460 F.3d 1365
United States Court of Appeals,
Federal Circuit.

COOK BIOTECH INCORPORATED,
Plaintiff–Cross Appellant,
and
Purdue Research Foundation,
Plaintiff–Cross Appellant,
v.
ACELL, INCORPORATED, Stephen F. Badylak and Alan R. Spievack, Defendants–Appellants.

Nos. 05–1458, 05–1558, 05–1559.
|
Aug. 18, 2006.
|
Rehearing and Rehearing En Banc Denied Oct. 18, 2006.

Synopsis

Background: Patent holder brought action for infringement of patents for a tissue composition used as a scaffold for tissue reconstruction. The United States District Court for the Northern District of Indiana, Allen Sharp, J., 2005 WL 2136107, 2005 WL 1500301, ruled that the patents was infringed and that the patent holder's employee was not a co-inventor of alleged infringer's patent. Parties appealed.

Holdings: The Court of Appeals, Prost, Circuit Judge held that:

[1] alleged infringer's product did not literally infringe patent;

[2] patent was not infringed under the doctrine of equivalents; and

[3] patent holder's employee was not a co-inventor.

Affirmed in part and reversed in part.

Attorneys and Law Firms

***1367** Daniel J. Lueders, Woodard, Emhardt, Moriarty, McNett & Henry LLP, of Indianapolis, Indiana, argued for plaintiff-cross appellant, Cook Biotech Incorporated. With him on the brief was Holiday W. Banta.

William P. Kealey, Stuart & Branigin LLP, of Lafayette, Indiana, argued for plaintiff-cross appellant, Purdue Research Foundation.

J. Alan Galbraith, Williams & Connolly LLP, of Washington, DC, argued for defendants-appellants. With him on the brief were Thomas H.L. Selby, Shruti Rana, and Jessamyn S. Berniker.

Before NEWMAN, LOURIE, and PROST, Circuit Judges.

Opinion

PROST, Circuit Judge.

Defendant-appellants, ACell, Inc. ("ACell"), Stephen F. Badylak, and Alan R. Spievack appeal the decision of the United States District Court for the Northern District of Indiana denying ACell's post-trial motions pertaining to claim construction, infringement, and the adequacy of the jury verdict form following the jury's finding that ACell's commercial product, ACell Vet ™, infringed U.S. Patent No. 5,554,389 (the "'389 patent") owned by Purdue Research Foundation and that Drs. Badylak and Spievack willfully induced ACell to infringe. *Cook Biotech Inc. v. ACell, Inc.*, No. 4:03–CV–0046 AS, 2005 WL 2136107 (N.D.Ind. Aug.17, 2005) ("*Post–Trial Order* "). Plaintiffs-appellees, Cook Biotech Inc. and Purdue Research ***1368** Foundation (respectively, "Cook" and "PRF"; collectively, "appellees" or "cross-appellants"), cross-appeal the district court's grant of summary judgment with respect to inventorship and the district court's denial of their post-trial motions pertaining to willful infringement and whether any relief should have been awarded following the jury's finding of infringement. Because the district court erred in its claim construction which formed the basis for the jury's finding of infringement and because, under the correct construction, there is no material factual dispute that the ACell Vet ™ product cannot infringe claims 1, 7, and 8 of the '389 patent literally or under the doctrine of equivalents, the judgment of infringement is reversed. As a result, the issues raised in Cook's cross-appeal pertaining to its willful infringement case and its requests for relief following the jury verdict in its favor are rendered moot.

Finally, because the district court did not err in determining on summary judgment that (1) Dr. Badylak is not a co-inventor of U.S. Patent No. 6,576,265 (the " '265 patent"), (2) Dr. Spievack is an inventor of the '265 patent, and (3) PRF's unjust enrichment claim must fail, we affirm the district court's rulings with respect to those issues as raised in PRF's cross-appeal.

I. BACKGROUND

A. Factual Background

1. Dr. Badylak's activities and the '389 patent

Dr. Badylak was employed by Purdue University from 1977 until October 6, 2002. In the mid–1980s, Dr. Badylak and others in his laboratory at Purdue University discovered that certain tissue compositions could be used as scaffolds for tissue reconstruction. As advancements were made using these tissue compositions, now known as extracellular matrices or ECMs, the tissues came to be categorized according to the source of the tissue, e.g., small intestinal submucosa ("SIS"), stomach submucosa, liver basement membrane, urinary bladder submucosa ("UBS"), and urinary bladder matrix ("UBM"). The two organ tissue sources relevant to this case are UBS and UBM.

The '389 patent, entitled "Urinary Bladder Submucosa Derived Tissue Graft," issued on September 10, 1996. The '389 patent is directed to a urinary bladder submucosa derived tissue graft composition comprising bladder submucosal tissue "delaminated from the abluminal muscle layers and at least the luminal portion of the tunica mucosa of the urinary bladder tissue, " '389 patent, col. 1, ll. 56–58, that can be implanted to replace or support damaged or diseased tissues. Claim 1 of the '389 patent is representative of the claims at issue:

> 1. A composition comprising *urinary bladder submucosa* delaminated from both the abluminal muscle layers and at least the luminal portion of the tunica mucosa of a segment of a urinary bladder of a warm blooded vertebrate.

'389 patent, col. 5, ll. 20–23 (emphasis added).

The '389 patent names four inventors, one of whom is Dr. Badylak. Pursuant to his employment contract, Dr. Badylak assigned the '389 patent and the rights to other patents on inventions he had developed to PRF. On February 9, 2003, PRF granted Cook an exclusive license with respect to many of its patents in this field of tissue engineering, including the '389 patent for all non-orthopedic and non-cardiac applications.

2. Dr. Spievack, the '265 patent, and ACell

Dr. Spievack, a Harvard University professor and surgeon, developed an interest ***1369** in the regenerative capabilities of the epithelial basement membrane during his studies as a Fulbright scholar in the 1950s. In early 1996, Dr. Spievack first met Dr. Badylak at a conference during a presentation given by Dr. Badylak pertaining to SIS.

According to Dr. Spievack, in March 1996, he tested techniques for removing various tissue layers of the bladder wall and in July of that year, he successfully treated poison ivy on one of his legs with a bladder basement membrane composition. Dr. Spievack testified that between February and October 1996, he did not discuss the results of his basement membrane tests with Dr. Badylak, but from the end of 1996 through the end of 1999, he visited Dr. Badylak at Purdue University and discussed his work on graft compositions.

Beginning in 1998, Dr. Spievack sought to obtain a license from PRF for non-SIS products. When PRF ultimately turned him down, Dr. Spievack continued to work on what he considers to be his own UBM technology. In 1999, Dr. Spievack formed ACell, Inc. to research and develop extracellular matrix technology. On December 22 of that year, Dr. Spievack filed a provisional application on a UBM composition, which led to the issuance of two patents naming him as the sole inventor, the '265 patent and U.S. Patent No. 6,579,538 (the " '538 patent"). The term UBM first appeared in the '265 patent, which issued on June 10, 2003. UBM refers to a matrix of tissues including the basement membrane and tunica propria of the urinary bladder of a mammal. The '265 patent discloses and claims, inter alia, a tissue graft composition including the epithelial basement membrane.

On August 27, 2002, while the '265 patent was still pending, PRF asked the United States Patent and Trademark Office (the "PTO") to declare an interference pursuant to 37 C.F.R.

§ 1.47(a). In its petition, PRF asserted that four other individuals, including Dr. Badylak, were co-inventors with Dr. Spievack of the invention claimed in the '265 patent. [1]

The accused product, ACell Vet ™, is sold by ACell in three forms: hydrated, lyophilized, and powdered. Since the issuance of the '265 patent, ACell has represented that its product includes the epithelial basement membrane as disclosed and claimed in the '265 patent.

B. Procedural History

1. Appellees' infringement case

Cook and PRF sued ACell for, inter alia, patent infringement of claims 1, 7, and 8 of the '389 patent, correction of inventorship for a number of issued patents [2] (collectively, the "Disputed Patents"), and common law unjust enrichment for the research and inventions disclosed in the Disputed Patents. On September 4, 2003, appellees moved for a preliminary injunction, seeking to enjoin the sale of ACell Vet ™. The district court denied the motion based on the record before it, preliminarily finding that claim 1 of the '389 patent "does not ... extend beyond an essentially submucosa composition," and emphasized that its findings were based on a preliminary record and were not intended to be a *Markman* ***1370** ruling on claim construction. *Cook Biotech Inc. v. ACell, Inc.,* No. 4:03–CV–0046 AS, slip op. at 10 (N.D.Ind. Dec.22, 2003).

After conducting a *Markman* hearing, during which the district court solicited the parties' proposed constructions in the form of jury instructions, the district court adopted appellees' proposed instructions. *See Cook Biotech Inc. v. ACell, Inc.,* No. 4:03–CV–0046 AS (N.D.Ind. Oct.25, 2004) ("*Markman Order* "). Of particular relevance, the district court rejected ACell's proposed construction for "urinary bladder submucosa" and "at least the luminal portion of the tunica mucosa" and adopted appellees' proposed construction of the phrase "at least the luminal portion of the tunica mucosa." The district court rejected ACell's proposed construction of "urinary bladder submucosa" because it believed that the invention disclosed in the '389 patent was broad enough to include compositions that contained tissues other than submucosa. *Id.,* slip op. at 9–10. Further, because the district court believed that ACell's proposed construction of "urinary bladder submucosa" would rewrite the claims (i.e., change an open transition, comprising, into a closed transition, consisting essentially of), it was unwilling to accept that construction. The district court was also convinced by the evidence presented at the hearing and the ordinary meaning of the tunica mucosa that "the luminal portion of the tunica mucosa" refers only to the epithelial cells. *Id.,* slip op. at 10–11.

On June 17, 2005, the district court considered a motion by appellees seeking summary judgment of patent infringement or, in the alternative, partial summary judgment that the only issue remaining for the jury with respect to whether ACell infringes claims 1, 7, and 8 of the '389 patent is whether ACell's product contains submucosa. Based on the submissions of the parties, the district court granted appellees' alternative motion for partial summary judgment leaving only one issue for trial with respect to infringement of those claims: whether the ACell product contained any urinary bladder submucosa. [3] Accordingly, the district court instructed the jury that appellees must prove

> [t]hat it is more likely than not that ... [ACell's] product includes any amount of submucosa. In making this determination you should keep in mind that submucosa, as I have defined it, does not require any particular amount of submucosa, and that the presence of any submucosa in the ACell product requires a finding of infringement.
>
> In response, the jury returned a verdict finding that ACell infringed claims 1, 7, and 8 of the '389 patent, but found that the infringement was not willful.

With respect to damages, on the first day of trial, the district court granted ACell's motion in limine seeking to preclude appellees from presenting lost profits damages to the jury because the district court found that appellees failed to establish an "appropriate record" with respect to damages sufficient to raise a jury issue. That ruling effectively precluded appellees from obtaining damages because they had sought only lost profits damages, and not a reasonable royalty. Thus, even though the jury returned a verdict in their favor, appellees were not awarded any damages.

Following the judgment, both parties filed post-trial motions. ACell moved the ***1371** district court to amend the judgment after this court issued its opinion in *Phillips v. AWH Corp.,* 415 F.3d 1303 (Fed.Cir.2005) (en banc). ACell contended that this court's decision in *Phillips* made it clear that ACell's proposed claim constructions were correct and that a product that did not remove the lamina propria, basement

membrane, and epithelial cells could not infringe the '389 patent. Appellees filed post-trial motions for lost profits damages, willfulness as a matter of law, and attorney fees. While the district court denied the parties' motions, it also stayed enforcement of a permanent injunction because it found that this court's decision in *Phillips* "raises enough doubt at this point under these under [sic] the totality of the circumstances of this case to cause this court to stay its hand and grant the stay of enforcing a permanent injunction pending the appeal in this case." *Post–Trial Order,* slip op. at 3.

2. PRF's Case and Inventorship

The district court also considered several motions for summary judgment relating to inventorship issues filed by appellees and ACell. Specifically, appellees sought to establish on summary judgment that Dr. Badylak is a joint inventor of the '265 patent. Appellees alleged that Dr. Badylak collaborated with Dr. Spievack in developing the urinary bladder as a tissue graft composition as claimed in the '265 patent, and that because Dr. Badylak is under an obligation to assign the inventions he made while at Purdue to PRF, PRF is a rightful owner of the '265 patent. ACell filed its own summary judgment motion on Count IV ("unjust enrichment") of PRF's complaint and a partial summary judgment motion on Counterclaim Counts I ("rights to technology") and II ("inventorship").

The district court first noted that appellees had failed to assert that Dr. Badylak is the sole inventor of the '265 patent in their complaint, their interrogatory responses, and the Pretrial Order. Instead, the district court found that appellees' assertions were limited to "omitted" inventors. Thus, the district court precluded appellees from asserting that Dr. Badylak was the sole inventor or that Dr. Spievack was not a proper inventor of the '265 patent because of those failures.

Second, the district court found that appellees had failed to present clear and convincing evidence that Dr. Badylak contributed in some significant manner to the conception of the invention claimed in the '265 patent. In reaching that conclusion, the district court began its analysis with the presumption that the named inventors on a patent are correct, and also found that: (1) Dr. Badylak had filed papers under oath with the PTO in which he denied inventorship of the '265 patent; (2) the evidence demonstrated that Dr. Spievack conceived and reduced to practice the invention claimed in the '265 patent; (3) Dr. Spievack had completed the invention claimed in the '265 patent by the summer of 1996 when he successfully treated his poison ivy with it; and (4) any discussions between Drs. Badylak and Spievack after the summer of 1996 were irrelevant to the issue of inventorship because Dr. Spievack conceived the '265 patented invention by that summer.

Finally, the district court found that the deposition excerpts cited by appellees, in support of their assertion that Dr. Spievack discussed the use of the basement membrane as a tissue graft material with Dr. Badylak at the 1996 conference, "fail[ed] to show that [Dr.] Badylak contributed anything to [Dr.] Spievak's [sic] conception of the invention, let alone that [Dr.] Badylak contributed 'in some significant manner' " as required by our holding in ***1372** *BJ Services Co. v. Halliburton Energy Services, Inc.,* 338 F.3d 1368, 1373 (Fed.Cir.2003). *Cook Biotech Inc. v. ACell, Inc.,* No. 4:03–CV–0046 AS, slip op. at 9 (N.D.Ind. June 22, 2003) ("*Inventorship Order* "). Because the district court found that appellees' evidence failed to meet the clear and convincing evidence standard to correct inventorship, it denied appellees' motion for summary judgment that Dr. Badylak was a co-inventor of the '265 patent.

In considering ACell's partial summary judgment motion on Counterclaim Counts I ("rights to technology") and II ("inventorship"), the district court noted that it interpreted ACell's motion as a request for a declaration to the effect that Dr. Spievack is an inventor of the '265 patent. Relying on its previous determinations with respect to inventorship, the district court granted ACell's motion for a declaration that Dr. Spievack is an inventor of the '265 patent. *See infra* Part II.B.4.

With respect to ACell's motion for summary judgment on appellees' Counterclaim Count IV ("unjust enrichment") under Indiana law, the district court found that because the rights of the parties were controlled by an express contract, recovery could not be based upon a theory implied in law, e.g., unjust enrichment. Additionally, the district court found that appellees' chosen remedy, assuming they could prove unjust enrichment, of a constructive trust was not available because they failed to assert either actual or constructive fraud in their complaint.

ACell appeals the district court's construction of "urinary bladder submucosa" and "at least the luminal portion of the tunica mucosa," the jury's findings of infringement of claims

1, 7, and 8 of the '389 patent, and the adequacy of the verdict form. Cook cross-appeals several rulings by the district court with respect to its willfulness case and the district court's decision to stay an award of a permanent injunction until after appeal to this court. PRF cross-appeals several of the district court's rulings pertaining to inventorship and its dismissal of PRF's unjust enrichment claim. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

II. DISCUSSION

A. Standard of Review

We review a district court's grant of summary judgment de novo, reapplying the standard applicable at the district court. *Rodime PLC v. Seagate Tech., Inc.,* 174 F.3d 1294, 1301 (Fed.Cir.1999). Summary judgment is appropriate when it has been shown "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); *Scaife v. Cook County,* 446 F.3d 735, 739 (7th Cir.2006).

We review the district court's denial of a motion for JMOL de novo. *Harris Corp. v. Ericsson Inc.,* 417 F.3d 1241, 1248 (Fed.Cir.2005). A court may grant JMOL on an issue when "there is no legally sufficient evidentiary basis for a reasonable jury to find for [the nonmoving] party on that issue ...." Fed.R.Civ.P. 50(a)(1).

[1] Determining infringement generally requires two steps. "First, the claim must be properly construed to determine its scope and meaning. Second, the claim as properly construed must be compared to the accused device or process." *Carroll Touch, Inc. v. Electro Mech. Sys., Inc.,* 15 F.3d 1573, 1576 (Fed.Cir.1993).

[2] **[3]** **[4]** Claim construction is an issue of law that we review de novo. *Cybor Corp. v. FAS Techs., Inc.,* 138 F.3d 1448, 1456 (Fed.Cir.1998) (en banc); *Markman v. Westview Instruments, Inc.,* 52 F.3d 967, 979 (Fed.Cir.1995) (en banc), *aff'd,* 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). "When interpreting claims, we inquire into how a person of ordinary skill in ***1373** the art would have understood [the] claim terms at the time of the invention." *Pfizer, Inc. v. Teva Pharms. USA, Inc.,* 429 F.3d 1364, 1372–73 (Fed.Cir.2005) (citing *Phillips,* 415 F.3d at 1313). "The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation." *Id.* "Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* "[O]ur cases recognize that the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips,* 415 F.3d at 1316.

[5] **[6]** Infringement, whether literal or under the doctrine of equivalents, is a question of fact. *Bai v. L & L Wings, Inc.,* 160 F.3d 1350, 1353 (Fed.Cir.1998). The proper inquiry is whether the evidence is such that a reasonable jury could return a verdict for the non-movant. *See Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 252, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). We must draw all justifiable inferences in favor of the non-movant. *Id.* When a district court's determination of infringement is premised on an erroneously construed claim, however, that determination is not entitled to deference. *Playtex Prods., Inc. v. Procter & Gamble Co.,* 400 F.3d 901, 906 (Fed.Cir.2005) (citing *Elkay Mfg. Co. v. Ebco Mfg. Co.,* 192 F.3d 973, 976 (Fed.Cir.1999)).

[7] **[8]** Evidentiary rulings are generally not unique to patent law and therefore we review them under the law of the regional circuit. *Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc.,* 265 F.3d 1294, 1308 (Fed.Cir.2001). The Seventh Circuit reviews a district court's evidentiary rulings for an abuse of discretion. *Wollenburg v. Comtech Mfg. Co.,* 201 F.3d 973, 977 (7th Cir.2000) (citations omitted).

[9] **[10]** **[11]** Generally, inventorship is a question of law that is reviewed de novo, subject to review of underlying factual findings for clear error. *Univ. of Colo. Found., Inc. v. Am. Cyanamid Co.,* 342 F.3d 1298, 1308–09 (Fed.Cir.2003). However, where the inventorship issues were resolved on summary judgment, "such factual inferences as are material to the grant [of summary judgment] are not reviewed under the clearly erroneous standard, as if they were findings of fact made following a trial of issues[,]" *Lemelson v. TRW, Inc.,* 760 F.2d 1254, 1260 (Fed.Cir.1985), but rather are reviewed de novo, reapplying the standard applicable at the district court, *see Rodime PLC,* 174 F.3d at 1301 (Fed.Cir.1999). "[T]o be a joint inventor, an individual must make a contribution to the conception of the claimed invention that is not insignificant in quality," and the inventors must "have some open line of communication during or in temporal

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