Trademark Use in Clinical Trials: Use in Commerce?

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U.S. trademark applicants must, as a condition of obtaining a U.S. registration, establish use of their mark by displaying the mark on their goods when transported or sold in interstate commerce in the ordinary course of business. That standard contemplates transporting or selling a reasonably high volume of goods to the consumer with a relatively high degree of both frequency and continuity, which seems to preclude limited use of a mark during pre-clinical and clinical trials. Or does it?

Clinical Trials Conducted Within the U.S.

In *G.D. Searle & Co. v. Nutrapharm, Inc.*, 1999 WL 988533 (S.D.N.Y.), Searle relied on shipments made in the course of its clinical trials conducted in the U.S. to assert rights in its unregistered CELEBRA mark to allege infringement arising from Nutrapharm's use of the CEREBRA mark. In pressing its claim, Searle presented evidence that it had conducted FDA-approved clinical trials, during which it shipped celecoxib under the name CELEBRA to an independent laboratory in the U.S., and had used the CELEBRA mark in ongoing clinical trials. Searle also submitted a declaration alleging that it had commenced Phase III clinical trials for celecoxib, involving patients in a clinical setting approximating the environment in which the drug would be used. The declaration stated that Searle used the CELEBRA mark on labels affixed to cartons of celecoxib during an open label safety study as part of its Phase III clinical program. Searle further averred that it had shipped to selected clinical investigators and hospitals throughout the country approximately 1,400 cartons of celecoxib bearing the CELEBRA label, and continued to make shipments at an approximate rate of 300 cartons per month.

Nutrapharm moved to dismiss on the ground that Searle had not made a *bona fide* use of the CELEBRA mark in the ordinary course of trade because neither the shipments made for clinical testing nor the pre-sale advertising and promotional activity constituted a bona fide use of the mark in commerce. Nutrapharm argued that such shipments did not meet the requirement of bona fide use because the testing laboratories were not purchasing or otherwise acquiring the drug as consumers, and laboratory testing did not create any association between the mark and the product in a significant segment of the purchasing public.

The court first reviewed the standard for determining "use in commerce" as set forth in Section 43(a) of the Lanham Act, then turned to the legislative history of the Trademark Law Revision Act of 1988, which became effective in 1989:

In the legislative history discussing the 1989 Amendment to the Lanham Act, the Senate Judiciary Committee Report and the House Report cite as an example of sufficient use in commerce a pharmaceutical company's shipment to clinical investigators during the FDA approval process. S.Rep. No. 100-515, at 44-45 (1998) (other citations omitted).

While the purpose of the amendment was to preclude token use of a mark undertaken solely to claim use in commerce to facilitate registration, Congress understood that certain uses, although limited, were genuine. Based on the statutory language and the legislative history, the Court concluded that Nutrapharm had not shown, beyond any triable issue of fact, that Searle's use of the mark in commerce was not genuine, and therefore denied Nutrapharm's motion to dismiss.

Pre-Clinical Trials Conducted Outside the U.S.

More recently, in *Alfacell Corporation v. Anticancer, Inc.*, 2002 WL 31121389 (Trademark Tr. & App. Bd.), Alfacell petitioned to cancel Anticancer's ONCASE mark based in part on a claim that Anticancer's drugs were not the subject of any ongoing clinical trial in the U.S. Specifically, Alfacell argued that Anticancer's activities did not constitute "use in commerce," alleging that pre-clinical trials which take place in foreign countries do not constitute "use in commerce" inasmuch as Congress lacks authority to regulate clinical trials outside the U.S.

In response, Anticancer maintained that it had 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, it had placed labels bearing the ONCASE mark on bottles containing the pharmaceutical products; and that shipments of pharmaceuticals for the purpose of clinical trials constitute "use in commerce" within the meaning of the Trademark Act.

The question before the Trademark Trial and Appeal Board (TTAB) was whether Anticancer's shipments of its pharmaceuticals for purposes of clinical trials within the U.S. and to foreign countries constituted "use in commerce."

Like the Court in G.D. Searle, the TTAB began its analysis with the text of the statute and then turned to the legislative history of the Trademark Law Revision Act of 1988:

> 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).
> …
> 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 …" Senate Judiciary Committee Report on S. 1883, S. Rep. No. 100-515, p. 44-45 (Sept. 15, 1988) (other citations omitted).

The TTAB concluded that Congress intended that "use in commerce" encompass shipments of pharmaceuticals for pre-clinical studies as a reflection of common industry practice. Further, the TTAB rejected Alfacell's argument that shipments to foreign countries for clinical testing do not constitute "use in commerce:" "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."

Clearly, Congress understood that shipments to clinical investigators constitute "use in commerce" in the pharmaceutical industry because such shipments– although limited and not directed to consumers – are genuine trademark use. Pharmaceutical companies based in the U.S. having long drug development and approval cycles should leverage their trademark use during pre-clinical and clinical trials in both the U.S. and in foreign countries to establish and facilitate the registration of those rights.

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