India

Contributing firm
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Selection, clearance and registration

Regulatory bodies and requirements

The drug controller general of India (DCGI) approves new chemical products introduced into the country. The manufacture, distribution, sale or stocking of any drug requires a licence issued by the authorities established under the Drugs and Cosmetics Act 1940. Under these provisions, a penalty can be imposed for the manufacture, sale, stocking, exhibition or distribution of drugs without a valid licence.

An inherently distinctive trademark, which is not closely similar to the trademark of any other proprietor, may be selected to designate a pharmaceutical product. Although the use of such trademark accrues common law proprietary rights therein, the rights holder can apply to the registrar of trademarks to register its trademark under the Trademarks Act 1999. Even a non-used mark can be registered under the act, provided that the proprietor has a good-faith intention to use it.

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

Case law

The Indian judiciary has always been sensitive to the rules governing the handling and sale of medicinal and pharmaceutical preparations. Because of the risk to public health, confusion and deception between rival goods must be prevented at all costs. Below is a selection of recent case law that illustrates important aspects of how pharmaceutical trademarks are treated.

In *Cadila Healthcare Limited v Gujarat Co-operative Milk Marketing Federation Ltd* (MANU/DE/2282/2009), the High Court refused to grant the appellant a permanent injunction to restrain the defendants from using the expression 'sugar free' in respect of frozen dessert. Although the court concluded that 'sugar free' is a well-known expression and accepted that it had achieved a secondary meaning in respect of sugar substitutes, it refused to grant the injunction. Instead, it held that the respondent was using the expression not as a trademark, but rather as a common descriptive adjective.

In *Acme Pharmaceuticals v Torrent Pharmaceuticals Ltd* (MANU/GJ/0001/2010), a court found that the respondent's mark DROXYL was nothing but the last letters of the drug Cefadroxil and thus its claim of monopoly over DROXYL was not sustainable, since Cefadroxil is an international non-proprietary name (INN) that merely designates the kind of goods and is devoid of any distinctive character. Since the appellant claimed to have coined its mark AROXIL by taking 'A' from its own trading name Acme and 'roxil' from the drug Cefadroxil, the use of the mark AROXIL was not considered to infringe DROXYL.

It is significant that generic or descriptive marks cannot be registered under the Trademarks Act, and also that there is a specific restriction on registering

the names of certain commonly used chemical elements and compounds under Section 13 of the act. So, even if such words are registered, no rights are conferred on their owners.

Similarly, in *Schering Corporation v Alkem Laboratories Ltd* (MANU/DE/3179/2009), the High Court upheld a refusal to grant an injunction to the plaintiff, which alleged that by using the trademarks TEMOKEM and TEMOGET for medicinal preparations containing Temozolomide, the defendants were infringing and passing off the drug containing the Temozolomide molecule. The plaintiff claimed to have synthesised and secured the patent for the Temozolomide molecule, and to market and sell drugs containing it under the trademarks TEMODAL and TEMODAR. The court considered the defendants' marks to be different and dissimilar from the plaintiff's marks.

The court equated the facts with those of *Astrazeneca UK Ltd v Orchid Chemicals and Pharmaceuticals Ltd* (2007(34) PTC469 (Del)). It found that in TEMOKEM and TEMOGET, the prefix 'temo' was derived from Temozolomide, which is an INN; the suffixes 'kem' and 'get' were derived from the names of the respondents (ie, Alkem and Getwell, respectively). In *Astrazeneca*, the active ingredient was Meropenem and the plaintiff, the rights holder for the trademark MERONEM, objected to the defendant's use of the mark MEROMER. The court held that the prefix 'mero' – being derived from the name of the active ingredient Meropenem – was incapable of being appropriated by anyone.

In *Sun Pharmaceuticals Industries Limited v Cadila Healthcare Limited* (MANU/TN/3536/2009), the appellant filed suit for an injunction to restrain the respondent from infringing and passing off its trademark VENIZ-XR, which it had registered and used substantially for anti-depressants. The respondent was using the mark VENZ-OD, which was alleged to be similar to the appellant's mark VENIZ-XR. It is pertinent to mention that terminologies such as 'XR', 'OD' and 'SR' refer to particular characteristics of the drug (ie, 'extended release', 'once a day' and 'sustained release', respectively). Notwithstanding the fact that the appellant held the registration of VENIZ-XR in respect of medicinal and pharmaceutical substances, the injunction was refused as the court found the marks VENIZ-XR and VENZ-OD, when taken as a whole, to be different and dissimilar.

On appeal, the rival marks VENIZ-XR and VENZ-OD were held to be closely similar, as an unwary consumer could easily be led to believe that the VENIZ and VENZ marks were identical, one being an extended-release medicine and the other a once-a-day medicine. The Madras High Court equated the case with *Medley Laboratories (P) Ltd v Alkem Laboratories Ltd* (2002(25)PTC592), where an injunction was granted against Alkem restraining it from using the mark SUPAXIN, as this was considered similar to Medley's prior trademark SPOXIN. This case re-emphasised the principle in *Cadila* (MANU/SC/0199/2001) that the possibility of confusion and deception being caused, and not actual confusion and deception, should be considered.

In *Modi Mundi Pharma Private Limited v Matrix Formulations* (MANU/DE/3126/2009) the plaintiff filed a suit of infringement and passing off, seeking a permanent injunction to restrain the defendant from using the mark NEUROCONTIN-800, which the plaintiff found to be closely similar to its CONTIN series of trademarks. The plaintiff had been using several trademarks, which can be identified as the CONTIN series of marks (CONTINUS, DILCONTIN, NITROCONTIN, INDICONTIN, ARCONTIN, BUCONTIN, CORNUCONTIN, DIUCONTIN-K and FECONTIN-F) and alleged infringement of its registered trademark CONTIN by the defendant's mark NEUROCONTIN-800.

Relying on *Cadila* (MANU/SC/0199/2001), the plaintiff alleged that the presence of CONTIN within the mark NEUROCONTIN-800 would lead consumers to believe that the goods bearing this mark originated from the plaintiff. The court found for the plaintiff and agreed that the continuous use of NEUROCONTIN-800 would tarnish or dilute the plaintiff's distinctive trademark and its reputation, and that such acts amounted to infringement and passing off.

In *United Biotech (P) Limited v Schon Pharmaceuticals Limited* (MANU/DE/3172/2009), the principles of passing off were yet again reaffirmed in a suit filed against the defendant for dishonest adoption and use of its trademark TAZIN. It became clear that the defendant was indulging in acts of passing off by representing its business as that of or associated with the plaintiff by using the mark TAZIN, which is registered by the plaintiff and has been used substantially by it since 2001.

The court found that the defendant was selling disputed medicinal preparations under the TAZIN mark, and was conspiring in and abetting the sale of counterfeit medicines. It found in favour of the plaintiff, saying that the law of passing off prevents commercial dishonesty and representing one's goods as the goods of somebody else.

Conversely, in *Alkem Laboratories Limited v Mega International (P) Limited* (MANU/DE/2401/2009), where the plaintiff and the defendant had both been using the trademark GEMCAL since July 2000 and November 2000 respectively for their medicinal and pharmaceutical preparations, the court refused to grant an injunction against the defendant. After analysing the annual turnovers in respect of the mark's use by both parties in respect of their respective medicinal preparations, it held that this was not a case of passing off, but of honest concurrent use.

In *Orchid Healthcare v Aglowmed Limited* (MANU/BH/0384/2009), the respondent, on the basis of prior trademark rights in the mark AVASTIN, sued the appellant for using the mark AVASTIN in respect of medicinal and pharmaceutical preparations and applied for an injunction to restrain it from using the mark AVASTIN for its products.

No material documents were produced at the trial stage by either party to establish prior use of the mark. The respondent was the prior applicant for the trademark AVASTIN in the Trademarks Registry. However, merely filing a trademark application is not conclusive of prior use. The status of use must be judged from the placing of products onto the market for sale, which cannot be proved on the basis of a trademark application alone, but rather through advertisements, invoices and dealings with dealers and retailers. Similarly, a survey report by ORG IMS Retail Audit could not be used blindly to conclude that a product had been launched on the market. The appeal court found that an injunction may be granted only when a *prima facie* case can be established. As a result, no injunction was granted to either party.

It can be seen from these cases that the Indian courts broadly agree that a descriptive expression or an INN cannot be monopolised and does not serve as a good trademark. In addition, they have affirmed principles of passing off, honest concurrent use and that common law rights are stronger than statutory rights. Cases related to pharmaceutical trademarks clearly benefit from special attention and consideration, since the implications of any kind of confusion between such marks poses an immensely severe health risk. The courts carefully weigh the pros and cons of each matter, not only to adjudicate issues involved therein, but also to set appropriate precedents.

Parallel imports and repackaging

Parallel imports of goods bearing registered trademarks are permitted under Indian trademark law, provided that such goods are genuine (ie, not materially altered after they are put to use in commerce with the consent of the proprietor of said goods). Once genuine goods are sold in commerce with the proprietor's consent, all associated trademark rights are exhausted. India follows the policy of international exhaustion for the purpose of parallel trade in relation to trademarks. This principle applies to pharmaceutical trademarks.

Anyone wishing to import drugs manufactured by international pharmaceutical companies must obtain an import licence from the DCGI under the Drugs Act and the corresponding Drugs Rules. The licence is granted upon assurance that the exporter complies with Indian production and safety standards. Further, the importer is required to submit a drug sample to the Central Drug Control Organisation (CDCO) for testing. On approval, the importer is granted a licence. The importer must supply the following additional documents to the CDCO:

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

The Indian authorities are empowered under the Drugs Act to prohibit the import of drugs that are of sub-standard quality, misbranded or adulterated, or which have not been labelled in accordance with the law. The import may also be prohibited in the public interest. Any party can make a written complaint to the DCGI 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

Counterfeit drugs account for a large part of world trade every year. Though there are few prevention strategies to combat this global problem, there are ways and means of restricting the flow of fake medicines in the pharmaceuticals market. Mass serialisation is one such strategy and has been adopted by Roche India for most of its products sold in India. Under this process, product packaging is given a unique 16-digit alpha-numeric computer-generated code, which can be validated by the customer by sending the code by email or SMS to the manufacturing company.

Regulatory framework

The Trademarks Act penalises the falsification or use of false trademarks and trade descriptions by imprisonment and a fine. The offences under the act are cognisable offences. Police authorities are empowered to search and seize without 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 accounts of profit.

The Drugs Act contains provisions which prohibit the manufacture, sale or import of drugs which are misbranded or counterfeit. It also sets out a number of penalties for breach of these provisions.

Border control measures

The Customs Act prohibits the import or export of goods infringing IP rights and allows for the confiscation thereof. Under the Intellectual Property Rights (Imported Goods) Enforcement Rules, which came into force in 2007, the customs authorities are authorised to suspend clearance of imported goods suspected of infringing IP rights. The rules have already been applied on several occasions.

Advertising

Regulatory framework

The Drugs 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 governs the issue of advertising of drugs. Specific diseases are mentioned therein for which no pharmaceutical advertising is allowed.

Generic substitution

India is a signatory to the Agreement on Trade-Related Aspects of Intellectual Property Rights and has now included a system for protecting pharmaceutical product patents 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, route of administration, quality, performance characteristics and proposed use.

Online issues

E-pharmacies

Indian cyber-criminals are at the forefront of the illegal online trade in pharmaceuticals at an international level. They market drugs banned in other jurisdictions under different trademarks through e-pharmacies. This illegal trade is worth considerable amounts of money.

In *Kedia v Narcotic Control Bureau* ((2008) 2 SCC 294), the Supreme Court of India refused to grant bail to the chief executive of Xponse Technologies, an individual by the name of Sanjay Kedia. He was arrested by the Narcotic Control Bureau under the provisions of the Narcotic Drugs and Psychotropic Substances Act 1985 for using online facilities to sell drugs illegally and for arranging the supply of banned psychotropic substances to countries such as Canada, Sweden and the United States. WTR

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Ms Mundkur holds a bachelor's in law from Government Law College, Mumbai, and a bachelor's in commerce from Narsee Monjee College of Commerce & Economics. She is registered with the Bar Council of India. She holds a diploma in cyber-laws from the Asian School of Cyber-Laws, Pune. Ms Mundkur also holds a *Diplome de Langue Francaise* – a degree in French offered by the *Alliance Francaise de Bombay*.