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United States Court of Appeals for the Federal Circuit

05-1215

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

Plaintiff-Appellant,

v.

ALCON LABORATORIES, INC.,
ALCON REFRACTIVE HORIZONS, INC.,
SOUTHWESTERN EYE CENTER, LTD.,

Defendants-Appellees,

and

BAUSCH & LOMB INCORPORATED,
SWAGEL-WOOTTON EYE CENTER, LTD.,

Defendants-Appellees.

DECIDED: December 28, 2005

Before LOURIE, Circuit Judge, ARCHER, Senior Circuit Judge, and PROST, Circuit Judge.

LOURIE, Circuit Judge.

Koepnick Medical & Education Research Foundation, L.L.C. ("Koepnick") appeals from the decision of the District Court for the District of Arizona granting judgment of noninfringement of U.S. Patent 5,658,303 in favor of Alcon Laboratories, Alcon RefractiveHorizons, Inc., Southwestern Eye Center, Ltd., Bausch & Lomb and

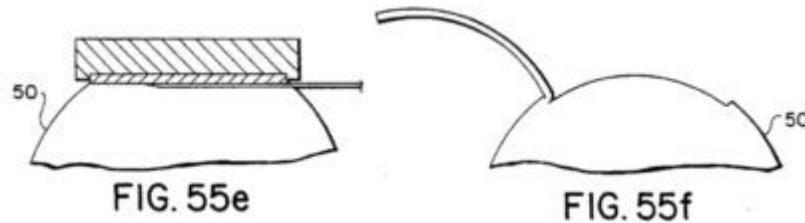
Swagel-Wootton Eye Center, Ltd. Koepnick Med. & Educ. Research Found., L.L.C. v Alcon Labs. Inc., No. Civ 03-0029 (D. Ariz. Dec. 28, 2004). Because the district court properly construed the claim limitation “excising,” and the parties agreed that, under that claim construction, there was no infringement, we affirm.

BACKGROUND

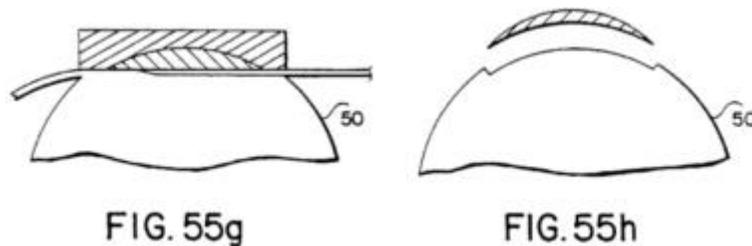
The '303 patent is entitled “Universal Automated Keratectomy Apparatus and Method,” and was issued to Russell G. Koepnick as inventor. The invention relates to a surgical method for performing refractive eye surgery. Refractive eye surgery is a surgical procedure that alters the curvature of the eye to reduce the amount of refractive error, which is described and manifested as myopia (nearsightedness), hyperopia (farsightedness), and/or astigmatism. Refractive surgery was first performed in the 1960's using microkeratomes, cutting devices with a knife edge. Id., col. 1, ll. 26-39. In those early procedures the cut disk was frozen, reshaped with a lathe according to the patient's prescription, and sewn back onto the patient's cornea. Id. Later refinements in the 1980's eliminated the need to freeze the disk. Id., col. 1, ll. 39-45. One such technique, known as keratomileusis in-situ or lamellar keratectomy, involved the creation of a corneal flap using a microkeratome, and then the removal of a second, smaller piece of corneal tissue by a second pass of the microkeratome. The original flap was then replaced on the eye back into its original position. Id., col. 1, ll. 39-45; col. 13, ll. 19-22. The amount of optical correction was controlled by the diameter and thickness of the second disk. Id., col. 13, ll. 27-29. Another technique for performing refractive eye surgery was a procedure known as Laser In-Situ Keratomileusis (“LASIK”), developed in the early 1990's. In the LASIK procedure, a microkeratome

was used to cut a lamellar (sides parallel to the corneal surface) flap of tissue that remains hinged to the eye. With the corneal flap folded back, a laser then “ablate[d] (remove[d] by vaporization) the cornea in a manner that result[ed] in removing a lenticular (sides not parallel to the surface of the cornea) disk from the cornea . . .” Id., col. 2, ll. 2-5.

The '303 patent is directed to a surgical method involving an improved microkeratome capable of cutting lamellar and lenticular shaped disks from the eye by using special inserts that allow the microkeratome to cut disks having different shapes. Id., col. 3, ll. 1-25. As illustrated in Figures 55e and 55f, a corneal flap is first cut using a lamellar insert, such that the disk created by the cut remains hinged to the eye.



Next, as illustrated in Figures 55g and 55h, a second lenticular-shaped disk is removed using a lenticular insert. According to the '303 patent, it is the removal of this second disk that provides the prescriptive correction. Id., col. 5, ll. 11-15.



On January 8, 2003, Koepnick filed suit against Alcon Laboratories, Alcon RefractiveHorizons, Inc.,¹ Southwestern Eye Center, Ltd., Bausch & Lomb and Swagel-Wootton Eye Center, Ltd. in the United States District Court for the District of Arizona for infringement of independent claim 1 and dependent claims 2, 3, 4, 5, and 6 of the '303 patent.² The LASIK procedures accused of infringement are performed by Southwestern Eye Center and Swagel-Wootton Eye Center using equipment supplied by Alcon Laboratories, Inc., Bausch & Lomb Inc., and/or Alcon RefractiveHorizons, Inc. Alcon Laboratories, Alcon RefractiveHorizons, Inc., and Southwestern Eye Center, Ltd., (collectively "Alcon") and Bausch & Lomb and Swagel-Wootton Eye Center, Ltd. (collectively "B&L") denied Koepnick's allegations of infringement and counterclaimed for declaratory relief that the '303 patent was invalid and not infringed. Additionally, Alcon counterclaimed for a declaration that the '303 patent was unenforceable. On December 7, 2004, after conducting a Markman hearing, the district court construed certain limitations contained in claims 1-6. Koepnick Med. & Educ. Research Found.,

¹ Koepnick filed its original complaint against Summit Autonomous, Inc. Summit Autonomous Inc. merged into Alcon RefractiveHorizons, Inc. in July 2003, and was replaced as defendant by Alcon RefractiveHorizons, Inc.

² 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 shaped to provide said desired prescriptive correction; and
replacing said first disk on said eye.

Id., col. 15, ll. 5-15 (emphasis added). Claims 2-6 depend from claim 1. None of the dependent claims contains additional limitations that are at issue in this appeal.

L.L.C. v Alcon Labs. Inc., 347 F. Supp. 2d 731 (D. Ariz. 2004) (“Claim Construction Order”).

The court construed the claim limitation “excising” to mean “cutting out” and “desired prescriptive correction” to mean “a refractive correction sought to reduce a patient’s refractive error, expressed as in a doctor’s prescription for eyeglasses or contact lenses.” Id. at 743. In construing the term “excising,” the court determined that the ordinary and customary meaning of the term is “cutting out,” and that this definition is consistently used throughout the intrinsic evidence, i.e., the patent specification and prosecution history. Id. at 741. The court explained that “the claim term ‘excising’ cannot mean ‘removing’ generally so as to encompass removal by laser ablation” because the written description distinguishes the term “excise” from “ablate.” Id. at 743. Further, the court observed that the language of the claims does not contemplate a meaning of “excise” that encompasses “ablation” because it requires a “second disk” having a particular shape, and ablated tissue that has been vaporized into a gas has no shape. Id. at 741. The court also reasoned that construing the term “excising” to encompass “ablation” would render the patent invalid by the wealth of prior art LASIK procedures and would read out the invention’s “major advantage” of reversibility. Id. at 742. Finally, the court concluded that Koepnick’s failure to dispute the Patent and Trademark Office (“PTO”) examiner’s sole stated reason for allowance of the ’303 patent – “that the prior art of record fails to teach or adequately disclose the steps of cutting two disks from the eye” – supports the construction of the term “excising” to mean “cutting out.” Id.

The district court also construed the term “determining a desired prescriptive correction” to mean “a refractive correction sought to reduce a patient’s refractive error, expressed in a doctor’s prescription for eyeglasses or contact lenses.” Id. The court gave the phrase its ordinary meaning, reasoning that it contained no technical terms of art and there was no evidence supporting any of Koepnick’s proposed limitations. Id. at 742-43. The court pointed out that the ordinary meaning was supported by the written description, which clarifies that the claim language simply refers to a doctor’s prescription. Id.

Based on the district court’s claim constructions, both parties stipulated to noninfringement, agreeing that the “accused LASIK procedures remove tissue by laser ablation and do not meet the ‘excising’ limitation as construed by the Court, either literally or under the doctrine of equivalents.” Koepnick Med. & Educ. Research Found., L.L.C. v Alcon Labs. Inc., No. Civ 03-0029 (D. Ariz. Dec. 21, 2004). The court entered final judgment of noninfringement on December 28, 2004, and Koepnick timely appealed to this court. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

Claim construction is an issue of law, Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-71 (Fed. Cir. 1995) (en banc), that we review de novo, Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc).

On appeal, Koepnick argues that the district court’s decision was based on an erroneous construction of the claim limitation “excising.” According to Koepnick, by interpreting “excising” to mean “cutting out” rather than “removing tissue,” the court failed to give the contested term its ordinary meaning, as defined in dictionaries and

relevant patents and articles. Koepnick also contends that because the claims contain both the words “cutting” and “excising,” they should be presumed to mean different things. Koepnick argues that the ordinary meaning of the term “excising” encompasses non-cutting mechanical techniques such as laser ablation and the court unduly narrowed the scope of the claims by importing the word “intact” from the specification into the element “excising a second disk” and relying on the statement in the specification that one advantage of the invention was “reversibility.” Koepnick also maintains that its failure to dispute the PTO examiner’s statement during prosecution that the invention relates to “cutting” two disks from the eye could not have restricted the scope of the claims because the statement was not directed to any specific claim or the scope of the claims. Finally, Koepnick argues that the failure of the ’303 patent to describe how to use a laser to remove corneal tissue in a mathematically precise way to achieve emmetropia should not preclude recovery because, at the time the patent issued, the use of lasers in refractive eye surgery, although disclosed in the prior art, had not yet been perfected.

Alcon and B&L respond by essentially repeating the analysis contained in the district court’s Claim Construction Order. Alcon and B&L assert that the claim language and specification consistently use “excising” to mean “cutting out,” and the prosecution history confirms that understanding because the PTO examiner recognized that the invention required cutting the second disk. Alcon and B&L also note that the ’303 patent specification contrasts “excising” with removal by laser “ablation” and distinguishes LASIK procedures as prior art. According to Alcon and B&L, the written description and drawings require the “excised” second disk to have a specific shape,

which does not occur when eye tissue is removed by laser ablation. Alcon and B&L point out that the “Summary of the Invention” section supports this interpretation because it touts “reversibility” as one of the invention’s many advantages over LASIK procedures. Finally, Alcon and B&L argue that the claim limitation “excising” cannot be read to encompass future improvements that were not possible when the ’303 patent was filed, such as accurate removal of eye tissue with laser ablation.

We agree with Alcon and B&L that the district court properly construed the claim limitation “excising” to mean “cutting out.” Our primary focus in determining the ordinary and customary meaning of a claim term is to consider the intrinsic evidence of record, viz., the patent itself, including the claims, the specification and, if in evidence, the prosecution history, from the perspective of one of ordinary skill in the art. Phillips v. AWH Corp., 415 F.3d 1303, 1312-17 (Fed. Cir. 2005) (en banc). Here, the construction of “excising” that is consistent with the claims, specification, and prosecution history is “cutting out,” and thus we give the claim limitation that ordinary and customary meaning.

We begin with the language of the claims. Claim 1 requires “excising a second disk, said second disk being shaped to provide said prescriptive correction.” ’303 patent, col. 15, ll. 13-15. Claim 6 further requires that the second disk must have a “positive or negative meniscus shape.” Id. at col. 15, ll. 28-30. Because the claims make clear that the excised second disk has a defined shape, the scope of what constitutes “excising” is expressly limited to surgical techniques that create such a defined shape. Koepnick urges a construction of “excising” as “removing tissue.” However, that interpretation is inconsistent with the requirements of the claim because it would encompass methods in which the “excised” tissue does not have a defined

shape, such as laser ablation. As the district court correctly observed, “[a]blating’ 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.” Id. The claim therefore requires a construction of “excising” that excludes laser ablation.

The specification supports that interpretation of “excising” as “cutting out.” The term “excising” is unambiguously used to mean cutting with a knife blade in both the “Abstract” and “Summary of the Invention” sections. ’303 patent, Abstract; col. 2, ll. 31-32. Further, every embodiment disclosed in the patent uses a knife edge to make a cut in the cornea. There is no evidence supporting Koepnick’s assertion that “excising” also refers to laser ablation. Indeed, the specification makes clear that LASIK procedures are an existing surgical technique, i.e., that they are not the invention. The written description repeatedly distinguishes the invention from procedures involving lasers. Id., col. 2, ll. 1-4; col. 13, ll. 9-17. The “Detailed Description” section also contrasts “excising” with laser “ablation,” noting that, in the prior art LASIK procedures, a disk is first “excised” before a laser is used to “ablate” the second disk of tissue from the eye. Id., col. 13, ll. 9-17.

Moreover, the “Summary of the Invention” section explains that the “invention has many advantages over mechanical keratomes, radial lasers and radial keratectomy. One major advantage is that surgery utilizing the device is reversible . . . by simply replacing the [second] excised corneal disk or by excising another disk from a donor cornea using the same insert as used for the original operation.” ’303 patent, col. 2, ll. 53-60 (emphasis added). Although a disk of tissue cut with a knife edge can be put back onto the eye as described in the specification, a disk of tissue that is vaporized by

laser ablation cannot be replaced as contemplated in the specification. We conclude therefore that the specification does not support Kopenick's proposed construction of "excising" as encompassing laser ablation.

The prosecution history further confirms the district court's construction of "excising" as "cutting out." The PTO examiner asserted in the Notice of Allowance of the '303 patent that "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." J.A. at 3246 (emphasis added). Koepnick did not challenge the examiner's characterization of its invention. Indeed, Koepnick concedes that at the time of filing, the inventor did not believe that claim 1 encompassed LASIK procedures. Appellant's Br. at 29 (explaining that "[l]asers in 1995 could not remove corneal tissue in a mathematically precise way to achieve emmetropia."). Consistent with that understanding, the claims do not describe a surgical method of refractive eye surgery using lasers. Indeed, Koepnick disclaimed the only claim directed to LASIK procedures, claim 13,³ by filing a statutory disclaimer in the PTO on July 22, 2003. Although we find the timing of the disclaimer on the eve of

³ Independent claim 13 reads as follows:

A method of performing refractive surgery comprising the steps of:
placing a keratome device on an eye, said keratome device having an element with surface portion recess the depth epithelium of said eye;
operating said keratome device such that vacuum is applied to said eye urging said eye into contact with said recess;
operating said keratome device in an automatic mode such that a knife edge traverses said element to excise a flap, said knife edge being stopped before said flap is severed;
removing said keratome device;
utilizing a laser to remove corneal tissue to produce a prescriptive correction; and
replacing said flap.

'303 patent, col. 16, ll. 41-56 (emphasis added).

the lawsuit to be interesting, to say the least, we express no opinion as to the reason why Koepnick decided to disclaim claim 13, and whether it was related to issues of patentability or validity. Irrespective of the reasons for the disclaimer, the result of the disclaimer is to strip the claims of any reference to lasers, even though the technology was discussed elsewhere in the specification.⁴ We therefore conclude that the claim language, specification, and prosecution history support a construction of “excising” as “cutting out.”

Finally, Koepnick argues that the district court erred in not considering extrinsic evidence in construing the claims. As we discussed in Phillips, “extrinsic evidence may be useful to the court, but it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.” 415 F.3d at 1319. We recognize that our decision in Phillips had not yet issued at the time the district court rendered its claim construction order and the parties submitted their appellate briefs. Nevertheless, the district court displayed considerable prescience in its analysis, correctly noting that because the intrinsic evidence was sufficient to support the claim construction, it was not necessary to consider extrinsic evidence, such as expert testimony, inventor testimony, and technical treatises and articles. Claim Construction Order, 347 F. Supp. 2d at 741, n.3. Accordingly, the dictionary definitions put forth by Koepnick do not compel a different construction of “excising.”

⁴ We have not yet addressed the issue whether a statutory disclaimer filed after the patent was issued is considered as part of the prosecution history during claim construction, and whether that statutory disclaimer may operate during claim construction to preclude a patentee from recapturing subject matter it has surrendered in certain instances. We will not decide that issue here because it is otherwise clear from the claims, specification, and prosecution history that the ordinary and customary meaning of “excising” does not encompass laser ablation.

Because we conclude that the term “excising” does not encompass removal by laser ablation, Koepnick’s appeal of the district court’s claim construction of the phrase “desired prescriptive correction” is moot.

CONCLUSION

We affirm the decision of the district court granting judgment of noninfringement of the ’303 patent in favor of Alcon and B&L.