India

Contributing firm
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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's provisions, a penalty can be imposed for the manufacture, sale, stocking, exhibition or distribution of drugs without a valid licence.

An inherently distinctive trademark 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 proprietor. In addition to such common law rights, the proprietor of such a trademark 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 proprietor has a good-faith intention to use that mark.

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

- is the commonly used and accepted name of any 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 have been several instances of pharmaceutical companies creating trademarks from the stems of INNs. In compliance with Resolution 46.19 passed by the World Health Assembly issuing directions to WHO member states to discourage such misuse of INNs, Section 13 of the Trademarks Act specifically prohibits the use as trademarks of:

- any word declared an INN by the WHO and notified by the registrar of trademarks as such; and
- any name 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.

Parallel imports and repackaging

The Trademarks Act follows the principle of international exhaustion of trademarks. Section 30(3) of the act provides that where the goods bearing a registered trademark are lawfully acquired by a person, selling those goods in the market, or otherwise dealing in

those goods by that person or by a person claiming under or through him or her, does not amount to infringement of the trademark if the goods have been put on the market under the registered trademark by the rights holder or with its consent. The general rule is that once goods bearing a particular trademark are released anywhere in the world, by or with the consent of the proprietor of the trademark, the proprietor 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 proprietor in such cases may be express or implied, direct or indirect. The proprietor of the trademark may, however, impose contractual restrictions on third parties such as foreign licensees against importing goods into India, as long as those restrictions are valid under the Competition Law, among other statutes.

The courts have held that although parallel imports *per se* could not be deemed to be infringement in view of the legal provisions in India, a cause of action for trademark infringement may be available to the proprietor against an importer where genuine goods have been materially altered, without the proprietor's consent, after placing them on the market. Further, a cause of passing off may also be available if the proprietor can show that the importer is passing off the goods in a misleading or improper manner, causing confusion in the minds of the public.

However, 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 upon assurance that the exporter complies with Indian production and safety standards. In order to obtain a licence, the importer is also required to 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 substandard quality, are misbranded or adulterated, or have not been labelled in accordance with the law. The 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 have also been given powers to 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 penal provisions that act as sufficient deterrent for malpractice relating to drugs and medicines. Since the Drugs and Cosmetics Act is a central enactment, the implementation of measures meant to deter the production and sale of spurious drugs is better coordinated between states, as well as the central government. Despite these deterrent provisions, however, the availability of spurious drugs on the market is a fact that cannot be denied altogether. The drug controller general of India acts in coordination with the state drug control authorities, the revenue intelligence authorities, the customs authorities and all port officials to keep a close watch on such clandestine activities and to check the menace that they represent.

The Central Drugs Standard Control Organisation has conducted a survey to assess the extent of availability of spurious drugs in the country by drawing samples from different regions and different strata of population 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 to establish new drug testing laboratories so as to enhance the capacity of laboratories to analyse large numbers of sample. Under the project, 23 states and six central drug laboratories have been strengthened through renovations, extensions and new equipments. Further, Schedule M of the Drugs and Cosmetics Rules pertaining to good manufacturing practices makes it mandatory, at par with the international standards, for drug manufacturers to comply with the requirements for quality control of drugs manufactured by them. The state governments have also issued detailed guidelines to undertake focused surveillance of possible movement of spurious drugs. Specific training programmes have been conducted for regulatory officials of state governments on the logistics of intelligence work and prosecutions, among other things, with the assistance of the Food and Drug Authority, Maharashtra. The pharmaceutical industry and the trade have been motivated to fight the menace of spurious drugs as a shared responsibility.

The Drugs and Cosmetics Act was recently amended by the Drugs and Cosmetics (Amendment) Act 2008 to provide for more stringent penalties for those involved in the trade of spurious drugs. However, as various stakeholders complained about the envisaged difficulties in implementing these amended provisions and expressed concern about their misuse, a committee under the drugs controller general of India was set up to look into establishing suitable guidelines. Following the issuance of such guidelines, the amended act came into effect on August 10 2009.

Since spurious or fake drugs is a sensitive issue affecting 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 menace as a priority. With this in mind, India's central government has set up a scheme to reward whistleblowers. The scheme is already operational in other enforcement departments of the government and is effective in terms of the volume of seizures. It provides handsome monetary rewards to informers who bring specific information to the designated authorities leading to the seizures of drugs, cosmetics and medical devices that are spurious, adulterated, misbranded or not of prescribed standards. 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 a fine. The offences under the act are cognisable offences. The police authorities are empowered to search and seize, without a warrant, the instruments involved in committing the offence of counterfeiting.

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

account of profits.

The Drugs and Cosmetics Act contains provisions that prohibit 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 government issued Notification 47/2007-Cus (NT), which led to the introduction of the Intellectual Property Rights (Imported Goods) Enforcement Rules 2007. The rules sought to 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 goods infringing IP rights. The rules envisage the following steps:

- the filing of a notice or application by the rights holder;
- registration of that notice by the customs authorities;
- a time limit for participation of rights holders in the proceedings;
- the provision of 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 relating to 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 also governs the 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 for Self-Regulation in Advertising is to be adhered to 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 and misleading content.

Generic substitution

India is a signatory to the TRIPs Agreement and has now included a system for protecting patents for pharmaceutical products in its patent law. However, the courts still consider the issue of overpricing of medicines to be of grave concern.

Indian manufacturers are among the leading producers of generic pharmaceuticals. Such drugs are sold at a much cheaper rate than branded drugs. Due to earlier Indian patent law, which did not allow for product patents for pharmaceuticals, medicines in India are available at substantially lower prices than in many other jurisdictions. Moreover, generic substitution is permitted, provided that the generic substitute is equivalent to the branded drug in dosage form, strength, safety, method of administration, quality, performance characteristics and proposed use.

Online issues

E-pharmacies

There is no separate legislation governing the online sale of medicinal and pharmaceutical products through web pharmacies hosted in India. Therefore, the Drugs and Cosmetics Act and the Drugs and Magic Remedies (Objectionable Advertisements) Act, which are applicable to the physical sale of medicinal and pharmaceutical products, also regulate the online sale of such products.

In a recent case, the Chennai Zonal Unit of the Indian Narcotics Control Bureau dismantled an illegal online pharmacy network used for shipping psychotropic drugs from India to customers abroad. Two persons were arrested. Overseas customers requiring psychotropic drugs, which are banned in many foreign countries, would approach merchant account holders online for delivery of the drugs. The account holders, who are suspected to be operating from abroad, had contacts in India to whom lists of required drugs, along with overseas addresses to which the delivery was to be made, were emailed. The account holders paid substantial amount of money as the drugs were not easily available overseas. Investigation based on specific intelligence found that an individual named Vyukhin was such a contact for a merchant account holder named John whose customers were based 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 meant for delivery overseas. A further probe is being conducted 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 Dr Reddy's Laboratories Limited, a renowned Indian pharmaceutical company, 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. WTR

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Kavita Mundkur Nigam is an associate at Krishna & Saurastri Patent and Trademark Attorneys. Her practice areas include trademark prosecution and oppositions, copyright, designs, domain names, technology transfer and IP licensing. Ms Mundkur has initiated successful domain name arbitrations under the Uniform Domain Name Dispute Resolution Policy, as well as at the '.in' registry in India. She also deals with matters relating to infringement, passing off, counterfeiting and due diligence. She has worked on projects relating to company mergers and acquisitions, private equity, project finance and foreign investment.

Ms Mundkur holds a bachelor's degree in law from Government Law College, Mumbai and a bachelor's degree in commerce from Narsee Monjee College of Commerce and Economics. She is registered with the Bar Council of India. She holds a diploma in cyber law from the Asian School of Cyber Law, Pune, as well as a degree in French from the *Alliance Française de Bombay*.