

Brands in the Boardroom 2009

Side effects of pharmaceutical trademarks

Dickstein Shapiro LLP

Side effects of pharmaceutical trademarks

Pharmaceutical trademarks are uniquely challenging, but a firm grasp of the regulatory requirements and a strategy coordinating trademark registration with development and marketing decisions can relieve any headaches

By **Stephanie K Wade**, Dickstein Shapiro LLP

While pharmaceutical products are intended to make us feel better, their trademark issues can cause headaches. Pharmaceuticals are unique products. The approval, sale and advertising of pharmaceuticals are tightly regulated. Their timelines from development to marketing launch can be long and difficult. Even the manner in which pharmaceuticals are purchased is unique, requiring a doctor's prescription and a dispensing pharmacy. These factors present unique issues for trademark protection, especially in the United States. This article diagnoses trademark issues faced by US pharmaceutical companies and suggests remedies to treat them.

US registration issues

Many products take years to bring to market, but few face as arduous a path as pharmaceuticals. Each pharmaceutical product involves years of research, several stages of clinical trials and many levels of review by the US Food and Drug Administration (FDA). Setbacks can occur at any point in the process. Years before a product is ready to launch, pharmaceutical companies select marks and file intent-to-use applications to register them. But timing can be a critical concern.

A US trademark application based on intent to use has a limited lifespan. It will die if the mark is not in actual use within three years of the US Patent and Trademark Office (USPTO) issuing the notice of allowance (or, stated differently, a total of four to five years after filing, depending on the length of the examination phase of the application). The reason for this limitation applies to most industries: if the mark has not been used within five years, then it probably never will be. However, this limitation and the reasoning behind it are incompatible with the extraordinary timeline for pharmaceutical products. Pharmaceutical companies often find that the application for their chosen mark is due to lapse just as the product is entering the final stages of regulatory approval. But there are ways to manage this situation effectively.

Clinical trials

For pharmaceutical products, use of the mark necessary to obtain a registration can be satisfied by use of the mark in clinical trials. Unlike the owner of a mark for ice cream or athletic shoes, the owner of a mark for a pharmaceutical need not wait until the trademarked product is in the marketplace in order to claim use. For registration purposes, adequate use of a pharmaceutical mark is made when the mark is applied to the pharmaceutical product or its packaging, and the product is sent in interstate commerce for use in a clinical trial. (A completely blind clinical trial does not provide the necessary use for registration purposes because although the product is in use, the trademark is not seen by either the researcher or the subjects.) This interpretation of "use" in the pharmaceutical context can result in the issuance of a trademark registration years before the product is actually marketed.

Re-filing strategies

As noted above, a US intent-to-use application will lapse three years after the notice of allowance is issued by the USPTO if the mark has not been used. During that three-year period, the trademark owner must obtain an extension of time every six months to keep the application alive. This provides an opportunity for pharmaceutical companies to coordinate the trademark registration process with any delay in the product development or approval process. At each extension, the trademark owner should review the timeline for the product. As soon as it becomes clear that the product will not be launched before the application lapses, the trademark owner should begin to consider strategies for filing new applications for the mark.

The new application should be filed as soon as possible. In the United States, rights in a trademark depend on who used it first. The Trademark Act provides that the owner of an intent-to-use trademark application can claim the filing date of the application as its date of first use. An earlier filing date will be more useful in a priority contest with other users of similar marks. But the benefit of the filing date is lost when the application lapses, leaving the trademark owner to rely on the filing date of the new application in any priority contest. For this reason, the safest course is to file a new application and obtain a new filing date as early as possible.

Typically, the first application filed for a pharmaceutical mark is as a word mark, without a design or stylised lettering. The USPTO will not allow two pending applications of the same mark for the same goods. For this reason, the new application must vary the mark in some way, such as by adding a design or showing the mark in colour or in stylised lettering. Once an application for a variation of the mark has been filed and a new filing date has been secured, the trademark owner can wait until the original word mark application lapses and then file another application for the word mark.

Slogan marks

Slogans or taglines are useful marketing tools, but they present a special challenge for pharmaceutical firms. Companies use slogan marks to announce their goals or position their products. To register a trademark, including a slogan mark, the laws of the United States require that the mark be placed on the goods or on packaging for the goods. Companies in most industries can easily comply with

this requirement by printing their slogans on packaging for the goods, such as “JUST DO IT” on a box for athletic shoes. But pharmaceutical companies are at a disadvantage in registering their slogan marks for the goods they sell. The packaging of pharmaceuticals is regulated by the FDA, which prohibits pharmaceutical companies from placing marketing slogans directly on their products or packaging.

The challenge for registration is to identify other acceptable uses of the slogan on pharmaceuticals or to register the slogan mark for other pharmaceutical-related goods and services. For registration purposes, the USPTO has long accepted use of a mark on displays associated with the product. The conventional example of an acceptable display is a menu board in a fast-food restaurant or a sign above a bin where the goods are located. The idea is that, although not applied directly to the goods, the mark appears with the goods in a purchasing environment in such a way that the consumer associates the mark and the goods.

The USPTO also accepts uses of marks on less conventional displays for registration purposes. For example, use of a mark in a mail-order catalogue or in a television infomercial is acceptable as a display, because the order form in the catalogue and the telephone number on the television screen create a purchasing environment for the consumer. The display concept provides a means of showing use of slogan marks on pharmaceutical products for registration purposes. Adequate displays include use of a pharmaceutical mark on a trade show booth and on materials bearing the mark that are provided in meetings with physicians, pharmacies and hospitals, as long as the means of ordering the products is indicated. This information creates the necessary purchasing environment for these uses of the mark.

An alternative to registering the slogan mark for pharmaceuticals is to register the mark for goods and services in the medical field. Most pharmaceutical companies engage in promotional and educational activities. And the use of the slogan in connection with these activities can provide the basis for registration. Identifications that are frequently used in applications for pharmaceutical slogan marks include:

- Promotion of public awareness of healthcare issues through an educational campaign.
- Booklets, pamphlets and leaflets on healthcare topics (either printed or online).

- Provision of medical information via a website.

FDA trademark review

In most industries, companies select one, or at most a few, candidate marks for each new product. Comprehensive trademark searches identify potential risks of confusion in the marketplace, as well as potential obstacles to registration of the mark. The mark with the brightest prospects for use and registration is selected and an application to register the mark is filed. Infrequently, the chosen mark will encounter some unanticipated conflict. But most of the time, the mark moves forward to registration and use.

The path to registration and use is very different in the pharmaceutical industry. The FDA decides which marks can be used for pharmaceutical products in the United States and rejects as many as one-third of the marks proposed for use in the United States. Even a mark that has been registered in the United States (based on use in clinical trials) can be rejected by the FDA for use in the United States. The FDA makes its decision regarding a proposed trademark approximately 90 days before it approves the product for sale. If the mark is rejected, the product launch may be delayed while the company searches for a new mark.

A pharmaceutical company can avoid the disruption that could result from the FDA's rejection of its chosen mark by undertaking strategic planning at every step in the trademark process. This planning begins with the clearance process. Unlike in other industries, the clearance process in the pharmaceutical industry must identify more than one mark, and preferably as many as five marks, for each product. These must be marks that the company is willing to use for the product, because if the first choice is rejected, an alternative (acceptable to both the FDA and the company) must be available immediately. To find five viable trademark candidates, pharmaceutical companies must identify and search a large number of potential marks.

The pharmaceutical trademark clearance process includes a unique step: medical errors testing. The FDA's goal in evaluating proposed trademarks is to prevent medical errors. To this end, the FDA considers the similarity of the marks (eg, whether they are similar when handwritten), as well as the product characteristics (eg, whether they are packaged or administered similarly). A pharmaceutical company should anticipate the FDA's review and consider the medical error potential of its

trademark candidates. Several companies specialise in the testing of trademarks for the possibility of medical errors. Medical errors testing is often conducted contemporaneously with traditional trademark searching.

Once a number of trademark candidates have been cleared, intent-to-use applications should be filed for all of them. As development of the product continues, the trademark applications will proceed towards registration through the examination stage and opposition period. One or more marks may be abandoned during this process. Nonetheless, because multiple marks have been cleared, several viable trademark candidates will remain when the company is ready to file its application for approval to market the product. In that application, the FDA will allow the company to include two proposed marks for the product, designated as the first choice and an alternate. Two marks should always be submitted. The FDA will evaluate the alternate mark only if it rejects the company's first choice.

Another important trademark strategy is to seek FDA evaluation of the proposed trademark early in the product development process. As noted above, once a pharmaceutical product has been developed, evaluation of the trademark is part of the FDA's product approval process. However, if requested, the FDA will evaluate a proposed trademark much earlier in the drug development process. Once Phase 2 clinical trials have been completed, the FDA can provide an initial evaluation of proposed trademarks. Later, the FDA will conduct a second trademark evaluation as part of its marketing approval decision.

International registration issues

When the United States joined the Madrid Protocol in 2003, US trademark owners welcomed the opportunity to participate in this international trademark registration treaty. The Madrid Protocol provides an easy and less expensive way for US companies to file applications to register their trademarks in more than 70 countries. Under the Madrid Protocol, trademark applications in other countries can be based on a US application, provided that the mark, the applicant and the goods are the same as in the US application. Many US trademark owners leapt at the chance to take advantage of the benefits of the Madrid Protocol.

Many US pharmaceutical companies did not find the treaty as advantageous because the coverage of their foreign trademark registrations would be broader

if they continued to file in each country directly, rather than under the Madrid Protocol. The problem is that the coverage of foreign registrations obtained under the Madrid Protocol must be identical to the coverage in the home country registration. This requirement presents no issue for companies in countries where broad coverage can be claimed because the coverage in their Madrid filings will be equally broad. But in the United States, only narrow coverage can be claimed for pharmaceutical products.

Specifically, coverage for a pharmaceutical mark in a US application must be identified by type (eg, “analgesics”) or treatment (eg, “pharmaceuticals for the treatment of pain”). In contrast, many countries and the Community Trademark Office allow use of the broader identification “pharmaceuticals”. If a US company uses the Madrid Protocol, its foreign trademark protection will be as narrow as its US protection instead of as broad as the foreign country would otherwise allow. US pharmaceutical companies must therefore choose between the ease and cost advantages of obtaining foreign trademark protection by filing under the Madrid Protocol and the breadth of protection useful for enforcement obtained by filing directly in each country.

Many US pharmaceutical companies

have chosen to forgo the advantages offered by the Madrid Protocol in favour of the broader coverage that can be obtained by filing directly in each country. However, the inefficiency of filing directly has been mitigated in recent years by the general streamlining of filing requirements around the world and the ability to send instructions and filing documents by email.

Some US pharmaceutical companies have resolved the issue in a different way. Rather than base Madrid filings on its US application, a parent company with a subsidiary outside of the United States may permit the subsidiary to file an application for the mark in the country where that subsidiary is located. The application may then cover “pharmaceuticals” broadly and the Madrid applications based on it will be equally broad. Under this approach, the limitations of reliance on the US application can be avoided, but the foreign protection for the mark will be in the name of the subsidiary.

Conclusion

Pharmaceutical marks present unique challenges for trademark owners. Understanding the FDA regulatory requirements and devising a strategy for coordinating the registration of marks with development and marketing decisions can alleviate your trademark headaches. **iam**



Stephanie K Wade is a partner in Dickstein Shapiro LLP's intellectual property practice. Her practice focuses on trademark, unfair competition and copyright law. She has more than 25 years' experience in counselling clients from the United States and abroad in all aspects of trademark practice, including selection, searches and opinions, registration, licensing, enforcement, due diligence in corporate acquisitions and internet issues, as well as the selection and international clearance of marks for new product launches.

Stephanie K Wade
Partner
wades@dicksteinshapiro.com
+1 202 420 3126

Dickstein Shapiro LLP
United States
www.dicksteinshapiro.com

Dickstein Shapiro LLP
1825 Eye Street NW
Washington, DC 20006-5403
United States
Tel +1 202 420 2200
Fax +1 202 420 2201
www.dicksteinshapiro.com