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*Dheeraj Kapoor and Aprajita Nigam*

# Pharmaceutical Trademarks 2020/2021

**A Global Guide**



Authors

**Dheeraj Kapoor and Aprajita Nigam**

### **Selection, clearance and registration**

The Ministry of Health and Family Welfare and the Ministry of Chemicals and Fertilisers play a major role in regulating 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.

Further, 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 which 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 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.

In order to increase their competitive edge, brand owners are developing more advanced and innovative ways to distinguish their products. Conventional marks include those consisting of letters, numerals, words, logos, images or combinations of these elements. 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.

### Parallel imports and repackaging

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*.

For the import of any drug, an import licence is required from the DCGI, which is valid for three years. No drug which 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.

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.

In early 2019 the Department of Industrial Policy and Promotion released a draft e-commerce policy to strengthen enforcement mechanisms for IP owners. Although the steps taken are generally welcome, there are some clauses which require further contemplation. Clause 3.12 allows a trademark owner to ask the e-commerce platform not to list any of its products without prior concurrence, while Clause 3.13 requires online marketplaces to seek trademark owners' authorisation before listing any products which will have an impact on public health. These clauses could conflict with the principle of 'exhaustion of rights', which allows traders to sell genuine products freely.

### Anti-counterfeiting and enforcement Prevention

Brand owners may consider the following points for effective prevention:

- Ensure that inherently distinctive marks are adopted and protected for the purpose of effective deterrence.
- Use the mark in such a manner that its genericide is avoided at all costs.
- Collect and preserve all documentary evidence of use and publicity of a pharmaceutical trademark in order to build a winnable case in future.
- Maintain a clear record of all such documents for each brand and accumulate them to show continuity.

The available remedies against falsification and false application of trademarks (including counterfeiting) are imprisonment for a term of six months to three years and a fine of Rs50,000 to Rs200,000 (approximately \$725 to \$2,885). These offences are cognisable under



## The import of spurious drugs entails a punishment of imprisonment for up to three years and a fine of up to Rs5,000

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.

### Enforcement

For the purpose of enforcement, a civil action for infringement of a registered trademark may be initiated alongside a criminal action for effective deterrence. Through a civil action the rights holder can also 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).

If the mark is not registered in India, a civil action for the tort of passing off can be initiated, provided that the mark carries 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.

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 Rs5,000 (\$73). 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 which 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 Rs1 million (\$14,410) 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 Rs300,000 (\$4,325) or three times the value of the drugs confiscated.

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 DCGI and the state food and drug administrations – in approving drugs which 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



## Any misleading statement with respect to the name, composition, strength or other elements of the drug connotes a misbranded drug

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. Accordingly, the draft rules have been prepared and circulated, while the final rules, after inviting comments from the public, will be notified as law on 31 December 2019.

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.

Counterfeiting is defined in the Indian Penal Code 1860, Section 415 of which – read with Illustration (b) – makes counterfeiting an act of cheating which can entail imprisonment of up to one year, a fine or both.

In 2017 the Bihar police and drug control wing authorities notably seized fake, expired and spurious medicines and surgical items worth over Rs100 million (\$1.44 million) from certain pharmacies. This was officially described as the biggest breakthrough against the life-threatening trade in the state in 13 years.

### Advertising

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


**Dheeraj Kapoor**

Senior associate

[dheeraj@lexorbis.com](mailto:dheeraj@lexorbis.com)

Dheeraj Kapoor is a senior associate with extensive knowledge and expertise in IP law. He is experienced in handling diverse matters before the High Courts, the Intellectual Property Appellate Board, the Trademarks Office and the Copyright Office, as well as providing advice on various related laws. He also specialises in pharmaceutical trademarks and contentious trademark issues pertaining to trademark prosecution, oppositions, litigation, border protection and control measures, as well as enforcement. He works closely with the LexOrbis legal research and publication team and has authored many articles and papers in leading IP publications. Mr Kapoor advises numerous Fortune 500 companies, multi-national corporations, small and medium-sized enterprises and technology start-ups.


**Aprajita Nigam**

Senior associate

[aprajita@lexorbis.com](mailto:aprajita@lexorbis.com)

Aprajita Nigam is an advocate, enrolled with the Bar Council of Delhi since 2013. Having started her career in general litigation, she gradually moved towards IP specialisation. Ms Nigam holds an LLM in IP rights from NALSAR University of Law, where she earned a gold medal. She has also completed an executive programme in M&A law and a certificate course in the Korean language.

Ms Nigam has a thorough understanding of IP law and is particularly interested in niche and specialised areas. At LexOrbis she handles trademark and copyright matters (prosecution, contentious and non-contentious) and domain name complaints, as well as drafting privacy policies, terms of agreement and opinions for complaint procedures. She regularly attends hearings at the Trademarks Office and represents the firm at prestigious conferences. She handles a diverse client portfolio, comprising various Fortune 500 companies, multinational corporations, small and medium-sized enterprises, media and entertainment companies, pharma companies and technology start-ups.

before the procurement of such approval or a drug licence.

**Generic substitution**

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



## 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

new drugs), even where the manufacturer applying for a licence relies on the past research data submitted by original manufacturing pharmaceutical companies.

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.

### Online issues E-pharmacies

The DCGI 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 new 2019 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 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 case of non-compliance by the e-pharmacy, a cause of action based on internet intermediary liability is available.

### **Domain names**

Like any other sector, pharmaceutical companies may come to be at loggerheads over domain names. In such cases, a complaint may be instituted with the National Internet Exchange of India. As domain names are akin to trademarks, the same remedies available for trademark infringement and passing off are also available with respect to domain names. **WTR**



### **LexOrbis**

709-710 Tolstoy House  
15-17 Tolstoy Marg  
New Delhi 110001  
India

**Tel** +91 11 2371 6565

**Fax** +91 11 2371 6556

**Web** [www.lexorbis.com](http://www.lexorbis.com)