United States

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Selection, clearance and registration

Regulatory bodies and requirements

Selection, clearance and registration processes for pharmaceutical trademarks are unique due to safety concerns and the chemical nature of the products. A pharmaceutical trademark must avoid confusion with the chemical and generic names of the drug. To market a pharmaceutical product in the United States, a US adopted name (USAN) – a generic non-proprietary name – must first be obtained. Existing USAN stems that describe the substance, its action or its use should be employed. The USAN is reviewed by the World Health Organisation (WHO) to ensure international harmonisation. The WHO also assigns a unique, international non-proprietary name (INN), which is typically identical to the USAN.

In the United States, two government agencies with independent statutory authority, purposes and goals oversee the approval of pharmaceutical trademarks: the US Patent and Trademark Office (USPTO) and the Food and Drug Administration (FDA).

The Lanham Act grants the USPTO the authority to review and register federal trademarks (15 USC §§ 1051 *et seq*). Federal registration is not a prerequisite to obtaining trademark rights; however, there are significant advantages to registration, including:

- presumption of the validity, ownership and exclusive right to use the trademark;
- constructive notice to third parties;
- possibility of incontestability after five years;
- federal court jurisdiction;
- possibility of treble damages and attorney's fees; and
- bar to the import of goods bearing infringing and counterfeit marks.

USPTO considerations when assessing an application include whether the mark is sufficiently distinctive and there is a likelihood of confusion with respect to other registered marks. The 'likelihood of confusion' test considers factors such as: similarities in marks, relatedness of goods/services, relatedness of trade channels, market conditions, and the number and nature of similar marks in use on similar goods.

While federal registration of a pharmaceutical brand is not mandatory prior to use, FDA approval is. The FDA's authority to evaluate and regulate pharmaceutical brands is rooted in the Federal Food, Drug and Cosmetic Act (FDCA). Under the FDCA, a drug is misbranded when "its labeling is false or misleading in any particular" (21 USC § 352(a)).

Various divisions of the FDA oversee the review process of proprietary drug names, which includes promotional and safety reviews of the proposed names. The promotional reviews evaluate whether the proposed name is overly fanciful, so as to be misleading. The safety reviews involve various methods, including:

- preliminary screening to identify common errors;

- USAN stem search;
- orthographic/phonological similarity assessment, using the 'lookalike/soundalike' test; and
- drug database searches/computational method and/or prescription studies.

USPTO registration is awarded to the party which is first to file and perfect filing by establishing use. However, FDA approval depends on the lookalike/soundalike test and how quickly the FDA application moves through the approval process. Thus, there exists a potential priority battle between the two agencies.

Non-traditional trademarks

In the pharmaceutical context, non-traditional trademarks may include a particular pill shape or colour, or medication flavour. These marks may require threshold showings of non-functionality and/or secondary meaning (acquired distinctiveness) to be protectable.

For instance, to function as a taste mark, a "substantial showing" of acquired distinctiveness must be made. Flavour marks often encounter functionality refusals because flavour is commonly added to medication to improve taste and patient compliance.

Similarly, configuration or shape marks for pills require a showing of non-functionality to be protectable. A functional mark is not protectable as such would inhibit competition by allowing a monopoly over a useful product feature.

Courts have found colour pills to be non-functional indicators of source not affecting the function of the drug itself. However, functionality of colour may be found, for instance, if the pill colour or colour combination functions to identify correct dosage or promotes acceptance as a generic substitution.

Parallel imports and repackaging

Key issues

Parallel imports and repackaging continue to be significant topics of debate. Parallel imports, often called grey market goods, are authentic products that are legitimately sold abroad and then, without authorisation, imported for sale into the United States.

While the United States generally follows a policy of national exhaustion, whereby exclusive IP rights cease upon an authorised first sale within a country, an exception occurs for parallel imports. Exclusion of parallel importation is justified by protections assured to consumers regarding the quality and safety of drugs, and encouragement of innovation and development of new pharmaceuticals.

Enforcement

The FDCA creates an exception to the national exhaustion policy by providing that no exported US manufactured prescription drug may be imported into the United States, other than by the drug manufacturer or as authorised by the secretary of health and human services (21 USC § 381(d)). The FDCA allows brand owners to seek an injunction against the unauthorised importation of parallel imports and provides for civil penalties.

The Lanham Act also provides brand owners with a cause of action against parallel importation (15 USC §§ 1114, 1124). However, the Lanham Act blocks the importation and sale of parallel goods only if the domestic and foreign products are materially different. Ultimately, materially different parallel imports will be excluded under the Lanham Act if there is potential to mislead or confuse consumers about the nature or quality of the product that they are buying.

Brand owners may also have recourse against parallel importation under the Tariff Act, which prohibits the unauthorised importation of goods bearing federally registered trademarks owned by US citizens (19 USC § 1526(a)). However, this recourse is limited to domestic US trademark owners that have no corporate affiliation with the foreign manufacturer importing the branded products – the 'common control' exception. This exception does not apply where there are physical and material differences in the goods.

Lastly, US Customs and Border Protection has authority to deny importation of parallel imports, provided that the mark applied to the goods being imported is federally registered on the Principal Register and recorded with US Customs.

Anti-counterfeiting and enforcement

Prevention

Several mechanisms enable pharmaceutical companies to be proactive in curtailing the proliferation of counterfeit drugs. As a threshold matter, drug companies should pursue federal trademark registration on the Principal Register. Trademarks provide consumers with a basis for expectations concerning the quality and source of medicines. Moreover, registration entitles pharmaceutical companies to *ex parte* seizures of counterfeit drugs, and subjects counterfeiters to possible criminal sanctions.

Customs is a cost-efficient and effective first line of defence against the importation of counterfeits, provided that the mark is registered with the USPTO and recorded with Customs. Customs is authorised to exclude, detain, seize and/or destroy pharmaceuticals bearing counterfeit marks. It may also levy civil fines against counterfeiters.

The use of anti-counterfeit technology can be an effective preventative mechanism. Examples include complex packaging designs, expiration dates, traceable model numbers and holograms. Radio frequency identification technology may also be used to allow for the tracking of authentic drugs from manufacture to consumer. These measures are often expensive for counterfeiters to reproduce, and can facilitate identification of counterfeiters and product recalls.

Requiring that products be purchased only from authorised and licensed wholesalers may also help prevent distributors from buying counterfeit products on the secondary market, ultimately reducing the likelihood of distribution of counterfeit drugs to unsuspecting consumers.

Lastly, drug companies should take every opportunity to educate consumers and law enforcement with information concerning specific known counterfeit drugs and sources.

Enforcement

The US government has enacted legislation designed to increase criminal and civil penalties, and expand government agencies' power to combat counterfeit goods. This legislation includes:

- the Federal Trademark and Counterfeiting Act (FTCA), which provides criminal penalties for intentional trafficking or attempts to traffic;
- the Lanham Act, which provides a civil cause of action for goods bearing counterfeit marks. Remedies include mandatory treble damages or profits (whichever is greater), or statutory damages;
- the FDCA, which provides for government enforcement through FDA inspectional observations, warning letters and civil penalties. More effective judicial actions include seizures and injunctions, as well as criminal sanctions;
- the Anti-counterfeiting Consumer Protection Act of 1996, which provides additional penalties and procedures to combat counterfeiting, including statutory damages as an alternative to Lanham Act claims, permitting *ex parte* seizures under the Lanham Act, and making trademark counterfeiting a

predicate offence for a violation of the
- the Stop Counterfeiting in Manufactured Goods Act of 2006, which requires courts to order the destruction of all seized counterfeit products and convicted counterfeiters to surrender all profits and equipment used in the counterfeiting process; and
- 18 USC § 2320, which provides criminal penalties, including fines and imprisonment, for intentional trafficking or attempts to traffic in counterfeit goods.

Advertising

Regulatory framework

The FDCA establishes the regulatory framework for pharmaceutical advertising. Drug companies are required to include certain information in direct-to-consumer advertising concerning the advertised product's uses and risks, including, for instance, side effects, contraindications and effectiveness (21 USC 352(n)).

The FDCA also grants FDA authority to enforce regulations concerning the labelling of pharmaceuticals. Under the FDCA (21 USC § 352(a)), a drug is misbranded if its labelling is false or misleading "in any particular". FDA regulations provide guidance on false or misleading labelling, and provide specific examples of misleading labelling, including failure to reveal the proportion of an active ingredient (21 CFR 210.10(c)(3)a).

The Lanham Act also contains provisions against false advertising, which may be applied to pharmaceuticals. Section 43(a)(1)(B) of the Lanham Act forbids the use of any "false or misleading description of fact, or false or misleading representation of fact, which... misrepresents the nature, characteristics, [or] qualities" of goods (15 USC § 1125(a)(1)(B)).

Considerations and application

Both the Lanham Act and FDCA govern the marketing of prescription drugs, but with different – albeit overlapping – purposes. The FDCA is focused not on the truth or falsity of advertising claims, but instead on ensuring that drugs in the marketplace are safe, effective and not misbranded. Neither the FDCA nor FDA regulations contain provisions to pre-empt or act to the exclusion of the Lanham Act. However, courts may not pre-emptively determine how a federal agency such as the FDA will interpret and enforce its own regulations. Thus, when determining whether the Lanham Act or FDCA applies to a misbranding/false advertising situation, the key point is whether the claim calls for direct interpretation of an FDA regulation. If so, the Lanham Act claim must be denied.

Generic substitution

Patent exclusivity is granted to encourage new drug innovation. Conversely, there is a public interest in the development and availability of generic drugs. The Hatch-Waxman Act, which permits the generic manufacturer to proceed with approval of the drug in an abbreviated new drug application, balances these considerations by allowing generic drug companies to take advantage of an abbreviated approval process – a faster, less expensive approval path (ie, without duplicating clinical trials) (21 USC § 355(j)).

Under Hatch-Waxman, the generic drug must be demonstrated to be bio-equivalent to the innovative drug – that is, the generic drug must have the same effectiveness and similar bioavailability as the innovative drug. The FDA publishes lists of drugs that are considered bioequivalent in the "Orange Book", which provides a reference to pharmacists and doctors as to which drugs may be substituted.

Laws governing the substitution of generics vary by state. For example, some states permit generic substitution by the pharmacist only where the physician does not specify "brand only", while other states mandate this substitution only where the physician does not specify "brand only". Some states specify specific drugs that cannot be substituted.

Lanham Act causes of action for trademark infringement and unfair competition may apply to generic pharmaceuticals. For instance, there may be liability if the generic company markets its product with a trademark or trade dress with the intent to induce substitution or with the knowledge that pharmacists are substituting on the mistaken belief that it is the brand name drug.

Online issues

E-pharmacies

Threats presented by illegal e-pharmacies – including consumer safety, harm to trademark owners' goodwill and discouragement of innovation – are increasingly difficult to curtail. While federal and state laws attempt to regulate internet pharmacies, illegal e-pharmacies are challenging to regulate due to the ease of creating new sites. Recent amendments to the Controlled Substances Act prohibit the sale of controlled substances over the Internet without a valid prescription, and impose registration and reporting requirements on e-pharmacies (21 USC §§ 829(e), 831).

The FDA also has authority to regulate e-pharmacies' sales of prescription drugs and is expanding its enforcement efforts by increasing monitoring and investigations. The FDA investigates criminal action related to the sale of pharmaceuticals through the Office of Criminal Investigations (OCI) and sends warning letters upon request. The FDA also collaborates with other governmental agencies.

Private efforts may also reduce the threat of illegal e-pharmacies. One such example is the Verified Internet Pharmacy Practice Sites (VIPPS), established by the National Association of Boards of Pharmacy (NABP). VIPPS-accredited pharmacies follow criteria requiring them to comply with state licensing and inspection requirements. The VIPPS site, www.vipps.nabp.net, enables consumers to verify that the e-pharmacy is NABP and VIPPS-compliant.

Domain names

Cybersquatters also pose a significant problem to pharmaceutical trademark owners. The Anti-cybersquatting Prevention Act (ACPA) provides a cause of action against the bad-faith registration of a domain name that is identical or confusingly similar to, or dilutive of, a mark (15 USC 1125(d)). The ACPA provides for forfeiture or cancellation of the domain name and monetary relief.

Pharmaceutical trademark owners can also use the Uniform Dispute Resolution Policy (UDRP) administered by the Internet Corporation for Assigned Names and Numbers (ICANN). The UDRP remedy is limited to the cancellation or transfer of domain names.

Recent developments to domain name registration will also affect pharmaceutical trademark owners. ICANN approved the expansion of generic top-level domains (TLDs), which will allow companies and organisations to create domains for their brand (e.g., '.lipitor') or create generic names (e.g., '.drug'). Interested trademark owners may apply to register a new TLD between January 12 2012 and April 12 2012. Trademark owners may use a new ICANN dispute resolution procedure, similar to that of the current UDRP, to object to any TLD that infringes its brand or improperly reserves an industry-related word. WTR

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Nick de la Torre is a shareholder at Brinks Hofer Gilson & Lione. His practice is international in scope and focuses on all aspects of trademark, unfair competition, trade dress, counterfeiting, dilution and false advertising law. Mr de la Torre also has extensive experience handling matters before the US Patent and Trademark Office's Trademark Trial and Appeal Board; trademark prosecution matters, both in the United States and abroad; and domain name dispute proceedings for the Internet Corporation for Assigned Names and Numbers. He has represented a wide variety of trademark clients across many industries, including aviation, consumer products, retail, electronics and government.

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