India

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Selection, clearance and registration
Regulatory bodies and requirements
The manufacture, distribution, labelling, packaging, sale or stocking of any drug in India is regulated by the Drugs and Cosmetics Act 1940. Under the act, a penalty can be imposed for the manufacture, sale, stocking, exhibition or distribution of drugs without a valid licence, or for contravening the conditions of a licence.

An inherently distinctive trademark (ie, one that is not closely similar to an earlier trademark of any other proprietor) may be selected for use in respect of medicinal and pharmaceutical products. Under the common law principles followed in India, use of such a trademark itself generates common law rights in favour of the rights holder. In addition to such common law rights, the rights holder may apply to the registrar of trademarks under the Trademarks Act 1999 to register the trademark in its name. An application for registration of an unused trademark may also be made under the Trademarks Act, provided that the rights holder has a good-faith intention to put the mark to use.

Section 13 of the Trademarks Act prohibits registration of a trademark that:

- is the commonly used and accepted name of a single chemical element or single chemical compound in respect of a chemical substance or preparation; or
- is declared by the World Health Organisation (WHO) and notified by the registrar as an international non-proprietary name (INN), or is deceptively similar to such name.

INNs are generic names given to pharmaceutical drugs. By their very nature, they can be used by all manufacturers with respect to pharmaceutical substances and drugs, irrespective of the name under which such substances or drugs are marketed. Theoretically, INNs cannot be used to coin trademarks or brand names. However, there are several instances of pharmaceutical companies creating trademarks from the stems of INNs. In recognition thereof, the World Health Assembly

passed Resolution 46.19, issuing directions to WHO member states to discourage such misuse of INNs. In compliance with this, Section 13 of the Trademarks Actspecifically prohibits the use as trademarks of:

- any word that has been declared an INN by the WHO and notified by the registrar of trademarks as such; and
- any name that is deceptively similar to such INN.

Appeals against the registrar's decisions must be referred to the Intellectual Property Appellate Board within three months of receipt of the disputed order.

In addition to the above prerequisites, when coining a trademark the Drugs and Cosmetics Act 1940 must be complied with.

Parallel imports and repackaging

Under Section 30(3) of the act, where goods have been put on the market under the registered trademark either by the rights holder itself or with its consent, and are lawfully acquired, their subsequent sale or other disposition by either the person that acquired them or another party acting on its behalf does not amount to infringement of the trademark.

In *Samsung Electronics Co Ltd v KapilWadhwa*(2012) the appellate bench of the High Court of Delhi held that India follows the principle of international exhaustion. Therefore, once the goods bearing a particular trademark are released anywhere in the world by or with the consent of the rights holder, the latter cannot assert its rights under trademark law to prevent imports of goods into India, provided that the goods remain materially unaltered or unimpaired. The consent of the rights holder in such cases may be express or implied, direct or indirect. The rights holder may, however, impose contractual restrictions on third parties such as foreign licensees against importing goods into India, as long as these restrictions are valid under the provisions of the Competition Law, among other statutes.

However, passing off may apply if the rights holder can show that the importer is passing off the goods in a misleading or improper manner, causing confusion in the minds of the public.

Any import of drugs manufactured by international pharmaceutical companies requires an import licence from the drug controller general of India under the Drugs and Cosmetics Act and the corresponding rules. The licence is granted on assurance that the exporter complies with Indian production and safety standards. In order to obtain a licence, the importer must also submit a drug sample to the Central Drugs Standard Control Organisation for testing. The importer must also submit the following documents to the Central Drugs Standard Control Organisation:

- the import documents;
- the protocol tests and analysis; and
- a sample of the product labels.

The Drugs and Cosmetics Act empowers the Indian authorities to prohibit the import of drugs that are of sub-standard quality, are misbranded or adulterated, or have not been labelled in accordance with the law. Import may also be prohibited in the public interest. Any party may make a written complaint to the drug controller general of India in respect of the quality of a drug, indicating the nature of the complaint and the particulars of the drug. The customs authorities can also inspect imported drugs and take appropriate steps under the Customs Act 1962.

Anti-counterfeiting and enforcement

The Drugs and Cosmetics Act and the Drugs and Cosmetics Rules 1945 contain comprehensive criminal provisions that act as sufficient deterrents for violation of drug and medicine regulations prescribed therein. Since the Drugs and Cosmetics Act applies across the country, the implementation of measures intended to deter the production and sale of spurious drugs should be coordinated between states, as well as by the central government. Despite this deterrent, however, such drugs are still available on the market. The drug controller general of India coordinates with the state drug control authorities, the revenue intelligence authorities, the customs authorities and port officials to keep a close watch on such activities and to check the threat that they pose.

The Central Drugs Standard Control Organisation has conducted a survey to

gauge the availability of spurious drugs in the country by drawing samples from different regions and different population segments on the basis of statistical principles provided by the Indian Statistical Institute, Hyderabad. The samples are analysed and action is taken as per the provisions of the law. This helps to identify the geographical areas where spurious drugs are available, so that the relevant authorities can focus their actions. Assistance has also been provided under the World Bank Assisted Capacity Building Project to upgrade testing facilities and establish new drug-testing laboratories so as to enhance the capacity of laboratories to analyse large numbers of samples. Under the project, 23 states and six central drug laboratories have been upgraded through renovations, extensions and new equipment. Further, Schedule M of the Drugs and Cosmetics Rules pertaining to good manufacturing practices makes it mandatory, on a par with international standards, for manufacturers to comply with the requirements of the quality control schedule for their products. The state governments have also issued detailed guidelines to undertake focused surveillance over possible movement of spurious drugs. Specific training programmes have been conducted for state regulatory officials on the logistics of intelligence work and prosecutions, among other initiatives, with the assistance of the Food and Drug Authority, Maharashtra. The pharmaceutical industry and trade have been motivated to fight the menace of spurious drugs as a shared responsibility.

The Drugs and Cosmetics Act was amended by the Drugs and Cosmetics (Amendment) Act 2008 to provide more stringent penalties for those trading in spurious drugs.

Since spurious drugs is a sensitive issue that affects the health of citizens, as well as the prestige of the country's pharmaceutical trade interests, there is a sense of urgency in tackling the problem. With this in mind, India's central government has set up a scheme to reward whistleblowers. The scheme is already operational in other government enforcement departments and is effective in terms of the volume of seizures. It provides handsome monetary rewards to informers who bring specific information to the authorities leading to the seizure of drugs, cosmetics and medical devices that are spurious, adulterated, misbranded or sub-standard. This reward scheme is applicable to both informers and officers of the Central Drugs Standard Control Organisation.

The Trademarks Act penalises the falsification or use of false trademarks and trade descriptions with imprisonment and fines. Offences under the act are cognisable offences. The police are empowered to search and seize, without a warrant, instruments involved in committing the offence of counterfeiting.

The Trademarks Act also provides for civil remedies in the form of suits for infringement, passing off or both. Due to significant amendments to the Code of Civil Procedure, it has become expedient to have recourse to civil remedies such as orders for injunctions, seizure of counterfeit goods, damages or accounts of profit.

The Drugs and Cosmetics Act prohibits the manufacture, sale or import of drugs that are misbranded or counterfeit. It also sets out a number of penalties for breach of these provisions.

Border control measures

In order to implement the obligations envisaged under Articles 51 to 60 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), the Indian government issued Notification 47/2007-Cus (NT), which led to the introduction of the IP Rights (Imported Goods) Enforcement Rules 2007. The rules define the role of the Indian customs authorities in combating infringement of IP rights – including patents, trademarks, copyright, designs and geographical indications – at the country's borders.

The rules provide for actions such as suspension, confiscation, penalty and disposal of confiscated goods to be taken against infringing goods. The rules envisage the following steps:

- filing of a notice or application with the rights holder;
- registration of the notice by the customs authorities;
- a time limit for participation of rights holders in the proceedings;
- provision of an adequate indemnity to Customs for good-faith acts;

- *suo motu* action by Customs in specified circumstances; and
- disposal of the confiscated goods.

Advertising

Regulatory framework

The Drugs and Cosmetics Act contains provisions on the packaging and labelling of prescription drugs and drugs taken only under medical supervision.

In addition, the Drugs and Magic Remedies (Objectionable Advertisements) Act 1956 governs the issue of advertising of drugs. Specific diseases are mentioned therein for which no advertising is allowed.

The Advertising Standards Council of India, a not-for-profit organisation, has also framed self-regulatory advertising guidelines and standards of conduct. Its Code of Self-Regulation in Advertising must be followed by advertisers, advertising agencies and the media. The purpose of the code is to control advertisements for all products and services to restrain any offensive or misleading content.

Generic substitution

India is a signatory to TRIPs and has included a system for protecting pharmaceutical patents in its patent law.

However, public interest remains a primary consideration, and to protect this, Indian patent law provides for the grant of a compulsory licence in order to make a pharmaceutical drug widely available to the public at affordable prices. In *Bayer Corporation v Union of India* (2012) the Intellectual Property Appellate Board (IPAB) upheld the first-ever grant of a compulsory licence to NatcoPharma Limited, a generic drug maker, to produce and market Nexavar, a patented cancer drug of multinational Bayer Corporation. The IPAB observed that even after obtaining a patent, Bayer had not made the drug available on a large scale and at an affordable price within the stipulated timeframe. The IPAB order has paved the way for a reduction in the prices of costly life-saving drugs.

Indian manufacturers are among the leading producers of generic pharmaceuticals. Such drugs are sold at a much cheaper price than branded drugs, and are available in India at substantially lower prices than in many other jurisdictions. The generic substitute must be equivalent to the branded drug in dosage form, strength, safety, route of administration, quality, performance characteristics and proposed use.

Online issues

E-pharmacies

No separate legislation governs the online sale of medicinal and pharmaceutical products. Therefore, the Drugs and Cosmetics Act and the Drugs and Magic Remedies (Objectionable Advertisements) Act, which apply to the physical sale of medicinal and pharmaceutical products, also regulate the online sale of such products.

In one case the Chennai Zonal Unit of the Indian Narcotics Control Bureau closed down an illegal online pharmacy network used to ship psychotropic drugs from India to customers abroad. Two people were arrested. Overseas customers seeking psychotropic drugs, which are banned in many foreign countries, would approach merchant account holders online for delivery of the drugs. The account holders, who were suspected to be operating from abroad, had contacts in India to whom lists of drugs, along with overseas addresses to which delivery was to be made, were emailed. The account holders paid substantial amount of money as the drugs were not easily available overseas. Investigations based on specific intelligence found that an individual named Vyukhin was such a contact for a merchant account holder named John, whose customers were in the United States, parts of Europe and Canada. Vyukhin received emails with drug orders on a regular basis from John. He would pass them on with delivery addresses to a third person called Shankar, who had a pharmaceutical background. Shankar travelled around India procuring psychotropic drugs such as alprax, diazepam, oxycodone and hydrocodone and sent them overseas through express mail service and railway mail service. The Indian duo are suspected of having made an overall profit of over Rs15 million. The Narcotics Control Bureau team raided Shankar's house in Villupuram and seized three boxes of drugs and some parcels intended for delivery overseas. Further investigations are ongoing to identify their overseas contacts and track down those who sold drugs in bulk to Shankar.

Domain names

Indian pharmaceutical companies have been diligent in safeguarding and enforcing their trademark rights in their domain names. In one such case between renowned Indian pharmaceutical company Dr Reddy's Laboratories Limited and Manu Kosuri, the Delhi High Court issued a permanent injunction (2001 PTC 859) against the defendant precluding him from using the domain name 'drreddyslab.com' or any other domain name similar or identical to the plaintiff's trading name and mark DR REDDY'S, as such use amounted to passing off of the business and goods of the defendant as those of the plaintiff.

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Kavita Mundkur Nigam is an associate at Krishna & Saurastri Associates. Her practice areas include trademark prosecution and oppositions, copyright, designs, domain names, technology transfer, due diligence, IP licensing and acquisitions. Ms Nigam has initiated successful domain name arbitrations under the International Corporation for Assigned Names and Numbers Uniform Domain Name Dispute Resolution Policy at the World Intellectual Property Organisation, as well as at the .IN Registry in India. She also deals with matters relating to infringement, passing off and counterfeiting. She has worked on projects relating to mergers and acquisitions, private equity, project finance and foreign investment.