UNITED STATES PATENT AND TRADEMARK OFFICE
Trademark Trial and Appeal Board
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Arlington, Virginia 22202-3513

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Mailed: September 24, 2002

Cancellation No. 32,202

Alfacell Corporation

v.

Anticancer, Inc.

Before Quinn, Hohein and Chapman, Administrative Trademark Judges.

By the Board:

Alfacell Corporation ("petitioner") seeks to cancel the registration of Anticancer, Inc. ("respondent") for the mark ONCASE for "therapeutic compositions containing reagents for in vivo anti-cancer use" in International Class 5.[1] The petition to cancel is based on allegations of likelihood of confusion, priority of use, and abandonment. Specifically, with regard to the claim of abandonment, petitioner alleges that respondent is not using the mark in commerce; that any use respondent may have recently made of the mark was "not in the ordinary course of trade"; that in the United States, respondent is either not using the mark at all or only using

[1] Registration No. 1,987,445, issued on the Principal Register on July 16, 1996, reciting October 16, 1995 as the date of first use and first use in commerce, Section 8 affidavit accepted.

the mark to a minimal extent; that respondent has not published any scientific papers or made any scientific presentations relating to its involved pharmaceutical products; that respondent's pharmaceuticals are "not the subject of any ongoing clinical trial in the United States"; and that since respondent "has not used its mark in commerce for the three consecutive years immediately preceding the filing date of the petition to cancel, [such] nonuse constitutes a prima facie case of abandonment." With respect to the likelihood of confusion claim, opposer makes, among other allegations that "even if Anticancer's ONCASE product is approved by the FDA, the FDA will not permit Anticancer to use the ONCASE mark on a label for the product, because of the likelihood that the ONCASE products will be confused with Alfacell's ONCONASE product."

In its answer, respondent admits that its "ONCASE product is currently the subject of pre-clinical trials in the United States" and that the product has not yet been approved by the Food and Drug Administration (FDA) for human use. Otherwise, respondent denies the salient allegations of the petition, and asserts various affirmative defenses, including that respondent's conduct constitutes excusable nonuse and is not due to any intention to abandon its mark.

This case now comes up for consideration of respondent's motion for partial summary judgment on the

ground that it has not abandoned use of its ONCASE mark, and petitioner's cross-motion for partial summary judgment on the basis that respondent has indeed abandoned use of the ONCASE mark.

In its motion for summary judgment, respondent argues that it has never abandoned, or intended to abandon its mark; that from 1995 to the present, respondent has engaged in clinical and pre-clinical trials of its pharmaceutical products bearing the ONCASE mark as well as in licensing the product for use in clinical studies in foreign countries; that between 1998 and 2001, numerous scientific papers were published regarding respondent's ONCASE pharmaceutical products; and that respondent has publicly used its mark in industry trade shows from 1998-2001. In support of its motion, respondent submitted the declaration of its president, Robert M. Hoffman, Ph.D., as well as numerous exhibits.

In its cross-motion for summary judgment, petitioner contends that respondent's activities do not fall within the definition of "use in commerce" under the Lanham Act. Specifically, petitioner asserts that respondent has failed to demonstrate use of its mark on containers, tags or labels; that clinical trials which take place in foreign countries do not constitute “use in commerce” inasmuch as Congress has no authority to regulate clinical trials

outside the United States; and that the publication of scientific papers regarding respondent's pharmaceuticals does not constitute "use in commerce."

In response, respondent maintains that from 1995 to the present, it has sold its pharmaceutical products in interstate and foreign commerce for use in connection with pre-clinical and clinical studies; that in connection with such sales, respondent has placed labels bearing the ONCASE mark on bottles containing the pharmaceutical products; that respondent has taken the standard steps to test its pharmaceuticals in efforts to obtain approval from the FDA; and that shipments of pharmaceuticals for the purpose of clinical trials constitute "use in commerce" within the meaning of the Lanham Act. In further support of its motion, respondent submitted a second declaration from Robert M. Hoffman, with supporting exhibits, including photocopies of labels bearing respondent's mark, as well as other materials.

As has often been stated, summary judgment is an appropriate method of disposing of cases in which there is no genuine issue of material fact in dispute, thus leaving the case to be resolved as a matter of law. *See* Fed. R. Civ. P. 56(c). The party moving for summary judgment has the initial burden of demonstrating the absence of any genuine issue of material fact and that is entitled to

judgment as a matter of law. *See Celotex Corp. v. Catrett,* 477 U.S. 317 (1986), and *Sweats Fashions Inc. v. Pannill Knitting Co.,* 833 F.2d 1560, 4 USPQ2d 1793 (Fed. Cir. 1987). The evidence must be viewed in a light most favorable to the non-movant, and all justifiable inferences are to be drawn in the non-movant's favor. *See Lloyd's Food Products Inc. v. Eli's Inc.,* 987 F.2d 766, 25 USPQ2d 2027 (Fed. Cir. 1993), and *Opryland USA Inc. v. Great American Music Show Inc.,* 970 F.2d 847, 23 USPQ2d 1471 (Fed. Cir. 1992).

It is undisputed that since 1995, respondent has made shipments of its involved pharmaceuticals within the United States and overseas for use in clinical testing, and that respondent has placed labels bearing the mark ONCASE on bottles containing the goods. Thus, the question before us is whether, as a matter of law, respondent's shipments of its pharmaceutical products for purposes of clinical trials within the United States and to foreign countries constitute "use in commerce."

The starting point for our analysis is the text of the statute. Section 45 of the Lanham Act provides that the term "use in commerce" means

> the bona fide use of a mark in the ordinary course of trade, and not made merely to reserve a right in a mark. For purposes of this chapter, a mark shall be deemed to be used in commerce--
>
> (1) on goods when--

> (A) it is placed in any manner on the goods or their containers or the displays associated therewith or on the tags or labels affixed thereto, or if the nature of the goods makes such a placement impracticable, then on documents associated with the goods or their sale, and
>
> (B) the goods are sold or transported in commerce ....

15 U.S.C. § 1127.

A mark is abandoned when "its use has been discontinued with intent not to resume use. ... Nonuse for three consecutive years shall be prima facie evidence of abandonment." *Id.*

The legislative history of the Trademark Law Revision Act of 1989 speaks directly to this issue. The amended definition of "use in commerce" was intended to be flexible and accommodate the individualized practices of a particular industry. Both the House Judiciary Committee Report and the Senate Judiciary Committee Report explicitly contemplate the shipment of pharmaceuticals to clinical investigators awaiting FDA approval as an example of such industry specific "use in commerce." As stated in the House Report:

> While use made merely to reserve a right in a mark will not meet the standards, the [House Judiciary] Committee recognizes that the "ordinary course of trade" varies from industry to industry. Thus, for example, it might be in the ordinary course of trade for an industry that sells expensive or seasonal products to make infrequent sales. Similarly, a pharmaceutical company that markets a drug to treat a rare disease will make correspondingly few sales in the ordinary course of its trade; the company's shipment to clinical

> investigators during the Federal approval process will often be in its ordinary course of trade . . .

House Judiciary Committee Report on H.R. 5372, H.R. No. 100-1028, p. 15 (Oct. 3, 1988).

Consistent therewith, the Senate Report recommends that the definition of "use" be interpreted in accordance with the practices of a particular industry, citing as an illustration the unique circumstances presented in the pharmaceutical industry:

> The [Senate Judiciary Committee] intends that the revised definition of "use in commerce" be interpreted to mean commercial use which is typical in a particular industry. Additionally, the definition should be interpreted with flexibility so as to encompass various genuine, but less traditional, trademark uses such as those made in test markets, infrequent sales of large or expensive items, or ongoing shipments of a new drug to clinical investigators by a company awaiting FDA approval, and to preserve ownership rights in a mark if, absent an intent to abandon, use of a mark is interrupted due to special circumstances.

Senate Judiciary Committee Report on S. 1883, S. Rep. No. 100-515, p. 44-45 (Sept. 15, 1988). *See also* Remarks of Sen. DeConcini, Oct. 20, 1988, Cong. Rec. S. 16973, reprinted in USTA, *The Trademark Law Revision Act of 1988,* p. 334 (1989).

The statutory language, coupled with the legislative history, lead us to conclude that, as a matter of law, Congress intended the term "use in commerce" to encompass

shipments of pharmaceuticals for clinical studies prior to receiving FDA approval as a reflection of common industry practice. *See G.D. Searle & Co. v. Nutrapharm, Inc.,* 199 U.S. Dist. LEXIS 16862[2] (S.D.N.Y. 1999) (citing the legislative history of the 1989 Amendment to the Lanham Act, the court denied defendant's motion for summary judgment and found that shipments of plaintiff's pharmaceuticals for clinical testing constitutes "use in commerce"). *See also,* J. Thomas McCarthy, McCarthy on Trademarks and Unfair Competition, § 19:118, at 19-271, (4th ed. 2001).

Petitioner's argument that shipments to foreign countries for clinical testing do not constitute "use in commerce" because Congress has no such authority to regulate the testing is misplaced. In such circumstances, the "use in commerce" that Congress can regulate is the actual shipment of the pharmaceuticals overseas, and it is not necessary that Congress be able to regulate the clinical testing.

In view of the foregoing, respondent's motion for partial summary judgment on the ground of non-abandonment is

[2] The clerk of the District Court of New York informed an attorney at this Board that the court identified this decision as citable precedent. However, the Board could not locate any parallel citation.

granted;[3] petitioner's cross-motion for partial summary judgment on abandonment is denied. Accordingly, this case will proceed solely on the issues of likelihood of confusion and priority of use.

Proceedings herein are resumed and trial dates are reset as follows:

THE PERIOD FOR DISCOVERY TO CLOSE:	CLOSED
30-day testimony period for party in position of plaintiff to close:	December 15, 2002
30-day testimony period for party in position of defendant to close:	February 13, 2003
15-day rebuttal testimony period for plaintiff to close:	March 30, 2003

In each instance, a copy of the transcript of testimony together with copies of documentary exhibits, must be served on the adverse party within thirty days after completion of the taking of testimony. Trademark Rule 2.l25.

Briefs shall be filed in accordance with Trademark Rule 2.128(a) and (b). An oral hearing will be set only upon request filed as provided by Trademark Rule 2.l29.

[3] The parties are reminded that this decision is interlocutory in nature and may not be appealed until a final decision is rendered in the proceeding. *See Copelands' Enterprises, Inc. v. CNV, Inc.,* 887 F.2d 1065, 12 USPQ2d 1563 (Fed. Cir. 1989).