NOTE: Pursuant to Fed. Cir. R. 47.6, this disposition is not citable as precedent. It is a public record.

United States Court of Appeals for the Federal Circuit

05-1545

MASSACHUSETTS EYE AND EAR INFIRMARY,

Plaintiff/Counterclaim Defendant-Appellant,

and

EVANGELOS S. GRAGOUDAS, M.D. and JOAN W. MILLER, M.D.,

Counterclaim Defendants-Appellants,

v.

NOVARTIS OPHTHALMICS, INC.,

Defendant-Appellee,

and

QLT, INC.,

Defendant/Counterclaimant-Appellee,

and

THE GENERAL HOSPITAL CORPORATION,

Intervenor-Appellee.

DECIDED: October 6, 2006

Before NEWMAN, MAYER, and LINN, Circuit Judges.

LINN, Circuit Judge.

Massachusetts Eye & Ear Infirmary ("MEEI"), Dr. Evangelos S. Gragoudas, and Dr. Joan W. Miller ("Dr. Miller") (collectively, "appellants") appeal from the judgment of the United States District Court for the District of Massachusetts, Case No. 01-CV-10747, granting Novartis Ophthalmics, Inc.'s, QLT, Inc.'s, and the General Hospital Corp.'s (collectively, "appellees") motion for partial summary judgment that Dr. Julia Levy (Dr. Levy) was a co-inventor of U.S. Patent No. 6,225,303 ("the '303 patent"). Mass. Eye & Ear Infirmary v. Novartis Ophthalmics, Inc., 353 F. Supp. 2d 170 (D. Mass. 2005) ("Inventorship Order"). Because we conclude that there are genuine issues of material fact with regard to whether Levy made a significant contribution to the 900 mW/cm^2 upper limit of the claimed irradiance range, we reverse the grant of partial summary judgment and remand for further proceedings.

I. BACKGROUND

MEEI is the owner of the '303 patent, which relates to a method of treating choroidal neovascularization ("CNV") by photodynamic therapy ("PDT"). CNV refers to the proliferation of unwanted, leaky new blood vessels in the choroid, a vascular layer underlying the retina. PDT is a procedure involving the administration of a photosensitive drug into the bloodstream, accumulation of the drug in the target tissue, and activation of the drug by light, causing photochemical destruction of the target tissue.

The ’303 patent issued from a continuation application claiming priority to an earlier patent application, filed jointly by researchers from MEEI, Massachusetts General Hospital, and QLT, which led to the issuance of U.S. Patent No. 5,798,349 (“the ’349 patent”). The ’349 patent lists as inventors Dr. Levy of QLT, Drs. Miller and Grougadas of MEEI, and Drs. Tayyaba Hassan and Ursula Schmidt-Erfurth of intervenor General Hospital Corp. Only Drs. Miller and Gragoudas of MEEI are named as inventors on the ’303 patent.

The written descriptions of the ’303 patent and the ’349 patent are identical. The claims of the ’303 patent include an irradiance range of “about 300 mW/cm^2 to about 900 mW/cm^2” that results in a “shortened treatment time.” ’303 patent, col. 15, ll. 20-28. The United States Patent and Trademark Office (“PTO”) initially rejected, on obviousness-type double patenting grounds, the patent application that resulted in the ’303 patent. In response, MEEI pointed out to the examiner that the claims of the ’349 patent made no reference to the irradiance of the laser light or to the length of the treatment time. The PTO, in turn, suggested that MEEI amend the pending claims to add the phrase “in a shortened treatment time” and MEEI accepted the change. The PTO thereafter issued the ’303 patent.

On May 1, 2001, MEEI sued QLT and Novartis Ophthalmics for infringement of the ’303 patent. QLT filed a counterclaim alleging, among other things, correction of inventorship under 35 U.S.C. § 256 to add the researchers of Massachusetts General Hospital and QLT as co-inventors. After the close of discovery, Massachusetts General Hospital and QLT filed a joint motion for correction of inventorship and sought summary judgment on that issue. QLT submitted a statement of undisputed facts pursuant to

Local Rule 56.1. MEEI "did not dispute" some of the facts, but contested the "characterization of those facts."

On January 25, 2005, the district court issued a Memorandum and Order on Massachusetts General Hospital's and QLT's joint motion, concluding that Dr. Levy had contributed significantly to the upper end of the irradiance range claimed in the '303 patent, and treating MEEI's failure to controvert the facts in the statement of undisputed facts as admissions. Inventorship Order, 353 F. Supp. 2d at 174-75. Subsequently, MEEI filed a motion to amend its response to paragraphs 115 and 120 of QLT's statement of undisputed facts to replace the phrase "does not dispute" with "denies." The district court denied the motion. Pursuant to Rule 54(b), the district court entered final judgment on July 14, 2005.

The appellants timely appeal to this court. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

II. ANALYSIS

A. Standard of Review

"We review a district court's grant of summary judgment de novo." 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). "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). Inventorship is a question of law that we review without deference. Caterpillar, Inc. v. Sturman Indus., 387 F.3d 1358, 1376 (Fed. Cir. 2004).

B. Discussion

The appellants argue that the district court erred in granting summary judgment because there is a genuine issue of material fact as to whether Levy made a significant contribution to the conception before it was complete. Specifically, the appellants argue that the district court erred in concluding that the conception of the invention by Drs. Miller and Gragoudas was not complete in 1992, and that there was nothing significant about the 900 mW/cm^2 irradiance value. The appellants further argue that the district court erred by concluding that there was clear and convincing evidence of sufficient corroboration. Finally, MEEI argues that the district court abused its discretion in denying its motion to clarify its factual responses.

The appellees respond that based upon undisputed facts, the district court correctly determined that Dr. Levy contributed significantly to the conception of the claimed irradiance range. Specifically, the appellees argue that MEEI admitted that Dr. Levy was the first to propose using an irradiance of 900 mW/cm^2. The appellees further argue that Dr. Levy's contribution to the claimed irradiance range is sufficiently corroborated, based on MEEI's admission and on additional evidence including the contemporaneous documentary record. Finally, the appellees argue that the district court did not abuse its discretion in denying MEEI's motion to amend its response.

The district court concluded that "the undisputed facts clearly and convincingly show[ed] that Dr. Levy conceived of the upper end of the irradiance range."

Inventorship Order, 353 F. Supp. 2d at 176. However, in doing so, the district court failed to appreciate the presence of a number of genuine issues of material fact. First, the district court failed to consider the fundamental question of whether the named inventors had already conceived of a broader range including the 900 mW/cm^2 upper limit recited in the claims. If they had, then the district court would have had to consider the question of whether the claimed narrower range is of any consequence, and thus whether any contribution by Dr. Levy of that upper limit reflects an inventive "contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention." Acromed Corp. v. Sofamor Danek Group, Inc., 253 F.3d 1371, 1379 (Fed. Cir. 2001) (internal quotations omitted).

As to the 900 mW/cm^2 upper end of the irradiance range, the district court based its conclusion on the following four "undisputed" facts: (1) Dr. Levy insisted that Dr. Miller test 900 mW/cm^2; (2) Dr. Miller had never tested 900 mW/cm^2 before collaborating with QLT; (3) 900 mW/cm^2 became the upper end of the irradiance range claimed in independent claims 1 and 9 of the '303 patent; and (4) 900 mW/cm^2 is the highest irradiance level at which a practitioner may safely administer PDT in the manner claimed by the '303 patent. Id.

The appellants do not dispute facts (2) and (3) stated above. Regarding fact (1), paragraph 115 of QLT's statement of undisputed facts states that "Levy insisted that the protocol evaluate four different irradiance levels, including 900 mW/cm^2." MEEI's response to paragraph 115 stated that "MEEI does not dispute the 'facts' set forth in ¶ 115," but it noted its disagreement with QLT's characterization of the those facts.

Consistent with the language of Local Rule 56.1, which states that "[m]aterial facts of record set forth in the statement . . . will be deemed for purposes of the motion to be admitted by the opposing parties unless controverted by the statement required to be served by opposing parties," the district court did not err in concluding that MEEI admitted the facts set forth in ¶ 115. See Stonkus v. City of Brockton Sch. Dep't, 332 F.3d 97, 102 (1st Cir. 2003). Further, we cannot say that the district court abused its discretion in denying MEEI's motion to amend its response. See Ramsdell v. Bowles, 64 F.3d 5, 7 (1st Cir. 1995) (acknowledging the district court's great leeway in the application and enforcement of its local rules). Nevertheless, MEEI's admission is restricted to the specific statement in ¶ 115, namely that Levy insisted that the protocol evaluate four different irradiance levels, including 900 mW/cm^2. The mere insistence by Dr. Levy does not, as the district court concluded, "show that the parties do not dispute that QLT's Dr. Levy contributed to the conception of the upper end of the 300 mW/cm^2 to 900 mW/cm^2 irradiance range." Inventorship Order, 353 F. Supp. 2d at 174.

Regarding (4), the district court's conclusion that 900 mW/cm^2 was the highest irradiance level at which a practitioner may safely administer PDT was based in part on its assessment that the 1992 experiments using 1200 mW/cm^2 and 1800 mW/cm^2 were unsuccessful. See id. at 178. The appellants, citing Miller's submissions to QLT, contend that Miller recognized that irradiances as high as 1200 mW/cm^2 were both safe and effective. Drawing inferences in favor of the appellants, there is a genuine issue of material fact regarding the highest irradiance level at which a practitioner may safely administer PDT. Moreover, there is no evidence to suggest what level of damage

caused at high irradiance levels renders the PDT "unsafe." These are questions that remain for resolution at trial.

As to the significance of the 900 mW/cm^2 upper limit, although the appellants do not dispute the fact that Dr. Miller had never tested at the specific value of 900 mW/cm^2, they contend that her first set of experiments in 1992 involved performing PDT at specific irradiances of 300 mW/cm^2, 600 mW/cm^2, 1200 mW/cm^2, and 1800 mW/cm^2. The appellants contend that on the basis of these experiments, Dr. Miller concluded that irradiances up to 1200 mW/cm^2—including the specific irradiance value of 900 mW/cm^2—were useful for PDT treatment of age-related macular degeneration. Thus, the appellants argue that Dr. Levy's insistence on evaluating at 900 mW/cm^2 was not a significant, and thus inventive, contribution because the testing conducted by Drs. Miller and Gragoudas in 1992 on healthy animals evinced conception of the entire irradiance range prior to any suggestion of testing at the claimed upper limit of 900 mW/cm^2. The appellees, on the other hand, contend that because the 1992 experiments involved monkeys with normal choroidal vessels, they could not demonstrate closure of CNV. Thus, the appellees argue that Dr. Levy's insistence on testing at 900 mW/cm^2 was a significant contribution. The district court improperly determined that because "900 mW/cm^2 is the upper limit claimed in the '303 patent, the critical inquiry is whether Dr. Miller or Dr. Levy conceived of this specific figure." The upper limit of the claim is nothing more than that. The suggestion of an upper limit of a claim limitation does not necessarily constitute an inventive contribution if the upper limit is contained within a previously conceived broader range and is of no demonstrated significance. See Burroughs Wellcome Co. v. Barr Labs., Inc.., 40 F.3d 1223, 1229 (Fed. Cir. 1994)

(noting that "each inventor must contribute to the joint arrival at a definite and permanent idea of the invention as it will be used in practice"). Further, the district court's reliance on the testimony of MEEI's patent law expert to support its conclusion that Dr. Levy made a significant contribution is misplaced. The patent law expert testified that a proposed experiment to test 200 mW/cm^2, 250 mW/cm^2, 300 mW/cm^2, and 600 mW/cm^2 could not serve as the basis for conception of a range of 300 mW/cm^2 to 900 mW/cm^2 because the experiments did not test beyond 600 mW/cm^2. Based on this testimony, the district court improperly concluded that an inventor must actually test at 900 mW/cm^2 to conceive a range of 300 mW/cm^2 to 900 mW/cm^2. Testing at exactly the end points of a range is not necessarily required for a conception of that range. See Ralston Purina Co. v. Far-Mar-Co, Inc., 772 F.3d 1570, 1575 (Fed. Cir. 1985) (holding that ranges found in an applicant's claims need not correspond exactly to those disclosed in a parent application).

Because a trier of fact could conclude that Dr. Miller's 1992 tests amounted to a conception of the full irradiance range claimed, thus rendering any contribution by Dr. Levy of the claimed upper limit of no inventive consequence, the district court's grant of summary judgment was in error.

III. CONCLUSION

In sum, we conclude that summary judgment was incorrectly granted based on the presence of genuine issues of material fact as to both the significance of the 900 mW/cm^2 upper limit and the contribution, if any, made my Dr. Levy with respect thereto. Accordingly, we reverse the grant of partial summary judgment and remand to the district court for further proceedings.

IV. COSTS

No costs.