chiron had licensing discussions with P^3 regarding licensing of VISX's U.S. patents. Summit's President announced no licenses to P^3 patents were available. (Tr. 637-639). Chiron's former CEO, Dr. William Link, testified that Chiron wanted a license from P^3 prior to receiving FDA approval in order to eliminate uncertainty prior to a commercial launch, (Tr. 1159), but he felt Chiron did not need to have a license to VISX's U.S. patents until Chiron received its FDA approval or got further along in the process. Tr. 1207-1208.

582. VISX reported in 1992 that the issuance of the '388 patent to VISX "solidified" its patent portfolio. CX 203; Tr. 3778-3779.

583. Dr. Levy testified that the '388 is a very important patent that contributes to VISX's market power in the apparatus market by, among other things, helping it exclude competitors (or forcing them to take licenses on terms favorable to VISX) and ensuring that VISX can preserve its market power against dissipation by excimer laser competitors. Tr. 1312-1313.

584. VISX has communicated to the trade that a laser manufacturer will infringe the '388 patent if it seeks to enter the U.S. market without a license from VISX, whereas it is not certain that other laser manufacturers will infringe the other patents in VISX's portfolio. Tr.403-404; Tr. 3215-3217; Tr.1308-1309.

585. Only VISX can license the '388 to other manufacturers of laser refractive surgery devices. (Tr. 3467-3468). Since June of 1998, VISX has had unilateral control over the licensing of its patents in the United States. Summit can extend its royalty-free license only to manufacturers (such as Autonomous) that it acquires.

586. If VISX licenses its patent, including the '388, the terms of the license are a cost which the licensee would have to pass on to its customers. (Tr. 3202). Since a laser manufacturer would not share in the $250 per-procedure fee, it would be at a financial disadvantage when competing with VISX, (Tr. 3204-3205), because VISX could lower its fee to its customers while a new entrant licensee would still be required to pay VISX the $250 per-procedure fee. (Tr. 3203-3204; Tr. 3395; 3489-3491). Dr. Levy testified that even assuming that VISX charged manufacturer licensees a $220 per procedure fee, that would still be high enough that they could not engage in substantial price competition. Tr. 1320.

With the exception of Autonomous, if it merges with Summit, VISX will require a new entrant either to license the '388 patent or litigate against VISX. VISX has stated publicly that it will "vigorously enforce its patents." In a VISX letter to shareholders by Cabot Money Management about the VISX/Taunton merger, VISX stated that: "The combined Company plans to vigorously enforce its patents . . . in the United States. . . which we feel will result in reduced competition or significant revenues from license fees." (CX 82 (Letter, dated 11/30/90, to David Muller and Helen Masloka, Summit Technology, from Charles Munnerlyn and Alan McMillen (S18 007653-55)); *See also*, Tr. 400-401; CX 34 at 35; CX 27 (VISX 0020590-95) at 591; CX 181 (VISX 058865-75) at 58866, 58871). This constitutes a barrier to entry. Tr. 1318,1332-33.

587. The '388 patent provides VISX insurance against its other patents not barring entry. **IN CAMERA**

Dr. O'Donnell, LaserSight's Chairman, testified that in a meeting to discuss the patent situation: "[S]omebody from VISX [Chief Operating Officer Davila or General Counsel Church] said: Look, if you are doing PRK, then you are infringing the Trokel patent, which is the '388, so case closed, it doesn't really matter, you can argue all day and all night about whether or not you are infringing the '418, the fact is if you are infringing the '388, you are not going to be able to do PRK without a license from Pillar Point, and so that was it." Tr. 3216-3217.

588. Charles Munnerlyn, formerly the CEO of VISX, explained that the '388 patent strengthens VISX's patent position in that it adds "a big chunk" to the "picket fence" of its patent portfolio which can be used to exclude competitors. Tr. 3779.

589. VISX sent letters warning firms that the '388 may be infringed. (*See*, CX 83). Although it has never actually sued for infringement of the '388 patent alone, (Tr. 3475). It has, acting through the P³ entity, sued to enforce the '388 patent and other patents on four occassions. *See*, CX 84 (Complaint in the matter of Pillar Point Partners, Summit Partner, Inc., and VISX Partner, Inc. v. David Dulaney and Anna Marie Dulaney, Ronald Barnet and Teri Lynn Barnet, and Barnet Dulaney Eye Center, Civil Action 96-2051 PHX PGR); Stipulation No. 55; CX 97, (Complaint in the matter of Pillar Point Partners, Summit Partner, Inc., and VISX Partner, Inc. v. William D. Appler) ; CX 96 (Complaint, Pillar Point Partners et al. v. Jui-Teng Lin et al.); CX 98, (Summons, Pillar Point Partners et al. v. Jon G. Dishler et al.) ; Stipulation No. 56.

Control of Price

590. While P³ was functioning, from June 1992 until June 1998, VISX and Summit agreed to implement a per-procedure fee and set a $250 per-procedure contribution to the pool that affected the amount of the per-procedure fee each partner charged purchasers of its machines. The $250 per-procedure fee paid into the pool was set by the partners, based on who proposed the highest amount.

While there was nothing in the pooling agreement that required VISX and Summit to pass on the $250, the nature of that agreement gave VISX and Summit the incentive to pass on to doctors all or a substantial portion of the per-procedure fee. Tr. 1302-1308, 1643-1648, 1650-1651; CX 45 (P³ Agreement); CX 157 at 66-71, 73-75 ; Tr. 3185.

591. The founder and former president of Summit, David Muller, stated that the laser vision correction industry would be forced to pay the fee associated with the P³ patents. In a letter to Alan McMillen, president of VISX, during the formation of P³ and, in discussing user fees, stated, "I anticipate no problem in the marketplace with respect to whatever fee the partnership may set . . . ." CX 79 A-B (VISX 032529-30 at 30).

592. Summit's laser received FDA approval first and thus Summit was, for a time, the only firm selling lasers and collecting a $250 per-procedure fee. VISX, however, was able to share in the revenue from procedures performed on Summit machines during this time period. When Summit collected royalties on the pooled patents, including the '388 patent, it passed on the majority of those revenues to VISX even though VISX had not yet received FDA approval. CX 296 (VISX 1995 10 K) at 1, 6, 10; Tr. 1277-1279; CX 45.

593. Prior to VISX receiving FDA approval, Summit sold excimer lasers and retained the proceeds from the sale of each $500,000 laser. (Tr. 3404). Summit placed 200 lasers by the time that VISX entered the U.S. market. Tr. 3405.

594. VISX does not own a foreign patent that is a counterpart to the '388 patent. CX 303 at BD 0300975; CX 36 (VISX 037534-36); CX 182 dated 1/30/95 (AL00041456-70 at 41468-69).

595. VISX has entered into patent licenses with other companies for its non-United States patents. The terms of those patent licenses are for 6% on the sales price of the laser, with certain adjustments. For LaserSight's $300,000 laser, the VISX's non-United States license costs approximately $15,000. Illustrating the difference between the cost of a license to VISX's foreign patents and the price VISX demands for a license to its United States patents, Dr. O'Donnell explained that assuming the LaserSight laser were used for five years and performed 1000 procedures per year, the license for VISX's foreign patent portfolio would be the equivalent of a $3.00 per-procedure fee. (CX 294; Tr. 3189-3192; CX 42 at 21; CX 182 at 8). Of course, the estimate of per-procedure fees would increase as the number of assumed procedures decreases.

596. Most foreign countries do not allow medical method patents (eg., the '388 and LASIK patent covered by the '388 are not registered abroad) but do allow apparatus patents. It is reasonable to infer that a portion of the per-procedure fee charged by VISX in the United States is attributable to the medical method technology embodied in the '388 patent. CX 303; Tr. 3192.

597. VISX's revenue and earnings potential is primarily dependent on collecting per-procedure fees. VISX's overall revenues are growing at a rapid rate. **IN CAMERA.**

Industry analyists expect VISX's per-procedure fee to decrease in 1999 despite improvements in its product.
IN CAMERA.

598. Now that P^3 is dissolved, the record shows that VISX charges $260 per procedure, (CX 157 at 83-85, 87-88, 88-90; Tr. 3381), **IN CAMERA.**

VISX's procedure fee is projected to drop to an average of $220 per procedure by the year 2000. CX-354 at 11.

599. VISX charges a royalty of approximately 10-14% of the final per-procedure fee for laser vision correction, which is comparable to an average 10.4% royalty rate in the ophthalmics industry, an average 9.5% royalty rate regarding in-licensed devices, and an average 11.3% royalty rate regarding in-licensed devices with FDA approval. (Tr. 5233-5235; RX-1593 at 12 and Ex. 7). VISX's royalty rate is consistent with the royalty rates charged by companies who face risk, and who develop products in a regulated market, (Tr. 5235), even when the one-time machine royalty is included in VISX's royalty rate. (CX-508 at 325-326; 329).

600. **IN CAMERA.**

A VISX Vice President (Davila) testified at deposition that VISX has not lowered its per-procedure fees to purchasers of its lasers, despite requests for discounts, and has not given any consideration to doing so. (Davila Dep.) at 83-85, 87-90; *See also*, Tr. 3515-3518). The record shows that VISX's $260 procedure charge technically is divided between a $250 license fee and a $10 card.
IN CAMERA

601. There are two explanations that appear to account for these falling prices. First, VISX currently faces competition from other laser manufacturers. In the future, it may also face entry from additional excimer laser manufacturers such as Chiron and LaserSight, who will exert further downward pressure on prices. (Tr. 5237-5238; RX-1593 at 14). Second, VISX faces price pressure as a result of downstream competition, both from existing alternatives and from technologies that may get FDA approval in the near future, such as corneal rings and phakic IOLs. (Tr. 5238-5239). VISX's machine and procedure prices both have declined.

Durability of Market Power

602. Summit has a royalty-free license to VISX's entire patent portfolio. It entered the market before VISX, and although its market share declined in subsequent competition with VISX, Summit currently accounts for about 30% of the revenues and equipment sales. VISX presently does not regard Summit as a formidable threat to its leadership in excimer laser placements. Even if Summit acquires Autonomous and its LADARvision system, its system has not sold well internationally (estimated that only three of these systems have been placed internationally as compared to 250 for VISX); the FDA labeling approvals are significantly broader for VISX; and VISX has an established track record of reliability and predictability, which is a key selling point with high-volume laser centers. CX 354 at 1, 9; Tr. 3328, 3528-3529.

603. **IN CAMERA.**

Dr. Levy, commenting upon an analyst report (CX 354), in response to a question concerning whether these dropping prices suggest that there is competition out there somewhere, explained that it does suggest the presence of competition in the environment somewhere, if not from anyone who would license the '388 patent, then from possible entry from alternative technologies. (Tr. 1740-1741). Industry forecasts anticipate VISX will experience falling market share and declining prices. CX 354 at 11.

Return On Investment

604. Although the Intellectual Property Guidelines define market power as the ability to maintain prices above "competitive levels," the Guidelines do not define the term, "competitive level." (Tr. 5224; RX-1593 at 6.) While economists in antitrust cases generally set marginal costs as the measure of "competitive level," Dr. Putnam opined that the marginal cost of a patent has no real economic content. In order to obtain a patent, a firm usually must make capital investments in research in prior periods. To recoup that investment and make a profit, the firm must take into account the current cost of production and the past investment in research and development that generated the invention. Tr. 5224-5225.

605. Evidence regarding VISX's return on investment from its initial public offering in 1988 through today shows that VISX's investors historically have earned the market rate of return on their investment. (Tr. 5227-5228; RX-1457 at 15-17). Adjusted for risk, VISX's average annual return from 1988 to 1998 is virtually indistinguishable from the average annual return of the NASDAQ stock market generally. VISX's return over this period was 22.2% while the NASDAQ's return was 21.8%. (*Id.*). As of September 22, 1998, however, VISX's risk-adjusted return over the prior ten years was only 0.4% over the market index (22.2% versus 21.8%); as of January 6, 1999, it was still only 0.4% over the relevant benchmark (27.2% versus 26.8%). (Tr. 5520-5521). VISX's expected future stock market performance, measured by the common technique of comparing the price for VISX's product to the company's earnings (the so-called "price/earnings" or "P/E" ratio), also is comparable to that of similar companies. (Tr. 5229-5231; RX-1457 at 17 and Ex. 3). Specifically, VISX's P/E ratio of 32 ranked it above 61% of its peers. RX-1457 at 17; Tr. 5230.

606. Yet, it is unclear what, if any, probative value VISX's share price over ten years has in determining VISX's market power, particularly considering the fact that Dr. Putnam did not define relevant markets. Dr. Putnam conceded that he had to assume that the events depicted on his chart were not anticipated by investors, that news of the events was disseminated to all investors, that investors understand the significance of the

events and that investors act rationally. (Tr. 5430-5432). There is no evidence that VISX investors satisfied all of Dr. Putnam's requisite assumptions. Further, Dr. Putnam's stock analysis only compared VISX to companies that both showed a profit and were within a discrete group (SIC 3845). (RX 1457,Tab 3, Tr. 5226, 5442). VISX derives a significant amount of its revenues from its intellectual property licensing activities. (Tr. 5444). Dr. Putnam did not know if the SIC 3845 companies that he used as a comparison derived any revenues from licensing activities. *Id.*

Research And Development

607. VISX devotes 22% of its sales receipts to research and development, compared with the average company in the United States which devotes 3% of sales to research and development, and the average "high technology" company which spends 9% of sales on research and development. (Tr. 5231-5233; RX-1457 at 17-19 and Exs. 4, 5). This level of R&D indicates that real prices for excimer lasers would have been falling even if nominal prices had stayed constant. (Tr. 5233). There is, however, no reference in either the Merger Guidelines or Intellectual Property Guidelines regarding the use of "R&D expenditures" to measure market power. *See,* FTC/DOJ Horizontal Merger Guidelines and Intellectual Property Guidelines.

VISX's Non-388 Patents

608. In addition to the '388 patent, the VISX patent portfolio includes other PRK-related patents. (Order No. 4 ¶ 8.) These patents include the '913, '418, '372, '148, '695, '934, '762 and '843 patents. (RX-1441A; RX-1028A; RX-1032A; RX-1034; RX-1090; RX-1064; RX-1084; RX-1087.)

609. Dr. Levy testified that if patents are perfect complements, (*i.e.* if both are necessary to produce a product, Tr. 1601-1602), there is no separate demand for any one of the patents. (Tr. 1595-1596). Thus, if VISX's other patents are perfect complements to the '388, there is no separate demand for the '388. (Tr. 1596). Dr. Levy does not necessarily agree, however, that other VISX patents are perfect complements to the '388. (Tr. 1488-1489). In his view, the '388 patent is sufficient by itself to prevent any potential entrant from entering the market, but it is less clear that VISX's other patents prevent entry. Tr. 1309-1313.

Competitors' Systems

610. Representative commercial excimer laser systems worldwide can be categorized into four categories which describe different approaches to deliver energy to the surface of the cornea: iris, ablatable mask, scanning, and slit scanning. (Tr. 5027; Tr. 5115-5116.

611. The iris system is one in which the pattern of ultraviolet radiation exposure on the cornea is defined at its periphery by an iris or diaphragm interposed in the path of the laser beam between the laser source and the cornea. (Tr. 5028-5030; RX-1225 ¶ 9; RX-1459 ¶ 8; RX-1580.) Commercial iris systems include the Summit ExciMed and Apex/OmniMed. Tr. 5030.

612. The ablatable mask system is one in which the pattern of ultraviolet radiation exposure on the cornea is defined by an optical membrane (mask) which is opaque to the laser radiation and generally has a thickness which varies with position. The mask is interposed in the path of the laser beam between the laser source and the cornea. During the course of treatment, regions of the mask are ablated by the laser beam, and the pattern of laser beam exposure on the cornea changes accordingly as the laser radiation removes regions of the mask. (Tr. 5030-5033; RX-1225 ¶ 10; RX-1459 ¶ 9; RX-1581; RX-1582.) Commercial ablatable mask systems include the Summit Apex Plus/Apogee. Tr. 5033.

613. The scanning system is one in which the ultraviolet radiation exposure on the cornea is a spot that is smaller than the cornea, and in which the spot (*i.e.*, intensity pattern at the cornea) is moved in time so as to irradiate the overall area to be treated. (Tr. 5033-5034; RX-1225 ¶ 11; RX-1459 ¶ 10; RX-1583.) Scanning systems include the Autonomous T-PRK, the LaserSight Compak-200, and the Bausch & Lomb Keracor 116 and Technolas 217 C-Lasik. Tr. 5034.

614. The slit scanning system is one which shares characteristics of a scanning system, but in which the ultraviolet laser beam is rectangular in shape prior to reaching an aperture interposed in the path between the laser source and the cornea. The rectangular beam is moved in time across the aperture, which in part defines regions of the cornea to be treated. (Tr. 5034-5036; RX-1225 ¶ 12; RX-1459 ¶ 11; RX-1584.) Slit scanning systems include the Nidek EC-5000. Tr. 5036.

Coverage of VISX's '913, '418, '372 and '418 patents

615. Dr. J. Gary Eden, Professor of Electrical and Computer Engineering, Research Professor Coordinated Science Laboratory, and Director , Laboratory for Optical Physics and Engineering, University of Illinios, Urbana, was called as an expert witness by Respondent. (Tr. 5004-5005). Dr. Eden considered a subset of VISX's patent portfolio: the '913, '418, '372 and '148 Patents, and a selected number of independent claims. (Tr. 5016-5018). The patents are presumed to be valid, and each claim of a patent is presumed valid independently of the validity of other claims. 35 U.S.C. § 282.

616. In Dr. Eden's opinion, (1) the independent claims of VISX's '913, '372 and '148 Patents are covered by the iris systems, (Tr. 5059), in that at least eleven independent claims of these VISX patents cover the iris systems, (Tr. 5073-5074; RX-1579); (2) the independent claims of VISX's '913 and '148 Patents cover the ablatable mask systems, (Tr. 5068), in that at least twelve independent claims of these VISX patents cover the ablatable mask system, (Tr. 5073-5074; RX-1579); (3) the independent claims of VISX's '913 and '418 Patents cover the scanning systems, (Tr. 5037), in that at least twenty-six independent claims of these VISX patents cover the scanning systems, (Tr.

5073- 5074; RX-1579); (4) the independent claims of VISX's '913, '418, '372 and '148 Patents cover the slit scanning system, (Tr. 5053), in that at least sixteen independent claims of these VISX patents cover the slit scanning system. (Tr. 5074; RX-1579.)

617. Dr. Eden did not quantify the likelihood of infringement in his expert report or at his deposition. (Tr. 5478-5479). At trial, he was 80-95% certain in his conclusions that any particular patent claim listed in his Expert Report (RX-1225) did in fact cover the systems about which he opined. (Tr. 5024). Although he is not an ophthalmologist, Dr. Eden, is an ultraviolet laser expert, and he testified concerning the laser systems and the means by which they deliver laser radiation to the eye. (Tr. 5017). Dr. Eden acknowledged, however, that there were terms in claims that were not clear to him and that he referred to the patent specification to understand them, (Tr. 5078), and because he is not an ophthamologist, he is not qualified to provide opinions about medical procedures he has never performed or watched, and about which he has no medical expertise.

Dr. Eden testified that the '913 patent is not clear on whether laser spots should be lined up adjacent to each other or overlap. (Tr. 5098-5099). He did not agree with Dr. Munnerlyn's statement in the '934 patent that the '913 patent's suggestion to use a small spot made it impossible to form a smooth surface by accurately placing spots adjacent to each other in a scan, (Tr. 5099-5100), but he acknowledged that Dr. Munnerlyn's statement may have been correct at the time Dr. Munnerlyn wrote the statement. (Tr. 5101). He further acknowledged that he does not know whether scanners were available in 1983 with sufficient positional accuracy to overcome the problem noted by Dr. Munnerlyn. Tr. 5101.

618. Dr. Eden also agreed that there are a number of claims which require confining the laser to a projected spot which is small compared to the area containing refractive errors. (Tr. 5096-5097). At his deposition, Dr. Eden acknowledged he interpreted the meaning of claim language in light of the specification and his own experience, (CX 509 at 367, 424, 464-465), and that the '913 patent discloses only two spot sizes: one approximately 113 fold smaller than the area to be treated and one approximately 31,000 fold smaller than the area to be treated. (Tr. 5086-5087). The '913 patent does not disclose a range of spot sizes and is silent on the issue of how to use a spot size that is not small. Tr. 5087, 5093.

619. The formula in Dr. Putnam's report assumes a 100% degree of independence between VISX's patents and claims. (Tr. 5454-5455). Dr. Putnam testified, however, that his results remained valid "even if you have actually fairly high dependence among the patents," (Tr. 5267-5268), and even if it was only 60% certain that VISX's patents were valid and infringed. Tr. 5256-5261.

Coverage of VISX's '695, '934, '762 and '843 Patents

620. Dr. Motamedi considered the '695, '934, '762 and '843 Patents, and a selected number of independent claims. (Tr. 5017; 5117-5118). These patents are presumed to be valid, and each claim of a patent is presumed valid independently of the validity of other claims. 35 U.S.C. § 282.

621. In Dr. Motamedi's opinion, the iris, ablatable mask, scanning, and slit scanning systems are covered: (1) by claim 1 of the '695 Patent when used to perform LASIK, (Tr. 5120, 5123-5124); (2) by claims 1, 9, 24, 32, 40, 48, 59, 60 and 62 of the '934 Patent when used to perform PRK after first removing the corneal epithelium, (Tr. 5133 -5134); (3) by claim 1 of the '762 patent, (5153); and by claim 1 of the '843 patent when used to treat myopia. Tr. 5160-5162.

Dr. Motamedi admitted that a procedure where the entire lenticule is cut off is not necessarily covered by claim 1 of the '695 patent and that he was never asked to consider the question as part of his analysis. (Tr. 5169). He did not recall whether the word "hingedly" from claim 1 of the '695 patent is defined in the specification, (Tr. 5171), nor did he know if the LASIK procedure is performed with a vacuum holding device depicted in Figures 6 and 7 of the '695 patent. (Tr. 5172-5173). He also was unaware whether a removal of 30% more tissue fell within the definition of "approximately" in the '762 patent. (Tr. 5177-5180). A refractive surgeon, rather than an engineer, would be better qualified to offer an opinion as what an ophthalmologist (Dr. Trokel) meant in 1983 by "approximately." Dr. Motamedi is fully qualified to opine about laser/material interactions involved in the patents he selected, (Tr. 5017), but he is to address medical procedures. Tr. 3859, 4015-4016.

622. Dr. Motamedi testified that his opinions about the coverage of the four VISX patents, the '695, '934, '762 and '843 Patents, are all independent from each other, (Tr. 5163), and although he did not quantify the likelihood of infringement in his expert report, (Tr. 5478-5479), at trial, he held a 90% or greater level of certainty in his conclusions about the patent coverage set forth in his Expert Report (RX-1459). Tr. 5127-5128.

623. At present, there are no clinically acceptable methods to perform refractive surgery with an excimer laser on the optically active portion of the cornea other than LASIK and PRK. (Tr. 5164; RX-1459 ¶ 17.). However, Dr. Motamedi admitted that a procedure where the entire lenticule is cut off is not necessarily covered by claim 1 of the '695 patent, and that he was never asked to consider the question as part of his analysis. (Tr. 5169).

624. The iris, ablatable mask, scanning, and slit scanning systems are covered by claim 1 of the '762 Patent. (Tr. 5153). Dr. Motamedi testified that the ablation rates of the various commercial excimer systems are all approximately 1 micron for each accumulation of one joule per square centimeter of energy applied, (Tr. 5151-5152), and that the variation in the literature was within the range contemplated by the '762 Patent. (Tr. 5176-5177). However, he was not sure what removal of approximately 1 micron of tissue in the context of the '762 patent claim 1, element (c), means. He testified that the '762 patent requires that approximately 1 micron of tissue be removed for every accumulation of one joule of energy per square centimeter, (Tr. 5147), and agreed that a laser operating at 180 mj/cm2 and that removes corneal tissue at a rate of 0.23 microns per pulse would remove approximately 1.28 microns of corneal tissue after accumulating a total of 1 joule of energy. (Tr. 5174-5175). Dr. Motamedi acknowledged that 1.28 is approximately 30% more than 1, (Tr. 5175-5176), and further testified he does not know if the '762 patent defines what is meant by "approximately" 1 micron of tissue removed for every accumulation of 1 joule of energy. (Tr. 5177). Dr. Motamedi acknowledged that he did not know if the accuracy of tissue removal during a refractive procedure was off by 30%, the outcome of the procedure would be negatively affected. Tr. 5178-5180.

625. The iris, ablatable mask, and slit scanning systems are covered by claim 1 of the '843 Patent when used to treat myopia. Tr. 5160-5262.

626. The ablatable mask system is covered by claim 14 of the '843 Patent when used to treat hyperopia. Tr. 5162.

627. While Dr. Eden believed there is no practical way to design around VISX's '913, '418, '372 and '148 Patents, (Tr. 5075), Dr. Munnerlyn acknowledged the possibility that licensing and design around were the two ways to deal with Taunton's patent portfolio which included the '913, '418, '372 and '148 patents. Tr. 3690-3691.

628. While six of VISX's competitors have chosen to license VISX's non-U.S. patent portfolio, Nidek has litigated infringement of some of VISX's non-U.S. patents. Tr. 402-403. **IN CAMERA.**

629. The declarations submitted by Summit's board members indicate that, "We were particularly concerned about the patent that issued as the Trokel '388 patent, though we had serious concerns about other VISX patents as well." (Tr. 1488).

630. Dr. Link has testified that he hoped that Chiron would eventually get a license from P^3 to its patents calling for royalties that would be similar or identical to royalties paid to P^3 by VISX and Summit. Tr. 1211-1213.

Incremental Effect of the '388

631. VISX contends that even if it possesses market power, the '388 has no incremental effect on its market power. It bases this contention on the results of a formula contained in Dr. Putnam's report. (RX 1457 ¶ 39). The formula assumes a 100% degree of independence between VISX's patents and claims, (Tr. 5454-5455), however, independence is not something that's necessary to the conclusion. Dr. Putnam clarified that, ". . . I allowed for that in my calculations, and it turns out that even if you have actually fairly high dependence among the patents, it still doesn't make any statistically significant difference if you can add the sixth patent, which is the '388." (Tr. 5628). With respect to quantifying the likelihood of validity and infringement, (RX 1457 ¶ 39), Dr. Putnam chose this likelihood to be 60%. (*Id).*

632. At the time Dr. Putnam prepared his report, no VISX technical expert had quantified the likelihood that VISX's patents would be infringed. (Tr. 5478-5479). Dr. Putnam conceded that the first time he heard VISX's experts quantify the likelihood that VISX's patents would be infringed was in their testimony the day before the hearing, (*Id),* at which time, they "quantified" the likelihood of infringement as at least 60% which coincidently conformed with Dr. Putnam's formula.

633. Drs. Putnam and Levy testified that two patents are perfect complements if both are necessary to produce a product. (Tr. 1601-1602; Tr. 5248). They also agreed that where patents are perfect complements, the price of buying both together is equal to the price of buying one separately. (Tr. 1426-1427; RX-1457 at 26). Accordingly, where two valid patents are perfect complements, the marginal value of either patent is zero. Tr. 1425; RX-1457 at 26.

634. Both economists agreed that the results of the probability formula do not change, and the marginal value of a patent remains zero, if the perfect complement is a patent portfolio rather than a single patent. The marginal value of the patent is zero even if there is a 100% probability that the patent is valid, enforceable, and infringed. (Tr. 1432-1433; Tr. 5256-5261). Dr. Levy agreed that the model was appropriate, and that if the factual underpinnings of Dr. Putnam's model proved true, it would be appropriate to conclude that the '388 had no incremental effect on VISX's market power. Tr. 1429, 1436-1437.

635. In theory, if the joint probability of validity remains close to one regardless of the addition or subtraction of any one patent, then the royalty rate, in theory, is not going to be affected by the addition or subtraction of the patent, and the economists agreed that there would be no incremental price increase associated with that one patent. In theory, there also would not be any decrease in insurance value associated with removing one patent from the portfolio. Tr. 1433-1434, 1436-1437; RX-1457 at 26-27.

636. Assuming that (a) there is a 60% likelihood that five other valid VISX patents were infringed, and (b) the patents were independent in a probabilistic sense, (Tr. 1420-

1421; Tr. 5257-5262; RX-1457 at 25.), the economists agreed that eliminating the '388 from VISX's patent portfolio would have very little effect on the likely royalty rate for licensees (and hence little or no incremental effect on prices or the power to exclude). The conclusion does not change if the likelihood of validity and infringement is 50% instead of 60%. (Tr. 5262). The issue of infringement, however, is a legal issue, and neither Dr. Motamedi nor Dr. Eden have legal expertise. Tr. 5483-5486.

637. As noted previously, Dr. Levy accepts VISX's probabilistic modeling of the incremental effect of the '388. He testified at trial as follows: "Q. Okay. So we don't have any disagreement about the model, we just have a disagreement about whether it applies here; is that right? A. Yes. . . . [T]hat is a textbook equation. . ." (Tr. 1437). If one puts the same variables in the formula and performs the math correctly, the results will be the same. The formula can accurately determine the probability of a single coin landing on "heads" when flipping multiple coins, (*Id),* but the record shows that this matter involves complications beyond a coin-flipping scenerio. Tr. 5456.

638. Dr. Levy also raised as a conceptual issue the question whether VISX's patents were independent in a probabilistic sense. The formula has no variable for the degree of independence or dependence. (Tr. 5453-5455). At his deposition, Dr. Putnam used a formula with an "Alpha" variable to reflect the degree of dependence, (Tr. 5482-5483); however, at trial, he relied on the formula contained in his report.

639. The extent to which VISX derives incremental anticompetitive advantages from the '388 patent is not accurately reflected in the output of a probabilistic formula based on theoretical modeling, perhaps because the formula must, in this instance, rely so heavily upon subjective assessments of the complex factors hereinbefore set forth. (*See*, Findings 610-630; Tr. 3215-3218). The record shows that the '388 patent has a tendency and capacity to deter entry into the laser vision correction business, thereby contributing an exclusionary increment to VISX's patent portfolio. (Finding 609, *supra.*). A Nidek executive testified, for example, that no patent other than the '388 will keep its laser from being lawfully marketed. (Tr. 403-404). Moreover, the '388 patent has a tendency and capacity to stifle innovation, for example, by discouraging development of new types of laser apparatus systems not covered by existing scanning, split scanning, iris, or ablatable mask technology. While Drs. Motamedi, Eden, and Putnam considered it unlikely that new apparatus technologies could avoid VISX's existing patent coverage even without the '388 patent, their creativity or inventiveness cannot provide the last word. A fourth apparatus was invented which was patentable over the three before it, and a fifth or sixth cannot be ruled out simply because experts are currently unable to conceive of the path to invention. (Tr.5535-5536). The medical methods of the '388 patent, however, could stand in the way of such developments. (*See*, Finding 556). Thus, VISX had access to Dr. Putnam's opinions and formula regarding the purported worthlessness of the '388 patent and, despite this opinion, chose to expend "significant" corporate resources "fighting for the '388 patent." (Tr. 5490-5493). VISX executives have a fiduciary obligation to both VISX and its shareholders not to waste funds and to maximize value for VISX's shareholders. (Tr. 5490-5491).

While Respondent, of course, has a right to defend against the charges filed in this matter notwithstanding Dr. Putnam's theory in respect to the lack of value of the '388, the record shows VISX does not merely pursue vindication here. Logan and other VISX officials do not regard the '388 patent as devoid of competitive value against potential rivals. (See, Findings 437-439, 575, 577, 587). To the contrary, the record shows that they have expended corporate assets to defend the '388 patent, at least in part, because, like their potential competitors, they do not regard this patent as completely benign in the marketplace. (Tr. 5490-5493).

Specific Intent

640. A VISX document entitled "Patent Strategy," states: "Revenue stream (sales price) that our patent can protect - by creating monopoly or forcing licenses." (CX 202, (AM000380-91 at 381); CX 34 (AL40834-42) at 40834).

641. Four years before it received FDA approval of its excimer laser, VISX boldly proclaimed its philosophy to use patents to monopolize the market: "One of the basic tenets of our business philosophy was that VISX had to have a solid patent position *to insure* dominant market share in the U.S. market and 'control' over competitive entries into the excimer PRK and PTK markets." VISX reported that: In 1988, this position was being challenged by the issuance of the L'Esperance patent series. This issue was resolved by two events. The first (and most important) event was the acquisition of VISX by Taunton on November 27, 1990. This resolved the existing interferences. . . .The second event was the formation of Pillar Point Partners (PPP) with Summit Technologies Inc. PPP buffers both VISX and Summit from PRK/PTK related patent actions and commits both companies to the per procedure fee (PPF) concept in the U.S. Consequently, one can reasonably conclude that the major patent related issues for the U.S. market have been resolved since 1988. In the process, VISX has eliminated one of three competitors, [and] committed the remaining competitor to a compatible market approach (PPP). CX 47 (Strategic Update 1988 - 1992) (VISX 036412-036424) at 036419.

VISX's licensing practices and enforcement initiatives as hereinbefore set forth are consistent with the implementation of its policy announcement.[7]

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[7] Respondent, on May 11, 1999, moved to reopen the record for receipt of documents marked RX 1602 through 1606 which reflect ongoing patent licensing negotiations, and which Respondent believes demonstrate an absence of demand for the '388 patent, alone, and an absence of incremental market power. Because these documents are cumulative of evidence already in this record and discussed at Findings 433, 443, 567, 569, 570, and 631-639, the Motion to reopen is denied in accordance with Rule 3.43(b). VISX's request for *in camera* treatment of RX 1602-1606 satisfies the requirements of Rule 3.45 and is granted for a period of 3 years from the date hereof, subject to further extension at that time for good cause shown.

Conclusions of Law

Trokel '388 is a medical method patent covering surgical procedures which can change the optical properties of the eye by operating solely on the anterior surface of the cornea using an argon floride or excimer laser. This particular laser generates a light beam of ultraviolet photons having 6.4 electron volts of energy at a wavelength of 193 nanometers. When directed at biological tissue, the beam yields remarkable results. As each molecule absorbs a photon of light, the energy of the photon breaks the molecular bonds, precisely decomposing the beam's target and ejecting the molecular debris into the atmosphere with little disturbance of neighboring molecules. So long as excess energy is not introduced, all is absorbed, and then dissipated in the subsequent "explosion" of the energized molecule, leaving behind no residual thermal damage. The process is known as ablative photodecomposition, and its effect on biological tissue was first described by IBM scientists in the '135 patent.

Dr. Trokel's invention, embodied in the '388 patent at issue here, is the method for using the excimer laser in a controlled manner to ablate the anterior surface of the cornea without thermal damage, thin layer by layer, in a volumetric removal of tissue with depth penetration into the stroma to a predetermined curvature profile. The method can be used for a variety of ophthalmological applications, including refractive procedures to correct various vision problems including myopia and hyperopia. Indeed, since the excimer laser was first approved by the FDA in October of 1995, the number of consumers who have elected to undergo laser vision correction surgery, or PRK, to improve their eyesight has steadily grown, reaching approximately 400,000 in 1998. Count 3 of the complaint charges VISX with fraudulantly or inequitably procuring the '388 patent, and then using its market power in violation of Section 5 to monopolize '388 patent technology and attempting to monopolize the sale and lease of excimer laser equipment used by ophthalmologists to perform PRK.

Patent/Antitrust Enforcement
The Sherman Act

The '388 patent which issued to Dr. Trokel on April 28, 1992, has no foreign counterparts. Most countries do not permit medical method patents, however, it was a proper field for patenting in this country when issued, and, as such, it conferred upon VISX, as Dr. Trokel's assignee, exclusive, anticompetitive rights to its technology. As the Federal Circuit Court of Appeals observed in *FMC* v. *The Manitowoc Co., Inc.*, 835 F.2d 1411, 1418 (Fed Cir. 1987), "There is no relationship between the antitrust laws and Manitowoc's patent, if the patent were valid, properly procured, and enforced." A properly procured patent, if not misused, may be a barrier to new entrants and others, but its good faith enforcement constitutes a legitimate anticompetitive intent beyond the purview of the antitrust laws or Section 5 of the FTC Act. *E.I. DuPont De Nemours* v. *Berkley & Co.*, 620 F.2d 1247, 1273 (8th Cir. 1980). A patent obtained by fraud, however, provides no safe harbor from antitrust prosecution under the

Sherman Act. *Walker Process Equipment, Inc.* v. *Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965). In this instance, the '388 patent is challenged by Complaint Counsel on the ground that it was, indeed, procured by fraud or inequitable conduct perpetrated by VISX on the PTO. *American Cyanamid*, decades ago, confirmed the Commission's jurisdiction to pursue such abuses of the patent system under Section 5.

The elements of a patent/antitrust monopolization claim are well settled. They were delineated by the Court in *Walker Process* and include: (1) fraud in the procurement of a patent, (2) monopoly power in the relevant market, and (3) the use of the fraudulently procured patent, such as enforcement or threats of enforcement, to restrain competition. *Spectrum Sports v. McQuillan*, 506 U.S. 447, 455 (1993); *C.R. Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1367 (Fed. Cir. 1998); *Brunswick Corp. v. Riegel Textile Corp.*, 752 F.2d 261, 265-66 (7th Cir. 1984), *cert. denied*, 472 U.S. 1018 (1985). An attempt to monopolize violation in a patent/antitrust case under *Walker Process* requires proof of: (1) fraud in the procurement of a patent, (2) specific intent to monopolize the relevant market, (3) some type of enforcement conduct, and (4) a dangerous probability of success in achieving monopoly power. *Spectrum Sports*, 506 U.S. at 455; *C.R. Bard*, 157 F.3d at 1367-68; *Kearney & Trecker*, 562 F.2d at 372. Thus, the analytical framework of a Section 5 or Sherman Act patent/antitrust case focuses initially upon the issue of fraud.[8] Illustrative is the Commission's landmark *American Cyanamid* decision involving the deliberate misrepresentation of experimental data or other material information uniquely within the applicant's knowledge and crucial to the PTO's determination of patentability. Conduct short of fraud, however, does not strip the patent holder's antitrust immunity. *Walker Process*, at 174.

Patent/Section 5 Enforcement
Fraud and Inequitable Conduct

The Courts have held that inequitable conduct before the PTO may be sufficient to render a patent unenforceable against an infringer; but absent fraud, the antitrust laws, and corresponding treble damage liability, cannot be invoked. *Walker Process*, at 174; *Du Pont* v. *Berkley & Co.*, 620 F.2d 1247 (8th Cir. 1980). Cognizant of the limitations of the Sherman Act, Respondent formulates a threshold legal contention that mere inequitable conduct is also beyond the Commission's purview under Section 5. Respondent contends that, under the *Noerr-Pennington* doctrine, it has First Amendment immunity to engage in a little inequitable conduct in seeking to persuade the PTO to issue it a patent at least so far as the reach of Section 5 is concerned. *See*, Resp. Br. at 92-94. Respondent acknowledges that in *American Cyanamid Co.*, 72 FTC 623 (1967) at 684-685, the Commission determined that Section 5 encompassed both

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[8] Whether conduct in procuring or enforcing a patent is "sufficient to strip a patentee of its immunity from antitrust laws is to be decided as a question of Federal Circuit law." *Nobelpharma AB* v. *Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (Fed. Cir. 1998).

fraud and inequitable conduct, and emphasized, in its first *American Cyanamid* decision several years earlier, that fraud was unnecessary to invoke its jurisdiction. *American Cyanamid*, at 63 FTC at 1851-1852, 1860, (1963), *vacated on other grounds*, *American Cyanamid Co.* v. *FTC*, 363 F.2d 757, 771-773 (6th Cir. 1966). Respondent contends, however, that the Sixth Circuit, relying on *Walker Process*, only affirmed the fraud finding specifically. Consequently, it argues that the Commission's *American Cyanamid* decision, and the Commission's Intellectual Property Guidelines, which maintain that "...patents obtained by inequitable conduct that falls short of fraud under some circumstances may violate section 5...," are in error. Resp. Br. at 94. Yet, Respondent's perspective on this issue is a bit too narrow.

The Sixth Circuit did not reject the Commission's determination that inequitable conduct in the procurement of a patent may violate Section 5. The Court merely affirmed the finding of deliberate, affirmative misrepresentation, and as such, was required to look no further to sustain the Section 5 violation. *Charles Pfizer & Co.* v. *FTC*, 401 F.2d 574 (6th Cir. 1968). Any lingering doubt about the scope of the Commission's jurisdiction was clarified a few years later when the Supreme Court determined that unfair methods of competition beyond the reach of the antitrust laws may nevertheless violate Section 5. In *FTC* v. *Sperry & Hutchinson Co.*, 405 U.S. 233 (1972), the Court observed:

> Thus, legislative and judicial authorities alike convince us that the Federal Trade Commission does not arrogate excessive power to itself if, in measuring a practice against the elusive, but congressionally mandated standard of fairness, it, like a court of equity, considers public values beyond those enshrined in the letter or encompassed in the spirit of the antitrust laws. *Id.* at 244.

A careful reading of the precedents which distinguish fraud from inequitable conduct scenarios reveal no First Amendment, *Noerr-Pennington* concerns with challenging a patent obtained by inequitable means under Section 5. Practical policy considerations dictate that, given the complexity of the patent process, an applicant should not be exposed to treble damage liability for "honest mistakes" or those mistakes described in the case law as "technical fraud" which occur in the absence of a deliberate plan to deceive and mislead the PTO. Inequitable conduct is, at once, a broader, more inclusive concept than fraud, but also the "lesser offense," *Nobelpharma AB* v. *Implant Innovations, Inc.*, 141 F.3d 1059, 1069, 1070 (Fed Cir. 1998). Section 5 remedies are perfectly compatible with the Court's approach to inequitable conduct cases.

Thus, it is the applicant's state of mind that determines exposure to Sherman Act charges and potential antitrust treble damage liability. Justice Harlan's concurring opinion in *Walker Process* explained:

> To hold, as we do, that private suits may be initiated under Section 4 of the Clayton Act to recover damages for Sherman Act monopolization knowingly practiced under the guise of a patent

> procured by deliberate fraud, cannot well be thought to impinge upon the policy of the patent laws to encourage inventions and their disclosure. Hence, as to this class of improper patent monopolies, antitrust remedies should be allowed room for full play. On the other hand, to hold, as we do not, that private antitrust suits might also reach monopolies practiced under that for one reason or another may turn out to be voidable under one or more of the numerous technicalities attending the issuance of a patent, might well chill the disclosure of invention through the obtaining of a patent because of fear of the vexations or punitive consequences of treble damage suits. Hence, private antitrust remedy should not be deemed available to reach Section 2 monopolies carried on under a nonfraudulantly procured patent. *Walker Process*, at 179-180

The policy which supports the determination not to lift antitrust immunity in inequitable conduct situations under the Sherman Act is not applicable to Section 5 enforcement policy. Under Section 5, the Commission's remedy is analogous to the defense of nonenforcement which courts routinely grant in infringement cases. In private civil actions, the courts do not hesitate to protect the alleged infringer's rights against inequitable conduct by declaring the patent unenforceable. Similarly, under Section 5, whether fraud or inequitable conduct is present, the relief is the same. The Commission may, for example, require compulsory licensing, with or without a nominal royalty, among other remedies, but it neither declares the patent invalid nor imposes damages. *See, Charles Pfizer & Co. at 586; American Cyanamid,* 63 FTC at 1831; *Case no. 74,* 1 FTC 560 (1915-1919). Its relief removes an impediment to free and open competition in a manner entirely consistent with the approach taken by the courts when faced with patents obtained by inequitable means.

The Commission's relief is wholly prospective. It wields no treble damage "sword." *See, Nobelpharma,* at 1070. Sherman Act precedents, even broadly construed, therefore, do not cast the inequitable procurement of a patent beyond the reach of Section 5. *American Cyanamid*, 72 FTC at 684. If a patent obtained either by inequitable means or fraudulant conduct before the PTO adversely affects competition, it may constitute an unfair method of competition within the meaning of Section 5. *See, Sperry & Hutchinson, supra; American Cyanamid*, 63 FTC at 1862, *vacated on other grounds*, 363 F.2d 757 (6th Cir. 1966), 72 FTC 623 (1967), *affm'd* 401 F.2d 574 (6th Cir. 1968). Accordingly, in this adjudication evidence establishing either fraud or inequitable conduct will satisfy Complaint Counsel's threshold burden of proof.

The Fraud Standard

The complaint in this matter alleges that VISX committed fraud by withholding four items of prior art from the PTO during the prosecution of the '388 patent: the *Keates* article, the Blum patent, the Karp Patent, and the *Girard* textbook. The complaint thus embraces the concept of "fraud by omission," which the Federal Circuit recently employed in an antitrust

context. *Nobelpharma AB* v. *Implant Innovations, Inc.*, 141 F3d 1059, 1070 (Fed. Cir. 1998). Such fraud is evidenced by a clear intent to deceive the examiner and thereby cause the PTO to grant an invalid patent. It may be distinguished from inequitable conduct by evidence of a lesser misrepresentation or an omission of a reference that would merely have been considered important to the patentability of a claim by a reasonable examiner. *Id.* A finding of fraud requires more than a mere failure to cite a reference. Clear and convincing evidence of an intent to deceive the examiner and reliance must be adduced. *Id.* at 1071.

Disclosure of the Prior Art
Duty of Candor

Complaint Counsel contend that VISX owed the PTO the "highest degree of candor and good faith," *Kingsland v. Dorsey*, 338 U.S. 318, 319 (1949); and VISX does not dispute this principle. The Supreme Court's unambiguous admonition places applicants on fair notice:

> 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. . . . Public interest demands that all facts relevant to such matters be submitted formally or informally to the Patent Office, which can then pass upon the sufficiency of the evidence. Only in this way can that agency act to safeguard the public in the first instance against fraudulent patent monopolies. *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 818 (1945).

VISX knew that it was required to disclose all known material information, including prior art that might impair or limit the patentability of the '388 claims. PTO Rule 1.56 sets forth the guiding principles:

> A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. . . . However, no patent will be granted on an application in connection with which fraud on the Office was

> practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. 37 C.F.R. § 1.56 (1992).

Yet, this case presents issues of first impression. The parties have found no case in which a patentee has been challenged for an actionable omission of material information under circumstances in which the prior art was so abundantly disclosed to PTO as the prior art in this case. I am mindful that Complaint Counsel contend that the prior art was not properly disclosed to the Examiner during the course of the *ex parte* prosecution following the interference; however, the case law imposes upon Complaint Counsel the burden of establishing, by clear and convincing evidence, that the prior art was actually withheld with intent to deceive. On this record, that burden has not been satisfied.

The MPEP

In dealing with the PTO, applicants are guided by The Manual of Patent Examining Procedures ("MPEP").[9] The MPEP § 2001.06 instructs applicants to take steps to alert the examiner to known material prior art:

> [One] cannot assume that the examiner of a particular application is necessarily aware of other applications 'material to the examination' of the application in question, but must instead bring such other applications to the attention of the examiner. . . . Similarly, the prior art references from one application must be made of record in another subsequent application if such prior art references are 'material to the examination' of the subsequent application.[10]

MPEP § 2004, paragraph 10, further provides:

> When in doubt, it is desirable and safest to submit information. Even though the attorney, agent or applicant doesn't consider it necessarily material, someone else may see it differently

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[9] The MPEP is considered an authoritative source on the workings of the patent examination process, and is "entitled to judicial notice as an official interpretation of statutes or regulations as long as it is not in conflict therewith." *Molins*, 48 F.3d at 1180, fn. 10.

[10] MPEP § 2001.06(b) (1989). MPEP § 2004, paragraph 9, is similar to section 2001.06: "Do not rely on the examiner of a particular application to be aware of other applications belonging to the same applicant or assignee. It is desirable to call such applications to the attention of the examiner even if there is only a question that they might be 'material to patentability' of the application the examiner is considering." MPEP § 2004 (1989).

and embarrassing questions can be avoided. The court in U.S. Industries v. Norton Co., 210 USPQ 94, 107 (N.D.N.Y. 1980) stated: "In short, the question of relevancy in close cases, should be left to the examiner and not the applicant." MPEP § 2004 (1989).

Disclosures During the ' 026 Interference
The Initial Declaration

Complaint Counsel argue that VISX failed to discharge its duty of candor and good faith when the four prior art references were cited during the Trokel Interference. The record does not support that contention.

In October, 1987, Dr. Trokel filed an amended application which was designed to provoke an interference with the L'Esperance '913 patent. Prior to the declaration of the interference, Primary Examiner Cohen, assisted by Examiner Shay, completed an initial interference memorandum on PTO Form 850. Because interference proceedings are a time-consuming and costly undertaking for the parties and the PTO, the decision to declare an interference includes an assessment of patentability of the claims to each party. As the Court observed in *Conservolite, Inc.*, v. *Widmayer*, 21 F.3d 1098 (Fed. Cir. 1994), it is a prerequisite to the declaration of an interference between an application and an issued patent that the PTO: "determine that the subject matter of the application ...is patentable and whether the claims are drawn to the same invention. The declaration of an interference, thus *prima facie*, establishes those prerequisite conditions." *Conservolite, Inc.* at 1101.

While Complaint Counsel challenge the testimony of Respondent's patent expert, Saul Serota, that the examiners had to review the prior art listed in the '913 patent before allowing the interference to proceed, they have failed to adduce persuasive evidence to refute Serota or explain how Assistant Examiner Shay and Primary Examiner Cohen could have determined whether the claims in the interference were patentable to Trokel without considering *Karp* or *Girard*. Although Trokel copied claims from the '913 patent to provoke the interference, the record shows that the Trokel application revealed prior art different from disclosures in the '913 patent, and, when combined with *Karp* or *Girard*, could have rendered the claims obvious. *See*, MPEP Sec. 2307.2. Thus, Primary Examiner Cohen allowed some claims from Dr. Trokel's application to proceed to the interference over the prior art references, and some he rejected. Obviously, he fulfilled his obligation to determine patentability, and the Examiner-in-Chief's subsequent declaration of the interference confirms Examiner Cohen's diligence.

Complaint Counsel argue further that *Jacobs, III, v. Moriarity*, 6 U.S.P.Q. 2d 1799 (Bd. Pat. App. & Int., 1988), demonstrates that *Karp* and *Girard* would not have been "part of the file" and, therefore, were not reviewed since they had been relied on by the Examiner to reject claims. (CC Br. At 26). *Jacobs III*, however, is inapplicable. Not only was a copy of *Karp* placed in the '913 file, *Girard* was cited in the '913 patent prosecution both by the Examiner

and by Taunton, and both *Karp* and *Girard* are listed on the cover of the '913 patent. *See, Ristvedt-Johnson* v. *Brandt, Inc.*, 805 F. Supp. 557 (N.D. Ill. 1992).

The '026 Interference
Disclosures In Preliminary Motions

Complaint Counsel assert that the prior art was not adequately disclosed in the course of the preliminary motions practice before the Examiner-in-Chief during the interference, and was not before the Board when, on January 16, 1991, it rendered its determination that claims 4 and 5 were patentable to Dr. Trokel.

The disclosures of *Karp, Keates,* and *Blum*, during the '026 interference are voluminous. The record shows that *Karp* was cited at least 65 times in at least 10 different documents during the interference (Findings 105-115); *Blum* was cited at least 25 times in 9 separate documents (Findings 118-127); and *Keates* was cited at least 19 times in at least 11 documents (Findings 128-138). *Girard* was specifically cited as prior art in the text of L'Esperance's Motion to Designate a Claim as Not Corresponding to the Count, and the substance of *Girard* was described in a footnote as follows:

> Girard teaches methods of restricting corneal curvature including... arc, radial, parallel incisions and combinations thereof to remedy myopia and astigmatism.... It would be obvious to one with ordinary skill in the art to substitute an excimer laser as a cutting tool in the techniques taught by Girard.

This argument to the Examiner-in-Chief indeed captures the essence of *Girard* which Complaint Counsel contends was withheld.

The record further demonstrates that in order to rule on the Motion for Reconsideration, the Examiner-in-Chief had to review the '913 file history which included the *Girard* reference. *Girard* was cited both in the '913 patent and L'Esperance's Section 1.633(a)(4) Motion. (*See*, Findings 116-117). Complaint Counsel, nevertheless, assert that the only way patentability over prior art could have been addressed during the interference was if the Examiner-in-Chief or the Board did so, *sua sponte,* because neither VISX nor Taunton raised the issue. Citing *Jacobs III*, Complaint Counsel contend that neither the Examiner-in-Chief nor the Board will comb through a voluminous record to determine, *sua sponte*, whether prior art renders the claims in the interference unpatentable on obviousness grounds, and neither will decide, *sua sponte,* patentability over prior art. Yet the record is clear. Both the Examiner-in-Chief and the Board not only raised the issue of patentability, *sua sponte*, with respect to claims 4 and 5, they decided the issue.

Dr. L'Esperance asserted in his motion that Trokel claims 41 to 50 were not enabled, and the Examiner-in-Chief agreed. He ruled, however, that claims 41 and 50 were "broad enough to read on merely providing incisions" and that Dr. Trokel had enabled making "incisions." CX 16. Dr. L'Esperance sought reconsideration of this ruling because his own incision claims had been rejected as obvious in the '913 application. His petition for reconsideration was denied, but his subsequent request for a special testimony period on the question of patentability was granted. The Examiner-in-Chief authorized a special testimony period because, at the time, he interpreted claims 41 and 50 broader " than either party did in presenting their motions." Complaint Counsel note that in granting the special testimony period, the Examiner-in-Chief did not refer to any prior art references and clearly reserved the patentability issue for final hearing, because:

> claim 41 is identical to claim 1 of L'Esperance and to the count, any holding that claim 41 of Trokel is unpatentable over prior art may result in a holding at final hearing that the subject matter in issue is unpatentable to both parties and that neither party is entitled to a patent on his claims corresponding to the count. (CX 178).

The Examiner-in-Chief thus raised the issue of patentability, *sua sponte*.

Disclosures Before the Board

As a result of the merger of VISX California and Taunton, the final hearing did not convene, but the Examiner-in-Chief and the Board, nevertheless, determined the patentability of Trokel's claims 41-50 in the interference. The Examiner-in-Chief first issued an order to show cause why judgment should not be entered against claims 42 through 49 on the ground they were not patentable. VISX filed a statement of non-opposition to the order to show cause. The Board then entered final judgment on all of Dr. Trokel's claims in the interference, holding: "Based on the record before us, Stephen L. Trokel is entitled to a patent on his claims 41 and 50, but is not entitled to a patent on his claims 42 through 49 corresponding to the count." RX 206.

Now Compliant Counsel question the meaning of the phrase "on the record before us" in the Board's decision. Relying upon Colaianni's testimony, Complaint Counsel contend that the record before the Board did not include the prior art references at issue here, but rather consisted solely of the three documents cited in the Board's decision. Serota, in contrast, testified that the record before the Board included the patent application files and all documentation generated during the interference. The record as defined by Serota includes references to *Keates, Blum, Karp,* and *Girard.*

To the extent Colaianni and Serota could not agree on what constitutes the record before the Board in an interference matter, I have accorded greater weight to the opinion of Serota. His experience in interference matters is more comprehensive and more recent than Colaianni's, and the case law supports the notion that the Board's "record" includes considerably more than

Colaianni suggests. Thus, a court record in an interference case includes the administrative record developed at the PTO, and encompasses, for example, preliminary motions, motions to correct inventorship, miscellaneous motions, belated motions delayed for good cause, or opposition to these motions. *See*, 35 U.S.C. 146. *General Instrument Corp.*, v. *Scientific-Atlanta, Inc.*, 995 F.2d 209 (Fed. Cir 1993); *Conservolite, Inc.*, at 1101-02. As Serota explained, and Colaianni confirmed, at least initially at his deposition, the administrative record before the Board in the interference included the '913 patent, the Trokel application, and the information placed before the PTO, either by the examiners or by the parties during the interference including, as Complaint Counsel have emphasized, information which may be of doubtful materiality. *See*, MPEP Section 2004 Para 10; *Conservolite, Inc.*, at 1102. *Karp, Keates, Girard,* and *Blum* were part of that record.

Buried References

Relying upon *A.B. Dick Co. v. Burroughs Corp.*, 798 F.2d 1392 (Fed. Cir. 1986), and *Mechanical Plastic Corp. v. Rawlplug Co.*, 14 U.S.P.Q.2d 1058 (S.D.N.Y. 1989), Complaint Counsel contend that none of the many disclosures during the interference satisfies VISX's duty of candor to the PTO. Yet, these types of cases are not applicable.

Rawlplug involved an issue of collateral estoppel which arose after an interference terminated. In that case, a defendant lost the interference, but sought to continue prosecuting the application. Because the potential for inconsistent judgments in such circumstances is significant, the MPEP imposes an obligation on the *ex parte* examiner to carefully consider whether estoppel applies. In fulfilling that duty, the examiner is expected to review the entire interference file.

Although the *Rawlplug* examiner noted that he had reviewed the entire interference record, the court denied summary judgment and observed:

> [T]he question presented by the motion to strike the defense of inequitable conduct is whether or not a question of fact arises out of Rawlplug's contention that McSherry's failure to advise the patent examiner of the position he took at the prior proceeding might have been motivated -- in part at least -- by McSherry's hope that this nugget of information would not surface during the patent examiner's required study of the voluminous work product of his predecessor examiner. We conclude that such question must be answered in the affirmative. *Id.*

The court thus treated the matter as a "buried" information case.

A.B. Dick also involved "buried" information. To be sure, Respondent has consistently maintained that the central holding of *A.B. Dick*, although not overruled, was superseded in 1991 by *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. (1991). Under *A.B. Dick*, a case of inequitable conduct or fraud could be predicated upon prior art found by the examiner rather than disclosed by the applicant. In *Scripps Clinic*, the Court held: "When a reference was before the examiner, whether through the examiner's search or the applicant's disclosure, it cannot be deemed to have been withheld from the examiner." *Scripps Clinic*, at 1582. A review of the case law, therefore, confirms Respondent's interpretation of the precedents as superseding this aspect of *A.B. Dick*, *See, Molins,PLC* at 1185; *Litton Systems, Inc.*, at 1571; but the case remains viable in another important respect.

Although it arose under pre-1984 interference practice, when the interference examiner had no jurisdiction over patentability issues and disclosure during an interference did not place the reference before an official with responsibility to consider patentability, the reference at issue in *A.B.Dick* was not actually disclosed in the interference. The Federal Circuit observed that a 1964 Report and a 1965 article were brought to the attention of the Board of Interferences, and these references, in turn, cited the allegedly omitted *Magarvey* article. *See, A.B. Dick*, at 1395, 1398. The Court determined that such disclosure of a reference within a reference is not adequate, and subsequent decisions have not disturbed that conclusion.

Thus, the Federal Circuit has made clear its intention to root out clever schemes to mislead the PTO. It requires that prior art be timely submitted, and not be buried in voluminous submissions or misrepresented through mischaracterization of its origin, content, or timing. *See, Molins PLC* v. *Textron, Inc.*, 48 F.3d 1172, 1179, 1182-83 (Fed. Cir. 1995). It considers such examples of burying probative of bad faith. *Molins* PLC, at 1184. Yet, no case involving hidden prior art cited by Complaint Counsel approximates the shear volume and openness of the prior art disclosures actually made in this instance. Indeed, three of the four references allegedly withheld were attached to pleadings filed by VISX in the interference, and numerous documents filed in the Board's record cited these references. The only reference not physically delivered to the PTO was *Girard*, but a pleading submitted to the Examiner-in-Chief described *Girard's* disclosure, and the '913 prosecution history discussed *Girard*. While Complaint Counsel suggest that perhaps the references were mischaracterized because neither party to the interference raised the issue of patentability over prior art, both the Examiner-in-Chief and the Board, *sua sponte*, rendered patentability decisions on a record which contained clear citations and references to *Keates, Karp, Blum*, and *Girard*. When the Board decided to address the patentability of claims 4 and 5, nothing involving the four references at issue here was hidden from its scrutiny.

Patentability of Claims 4 and 5

Complaint Counsel argue vigorously that the issue of patentability was not before the Board, but the facts suggest otherwise. Prior to 1984, if patentability issues arose during an interference, the interference would be stayed, *ex parte* examination would resolve the patentability issue, and thereafter the interference proceeding would resume. If other issues of

patentability were still pending at the conclusion of the interference, the application was once again returned to *ex parte* examination for resolution of those issues. In 1984, Congress created the Board. Instead of separate proceedings to determine priority and patentability issues, the interference proceeding and *ex parte* prosecution were "unified" before a Board authorized to decide all issues of patentability as well as priority. *Schulze v. Green*, 136 F.3d 786, 790 (Fed. Cir. 1998). Thus, the Federal Circuit observed in *Perkins v. Kwon*, 886 F.2d 325, 328 (Fed. Cir. 1989): "Congress intended that if patentability is fairly placed at issue in the proceeding, it will be determined." Consequently, while the Board's decision in *Jacobs III* involved avoidance of a patentability decision on procedural grounds, nothing in *Jacobs III* suggests that the Board would avoid consideration of any element of patentability when it actually renders a patentability decision.

In this instance, the issue of patentability was, as previously noted, raised *sua sponte* by the Examiner-in-Chief, who was a member of the Board panel which rendered the final patentability decision on claims 4 and 5. *In Re Van Geuns*, 988 F.2d 1181 (Fed. Cir. 1993); *L'Esperance* v. *Nishimoto*, 18 U.S.P.Q. 2d 1534 (Bd. Pat. App. & Int. (1991). Although Complaint Counsel, relying upon Colaianni, contend that the Examiner-in-Chief raised the patentability question only in the context of whether Dr. Trokel had enabled his claims, not whether the claims were patentable over the prior art, the Examiner-in-Chief did not hesitate to issue a show cause order when he questioned the patentability of claims 42 through 49; and there is no reason to doubt he would have done the same if he continued to question any aspect of the patentability of claims 41 and 50 before the Board determined these claims were patentable to Dr. Trokel. Nor was a special testimony period required as a predicate to the Board's action. *Schulze*, at 788-89. While the Examiner-in-Chief originally planned but failed, for reasons not revealed in this record, to pursue a special testimony period, there is no indication he questioned the ripeness of the patentability issue when the matter was pending before the Board; and he did not dissent from the Board's patentability determination. *See, Schulze*, at 789. [11]

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[11] Both parties have, from time to time, proposed findings of fact and propounded arguments which invite speculation about the Board's decision making process or examiners' thought processes, intentions, or understandings under a variety of circumstances. Neither party, however, attempted to call either Examiner Shay, who is still an official at the PTO, (*See*, Pre-Trial Hearing transcript, December 9, 1998, at 168), or former Examiner-in-Chief Boler, who retired from the PTO and is now in private practice. Yet, *American Cyanamid* teaches that reams of pages, spent by both the hearing examiner and the Commission in attempting to divine the intentions and understandings of the examiner who issued the tetracycline patent, were ultimately unproductive. After years of protracted litigation, the Sixth Circuit rejected all of it in favor of a remand to secure the examiner's testimony. *American Cyanamid Co.* v *FTC*, 363 F.2d 757 (6th Cir. 1966). Heeding the lessons of *American Cyanamid*, I have declined invitations to speculate about the non-public decision making process of the examiners and the Board or draw unwarranted conclusions about their undisclosed deliberations.

Whether or not the Board mentioned all of the information it considered in rendering its decision, its determination that claims 41 and 50 were patentable to Dr. Trokel was based on the administrative record before it, which included not only the issue of patentability as fairly raised *sua sponte* by the Examiner-in-Chief, but the *Keates, Karp, Girard*, and *Blum* references as well. The Board's final judgment on the merits allowed claims 4 and 5 over this prior art.

Prior Art Disclosures
to the Ex Parte Examiner

The Interference Record

Upon completion of the interference, the administrative file was sent to the Examiner for resumption of the *ex parte* prosecution of claims 1 through 3. Complaint Counsel contend that the Examiner did not see in the interference file the "disclosure" or the "determination of patentability over prior art." MPEP § 1302.12 required him to make "of record" all references from the Trokel Interference that were not already of record and "which were pertinent to any motions to dissolve which were discussed in the decisions on motion."[12] The Examiner-in-Chief 's decision on preliminary motions never discussed the references in the context of a motion to dissolve, and the Examiner made nothing "of record."

Complaint Counsel thus argue that VISX did not disclose and the Examiner never considered the Blum patent, *Keates*, *Karp* or *Girard* in connection with the '388 patent prosecution. Clearly, VISX never submitted an IDS listing any of the four references, nor does the '388 patent's "background" section specifically identify any of the references. In Complaint Counsels' view, the record is thus barren of : (1) documents discussing the four references or discussing them in the context of patentability of the claims at issue; (2) testimony that a single participant in the process believed, at that time, that use of the references in the interference discharged his duty of candor and good faith; or (3) documents indicating that anyone involved in the interference believed the duty of disclosure was discharged.

Yet, the record shows that an interference is not entirely separate from the prosecution of the application. As previously mentioned, claims 4 and 5 of the '388 patent were, for example, approved by the Board at the conclusion of the interference proceeding. While PTO rules require the *ex parte* examiner to note the final decision in the interference and make "of record" in the application, references cited in the decision on certain motions,[13] Complaint Counsel proffered no specific provision of the MPEP which required VISX to re-cite to the Examiner, references

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[12] MPEP 1302.12 (1989). A motion to dissolve is a motion pursuant to 37 C.F.R. 1.633(a), in which the patentability of a party's claims in the interference are challenged. CPRF 274.

[13] *See* MPEP § 1302.12; MPEP § 2363.

previously cited during the interference. Although Colaianni considered re-disclosure the better practice and inferred from the rules the existence of such a requirement, Serota testified, based on his experience, that no statute, rule, or regulation specifically requires the resubmission of references in the *ex parte* prosecution previously disclosed during the interference. The case law further demonstrates that the absence of an explicit disclosure rule governing these circumstances is indeed consequential. In *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534 (Fed. Cir. 1998), for example, the Federal Circuit rejected an inequitable conduct claim based on the failure to re-cite a reference in a "divisional" application that had been cited in the predecessor application under circumstances in which the rules of the PTO did not specifically require the applicant to re-cite the reference.

Nor are the facts here akin to *A.B. Dick* style references buried within cited references or a *Rawlplug* nugget of material information imbedded in a mountain of paperwork. Even *Girard*, which was referenced the fewest number of times, was clearly disclosed. As such, if disclosure of information during an interference proceeding can ever satisfy an applicant's duty of candor upon resumption of an *ex parte* prosecution, it is difficult to imagine a more compelling case. Unlike *Rawlplug*, a superficial perusal of the interference record in this matter yields not a nugget of useful data, but rich veins of prior art paydirt.

Disclosures in Addition to the Interference Record

The Keates Reference

On September 24, 1991, the Examiner and VISX discussed *Keates* at an interview which involved the Trokel application and pending L'Esperance applications in a context concerning potential double-patenting. While the Examiner's notes concerning the two L'Esperance applications mention *Keates* and his notes regarding the Trokel application do not, Colaianni explained that the double-patenting review required the Examiner to compare the claims of the L'Esperance applications to the claims of the '388 application because: "there is no other way to do it." As participants at the meeting, Gholz and Munnerlyn could not recall the specific format of the discussion, but this record confirms that the Examiner plainly knew about *Keates* during their conversations. With *Keates* thus before him at the same meeting, the Examiner decided to allow claims 1-3 of the '388 application after VISX agreed to make certain changes to those claims. (*See*, Findings 150-156, *supra*).

Co-Pending Applications

The record shows that VISX disclosed *Keates, Karp, Girard,* and *Blum* to the Examiner in connection with co-pending applications assigned to him while prosecution of the '388 was in progress. Indeed, the Examiner was virtually inundated with these references. During his consideration of co-pending applications between 1985 and 1992, *Karp* was cited to him at least

83 times on 16 different occasions, (Findings 162-182); *Girard*, even assuming it was overlooked in the interference file, was cited to him at least 192 times on at least 50 different occasions, (Findings 183-240); *Keates* was cited to him at least 88 times on at least 11 different occasions, (Findings 249-264); and *Blum* was cited to him at least 10 times on at least 4 different occasions. (Findings 241-248).

Complaint Counsel contend, however, that it is irrelevant how many times a reference is cited to an Examiner in a co-pending application because MPEP Section 2004 "warns against disclosures in other applications." Yet, evidence in the record confirms that if two patent applications are pending at the same time before the same examiner, it is not necessary to cite the references from either application in the other application, because the same examiner has both applications before him, and will be aware of "what is going on" in both applications. This evidence is consistent with applicable authority. In *Kimberly-Clark Corp.* v. *Johnson & Johnson, Inc.*, 745 F.2d 1437 (1984), the court invited the reader to:

> Consider too the fact that the same examiner, Mr. Rosenbaum, was examining both these co-pending applications filed only 3 months apart, and had previously examined Hendrick's patent 3,463,154 issued in 1969 in which, over his name, is a list of the references he cited which included Tyrrell. Roeder's specification lists that Hendrick's patent as prior art. Tyrrell was not being concealed from Examiner Rosenbaum. Most certainly he was not affirmatively misled. Id. at 1456.

The co-pending applications in this record were filed by VISX or its predecessor in interest, Taunton, thus affording VISX the requisite nexus to the co-pending applications found missing by the court in *FMC Corp.* v. *Hennessey Industries, Inc.*, 836 F.2d 521 , 526-27 (Fed. Cir. 1987). Nor has Respondent ever suggested that the examiner, based upon his considerable skill in the art, acquired omniscient appreciation of the existence of all pertinent prior art.[14] In these circumstances, cases such as *Semiconductor Energy Laboratory Co. v. Samsung Electronics Co.*, 4

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[14] Complaint Counsel argue that examiners on average handle between 50 to 100 applications at a time and process them under a quota system which, as a practical matter, allows the examiners to spend an average of only 17 to 18 hours on each application. As they gain experience, their workload increases. Examiners thus cannot be expected to recall every application and prior art reference they dealt with in the past. In view of these considerations, Complaint Counsel argue that there are three ways to disclose material prior art to the PTO, consistent with the duty of candor and good faith: (1) an information disclosure statement ("IDS"); (2) an interview with the patent examiner; and (3) in the patent application itself. Yet, the record demonstrates that these are preferred disclosure methods not required and exclusive methods.

F.Supp. 2d 477 (E.D. Va., 1998) are inpplicable to the extent they dismiss the misguided contention of the applicants in those cases that an examiner's skill in the art presumes an awareness of the existence of all prior art. As the foregoing disclosures demonstrate, and as Complaint Counsels' Proposed Rebuttal Finding 80 at least partially confirms, the Examiner and the Examiner-in-Chief were well aware of the four references, and VISX knew they were aware of the references.[15]

The Cover of the '388 Patent

Complaint Counsel also note that none of the four references appear on the cover of the '388 patent, but the significance of that observation is not readily apparent. VISX disclosed, by name and number, four patents in the "background" section of the patent specification, but three of the four patents were not printed on the cover of the patent. Consequently, it would be difficult to conclude on this record that the failure of a prior art reference to appear on the patent cover demonstrates anything significant about the Examiner's awareness or consideration of the reference.[16]

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[15] At footnote 74 of their Post-Hearing Brief, Complaint Counsel cite *J.P. Stevens*, at 1565 as rejecting any contention that the duty to disclose can be satisfied through co-pending applications. *J.P. Stevens*, however, is distinguishable on several grounds. Unlike the evidence in this record, there was no evidence in *J.P Stevens* that the primary examiner actually knew about a reference cited in the other application, *Id.* at 1563; there was no showing that the primary examiner responsible for examining the related application was also primarily responsible for examining the application at issue, *Id.* at 1564, fn10; and the situation involved a reissue, not a co-pending application before the same examiner. Further, the *J.P. Stevens* applicant misrepresented the teaching of the prior art DeGasso patent. *Id.* at 1565. Thus, the circumstances considered by the court in *Kimberly-Clark*, 745 F.2d at 1455-1457, are closer than *J.P. Stevens* to the situation here presented involving co-pending applications before the same examiner.

Respondent's discussion of *J.P. Stevens* is also a bit off target. Respondent cites *Tol-o-Matic, Inc.*, v. *Proma Produkt-und Marketing Gesellschaft m.b.H.*, 945 F.2d 1546, 1554 (Fed. Cir. 1991) in footnote 155 of its Post-Hearing Brief , and argues that *J.P. Stevens* was overruled. The *Tol-o-Matic* Court's comments indicate that its *en banc* decision in *Kingsdown* overruled portions of *J.P. Stevens*. A careful reading of *Kingsdown* and *J.P. Stevens* reveals that *J.P. Stevens* was not overruled on any salient holding here involved. The *Tol-o-Matic* court seems to be referring to dicta in *J.P.Stevens* which suggested that gross negligence may be sufficient to support a finding of inequitable conduct. *Kingsdown* did dispel any lingering doubt about the relevance of negligence, but *J.P. Stevens* was not otherwise disturbed.

[16] Respondent contends that it is also clear that the Examiner was aware of *Karp* and *Blum* based upon his own prior art classification searches during the prosecution of the '388 patent. The record shows that the Examiner searched in the classes and subclasses containing the

Reexamination of the '388

1. The Request

The '388 patent issued on April 28, 1992. On April 4, 1998, a PTO office action issued granting a request for reexamination based upon four items of prior art including the Blum patent, *Keates*, Beckman, et. al., *Limbectomies, Keratectomies, and Keratostomies Performed with a Rapid Pulse Carbon Dioxide Laser*, 71 Am J. Ophthalmology, 1277 (1971); and Peyman, et. al., *Modification of Rabbit Corneal Curvature with Use of Carbon Dioxide Laser Burns*, 11 Ophthalmology Surgery 325 (1980). Notably, the request relied upon combinations of *Keates* and *Beckman* or *Peyman*, and the Blum patent and *Beckman* or *Peyman*. It did not rely on *Keates* alone, *Blum* alone, or a combination involving just *Keates* and *Blum*. Complaint Counsel contend, however, that the grant of reexamination proves that *Blum* and *Keates* were "new" references in the prosecution, and, therefore, were not before the PTO prior to issuance of Trokel '388. Such a conclusion is unwarranted.

Ninety percent of all requests for reexamination filed with the PTO are granted. Of the requests that are granted, 10% result in a determination that the claims of the patent under reexamination are invalid. In 25% of the granted requests, the PTO determines that no changes of any kind need be made to the claims. In the remaining requests that are granted, the PTO determines that some type of change should be made to at least one claim. If such changes are not made, the patents could be held invalid. The record shows that the claims of a patent are either cancelled or changed in 75% of the cases in which reexamination is granted.

The office action granting reexamination states that with respect to the Blum patent, *Keates*, and two other references not here in issue, "consideration of any or all of the references raise a substantial new question of patentability." CX 154. Serota acknowledged that "any or all" could suggest that the IBM patent or *Keates* individually could be the sole basis for granting the

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Karp reference on at least four occasions in the course of the '388 application. He also searched in the classes and subclasses containing the Blum patent on at least four occasions in the course of the '388 application. VISX asserts that given the number of searches in the same and different classifications, it defies reason to suggest that the *Karp* and *Blum* references were "missing" from the "shoes" each and every time that the Examiner conducted his searches. VISX reasons that given this Examiner's extensive history and experience with each of these references, the most likely person to have "checked out" those references was Examiner Shay himself. Nevertheless, such searches can raise only a possibility that the Examiner knew about the references; and as the court in *J.P. Stevens* held, such a possibility will not suffice. *J.P. Stevens* & Co. v. Lex Tex LTD, Inc., 747 F.2d 1553, 1563-64, (Fed. Cir. 1984), *cert. denied*, 474 U.S. 872 (1985).

reexamination.[17] A careful review of the reexamination request, however, demonstrates that it was based on a combination of two new references, *Peyman* and *Beckman* plus *Keates* and *Blum.* Neither *Keates* nor *Blum* without *Beckman* or *Peyman* were specified as grounds for reexamination. *Keates* and *Blum,* therefore, need not be "new" references to support a combination which merits reexamination. *In re Hiniker*, 150 F.3d 1362 (Fed. Cir. 1998).

In *Hiniker*, the PTO initially granted a reexamination request based on references disclosed to the examiner during the examination of the application that matured into the patent. After the grant of reexamination, the Federal Circuit ruled in *In re Recreative Technologies Corp.*, 83 F.3d 1394 (Fed. Cir. 1996), and *In re Portola Packaging, Inc.*, 110 F.3d 786 (Fed. Cir. 1997), that a reexamination was not proper if based only on prior art references which were before the original examiner. The examiner in the *Hiniker* reexamination thus avoided *Recreative Technologies* and *Portola* in an office action which rejected the claims based on combinations of two previously submitted references and three new references. The Board approved the action; and the court in *Hiniker* affirmed the Board's decision, noting that the Board did not rely solely on old art but considered it in context with new art, thus raising "a substantial new question of patentability." *See*, *Hiniker*, at 1365-67. Since a combination of old and new references is a proper basis for reexamination, the grant of reexamination does not establish that the Examiner was unaware of *Blum* and *Keates* during the prosecution of the '388 patent; and indeed his decision rejecting the claims provides confirming evidence to the contrary.

2. Decision Rejecting the Claims of the '388 Patent

On March 30, 1999, the Examiner issued rulings on the Reexamination Petitions involving the '388 patent and the '695 patent. He determined to reject claims 1 through 3 of the '388 patent as being unpatentable over *Beckman* In combination with *Blum*. Although Complaint Counsel contend that *Beckman* was "unnecessary" to his analysis, the Examiner ruled that *Beckman* produces a surgical excision of controlled depth and shape, wherein a beam of carbon dioxide laser radiation is used to remove corneal tissue, and teaches the method claimed, except for the ultraviolet radiation. He reasoned that since *Blum* teaches the use of a 193 mn light to remove tissue, it would have been obvious to the artisan of ordinary skill to use the ultraviolet wavelength of *Blum* in the method of *Beckman,* because *Blum* allows a method of removing organic material without heating.

The Examiner also rejected claims 4 and 5 of Trokel '388 as being unpatentable over *Keates* in view of *Beckman* and *Blum.* He ruled that *Keates* teaches the use of a carbon dioxide laser to modify the refractive properties of the eye by operating on the anterior surface of the

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[17] Tr. 4865-4866, 4972. The MPEP adds that in a request for reexamination, "The citation also should not contain argument and discussion references previously treated in the prosecution of the invention which matured into the patent." MPEP § 2205 (1998).

cornea in a volumetric removal of corneal tissue and with depth penetration into the stroma, while *Beckman* teaches that reducing the heating of the remaining tissue provides superior results in corneal surgery. *Blum,* he reasoned, provided the teaching that the 193 nm laser removed tissue without heating. As such, the Examiner ruled that it would have been obvious to the artisan of ordinary skill in the art to employ the wavelength of *Blum* in the method of *Keates* as taught by *Beckman.* Again, *Beckman* was integral to his analysis. The Examiner's reliance on *Beckman,* but not *Peyman*, when both were cited in the original request, indicates that the Examiner did not employ references he deemed unnecessary. Because the rejections, like the original grant of reexamination, were based upon combinations involving, at least so far as this record is concerned, the new *Beckman* reference, no inference arises that *Keates* and *Blum* must also be "new" art. [18]

Since combinations of old and new art are permissible on reexamination, Complaint Counsels' assertions are unsound. Neither office action establishes that *Keates* or *Blum* were withheld from the Examiner by Respondent. To the contrary, if the fact both office actions were taken based on combinations with *Beckman* is not sufficient, the evidence in this record of their disclosure to the PTO rather convincingly confirms that *Keates* and *Blum* are not "new art."

Actual Disclosures

Pursuing the premise that Respondent's disclosures were inadequate, Complaint Counsel emphasize the Court's admonition in footnote 7 of *A.B. Dick*:

> [T]he PTO cannot realistically be thought of as the equivalent (say) of a small law office, in which notice to one person may fairly be deemed notice to all. It is not necessarily true that the PTO Examining Division will have access to proofs filed in the course of an interference. *A.B. Dick*, at 1399, fn.7.

Also true, however, is the notion that:

> [E]xaminers "must" rely on counsel's candor ...only when the examiner does not have the involved documents or information before him, as the examiner did here. Blind reliance on presumed candor would render examination unnecessary, and nothing in the statute or Manual of Patent Examining Procedure would justify reliance on counsel's candor as a substitute for an examiner's duty to examine the claims. *Kingsdown,* at 874, fn. 8.

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[18] The Examiner also determined to reject claims 1 through 5 of the '388 patent on grounds of double patenting over claims 1 through 23 of the '843 patent and claims 1 through 23 of the '762 patent. VISX may overcome this rejection by filing terminal disclaimers in compliance with 37 C.F.R. 1.321.

The record demonstrates that each reference was disclosed during the interference proceeding involving Dr. Trokel's application which matured into the '388 patent. The record shows that Examiner Shay was the Assistant Examiner on the '913 patent which not only listed both the *Karp* and *Girard* references, but was the target of the '026 interference provoked by the Trokel application. In fact, each reference was in the record before the Examiner-in-Chief during the interference, and each was in the record before the Board when it determined that claims 4 and 5 were patentable to Dr. Trokel. The four prior art references were in the administrative record the Examiner received when the interference proceeding concluded and *ex parte* prosecution resumed. The record now before me reveals that the *Keates* article, in particular, was cited and discussed with the Examiner during an interview involving several of VISX's applications, including the '388, and all four references were cited to the Examiner on numerous occasions in co-pending VISX applications.

Fraud by omission is a "reprehensible" practice, *Nobelpharma AB*, at 1070, and withholding material information to skew the patent process, while perhaps less culpable, can fatally taint a patent. Yet, the only cases in which fraud or inequitable conduct have been found in situations in which the allegedly omitted prior art was actually contained in the administrative file involve instances of buried or mischaracterized information. This is not such a case. Clear and convincing evidence has not been adduced on this record showing any "failure to disclose" to the PTO. *Molins, PLC* at 1178, 1181; *See also, FMC, Corp.* at 1415; *Baxter International,* at 1327-29; *Litton Systems, Inc.* at 1571, vacated on other grounds, 520 U.S. 1111(1997); *Akron Polymer*, at 1383. To the contrary, the evidence establishes that VISX or its predecessor-in-interest, Taunton, disclosed to the PTO, and specifically to the Examiner-in-Chief, the Board, and subsequently to the Examiner, each of the allegedly omitted references on scores of occasions. It would thus be difficult to conclude that *Blum, Girard, Keates*, or *Karp* were either omitted or withheld from the PTO.

Culpability

Viewed in light of all the evidence, Complaint Counsel have failed to establish that VISX's conduct, considered in its totality, indicates any culpability "[requiring] a finding of intent to deceive." *Molins PLC*, at 1181. The *Keates, Karp, Girard*, and *Blum* references were before the PTO officials responsible for determining the patentability of the '338 claims. *Scripps Clinic*, at 1185; *Litton Systems, Inc.*, at 1571, *vacated on other grounds*, 520 U.S. 1111(1997). They were not misrepresented, mischaracterized, or effectively hidden from scrutiny. They were laid out in the open, and the sheer volume of their iteration and reiteration over a number of years in motions, office actions, co-pending applications, interviews, and the like dispels any notion that a scheme to defraud, deceive, or withhold was afoot. If there is any evidence of a plot hatched by Respondent with intent to deceive the PTO by withholding prior art, Complaint Counsel have failed to explain how it operated under the glare of the copious prior art disclosures revealed in this record. PTO workloads and Examiner work quotas simply do not provide a plausible foundation premise upon which to construct a theory of intent to defraud or deceive in

this instance. The record, considered as a whole, is devoid of clear and convincing evidence that either Dr. Trokel or anyone acting on his behalf committed fraud in the procurement of the '388 patent. Accordingly, the charge in Count 3 of the complaint that VISX engaged in a *Walker Process*-type Sherman Act violation is, on this record, lacking in merit.

Section 5/ Inequitable Conduct

Should the Commission deem the actual disclosures of these sources inadequate, contrary to my foregoing findings and conclusions, the relative materiality of the prior art must be assessed and compared with the degree of Respondent's intent to mislead and deceive the PTO. Complaint Counsel have further agreed they must demonstrate that "but for" the omitted prior art references, the '388 patent would not have issued.

In contrast with the burden of proof required to establish fraud, the Federal Circuit has established a balancing test for the adjudication of the issue of inequitable conduct. One who alleges a "failure to disclose" type of inequitable conduct must adduce clear and convincing evidence of; (1) prior art or information that is material; (2) knowledge chargeable to applicant of the prior art or information and its materiality; and (3) failure of the applicant to disclose the art or information resulting from an intent to mislead the PTO. *FMC Corp.* v. *Manitowoc Co., Inc.* 835 F.2d 1411, 1415 (Fed. Cir. 1987). Respondent may then rebut such proof by showing that the prior art was either not material or cumulative, or the failure to disclose it did not result from an intent to deceive. *Baxter International, Inc.* v. *McGaw, Inc.*, 149 F.3d 1321 (Fed Cir. 1998). In summary, the burden rests with Complaint Counsel to establish that VISX, by inequitable means, obtained a patent which adversely effects competition in violation of Section 5.

Materiality

The parties join issue over the materiality of the four prior art references allegedly withheld. A reference was considered material, during the time the '388 parent was under consideration, if there was "a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." CX-375 at §1.56(a); *Molins PLC,* at 1179. The PTO revised its rules in 1992, but the substance of the duty of candor remains the same: there is a "duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. § 1.56(a). It should here be emphasized that an applicant has no duty to disclose cumulative references. The Court has determined that cumulative references are not material and their nondisclosure cannot be deemed inequitable or fraudulant. *Scripps Clinic,* at 1582. Nor is there an obligation to disclose references which are less material than references before the examiner. *Halliburton,* at 1440.

A materiality determination also requires consideration of " portions of prior art references which teach away from the claimed invention." *Halliburton,* at 1441. A reference teaches away "if it suggests that the line of development flowing from the reference's disclosure

is likely to be unproductive of the result sought by the applicant," *Baxter International*, at 1328, or if it discourages or leads in a direction different from the path taken by the applicant. *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 885 (Fed. Cir. 1998). The prior art reference is evaluated for similarities with and differences from the claimed invention, and reviewed for any portions which teach away from the invention. *Halliburton Co.*, at 1441; *W.L. Gore & Assocs., Inc., v. Garlock, Inc.*, 721 F.2d 1540, 1550 (Fed. Cir. 1983); *See also, In re Dow Chemical Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988).

Materiality of the Blum Patent in Light of the *Laser Focus* Article

On reexamination, the Examiner relied on the Blum patent in combination with *Beckman* to reject claims of the '388 patent. The Examiner's partial reliance on *Blum* has "strong probative value" in determining its materiality. *Molins PLC*, at 1179. It should here be emphasized, however, that nothing in this decision addresses the Examiner's determination to reject the '388 claims based upon the combination of references he considered. Indeed, none of the reference combinations before the Examiner for reexamination are at issue here. *Beckman* is not a reference Respondent is alleged to have withheld.

In this proceeding, Respondent disputes the materiality of the Blum patent only to the extent it believes *Blum* is cumulative of the May, 1983, *Laser Focus* article, entitled *Far-UV Photoetching of Organic Material*. Colaianni explained that the issue of whether the Blum patent is cumulative of *Laser Focus* must be made "vis-a-vis the claims" of the '388 patent. The *Laser Focus* article (RX 513) was considered by the Examiner during the prosecution of the '388 Patent.

The record evidence, including Dr. Thompson's report and testimony in particular, demonstrates that *Laser Focus* discloses the same claim elements of the '388 Patent disclosed by the Blum patent. Like the '388 patent, *Blum* discloses ablative photochemical decomposition, the generation of a far ultraviolet laser beam at 193 nm, and its use on biological tissue without thermal damage. The *Laser Focus* article, however, also discloses generating a laser beam at 193nm to produce ablative photochemical decomposition creating a surgical excision of controlled depth and shape without thermal damage, and both *Laser Focus* and *Blum* disclose the use of a far ultraviolet laser as a tool to etch all biological tissue. Neither the Blum patent nor *Laser Focus* specifically mentions ablating corneal tissue. Corneal tissue is, of course, a type of biological tissue, and the implications of this will be considered later when the obviousness of the '388 patent is discussed.

Dr. Thompson identified column 2, lines 24-26, and column 7, beginning at line 9 of the Blum patent, as the passages which teach volumetric removal of tissue. He explained that the

passage in column 2 teaches volumetric removal because "control or volumetric removal are really the same things," and providing "effective photo etching of the surface of biological material in a controlled manner" is one of the patent's objectives. Dr. Thompson further explained that the "absorption of a very large proportion (95 percent) of the photons in a very -- in a thin (less than 2700 angstroms) layer of organic material" is how *Blum* achieves volumetric, controlled removal. Yet, the *Laser Focus* article also discloses 95% absorption in a thin, less than 300nm, layer of material. Thus, these data are nearly identical. While this suggests a linear ablation effect, *Laser Focus* also discloses the removal of hair tissue at a rate of 400nm/pulse, and Drs. Trokel, Keates, and Motamedi agreed that this teaches a linear rate of ablation.

The *Blum* scientists tested the excimer laser beam's effect on hair and bird tissue. Dr. Motamedi testified that *Laser Focus* discloses that the ablation rate is constant in hair, and hair is a non-homogenous material with multi-layer structure and variable presence of keratin and epidermal cells. While Dr. Motamedi is not a chemist, neither is Dr. Thompson; consequently, their differences on this issue cannot be resolved on the basis of expertise. Nevertheless, regardless of which witness is correct in his assessment of the non-homogeneity of hair, the record shows that the *Laser Focus* disclosure regarding non-homogeneities in hair is based on the same experiment disclosed in the Blum patent. Similarly, the *Laser Focus* article and *Blum* both disclose creating a surgical channel of controlled width and to a depth of 150 micrometers. While the *Laser Focus* disclosure, at Figure 1, is an experiment on bird muscle tissue, and the Blum patent refers to an experiment performed on bird cartilage, these avian studies both compared the results of the excimer laser with frequency-doubled, pulsed nd:YAG lasers; and the record shows that the experiments are essentially the same.

Now, *Blum* teaches that non-homogeneities in tissue do not affect ablation rate. Yet, it does not specifically address the ablation rate or the homogeneity of corneal tissue. When non-homogenous corneal tissue is ablated, however, the ablation rate may vary notwithstanding the teaching in *Blum*. The record shows, for example, that scar tissue ablates at a rate different from clear tissue. Similarly, "if you have an etching tool that is highly sensitive to variations in homogeneity or, say, water content, you may not have a very good etching tool." (Tr. 2234). While tissue homogeneity technically may not include concerns about its moisture content, the hydration levels of corneal tissue cause the ablation rate to vary considerably, and this effect is not noted in either *Blum* or *Laser Focus*. Finally, *Blum* and *Laser Focus* both disclose that ablative photo-decomposition occurs at radiation wavelengths less than 200 nanometers, and both reveal that minimizing beam transmission through oxygen, using nitrogen flushing or a vacuum, is a preferred, not a required design.

Consequently, with respect to the disclosures involving the homogeneity of tissue, linearity of ablation, volumetric removal of tissue, oxygen purging, and others noted above, the record shows that the Blum patent is no more pertinent than the *Laser Focus* article to the claims of the '388 Patent. Accordingly, this record demonstrates that *Blum* is cumulative of *Laser Focus*.

Materiality of the *Karp* Reference

Karp discloses the use of a laser to perform RK and volumetric removal of corneal tissue. The *Karp* reference does not disclose what type of laser to use, nor does it disclose what type of microprocessor to use in conjunction with the laser. Dr. Sher testified, without contradiction, that *Karp* misapprehends how to perform RK, because RK requires relaxing cuts, and *Karp* discloses scarring which may contract the cornea.

During the '026 interference, VISX described *Karp* was "highly relevant" to RK claims and "more material than any reference previously known" to Examiner Shay. (See CX 109 and 143). Dr. Munnerlyn testified that *Karp* disclosed movement of the laser beam, which he interpreted as scanning to make the incisions, and the previously pending L'Esperance claims concerned RK with a scanning laser. The '388 patent does not disclose scanning, and VISX specifically noted, during the interference, that it was not claiming that the *Karp* reference was pertinent to any of L'Esperance's sculpting claims. This is consistent with Dr. Thompson's testimony. Of the four prior art references cited in the complaint, Dr. Thompson considered *Karp* the least pertinent to the '388 patent.

The *Karp* Reference in Light of the Baron Patent

The Examiner understood *Karp* to teach "the use of a microprocessor controlled laser scalpel which is used to perform keratotomies using arced or diametrical cuts." (RX 1536,Tab 48,at 2-3; *See,* CC Proposed Rebuttal Finding 80(c)). The Baron patent (RX 1010) which was cited to the Examiner during the prosecution of the '388 patent discloses RK incisions. To be sure, *Baron* and *Karp* are different in several respects. *Baron,* for example, discloses removal of the epithelium from the cornea, the application of a light-absorbing dye to the surface of the cornea, and the generation of scars on the corneal surface through use of an argon laser beam to vaporize corneal tissue containing the dye. *Karp* does not require removal of the epithelium and does not disclose the use of dye as a mediator of the interaction of the laser and the corneal tissue.

In the Baron patent, the diffusion of the dye into the cornea must be carefully controlled to achieve a reproducible result. If diffusion of the dye is not controlled, a laser incision of controlled depth or shape in the cornea will not occur. Both *Karp* and *Baron,* however, disclose creating a surgical excision of controlled depth and shape with a laser.

Dr. Motamedi testified that, like *Karp,* the Baron patent teaches that laser energy is applied to form scar tissue, and he reasoned that the *Karp* laser must have been a thermal laser.

Moreover, *Karp* discusses using a laser in the RK procedure of Fyodorov, which, the record shows, necessarily results in depth penetration into the stroma. Although the use of the dye as specified in *Baron* made it unclear whether changes in corneal shape were caused by an incision or some other mechanism, and, as such, initially cast doubt about whether *Karp* was cumulative of *Baron,* after reviewing the language of the Baron patent, Dr. Thompson did opine that *Baron* discloses making computer-controlled RK incisions.

Thus, the Baron patent, like the *Karp* reference, discloses a laser controlled by a computer to make incisions on the cornea; and while the Baron patent introduces other variables, such as the use of the riboflavin dye, both *Karp* and *Baron* disclose applying laser radiation to corneal tissue creating a surgical excision of controlled depth and shape with depth penetration into the stromal tissue. Neither reference, however, discloses ablating corneal tissue without thermal damage or volumetric removal of corneal tissue without thermal heating. As previously noted, Dr. Thompson described *Karp* as the least material of the four references involved in this proceeding. The record confirms his assessment. *Karp's* materiality is marginal, at best, if not cumulative in light of *Baron.*

Materiality of the *Keates* Article

Keates discloses applying C02 laser light to corneal tissue, directing the laser radiation in a controlled manner at the cornea, creating a surgical excision of controlled depth and shape, with depth penetration into the stroma, volumetric removal of corneal tissue, and operating on the anterior surface of the eye to change its optical properties. Like the Blum patent, *Keates* was a reference the Examiner relied upon on reexamination in combination with *Beckman* to reject the '388 claims. Again, the Examiner's partial reliance on *Keates* has "strong probative value" in determining its materiality. *Molins*, at 1179. Also probative, however, in assessing materiality is Dr. Keates' testimony which indicates that portions of his article teach away from the claimed invention. Indeed, Dr. Keates did not cite his article as prior art in his application seeking a patent for the use of the excimer laser to perform surgery on the cornea. He testified that he did not consider the carbon dioxide laser prior art relevant to his invention.

In *Gambro Lundia AB* v. *Baxter Healthcare Corp.*, 110 F.3d 1573 (Fed. Cir. 1997), the Federal Circuit rejected a determination by a District Court which was inconsistent with the testimony of the author of an article which indicated that his work taught away from the invention. *Id.* at 1579. Consequently, both the author's comments and the Examiner's reliance on *Keates* are probative of the reference's materiality, but each sheds a different perspective on the similarities and differences and portions of *Keates* which teach away from the claimed invention. *Halliburton*, at 1441.

The '388 patent discloses the ablation of corneal tissue without thermal damage. The *Keates* article does not disclose this element, and Dr. Keates testified that he was not, in his article, "suggesting that you want to avoid the shrinkage and the charring caused by the CO-2

laser." Tr. 604. The '388 patent discloses directing the far ultraviolet radiation in a controlled manner onto corneal tissue to induce ablative photochemical decomposition of the corneal tissue. The *Keates* article, in contrast, does not discuss the use of far-ultraviolet radiation or the volumetric removal of corneal tissue without thermal heating. Rather, it indicates that the carbon dioxide laser causes charring, vaporization, and damage; and although Complaint Counsel argue to the contrary, it describes the carbon dioxide laser as an ideal knife, and as a safe and useful tool for laser surgery. The actual language of the article's summary reads:

> The controllable penetration width and depth of the C02 laser incisions seem to make the laser an ideal "knife" for such corneal modifications as radial keratotomy and epikeratophakia. Our results indicate that the C02 laser, when successfully integrated with the standard slit lamp, may be a safe and useful tool in laser surgery of the cornea. CX 30 at 117.

Thus, Dr. Keates testified that he was advocating the use of the carbon dioxide laser as a corneal surgical tool based on the results reported in his article. He testified that he suggested, in his article, minimizing, not avoiding, the shrinkage and the charring caused by the C02 laser. In *Keates*, thermal damage is acceptable if controlled. This teaches away from the claims of the '388 patent.

Further, the record shows that the Background of the Invention Section of the L'Esperance '913 patent, which was before the Examiner and the Examiner-in Chief, discloses every element of the independent claims of the '388 Patent disclosed by the *Keates* article. After the merger of VISX California and Taunton, VISX, Inc. resolved the 102,026 Interference by awarding priority of invention to Dr. Trokel over L'Esperance '913. Because priority of invention was awarded to Dr. Trokel over Dr. L'Esperance's '913 patent, Complaint Counsel argue that the '913 patent technically cannot be prior art pursuant to 35 U.S.C. 102(e). In *In Re Yale*, 347 F.2d 995, 1000 (C.C.P.A., 1965), the court emphasized that disclosures corresponding to the interference counts "are not references under 35 U.S.C. 102(e), [but] .... Under proper circumstances, a concession of priority or disclaimer of interference counts renders those counts available with the same effect as a prior art reference disclosing such subject matter." Respondent relies upon the disclosures in the Background Section of the '913 patent to demonstrate the cumulative nature of *Keates*.

It is undisputed that the Examiner cited the '913 patent during the prosecution of the '388 patent, and listed it on the front of the '388 patent. Accordingly, information before the Examiner during the prosecution of the '388 patent disclosed the application of laser radiation to perform radial keratotomies on corneal tissue and surgical excisions of controlled depth and shape with depth penetration into the stroma. Moreover, the L'Esperance '913 Background disclosed the controlled use of precisely the same 10.6 micron wavelength infrared radiation disclosed by *Keates*.

Now I should reemphasize that my conclusions here neither address nor comment upon the merits of the Examiner's determination on reexamination to reject the claims of the '388 patent based on the combination of references he considered. I conclude only that, on this record, considering the author's assessment of the materiality of his CO2 laser work to excimer laser methods, and portions of the *Keates* article which teach away from the claimed invention, *Keates*, like *Karp,* is not highly material, even if it were deemed not cumulative of information disclosed to the PTO in the Background of the '913 patent.

Materiality of the *Girard* Reference

Girard discloses changing the optical properties of an eye by operating solely on the anterior surface of the cornea. It discusses various types of surgical procedures. Some, like Dr. Barraquer's keratomileusis, involve refractive surgery; and others are therapeutic, such as superficial keratectomy, which employs a diamond dental burr to smooth the corneal surface in the treatment of pterygium, a disease in which growths occur on the cornea. *Girard* notes that the depth of such superficial keratectomy can be controlled by adjusting the motor speed of the drill and the pressure on the cornea, as well as by careful observation. Pterygium and other conditions of the cornea can cause superficial opacities or irregularities that interfere with vision. The purpose of remedying these conditions is to change the optical properties of the eye. Treatment of these conditions via superficial keratectomy generally involves depth penetration into the stroma.

The general technical subject matter of the '388 Patent is directed to the use of the excimer laser as a tool to perform medical procedures on the cornea. Dr. Trokel, using the excimer laser, invented a new way to perform surgical techniques discussed in *Girard,* but Complaint Counsel do not argue that *Girard* is material on the basis of its reference to lasers. *Girard* is allegedly material because it discloses mechanical techniques of corneal surgery, and perhaps combinations of techniques which can be performed in a new way with the excimer laser. It may be recalled that Dr. L'Esperance advanced a similar argument to the Examiner-in-Chief during the interference in his Motion to Designate. (*See*, discussion at pg. 114, *supra*). Moreover, at various times, the *ex parte* Examiner opined that *Girard* teaches reshaping the cornea through the volumetric removal of corneal tissue to create an excision of controlled depth and shape, with depth penetration into the stroma. Yet, upon consideration of the *Girard* reference and the independent claims of the '388 patent, Dr. Motamedi explained that *Girard* discloses no elements of the '388 patent unless claim language, which discloses the excimer laser and its effects, is stricken.

Obviousness

Surgeons are motivated to search for better tools to perform their operations. The excimer laser is a surgical tool for refractive surgery. It provided an answer for taking off large

amounts of tissue in a very controlled fashion without producing thermal damage. Prior to 1983, no one had suggested in the literature that the excimer laser could be used to surgically remove corneal tissue without causing thermal damage to the surrounding tissue. In that year, Dr. Trokel, in his December, 1983, American Journal of Ophthalmology article, *Excimer Laser Surgery of the Cornea*, was the first to publish the suggestion to use an excimer laser for refractive procedures.

The Artisan of Ordinary Skill

In 1983, ophthalmic surgeons were experimenting with RK, and a few were performing keratomileusis as developed and taught by Dr. Barraquer. Various therapeutic procedures required volumetric removal of corneal tissue; and ophthalmic surgeons were, in 1983, testing various lasers, including the carbon dioxide laser and the neodymium YAG laser, to determine if they were appropriate for various types of corneal surgery. The record shows that, in 1983, the level of ordinary skill in the field of the invention was represented by a general ophthalmologist who performed corneal surgery, had an interest in refractive surgery, and had knowledge of radial keratotomy, anterior and posterior keratomileusis, superficial keratectomy, and epikeratophalia.

Refractive Surgery in 1983
Radial Keratotomy

RK was not commonly practiced in the United States until the late 1980's. Initially, ophthalmologists believed the excimer laser could be used to perform RK because of its general ability to etch tissue in a very precise manner. Although the Examiner-in-Chief initial thought that claims 4 and 5 of the '388 patent were broad enough to read on making "incisions" with a laser, this record reveals a fundamental difference in the interaction between a laser and tissue, and the action of a knife used in RK to cut and separate tissue. The *Keates* article demonstrated that the CO2 laser is inappropriate for RK, because it could not make a sufficiently thin cut. The width of its ablation weakened the cornea. Indeed, this record contains no evidence of any ophthalmologist who, today, performs RK with any type of laser, including the excimer laser.

Manipulation of Bowman's Layer

The record establishes that the '388 patent contemplates elective refractive procedures. In 1983, removal of Bowman's layer was thought to be incompatible with maintaining 20/20 vision. Surgeons were taught that Bowman's membrane, below the epithelium, should not be disturbed or removed except to treat scars, injuries, or infections, because injury to Bowman's layer could produce permanent corneal opacification, loss of transparency, and irregular astigmatism. Conventional wisdom held that removal of Bowman's layer could result in irreparable scarring.

Concern about removing Bowman's layer really diminished any motivation to combine anterior keratectomy (a therapeutic procedure) with keratomileusis (a refractive procedure). The

problem posed by Bowman's layer contributed to the skepticism Dr. Trokel encountered from his colleagues about using the excimer laser on the central optically active area of the cornea to steepen or flatten it, particularly for the purpose of myopia and hyperopia correction. Indeed, as late as 1988, Dr. Thompson believed that removal of Bowman's layer with an excimer posed "very significant" and "fundamental" risks of corneal scarring and dense corneal opacification. In 1983, it was regarded as anathema and considered repugnant surgical practice to interfere with Bowman's layer in healthy corneas, and Dr. Schallhorn confirmed the even today there is concern among surgeons about disturbing Bowman's membrane.

Girard's Discussion of Keratomileusis

As previously described, Dr. Barraquer's keratomileusis procedure, as described in *Girard,* involves slicing a button of the cornea off the front surface of the eye, freezing the button under carbon dioxide, putting it in a lathe and milling it to precise thicknesses, defrosting it, and sewing it back on the eye. The process kills the tissue, and viable keratocyte cells are no longer present. It takes months to restore any living function in the tissue.

Keratomileusis was never commonly practiced in the United States. In 1983, a few surgeons performed this procedure, but ophthalmologists never adopted it as a standard procedure for treating refractive disorders of the eye. It yielded mixed results, was extremely difficult to perform, very risky, and required months of recovery time. Sutures remained in place for four to six months. While the doctors who studied and were interested in Dr. Barraquer's refractive surgery techniques sought ways to improve his work, keratomileusis in the early 1980's was considered a "dangerous curiosity."

Girard's Discussion of Superficial Keratectomy

Superficial keratectomy is carried out to treat disease of the cornea such as scars, foreign bodies, or infection. While superficial keratectomy can change the optical properties of the eye, it is performed for the purpose of treating therapeutic disorders of the eye. Superficial keratectomy is not meant for refractive purposes, and the *Girard* reference categorizes it as a therapeutic procedure.

Anterior grinding

Dr. Barraquer and others investigated anterior surface grinding of the cornea and abandoned it because the surface it produced was too rough, resulting in corneal clouding and scarring.

Trokel's New Method

Using an excimer laser, Dr. Trokel suggested a new methodology to perform surgical procedures on the cornea. The record shows that his work is recognized among his peers as one of the 15 most significant achievements in ophthalmology in the last century and one of the 3 most important achievements in refractive surgery. Dr. Trokel's American Journal of Ophthalmology article has been cited 242 times through 1997, while the *Keates* article, for example, was cited 16 times, and even Dr. Thompson has acknowledged the *Trokel* article as the first to suggest that the excimer laser can be used to perform refractive surgery.

To be sure, the IBM patent discloses ablative photochemical decomposition, volumetric removal, thin layer by thin layer, of biological tissue like cartilage with compositions similar to the cornea. It described photo etching the surface of biological material in a controlled manner, the use of ultraviolet light at 193 nm, the absence of thermal damage, and it applies generally to biological tissue. (CX 184). Yet, the clean cutting lines in aortic tissue, for example, demonstrated at IBM did not suggest the same effect on the cornea. Many lasers cleanly cut aortic tissue but fail to cut corneal tissue cleanly. The cornea is singular in its structure and transparency, consisting, as Dr. Schallhorn testified, largely of a protein collagen. It is, according to Dr. Trokel's unrefuted testimony, unique in its "highly organized macro-molecular structure" which permits the transmission of light. Unlike tissue in blood vessels, it does not "take much to cause this macro-molecular structure to become disorganized." With the excimer, there is no collateral thermal damage and no collagen delamination.

The use of the excimer laser to cut corneal tissue required a new understanding of the cutting process. I am mindful that Dr. Keates testified that he thought the excimer was "obvious to try" in light of his CO2 article, but he further testified that, prior to the excimer, all laser surgical cutting was below 5ev. Once that threshold energy level was achieved with the excimer laser operating at 193nm, the cutting process itself changed. It is highly probative that Dr. Keates himself believed the excimer laser beam's photochemical reaction in tissue "required a new understanding of the cutting process to be able to invent this new teaching." Thus, Dr. Keates' testimony is entirely consistent with objective manifestations which indicate that Dr. Trokel's work was new and inventive.

Combining Prior Art

Now, prior art must be considered as a whole to determine whether there is a suggestion for a combination which renders the invention obvious, *See, Panduit* v. *Dennison Mfg. Co.*, 810 F.2d 1561, 1567-1568 (Fed. Cir. 1987), *cert. denied.* 481 U.S. 1052 (1987); but Complaint Counsel correctly contend that it is not fatal to their case if no suggestion to combine is specifically found in the prior art. *In Re Oetiker*, 977 F.3d 1443, 1448 (Fed. Cir. 1992); *In Re Napier*, 55 F. 2d 610,613 (Fed. Cir. 1995). Thus, Complaint Counsel propose a variety of permutations and combinations of the four prior art references as paths which allegedly render Trokel '388 obvious. The Federal Circuit has observed, however, that "the suggestion

to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness." *In Re Rouffet*, 149 F.3d 1350, 1358 (Fed. Cir. 1998). Consequently, the presence or absence of a suggestion to combine is probative in an obviousness determination. *Litton Systems*, at 1569, *vacated on other grounds*, 50 U.S. 1111 (1997).

While Complaint Counsel have failed to demonstrate any suggestion to combine in the prior art, the motivation to combine can, of course, emanate more generally from the nature of the problem or knowledge of those skilled in the art. *Pro-Mold and Tool Co.* v. *Great Lakes Plastics, Inc.*, 75 F.3d 1568 (Fed. Cir. 1996). The record, however, does not support the contention that the '388 invention was obvious because surgeons desired better tools and were, in 1983, generally experimenting with lasers. Obvious to try is not synonymous with obviousness. *In Re O'Farrell*, 853 F.2d 894, 902 (Fed. Cir. 1988).

Complaint Counsel contend that *Keates* is an example of a physician motivated to take Dr. Barraquer's techniques and explore them by using a different surgical tool, the carbon dioxide laser. But *Keates* disclosed no improvement on Barraquer's techniques. The CO2 laser never successfully made cuts on the cornea useful for refractive purposes, never successfully substituted for a dental burr or grinding lathe in corneal surgery, and was never used clinically for refractive surgery. The failure of the CO2 laser experiment was a learning experience, but it did not render the use of the excimer laser obvious. To the contrary, Dr. Keates believed he could minimize thermal damage to acceptable levels using a CO2 laser, and accordingly, he advocated the use of the CO2 laser in his article, not an alternative laser. Similarly, *Karp*, using what in all likelihood was a thermal laser, misapprehended how RK is performed. In these respects, both *Keates* and *Karp* teach away from the claimed invention.

In his expert report, Dr. Thompson wrote that "it would have been obvious in 1983 to one skilled in the art of refractive surgery to combine *Girard*'s observation of corneal clarity following superficial keratectomy through Bowman's layer with Barraquer's demonstration of correcting ametropia by keratomileusis to deduce that optical reprofiling of the anterior cornea through Bowman's layer could be done, provided that an instrument was available (or a surgeon skilled enough) to achieve a sufficiently smooth surface." Tr. 2100-2101. Considering the record as a whole, I find this testimony unpersuasive. In the hands of the most experienced surgeons, keratomileusis was an extremely risky, cumbersome refractive procedure. To combine it with what may have been an even riskier therapeutic procedure, which involved removal of Bowman's layer to achieve a non-therapeutic result, would not likely have been obvious to an ophthalmologist skilled in the art in 1983. Nor would adding the thermal damage of a CO2 laser disclosed by *Keates* render the combination of superficial keratectomy and keratomileusis any more viable.

Considering the prior art references at issue here, alone and in combination as a whole, there is no suggestion for the combinations Complaint Counsel propose. *Panduit v. Dennison Mfg. Co.*, 810 F.2d 1561, 1567-68 (Fed. Cir. 1987), *cert. denied*, 481 U.S. 1052 (1987); *Cable Elec. Prods., Inc. v. Genmark, Inc.*, 770 F.2d 1015, 1025 (Fed. Cir. 1985). But even eschewing

the absence of a suggestion to combine these references, for the reasons set forth above, *Blum* and *Keates* do not, render claim 1 obvious; *Blum, Keates,* and *Karp* do not render claim 3 obvious; and *Karp, Keates, Girard*, and *Blum* do not render any of the claims obvious. Furthermore, in the absence of a suggestion in the prior art to combine these references, what remains is a record which shows that, while surgeons generally seek to improve their instruments, the teachings of *Karp, Keates*, and *Girard* are marginally material, while *Blum* is cumulative. Together they provide, to the extent they relate to the claims of the'388 patent, the same information as the combination of *Laser Focus, Baron,* and the Background Section of the L'Esperance '913 patent, all of which were before the Examiner.

Secondary Considerations

In assessing obviousness, hindsight reconstruction is always a risk. Thus, the Court has developed certain objective criteria which indicate whether or not an invention would have been obvious. Objective evidence of non-obviousness includes: (a) evidence that there was a long-felt need for the invention, *Micro Chemical, Inc., v. Great Plains Chemical Co.*, 103 F.3d 1538 (Fed. Cir. 1997) at 1547; *Hodosh v. Block Drug Co.*, 786 F.2d 1136, 1144 (Fed. Cir. 1986); (b) evidence that others tried, but failed, to fill that long-felt need before the invention was made, *In re Rouffet,* 149 F.3d at 1355; (c) evidence that after the invention was made, it was greeted with skepticism by others in the field, *Environmental Designs v. Union Oil Co.*, 713 F.2d 693, 697-98 (Fed. Cir. 1983); *see also In re Dow Chemical Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988); (d) evidence that the invention became a commercial success. *Litton Systems*, at 1570, *vacated on other grounds, 520 U.S.,1111 (1997)*; and (e) simultaneous invention, *E.I. du Pont de Nemours & Co. v. Berkley & Co.*, 620 F.2d 1247, 1265 (8th Cir. 1980).

In the early 1980's, the ophthalmology establishment viewed refractive surgery with a great deal of skepticism. The concept of operating on a normal cornea to correct refractive errors was not welcomed by ophthalmic surgeons. Ophthalmologists generally were unreceptive to Dr. Trokel's invention and thought it would never be widely accepted. The head of Columbia University's ophthalmology department, for example, scoffed at the idea and thought it would never be a successful surgical procedure. Operating on the central area of the cornea, particularly for elective purposes, posed serious risks of side effects such as scarring and opacification. Dr. Thompson wrote in 1988 that operating on the visual axis of the cornea poses "very significant risks" (RX-1480); and Dr. Schallhorn confirmed that during the 1980's there was "a lot of concern" about operating on the optically active central portion of the cornea. While Complaint Counsel contend, in numerous proposed findings, that the '388 patent does not contemplate vision correction or avoidance of scarring or opacification, their contention is not supported by the record. Dr. Thompson testified that the '388 patent specification discloses the "refractive procedure" of removing tissue to steepen or flatten the cornea which treats myopia and hyperopia, and '388 patent specification states that the excimer laser can "selectively shape the cornea surface [which] allows modification of the refractive status of the eye."

As of 1983, there had been a long-felt need for a surgical method to permanently correct refractive errors. Other refractive surgerical methods at the time were clinically unsuccessful. The excimer laser had been available since the 1970's; however, Dr. Trokel was the first to use it on the cornea. As of October, 1990, it was still undergoing FDA clinical trials, but once it received clinical approval from the FDA, it gained acceptance among refractive surgeons and their patients. And Dr. Trokel's professional peers afforded him considerable recognition for his accomplishment.

The '388 Patent was not Obvious

The availability of the excimer laser did not render the invention of the '388 patent obvious. While the excimer held promise as a potentially new surgical tool, its use required a new understanding of the cutting process. Complaint Counsel note that the excimer laser ablates all organic tissue, including corneal tissue, so its effect on the cornea arguably was nothing new. Yet, the record does not support the notion that it was simply a matter of picking up an excimer laser and using it like a knife or a burr, or, for that matter, any other laser previously used for ophthalmological purposes. The cornea is unique in its function and structure. The techniques and methods employed to avoid or minimize scarring and opacification, and achieve a desired result using a scalpel, burr, or thermal laser were not necessarily applicable to the use of this new tool. The excimer laser may have answered the thermal damage problem, but each photon of its light had energy in excess of 5ev, and new reactions took place when its photons were absorbed by protein molecules. These new reactions required a new understanding of the surgical cutting process. Considering the prior art involved in this proceeding, only with the experience of hindsight does this invention appear so obvious.

In summary, the record contains ample objective evidence of non-obviousness, including recognition of the importance of the invention, evidence of commercial success, and evidence of failure by others to solve the problem. This objective evidence, combined with the lack of a teaching to combine, requires a holding of non-obviousness, *Gambro Lundia AB*, at 1580; *Litton Systems*, at 1570, notwithstanding the fact that Dr. Trokel's application was involved in an interference with L'Esperance '913. *DuPont*, at 1265. Consequently, the record neither demonstrates the withholding of *Karp, Keates, Girard*, and *Blum*, nor does it support the contention that the '388 patent is obvious and would not have issued in light of these references.

Inequitable Conduct

To establish inequitable conduct, clear and convincing evidence must demonstrate both the materiality of the reference, *Scripps Clinic*, at 1573, 1582; *Micro Chemical, Inc., v. Great Plains Chemical Co.*, 103 F.3d 1538, 1549 (Fed. Cir.) *cert. denied*, 117 S. Ct. 2516 (1997); *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 547 (Fed. Cir. 1998); (Fed. Cir. 1988), and a deceptive intent in withholding the reference. *Akron Polymer*, at 1383; *Baxter international*, at 1327-1328; *Micro Chemical*, 103 F.3d at 1549; *Kingsdown, at* 872. If both materiality and intent are established, it is then necessary in an inequitable conduct case, unlike a *Walker Process* fraud

situation, to balance the deceitful intent and the degree of materiality. *See, Nobelpharma AB*, at 1011. The more material the reference, the less the showing of deceitful intent required to demonstrate inequitable conduct. *N.V. Akzo v. E.I. DuPont De Nemours*, 820 F.2d 1148, 1153 (Fed. Cir. 1987); *Halliburton Co.*, at 1439. Thus, "mere showing that a reference having some degree of materiality was not disclosed does not establish inequitable conduct." *FMC Corp.* At 1411; *Halliburton Co.*, at 1442. Consequently, should the Commission conclude that *Blum, Keates, Karp*, and *Girard* were not adequately disclosed, it will be necessary to balance the materiality of the references against the degree of intent manifest by the inadequacy of VISX's disclosures.

Intent

The element of intent is a subjective consideration. In most instances, it must be inferred. *Molins, PLC* at 1181. Direct proof is rarely available, and the Court does not require "smoking gun evidence of intent." *Grain Processing Corp.*, v. *American Maize-Products Co.*, 840 F.2d 902 (Fed. Cir.1988); *Baxter International*, at 1329. The conduct in question must be viewed in light of all the evidence, including evidence indicative of good faith, and must indicate sufficient culpability to "require a finding of intent to deceive." *Molins PLC*, at 1181; *Baxter International*, at 1330. The trier of fact must determine whether the conduct in its "totality" manifests a sufficiently culpable state of mind to warrant a determination that it was inequitable. *Id.* at 1181; *Baxter International*, at 1327. As the Court observed in *Scripps Clinic*, "Conduct that requires forfeiture of all patent rights must be deliberate, and proved by clear and convincing evidence." *Scripps Clinic* at 1574; *See also, Molins PLC*, at 1181, 1184.

Complaint Counsel note that VISX did not file an IDS with the Examiner or expressly disclose material prior art when the prosecution of the '338 patent resumed following the interference. Complaint Counsel believe VISX had ample motive to withhold the prior art, and contend, for example, that Dr. Trokel thought *Keates* anticipated his claims, that Gholz and Dr. Munnerlyn believed that *Blum* rendered Trokel '388 unpatentable, and that VISX considered *Karp* highly material to claims in the '388. Complaint Counsel question the credibility of their testimony denying any intent to withhold information or deceive the PTO.

The Federal Circuit considers inequitable conduct determinations as matters "within the discretion of the trial court," and it reviews the trier of fact's findings under "an abuse of discretion standard." *Baxter International*, at 1327; *Litton Systems*, at 1570, *vacated on other grounds*, 520 U.S. 1111 (1997). Although the Commission reviews the matters before it, *de novo*, having observed the appearance and demeanor of Dr. Trokel in testimony at the hearing, I found his testimony credible. Dr. Trokel had, at one time, received a legal explanation of the technical meaning in patent practice of the term "anticipate," but he credibly testified that he was not attempting to use the term in its technical sense in connection with his comments regarding the *Keates* article. Indeed, Complaint Counsel's witness, Dr. Thompson, also experienced some difficulty, in general, with the use of the term "anticipate" in its patent context, but all parties

now agree that *Keates* does not anticipate the claims of the '388 patent. Similarly, Dr. Munnerlyn was also a credible witness. He acknowledged that he was initially concerned that *Blum* might mention corneal tissue, but after the Blum patent issued, and he had a chance to review it and determine that it did not mention the cornea, his concern shifted to the need to obtain a license to the '135 patent from IBM. In these and other respects, Drs. Trokel and Munnerlyn were credible witnesses.

Complaint Counsel also challenge Gholz's credibility. With respect to *Karp*, Gholz testified that he considered *Karp* material to claims in the '913 patent which were not involved in the '026 interference, and his testimony is confirmed by the motion papers filed with Examiner-in-Chief Boler in which Gholz expressed the same contention. I found less credible Gholz's testimony that he merely forgot to file an IDS upon resumption of the prosecution. The Court has held that negligence, or even gross negligence, will not support a finding of intent to deceive. *See, Molins PLC*, at 1181; *Baxter International*, at 1382; *Grain Processing*, at 907. Consequently, a finding of negligence has actually evolved as a type of defense in fraud and inequitable conduct cases. Under such circumstances, an attorney's *mea culpa* requires careful scrutiny.

Having observed his appearance and demeanor at the hearing, I found that Gholz is precise in his use of language, meticulous in his demeanor, and highly skillful and nuanced in the presentation of his testimony. (*See, eg.* Tr. 4465-4466.) There is nothing haphazard about him. While all things are possible, I am not persuaded, in this instance, that he forgot to file an IDS in his client's interest, or that it never occurred to him to file during the entire course of the prosecution. But neither am I persuaded that he intended to deceive the PTO. PTO rules did not specifically require him to file an IDS. Obviously, had he invested the extra effort, it would have been helpful to the Examiner and, as events have unfolded, to his client as well, but his failure to file an IDS does not establish an intent to mislead or deceive. Considering the totality of his dealings with the PTO on VISX's behalf, the record, on balance, establishes no lack of good faith by Gholz in filings with the Examiner-in-Chief during the interference, *See, Gambro Lundia AB* v. *Baxter Healthcare Corp.*, 110 F.3d 1573, 1581 (Fed. Cir. 1997), and no duty to file an IDS thereafter.

Complaint Counsel have thus tested the credibility of these witnesses as a factor probative of their alleged intent to deceive the PTO. Yet, the witnesses, having survived the challenge, are still not exonerated. The fact remains their mere denials alone are insufficient to refute evidence of motivation when inequitable conduct is alleged. *Labounty Mfg., Inc. v. U.S. Intern. Trade Com'n*, 958 F2d 1066, 1076 (Fed Cir. 1992).

Thus discounting their denials, the evidence in this record demonstrates overwhelmingly that neither Dr. Trokel, nor Dr. Munnerlyn, nor anyone acting on VISX's behalf intended to mislead or deceive the PTO. To the contrary, the record shows that no clear duty to re-cite prior art disclosed during an interference was imposed by the PTO upon an applicant. To be sure, the MPEP contained recommendations to that effect and suggested that it would be advisable; but

the absence of a clear mandate to re-cite the references, if not entirely exculpatory, is at least a probative consideration. *Baxter International*, at 1329-30. The alleged conduct must not amount " merely to the improper performance of, or omission of, an act one ought to have performed. Rather, clear and convincing must prove that an applicant had the specific intent to accomplish an act that the applicant ought not to have performed, viz., misleading and deceiving the PTO." *Molins PLC,* at 1181, 1184. Under such circumstances, the absence of a clear duty constitutes a substantial factor weighing against a finding of inequitable conduct or fraud.

Complaint Counsel also note that the '388 patent is an improvement of the Blum patent, and, thus, cite as pertinent the observation of the district court in *Arcade, Inc.* v. *Minnesota Mining and Manufacturing Co.*, 24 U.S.P.Q 2d 1578, 1589 (E.D. Tenn. 1991): "[I]t seems obvious to this Court that one claiming an improvement over a particular product would cite such prior art to the PTO in an attempt to distinguish it." In *Arcade,* the undisclosed prior art was Arcade's "scratch 'n sniff" C1S paper samplers used by advertisers to provide a whiff of perfume fragrance, for example, to consumers. 3M not only withheld the existence of C1S samplers from the PTO for years, but subsequently misrepresented the nature of Arcade's product to the PTO. *Id.* at 1589. Thus, 3M's conduct in *Arcade* is distinguishable from VISX's conduct here.

The *Arcade* court first differentiated the culpability of a 3M employee who knew about the prior art and failed to disclose it, finding him "grossly negligent," while finding an attorney who not only withheld the prior art, but affirmatively misrepresented its "nature" guilty of culpable intent to deceive the PTO. Consequently, in *Arcade*, the failure to disclose the prior art product over which the improvement was claimed, alone, constituted gross negligence, and only when coupled with misrepresentation of the prior art, did the court find culpable intent to deceive. In this instance, in contrast, it is not alleged, and the record would not support a charge, that VISX misrepresented the prior art. Under *Arcade*, nondisclosure, alone, amounted only to gross negligence, a ground clearly insufficient to support a finding of inequitable conduct. *Kingsdown*, at 876.

Arcade is also distinguishable in another important respect. There was no contention by the parties or discussion by the *Arcade* court suggesting that the C1S sampler was cumulative of any prior art before the PTO. The prior art over which Dr. Trokel claimed his improvement, however, was fully described in the *Laser Focus* article which the Examiner listed on the cover of the '388 patent. Accordingly, as a cumulative reference, VISX had no duty to disclose *Blum*, and *Arcade* does not hold to the contrary. *Halliburton*, at 1440.

Balancing Intent and Materiality

Having considered the Examiner's action on reexamination as strong probative evidence of the materiality of *Blum* and *Keates,* and having weighed this indication of materiality in the context of the record evidence, viewed in its entirety, it is clear that, on balance, *Blum* is a cumulative reference, and that the materiality of the other prior art references is not very high.

In view of *Karp's* failure to disclose the type of laser or computer it uses, and its misapprehension of the RK procedure, the record confirms that its materiality is marginal, at best, if not cumulative in light of *Baron*. The materiality of *Girard*, too, is not substantial. It discloses various ophthalmological procedures, but the notion to combine therapeutic and nontherapeutic procedures, performed mechanically in 1983 to render obvious the claims of the '388 has not, on this record, been shown to be realistic. Dr. Barraquer's keratomileusis procedure, as discussed in *Girard*, was not clinically successful, and while a few surgeons with ordinary skill in the art travelled to Dr. Barraquer's clinic in Bogota to study his methods, fewer still returned home willing to risk implementing his teaching on the optically active axis of the cornea to correct their patients' nontherapeutic refractive problems. As such, the degree of intent required to support an inequitable conduct charge for failure to disclose references as marginal as *Karp* and *Girard* would be quite high. *Halliburton*, at 1439; *DuPont, supra*, at 1153. Similarly, the *Keates* reference has not, on balance, been shown to be particularly material. The Examiner's use of *Keates* on reexamination is surely probative, but Dr. Keates' inclination to dismiss the materiality of his CO2 laser work to excimer laser methods is also quite probative. Weighing the foregoing factors in light of portions of this reference which teach away from the claimed invention significantly attenuates the materiality of *Keates*. In other respects, information disclosed to the PTO in the Background of the '913 patent, as previously discussed in detail, renders *Keates* largely cumulative even if it had not been specifically brought to the Examiner's attention at the September 24, 1991 interview. And finally, *Blum* is cumulative of *Laser Focus*, and VISX had no duty to disclose it.

The record further shows that L'Esperance claim 1 was patented over both *Karp* and *Girard*, and claim 4 of the '388 patent was copied from L'Esperance claim 1. Thus, VISX already had a reasonable basis for concluding that claim 4 would be patentable over *Karp* and *Girard* even before the Board found claims 4 and 5 patentable to Dr. Trokel over all four prior art references. Moreover, because claim 4 is perhaps the broadest of its claims, VISX could reasonably believe, based on the Board's action, that narrower claims of the '388 also would be patentable over *Karp*, *Girard*, *Keates*, and *Blum*. Although there is contrary opinion evidence in this record, the question of intent is a matter for the trier of fact to decide, and I conclude that these determinations by the PTO, allowing claims 4 and 5, would tend to diminish the motivation to deceive the PTO by withholding any of these prior art references. But even stronger evidence of the absence of intent to deceive by withholding *Karp*, *Girard*, *Keates*, or *Blum* is the fact that all four were disclosed to the PTO.

As such, even if the disclosures are deemed technically inadequate, it must yet be acknowledged that they were not "buried" or hidden, affirmatively mischaracterized or misrepresented. Under these circumstances, because *Karp*, *Keates*, and *Girard* are not highly material, and *Blum* is cumulative, the evidence of intent required to support an inequitable conduct charge for any inadequacy in disclosing them must be quite strong. *Halliburton*, at 1439; *DuPont*, at 1153; *Gambro Lundia AB*, at 1581. Yet, on this record, the opposite is demonstrated. Any evidence in this record which could be construed as indicative of an intent to deceive is fairly tenuous.

Now, weak evidence of intent to withhold marginally material, if not cumulative, prior art is not the paradigm of a case which can sustain a charge of inequitable conduct. If prior art materiality is low, intent evidence must be fairly compelling. Thus, far stronger evidence of intent or considerably greater prior art materiality than this record provides would be needed to establish a violation of Section 5. In the absence of evidence demonstrating a clear duty to recite references disclosed during the interference or in co-pending applications by the same applicant before the same examiner, the voluminous evidence in this record documenting the actual disclosure of all four references to the PTO, amply refutes the contention that VISX, by omission or otherwise, intended to deceive the PTO. Indeed, even if *Blum* were deemed not cumulative of *Laser Focus*, the requisite degree of intent would be lacking. Consequently, neither fraud nor inequitable conduct in the procurement of the '388 patent is established on this record.[19]

Other Antitrust Issues

I have provided a detailed set of Supplemental Findings in respect to the alleged product markets in '388 technology and the sale and lease of PRK equipment, including actual and potential competitors in excimer laser sales, downstream competition arising from RK and a host of new vision care technologies in various stages of development. These Supplemental Findings also include concentration data, barrier information, VISX's conduct and performance in the marketplace, specific intent to monopolize, and market power issues, including evidence of VISX's response to competitive pressure in the pricing of its laser equipment and in its per-

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[19] Complaint Counsel seek to prohibit the enforcement of U.S. Patent Nos. 5,711,762 and 5,735,843. Both are apparatus patents with lineage stemming from the applications for the '388 patent. Each was a separate division of a division of a continuation of a continuation of the application which issued as the '388 patent. The divisional applications were filed as a result of two restriction requirements issued by the Examiner. A restriction requirement is issued when two or more independent and distinct inventions are claimed in a single application. 35 U.S.C. 121; 37 C.F.R.1.142(a).

The Examiner did not issue any double-patenting rejections in the applications which issued as the '762 or '843 patents and did not require any terminal disclaimers. On reexamination of the '388 patent, however, he rejected claims 1-5 for double-patenting over both the '843 and the '762 patents and required terminal disclaimers to overcome his provisional rejection.

In any event, the remedy Complaint Counsel seek against the '762 and the '843 patents is based upon the doctrine of "infectious unenforceability" emanating from the notion that a patentee who has procured a patent by fraud or inequitable conduct is barred from enforcing related patents. Since the record fails to establish by clear and convincing evidence that the '388 patent was obtained by fraud or inequitable conduct, no basis exists for any action against the '762 or the '843 patents in this proceeding.

procedure fees, as well as its theory that the '388 is essentially a worthless patent which affords its owner no incremental market power. Yet, unless a patent is procured by fraud or inequitable conduct, "such that the market position had been gained illegally, the patent right to exclude does not constitute monopoly power prohibited by the Sherman Act." *C.R.Bard, Inc.* v. *M3 Systems, Inc.*, 157 F.3d 1340, 1369 (Fed. Cir. 1998).

In this instance, there is no allegation that the P^3 agreement with Summit Technology was in any way implicated in the allegations and charges in Count 3 of the complaint. Nor is VISX charged in Count 3 with engaging in "sham" enforcement or misuse of the patent apart from the manner in which it was acquired from the PTO. The adverse competitive effects challenged in Count 3 arise solely as a consequence of the alleged *Walker Process*-type fraud and the *American Cyanamid*-type inequitable conduct.

The patent grant allows the patentee to exclude competition in the use of the patented invention, and the absence of clear and convincing evidence of concealment or omission of the prior art with intent to deceive necessarily strips complaint charges of monopolization, attempted monopolization, and unfair competition of all foundation and support. *See, C.R. Bard*, at 1368; *Accord, Dupont,* at 620 F.2d at 1275. Absent fraud or inequitable conduct, the other elements of the violations alleged in the complaint are not material under Rule 3.51(c)(1). *See, Beckman Instruments, Inc.* v. *Chemtronics, Inc.*, 428 F.2d 555, 567 (2nd Cir. 1970) ("The trial court should look first to the evidence to determine whether appellants indulged in knowing, willful misrepresentation of material facts. If it finds they did, it should then look to see whether the other elements of Sherman Act violations are present...."). Relevant market and market power issues "...come into play only after it has been determined that [Respondent] has knowingly attempted to enforce a fraudulently obtained patent." *FMC Corp*, at 1418. Since Complaint Counsel have failed to adduce clear and convincing evidence that prior art was either withheld or omitted with intent to deceive the PTO, a Section 5 violation cannot, as a matter of law, be sustained against VISX on *Walker Process* or *American Cyanamid* grounds. *See, C.R. Bard*, at 1368. Accordingly, Count 3 of the complaint must be dismissed. Therefore:

ORDER

IT IS ORDERED that Count 3 of the complaint be, and it hereby is, dismissed.

Stuart A. Levin
Administrative Law Judge