United States District Court, D. Arizona.

KOEPNICK MEDICAL & EDUCATION RESEARCH FOUNDATION, L.L.C, Plaintiff.

V.

ALCON LABORATORIES, INC.; Bausch & Lomb Incorporated; Summit Autonomous, Inc.; Swagel-Wootton Eye Center, Ltd.; Southwestern Eye Center, Ltd, Defendants.

No. CV 03-0029-PHX-JAT

Dec. 7, 2004.

Background: Suit was brought alleging that defendants infringed or contributed to the infringement of patent disclosing a device or procedure used to perform LASIK surgery.

Holdings: In construing disputed terms of claim at issue, the District Court, Teilborg, J., held that: (1) word "excising" conformed with the term's ordinary meaning and therefore meant "cutting out," and (2) "determining a desired prescriptive correction for a patient's eye" meant determining a refractive correction sought to reduce a patient's refractive error, expressed as in a doctor's prescription for eyeglasses or contact lenses.

Claim construed.

5,658,303. Construed.

Peter C. Warner of Tempe, AZ, for Plaintiff Koepnick Medical & Education Research Foundation.

Robert G. Krupka, David S. Shukan, Eric W. Hagen, Erica S. Olson, and Timothy Majors of Kirkland & Ellis LLP in Los Angeles, CA by Mark Deatherage of Gallagher & Kennedy, P.A. in Phoenix, AZ, for Defendants Alcon Laboratories, Inc.; Alcon Refractive Horizons, Inc.; and Southwestern Eye Center, Ltd.

Joseph R. Re, Joseph S. Cianfrani, and Christy G. Lea of Knobbe Martens, Olson & Bear, LLP by Timothy J. Burke of Fennemore Craig in Phoenix, AZ, for Defendants Bausch & Lomb Incorporated and Swagel-Wootton Eye Center, Ltd.

ORDER

TEILBORG, District Judge.

Pending before the Court is the issue of the construction of the asserted claims of United States Patent No. 5,658,303 (the "'303 patent"). This matter came before the Court for a *Markman* hearing on August 6, 2004. The parties submitted Revised Proposed Findings of Fact and Conclusions of Law after the *Markman* hearing (Doc. Nos. 106, 107, 108) and pursuant to this Court's were allowed to file objections to the Proposed Findings of Fact and Conclusions of Law (Doc. Nos. 110, 111, 112). The Court makes the following Findings of Fact and Conclusions of Law.

I. FINDINGS OF FACT

The Parties

1. The Court held a Markman Hearing on August 6, 2004 to determine the meaning and scope of Claims 1-6 of the patent-in suit, U.S. Patent No. 5,658,303, which is entitled "Universal Automated Keratectomy Apparatus and Method".

2. Plaintiff Koepnick Medical & Education Research Foundation, LLC ("Koepnick Foundation") is the assignee of the '303 patent.

3. Defendant Alcon Laboratories, Inc. ("Alcon Labs") makes and sells products used to perform LASIK surgery, including SVS Apex Plus Excimer Laser Workstation emphasis(R) "M" discs and LADARVision(R) Excimer Laser Systems, as did Summit Autonomous Inc. ("Summit") which is now Alcon Refractive Horizons ("Alcon Refractive"). Southwestern Eye Center Ltd. ("Southwestern") provides certain LASIK services. Alcon Labs, Alcon Refractive and Southwestern are collectively referred to herein as the "Alcon Defendants".

4. Defendant Bausch & Lomb Incorporated ("B & L") makes and sells products used to perform LASIK surgery, including TECHNOLAS(R) 217A and 217Z Excimer Laser Systems and the Hansatome(R) microkeratome, Swagel-Wootton Eye Center, Ltd. ("Swagel Wootton") provides certain LASIK services. B & L and Southwestern Eye Center are collectively referred to herein as the "B & L Defendants."

The Disputed Claim Construction Issues

5. Plaintiff, the asserted owner of the '303 patent, asserts that Defendants infringe or contribute to the infringement of Claims 1-6 of the '303 patent.

6. Claim 1 of the '303 patent reads as follows:

A method of performing corrective eye surgery comprising the steps of:

determining a desired prescriptive correction for a patient's eye;

cutting a first disk to remove the epithelium of said eye, said first disk being formed as a flap;

excising a second disk from said eye, said second disk being formed as a flap; and

replacing said first disk on said eye.

(Ex. 1, col. 15, ll 6-15).

7. The parties in this case dispute the meaning of two phrases in Claim 1 of the '303 patent: "excising" and "desired prescriptive correction." The remaining limitations of Claims 1-6 are not in dispute and need not be construed by the Court.

8. Plaintiff contends that the third element of Claim 1 ("excising a second disk from said eye, said second disk being shaped to provide said desired prescriptive correction") encompasses ablation of corneal tissue with an excimer laser. Defendants contend that the ordinary meaning of "excising a second disk" that is "shaped to provide [a] desired prescriptive correction" does not encompass repeatedly vaporizing small areas of tissue, and a person having ordinary skill in the art at the time the '303 patent was filed would not have understood it that way. Rather, defendants contend, the ordinary meaning of the term, and the way in which a person of ordinary skill would have understood it, is cutting away and removing an intact disk having a particular shape.

9. Plaintiff contends that the claim phrase "desired prescriptive correction" should be construed to mean a "mathematically precise, optically correct, measurement in terms of power (in diopters) of myopia (nearsightedness) and hyperopia (farsightedness) and astigmatism (power and axis) for correction of a patient's eye." The Alcon Defendants contend that the claim phrase desired prescriptive correction should be construed to mean "determining a refractive correction sought to reduce a patient's refractive error, expressedas in a doctor's prescription for eyeglasses or contact lenses." The B & L Defendants contend that the claim phrase desired prescriptive error, expressed prescriptive correction "needs no construction because the ordinary meaning of that phrase would be clear and understandable to a jury." The B & L Defendants also state, however, that if the Court chooses to construe the claim phrase, it should be construed to mean "the patient's refractive error to be reduced."

Level of Ordinary Skill in the Art

10. Plaintiff contends that a person of ordinary skill in the art as of 1995 who potentially would have used the methodology claimed in the '303 patent would include a trained ophthalmologist with some previous experience in refractive surgery and a knowledge of refractive surgery principles. That person would have prior training in the use of microkeratomes and some early training in the science of excimer laser technology.

11. The Court finds that a person with ordinary skill in the art as of the filing date of the '303 patent in 1995 would have been an ophthalmologist trained in refractive surgery techniques and who had performed corneal refractive surgery for at least 2-3 years and had performed at least 1000 refractive surgery procedures.

The Parties' Dictionary Definitions of "Excised"

12. The word "excise" is not a unique technical term in ophthalmology and point out that the *Dictionary of Ophthalmic Optics* does not include a definition of "excise" or "excision". Ex. 209.

13. Non-medical dictionaries define excising to mean "cut out." *The Oxford English Dictionary* (2d ed., 1989) defines "excise" as to "cut out (a limb, organ, etc.)." Ex. 218. *Webster's New World Dictionary & Thesaurus* (1996) defines "excise" to mean "to remove by cutting out." Ex. 220. *The Barnhart Concise Dictionary of Etymology* (1995) defines "excise" to mean "cut out." Ex. 221.

14. Medical dictionaries also define "excising" to mean "cutting out." *Dorland's Illustrated Medical Dictionary* (28th ed.1994) defines "excise" as "to cut out or off" and defines "excision" as "removal, as of an organ, by cutting." Ex. 207. *The American Heritage Stedman's Medical Dictionary* (2002) defines "excise" to mean, "to remove by cutting" and defines "excision" to mean "surgical removal by cutting, as of a tumor or a portion of a structure or organ." Ex. 212.

15. Indeed, Plaintiff's offered dictionary, *The Dictionary of Eye Terminology* defines "excision" to mean cutting out. Ex. 164.

16. Accordingly, the Court finds that the term "excise" means to cut out.

The History of the '303 Patent

17. The '303 patent is the third patent resulting from a chain of applications filed in the PTO. The first application, Serial Number 08/245,288, was filed on May 17, 1994 and resulted in U.S. Patent No. 5,496,339 (the "339 patent"), which issued on March 5, 1996. On May 16, 1995, the second application, Serial Number 08/441,789, was filed as a continuation-in-part of the first application and resulted in U.S. Patent No. 5,690,657 (the "657 patent"), which issued on November 25, 1997. On July 27, 1995, the third application, Serial number 504,114, was filed as a continuation-in-part of the second application and resulted in the '303 patent, which issued on August 19, 1997. Thus, the applications that issued as the '657 and '339 patents are parent and grandparent patents, respectively, to the patent-in-suit.

The '303 patent consistently uses the term "excising" to mean "cutting out".

18. The '303 patent, as described in the Abstract and Background of the Invention, is directed to a surgical *device* and surgical *method* for correcting refractive errors of the human eye. (Id. Abstract; id. Col. 1:24-26 ("This invention pertains to an ophthalmic surgical device and to methods for performing corrective refractive surgery on the eyes.").) The title of the '303 patent, "Universal Automated Keratectomy Apparatus and Method," indicates the same.

19. The device is generally described as a microkeratome that makes prescriptive cuts with a knife edge:

A surgical device for altering the curvature of an eye includes a base which carries a transparent insert, a drive device, a knife edge coupled to the drive device and movable to a plane immediately adjacent the under surface of the transparent insert. The transparent insert includes a face having a surface portion shaped according to a predetermined correction.... Actuation of the drive device moves the knife edge whereby the cornea is cut. Only the knife edge traverses the insert.

(Ex. 1, Abstract; id. Col. 2:30-32) ("A surgical device in accordance with the principles of the invention alters the curvature of an eye by cutting a corneal disk with a knife edge");

20. The method is generally described as involving a microkeratome that cuts two disks in the cornea:

[I]n accordance with the principles of the invention, a surgical procedure with significant improved results over prior procedures is practiced with the keratome device of the invention. In the procedure, *a disk shaped flap is first cut* to remove the epithelium. Subsequently, *a corrective cut disk* is removed from the cornea.

(Id. Col. 3:16-19 (emphasis added); *see also* id. Abstract ("In a surgical procedure, a lamellar flap is first cut to remove the epithelium and a second prescriptive cut is made to excise a disk to provide the prescriptive correction.").)

21. The '303 patent consistently uses the term "excising", or a form thereof, to refer to cutting out an intact disk using a blade. For example, the specification of the '303 patent states: "The portion of cornea filling the depression in the insert is rapidly but smoothly excised by a knife oscillating from side to side." Ex. 1, col. 5, ll. 48-50. See also '303 patent Abstract ("Actuation of the drive device moves the knife edge whereby the cornea is cut. Only the knife edge traverses the insert.") The '303 patent later states that "when the vacuum is released, the cornea will return to its normal shape less the disk portion excised by the cut." Ex. 1, col. 5, ll. 56-58. The '303 patent further explains: "The surgeon will operate the keratome to advance the knife and excise the corrective disk." Ex. 1, col. 14, ll. 21-22.

22. The '303 patent specification repeatedly refers to the removal of the second disk as a "mechanical" technique, thereby implying a cutting instrument, such as a microkeratome. (*See* Ex. 1, Col. 2:61-65) ("In accordance with the principles of the invention, a method of corrective eye surgery is provided in which a *mechanical* resection of meniscus shaped lenses allows for an accurate, optically correct technique for the correction of refractive errors." (emphasis added)); id. Col. 2:66-3:1 ("In accordance with the principles of the invention, an optically correct, *mechanical* technique for attaining emmetropia is provided." (emphasis added)); id. Col. 13:44-46 ("The keratome of the present invention provides an optically correct *mechanical* technique for obtaining emmetropia." (emphasis added)). FN1

FN1. "Emmetropia" is an ophthalmological term meaning normal vision, i.e., the state of the eye in which no refractive error is present such that glasses or contact lenses are not needed for the eye to focus sharply on distant images. (Ex. 1, Col. 5:61; Tr. 184:16-20 (Nordan testimony); *see* Ex. 4, Nordan Rpt., diagram at Ex. C p. 1 (illustration of emmetropia).)

23. The '303 patent discloses two embodiments of the claimed device in Figures 26 and 28, both of which are mechanical cutting devices in which a knife edge traverses an insert to provide optical correction. (*See* Ex. 1, Col. 4:10-14) (referring to Fig. 26 as "a first embodiment of the present invention"); id. Col. 4:16 (referring to Fig. 28 as the "a second embodiment of the present invention"); id. Col. 11:57-59 ("Operation of this second embodiment is substantially the same as that of the first embodiment. As with the first embodiment, only the *knife* traverses the prescriptive insert." (emphasis added).)

24. In another preferred embodiment, the '303 Patent uses the term laser for performing an ablation step. Specifically, the '303 patent states "[i]n yet a further method in accordance with the invention, the keratome may be utilized to produce a lamellar flap for removal and replacement of the epithelium prior to use of LASIK or Lamellar Keratectomy. In addition, the disk may be completely excised rather than left as a flap, and then replaced after laser ablation." (Ex. 1, col. 14, ll.58-63).

25. In illustrating the invention of the '303 patent, the drawings show an intact disk removed from the eye after the excision. Figures 55a-h illustrate a method of performing corrective eye surgery in accordance with the invention of the '303 patent. Ex. 1 col. 5, ll. 1-2. Figure 55e illustrates the first step of cutting the first disk as a flap. Ex. 1, col. 14, ll. 9-11. Figure 55f shows the flap placed to a side. Ex. 1, col. 14, ll. 14-15. Figure 55g illustrates the second step of excising a corrective disk with a knife. Ex. 1, col. 14, ll. 18-22. Figure 55h then shows the excised disk removed in whole. Ex. 1, col. 14, ll. 24-26.

26. The '303 patent never states that lasers excise tissue, and nothing in the '303 patent describes how to use a laser to remove corneal tissue in a mathematically precise way or to achieve emmetropia. (*see* Ex. 1.)

The Parent and Grandparent Patents Are Consistent With The Ordinary Meaning of "Excising" as "Cutting Out".

27. Every embodiment disclosed in the '303, '657, and '339 patents discloses a device or procedure that uses a knife edge to make "cuts" in the cornea for the purpose of correcting refractive error. (*See* Exs. 1, 50, 51.)

28. Throughout the '303, '657, and '339 patents, the word "excise" and its derivatives always refers to cutting and removing corneal tissue mechanically with a blade. (*See* Exs. 1, 50, 51 *passim.*) By contrast, when referring to the removal of corneal tissue with an excimer laser, the patents consistently use the word "ablate" or "remove" and never use the word "excise." (*See* Exs. 1, 50, 51 *passim.*)

29. The parent and grandparent patents to the '303 patent likewise disclose cutting devices and methods. The grandparent '339 patent issued with fifty claims. Each surgical device claim includes a limitation that refers to cutting the cornea with a knife or knife edge. (Ex. 50, '339 patent Claims 1-26.) Each insert claim includes a limitation that refers to a knife or knife edge for altering the curvature of the cornea. (Id. Claims 27-49.) The single method claim also refers to making a cut on the cornea. (Id. Claim 50.)

30. The parent '657 patent issued with thirty-eight claims. Once again, each claim for a surgical device includes a limitation that refers to cutting the cornea with a knife edge. (Ex. 51, '657 patent Claims 1-25.FN2) Each claim for an insert includes a limitation that describes using a knife edge to reshape the cornea. (Id. Claims 26-38.)

FN2. Claim 13 of the '657 patent appears to have a drafting error because it recites "[a] surgical device in accordance with claim 13" Assuming the patentee intended this claim to depend from either Claim 1 or 3, Claim 13 also includes a limitation that refers to cutting the cornea with a knife edge.

The '303 Patent Distinguishes Prior Art LASIK and Uses the Term Ablate When Referring To Removing Tissue By Vaporization With a Laser

31. LASIK stands for laser in-situ keratomileusis. In LASIK, a microkeratome is first used to create a thin, hinged flap of corneal tissue. With the corneal flap folded back away from the operative site, an excimer laser is then used to ablate (remove by vaporization) small areas of the underlying tissue in order to reshape the cornea to provide optical correction for the patient. The corneal flap is then folded back into position over the cornea, and the procedure is complete.

32. On June 20, 1989, the PTO issued a patent to Dr. Gholam Peyman, who claimed a corneal refractive surgery procedure using a laser:

A method of modifying the curvature of a patient's live cornea comprising the steps of removing a thin layer from the front of the live cornea and thereby exposing the internal surface thereof, directing a laser beam onto the exposed internal surface in a predetermined pattern to ablate, and therefore remove, a three dimensional portion thereof, and replacing the originally removed thin corneal layer back onto the ablated internal surface of the live cornea from which the thin corneal layer was removed, the removing, directing

and replacing steps taking place without freezing the internal surface or the thin layer.

(Ex. 53, U.S. Patent No. 4,840,175 (the "Peyman patent") Claim 1, Col. 8:22-37.)

33. On February 27, 1990, the PTO issued a patent to John W. Warner, who claimed a similar method of laser refractive surgery. (Ex. 83, U.S. Patent No. 4,903,695 (the "Warner patent").) Among other things, the Warner patent describes a method where a first disk of corneal epithelium is cut and treated as a flap before laser pulses ablate the underlying stromal tissue. (Id. Col. 5:65-6:3.) In general, the method of laser refractive surgery described in the Warner patent is based on correcting the visual defects of the eye according to a "predetermined curvature profile." (Id. Claim 1.) After ablating the tissue, the flap, which is described as a "lenticle," is then replaced via the articulated hinge onto the eye. (Id.) The Warner patent claims various methods of using the laser ablative technique to achieve myopic, hyperopic, and astigmatic correction of the eye. (Id. Claims 3, 4, 6.)

34. Although the Peyman and Warner patents issued several years before the invention claimed in the '303 patent was allegedly conceived, neither reference was cited to the PTO during the '303 patent's prosecution. (*See* Ex. 1, References Cited.) Moreover, with the exception of mentioning the Barraquer cryolathe technique in the '303 patent's "Background of the Invention," the '303 patent's prosecution history includes none of the prior art referencescited in the Peyman and Warner patents. (*Compare* id. with Exs. 53 & 83.)

35. Well before the 1995 filing date of the '303 patent, Dr. Ioannis G. Pallikaris of Greece and Dr. Luccio Burrato of Italy also were widely known for performing refractive surgery using laser ablation in connection with a hinged corneal flap. (See Ex. 200, I.G. Pallikaris et al., Laser In Situ Keratomileusis, 10 Lasers in Surgery & Med. 463-68 (1990); Ex. 201, I.G. Pallikaris et al., A Corneal Flap Technique for Laser In Situ Keratomileusis, 145 Arch. Ophthalmol. 1699-702 (1991); Ex. 202, L. Buratto et al., Excimer laser intrastromal keratomileusis: Case reports, 18 J. Cataract Refract. Surg. 37-41 (1992); Ex. 203, L. Buratto et al., Excimer Laser Intrastromal Keratomileusis, 113 Am. J. of Ophthalmology 291-95 (1992). See generally Ex. 204, Color Atlas/Text of Excimer Laser Surgery: The Cornea 148-151 (F.B. Thompson & P.J. McDonnell eds., Igaku-Shoin 1993); Ex. 4, Nordan Rpt. at 3.) These publications describing pre-1995 LASIK procedures disclosed that laser ablation had achieved "utmost precision" with "an extremely smooth surface" on the corneal bed. (See, e.g., Ex. 202 at 37 ("The use of excimer laser to ablate the cornea to correct refractive errors was first suggested by Trokel [citing 1983 article]. It has subsequently been demonstrated that such an ablation can be performed with utmost precision, leaving a perfectly smooth surface [citing 1986 study]."); Ex. 200 at 463 ("A number of studies ... have shown that the excimer laser at 193 nm can remove corneal tissue with submicron accuracy, creating an extremely smooth surface with minimal damage to surrounding tissue.").)

36. The '303 patent distinguishes procedures that use an excimer laser to ablate corneal tissue, such as LASIK, as "prior art." (*See, e.g.*, Ex. 1, Col. 4:62-63 ("FIG. 52 illustrates the prior art LASIK correction for myopia."); id. Col. 12:18-13:18 ("To fully appreciate the present invention, it is helpful to understand how the *existing* surgical techniques obtain optical correction of the refractive errors of the eye.... In a procedure known as LASIK ..., [t]he laser is used to ablate tissue from the eye." (emphasis added)).)

37. The Summary of the Invention section of the '303 patent emphasizes that " [t]he invention has many advantages over other mechanical keratomes, eximer [sic] lasers and radial keratectomy." (Id. Col. 2:53-54 (emphasis added).) " One major advantage is that surgery utilizing the device is reversible. Reversibility can be accomplished by simply replacing the excised corneal disk or by excising another disk from a

donor cornea using the same insert as used for the original operation." (Id. Col. 2:53-60 (emphasis added).)

38. The patent further states that "[a]n additional advantage is that highly accurate prescriptive corrective cuts can be made." (Id. Col. 2:59-60.) In that regard, the patent speaks of the "smooth" cut that results from the invention's continuous advance of a knife edge through the cornea, as compared to the allegedly "less than smooth surface" that results from an "eximer [sic] laser ablat[ing] the cornea in a series of stepped ablations." (Id. Col. 2:7-9, 30-41.)

39. Although the '303 patent discusses the LASIK procedure and the removal of tissue with a laser, the '303 patent never uses the term "excise" to refer to removing tissue with a laser. Rather, the '303 patent specification uses the term "ablate" to refer to removing tissue by vaporization with a laser.

40. The '303 patent explains that the "laser ablates (removes by vaporization) the cornea." (Ex. 1, col.2, ll.2-3). The patent further states that "[w]ith the adventof the excimer laser, a new technique known as Photo Refractive Keratectomy (PRK) which reshapes the anterior of the cornea through tissue ablation was introduced." (Ex. 1, col.12, ll.33-36). The '303 patent later explains that "[i]n PRK, an excimer laser of 193 nm wavelength is used to ablate corneal stromal tissue, reshaping the anterior surface of the cornea." (Ex. 1, col.12, ll.65-67).

41. When describing the prior art LASIK procedure, the '303 patent uses different words to distinguish between the first step, in which a flap is cut or mechanically excised by a microkeratome, and the second step, in which the laser ablates the underlying tissue. "In a procedure known as LASIK ... a lamellar disk containing the epithelium is first excised from the corneal surface of the eye ... The laser is used to ablate tissue from the eye. The corneal ablation is performed on the underlying stroma." (Ex. 1, col.13, ll.9-17); *see also* (Ex. 1, col.14, ll.61-66)("the lamellar disk may be completely excised rather than left as a flap, and then replaced after laser ablation").

42. In contrast to Figures 55f-h, which show an intact disk that has been excised by a knife, when illustrating the prior art LASIK procedure in Figure 52, no intact disk is shown, Rather, Figure 52 shows a disk that has been excised by a blade (5211) and identifies the tissue to be ablated by the laser (5212). (Ex. 1, col. 13, ll. 14-15 Fig. 52).

The Prosecution History of the '303 Patent is Consistent With The Ordinary Meaning of "Excising" as "Cutting Out".

43. On September 4, 1996, the applicant received a Notice of Allowability in which the Examiner stated the reasons for allowing the application to issue. The Examiner stated: "the primary reason for allowance is that the prior art of record fails to teach or adequately disclose the steps of cutting two disks from the eye." Ex. 215 (Notice of Allowability dated 9/4/96). The applicant did not respond to the Examiner's Statement of Reasons for Allowance.

II. CONCLUSIONS OF LAW

Legal Standard

[1] [2] 44. Claim construction is a question of law for the Court to decide. Markman v. Westview Instruments, 517 U.S. 370, 389-91, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). "[I]n construing claims, the

analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention'[]." Texas Digital Sys., Inc. v. Telegenix, Inc., 308 F.3d 1193, 1201-02 (Fed.Cir.2002)(quoting Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 1331 (Fed.Cir.2001)). "The terms used in the claims bear a 'heavy presumption' that they mean what they say and have the ordinary meaning that would be attributed to those words by persons skilled in the relevant art." Tex. Digital Sys., Inc., 308 F.3d at 1202. Thus, "[a]bsent an express definition in the specification of a particular term, the words are given their ordinary and accustomed meaning; if a term of art, it is given the ordinary and accustomed meaning as understood by those of ordinary skill in the art." Zelinski v. Brunswick Corp., 185 F.3d 1311, 1315 (Fed.Cir.1999).

[3] 45. In determining the ordinary meaning, the Court may consult reference materials such as dictionaries, treatises and encyclopedias in general use at the time the patent was issued. Tex. Digital Sys., Inc., 308 F.3d at 1202-03. Where more than one dictionary definition is offered, a claim should be construed to encompass all proffered definitions only if each definition is consistent with the intrinsic evidence. Tex. Digital Sys., Inc. 308 F.3d at 1203. Here, more than one dictionary definition of excise is offered. The Court must therefore examine the patent itself to determine whether both definitions are possible constructions.

[4] [5] [6] [7] [8] 46. The Court construes the words in a claim "in light of the intrinsic evidence of record, including the written description, the drawings, and the prosecution history, if in evidence." Teleflex, Inc. v. Ficosa N.Am. Corp., 299 F.3d 1313-25 (Fed.Cir.2002). "Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language." Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed.Cir.1996). Accordingly, "[t]he specification must be examined in every case to determine which of the possible dictionary meanings is consistent with the use of the claim term in the context of the claims and the written description." Int'l Rectifier Corp. v. IXYS Corp., 361 F.3d 1363, 1369 (Fed.Cir.2004). Moreover, the Court must also examine the intrinsic record to determine whether the presumption of ordinary meaning is being rebutted. Tex. Digital Sys., Inc., 308 F.3d at 1204. "Indeed, the intrinsic record may show that the specification uses the words in a manner clearly inconsistent with the ordinary meaning reflected, for example, in a dictionary definition." Id. Although the Court must read the claim in view of the specification, the claims are not limited to preferred embodiments or illustrative examples appearing in the specification. Kraft Foods, Inc. v. Int'l Trading Co., 203 F.3d 1362, 1366 (Fed.Cir.2000). If after reviewing the intrinsic evidence, the Court is unable to resolve a disputed claim term, it may consider extrinsic evidence, such as expert testimony, inventor testimony, and technical treatises and articles. Vitronics Corp., 90 F.3d at 1584.

[9] 47. The patent examiner's reason for allowance is a part of the prosecution history and is relevant to the proper construction of the claims allowed. Torpharm, Inc. v. Ranbaxy Pharm., Inc., 336 F.3d 1322, 1330 (Fed.Cir.2003). "[T]he public is entitled to equate an inventor's acquiescence to the examiner's narrow view of patentable subject matter with abandonment of the rest." *Id*. Such acquiescence may be found where the patentee allows the examiner's narrow interpretation of a claim to stand. Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 979 (Fed.Cir.1999)(holding that patentee's failure to respond to examiner's statements in the reasons for allowance effectively prohibited a different construction of the claim).

Construction of "Excising a Second Disk from Said Eye"

[10] 48. The real dispute here centers around the definition of the word "excising". The Court begins its analysis with dictionary definitions of the word.

49. The word "excise" is not a unique technical term in ophthalmology. *Dictionary of Ophthalmic Optics* does not include a definition of "excise" or "excision". Ex. 209. Non-medical dictionaries define excising to mean "cut out." *The Oxford English Dictionary* (2d ed., 1989) defines "excise" as to "cut out (a limb, organ, etc.)." Ex. 218. *Webster's New World Dictionary & Thesaurus* (1996) defines "excise" to mean "to remove by cutting out." Ex. 220. *The Barnhart Concise Dictionary of Etymology* (1995) defines "excise" to mean "cut out." Ex. 221.

50. Medical dictionaries define "excising" to mean "cutting out." *Dorland's IllustratedMedical Dictionary* (28th ed.1994) defines "excise" as "to cut out or off" and defines "excision" as "removal, as of an organ, by cutting." Ex. 207. *The American Heritage Stedman's Medical Dictionary* (2002) defines "excise" to mean, "to remove by cutting" and defines "excision" to mean "surgical removal by cutting, as of a tumor or a portion of a structure or organ." Ex. 212. *The Dictionary of Eye Terminology* gives cutting out as a possible definition of "excision". Ex. 164.

51. The Court finds that "to cut out" is the customary meaning of the term excise. The Court further finds that defining excise to mean "to remove tissue" is inconsistent with the intrinsic record.FN3 As the Court stated above, the '303 patent consistently uses the term "excising" to mean "cutting out". The Parent and Grandparent Patents are also consistent with the ordinary meaning of "excising" as "cutting out". Further, the '303 Patent distinguishes prior art LASIK and uses the term ablate when referring to removing tissue by vaporization with a laser. Finally, the prosecution history of the '303 Patent is consistent with the ordinary meaning of "excising" as "cutting out".

FN3. Because the Court is able to resolve the claim term by reviewing the intrinsic record, it is not necessary to consider extrinsic evidence, such as expert testimony, inventor testimony, and technical treatises and articles. Vitronics Corp., 90 F.3d at 1584

52. Because the claim requires that the "second disk" have a particular shape, the scope of what constitutes "excising" is expressly limited. "Ablating" with a laser cannot fall within the scope of the claim because ablated tissue has been vaporized into a gas and therefore has no shape. Through the consistent use in the written description of "excise" to describe the action of a mechanical cutting device or method, and by contrasting it with "ablate" to describe the action of an excimer laser, the patentee has confirmed that the definition of "excise", as used in the patent, conforms with the term's ordinary meaning and therefore means cutting out. *See* Vitronics, 90 F.3d at 1582.

53. If the Court were to construe this claim limitation to include removal of corneal tissue by laser, then the invention's "major advantage" of reversibility is effectively read out of the description. *See* Toro Co. v. White Consol. Indus., Inc. 199 F.3d 1295, 1301 (Fed.Cir.1999)(construing claim as limited to a "unitary structure" where the specification describes the advantages of the unitary structure as important to the invention.); *see also* O.I. Corp. v. Tekmar Co., 115 F.3d 1576, 1581 (Fed.Cir.1997)(limiting claim construction to certain characteristics because the written description distinguished over the prior art based on these characteristics). Here, the patentee stated that a "major advantage" of his invention over refractive techniques using an excimer laser is reversibility. (Ex. 1, Col.2, II.53-59). And in every disclosed embodiment in the '303 patent, reversibility theoretically can be achieved because there is an intact disk that can be replaced on the corneal stroma. On the other hand, when an excimer laser is used, tissue is vaporized and no longer exists and, as a result, that tissue cannot be replaced on the corneal stroma to achieve

reversibility.

[11] 54. Where more than one claim construction is possible, the Court should not choose a construction that is broad enough to encompass prior art. ACS Hosp. Sys., Inc. v. Montefiore Hosp., 732 F.2d 1572, 1577 (Fed.Cir.1984). If the Court were to construe the third element of Claim 1 to cover the reshaping of the cornea with an excimer laser, then the patent would be invalidated by the wealth of prior art LASIK procedures. *See also* SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1343 (Fed.Cir.2001)(holding that the fact that the written description stated a particular feature that offered advantages over the prior art supported the conclusion that the claims cannot be read so broadly as to encompass the distinguished prior art.)

55. The Court also finds that the patentee's failure to not dispute the examiner's sole stated reason for allowance-"that the prior art of record fails to teach or adequately disclose the steps of cutting two disks from the eye" (Ex. 215) provides further support that the term excising should be interpreted to mean "cutting out". The examiner's view of the invention's breadth was restrictive, and the patentee allowed it to stand. The Court considers the patentee's lack of response as a factor in the prosecution history limiting the interpretation of the patent. Elkay, 192 F.3d at 979.

56. Plaintiff attempts to dismiss the examiner's reasons for allowance by citing to 37 C.F.R. s. 1.104(e) and to the administrative decision of EX PARTE YAMAGUCHI, 2001 WL 1049002, 61 U.S.P.Q.2d 1043 (Bd. Pat.App. & Interf.2001) for the proposition that, when Mr. Koenpnick filed is patent application, a patent applicant had no duty to respond to "erroneous" statements in an examiner's statement of reasons for allowance. But irrespective of the duty to respond during the prosecution of the patent, Federal Circuit authority holds that a patentee's acquiescence in the patent examiner's reason for allowance, and the examiner's narrow view of the patentable subject matter, may nevertheless be relied on for purposes of claim construction. The Elkay case stands for the proposition that the Court may consider an examiner's statements in the reasons for allowance to interpret the claim terms. The Court notes that the examiner's statement in Elkay was filed, and the patent issued, during the same period that the version of the PTO rule cited by Plaintiff (37 C.F.R. s. 1.104(e)) was in effect and before the examiner's statement was filed in the '303 patent's prosecution. (Ex. 214). In fact, EX PARTE YAMAGUCHI even cites Elkay as a warning that claim construction inferences may be drawn by a failure to respond to an examiner's statement of reasons for allowance. 2001 WL 1049002, 61 U.S.P.Q.2d at 1047 n. 4. Thus, the examiner's statement in this case, that "the prior art of record fails to teach or adequately disclose the steps of cutting two disks from the eye" and the fact that Plaintiff did not dispute it, may properly be used by this Court in construing the meaning of the term excise.

Construction of "determining a desired prescriptive correction."

57. To a person having ordinary skill in the art in 1995, the claim element "determining a desired prescriptive correction for a patient's eye" would have meant nothing more than the ordinary meaning of that phrase-the correction that is desired relates to a doctor's prescription for improving the patient's visual acuity. The phrase "desired prescriptive correction" contains no technical terms of art. The Court agrees with Defendants that Plaintiff has offered no evidence to support its contention that the claim phrase "desired prescriptive correction" should be construed to mean a "mathematically precise, optically correct, measurement in terms of power (in diopters) of myopia (nearsightedness) and hyperopia (farsightedness) and astigmatism (power and axis) for correction of a patient's eye." In fact, the '303 Patent's Detailed Description clarifies that the claim language is simply referring to a doctor's prescription:

The change in the corneal surface using the surgical device of the present invention will be determined by an optical correction formed into a custom made member or insert based upon a doctor's prescription. The prescription is similar to the prescription a doctor might give to an optical laboratory for the purpose of grinding lenses for eye glasses or for contact lenses.

Ex. 1 Col. 5, ll. 5-11. Plaintiff has not shown how or why the vague and subjective limitations of "mathematical precision" and "full correction" should be read into the claim term. The Court therefore finds that the word "prescriptive" in Claim 1 should be interpreted according to its ordinary meaning to describe that the "correction" that is "desired" relates to a doctor's prescription for improving a patient's visual acuity.

III. CONCLUSION

58. The term "excising" in Claim 1 is given its ordinary and accustomed meaning. Although the parties each assert that they have presented the ordinary meaning, the meaning most consistent with the intrinsic evidence is "cutting out." The claims and written description of the '303 patent distinguish between "excising" and ablation by a laser. Accordingly, the claim term "excising" cannot mean "removing" generally so as to encompass removal by laser ablation.

[12] 59. "Determining a desired prescriptive correction for a patient's eye" means determining a refractive correction sought to reduce a patient's refractive error, expressed as in a doctor's prescription for eyeglasses or contact lenses. This interpretation is based on the ordinary and accustomed meaning of the claim language read in light of the specification and prosecution history.

D.Ariz.,2004. Koepnick Medical & Educ. Research Foundation, L.L.C. v. Alcon Laboratories, Inc.

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