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TRADEMARKS

The authors explore what constitutes sufficient ''use in commerce'' of a drug name to qualify it for trademark protection.

A Prescription for Proving Use of Trademarks for Drug Names in the U.S.

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I. INTRODUCTION

Pharmaceutical companies regularly file trademark applications in the United States for names used in connection with drugs that are awaiting Food and Drug Administration approval. Either during the application or subsequent maintenance process, depending upon the circumstances, the applicant and/or registrant must claim use of the mark in U.S. commerce to obtain or retain registration, as the case may be.

Drugs that are still awaiting FDA approval are, by definition, not yet marketed or sold to the consuming public and, thus, proving use of the mark may be problematic in those circumstances.

A pharmaceutical must undergo various stages of clinical trial testing before the FDA will approve it for consumer consumption.[1] In certain circumstances, clinical trials held during the FDA approval process may constitute use of the mark in commerce under U.S. trademark law.

The FDA approval process can be quite lengthy.[2] As a result, allowing pharma companies to claim these clinical trials as technical trademark use is an enormous benefit to them. Applicants and/or registrants that could not otherwise prove use of their marks in commerce would be forced to abandon their applications or cancel their registrations with the concurrent loss in priority and cost to re-file.

Foreign applicants relying upon a home country registration can forgo claiming use at the application stage.[3] Thereafter, they are required to claim use before the maintenance deadline passes six years after registration (plus the six-month grace period).[4] In limited circumstances, however, in lieu of claiming use, the registrant may file a Declaration of Excusable Nonuse,

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[1] *See* 21 C.F.R. § 312.21 (2008).
[2] *See* James T. O'Reily, Food and Drug Administration §§ 13.79-13.80 (3d ed. 2008).
[3] *See* 15 U.S.C. § 1126(e) (2007).
[4] *See id.* at Section 1058.

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which may prevent unintentional cancellation of the mark for nonuse.

II. TRADEMARK USE IN U.S. COMMERCE

A. Ordinary Course of Trade

In order to constitute use in U.S. commerce, the applicant or registrant must make a ''bona fide use of the mark in the ordinary course of trade.''[5] The legislative history of the Trademark Law Revision Act of 1989 notes that the ''ordinary course of trade'' varies from industry to industry and that the definition of ''use in commerce'' should be flexible to account for differing industry practices.[6]

The question, then, is what is the ordinary course of trade for the pharmaceutical industry?

The House Judiciary Committee report speaks directly to this issue. The report states, ''[w]hile use made merely to reserve a right in a mark will not meet the standards, the Committee recognizes that the 'ordinary course of trade' varies from industry to industry. . ., 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. . . .''[7]

Similarly, the Senate Judiciary Committee noted that the definition of ''use in commerce'' should be pliable to ensure ''genuine but less traditional'' trademark uses.[8] The Senate Judiciary Committee also explicitly addressed the pharmaceutical industry and explained that ''ongoing shipments of a new drug to clinical investigators by a company awaiting FDA approval'' may constitute ''use in commerce.''[9]

Therefore, pharma companies' transportation and distribution of their products to investigators while conducting clinical trials for drugs involved in the FDA approval process will presumably be interpreted as within the ''ordinary course of trade'' as prescribed under the statute and interpreted by the legislative history. Indeed, the Trademark Trial and Appeal Board recently held, in a non-precedential decision, that 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.''[10]

However, whether the mark is deemed in ''use'' will most likely also depend upon the manner in which the mark is actually used on or in connection with those pharmaceuticals.

B. Mark Used on or on Connection With the Goods

A mark is deemed in use in commerce on goods when ''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 . . . and the goods are sold or transported in commerce.''[11]

Pharmaceuticals transported over state lines for clinical trial purposes should meet the second prong of the use in commerce test, as actual sale of product is unnecessary.[12] Case law suggests, however, that in order to qualify as use, the drugs being shipped in commerce must actually be labeled with the trademark.

In *Alfacell Corp. v. Anticancer Inc.*, respondent placed labels bearing the involved trademark directly on pharmaceutical bottles containing the goods.[13] The board held that respondent's shipment of the labeled goods throughout the United States for pre-clinical testing and abroad for clinical testing prior to FDA approval constituted use in commerce.[14] Likewise, the U.S. District Court for the Southern District of New York has indicated that a plaintiff's shipment of cartons of drugs affixed with the mark ''Celebra'' intended for an ''open label safety study'' performed during Phase III of plaintiff's clinical trials program met the use in commerce standard under the Lanham Act.[15]

Thus, available case law indicates that affixing the trademark to the goods, or using the mark in close association with the goods, may be a necessary predicate to determining whether the trademark is in use in commerce. This means that even where pharmaceuticals are shipped in interstate commerce for clinical testing in anticipation of FDA approval, the goods or their containers should still bear the trademark.[16]

Consequently, pharma companies should strive to use the trademark on or in connection with the drugs at the clinical testing stage where possible. Such labeling procedures will make proving use and obtaining and maintaining registration less difficult.

However, there are varying levels of clinical testing and it is possible that the pharmaceutical products may never include the trademark on the label, such as during a ''double blind'' study.[17] Therefore, pharmaceuti-

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[5] *Id.* at Section 1127.

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

[7] *Id.* at 15.

[8] Senate Judiciary Comm. Report on S. 1883, S. Rep. No. 100-515, p. 44 (Sept. 15, 1988).

[9] *Id.* at 44.

[10] *Alfacell Corp. v. Anticancer Inc.*, No. 32202, 2002 T.T.A.B. LEXIS 617 (T.T.A.B. 2002) (not citable as precedent).

[11] 15 U.S.C. § 1127 (2007).

[12] *Endo Laboratories Inc. v. Fredericks*, 199 USPQ 824, 827-28 (T.T.A.B. 1978) (noting that applicant's transportation of goods was sufficient to support its application, ''especially in view of applicant's efforts to test the product''); J. Thomas McCarthy, *McCarthy on Trademarks and Unfair Competition* § 19:118 (4th ed. 2007).

[13] *Alfacell Corp.*, 2002 TTAB LEXIS 617, at *5-6, 9.

[14] *Id.*

[15] *G.D. Searle & Co. v. Nutrapharm Inc.*, No. 98 Civ. 6890, 1999 U.S. Dist. LEXIS 16862, at *5, 9-10 (S.D.N.Y. Nov. 1, 1999).

[16] The Patent and Trademark Office has previously accepted specimens showing use of a mark in clinical testing. For example, in 1994, Zeneca Ltd. submitted drug labels used in clinical testing with its Section 8 Declaration of Use filed in U.S. Registration No. 1,517,746 of the mark ''Seroquel.'' The label, available for viewing on the Trademark Document Retrieval database of the PTO, includes the following caution: ''New Drug Limited by Federal Law (USA) to Investigational Use.''

[17] Blinded studies are when the testing subjects are not informed as to whether they are given the testing drug or a placebo. In double blind studies, both the testing subjects and the clinical investigator are kept in the dark as to who is given the testing drug. Blinded studies are frequently used during Phase III of clinical testing and are designed to test the efficacy of the drug and elicit neutral research results. *See* James T. O'Reily, Food and Drug Administration § 13.82 (3d ed. 2008).

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cal companies still need to be mindful of the balance between trademark use and regulatory concerns.

III. EXCUSABLE NONUSE

Determining and following the specific procedures related to trademark labeling for each drug involved in a clinical trial may be burdensome, especially for large drug companies. Numerous drugs undergo the detailed and ongoing clinical trial process, which includes various levels and forms of testing, potentially making it difficult to properly label each product for trademark purposes.

Additionally, as stated above, certain trials may require anonymity of the drug name, making normal trademark labeling improper. In such cases, where appropriate, it may be prudent for pharma registrants to file a Declaration of Excusable Nonuse to maintain their registrations.

A Declaration of Excusable Nonuse may be utilized by registrants that have either proved use earlier, but use has since been interrupted, or by those that were able to avoid proving use during the application process, such as through an extension from an International Registration or by claiming a home country registration as the basis for obtaining registration in the U.S. The declaration, however, is not available to applicants in pending trademark applications.[18]

The PTO permits registrants to file Declarations of Excusable Nonuse to meet maintenance or renewal deadlines in limited circumstances where the registered mark is not in use in commerce.[19] Among other things, the declaration must explain the reason for nonuse and demonstrate that nonuse is due to ''special circumstances.''[20] To determine if ''special circumstances'' exist, the office looks to whether the registrant's activities were that of a reasonable businessperson who had a bona fide intent to use the mark in commerce.[21]

The legislative history of the Lanham Act indicates that conducting clinical trials while awaiting FDA approval may be a form of excusable nonuse.[22] All pharmaceutical companies conduct clinical trials in anticipation of FDA approval, as it is required before the drugs can be sold or marketed to the American public.[23]

Thus, where a pharmaceutical company is unable to affix its mark to the drug bottles or containers, but is active in seeking FDA approval, it may be able to take advantage of the Declaration of Excusable Nonuse in lieu of filing a Section 8 Declaration of Use at maintenance or renewal deadlines. Indeed, some pharmaceutical companies have successfully filed such declarations.[24]

IV. ABANDONMENT CONCERNS

While a drug is undergoing clinical testing in the United States, some pharmaceutical companies may be concerned about the risk of abandonment of the mark due to nonuse where they cannot prove technical trademark use. However, in order to abandon a mark, under U.S. law, the owner must cease using the mark and also have an intent not to resume use of the mark.[25]

Three years of nonuse is prima facie evidence of abandonment.[26] Ongoing clinical trials and attempts to obtain FDA approval, however, would arguably show a continued intent to use the mark.[27]

Thus, it seems unnecessary to re-file a new application every three years after registration, even where the drugs are not yet sold in the United States, as any presumption of abandonment can likely be rebutted.

Furthermore, if a Declaration of Excusable Nonuse is eventually filed during the trademark maintenance process, it should mitigate the possibility of third parties successfully proving abandonment because the declaration includes an allegation of a continued intent to use the mark.[28]

V. CONCLUSION

Clinical trials performed in an attempt to obtain FDA approval may constitute ''use in commerce'' in the United States. There is consensus that clinical trials are conducted in the ''ordinary course of trade'' in the pharmaceutical industry.

However, in order to qualify as ''use in commerce,'' case law suggests that the mark must be used on or in close connection with the goods as they are shipped in commerce. Thus, where possible, pharmaceutical companies should label the shipment of drugs with the trademark sought to be registered. By doing so, they can take advantage of the ability to prove use and obtain registration before the drugs are ever sold or marketed to the public.

Where this is burdensome and the goods or their packaging do not bear the mark, at least in the post-registration process, pharma companies should determine whether the circumstances warrant their filing a Declaration of Excusable Nonuse. Finally, the difficulty in proving abandonment should provide a measure of comfort in the post-registration process, such that re-

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[18] The authors note the disparity in the consequences of one's inability to prove use during the application and registration phases, respectively. Namely, an applicant's inability to prove use results in abandonment of the application. A registrant, on the other hand, may have the opportunity to file a Declaration of Excusable Nonuse, which allows it to maintain its registration and priority in the mark. This presumably benefits foreign trademark owners who never had to prove use of the trademark in U.S. commerce before obtaining registration here.

[19] 37 C.F.R. § 2.161(f)(2) (2003).

[20] *Id.*

[21] *See Imperial Tobacco Ltd. v. Philip Morris Inc.*, 899 F2d 1575, 1581, 14 USPQ2d 1390, 1394-98 (Fed. Cir. 1990) (overruled on other grounds); *Bonafilia v. American Marketing Association*, No. 92032964, 2004 TTAB LEXIS 552 (T.T.A.B. 2004) (not citable as precedent).

[22] *See generally* Senate Judiciary Comm. Report on S. 1883, S. Rep. No. 100-515, p. 44 (Sept. 15, 1988).

[23] *See* 21 C.F.R. § 312.21 (2008).

[24] For example, a Declaration of Excusable Nonuse was filed by German pharmaceutical company Hoechst Aktiengesellschaft in 1990 in connection with Registration No. 1,337,510 for the mark ''Suprefact'' while the drug was undergoing testing. The PTO accepted the declaration and the registration was maintained (the registration has since lapsed).

[25] 15 U.S.C. § 1127 (2007).

[26] *Id.*

[27] Where a mark is not used on the pharmaceutical packaging in clinical testing, for example, in double blind testing, pharma companies should still maintain clear internal documentation referring to both the product code and the drug name, especially in connection with shipments of the drug to clinical investigators. This would help rebut any challenge as to abandonment and improper ''warehousing'' of the mark, as it would provide documentary evidence tying the mark sought to be registered together with the goods.

[28] *See* 15 U.S.C. § 1058 (2007).

filing seems unnecessary so long as the drug is undergoing clinical testing.

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