

# United States Court of Appeals for the Federal Circuit

05-1458, -1558, -1559

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.

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.

Appealed from: United States District Court for the Northern District of Indiana

Judge Allen Sharp

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DECIDED: August 18, 2006

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Before NEWMAN, LOURIE, and PROST, Circuit Judges.

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 (N.D. Ind. Aug. 17, 2005) (Post-Trial Order). Plaintiffs-appellees, Cook Biotech Inc. and Purdue Research 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 wilful 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 wilful 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 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.<sup>1</sup>

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<sup>2</sup> (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

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<sup>1</sup> Although the actions to initiate the interference were discussed by the parties, the ultimate resolution of the proceeding, if one in fact occurred, has not been the subject of the parties' briefs before us.

<sup>2</sup> PRF sought correction of inventorship and ownership for the '265 patent and eleven other patents that claim priority to the December 22, 1999 filing date of the provisional patent application that resulted in the '265 patent including U.S. Patent Nos. 6,579,538, 6,783,776, 6,849,273, 6,852,339, 6,861,074, 6,869,619, 6,887,495, 6,890,562, 6,890,563, 6,890,564, 6,893,666.

composition,” and emphasized that its findings were based on a preliminary record and were not intended to be a Markman 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.<sup>3</sup> 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 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

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<sup>3</sup> Apparently based on its rejection of ACell's proposed construction for claim 8, the district court did not require, as part of appellees' infringement case, that they prove that the accused ACell Vet™ product could in fact "induce endogenous connective tissue growth" as required by claim 8.

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 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).

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).

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 (1996). "When interpreting claims, we inquire into how a person of ordinary skill in 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.

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 (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)).

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).

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 proximity to their inventive efforts . . . .” Eli Lilly & Co. v. Aradigm, 376 F.3d 1352, 1358-59 (Fed. Cir. 2004).

Assignment of ownership is governed by state law doctrines. Univ. of Colo., 342 F.3d at 1308.

## B. Analysis

### 1. Claim Construction

#### a. “urinary bladder submucosa”

ACell asserts that the district court erred in construing the term “urinary bladder submucosa” in claims 1, 7, and 8 of the ’389 patent. ACell asserts that the PTO did not grant the ’389 patent inventors a patent to the naturally occurring submucosa layer of a urinary bladder, but rather that it granted them a patent covering a tissue graft composition derived from that layer. ACell argues that the ’389 specification makes

clear that “urinary bladder submucosa” is a defined term which was defined to expressly exclude other urinary bladder tissue layers, specifically the abluminal muscle cell layers and at least the luminal portion of the tunica mucosa layer.

Cook argues that the '389 patent specification, specifically in the “DETAILED DESCRIPTION OF THE INVENTION” section, teaches that the term “urinary bladder submucosa” is broader than ACell’s proposed construction because it states that the resulting composition “typically” consists essentially of urinary bladder submucosa. Cook thus asserts that the use of “typically” implies that there is another possible embodiment of the claimed composition that merely comprises urinary bladder submucosa, but may also include other tissues.

As noted above, claim 1 recites: “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 specification, in the “BACKGROUND AND SUMMARY OF THE INVENTION” section, states that “[u]rinary bladder submucosa for use in accordance with the present invention is delaminated from the abluminal muscle layers and at least the luminal portion of the tunica mucosa of the urinary bladder tissue.” Id. at col. 1, ll. 55-58 (emphasis added). The first paragraph of the “DETAILED DESCRIPTION OF THE INVENTION” section states:

The tissue graft or composition in accordance with the present invention comprises urinary bladder submucosa of a warm-blooded vertebrate delaminated from adjacent bladder tissue layers. The present tissue graft composition thus comprises the bladder submucosa delaminated from abluminal muscle cell layers and at least the luminal portion of the mucosal layer of a segment of urinary bladder of a warm-blooded

vertebrate. Typically the delamination technique described below provides a tissue composition consisting essentially of urinary bladder submucosa. These compositions are referred to herein generically as urinary bladder submucosa (UBS).

Id. at col. 2, ll. 1-4 (emphases added).

"[T]he 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. We believe that this is exactly what the '389 patentees did in this case. As the above quoted portions of the specification indicate, the composition invented was defined to be "urinary bladder submucosa delaminated from abluminal muscle cell layers and at least the luminal portion of the tunica mucosa of the urinary bladder tissue." See, e.g., '389 patent, col. 1, ll. 56-58. The specification also indicates that the resulting composition "typically" consists essentially of urinary bladder submucosa. Thus, while the composition clearly includes urinary bladder submucosa, it may also include other tissues, such as the non-luminal portion of the tunica mucosal layer. However, it cannot include that which was expressly excluded in the patentees' definition, i.e., the "abluminal muscle cell layers and at least the luminal portion of the tunica mucosa." Therefore, we construe "urinary bladder submucosa" as it is defined in the '389 patent specification to mean "urinary bladder submucosa delaminated from the abluminal muscle cell layers and at least the luminal portion of the tunica mucosa of the urinary bladder tissue," and it thus becomes necessary to determine which tissue layers are encompassed by the phrase "at least

the luminal portion of the tunica mucosa.”<sup>4</sup>

b. “the luminal portion of the tunica mucosa”

ACell argues that the district court erred in construing the term “the luminal portion of the tunica mucosa.” ACell asserts that this term was defined by the patentee through the ’389 patent’s incorporation by reference of the procedure for preparing intestinal submucosa as detailed in U.S. Patent No. 4,902,508 (the “508 patent”). According to ACell, the ’508 patent specification defines “the luminal portion of the tunica mucosa” as “layer G” which includes the lamina epithelialis mucosa (or the epithelium layer) and its lamina propria. Thus, ACell asserts that the term “the luminal portion of the tunica mucosa” in the ’389 patent should be given the same meaning, i.e., the epithelium layer and the tunica propria<sup>5</sup> layer.

Appellees argue in response that the phrase “at least the luminal portion of the tunica mucosa” does not require a special definition and accuse ACell of “fishing” for a special definition. Further, appellees assert that there is no basis for importing a definition, even assuming the term is defined as ACell alleges, of the term from the ’508 patent into the ’389 patent because the ’508 patent is directed to SIS whereas the ’389 patent is directed to UBS. Appellees assert that the district court’s construction of the term as “the epithelial cells” should be affirmed.

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<sup>4</sup> Because the parties’ dispute does not involve the phrase “abluminal muscle cell layers,” we do not address which tissue layers are referenced by that language.

<sup>5</sup> The parties and patents at issue refer to this layer as the tunica or lamina propria and either reference is understood to refer to the same tissue layer.

The phrase “urinary bladder submucosa” is present in all three claims at issue. Based on our construction of that term as meaning “urinary bladder submucosa delaminated from . . . at least the luminal portion of the tunica mucosa,” our construction of “the luminal portion of the tunica mucosa” applies to all three claims with equal force. We begin with the representative claim language from claim 1 of the ’389 patent, which states:

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 (emphases added). The ’389 patent specification informs our inquiry into the meaning of the claims. The “BACKGROUND AND SUMMARY OF THE INVENTION” section discloses that “[t]he wall of the urinary bladder is composed of the following layers: the tunica mucosa (including a transitional epithelium layer and the tunica propria), a submucosa layer, up to three layers of muscle and the adventitia (a loose connective tissue layer)—listed in thickness crossection from luminal to abluminal sides.” Id. at col. 1, ll. 49-55. The “DETAILED DESCRIPTION OF THE INVENTION” section sheds considerable light on the issue before us. It states:

The preparation of UBS from a segment of urinary bladder is similar to the procedure for preparing intestinal submucosa detailed in U.S. Patent No. 4,902,508, the disclosure of which is expressly incorporated herein by reference. A segment of urinary bladder tissue is first subjected to abrasion using a longitudinal wiping motion to remove both the outer layers (particularly the abluminal smooth muscle layers) and the luminal portions of the tunica mucosa layers—the epithelial layers. The resulting submucosa tissue has a thickness of about 80 micrometers, and consists primarily (greater than 98%) of a cellular, eosinophilic staining (H&E stain) extracellular matrix material.

Id. at col. 2, ll. 17-28 (emphasis added). That paragraph makes clear that “the luminal portions of the tunica mucosa layers”<sup>6</sup> were defined by the patentee as the “epithelial layers” and that “the procedure for preparing intestinal submucosa” as detailed in the ’508 patent is expressly incorporated by reference into the ’389 patent specification.

The term “epithelial layers” may arguably be subject to two interpretations. On the one hand, it refers to “layers” which appears to reflect that it was meant to encompass more than just the transitional epithelium layer, i.e., the transitional epithelium layer and the tunica propria layer, the only other layer that the ’389 patent teaches is part of the tunica mucosa. See id. at col. 1, ll. 51-52. On the other hand, as recognized by the district court, the epithelium in the urinary bladder is made up of multiple layers of epithelial cells. Markman Order, slip op. at 10. Even accepting that the disclosure in the ’389 patent specification itself is less than clear as to which interpretation is correct, the second important disclosure of the ’389 specification is dispositive. As noted, the ’389 patent specification expressly incorporates by reference the procedure for preparing intestinal submucosa from the ’508 patent.

“Incorporation by reference provides a method for integrating material from various documents into a host document . . . by citing such material in a manner that makes clear that the material is effectively part of the host document as if it were explicitly contained therein.” Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1282 (Fed. Cir. 2000) (citations omitted). “To incorporate material by reference, the host document must identify with detailed particularity what specific material it

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<sup>6</sup> While we recognize that the phrase in the specification refers to the luminal portions and the claim language refers to the luminal portion, this section of the specification sheds the most light on how the patentee chose to define the claim term.

incorporates and clearly indicate where that material is found in the various documents."

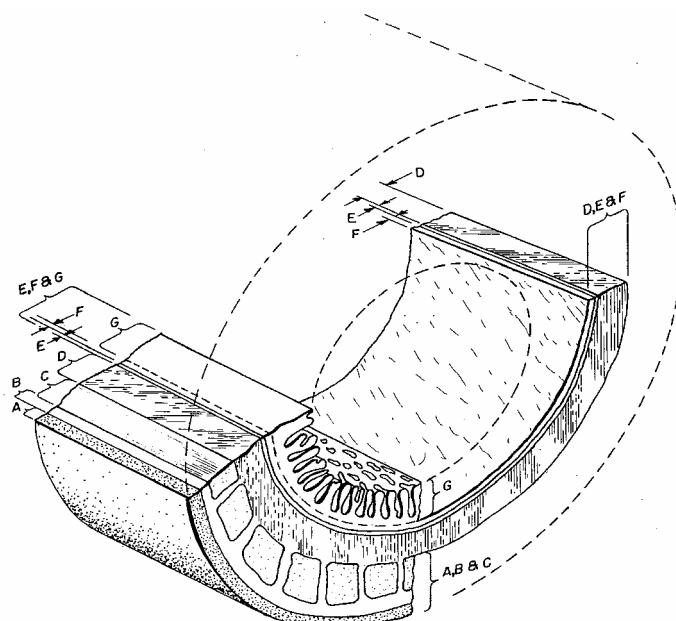
Id. (citations omitted). Whether and to what extent material has been incorporated by reference into a host document is a question of law. Id.

The relevant portions of the '508 patent specification are as follows:

Layers E, F, and G collectively represent the so-called tunica mucosa. Layer E is a layer of smooth muscle cells known as the lamina muscularis mucosa. Layer F, the stratum compactum, consists of acellular collagen and elastin fibers. Layer G consists of the lamina epithelialis mucosa and its lamina propria, which together are arranged in villous processes, a series of finger-like outgrowths of the mucous membrane.

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The tissue graft material of this invention is prepared by abrading intestinal tissue to remove the outer layers including both the tunica serosa and the tunica muscularis (layers B and C in FIG. 1) and the inner layers including at least the luminal portion (layer G) of the tunica mucosa (layers E through G in FIG. 1).

'508 patent, col. 3, ll. 13-20, 53-58 (emphases added).



Id. at fig. 1.

As this disclosure makes clear: (1) "the luminal portion of the tunica mucosa" is represented by "layer G" in Figure 1 of the '508 patent, and (2) layer G in that figure corresponds to the lamina epithelialis mucosa and its lamina propria. Id. Even

acknowledging appellees' argument that the layers of the wall of the intestine are somewhat structurally different than the layers of the wall of the bladder, neither party disputes that the basement membrane of the transitional epithelium is located between the epithelialis mucosa layer and its lamina propria layer in both organs. Thus, because the basement membrane is located between the two tissue layers explicitly identified, "the luminal portion of the tunica mucosa" must also refer to the basement membrane. Therefore, "the luminal portion of the tunica mucosa" means the lamina epithelialis mucosa (or transitional epithelium layer), the basement membrane, and the lamina propria.

The '389 patent's incorporation by reference of the '508 patent's procedure for preparing intestinal submucosa, in combination with the '508 patent's disclosure pertaining to which tissue layers are removed by that procedure, leads to the conclusion that the patentee's definition of the claim term as reflected in the '389 patent as the epithelial layers and in the '508 patent as the lamina epithelialis mucosa and its lamina propria was intended to refer to the same structures, i.e., the lamina epithelialis mucosa (or transitional epithelium layer), the basement membrane, and the lamina propria.

The district court's reasoning is contradicted by its own analysis. Relying on a medical dictionary, the district court recognized that the tunica mucosa comprises the epithelium, basement membrane, lamina propria mucosae, and lamina muscularis mucosae. Markman Order, slip op. at 10-11. The court then rejected ACell's proposed construction that "the luminal portion of the tunica musoca" means the epithelial cells (i.e., the transitional epithelium), the basement membrane, and the lamina propria because the term "would not require the entire tunica mucosa including the basement

membrane, tunica propria and all epithelial cells to be removed as ACell contends.” Id., slip op. at 11.

That statement by the district court reflects that it believed ACell’s proposed construction of that term encompassed the entire tunica mucosa, rather than just “the luminal portion” as the claim requires. The district court’s reasoning, however, overlooks the fact that ACell’s construction permits the retention of the lamina muscularis mucosae layer of the tunica mucosa. This construction is consistent with both the medical dictionary’s list of layers that comprise the tunica mucosa, and the teachings of the ’508 patent, which specifically refer to that layer as “layer E” of the tunica mucosa. ’508 patent, col. 3, ll. 14-15. As this discussion indicates, ACell’s proposed construction does not require removal of the entire tunica mucosa as the district court’s opinion suggests, but rather removal of only a portion of the tunica mucosa.<sup>7</sup> Therefore, we construe “the luminal portion of the tunica mucosa” to mean “the lamina epithelialis mucosa (or transitional epithelium layer), the basement membrane, and the lamina propria.”

## 2. Infringement

### a. Literal Infringement

ACell asserts that if we agree that the district court erred in its claim construction, a new trial is not necessary and we should reverse the judgment of literal infringement.

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<sup>7</sup> The district court also relied upon extrinsic evidence in the form of testimony from a Dr. Harbin who convinced the court that there was no compelling reason on the part of Cook to remove the basement membrane, lamina propria, or any other non-cellular component of the bladder wall layers. Markman Order, slip op. at 11. In light of the discussion above, however, such extrinsic evidence cannot override the patentee’s definition of the term contained in the intrinsic evidence of the ’389 and ’508 patent disclosures.

It submits that its ACell Vet™ product cannot infringe claims 1, 7, and 8 of the '389 patent because those claims require that the urinary bladder submucosa in the claimed compositions be delaminated from “the luminal portion of the tunica mucosa,” and its product is not so delaminated. Rather, ACell’s product retains part of “the luminal portion of the tunica mucosa” of a segment of a urinary bladder, i.e., the basement membrane and the lamina propria. Thus, ACell argues that because “the luminal portion of the tunica mucosa” is not delaminated as required by those claims, its product cannot infringe the asserted claims. Appellees agree with ACell that if we were to interpret any of the claims to exclude lamina propria, the ACell Vet™ product cannot literally infringe the asserted claims.

We agree with the parties that the ACell Vet™ product cannot, as a matter of law, literally infringe claims 1, 7, and 8 of the '389 patent because it contains the basement membrane and the lamina propria, tissue layers that are expressly excluded by the terms “urinary bladder submucosa” and “the luminal portion of the tunica mucosa” as the patentees have so defined them, and as we have thus construed them.

#### b. Infringement Under the Doctrine of Equivalents

Appellees assert, however, that even if summary judgment of non-infringement is appropriate with respect to literal infringement, a new trial may be necessary on the question of infringement under the doctrine of equivalents. They argue that the evidence supports the theory that compositions that include lamina propria and submucosa are equivalent to compositions that consist essentially of submucosa because the two compositions perform the same function, in the same way, to achieve the same result.

ACell makes two arguments in response. First, it asserts that appellees did not preserve any argument under the doctrine of equivalents because they failed to assert any such theories of equivalents in the detailed portion of the pretrial order relating to infringement. Second, ACell argues that the “all limitations rule” bars the capture, under the doctrine of equivalents, of elements specifically excluded by a claim limitation. Because claims 1, 7, and 8 claim a composition comprising urinary bladder submucosa, and such submucosa must have been delaminated from “the luminal portion of the tunica mucosa,” an accused product that contains some or all of “the luminal portion of the tunica mucosa” cannot infringe under the doctrine of equivalents.

Assuming that appellees could overcome their failure to preserve an issue with respect to infringement under the doctrine of equivalents, we conclude that applying appellees’ theory of equivalence with respect to asserted claims would violate “a corollary to the ‘all limitations rule[,]’ . . . that ‘the concept of equivalency cannot embrace a structure that is specifically excluded from the scope of the claims.’” Athletic Alternatives v. Prince Mfg., 73 F.3d 1573, 1582 (Fed. Cir. 1996) (quoting Dolly, Inc. v. Spalding & Evenflo Cos., Inc., 16 F.3d 394, 400 (Fed. Cir. 1994)). The ACell Vet™ product consists of basement membrane and tunica propria, two tissue layers specifically excluded from the claimed composition by delaminating “the luminal portion of the tunica mucosa.” See supra Part II.B.1.b. A claim that specifically excludes an element cannot through a theory of equivalence be used to capture a composition that contains that expressly excluded element without violating the “all limitations rule.” Permitting appellees to assert such a theory of equivalence would effectively remove the requirement that the urinary bladder submucosa be delaminated from “the luminal

portion of the tunica mucosa.” Thus, there is “no . . . material issue for the jury to resolve,” see Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co., 520 U.S. 17, 39 n.8 (1997), and a judgment of non-infringement under the doctrine of equivalents with respect to the asserted claims of the ’389 patent is appropriate.

In addition, because we have concluded that there was no direct act of infringement, the finding that Drs. Badylak and Spievack willfully induced ACell to infringe must also be reversed. Lastly, because we have concluded that ACell does not infringe claims 1, 7, and 8 of the ’389 patent as a matter of law, the other issues raised by ACell with respect to the jury instructions and verdict form are rendered moot.

### 3. Cook’s Cross-Appeal

Because we have concluded that no genuine issue of material fact remains with respect to whether ACell infringes claims 1, 7, and 8 of the ’389 patent, Cook’s cross-appeal pertaining to the district court’s refusal to award a permanent injunction, and the district court’s rulings with respect to its willful infringement case, including its challenge to several evidentiary rulings by the district court,<sup>8</sup> the jury instructions, and the verdict form, are rendered moot.

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<sup>8</sup> The evidentiary issues pertain to the district court’s exclusion of the “pre-September 2002” documents and grant proposals drafted by Drs. Spievack and Badylak. The district court did not abuse its discretion in excluding those documents and in limiting appellees’ infringement case to the ACell Vet™ commercial product because that was the only allegedly infringing product identified by appellees in the Pretrial Order: “Defendant ACell, Inc. manufactures, sells, uses, and offers for sale a veterinary product under the trade name ACell Vet.” Cook Biotech Inc. v. ACell, Inc., No. 4:03-CV-0046 AS, slip op. at 19 (N.D. Ind. Apr. 14, 2005).

#### 4. PRF's Cross-Appeal

In its cross-appeal, PRF raises two issues with respect to the district court's determination of inventorship and also challenges the district court's dismissal of its unjust enrichment claim. With respect to inventorship, PRF asserts that the district court erred by summarily determining that Dr. Badylak is not an inventor of the Disputed Patents and that Dr. Spievack is the sole inventor of the Disputed Patents.<sup>9</sup> PRF essentially asserts that the district court erred because the documentary evidence showed that Dr. Badylak worked on a graft composition that included the basement membrane as early as 1994 and that Dr. Badylak collaborated with Dr. Spievack before the priority date of the Disputed Patents. Specifically, PRF argues that the district court focused on the wrong time period, i.e., between 1994 and 1996, the date Dr. Spievack allegedly conceived, and reduced to practice, the invention claimed in the '265 patent,

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<sup>9</sup> Cross-appellants characterize the district court's Inventorship Order as having found on summary judgment that Dr. Spievack was the sole inventor of the '265 patent. ACell reframes the issue in its reply to the cross-appeal as whether the district court abused its discretion in holding that cross-appellants could not assert that Dr. Spievack was not an inventor of the '265 patent because cross-appellants failed to raise that issue in the Pretrial Order. With respect to inventorship, the district court's June 22, 2005 Order made the following determinations: (1) cross-appellants were precluded from asserting that Dr. Badylak is the sole inventor of the '265 patent because they failed to raise that theory of inventorship in their Complaint and the Pretrial Order, Inventorship Order, slip op. at 6-7; (2) cross-appellants' motion for summary judgment that Dr. Badylak is an inventor of the '265 patent was dismissed, *id.*, slip op. at 10; and (3) ACell's Motion for Partial Summary Judgment on Counterclaim Count II (inventorship) to the extent that the district court determined "that Spievak [sic] is an inventor of the '265 patent . . . , " was granted, *id.*, slip op. at 13 (emphasis added). As can be seen by the quoted portion above, the district court summarily determined that Dr. Spievack is an inventor of the '265 patent, not necessarily the sole inventor. Thus, we refer to the decision as finding that Dr. Spievack is an inventor of the '265 patent. Even if the district court had made the determination that Dr. Spievack is the sole inventor of the '265 patent, we do not find that cross-appellants have raised a genuine issue of material fact such that summary judgment on that issue would not have been appropriately granted for essentially the same reasons discussed herein.

rather than the period from 1994 through December 22, 1999, the date Dr. Spievack filed the provision application which led to the '265 patent. The premise of PRF's argument is that the district court erred in acting as though Dr. Spievack had established that he was entitled to a priority date earlier than the December 22, 1999 date on which the application leading to the '265 patent was filed. While Dr. Spievack testified that he had completed his invention by the summer of 1996, PRF asserts that the only other evidence offered as corroboration of Dr. Spievack's alleged completion was Dr. Spievack's unwitnessed laboratory notebooks. PRF asserts that under our precedent, unwitnessed notebooks are legally insufficient corroboration and that therefore there is a genuine issue of material fact as to whether Dr. Badylak communicated his work associated with basement membranes, described in the 1994 Disclosure,<sup>10</sup> to Dr. Spievack between 1994 and December 22, 1999.

ACell responds to PRF's appeal with several factual assertions: (1) there is no evidence that Dr. Badylak communicated a contribution to Dr. Spievack's invention during the relevant time period, (2) PRF admitted under oath that Dr. Spievack is an inventor of the '265 patent, (3) the 1994 Disclosure does not reveal a basement membrane composition, and (4) Dr. Badylak disavowed any role in the conception of the invention claimed in the '265 patent in his testimony and in a letter he sent to the PTO.

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<sup>10</sup> In 1994, Dr. Badylak prepared and submitted an "Invention Record and Disclosure" dated "8-17-94" (the "1994 Disclosure") describing some of his work on tissue graft compositions. The "Summary of Invention" section of the 1994 Disclosure discussed a tissue graft including basement membrane and submucosa delaminated from the transitional epithelial cell layer of the tunica mucosa.

We agree with the district court that Dr. Spievack is an inventor of the '265 patent and that PRF has failed to raise a genuine issue of material fact that survives summary judgment on the issue of whether Dr. Badylak is a joint inventor. Even if we were to accept that the district court may have focused on a more narrow time period, we agree with the district court that PRF has failed to point to evidence sufficient to create a genuine issue of material fact that Dr. Badylak "contributed in some significant manner" to the conception of the invention claimed in the '265 patent. See BJ Servs., 338 F.3d at 1373.

First, we do not read PRF's brief as challenging the district court's determination that Dr. Spievack is an inventor of the '265 patent. In fact, PRF admitted as much when it represented that Dr. Spievack was a co-inventor in an application it submitted to the PTO to provoke an interference with the '265 patent.

Second, the only record evidence argued by PRF to create a genuine issue of material fact is the 1994 Disclosure and Dr. Spievack's testimony in which he stated that "[Dr. Badylak] and I had talked about the basement membrane stuff somewhere along in '97 and '98, because I know at some point I had told him about my—the studies I had done in Boston with the dog bladders that we were talking about." (Spievack Dep. 38:4-7, Aug. 24, 2004.) Dr. Spievack's testimony, however, is not sufficient to create a genuine issue of material fact as to whether Dr. Badylak contributed "to the conception of the claimed invention that is not insignificant in quality" by sharing his knowledge of graft compositions, some of which is reflected in the 1994 Disclosure. See Eli Lilly & Co. v. Aradigm, 376 F.3d 1352, 1358-59 (Fed. Cir. 2004). This is especially so in light of Dr. Badylak's disavowal of having conceived of, reduced to practice, or recognized

the importance of a basement membrane graft composition. The district court also correctly recognized that even accepting Dr. Spievack's testimony as true, because of the other deficiencies noted, it was insufficient to overcome the presumption that the named inventors on an issued patent are presumed to be the actual inventors of that patent, such that summary judgment was appropriate. Thus, the district court's grant of summary judgment finding that Dr. Badylak is not a co-inventor of the '265 patent and that Dr. Spievack is an inventor of the '265 patent was proper.

Finally, with respect to PRF's unjust enrichment claim, PRF has not presented evidence to raise a genuine issue of material fact with respect to the district court's grant of summary judgment in ACell's favor. Without a viable claim for unjust enrichment, there is no basis for us to consider whether or not a constructive trust is an appropriate remedy in this case. Thus, there is no reason to disturb the district court's judgment with respect to those issues.

### III. CONCLUSION

Because the district court erred in construing the terms "urinary bladder submucosa" and "the luminal portion of the tunica mucosa" which formed the basis for the jury's finding of infringement and because, under the correct construction of those terms, there is no material factual dispute that the ACell Vet™ product cannot literally infringe claims 1, 7, and 8 of the '389 patent, we therefore reverse the judgment of infringement. Further, because the ACell Vet™ product cannot infringe those claims under the doctrine of equivalents without violating the "all limitations rule," it is not necessary to remand for a new trial on infringement under the doctrine of equivalents. In addition, without a direct act of infringement, the judgment finding that Drs. Badylak

and Spievack willfully induced ACell to infringe must also be reversed. Because of our conclusion with respect to those issues, Cook's appeal with respect to willfulness and relief are moot. Finally, because the district court did not err in determining on summary judgment that Dr. Badylak is not a co-inventor of the '265 patent, that Dr. Spievack is an inventor of the '265 patent, and that PRF's unjust enrichment claim and consequently its requested remedy of a constructive trust, must fail, we affirm the district court's rulings on those issues.

#### COSTS

Each party shall bear its own costs.

AFFIRMED-IN-PART AND REVERSED-IN-PART