United States

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Selection, clearance and registration

Relevant national and international regulatory bodies and requirements

The chemical name for the molecular structure of a drug, the generic name and, eventually, a brand name are the three components of the drug naming process. Each drug that is marketed to consumers must go through a complex process to be given a name that the Food and Drug Administration (FDA) approves – even after the US Adopted Name Council (USANC) has approved a name. 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 violation of the act. These regulations are not limited by the definition of over-the-counter (OTC) versus prescription drugs, but rather pertain to drugs sold to consumers, which may be either. All the agencies involved work together to achieve the objective of the act – namely, to protect consumers.

Confusion with INNs

According to the World Health Organization (WHO), international non-proprietary names (INNs) "facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized and is public property. A non-proprietary name is also known as a generic name."

The WHO provides leadership on global health issues to all the members of the United Nations system. 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 to those in the medical industry that the particular drug is part of a group of substances with similar pharmacological activity. It is more typical than not that the generic name given to a drug by the INN system is the same as the generic name given by the USANC.

Importantly, confusion among consumers – or worse, among 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, 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 by a variety of manufacturers and trademark owners 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, the 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 standardize the look of the information that appears on drug packaging, including the location of information such as active ingredients, directions, uses and warnings. 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 standardized format and content requirements by May 2002. Labelling regulations that require a 'drug facts' panel and direct as to its location, size and style, and 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

Key issues

One of the amendments to the Prescription Drug Marketing Act in 1992 was contained in Section 801, which added the following: "(1) Except as provided in Paragraph (2), no drug subject to Section 503(b) which is manufactured in a state [of the United States] and exported may be imported into the United States, unless the drug is imported by the person who manufactured the drug. (2) The secretary may authorize the importation of a drug the importation of which is prohibited by Paragraph (1) if the drug is required 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 restriction in international distribution – and, consequently, as anti-competitive. If the US owner of a trademark is able to exclude parallel importation of marked pharmaceuticals that are exported overseas for distribution, authorized 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 authorized US supplier are legitimate. However, in the case of patented prescription pharmaceuticals, there is no competition. The costs of the drugs and insurance are leading consumers to purchase what they believe is the same drug from parallel sources, taking 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 that "any person who violates Section 301(t) because of an importation of a drug in violation of Section 801(d)(1), because of a sale, purchase or trade of a drug or drug sample or the offer to sell, purchase or trade a drug or drug sample in violation of Section 503(c), because of the sale, purchase or trade of a coupon, the offer to sell, purchase or trade such a coupon, or the counterfeiting of such a coupon in violation of Section 503(c)(2), or the distribution of drugs in violation of Section 503(e)(2)(A), shall be imprisoned for not more than 10 years or fined not more than $250,000, or both."

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 issue of 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 even 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 medicine, and extends to generics and even OTC brands. It is often the active ingredient that is the problem, but in some instances the medicine 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 US Customs and Border Protection, accounting for 6% by value in fiscal year 2007, up from only 1.5% the previous year. Moreover, pharmaceuticals accounted for 40% 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." These figures are shocking.

In reaction to this global health crisis, US Trade Representative Susan C Schwab announced in October 2007 that the United States would participate in the negotiations of the terms of ACTA. ACTA would complement – but not replace or require the amendment of – other international treaties, having the independent goal of creating a stricter means for member countries to enforce IP rights against counterfeiters. As of early 2009, negotiations continue.

Enforcement

According to reports of the World Health Advocacy Organization (based on information obtained from the 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", US 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 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 importation of products bearing counterfeit trademarks.

Under these regulations, if counterfeit drugs are stopped at the border and the rightful trademark owner, within 30 days of notification of the seizure, refuses to permit importation of the drugs, the latter are destroyed. Although the importer has a 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 the shipment contains pharmaceuticals that are deemed to be 'controlled substances', as defined under 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 by the Fines, Penalties and Forfeitures Department as could occur under other circumstances; the contents will either be destroyed or held for evidentiary purposes in the event of a trial (§ 162(44), § 162(45)(a) [TD 00-37, 65 FR 33254, May 23 2000] and § 162(46)).

Under the act, the penalty for selling, offering to sell, purchasing or trading any adulterated drugs and devices or misbranded drugs and devices (Sections 501 and 502, respectively) 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 such advertising. 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 the like in the medical profession to disseminate their message 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

Regulation

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

Key considerations

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 the law of that state a requirement that non-resident pharmacies utilizing 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, a multi-faceted Organized Crime Drug Enforcement Taskforce investigation targeting major alleged pharmaceutical drug traffickers operating solely in the United States.

The FDA collaborates with trademark owners in strategizing 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 implication of the use as a domain name of an INN serving as a generic name for a pharmaceutical drug is of greater concern. On September 3 2001 the World Intellectual Property Organization 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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