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Exhibits

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Alfacell Corporation, Petitioner, v. Anticancer, Inc., Registrant.	Cancellation No.: 32,202 Registration No. 1,987,445

OPPOSITION TO CROSS-MOTION FOR SUMMARY JUDGMENT FOR FINDING OF NONUSE AND ABANDONMENT

INTRODUCTION

In Petitioner's Cross-Motion for Summary Judgment for Finding of Non-Use and Abandonment ("Petitioner's Cross-Motion"), Petitioner contends that Registrant has not used the ONCase mark in commerce in connection with its recombinant methionase ("rMETase") pharmaceutical product for the treatment of cancer. Petitioner is wrong. In fact, on numerous occasions since 1995, Registrant has sent its ONCase product in interstate and foreign commerce to various locations for use in connection with clinical and preclinical studies. The bottles are clearly labeled with the ONCase trademark. Such use constitutes trademark use in connection with the rMETase pharmaceutical product. Accordingly, Petitioner's Cross-Motion should be denied.

Furthermore, Registrant's actions with regard to its ONCase product demonstrate Registrant's continuing intent to bring its ONCase product to the U.S. market. Registrant has taken the standard steps to test a pharmaceutical product and continues to take appropriate steps to obtain approval of its product from the Food and Drug Administration ("FDA"). In sum, the evidence demonstrates that Registrant is still using the ONCase mark,

and has not abandoned and has no intent to abandon the mark and Petitioner's Cross-Motion should be denied.

STATEMENT OF FACTS

Since at least 1995, Registrant has used the ONCase mark in commerce in connection with its rMETase cancer-treating pharmaceutical product. (Declaration Of Robert M. Hoffman, Ph.D. In Support Of Opposition To Cross-Motion For Summary Judgment ("Hoffman Opposition Decl."), ¶ 2.)

From 1995 through and including the present, Registrant has consistently used the ONCase mark in connection with its rMETase pharmaceutical product, and has never used, nor considered using, a different mark in connection with the rMETase product. (*Id.*, ¶ 3.) Registrant has never intended to abandon, nor has it taken any steps toward abandoning, the ONCase mark. In fact, Registrant has consistently been using the ONCase mark in connection with product labeling on products that are being transported in commerce in connection with preclinical trials and clinical trials for the ONCase product. (*Id.*, ¶ 4.)

As part of its product development program, Registrant met with the FDA in 1996 to plan out a program to obtain FDA approval for its ONCase product for use in connection with the treatment of cancer. The first step to obtaining FDA approval is to file for permission to do clinical trials in the U.S. on an investigational new drug ("IND"). In connection with the IND application, Registrant will be required to submit evidence of preclinical trial results for the ONCase product. From the beginning, Registrant's plan has been to conduct preclinical trials on animal and on human tumors and tissues in vitro and in host animals, such as mice, inside and outside of the U.S. and to submit the results of those trials in connection with its IND application. (*Id.*, ¶ 5.)

In most cases, the ONCase products used in the preclinical trials are shipped from Registrant's headquarters in San Diego, California. The bottles bear labels with the ONCase

trademark. In addition, it is and always has been Registrant's custom to include a specification sheet with every shipment of the ONCase product. (*Id.*, ¶ 6.)

Moreover, as part of its program to develop the ONCase product, Registrant has arranged for Shionogi and Co., Ltd. of Osaka, Japan ("Shionogi") to produce clinical grade ONCase for use in human clinical trials in the United States. Registrant has supplied Shionogi with ONCase labels for use with the products. These labels are designed to be used both on the bottles of the ONCase product and also in connection with the outside packaging of the clinical materials. (*Id.*, ¶ 7.)

Since the mid 1990's, Registrant has conducted and continues to conduct preclinical and clinical trials of the ONCase product in a number of locations:

- Registrant conducted clinical trials on the ONCase product in Mexico during which the product was tested on human patients. For the purpose of these trials, doctors carried the ONCase product from California to Mexico in packages labeled with the ONCase mark. (*Id.*, ¶ 8.)

- From 1995 to the present, Shionogi has been conducting preclinical studies in Japan on the ONCase product, using mice test subjects. (*Id.*, ¶ 9.)

- From 1999 to the present, Institut de Recherches Internationales Servier has been conducting preclinical trials of the ONCase product in France. The ONCase product was tested on mice and in vitro with human leukemia cells. For purposes of these preclinical trials, Shionogi produced the ONCase product and shipped it the U.S. in bottles which had labels bearing the ONCase trademark. Registrant replaced Shionogi's labels with its own labels, also bearing the ONCase mark, and then sent the product to France for use in the preclinical trials on October 22, 2001. (*Id.*, ¶ 10, Exh. A.) In addition, in 1999, Robert M. Hoffman carried the ONCase product from San Diego, California to France. The product bore a label with the ONCase mark. (*Id.*)

- From 1997 to the present, Jiangsu Kingsley Pharma. Co. has been conducting preclinical trials of the ONCase product on monkey test subjects in China. Again, the ONCase product was shipped to China in bottles with labels bearing the ONCase mark. (*Id.*, ¶ 11, Exh. B.) Registrant intends to use the data from these preclinical trials to support its IND application with the Food and Drug Administration. (*Id.*)

- Beginning in 2000 and continuing to the present, Registrant has collaborated with Dr. Demetrius Kokkinakis and Dr. Eugene

Frankel at the University of Texas, Southwestern Medical School, located in Dallas, Texas, for preclinical trials of the ONCase product, using mice with human brain tumors as test subjects. In 1999, Shionogi shipped the ONCase product to Registrant for use in these preclinical studies. These products were shipped in bottles labeled ONCase. Registrant then shipped the ONCase-labeled bottles to Drs. Frankel and Kokkinakis at the University of Texas in Dallas, Texas. In addition, in January 2002, Shionogi shipped additional bottles of the ONCase product from Japan to Registrant in San Diego for use in the Southwestern Medical School preclinical trials. These bottles were also labeled with the ONCase mark. Registrant sent these bottles via Federal Express to Dr. Kokkinakis in Pittsburgh, Pennsylvania, where he is currently working. (*Id.*, ¶ 12, Exh. C.) The labels are the same as the labels used for the 1999 shipment. (*Id.*)

- Registrant has also given the ONCase product, in bottles labeled ONCase to Dr. Matthew A. Spear at the University of California, San Diego for use in preclinical studies in mice in conjunction with radiation therapy. (*Id.*, ¶ 13, Exh. D.)

Registrant intends to file, either late this year or early next year, an IND application with the Food and Drug Administration for the ONCase product. As soon as the FDA grants approval of Registrant's IND application, Registrant is prepared to ship the ONCase product from Shionogi in Japan to the University of Texas, Southwestern Medical School hospitals in Dallas, Texas for immediate use in clinical testing on humans. Registrant intends to have the product sent in bottles and packages, all labeled with the ONCase mark. (*Id.*, ¶ 14.)

ARGUMENT

I. APPLICANT HAS NOT MET ITS BURDEN OF ESTABLISHING THAT SUMMARY JUDGMENT SHOULD BE GRANTED.

Summary judgment is appropriate only "if the pleadings, depositions, answers on file, together with affidavits, if any, show that there is 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). The evidence must be viewed in the light most favorable to the nonmoving party. *SRI Int'l v. Matsushita Elec. Corp. of America*, 775 F.2d 1107 (Fed. Cir. 1985). Because abandonment results in a forfeiture of rights, courts are reluctant to find abandonment. 2 J. McCarthy, Trademarks and Unfair Competition, § 17:12 (3rd Ed. 2001). The party seeking cancellation must prove abandonment by a preponderance of the evidence.

Cerveceria Centroamericana, S.A. v. Cerveceria India, Inc., 892 F.2d 1021 (Fed. Cir. 1989). Where the challenger is relying on a presumption of abandonment due to alleged nonuse of the mark, the "registrant may rebut a prima facie case either by disproving the underlying fact from which the presumption arises, i.e., two consecutive years of nonuse, or the presumed fact itself, i.e., no intent to resume use." (*Id.* at 1026.) The facts will demonstrate that Petitioner has not met its burden of demonstrating that it is entitled to judgment. In fact, Registrant is the party that is entitled to summary judgment in this matter — judgment that it continues to use and has not abandoned its ONCase mark.

A. Registrant Continues To Use The ONCase Mark In Commerce.

An examination of the evidence in light of the legal standard cited by Petitioner, Section 45 of the Lanham Act, demonstrates that Registrant has used and continues to use the ONCase trademark in commerce. Section 45 of the Lanham Act defines "use in commerce" as follows:

> 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 Act, a mark shall be deemed to be in use 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 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. Registrant's use of the ONCase mark meets both of these requirements.

First, Registrant has placed labels bearing the ONCase mark on bottles holding the product. (Hoffman Opposition Decl., ¶¶ 10-13, and Exhs. A-D.) Such use is proper trademark use because it is use on a container for the product. 15 U.S.C. § 1127. Thus, Registrant has met the first requirement that the mark be placed on the goods.

Second, Registrant has met the requirement that the goods be sold or transported in commerce. Because Registrant has not yet obtained FDA approval for its ONCase product, it cannot sell the product in the ordinary cause of trade; instead, it is only permitted to use the product in connection with preclinical and clinical trials. Shipments for the purpose of clinical trials constitute "use" within the meaning of the Lanham Act. Senate Judiciary Committee Report on S. 1883, S. Rep. No. 100-515, pp. 44-45 (Sept. 15, 1988). The ONCase product has repeatedly been sent or transported across state and national lines to various locations for use in clinical and preclinical studies. For example, in the mid-1990's, doctors carried the ONCase product from San Diego, California to Mexico for use in clinical trials.[1] (Hoffman Opposition Decl., ¶ 8.) On more than one occasion, Registrant has sent the ONCase product from San Diego, California to France for use in preclinical trials. (*Id.* at ¶ 10.) Registrant has also arranged for the product to be shipped to China for use in additional preclinical trials. (*Id.* at ¶ 11.) Finally, Registrant has shipped the product, via Federal Express, from San Diego, California to Dallas, Texas and to Pittsburgh, Pennsylvania for use in connection with preclinical trials. (*Id.* at ¶ 12.) In sum, Registrant meets the standard for trademark use set forth in Section 45 of the Lanham Act, and Petitioner's Cross-Motion should be denied.

B. Registrant Intends And Has Always Intended To Sell Its Product Under The ONCase Mark.

Petitioner erroneously states that "Registrant's professed lack of intent to abandon ONCASE is ... irrelevant." (Petitioner's Cross-Motion at 1.) The Lanham Act states that a trademark may be found abandoned through proof of nonuse, *coupled with an intent by the owner not to resume use.* 15 U.S.C. § 1127. Moreover, the Federal Circuit has held that the rebuttable presumption of abandonment due to nonuse can be overcome with a showing that

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[1] Although Registrant agrees with Petitioner that "Congress has no right to regulate clinical trials in Mexico" (Petitioner's Brief at 4), Petitioner overlooks the fact that the product was transported from San Diego, California to Mexico and that Congress has the right to regulate such commerce between the United States and a foreign country.

the trademark owner intends to resume use of the mark. *Centroamericana S.A.*, 892 F.2d at 1026. Thus, the intent of the trademark owner is always relevant to the issue of abandonment.

First, Dr. Robert Hoffman, Registrant's president, attests to the fact that Registrant's plans to use the ONCase mark have been consistent since 1995 (Hoffman Opposition Decl., ¶ 3) and that Registrant has never intended to abandon, nor has it taken any steps toward abandoning, the ONCase mark. (*Id.*, ¶ 4.)

Second, Registrant has engaged in standard activities that are required to introduce a pharmaceutical product in the U.S. These activities are sufficient objective evidence of its continuing intent to use the ONCase mark to overcome the alleged presumption of abandonment. For example, to obtain FDA approval for pharmaceutical products for the treatment of human disease, the company developing the product must file for permission to do clinical trials in the U.S. on an investigational new drug ("IND"). (*Id.*, ¶ 5.) However, even prior to filing an IND application, the company must first subject the product to preclinical trials using animal and other non-human test subjects. Registrant has been conducting the proper preclinical trials so that it will be able to file its IND application this year or next. (*Id.*, ¶¶ 8-14 .)

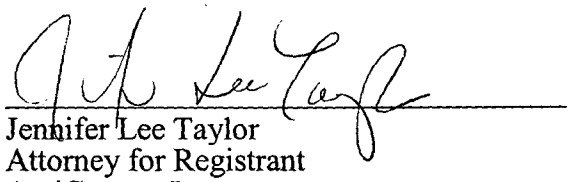
Furthermore, as part of its program to develop the ONCase product, Registrant has arranged for Shionogi and Co., Ltd. of Japan to produce clinical grade ONCase for use in human trials in the United States. (*Id.*, ¶ 7.) As soon as the FDA grants approval of Registrant's IND application, Registrant is prepared to have the ONCase product shipped from Shionogi to the University of Texas, Southwestern Medical School hospitals in Dallas, Texas for immediate use in clinical testing on humans. (*Id.*, ¶ 14.) In addition, Registrant has supplied Shionogi with ONCase labels and specification sheets for use with the product. (*Id.*, ¶ 7.) The labels are designed to be used both on the bottles of the ONCase product and also in connection with the outside packaging of the clinical materials.

These actions taken by Registrant objectively demonstrate Registrant's continuing intent to develop its ONCase product and rebut any presumption on which Petitioner seeks to rely to establish abandonment.

CONCLUSION

Registrant continues to use the ONCase mark, and has not abandoned and has no intent to abandon the mark. Petitioner has not met its burden to prove otherwise. Accordingly, Registrant respectfully requests that Petitioner's Cross-Motion for Summary Judgment be denied and that the Board instead issue a finding of nonabandonment and grant summary judgment in Registrant's favor.

Dated: March 28, 2002

By: 

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PROOF OF SERVICE BY MAIL

I am employed with the law firm of Morrison & Foerster LLP, whose address is 425 Market Street, San Francisco, California, 94105; I am not a party to the within cause; I am over the age of eighteen years and I am readily familiar with Morrison & Foerster's practice for collection and processing of correspondence for mailing with the United States Postal Service and know that in the ordinary course of Morrison & Foerster's business practice the document(s) described below will be deposited with the United States Postal Service on the same date that it is placed at Morrison & Foerster with postage thereon fully prepaid for collection and mailing.

I further declare that on the date hereof I served a copy of:

OPPOSITION TO CROSS-MOTION FOR SUMMARY JUDGMENT FOR FINDING OF NONUSE AND ABANDONMENT

DECLARATION OF ROBERT M. HOFFMAN, Ph.D. IN SUPPORT OF OPPOSITION TO CROSS-MOTION FOR SUMMARY JUDGMENT

on the following by placing a true copy thereof enclosed in a sealed envelope addressed as follows for collection and mailing at Morrison & Foerster LLP, 425 Market Street, San Francisco, California, 94105:

Mark H. Jay, Esq.
Marh H. Jay, P.A.
P.O. Box E
Short Hills, NJ 07078-0383

I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

Executed at San Francisco, California, this 28th day of March, 2002.

Lucia M. Sario
(typed)

(signature)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Petitioner:	Alfacell Corporation
Registrant:	Anticancer, Inc.
Cancellation No.:	32,202
Registration No.:	1,987,445

CERTIFICATE OF MAILING BY EXPRESS MAIL

Commissioner for Trademarks
2900 Crystal Drive
Arlington, VA 22202-3513

Dear Sir:

Express Mail Label No.: EL 900806895 US

Date of Deposit: March 28, 2002

I hereby certify that the attached Opposition to Cross-Motion for Summary Judgment for Finding of Nonuse and Abandonment; Declaration of Robert M. Hoffman, Ph.D. In Support Of Opposition To Cross-Motion For Summary Judgment with Exhibits A-D, and receipt verification postcard are being deposited with the United States Postal Service Express Mail delivery as "Express Mail Post Office to Addressee" service under 37 C.F.R § 1.10 on the date indicated above, and is addressed to: Commissioner for Trademarks, 2900 Crystal Drive, Arlington, VA 22202-3513.

Respectfully submitted,

By: _____
Chase Trombella