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Selection, clearance and registration Regulatory bodies and requirements

Safety concerns warrant rigorous scrutiny when it comes to the selection, clearance and registration of pharmaceutical trademarks. To market a new pharmaceutical product in the United States, a US adopted name – a generic non-proprietary name – must first be obtained. Existing US adopted name stems describing the substance, its action or use should be employed. The non-proprietary name is also reviewed by the international non-proprietary name programme of the World Health Organisation to ensure international harmonisation.

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

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

- presumption of 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
- prohibition on the import of goods bearing infringing and counterfeit marks.

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

The USPTO does not grant trademark

registration until the trademark has been used in commerce (typically through sale of the trademarked goods). For an intent-to-use application, there is limited time within which to meet the use requirement and thus perfect the application. This use requirement would normally pose a significant obstacle to registration for pharmaceutical products, given the significant length of time and the regulatory hurdles necessary to get a pharmaceutical to market in the traditional sense. Fortunately for pharmaceutical brand owners, branded pharmaceutical clinical trial shipments normally suffice to meet the USPTO's use requirements, enabling registration of the pharmaceutical trademark years before the drug is actually marketed or approved for marketing by the FDA.

In contrast to federal trademark registration, FDA approval is mandatory prior to use. The FDA's authority to evaluate and regulate pharmaceutical brands is rooted in the Federal Food, Drug and Cosmetic Act. Under the act, 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 proprietary name review process, which includes promotional and safety reviews. Promotional review evaluates whether the proposed name is false or misleading, such as by improperly suggesting or exaggerating effectiveness, minimising the risk or expanding the product indication. The safety review involves various methods, including:

- preliminary screening to identify common errors;
- USAN stem search;
- orthographic or phonological similarity assessment, using the 'lookalike/soundalike' test; and
- drug database searches and/or prescription studies.

Having identified lookalike or soundalike names, the FDA evaluates whether the respective product characteristics – such as dosage form, indication, frequency of administration and patient population – act either to increase or decrease the risk of confusion.

The FDA views medication errors as preventable and has essentially adopted a zero-risk tolerance policy. Additionally, the

FDA rejects proprietary names at a rate of 40% or more, making it difficult to identify an acceptable pharmaceutical brand. Thus, brand owners must generally review the legal and regulatory availability of dozens of potential candidates – including evaluation of the potential for medication errors – to arrive at a suitable name.

USPTO registration is awarded to the party which is first to file and perfect filing by establishing use. However, FDA approval depends on the proprietary name review process 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

Non-traditional pharmaceutical trademarks may include a particular pill shape or colour, or medication flavour. These marks will likely require threshold showings of non-functionality and/or secondary meaning (acquired distinctiveness) to be protectable. Functional elements of products are not protectable as trademarks, as such would inhibit competition by allowing a monopoly over a useful product feature.

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

Additionally, functionality of colour may be found, for instance, if the pill colour or colour combination functions to identify correct dosage.

Parallel imports and repackaging **Key issues**

Parallel imports, often called 'grey market goods', are authentic products that are legitimately sold abroad and then imported for sale into the United States without authorisation. These goods may have been formulated or packaged differently from products intended for sale in the United States.

The United States generally follows a policy of national exhaustion, whereby exclusive IP rights cease upon an authorised first sale within a country. However, an exception occurs for parallel imports. Exclusion of parallel

importation is justified by protections assured to consumers regarding pharmaceutical quality and safety, and encouragement of innovation and development of new pharmaceuticals.

Enforcement

The Federal Food, Drug and Cosmetic Act provides 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)). This exception to the national exhaustion policy 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 import 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 only if there is potential to mislead or confuse consumers about the nature or quality of the product they are buying.

In some cases brand owners 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)). US Customs and Border Protection has authority under the Tariff Act to deny the import of parallel imports, provided that the mark applied to the imported goods is federally registered on the Principal Register and recorded with US Customs. 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. However, this exception does not apply where there are physical and material differences in the goods.

Anti-counterfeiting and enforcement Prevention

Several mechanisms enable pharmaceutical companies to be proactive in curtailing the proliferation of counterfeit drugs. Trademarks provide consumers with a basis for

expectations concerning the quality and source of medicines. As a threshold matter, drug companies should pursue federal trademark registration on the Principal Register, and record the resulting registrations with US Customs. Customs provides a cost-efficient and effective first line of defence against the import of counterfeits, through the exclusion, detention, seizure and/or destruction of pharmaceuticals bearing counterfeit marks. Registration and recordation entitle pharmaceutical companies to *ex parte* seizures of counterfeit drugs, and subject counterfeiters to civil fines and possible criminal penalties.

The use of anti-counterfeit technology can be an effective preventive 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 the identification of counterfeiters and product recalls.

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

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

Enforcement

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

- the Federal Trademark and Counterfeiting Act, 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 Federal Food, Drug and Cosmetic Act, 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 penalties;

- the Anti-counterfeiting Consumer Protection Act of 1996, which includes 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 Racketeer Influenced and Corrupt Organisations Act;
- 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;
- Section 337 of the Tariff Act, which allows the International Trade Commission to issue an exclusion order prohibiting the import of goods that infringe a valid, enforceable and registered US trademark; 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 Federal Food, Drug and Cosmetic Act establishes the regulatory framework for pharmaceutical advertising and grants the FDA authority to enforce regulations concerning the labelling of pharmaceuticals. Drug companies are required to include certain information in direct-to-consumer advertising concerning the advertised product's uses and risks, including side effects, contraindications and effectiveness (21 USC § 352(n)).

FDA regulations also 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 provisions against false advertising are applicable to pharmaceuticals. Section 43(a)(1)(B) of the Lanham Act forbids 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 the Federal Food, Drug and Cosmetic Act govern the marketing of prescription drugs, but with different purposes. Unlike the Lanham Act, the Federal Food, Drug and Cosmetic Act is focused not on the truth or falsity of advertising claims, but rather on ensuring that drugs in the marketplace are safe, effective and not misbranded. Neither the Federal Food, Drug and Cosmetic Act 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 the Federal Food, Drug and Cosmetic Act applies to a misbranding or false advertising situation, the key is whether the claim calls for direct interpretation of an FDA regulation. If so, the Lanham Act claim must be denied.

Generic substitution

There is a public interest in the development and availability of generic drugs. This interest runs contrary to patent exclusivity, which is granted to encourage new drug innovation. 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 providing 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 have the same effectiveness and similar bio-availability as the innovative drug – that is, it must be bio-equivalent to the innovative drug. The FDA publishes lists of drugs that are considered bio-equivalent 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. Some states, for example, 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 identify specific drugs that cannot be substituted. Recently, various bills have been introduced in some of these state legislatures which would restrict the ability of pharmacists to substitute.

Lanham Act causes of action for trademark infringement, unfair competition and false advertising 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 in the mistaken belief that it is the brand name drug.

Online issues

E-pharmacies

While federal and state laws attempt to regulate internet pharmacies, threats from illegal e-pharmacies – including consumer safety, harm to trademark owners' reputation and goodwill and discouragement of innovation – are increasingly difficult to curtail. Illegal e-pharmacies prove challenging to regulate due to the ease of creating new sites. The Controlled Substances Act is designed to lessen the damage caused by illegal e-pharmacies by prohibiting the sale of controlled substances over the Internet without a valid prescription and imposing registration and reporting requirements (21 USC §§ 829(e), 831).

The FDA has authority to regulate e-pharmacies' sales of prescription drugs and is expanding its enforcement efforts by increasing monitoring and investigations. Specifically, it investigates criminal action related to the sale of pharmaceuticals through the Office of Criminal Investigations 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 must comply with state licensing and inspection requirements. NABP's website, www.nabp.net, enables consumers to verify that e-pharmacies are NABP and VIPPS compliant.

Domain names

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

Recent developments to domain name registration also affect pharmaceutical trademark owners. ICANN approved the expansion of generic top-level domains (gTLDs) which allows companies to create domains for their brand (eg, '.lipitor') or create generic names (eg, '.drug'). The first round of gTLD applications has closed, but a second round is forthcoming. Trademark owners may use a new ICANN dispute resolution procedure, similar to that of the current UDRP, to object to any gTLD that infringes their brands or improperly reserves an industry-related word.

This article is the opinion of the authors and is not attributable to the authors' employers or their clients.

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