Pharmaceutical Trademarks 2021

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India

Manisha Singh and Omesh Puri
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OVERVIEW

Legislation

1 | What is the primary law governing trademarks in your jurisdiction?

The Trade Marks Act 1999 (http://www.ipindia.nic.in/writereaddata/Portal/IPOAct/1_43_1_trade-marks-act.pdf) is the primary statute along with the corresponding Trade Marks Rules 2017, which govern protection and enforcement of trademarks in India.

Agencies

2 | Which agency is responsible for the grant and registration of pharmaceutical trademarks?

The Trade Marks Registry, with a head office at Mumbai and branch offices at Ahmedabad, Chennai, Delhi and Kolkata, is the responsible office for the grant and registration of all trademarks, including pharmaceutical trademarks.

Regulators

3 | What are the relevant national and international regulatory bodies and requirements that need to be considered when clearing a pharmaceutical trademark?

The Ministry of Health and Family Welfare and the Ministry of Chemicals and Fertilisers are the government bodies that regulate the healthcare and pharmaceutical sectors. The agencies primarily responsible for regulating the import, manufacture, distribution and sale of drugs in India include:

- the Central Drug Standard Control Organisation;
- the State Drug Standard Control Organisations; and
- the Drug Controller General of India (DCGI), established under the Drugs and Cosmetics Act 1940 (https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/acts_rules/2016DrugsandCosmeticsAct1940Rules1945.pdf).

Furthermore, the Drugs and Cosmetics Rules 1945 framed under the Drugs and Cosmetics Act set (among other things) the prescribed standards and procedural guidelines for its operation.

The pharmaceutical industry notably accounts for the most trademark registration applications of any sector in India.

Indian trademark law prohibits registration of marks that are descriptive in nature or devoid of distinctiveness, except where the mark has acquired distinctiveness or secondary significance on account of its use, publicity and popularity. However, a feature peculiar to pharmaceutical trademarks is that these marks are often derived from the name of the concerned ailment, organ or chemical compound contained in the relevant drug, and may thus lack inherent distinctiveness. Therefore, the deciding factor is the brand owner's evidence of a secondary meaning.

Section 13 of the Trademarks Act 1999 prohibits registration of the names of chemical elements, compounds and international non-proprietary names (INNs) (which have been declared by the World Health Organisation and notified by the registrar of trademarks in 2012), or which are deceptively similar to such names. If an INN is erroneously registered as a trademark, it is liable to be cancelled. Since INNs are generic names of active pharmaceutical ingredients, they can be used by all drug manufacturers. The existence of a large number of trademarks similar to INNs highlights the need for greater scrutiny of pharmaceutical trademark applications.

Non-traditional trademarks

4 | What non-traditional trademarks are available in your jurisdiction and how are they registered?

Notable non-conventional marks in the pharmaceutical field include shape marks, colour marks and holograms. Certain shapes and sounds have already been registered as pharmaceutical trademarks in India. Although the concept of sound marks is not new, they have been granted explicit recognition under the Trademarks Rules 2017 (as notified on 6 March 2017); as such, businesses would be wise to seek exclusivity for their musical or other auditory branding and marketing methods in order to appeal to consumers in today's highly disruptive market. One such sound mark registered in India for pharmaceuticals is the sound of 'HI' 'SA' 'MI' 'TSU' sung over certain musical notations and applied on a 'proposed to be used' basis by Hisamitsu Pharmaceutical Co Inc of Japan. The protection of colour combinations is recognised in India, but the possibility of claiming exclusivity over a single colour remains a grey area.

Cannabis-derived products

5 | Does your jurisdiction allow the registration of cannabis-derived products?

The use of substances such as Cannabis, Canabidiol, Tetrahydrocannabinol are not free in India which are chemical compounds that naturally occur in the resin of the Cannabis plant and in India, the Narcotic Drugs and Psychotropic Substances Act, 1985 prohibits a person to produce, manufacture, cultivate, possess, sell, purchase, transport, store consume any narcotic drug that includes cannabis and substances procured therefrom. However, cannabis cultivation and sale are allowed under the NDPS Act strictly for medical, scientific, horticulture and industrial purposes, provided the state governments issues a licence to that effect. The trademark registration is also allowed for cannabis-derived products.

PARALLEL IMPORTS

Regulation

6 | What are the rules governing parallel imports of pharmaceutical goods?

Where a person lawfully acquires goods bearing a registered trademark, the sale of or other dealings in those goods by that person or its agent will not amount to infringement in India. The concept of parallel imports is inextricably linked to the principle of exhaustion of rights. In respect of trademarks, India follows the principle of international exhaustion of rights as observed by the Division Bench of the Delhi High Court in *Kapil Wadhwa v Samsung Electronics*. The appeal against the judgment of Division bench is currently pending before Supreme Court of India, which will determine the exact position on parallel imports.

Strategies against parallel imports

7 | What strategies are available to police and enforce against parallel imports?

For the import of any drug, an import licence is required from the Drug Controller General of India, which is valid for three years. No drug that is prohibited in the country of origin can be imported into India, except for the purpose of examination, tests or analysis. The import of a drug is prohibited where it:

- is not of standard quality;
- is misbranded, adulterated or spurious;
- may involve any risk to human beings or animals; or
- does not hold the claimed therapeutic value.

The enforcement agencies such as the police may not be appropriate authority to enforce rights against parallel imports. The brand owners are advised to take civil route by filing suit for infringement and passing-off. Parallel importation may sometimes be followed by repackaging. At this stage, section 30(4) of the Trademarks Act comes into effect. This section mandates that a brand owner may oppose further dealings in the goods where the condition of the goods has been changed or impaired after having been put on the market. Therefore, if the repackaging of pharmaceuticals causes any material change or impairment, the brand owner may object to such repackaging; otherwise, the repackaging must duly conform to the relevant packaging and labelling requirements. The impairment of goods need not only be physical to preclude the immunity or exemption to the defendants from infringement under the 'First Sale' doctrine. Even differences in services and warranties, advertising and promotional efforts, packaging, quality control, pricing and presentation would amount to impairment of the products, under section 30(4) of the Act.

ANTI-COUNTERFEITING AND ENFORCEMENT

Types of proceedings

8 | What types of legal or administrative proceedings are available to enforce against infringing products?

A brand owner can initiate both civil and criminal proceedings against infringement of a registered trademark. If the mark is not registered in India, a civil action for the tort of passing-off can be initiated, provided that the mark has acquired substantial goodwill and reputation in the relevant markets and actual or potential injury will or is likely to be caused to the trademark owner as a result of the misrepresentation.

India has a robust border security and enforcement system under the Customs Act 1962, whereby rights holders can enforce their IP rights at the Indian border under the Intellectual Property Rights (Imported Goods) Enforcement Rules 2007.

Remedies

9 | What are the available remedies for infringement?

Through a civil action the rights holder can obtain remedies in the form of an injunction, seizure and destruction of infringing stock and damages (as the remedy of damages is not available under a criminal action).

The available remedies under the criminal route against falsification and false application of trademarks (including counterfeiting) are imprisonment for a term of six months to three years and a fine of 50,000 rupees to 200,000 rupees. These offences are cognisable under Indian criminal law procedure, which enables a police officer of a rank not below the deputy superintendent of police to search and seize counterfeit stocks and arrest accused persons in possession of such stocks without a warrant or prior court permission. However, the officer must obtain an opinion from the registrar of trademarks before any action is taken on a complaint filed by the rights holder.

In respect of pharmaceutical trademarks, specific actions are also available under the Drugs and Cosmetics Act, read with the Drugs and Cosmetics Rules. As one of the main objectives of this legislation is to ensure that publicly available drugs are safe and efficacious, it also stipulates criminal penalties for offences relating to the import, manufacture and sale of spurious drugs. According to sections 9B and 17B of the Drugs and Cosmetics Act, in relation to the import and the manufacture, sale and distribution of drugs respectively, a 'spurious drug' includes counterfeit products and the 2008 amendments have significantly upped the ante, making the penal framework much stricter. The import of spurious drugs entails a punishment of imprisonment for up to three years and a fine of up to 5,000 rupees. Further, section 11(2) of the Drugs and Cosmetics Act provides that the commissioner of Customs or an authorised officer may detain any imported package suspected to contain any drug whose import is prohibited.

The manufacture, sale or distribution of any spurious drug that is likely to cause a person's death or grievous harm on consumption will entail imprisonment of 10 years to life, along with a fine of no less than the greater of 1 million rupees or three times the value of the drugs confiscated. In all other cases involving spurious drugs, the penalty will be imprisonment of seven years to life and a fine of no less than the greater of 300,000 rupees or three times the value of the drugs confiscated.

Border enforcement

10 | What border enforcement measures are available to halt the import and export of infringing goods?

India has a robust border security and enforcement system under the Customs Act 1962, whereby rights holders can enforce their IP rights at the Indian border under the Intellectual Property Rights (Imported Goods) Enforcement Rules 2007. In this regard, the relevant IP rights must be validly registered. The term of customs protection is five years from recordation of the rights with the customs authorities or until expiry of the relevant IP rights registration, whichever is earlier. These rules are specifically designed to stop the import of infringing goods, but custom officials have wide powers to even stop the export of infringing goods if the knowledge of such export of infringing goods are brought to the attention of relevant officials.

Online pharmacy regulation

11 | What rules are in place to govern online pharmacies?

The Drug Controller issued a notification stating that the online sale of medicines must conform to the requirements laid down in the Drugs

and Cosmetics Act. The chief area of concern has been the online sale of prescription drugs. The rules regarding the operation of online e-pharmacies are yet to be finalised by the government and various e-pharmacies currently operate in the country, but those that do not meet the requirements of the Drugs and Cosmetics Rules – including those relating to sales from licenced premises and maintaining necessary records – are not permitted. There have also been deliberations regarding requirements for scanned and electronic copies of prescriptions in the context of prescription drugs sold through e-pharmacies. The Drugs and Cosmetics Rules mandate that a prescription be written and signed by the prescriber with his or her usual signature and usual date; further, the Pharmacy Practice Regulations 2015 define 'prescription' as a written or electronic direction from a registered medical practitioner or other properly licensed practitioner to a pharmacist to compound and dispense a specific type and quantity of preparation or pre-fabricated drug to a patient. Thus, electronic and scanned copies of prescriptions are acceptable. The government is planning to roll out the e-pharmacy project soon, having released the draft rules in August 2018. Under these rules, no person must sell, stock, exhibit or offer for sale drugs through e-pharmacy portal unless registered by the central licensing authority. Specific conditions need to be fulfilled by the e-pharmacy applicant before a registration is granted, which will be valid for a three-year period and is renewable. E-pharmacies must also retain prescriptions and verify details of patients and doctors. The rise of e-pharmacies has led to increased online sales of counterfeit drugs. In the case of any infringement or passing off, the rights holder not only has recourse to remedies against the seller or manufacturer of the counterfeit drugs, but can also initiate an action against the e-pharmacy under internet intermediary liability. Notice may be sent to such e-pharmacies to take down content relating to infringing products, which will fulfil the requirement of 'actual knowledge' on the part of the intermediary. In the case of non-compliance by the e-pharmacy, a cause of action based on internet intermediary liability is available.

Recent cases

12 What are the most notable recent cases regarding the enforcement of pharmaceutical marks?

On 5 June 2020, the Delhi High Court in *Sun Pharma Laboratories Limited v Bdr Pharmaceuticals International Pvt Ltd & Anr* held that the mark Lulibet is deceptively similar to Labebet even though the marks were used on products designed to treat different ailments. The court held that the following are key points that should be considered when deciding cases of deceptive similarity involving pharmaceutical trademarks:

- the marks have to be compared as a whole and they have to be judged by their look and sound;
- the consumer base has also to be considered;
- where medicinal products are involved, the test to check the likelihood of confusion should be strictly applied. In the case of non-medicinal products, confusion only creates economic loss but, in the case of medicinal products, it may have adverse consequences on the health and life of the individual; and
- though one drug may be sold in one form, such as tablets and injectables, and the other may be sold in such forms as a lotion and a cream, both drugs may be sold through common channels. Further, the similarity of the marks may give rise to possible deception or confusion.

On 10 May 2019, the Delhi High Court in *Sun Pharma Laboratories Ltd v Ajanta Pharma Ltd* ruled that the test for infringement and passing-off for nutraceutical products is the same and as strict as that applicable for pharmaceuticals.

On 6 February 2019, in *Curewell Drugs & Pharmaceuticals Pvt Ltd v Ridley Life Science Private Ltd*, the Delhi High Court not only awarded appropriate damages and costs against the defendant along with permanent injunction against manufacture and sale of infringing pharmaceutical products bearing identical trademarks and packaging, but also scrutinised the role of the Indian drug authorities – the Drug Controller General of India and the state food and drug administrations – in approving drugs that have an identical or almost identical brand name. The court emphasised the need to ensure that an identical brand name belonging to another entity is not permitted and the drug authorities should consider requiring the applicant to furnish a search report from the Trademarks Office for the brand name sought to be approved for the drug in question. This was also captured in the Supreme Court's judgment in *Cadila Health Care Ltd v Cadila Pharmaceutical Ltd* ((2001) 5 SCC 73), which called for the need for proper coordination between the drug authorities and the Trademarks Office. The drug authorities, upon detailed deliberation, recommended devising a mechanism under the Drugs and Cosmetic Rules 1945 to include provisions for regulating the brand names and trade names of pharmaceutical products.

ADVERTISING

Regulatory bodies

13 Which bodies are responsible for oversight of pharmaceutical advertising in your jurisdiction (and what are their powers)?

The authorities under Drugs and Cosmetics Act and Drugs and Magic Remedies (Objectionable Advertisement) Act and Advertising Standards Council of India along with Indian courts are the responsible bodies for enforcing rights against wrong pharmaceutical advertising and the violation may attract seizure, imprisonment and fine.

Advertising rules

14 What specific rules are in place regarding the advertising of pharmaceutical products?

Under the Drugs and Cosmetics Act, a drug will be deemed to be misbranded if it is not labelled in the prescribed manner or if the label contains anything misleading. For instance, any misleading statement with respect to the name, composition, strength or other elements of the drug connotes a misbranded drug.

The Drugs and Magic Remedies (Objectionable Advertisement) Act 1954, which applies to a specified category of drugs limited to a specified list of disorders, diseases and conditions, prohibits advertisements including the display of labels in connection with diagnoses, cures, mitigation, treatments or prevention; with respect to drugs in general, it prohibits false or misleading claims in advertisements. Advertisements for magic remedies are also prohibited under the act.

The Advertising Standards Council of India (ASCI) is a non-governmental organisation whose main objectives include developing self-regulation guidelines for advertising content in order to ensure that the claims made through advertisements are true, thereby preventing the spread of dishonest and misleading content among consumers. On 20 January 2017, the Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) signed a memorandum of understanding with the ASCI to undertake the monitoring of misleading AYUSH-related advertisements appearing in print and TV media, and to bring improper advertisements to the attention of the state regulatory authorities for necessary action.

Further, the Uniform Code for Pharmaceuticals Marketing Practices (which is a voluntary code) states that the promotion of any

drug must be consistent with the terms of that drug's approval for sale or supply and that such promotion cannot be undertaken before the procurement of such approval or a drug licence.

GENERIC SUBSTITUTION

Legality

15 | Is generic substitution permitted in your jurisdiction?

For the generic pharmaceutical market, Indian patent law includes a provision to apply for a compulsory licence. One of the grounds on which such an application may be submitted is the non-availability of the patented invention at a reasonably affordable price to the public. Therefore, generic versions of patented pharmaceuticals can be manufactured under such a licence.

To ensure safety and efficacy of generic drugs, the Drugs and Cosmetics (Ninth Amendment) Rules 2017 made bio-equivalency testing mandatory in relation to certain classes of generic drugs (including drugs that are not new drugs), even where the manufacturer applying for a licence relies on the past research data submitted by original manufacturing pharmaceutical companies.

Regulations

16 | Which regulations govern generic substitution by pharmacists of brand-name drugs?

In its endeavour to supply medicines across India at affordable prices, the government has championed the establishment of *jan aushadis* under the *Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana*. *Jan aushadis* are pharmacies that sell only generic name medicines at affordable prices. The hindrance to this scheme is in the form of Rule 65(11A) of the Drugs and Cosmetics Rules 1945, which does not allow pharmacies (including the *jan aushadis*) to substitute medicines while dispensing prescription drugs containing substances specified in Schedule H or Schedule H1 or X. To facilitate the smooth implementation of this scheme, in its 81st meeting on 29 November 2018, the Drugs Technical Advisory Board considered this issue and agreed to amend Rule 65(11A), thereby allowing *jan aushadis* to substitute medicines with generic versions of drugs specified in Schedule H, H1 or X.

The board has also recommended that the Drugs and Cosmetics Rules be amended with the introduction of a provision regarding the conspicuous display of a sign carrying the phrase 'generic medicines are also available', in addition to having a separate shelf or rack for generic medicines in retail pharmacies. The board further recommended that a definition be included for 'generic medicine' in the Drugs and Cosmetic Rules, since it is currently not defined.

UPDATE AND TRENDS

Key developments and future prospects

17 | What were the key judicial, legislative, regulatory and policy developments of the past year in relation to the protection and enforcement of pharmaceutical trademarks? What are the prospects for future developments?

On the judicial enforcement side, the rules of comparison for pharmaceutical trademarks have been stricter than those in other categories of products. The courts have frequently held that when pharmaceutical products are concerned, confusion may result in harmful consequences to the health of consumers. Therefore, a stricter approach has been applied by Indian courts whenever there is a question of similarity between two pharmaceutical brands.

LexOrbis INTELLECTUAL PROPERTY ATTORNEYS

Manisha Singh
manisha@lexorbis.com

Omesh Puri
omesh@lexorbis.com

709-710 Tolstoy House
15-17 Tolstoy Marg
New Delhi 11000
India
Tel: +91 23716565
www.lexorbis.com

In India, the regulatory provisions for manufacture and sale of medicines are appropriately covered. However, these do not define the regulations for online sale and monitoring of pharmaceutical medicines clearly. The Draft Rules governing such sales have already been published and it is expected that the government will soon implement the rules, which will be helpful in providing the much required definitive regulatory framework to make sure proper functioning of the e-pharmacies in India.

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ISBN 978-1-83862-568-9