

United States
Keith A Barritt
Fish & Richardson PC

Pharmaceutical Trademarks 2015/2016

**World
Trademark
Review**™

A Global Guide

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Author
Keith A Barritt

Selection, clearance and registration

A drug name can be registered as a trademark in advance of its approval by the Food and Drug Administration (FDA). An application for registration at the US Patent and Trademark Office (USPTO) can be based on intent to use a trademark or use of the mark in clinical trials, or ownership of a foreign trademark application that matures into a registration. Foreign applicants should keep in mind that a US application should include only those goods for which they actually use or have a good-faith intent to use the mark in US commerce. It is not permissible to claim simply “all of Class 5”, and it is unlikely that the same mark would be used for products that both treat children’s colds and kill vermin.

While registration is an important step, it has no bearing on FDA approval. The FDA’s review of a proposed drug trademark is complex and fraught with potential risks. The rejection rate is high and even if a name is tentatively approved, there is no guarantee that the name will ultimately be approved if a subsequent product is authorised for marketing first.

In May 2014 the FDA released draft guidance on best practices for developing pharmaceutical trademarks. The draft guidance gives drug makers valuable insight into how the FDA scrutinises proposed trademarks so that manufacturers can choose names with a better chance of FDA approval. The draft guidance complements the FDA’s 2010 final guidance on information required in an application for name approval.

Rationale for FDA involvement: preventing medication errors

Three billion retail prescriptions are sold annually in the United States, and there are an estimated 1.3 million injuries from medication errors each year. About 12.5% of medication errors are attributed to confusion between drug brand names by healthcare professionals.

The FDA Division of Medication Error Prevention and Analysis (DMEPA) is responsible for reviewing drug trademarks both before and after marketing. In reviewing names, the FDA considers whether a drug name will be confusing not only

for consumers, but also for physicians, pharmacists and nurses.

The DMEPA reviews all proposed names for confusing similarity to the names of other drugs or drug ingredients, including both trademarks and established or generic names. The DMEPA typically rejects about one-third of all names reviewed in order to avoid, among other things:

- names that suggest potentially exaggerated efficacy claims (eg, the hair-growth product known as REGAINE around the world is marketed as ROGAINE in the United States, as the FDA would not approve the name REGAINE since it does not work for everyone);
- names that could lead to erroneous prescriptions (eg, the wrong drug or dosage); and
- names that look or sound confusingly similar to other drug names (eg, while CELEBREX is an oral pain reliever, CEREBYX is an anti-seizure drug and CELEXA is an oral anti-depressant).

For a company seeking to introduce a new drug, DMEPA rejection can substantially increase time to market and threaten competitive advantage. Therefore, it is important to understand the FDA's perspective and select names with both the FDA and the USPTO in mind.

Avoid misleading names

To reduce the risk that the FDA will find a name misleading, a company should avoid:

- names that refer to an inactive ingredient in a way that suggests effectiveness;
- names that incorporate generic stems in the stem position;
- names that imply unique effectiveness (eg, 'Wonder');
- terms that imply maximum strength (eg, 'Ultra'); and
- 'recycled' trademarks of discontinued products.

Avoid names risking medication errors

To reduce the risk of choosing a name that the FDA will consider prone to potential medication errors, a company should avoid:

- names that contain numbers that might be

misinterpreted – some pharmacists have interpreted 'Percocet 5' to mean five tablets per dose; and

- letter prefixes, suffixes and abbreviations that may have different meanings in the medical field (eg, 'BID', which means twice daily to pharmacists).

In general, the FDA gives greater scrutiny to the names of prescription drugs than to those of over-the-counter (OTC) drugs. Illegible handwriting on written prescriptions and mispronounced phone orders can lead to pharmacy errors. 'XL' in a drug name may sound like 'SL', which indicates 'sublingual' to pharmacists. With OTC drugs, prefixes and suffixes are viewed directly by consumers so there is less risk of misinterpretation by pharmacists. As a result, the FDA allowed TAGAMET HB for heartburn and PEPICID AC for acid control.

The potential consequences of a medication error are also factors in the FDA assessment. The more severe the potential consequences, the more stringent the review.

Avoid names confusingly similar to other drug trademarks

The FDA regularly tests drug names by using volunteers inside the agency to help determine whether names are confusingly similar. This has led to the following guidelines to avoid names that might be confused with other existing trademarks:

- Consider the sound of the name when spoken (eg, ZANTAC/XANAX).
- Consider the appearance of names as printed (CELEBREX/CELEXA), knowing that the FDA may use computer technology to detect spelling and phonetic similarities.
- Consider the appearance of a name as written by a physician (physicians typically write the first couple of letters of a drug name with more care than the remaining letters).

The following should also be considered:

- the Rx status of the two products being compared (prescription drugs are less likely to be confused with OTC drugs);
- marks that draw too heavily on the generic name of another drug; and
- similarity with a company's own drug

names (many pharmacies arrange drugs by manufacturer).

Confusion of a different sort can arise when a company uses multiple trademarks for two of its products with the same active ingredient. The FDA discourages this, since it may increase the risk of overdose. An exception may be made where a stigma might be associated with one drug, such as PROZAC and SARAFEM for fluoxetine.

FDA review of trademarks for biologics

Trademarks for non-therapeutic biologics (eg, vaccines) are reviewed by the Advertising, Promotion and Labelling Branch of the FDA Centre for Biologics Evaluation and Research (CBER). CBER has issued the Standard Operating Procedures and Policies for evaluating trademarks. In general, the CBER process is similar to the DMEPA process, with the additional provision that the CBER discourages multiple trademarks for the same drug used for different indications.

OTC drug products

When a product goes from prescription to OTC, use of the same trademark may be acceptable if there is no change in indications, dosing or strength. However, if the OTC and Rx versions are not identical, the FDA believes that it “might be appropriate” to market the OTC product under a different or modified trademark.

The FDA will review a proposed trademark for an OTC drug that will be marketed pursuant to a new drug application or abbreviated new drug application. However, many OTC drugs are marketed under an FDA monograph and are not individually scrutinised by the FDA. For these, the FDA still recommends that the trademarks be evaluated by the sponsor for safety considerations.

Brand-name extensions

The use of brand-name extensions (also known as ‘family marks’ or ‘umbrella names’) is evaluated by the FDA on a case-by-case basis, considering whether the products share at least one common active ingredient, are differentiated by labelling and have appropriate modifiers. The FDA will also evaluate on a case-by-case basis the use of different trademarks

by the same manufacturer for products that contain the same active ingredient, but for different indications.

Navigating the DMEPA review process

When requesting DMEPA approval for a proposed drug name, a drug maker must submit (only) two proposed drug names, in order of preference. If the first is rejected, the DMEPA will evaluate the second.

The review of a proposed name submitted during the investigational phase must be completed and communicated to the sponsor within 180 days, as opposed to 90 days for a request for review submitted with an application for a new drug or therapeutic biologic. Names that receive tentative approval undergo a second evaluation 90 days before final approval of the drug or biologic. During the second evaluation, the DMEPA will compare the proposed name with drug names that have been approved since the initial evaluation. There is discussion to replace the initial tentative approval with something more definite, assuming that the product itself is finally approved for marketing.

The FDA’s May 2014 draft guidance contains detailed descriptions of how the FDA conducts – and how sponsors should conduct – name simulation studies to try to gauge the likelihood of any given name causing end-user error based on phonetic, spelling and orthographic similarities. Although sponsors are not required to submit their own studies, the FDA states that more comprehensive simulation studies “would be useful”.

Post-marketing surveillance

Even after a drug name has been approved, the DMEPA monitors reports of problems with marketed drugs and can order changes in drug names it has approved. For example, PEDIAPROFEN was changed to CHILDREN’S MOTRIN after reports that it had been confused with PEDIAPRED.

Sometimes the FDA orders changes only in labelling to eliminate confusion, rather than a complete name change. These changes may include changing the mix of upper and lower-case letters, as well as special shading and distinctive colours. For example, new labelling was ordered to distinguish

LamICTAL (an epilepsy drug) from LamISIL (an anti-fungal pill).

Parallel imports and repackaging

Section 381(d) of the Food, Drug, and Cosmetic Act states that prescription drugs (or drugs composed wholly or partly of insulin) made in the United States and exported to a foreign country can be re-imported only by the drug’s original manufacturer. Even when original manufacturers re-import drugs, the drugs must be real, properly handled and relabelled for sale in the United States if necessary.

The Medicine Equity and Drug Safety Act, enacted in 2000, theoretically allows prescription drugs manufactured in the United States and exported to certain foreign countries to be re-imported from those countries for sale to US consumers. However,

before the law can take effect, the secretary of health and human services must determine whether adequate safety could be maintained and whether costs could be reduced significantly, which thus far has not happened.

The Food, Drug and Cosmetic Act also prohibits the import of unapproved new drugs. Unapproved new drugs include any drugs – including foreign-made versions of US approved drugs – that have not been manufactured in accordance with FDA approval. Foreign manufacturers whose drugs are imported into the United States are required to register with the FDA and submit a listing of every product in commercial distribution in the United States. These requirements also apply to repackers and relabellers. Registration and listing does not denote FDA approval of the firm or its products. The FDA may refuse admission to any drug that “appears” to be unapproved, placing the burden on the importer to prove that the drug sought to be imported is in fact approved.

Anti-counterfeiting and enforcement

As of January 1 2015, to help to reduce the availability of counterfeit drugs under the federal Drug Quality and Security Act, pharmaceutical manufacturers supplying the US market, wholesale drug distributors, repackagers and many dispensers are required to:

- report product transaction histories regarding who handled drug packages;
- quarantine and investigate any drug that has been identified as suspect; and
- notify the FDA and other stakeholders if an illegitimate drug is found in the supply chain.

By 2017, manufacturers must also include serial numbers on packaging.

The goal of the new law is to provide a better method to track and trace drug packages as they move from manufacturers to distributors to pharmacies, which will help to identify potential counterfeit products. This new federal law should also pre-empt overlapping state laws, potentially easing the overall regulatory burden on manufacturers.

Advertising

In June 2014 the Supreme Court ruled that compliance with FDA food labelling laws does



Keith A Barritt
Principal
barritt@fr.com

Keith A Barritt is a principal in the Washington DC office of Fish & Richardson. His practice is primarily focused on all aspects of trademark law, including prosecution and *inter partes* proceedings before the US Patent and Trademark Office, internet domain name issues and trademark selection and enforcement, as well as all aspects of medical device regulation by the US Food and Drug Administration, including obtaining marketing authorisation for medical devices, use of new devices for investigational purposes and import and

not pre-empt a private party from bringing a deceptive advertising suit under the federal Lanham Act.

The case involved the labelling of Coca-Cola's Minute Maid juice product with the words 'pomegranate blueberry' in capital letters on two separate lines. Below those words was the phrase 'flavored blend of 5 juices', in much smaller type. POM Wonderful alleged that the label misled consumers into believing that the product consisted predominantly of pomegranate and blueberry juice, when in fact consisted predominantly of less expensive apple and grape juices. In overturning the Ninth Circuit's decision, the Supreme Court held that POM Wonderful's false advertising claim could proceed, despite Coca-Cola's arguments that such claims were pre-empted by its compliance with FDA regulations.

By the same logic, presumably such false advertising suits involving drugs and other FDA-regulated products are now also possible, even if the products comply fully with FDA labelling regulations (including the approval of trademarks).

Generic substitution

A hot topic in trademark law is the naming of biosimilars, which are subsequent versions of innovator biopharmaceutical products made by a different company. Because the manufacture of biopharmaceuticals relies on biotechnology, generic versions of innovator products may be similar, but rarely – if ever – identical to the original in the same way that traditional generic drugs may be chemically identical to the original.

Manufacturers of biosimilars, eager to sell lower-cost alternatives to innovator products, naturally want their products to share the same established name. Innovator companies, on the other hand, argue that using the same name for a product that is similar, but not identical would be detrimental to public health.

The primary alternatives for the FDA are whether a biosimilar should share the same established name as the innovator product, be given a slight modification (eg, by adding numbers or Greek letters, as the World Health Organisation (WHO) has done), be given

some other descriptive modifier or be given a completely new name. The more distinct the name, the harder it will likely be for the biosimilar to enter the market as a viable generic alternative to the innovator product.

Online issues

It is estimated that online sales of unregulated and counterfeit drugs total approximately \$75 billion a year. According to the WHO, more than 50% of drugs purchased online from illegal sites that conceal their physical addresses are counterfeit.

In an effort to foster trustworthiness in online pharmacies, the US-based National Association of Boards of Pharmacy (which includes members from Canada, Australia and New Zealand) has been awarded the '.pharmacy' generic top-level domain name. The goal is to establish '.pharmacy' as a known domain name worldwide, so that consumers can trust the information and medicine they receive from such websites.

Earlier efforts to establish a seal of approval for legitimate online pharmacies have suffered from the simple fact that it is easy for unauthorised sites to copy the seal of approval, making it difficult for consumers to know which sites are truly legitimate. The '.pharmacy' domain space will not have that issue, but there will still be a need to educate the public that pharmacies that operate a '.pharmacy' website have been fully vetted and monitored for continued compliance with appropriate standards. **WTR**



Fish & Richardson PC

1425 K Street, NW
11th Floor
Washington DC 20005
United States

Tel +1 202 783 5070

Fax +1 202 783 2331

Web www.fr.com