

## ► The drug name game

*Pharmaceutical companies must get nomenclature approved by the FDA and the U.S. Patent and Trademark Office.*

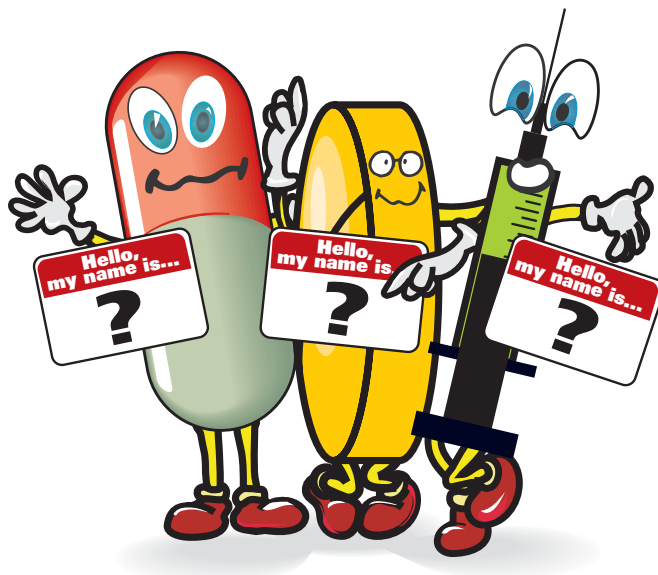
BY TRACY DURKIN AND JULIE SHIRK

Viagra, Allegra, and Ritalin—what do all of these have in common? They are blockbuster drugs, the crown jewels of their companies' assets. Why didn't they just call them sildenafil citrate, fexofenadine HCl, and methylphenidate HCl? Because their owners recognize the value of branding their products to more effectively promote them and increase market share.

Chances are their owners also know all too well the struggle that pharmaceutical companies face in choosing names that both are appealing and will pass scrutiny at the FDA, which approves drug names, and at the U.S. Patent and Trademark Office, which grants federal trademark registrations. The Trademark Office gives companies the federal authority to use the coveted ® after a trademark. These two government agencies are responsible for approving only trademarks that are unlikely to cause confusion in the marketplace. While the standards they apply are compatible, they are by no means coextensive. Thus, it is common for a mark to make it past the Trademark Office, only to be refused by the FDA.

Why are the standards so high? The ever-increasing instances of pharmaceutical confusion that have led to patient harm and, in extreme cases, fatalities has caused the FDA and Trademark Office to more closely scrutinize drug names. In a quality review publication, U.S. Pharmacopeia (USP) reported, "Confusion over the similarity of pharmaceutical trademarks and names, when either written or

spoken, constitutes approximately 15% of all reports to the USP Medication Errors Reporting (MER) Program between January 1, 1996, and December 31, 2000." USP's list of confusingly similar pharmaceutical trademarks and names, based on



reports to its MER and related programs, contains hundreds of confusing sets that include more than 750 different trademarks and names. A sampling of sets recently added to the list includes Amoxicillin and Amoxil, Celexa and Celebrex, Lotronex and Lovenox, Micatin and Miacalcin, and Serophene and Sarafem.

The report indicates that confusion exists not only between the sound and appearance of two or more pharmaceutical trademarks, but also between trademarks and generic or established USP names. The notoriously illegible handwriting of physicians, incomplete knowl-

edge of pharmaceutical trademarks and names, visually similar packaging and labeling, and incorrect selection of a pharmaceutical product from a computerized list have exacerbated the confusion.

### Preventing confusion

The Trademark Office prohibits the registration of any mark that so resembles a previously registered mark (or mark for which an application is previously pending) as to be likely to cause confusion or to cause a mistake, or to deceive the public. When assessing the likelihood of confusion between marks, at least the following factors are considered:

- ▶ similarities in sound, appearance, connotation, and commercial impression;
- ▶ similarities in the goods or services with which the marks are used;
- ▶ similarities in the established and likely-to-continue trade channels; and
- ▶ conditions under which and buyers to whom sales are made, that is, impulse versus careful, sophisticated purchasing by ordinary versus educated consumers.

Because of the potential for harm when consumers and health care providers confuse pharmaceutical trademarks, such as adverse patient reactions, other dangerous effects, or death, a "doctrine of greater care" is applied. This doctrine demands a cautious analysis of the likelihood of confusion between trademarks. For that reason, a reduced "quantum of proof" is required to show confusing similarity between pharmaceutical marks, and a greater-than-normal disparity between pharmaceutical trademarks is required to avoid confusion. Thus, in theory, pharmaceutical trademarks need not be highly similar in sound, appearance, connotation, and commercial impression, and the associated drug or

indications for use need not be identical or even closely related, for the Trademark Office to refuse to register a trademark on the basis of a likelihood of confusion in the marketplace.

Examples of pharmaceutical trademarks that the Trademark Office has found likely to be confusing are Paxetol for cancer treatment and Paxil for an antidepressant; Nicostatin for hyperlipidemia and Mycostatin for an antibiotic preparation; Presamine for an antidepressant and Premarin for menopausal conditions; and Nalex and Nolex, both for nasal decongestants.

Despite the high level of scrutiny needed to weed out confusingly similar marks, the universe that the Trademark Office considers is quite small. It does not necessarily consider nonproprietary pharmaceutical names, established USP or generic names, and trademarks approved for use by the FDA but not yet in use or registered trademarks. As a result, some drug names sail past the Trademark Office, only to be caught by the FDA, which casts a wider net.

### **FDA standards**

The Center for Drug Evaluation and Research, an arm of the FDA that reviews drug applications, formed the Office of Post-Marketing Drug Risk Assessment (OPDRA) in 1999 to facilitate the review of proprietary pharmaceutical names and trademarks. The OPDRA reviews proposed pharmaceutical trademarks and other information on the label, in view of all information available to the FDA, as well as data provided by the applicant about dosage form, strength, route of administration, and indications for use.

According to standards applied by the FDA, a drug label may be misleading if it designates a “drug or ingredient by a proprietary name that, because of similarity in spelling or pronunciation, may be confused with the proprietary name or the established name of a different drug or ingredient.” The FDA has also adopted the principles of the U.S. Adopted Names council (USAN). These principles discourage the use of substantial portions of generic names and stems in proprietary pharmaceutical trademarks, which could

cause confusion or prohibit the creation of future established names and stems. This second level of review by the FDA helps to accurately assess whether a proposed pharmaceutical trademark is likely to be confused with an existing pharmaceutical.

### **What to avoid**

So what is a pharmaceutical company to do when selecting a name for a new product, knowing that it must pass muster with the Trademark Office as well as the FDA? Although the FDA publishes many guides to assist the industry in completing its drug applications, it has no published guide for selecting a pharmaceutical trademark. A draft document,

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*Guidance for Industry on Proprietary and Established Drug Names*, was due to be published in 2001 for consideration and comment. However, it has yet to be published. In the meantime, guidance on selecting a pharmaceutical trademark must be gleaned from the positions that the FDA and Trademark Office have taken in the past, together with the language of the relevant statutes and related articles by those associated or working with the FDA. The following are some suggestions for successfully naming pharmaceuticals.

**Avoid similar-looking words and letters.** The Trademark Office and FDA closely inspect proposed trademarks on the basis of similarity in appearance, either in whole or in part, to other trademarks

and pharmaceutical names. Therefore, it makes sense to avoid, when possible, trademarks having “strings” of letters identical to existing trademarks, particularly at the beginning of the mark, which tends to be the most legible portion and would likely operate as the source of any confusion. The FDA also scrutinizes the letters i, u, v, w, l, and L, which physicians tend to lazily scratch on prescription pads and which often look similar to other letters of the alphabet. Thus, those letters should be used sparingly, if at all.

**Avoid similar-sounding words.** Because many prescriptions are ordered over the telephone, and pharmaceuticals are often asked for by name in clinical settings, consideration should be given to the sound or pronunciation of a proposed mark. Proposed trademarks should be avoided that are phonetically identical, equivalent, or similar, either in whole or in part, to existing pharmaceuticals.

**Make no suggestions beyond clinical data.** The FDA and Trademark Office permit trademarks to connote a particular meaning. Under the FDA standards, however, a proposed trademark should not suggest or imply a promise or condition not clinically supported by the data contained in the drug application. Nor should a proposed trademark imply that the drug has an indication for use other than that listed in the drug application.

**Carefully consider the use of prefixes and suffixes, both alphabetic and numeric.** Pharmaceutical manufacturers often apply alphabetic prefixes or suffixes to trademarks to indicate strength, route of administration, or duration. For example, the prefix ora- implies administration by mouth, and the suffix -stat implies fast action. Although the Trademark Office is unlikely to refuse to register a mark simply because someone has already registered a mark containing such a descriptive term, the FDA may believe that those same suffixes and prefixes could bring the proposed trademark dangerously close to the sound and appearance of an existing pharmaceutical. Thus, alphabetic prefixes and suffixes should be used only after careful consideration, and no use should be made of prefixes and suffixes having multiple meanings, such as HS, which means “half-

strength” and also is prescription shorthand for “at bedtime”.

Likewise, numeric suffixes used to signify duration or suggested dosage regimens could be easily confused by a prescribing physician, pharmacist, or patient for the strength of a pharmaceutical, especially where decimal points appear in a proposed trademark. The use of numeric suffixes is therefore discouraged to avoid prescribing and administration errors.

**Be original—don’t borrow from an established or generic name.** It is common for a pharmaceutical company to lift portions of an established USP or generic name for a proposed trademark. The FDA and USAN council, however, zealously discourage the practice of using pharmaceutical stems as prominent parts of trademarks or proprietary names. Use of the stem blurs the line between trademarks and generic or established names and limits USAN’s ability to create and assign established names in the future. Because medication errors between pharmaceutical trademarks and established names have been severe and even fatal, special care should be taken to avoid the use of derivations of established names to ensure patient safety and the approval of proposed trademarks.

**Limit terms that cause dosaging confusion.** Finally, stay away from terms such as “caps” and “tabs” when the pharmaceutical is available in other dosage forms, such as an oral suspension. Why create confusion? Select a trademark that encompasses all the dosage forms of a particular pharmaceutical.

Because nothing can be more devastating to a pharmaceutical launch than building a campaign around a Trademark Office-unregistrable or FDA-unacceptable trademark, it is worth the time and effort—and it is in the consuming public’s interest—to select a pharmaceutical trademark that avoids the pitfalls contributing to trademark confusion.

**Tracy Durkin** is a director of trademark practice and **Julie Shirk** is a patent and trademark specialist at Sterne, Kessler, Goldstein, & Fox PLLC in Washington, DC. Send your comments or questions about this article to [mdd@acs.org](mailto:mdd@acs.org) or to the Editorial Office address on page 3. ■