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United States Court of Appeals for the Federal Circuit

02-1582

ICN PHOTONICS, LTD.,

Plaintiff-Appellant,

v.

CYNOSURE, INC.,
(doing business as New England Cynosure, Inc.),

Defendant -Appellee.

DECIDED: July 16, 2003

Before LOURIE, LINN, and PROST, Circuit Judges.

LOURIE, Circuit Judge.

DECISION

ICN Photonics, Ltd. appeals from the decision of the United States District Court for the District of Massachusetts granting summary judgment that ICN's U.S. Patent 5,983,900 is invalid. ICN Photonics Ltd. v. Cynosure, Inc., No. CIV 01-11496 (D. Mass. July 15, 2002). Because there are genuine issues of material fact relating to issues underlying the validity of the '900 patent, we reverse.

BACKGROUND

ICN owns the '900 patent, which is directed to a method for removing wrinkles from skin by irradiation. '900 patent, col. 3, l. 37 – col. 4, l. 13. As pointed out by the '900 patent, mammalian skin comprises three layers: an outermost “epidermis” layer; an intermediate, thin “basal” layer; and an innermost, relatively thick “dermal” layer. Id. at col. 3, ll. 12-14. It is believed that heating the collagen naturally present in the dermal layer removes wrinkles in the skin. Id. at col. 1, ll. 59-61; col. 2, ll. 17-22. According to the patent, prior art wrinkle removal techniques would repeatedly apply laser irradiation to the surface of the skin, thereby sequentially burning and hence removing thin layers of skin (on the order of 30 µm per pass) until collagen was irradiated. Id. at col. 1, ll. 17-53. The invention of the '900 patent aimed to improve upon the prior art and to avoid some of the prior art's disadvantages, namely, causing damage to the skin by removing the skin's barrier to the outside world. Id. at col. 1, l. 54 – col. 2, l. 3; col. 3, ll. 22-27. To that end, the inventors sought to focus radiation into the interior of the skin structure where it would heat collagen after passing harmlessly through the more exterior portions of the skin. Id. at col. 2, ll. 7-30. To do so, the invention provides radiation at a frequency selectively absorbed by a chromophore in the dermal layer such that nearby collagen is heated. Id. Thus, according to the patent's “Summary of the Invention,” “the basal layer remains intact so as to substantially inhibit contact of the dermal layer with ambient air” when the invention is utilized, and the invention operates “without damage to the dermis (in other words, without causing second degree burns) because the barrier provided by the basal layer remains intact.” Id.

Claim 1, the sole independent claim in the '900 patent, defines the invention as follows:

1. A method of cosmetically removing wrinkles from a superficial area of mammalian skin tissue having, in the order specified, an epidermal layer, a basal layer having blood vessels with blood therein, and a dermal layer having blood vessels with blood therein, which method comprises:

irradiating said dermal layer through said basal layer by means of visible or infrared radiation, without coagulating the blood in the blood vessels of said basal layer and without coagulating the blood in the blood vessels of said dermal layer, said irradiation being selected to be absorbed by a chromophore in said dermal layer such that collagen present in said dermal layer is heated to cause said wrinkles to be [sic] removed, while said basal layer remains intact so as to substantially inhibit contact between ambient air and said dermal layers.

Id. at col. 3, l. 37 – col. 4, l. 13 (emphasis added). During prosecution, ICN amended claim 1 to add, inter alia, the “without coagulating” limitations emphasized above. ICN amended the claim to overcome a rejection under 35 U.S.C. § 102(e), stating that the claim was anticipated by U.S. Patent 5,755,751, issued to Eckhouse. The Eckhouse patent discloses an apparatus for providing pulsed electromagnetic radiation to the skin or underlying tissue. In one mode of operation, the frequency and pulse timing of the radiation produced by Eckhouse's apparatus are selected so as to coagulate “deep” blood vessels (i.e., 2 mm below the skin surface) without burning the epidermis. '751 patent, col. 13, l. 46 – col. 14, l. 9; col. 15, ll. 35-52. Eckhouse's patent also tersely

mentions that “skin rejuvenation (treating wrinkles) should be effective,” id. at col. 16, ll. 33-34, and on that basis the examiner rejected ICN’s claim 1 as originally submitted. In traversing that rejection, ICN characterized Eckhouse as “directed to removal of skin blemishes in the dermal region by coagulating (destroying) blood vessels in the dermal region,” while explaining that the invention as defined by the amended claim “is directed to removal of wrinkles by applying heat to the dermal region without coagulating blood in the basal or dermal region.” (emphases added). The examiner thereafter allowed the claims, and the ’900 patent issued.

ICN sued Cynosure, Inc. for infringement of the ’900 patent. Cynosure brought a motion for summary judgment, which the court granted, holding that the claims of the ’900 patent were invalid for failure to meet the written description requirement of 35 U.S.C. § 112, ¶ 1. More specifically, Cynosure contended that the “without coagulation” limitations added to claim 1 by amendment were limitations not described in the originally-filed patent application. ICN, while acknowledging that the language added to the claim did not appear in haec verba in the originally-filed application, responded with a declaration from Dr. Jeffrey Rapaport, M.D., in which he stated that one of ordinary skill in the art at the time the patent application was filed would have understood the “without coagulation” limitations to be inherent in the originally-filed specification. In particular, Dr. Rapaport opined that the specification’s statements that the “basal layer remains intact,” that treatment is performed “without damage to the dermal layer,” and that treatment takes place “without causing secondary burns” indicate that “the radiation is applied at an energy level that would reduce wrinkles without coagulating blood in the basal layer.” The court found Rapaport’s testimony to be deficient in that he did not adequately explain what he understood “inherent” to mean and that his opinion lacked “any factual foundation whatsoever.” ICN Photonics, slip op. at 7. The court accordingly granted Cynosure’s motion.

ICN appeals from the decision of the district court. We have jurisdiction pursuant to 28 U.S.C. § 1295(a) (1).

DISCUSSION

We review a district court’s grant of summary judgment de novo, reapplying the same standard used by the district court. Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp., 149 F.3d 1309, 1315 (Fed. Cir. 1998). Summary judgment is appropriate “if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if

any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.” Fed. R. Civ. P. 56(c). Thus, summary judgment may be granted when no “reasonable jury could return a verdict for the nonmoving party.” Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). In determining whether there is a genuine issue of material fact, the evidence must be viewed in the light most favorable to the party opposing the motion, with doubts resolved in favor of the opponent. Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc., 145 F.3d 1303, 1307 (Fed. Cir. 1998).

Furthermore, in deciding whether summary judgment is warranted, the court “must view the evidence presented through the prism of the substantive evidentiary burden” that would inhere at trial. Anderson, 477 U.S. at 245. The question whether the subject matter of a patent claim satisfies the written description requirement of 35 U.S.C. § 112, ¶ 1, is a question of fact, Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991), and, because a patent is presumed valid, 35 U.S.C. § 282 (2000), the evidentiary burden to show facts supporting a conclusion of invalidity is clear and convincing evidence, WMS Gaming Inc. v. Int'l Game Techs., 184 F.3d 1339, 1355 (Fed. Cir. 1999).

On appeal, ICN first argues that the court, rather than viewing the conflicting evidence in the light most favorable to ICN, engaged in improper fact-finding in crediting Cynosure’s attorney arguments over Rapaport’s testimony. According to ICN, Rapaport’s testimony, if found credible by a jury, would establish that one skilled in the art would necessarily find the “without coagulating” limitations to be present in the ’900 patent as originally filed. ICN also contends that the court did not view the evidence through the prism of the clear and convincing evidentiary burden, which is especially strong when, as with the ’900 patent, the PTO failed to object to the claim amendment as introducing new matter into the application.

Cynosure responds that the court properly viewed the evidence — including the ’900 patent itself, which is obviously the best evidence of its written description — in light of the procedural posture of the issue and the ultimate allocation of the burdens at trial when it concluded that no reasonable fact-finder could find the ’900 patent’s written description adequate to support the claims. Cynosure also responds that this case, like many others in which the court has found claims to be invalid for lack of an adequate written description, indicates that examiners at times err and that the presumption of validity is not determinative. Cynosure contends that the standard for complying with the written description requirement is strict: the limitations at issue must be “necessarily present,” “immediately discernible,” “clearly evident,” and “unambiguously described” to one skilled in

the art viewing the originally-filed specification. Under that standard, according to Cynosure, the '900 patent's written description is inadequate. Cynosure, also argues that Rapaport's declaration is deficient in that it lacks factual foundation and never opines that the disputed limitation is necessarily present, immediately discernable, etc.; instead, according to Cynosure, Rapaport probably used the term "inherent" as ICN improperly did in the district court (to mean "plausibly supports"). Cynosure further contends that the prosecution history of the '900 patent reveals that the "without coagulating" limitations are not inherent in the statement that "the basal layer remains intact." Cynosure also contends that if ICN's inherency argument is correct, then the claims would be anticipated by Eckhouse. Finally, Cynosure contends that ICN's argument is contrary to the accepted rule that a generic expression is not a written description of all of its variants.

The written description requirement is set forth in 35 U.S.C. § 112, ¶ 1, which provides, "The specification shall contain a written description of the invention" One of the roles of the written description requirement is to ensure that patent claims are not amended to claim subject matter different from what was described in the patent application on the date of its filing. Amgen Inc. v. Hoechst Marion Roussel, Inc., 14 F.3d 1313, 1330 (Fed. Cir. 2003). Often, patent applicants amend their claims during the patent application process to more narrowly define their invention by including in the claims some detail of their invention not present in the prior art cited by the examiner, but also not present in the originally-filed specification. In such cases, the written description requirement prohibits the introduction of so-called "new matter" into the patent claims. Schering Corp. v. Amgen Inc., 222 F.3d 1347, 1352 (Fed. Cir. 2000). In other words, a limitation added to the claims by amendment must find "support" in the patent application as originally filed. Id.

That support may be a verbatim statement in the specification, but it need not be. Indeed, different language that expresses the same meaning found in the originally-filed specification may be sufficient. Fujikawa v. Wattanasin, 93 F.3d 1559, 1570 (Fed. Cir. 1996). In some cases, we have found that the originally-filed specification supports the added limitation inherently. Schering, 222 F.3d at 1352 ("The fundamental inquiry is whether the material added by amendment was inherently contained in the original application." (emphasis added)). We have used varied language to express the test for determining whether a claim limitation added by amendment is inherent in the originally-filed specification. E.g., Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1323 (Fed. Cir. 2000) ("[O]ne skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims." (emphasis added)); Tronzo v. Biomet, Inc., 156 F.3d 1154, 1159 (Fed. Cir. 1998) ("In order for a disclosure to be inherent, however, the missing descriptive matter must necessarily be present in the parent application's specification such that one skilled in the art would recognize such a disclosure." (emphasis added)); Fujikawa, 93 F.3d at 1570 ("[T]he disclosure need only reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question." (emphasis added)). No matter how the test is stated, there is a genuine issue here whether the "without coagulating" limitations were inherent in the '900 patent as originally filed.

We should dispel the notion that the failure of the PTO to issue a new matter rejection automatically creates an "especially weighty presumption" of compliance with the written description requirement. Although there is dictum in Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1574-75 (Fed. Cir. 1993), to that effect, compliance with the written description requirement is a factually intensive inquiry, Vas-Cath, 935 F.2d at 1561, and how much deference the PTO's actions deserve must be evaluated on a case-by-case basis. The

presumption is far from determinative, however, and we have on occasion invalidated patent claims for including new matter, despite the PTO's having allowed those claims. E.g., *Turbocare Div. of Demag Delaval Turbomach. v. Gen. Elec. Co.*, 264 F.3d 1111 (Fed. Cir. 2001); *Purdue Pharma*, 230 F.3d 1320; *Augustine Med., Inc. v. Gaymar Indus.*, 181 F.3d 1291 (Fed. Cir. 1999) (holding certain claims invalid over prior art after finding that those claims were not supported by an earlier-filed parent application); *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565 (Fed. Cir. 1997) (same).

In this case, the affidavit of Dr. Rapaport, stating that the “without coagulating” limitations were inherent in the '900 patent as originally filed, raises a genuine issue as to whether the presumption of compliance with the written description requirement can be overcome. The faults found by the district court in Rapaport's affidavit, while potentially detracting from the weight that his testimony deserved, do not constitute fatal flaws. For example, ICN's argument in the district court that inherency means “plausibly supports” is circumstantial evidence that Rapaport had the same legally incorrect meaning in mind; however, Rapaport does state a conclusion that on its face may, if believed, lead a reasonable fact-finder to conclude that the “without coagulation” limitations were “inherent” in the originally-filed '900 patent, under the proper legal standard. Further elucidation of what Rapaport meant when he used the word “inherent” is a topic for later exploration by deposition or cross-examination. As for now, his opinion that the limitations were simply “inherent” is sufficient to create a genuine issue of material fact.

The district court's criticism that Rapaport's opinion was conclusory and lacking in factual foundation is likewise a factor going to the weight of his testimony, not a fatal flaw. Unlike the inadequate expert testimony in *New Railhead Mfg. v. Vermeer Mfg.*, 298 F.3d 1290 1295-96 (Fed. Cir. 2002), which was entirely subjective and erroneously conflated the written description requirement with the enablement requirement, Rapaport's affidavit properly focused on the written description issue and testified as to what an objective dermatologist would understand from reading the '900 patent application when it was filed in 1997. Furthermore, unlike the inadequate expert testimony in *Lockwood*, 107 F.3d at 1572, which opined as to what were obvious variants of the disclosure, Rapaport's opinion is confined to what the '900 patent actually teaches. Finally, unlike the inadequate expert testimony in *Augustine*, 181 F.3d at 1303, which was not anchored to any application language pertaining to the limitations at issue, Rapaport cited specific passages in the '900 specification and explained that a dermatologist in 1997 would have interpreted them to mean that coagulation does not occur. That is sufficient to create a genuine issue of material fact. Further probing of his basis for the opinion is, again, a topic for later exploration as the case proceeds.

Cynosure's contention that the prosecution history indicates that the "without coagulating" limitations were not inherent in the '900 patent application at the time of filing is not convincing at this stage of the proceedings. Specifically, Cynosure contends that, by amending the claims to explicitly recite the "without coagulating" limitations, when the claims previously simply stated that the "basal layer remains intact," and by arguing that the added language distinguished the claimed invention over Eckhouse, ICN effectively admitted that the added language was not inherent in the original phrase "[the] basal layer remains intact." ICN responds that the amendment simply made explicit what had been implicit in the claim. ICN may be correct; if it prevails on the written description issue in this case, that result may be due to the fact that the phrase "[the] basal layer remains intact," in combination with other statements in the specification, inherently (*i.e.*, necessarily) means that blood is not coagulated in the vessels of the basal and dermal layers. That is a fact question that cannot be decided on summary judgment.

Cynosure's contention that if ICN's inherency argument is accepted, then Eckhouse inherently discloses the same limitations and thereby anticipates the claims, is also not now convincing. According to Cynosure, Eckhouse's teaching that the epidermis can be irradiated without causing it damage must inherently result, under ICN's theory of inherency, in a lack of blood coagulation in the epidermis. Cynosure might ultimately prevail on this argument, but the record is not adequately developed to decide at this point. Eckhouse seems to teach blood coagulation without damaging the epidermis, but the blood that Eckhouse coagulates is in deep tissue vessels, which apparently are below the basal and dermal skin layers. *See* '751 patent, col. 13, ll. 61-62 ("This concept was tested with large and deep vessels (of the order of 2 mm in diameter and 2 mm deep)."). Thus, ICN may have mischaracterized Eckhouse when it stated to the examiner during prosecution that Eckhouse is "directed to . . . coagulating (destroying) blood vessels in the dermal region." (emphasis added). It is quite possible that Eckhouse teaches the simultaneous lack of coagulation in and damage to the dermal and basal layers. However, as neither we nor the district court have before us a challenge to the validity of the '900 patent on the ground of anticipation by Eckhouse, that issue must await further proceedings. As for the written description issue presently before us, we decline to rule in favor of Cynosure on this point.

Finally, Cynosure's contention that lack of coagulation is a species unsupported by the specification's mention of skin damage as a broad genus is not convincing. While it is true that disclosure of a genus encompassing a large number of species is not a written description of all such species, *In re Ruschig*, 379 F.2d 990, 994 (CCPA 1967), the genus here is not very large. In the context of the '900 patent, "skin damage" is damage to the skin resulting from irradiation. A fact-finder could reasonably

understand Rapaport's testimony to mean that the absence of skin damage from a laser necessarily implies the absence of blood coagulation in the layers of the skin because blood coagulation is one of the well-known forms of tissue damage that irradiation can cause.

Because ICN has raised a genuine issue of material fact as to inherent support for the "without coagulating" limitations that were added to the '900 patent claims during prosecution, the court erred in granting summary judgment of invalidity. Accordingly, we reverse and remand for further proceedings.