King & Spalding LLP

United States

Pharmaceutical trademarks must clear a number of hurdles, including distinct and independent reviews by the US Patent and Trademark Office and the Food and Drug Administration

The registration and enforcement of rights in trademarks for pharmaceutical products are significantly more complex than for other products. The following review highlights several important considerations, challenges and best practices relating to pharmaceutical trademarks in the United States.

Searching and clearance

A pharmaceutical company typically pursues a multi-step process in selecting and applying to register a proposed trademark for a pharmaceutical product. The first step in the procedure is for the company to generate a list of potential trademarks for the product. It is recommended to have several back-up names available in case there is an issue with any of the candidate names.

After identifying several proposed names, the company then conducts trademark searches for pre-existing marks that are visually and phonetically similar to the proposed marks. First is a preliminary online search to 'knock out' any direct (nearly identical) marks. Once that initial list has been pared down to those that cleared the preliminary search, the company proceeds to full searches conducted by an outside search company. The search reports are usually reviewed by the company's in-house lawyers or outside counsel, who evaluate any similarities with pre-existing marks for a likelihood of confusion. Once the mark has been cleared by counsel for use and registration, the company files an application for the mark with the US Patent and Trademark Office (USPTO).

The company may also undertake a factual investigation of the clinical setting in which the pharmaceutical product under the proposed marks will be used. Through this investigation, the company hears directly from medical professionals regarding how the proposed marks will be used in a real-world setting and any related concerns. This clinical perspective will consider not only the potential confusion that the proposed marks may cause, but also:

- facts regarding the frequency with which the pharmaceutical product under the marks will be prescribed;
- the environment in which the product will be dispensed;
- product dosage;
- the generic name for the product; and
- other relevant issues.

USPTO and FDA review

Pharmaceutical companies find that the selection of trademarks for their products in the United States is complicated by the requirement that two different federal agencies – the USPTO and the Food and Drug Administration (FDA) – must review and approve their marks. Each of these two agencies performs a distinct and independent review of proposed pharmaceutical trademarks based on different criteria and those reviews may lead to different conclusions regarding the availability of the marks.

Applicants for pharmaceutical trademarks face an unusual problem in demonstrating the use in commerce of the mark that is required for registration. Unlike typical consumer goods, pharmaceutical products may not be brought to market without lengthy testing and regulatory review. As a result, decisions such as *GD Searle & Co v Nutrapharm Inc* (98 Civ 6890 TPG, 1999 WL 988533 (SDNY 1999)) have established that in the pharmaceutical context, shipment of a product under the trademark to a laboratory for clinical testing constitutes a satisfactory use in commerce of the mark. In preparing trademark applications, however, applicants should be careful not to rely on the distribution of products to consumers prior to regulatory approval as use in commerce of the mark, since such use may be considered unlawful and thus inappropriate for alleging trademark use (*GoClear LLC v Target Corporation*, C 08-2134, 2009 WL 160624 (ND Cal, January 22 2009)). Use issues do not arise in the registration context if the basis of the US application is either the Paris Convention for the Protection of Industrial Property or the Madrid Protocol, since in those cases use need not be alleged or proven before registration.

The USPTO's trademark examination focuses on the inherent distinctiveness of the proposed mark and the likelihood that consumers will confuse the proposed mark with a pre-existing registration or application at the USPTO. When reviewing a trademark application, the examining attorney will draw information from a wide variety of sources – including other trademark registrations and applications, web searches, the dictionary and other publicly available information – in considering whether to approve the proposed mark for publication on its way to ultimate registration.

The FDA, with a narrower focus based on its legal mandate to regulate the safety and effectiveness of drugs, is concerned with:

- possible medication errors resulting from confusingly similar product names, packaging or labelling; and
- false or misleading messages conveyed by product names, packaging or labelling.

The FDA's 'confusion' review focuses on:

- the phonetic and visual similarity between a proposed mark and other pharmaceutical marks and medical terms; and
- the potential for confusion throughout the US healthcare distribution system.

The FDA also discourages certain naming conventions that may cause confusion – for example, the inclusion of the dosing form, the dosing interval or medical abbreviations in proposed marks.

The FDA compares proposed marks to the stem list created by the US Adopted Names Council (USAN) in cooperation with the international non-proprietary name programme of the World Health Organization. The use of these stems is intended to create a standardized way of accurately communicating the pharmacological or chemical traits of a named product. As a result, each stem is applicable to multiple products, so the use of stems in product trademarks may result in many confusingly similar names. The

FDA recommends that proposed marks not incorporate USAN stems.

The FDA's review of proposed pharmaceutical trademarks is coordinated by the Division of Medication Error Prevention and Analysis (DMEPA), which is responsible for accepting or rejecting new pharmaceutical trademarks before they are used in the market. A pharmaceutical company initiates this process by filing a request for proprietary name review of one or more proposed trademarks. The DMEPA then undertakes a multi-faceted review with the assistance of both FDA staff and external health care professionals. Among other aspects, this review by a panel of experts will include:

- searching for similar pharmaceutical trademarks among products currently on the market or in the FDA pipeline;
- conducting simulated prescription studies (oral and written);
- considering similar terms among common medical terminology;
- assessing risk and benefit (ie, potential for harm); and
- using sophisticated databases and software to identify and compare similar trademarks and terms.

If the FDA is satisfied with the outcome of this review, the proposed trademark will be approved subject to ongoing FDA restrictions on proper use and advertising of pharmaceutical trademarks.

The FDA's 'claims' review examines whether the proposed mark itself contains a false or misleading message about the product – for example, by overstating the product's effectiveness, uniqueness or superiority. In particular, a fanciful mark applied to a common substance will not be acceptable to the FDA if the mark suggests that the product has some "unique effectiveness or composition". The FDA may also find a proposed mark misleading if it suggests use for an unapproved indication, or includes or suggests the name of one or more – but not all – of the product's ingredients.

Non-traditional trademarks

In addition to identifying their products using words, pharmaceutical companies may find that other characteristics of their products can serve to identify the source of those products. The Lanham Act provides that these characteristics – such as shapes or colours – are eligible subject matter for trademark protection, pursuant to the act's definition of 'trademark' to include "any word, name, symbol, or device, or any combination thereof" (15 USCA § 1127). These characteristics may be registered as trademarks with the USPTO once they have acquired distinctiveness or secondary meaning (Section 1212 of the Trademark Manual of Examination Procedures). These aspects of the product may also be protected under trade dress/get-up protection under Section 43(a) of the Lanham Act.

A recent case illustrates the difficulty of trying to register non-traditional trademarks. In *In re Organon NV* (79 USPQ2d 1639 (TTAB 2006)), a pharmaceutical company applied to register "an orange flavour" as a trademark for "pharmaceuticals for human use, namely, antidepressants in quick-dissolving tablets and pills". The USPTO refused registration and the Trademark Trial and Appeal Board affirmed on the ground that the claimed trademark was functional. The orange flavour, as used by the applicant, delivered significant advantages – a pleasant taste, leading to increased patient compliance and medication efficacy. Moreover, these benefits provided the applicant with a competitive edge that would leave competitors at a serious commercial disadvantage. With so many utilitarian benefits, the orange taste was thus functional and could not be registered as a trademark.

Conclusion

Registration of trademarks for pharmaceutical products involves a thorough, two-tier review by the USPTO and the FDA. Success in registration and enforcement of pharmaceutical trademarks in the United States requires that companies:

- begin the selection and clearance of proposed marks early in the development of new products;
- carefully consider the many ways in which proposed marks could cause confusion or convey misleading messages; and
- recognize the limitations on the use of colour, shape or other product characteristics as trademarks or as trade dress/get-up.

If the proper precautions are taken, the United States offers comprehensive protection for pharmaceutical trademarks. WTR

Clark Lackert
Partner
clackert@kslaw.com

Clark Lackert is a partner in King & Spalding's IP group. He has lectured and written on the issues of pharmaceutical trademarks at specialized conferences sponsored by the Pharmaceutical Trademarks Group and PhRMA, and has consulted with several governments as well as clients on the special requirements of pharmaceutical trademarks and patents. Mr Lackert is consistently ranked as one of the world's leading trademark lawyers.

Keith Sharkin
Partner
ksharkin@kslaw.com

Keith Sharkin is a partner in the IP group in King & Spalding's New York office. He represents a wide range of clients in all aspects of trademark, unfair competition, false advertising and copyright law. His practice is heavily focused on litigation matters in federal courts and opposition proceedings before the Trademark Trial and Appeal Board.