

United States

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Selection, clearance and registration

Relevant national and international regulatory bodies and requirements

The drug naming process comprises three components: the chemical name for the molecular structure of a drug, its generic name and its brand name. The reason for having both a generic name and a brand name is because a generic name may be used by all who wish to refer to this substance, whereas a brand name is owned by the firm that markets that drug. As the proliferation of generic drugs continued, there came a need for generic names that could be used within the industry without fear of infringing a trademark holder's rights.

Each drug that is marketed to consumers must go through a complex naming process. Brand names must be approved first by the US Adopted Name Council (USANC) and

then separately by the Food and Drug Administration (FDA). The FDA uses the Phonetic Orthographic Computer Analysis (POCA) comparison algorithm to help to identify pharmaceutical brand names that are phonetically and orthographically similar to one another, and provides a percentage ranking based on similarity of the names. Since the POCA is available to trademark attorneys, they can use it to predict with greater success whether a drug name will be approved by the FDA.

The USANC is responsible for selecting simple, informative and unique non-proprietary names for drugs by creating a classification system based on pharmacological and/or chemical relationships. These non-proprietary names are referred to as 'generic names' and the system applies to all drugs marketed to consumers in the United States.

On April 12 1988 the Prescription Drug Marketing Act of 1987 became effective. The purpose of the act was to safeguard consumers against counterfeit, adulterated, misbranded, sub-potent and expired

prescription drugs. As drug distribution in the United States was more readily made directly to consumers, such safeguards became increasingly necessary to ensure that consumers obtained safe and effective drugs. The act was modified by the Prescription Drug Amendments of 1992 in order to clarify the punishment for violations of the act. These regulations are not limited to either over-the-counter (OTC) or prescription drugs, but rather pertain to all drugs sold to consumers. All the agencies involved work together to achieve the objective of the act – namely, to protect consumers.

Confusion with INNs

International non-proprietary names (INNs) facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients. According to the World Health Organisation (WHO), an INN is "a unique name that is globally recognised and is public property".

The WHO provides leadership on global health issues to all members of the United

Nations system. Since its inception, the aim of the INN system has been to provide a unique and universally available designated name to identify each pharmaceutical substance. The WHO collaborates closely with INN experts and national nomenclature committees to select a single name of worldwide acceptability for each active substance that is to be marketed as a pharmaceutical.

The INN system attempts to group drugs that are pharmacologically related with names that use a common stem. The stem serves to indicate that the particular drug is part of a group of substances with similar pharmacological activity. More typically than not, the generic name given to a drug by the INN system is the same as the generic name given by the USAN.

Importantly, confusion among consumers or medical professionals could severely endanger patients. Therefore, INNs must be kept generic (ie, in the public domain) and cannot be included as a component of a trademark, especially the stem.

Non-traditional trademarks

US trademark law permits registration of non-traditional trademarks (eg, for colours, shapes and sounds) once they have attained secondary meaning (in most cases) (see *Qualitex Co v Jacobson Products Co Inc* (115 S Ct 1300 (1995))). In the pharmaceutical industry, colour, size and shape may be used to identify a dose, rather than a source or origin.

The American Society of Health-System Pharmacists prepared a policy positions statement in this respect. Section 9608 provides that with regard to drug products, labelling and packaging, and the use of colour to identify drug products, best practice is to “support the reading of drug product labels as the most important means of identifying drug products; further, to oppose reliance on colour by health professionals and others to identify drug products; and further, to oppose actions by manufacturers of drug products and others to promulgate reliance on colour to identify drug products”. However, colour regulations (which may vary among countries) may also mandate the colour of a drug. Therefore, if the colour of the drug product is the result of a regulatory or functional restriction, it is unlikely to serve as a trademark in the United States.

Moreover, FDA regulations require that OTC drug companies standardise the look and location of the information that appears on drug packaging. In the Federal Register of

March 1999, the FDA published the OTC Drug Facts Label Regulation. The regulation required that most OTC drug products comply with standardised format and content requirements by May 2002. Labelling regulations that require a ‘drug facts’ panel and directions as to the drug’s location, size and style, and which prohibit logos, graphics or bar codes, affect the ability for other graphics on the packaging or the colour, size or shape of a pill or capsule to act as a trademark.

Parallel imports and repackaging

An amendment to the Prescription Drug Marketing Act of 1987 was made in 1992 by the Prescription Drug Amendments of 1992. This amendment added Section 801, which stated that no drug composed wholly or partly of insulin which is manufactured in a state and exported may be imported into the United States, unless the drug is imported by the drug manufacturer or authorised by the secretary for emergency medical care.

The act raises the issue of national exhaustion, which may be seen by some in the industry as government-enforced territorial restrictions in international distribution – and, consequently, as anti-competitive. If the US owner of a trademark can exclude parallel importation of marked pharmaceuticals that are exported overseas for distribution, authorised retailers in the United States are protected from certain competition. Consumers are protected by the assurance that pharmaceutical products purchased in the United States from an authorised US supplier are legitimate. However, in the case of patented prescription pharmaceuticals, there is no competition. The costs of the drug and insurance are leading consumers to purchase what they believe is the same drug from parallel sources, running the risk of compromising the quality and legitimacy of the drug.

Enforcement

The act sets forth severe penalties of fines and/or imprisonment for violation of its provisions. Section 303(b)(1) provides for imprisonment for up to 10 years and/or a fine of up to \$250,000.

Other penalties pertain directly to manufacturers or distributors that distribute drug samples that violate the act. These penalties include “a civil penalty of not more than \$50,000 for each of the first two such violations resulting in a conviction of any representative of the manufacturer or distributor in any 10-year period” or “a civil

penalty of not more than \$1 million for each violation resulting in a conviction of any representative after the second conviction in any 10-year period”.

Interestingly, the act provides for a reward for whistleblowers (manufacturers or distributors, or any representative thereof) that provide information leading to the arrest and conviction of any party that violates the act. The reward may amount to up to half of the criminal fine imposed and collected for such violation, but may not exceed \$125,000.

Anti-counterfeiting and enforcement

Prevention

One mission of the Prescription Drug Marketing Act was to address the integrity of the distribution system for prescription drugs, which at the time was insufficient to prevent the introduction and eventual retail sale of counterfeit drugs. This problem increases on an annual basis. The WHO has documented situations where people have been severely injured or killed by consuming counterfeit drugs. The counterfeit drugs are intentionally falsely labelled so as to appear to be the same as the brand-name drug. The problem is not limited to branded prescription medicines, but extends to generics and even OTC brands. Often the active ingredient is the problem, but in some instances the medicine actually contains poison.

According to a report prepared by the Generic Pharmaceutical Association on the Anti-counterfeiting Trade Agreement (ACTA) (March 21 2008):

“Pharmaceuticals represent the fastest-growing area of IP [right] seizures by U.S. Customs and Border Protection, accounting for 6 percent by value in [fiscal year] 2007, up from only 1.5 percent the previous year. Moreover, pharmaceuticals accounted for 40 percent of the domestic value of IP [right] ‘Import Safety’ Commodities seized by [Customs and Border Protection] in [fiscal year] 2007, making it far and away the [number one] public health and safety concern with respect to imported counterfeit goods.”

In reaction to this growing issue, US Trade Representative Susan C Schwab announced that the United States would participate in the negotiations of the terms of ACTA. ACTA would complement other international treaties, with the goal of creating a stricter means for member countries to enforce IP rights against

counterfeiters. ACTA aims to control the trade in fake physical goods. Negotiations are ongoing, with the latest round of talks held on April 16 2010 in Wellington, New Zealand.

Enforcement

According to reports from the World Health Advocacy Organisation (based on information obtained from US Customs and Border Protection), the value of pharmaceuticals seized increased 660% over the past year: "For the criminal element, pharmaceutical counterfeiting is relatively low risk. While pharmaceutical counterfeiting is as profitable as the narcotics trade, it is considerably less dangerous and subject to lesser criminal penalties. In addition, it is a crime that is difficult to uncover, even with the most sophisticated tools" (citing *Intellectual Property Rights, Seizure Statistics Mid-year 2007, U.S. Customs and Border Protection*, July 2007, and Lybecker, *Parallel Imports or Imposters: The Economics of Re-importation and Counterfeit Pharmaceuticals, Managed Care*, Volume 13, No 3, March 2004).

In the United States, Title 19, Chapter I of the Code of Federal Regulations (CFR) concerns the duties of the Bureau of Customs and Border Protection under the Department of Homeland Security. Specifically, 19 CFR §133.21 deals with articles bearing counterfeit trademarks and 19 CFR §133.22 deals with the restrictions on the import of products bearing counterfeit trademarks.

Under these regulations, if counterfeit drugs are stopped at the border and the rightful trademark owner refuses to permit the import of the drugs within 30 days of notification of the seizure, the drugs are destroyed. Although the importer has the right to petition for relief, it is doubtful that those attempting to import counterfeit pharmaceuticals will do so. Therefore, the punishment may simply be the lost ability to sell or distribute (19 CFR §§133.21(e) and 133.52(c)).

If a shipment contains pharmaceuticals that are deemed to be 'controlled substances', as defined by the Controlled Substances Act (84 Stat 1242, 21 USC 801 and following), in violation of the Code of Federal Regulations, an officer of the Fines, Penalties and Forfeitures Department will declare the shipment forfeited. The importer has no opportunity to try to obtain the lawful importation of the shipment. The shipment contents will not be sold; rather, the contents will either be destroyed or be held for evidentiary purposes in the event

of a trial (19 CFR §§162.44, 162.45(a), 162.46).

The penalty for selling, offering to sell, purchasing or trading in any adulterated drugs and devices or misbranded drugs and devices (Sections 501 and 502, respectively, of the Federal Food, Drug, and Cosmetic Act) consists of fines and/or imprisonment.

Advertising

Regulatory framework

Direct-to-consumer advertising of prescription drugs is permitted in the United States, but the FDA provides guidelines for it. Direct-to-consumer advertising allows pharmaceutical companies to advertise about a disease and a prescription drug that is available and intended to treat a particular disease. In this way, the manufacturers need not go through doctors or medical professionals to get their message out to the public. The FDA guidelines provide that the promotional material must contain statements such as:

- "Prescription medicine, consult your doctor";
- "If symptoms continue or you have side effects, see your doctor/pharmacist/health professional"; and
- "Use strictly as directed".

The information contained therein cannot be false or misleading in any respect and must include clear statements establishing the major risks involved in taking the particular drug.

Generic substitution

Generic substitution of pharmaceutical drugs in the United States is governed primarily by patent law and FDA regulations.

A key consideration in the market of generic pharmaceuticals is providing consumers with a bioequivalent to the patented pharmaceutical at a lower cost than is otherwise available.

Online issues

E-pharmacies

The ever-growing problem of dishonest online pharmacies that sell pharmaceuticals directly to consumers has led Indiana Governor Mitch Daniels to sign into law a requirement that non-resident pharmacies utilising the Internet obtain Verified Internet Pharmacy Practice Sites™ accreditation from the National Association of Boards of Pharmacy®, or an equivalent programme approved by the Indiana Board of Pharmacy, before shipping drugs into

Indiana (Senate Bill 302, effective July 1 2008). Criminals are engaging in more drug-related crimes through the use of modern technology, prompting the Drug Enforcement Administration, in 2005, to launch Operation CYBERx, an investigation targeting major alleged pharmaceutical drug traffickers operating solely in the United States.

The FDA collaborates with trademark owners in strategising to detect counterfeit pharmaceuticals more efficiently on a worldwide basis. The FDA's Office of Criminal Investigations continues to work with foreign law enforcement agencies directly and through INTERPOL on individual international counterfeiting cases. Training takes place through the US Patent and Trademark Office Intellectual Property Enforcement Academy. Research and development continues for electronic track-and-trace technology that can be implemented in the United States and elsewhere.

Domain names

Within the realm of trademarks, use of a generic term as a domain name is of less and less concern. A generic term is available to the public and, by definition, cannot serve to identify the source or origin of the products sold or services rendered on the particular website to which the domain name is attached. However, the implications of using an INN that serves as a generic name for a pharmaceutical drug as a domain name is of greater concern. On September 3 2001 the World Intellectual Property Organisation recommended stricter controls to prevent INNs from being used as domain names because of the risk to consumers of exploitation and harm. An INN used as a generic name takes on a different meaning to consumers than the generic term, as opposed to a trademark. If INNs serve as domain names in an unregulated manner, consumers might be misled into believing that drugs sold or offered for sale on the particular website are legitimate, safe and effective when, in fact, they are not. [WTR](#)

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Julie Katz is a partner in Husch Blackwell Welsh & Katz's IP and IP litigation departments. She graduated from the University of Illinois College of Law, Champaign-Urbana, Illinois, in 1990. Her practice consists of all aspects of IP litigation, including pharmaceutical patent infringement litigation. She also practises in matters of non-contentious trademark, copyright and design protection. Ms Katz has a focus on anti-counterfeiting protection for the firm's clients and works regularly with US Customs. She is an active member of both the International Trademark Association and the Pharmaceutical Trademark Group, as well as being a corporate partner of the National Association of Women Business Owners' Chicago Chapter.



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