

United States District Court,
N.D. Indiana, Hammond Division.

COOK BIOTECH INCORPORATED and Purdue Research Foundation Plaintiffs and Counter-Defendant,

COOK BIOTECH INCORPORATED and Purdue Research Foundation Plaintiffs and Counter-Defendants.
v.

ACELL, INCORPORATED, Stephen F. Badylak, and Alan R. Spievack,
Defendants and Counter-Plaintiffs.

June 17, 2005.

MEMORANDUM, ORDER AND OPINION

SHARP, J.

This matter is presently before the court on Plaintiffs Cook Biotech ("Cook") and Purdue Research Foundation's ("PRF") (collectively "plaintiffs") motion for summary judgment of patent infringement. The plaintiffs argue that the Vet product of defendant ACell, Incorporated ("ACell") infringes at least claims 1, 7, and 8 of U.S. Patent No. 5,554,389 (" '389 Patent"). In the alternative, the plaintiffs moved the Court to enter partial summary judgment that the only jury infringement issue would be whether ACell's product retains submucosa. For the reasons set forth below, the plaintiffs' motion in the alternative for partial summary judgment is granted.

STANDARD OF REVIEW

Summary judgment is proper if the pleadings, depositions, answers to interrogatories and admissions on file, together with any affidavits, show that there exists no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. FED.R.CIV.P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986); *Bragg v. Navistar Int'l Trans. Corp.*, 164 F.3d 373 (7th Cir.1998). *Celotex* addressed the initial burdens of the parties under Rule 56, and *Anderson* addressed the standards under which the record is to be analyzed within the structure of Rule 56.

The initial burden is on the moving party to demonstrate, "with or without supporting affidavits," the absence of a genuine issue of material fact and that judgment as a matter of law should be granted in the moving party's favor. *Celotex*, 477 U.S. at 324 (quoting FED.R.CIV.P. 56); *Larimer v. Dayton Hudson Corp.*, 137 F.3d 497 (7th Cir.1998). A question of material fact is a question which will be outcome determinative of an issue in the case. The Supreme Court has instructed that the facts material in a specific case shall be determined by the substantive law controlling the given case or issue. *Anderson*, 477 U.S. at 248. Once the moving party has met the initial burden, the opposing party must "go beyond the pleadings" and "designate 'specific facts shows that there is a genuine [material] issue for trial.'" ' *Id.* The nonmoving party cannot rest on its pleadings, *Weicherding v. Riegel*, 160 F.3d 1139 (7th Cir.1998); *Waldrige v.*

American Hoechst Corp., 24 F.3d 918 (7th Cir.1994); nor may that party rely upon conclusory allegations in affidavits. *Smith v. Shawnee Library Sys.*, 60 F.3d 317, 320 (7th Cir.1995).

During its summary judgment analysis, the court must construe the facts and draw all reasonable inferences in the light most favorable to the nonmoving party. *Bombard v. Fort Wayne Newspapers, Inc.*, 92 F.3d 560, 562 (7th Cir.1996). Furthermore, it is required to analyze summary judgment motions under the standard of proof relevant to the case or issue. *Anderson*, 477 U.S. at 252-55. Applying the above standard this Court will now address the present motion for summary judgment.

DISCUSSION

Determining patent infringement requires determining whether an individual without authority, makes, uses, offers to sell, sells, or imports the patented invention within the United States, its territories, or its possessions, during the term of the patent. 35 U.S.C. s. 271(a). A finding of infringement requires a two-step analytical approach. First, this Court is required to construe the claims at issue and second, compare the properly construed claims to the accused device. *Cybor Corp. v. FAAS Technologies, Inc.*, 138 F.3d 1448, 1454 (Fed.Cir.1998) (en banc); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed.Cir.1995) (en banc). A device infringes a patent claim if it contains every limitation set forth in that claim, whether literally or by equivalence. *Johnson Worldwide Assocs. v. Zebco, Corp.*, 175 F.3d 985, 988 (Fed.Cir.1999). "A patent is infringed if any claim is infringed." *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1220 (Fed.Cir.1995). While claim construction is a legal determination to be made by the court, infringement is a question of fact. *Instituform Techs., Inc. v. Cat Contracting, Inc.*, 161 F.3d 688, 692 (Fed.Cir.1998). Because the Court has already performed the first step through its *Markman* order, only the second step is at issue here.

It is clear from the submissions of both parties that the real issue before the Court is whether all of the urinary bladder submucosa has been removed from the ACell product. During the *Markman* phase of this case, the Court ruled:

The term, "submucosa" is the name for a type of tissue of the urinary bladder. "Submucosa" is defined as "the submucous tissue" in the bladder. "Submucosa" is the name of a tissue type, and therefore this term does not necessarily mean the entire submucosal *layer* or any particular amount of the submucosa.

Docket No. 193, p. 6 (*Markman* Order). This claim construction clearly indicates that the presence of any submucosa in ACell's product requires a finding of infringement.

The Plaintiffs assert that statements made by Dr. Spievack operate as admissions that Acell's product retains submucosa and therefore entitle Plaintiffs to summary judgment on this issue. Dr. Spievack stated in a deposition:

As I mentioned before, I have come in common usage and my company has come in common usage to describe UBM as being basement membrane and tunica propria, but with the understanding that there may be little it'sy-bitsy scraps of submucosa stuck here and there that have escaped removal. In other words, none of us know that every single piece has every last, you know, microscope bit of submucosa removed, but we think of UBM as basement membrane and tunica propria.

2004 Spievak Deposition, pp. 90-91. Spievak also stated that after Acell's processing technique is applied,

there is "probably some [submucosa] left." 2003 Spievak Deposition pp. 272-79. As noted above, this Court is required to construe the facts and draw all reasonable inferences in the light most favorable to the nonmoving party. *Bombard*, 92 F.3d at 562 (7th Cir.1996). Applying that standard, Spievak's statements can, at best, be viewed as speculation about the possibility that some submucosa is present in ACell's product. The statements are not, as the plaintiffs contend, outright admissions that the product does in fact contain submucosa.

More importantly, the declaration of Dr. Clifford is sufficient to create a disputed issue of material fact as to whether the ACell product contains submucosa. Dr. Clifford stated, unambiguously, that his evaluations of the ACell product "did not reveal any tissue which could be identified as submucosa." Clifford Report at 8. The plaintiffs cannot shift the burden of proof to require ACell to prove definitively that ACell's product does not contain submucosa.

As to the attempts by defendants to raise a factual issue regarding Claim 8, this Court is unpersuaded. They state, "as to claim 8, plaintiffs have presented no evidence that any material from the submucosa layer ... is quantitatively sufficient to induce endogenous connective tissue growth...." Defendants' Brief, pp 8-9. The defendants are attempting to challenge the rulings made during the *Markman* stage of this proceeding. That issue has been dealt with and will not be revisited here.

CONCLUSION

For the reasons stated above, the plaintiffs' motion in the alternative for partial summary judgment is GRANTED. The only remaining infringement issue for trial is whether ACell's product includes submucosa.

IT IS SO ORDERED.

N.D.Ind.,2005.

Cook Biotech Inc. v. ACell Inc.

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