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Food and Drug Administration review process v traditional trademark clearance

The FDA is conducting a pilot programme aimed at streamlining the regulatory trademark clearance process

Pharmaceutical trademark clearance is a complex process. A successful pharmaceutical trademark passes marketing muster only by resonating with relevant consumers and conveying the right brand message. It must also be available for use and registration on a global basis, and must survive regulatory scrutiny not only in the United States, but also in several foreign jurisdictions. Overcoming these sometimes unharmonious processes in order to arrive at a successful and enduring mark can be difficult.

The Food and Drug Administration (FDA) reviews new drug applications and pharmaceutical trademarks. The FDA review process overlaps with traditional trademark clearance (ie, evaluating similarity in sound and appearance), but also differs in important ways. Unlike trademark legal clearance, FDA regulatory approval has a consumer safety focus and evaluates potential errors in communicating either spoken or written drug orders. A handwriting comparison is an important component of FDA approval.

This article briefly examines the interplay between FDA regulatory approval and traditional trademark clearance, and explores the FDA two-year pilot programme which is aimed at streamlining the regulatory trademark clearance process.

A different landscape

The intertwined regulatory and legal review process for new pharmaceutical trademarks in the United States presents a challenging clearance landscape, with thousands of applied-for marks that are never put into use. These applications create congestion on the Trademark Register and often block the availability of an otherwise 'clear' new drug trademark.

Pharmaceutical companies appreciate the potential for regulatory rejection and file intent-to-use applications for numerous candidate marks, creating a pool of alternatives to pick from in the event of foreign trademark objections or regulatory rejection. It is not uncommon for a pharmaceutical company to file between 20 and 40 intent-to-use applications when attempting to clear one new drug name. Once approved, these intent-to-use applications are extended while the worldwide clearance and regulatory process is underway. They also serve to distract and mislead competition.

This cautious approach is taken because under the FDA review process, approximately 30% of names submitted for approval are rejected. There is a good chance that a proposed name which is available from a trademark perspective, and approved by the US Patent and Trademark Office (USPTO), will be rejected by the FDA. The current FDA approval process allows pharmaceutical companies to submit one name and one back-up name as part of a new drug application. If both are rejected, the pharmaceutical company will go back to its pool of accepted intent-to-use applications to choose another set of candidate marks.

Having a pool of approved candidate marks prevents significant delays and creates a more fluid process, but often causes frustration because of the sheer number of pending applications without use data to help to assess potential conflict.

A review of the federal Trademark Register reveals nearly 7,000 pending intent-to-use applications for pharmaceutical products in Class 5. The register contains 26,000 abandoned intent-to-use applications that covered pharmaceutical products. Pending intent-to-use and abandoned applications are potential landmines when clearing any mark, but in pharmaceutical mark clearance this is amplified tenfold.

FDA pilot programme

To provide greater transparency and to assist pharmaceutical companies in navigating the difficult clearance and regulatory process described above, the FDA is considering a new approach to its review.

Since 1994 the FDA has reviewed pharmaceutical names as part of its label review. Pharmaceutical companies evaluate the safety of drug names and carry out testing of their own, in addition to trademark legal clearance, to ensure the safety of consumers when encountering new drug names. The process used and material collected by pharmaceutical companies often overlap, and sometimes conflict, with the information collected by the FDA. As a result, the pharmaceutical companies have sought a more streamlined review process.

The FDA has responded with a pilot programme that will re-evaluate its Proprietary Name Review. The pilot programme was included in the Prescription Drug User Fee Act renewal in 2007. The pilot programme sought sponsor companies to participate in a two-year trial review process set to begin in 2010 and to culminate in a public hearing in 2012 to discuss the programme and how best to overhaul the regulatory process.

The pilot programme consists of a seven-stage process, which is to be completed by the pharmaceutical companies and submitted for evaluation to the FDA. The seven stages are:

- Stage 1, Preliminary screening – this involves a basic visual screen of the trademark for obvious deficiencies, such as the inclusion of dosing indications or dosage form. For example, pharmaceutical trademarks cannot end in 'bid' (a dosing indication) or contain 'tabs', 'caps' or 'oral' (dosing forms).
- Stage 2, US adopted names stem search –

this involves a search of generic name databases to ensure that a pharmaceutical trademark does not include all or part of the generic drug name.

- Stage 3, Orthographic and phonetic screen – this involves a search of databases for lookalike and soundalike names. This stage may be most familiar to trademark practitioners; but while similar to traditional trademark clearance, it differs in that a company owning an existing drug name can be the source of rejection, if that name is similar to the proposed trademark.
- Stage 4, Computational methods – this involves an assessment of similarity using various factors. This comparison is similar to the likelihood of confusion analysis.
- Stage 5, Medication error data – this involves a review of any prescribing errors that have already occurred in the United States or abroad. Since most of the drugs subject to this review will be in clinical trials, it is unlikely that there will be many, if any, errors to report. However, if the review is part of a line extension, previous prescribing errors in that line must be disclosed.
- Stage 6, Name simulation studies – this involves a replication of market conditions to assess potential errors made through handwritten and spoken drug orders. This analysis compares the handwritten visual similarity of a proposed trademark with existing drug names in order to prevent pharmacy errors in misinterpreting a written order. Simulation studies also evaluate the potential for error in spoken orders when prescribing information is provided over the telephone or in writing in a hospital setting.
- Stage 7, Failure mode and effect – this involves an evaluation of potential general errors in the pilot programme and aims to improve the project's general outcome.

The FDA has set a goal with regard to reviewing submissions which are part of the review process. Within 180 days of the date of submission, the FDA will review and either accept or reject an application. This goal will be met for 90% of the submissions.

Wyeth v Levine

The importance of selecting a safe trademark is highlighted in the landmark 2009 Supreme Court decision in *Wyeth v Levine* (555 US 555). In *Wyeth*, Wyeth's pharmaceutical Phenergan, which was used to treat allergy symptoms, was administered to a patient, Levine, by an injection method known as 'IV-push'. Upon administering the drug, Levine developed gangrene which resulted in the amputation of her forearm. Levine argued that the Phenergan product failed to provide adequate warning on the danger associated with its administration by the IV-push method. Wyeth argued that Levine's failure-to-warn claims were pre-empted by federal law because the Phenergan label had been approved by the FDA.

A Vermont jury determined that Levine's injury would not have occurred had the label included adequate warnings. The Vermont Supreme Court affirmed. The US Supreme Court held that federal law did not pre-empt Levine's claim that the Phenergan label provided no adequate warnings. More broadly, the *Wyeth* decision established that federal law does not pre-empt state court claim imposing liability on drug labelling that the FDA previously approved.

The application of this decision has implications for the regulatory approval of new drug names. After *Wyeth*, it appears that pharmaceutical companies may be held liable in tort for prescribing errors, even if a new drug name is approved by the FDA. In light of the *Wyeth* decision, the overall process introduced by the pilot programme is appropriate. If brand owners are ultimately responsible for the safety of a new trademark – even if the FDA approves it – then it is best to task the pharmaceutical companies with researching the safety of their new drug names. It then follows that having the brand owner carry out the testing and present its findings to the FDA will reduce duplication and offer a more comprehensive review.

Comment

What impact will the pilot programme have on US trademark practitioners? Pharmaceutical clients will have much more on their already full plates. Perhaps, outside counsel will be asked to assist with parts of the review process that overlap with traditional trademark clearance. It may be wise for outside counsel to familiarise themselves with the approval process and seek out assistance from regulatory specialists in order to provide the most comprehensive legal support for their clients.

Two things are certain: pharmaceutical clearance will continue to be an active and complex field, and the practice and assistance sought by pharmaceutical companies will be interdisciplinary in nature. WTR

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