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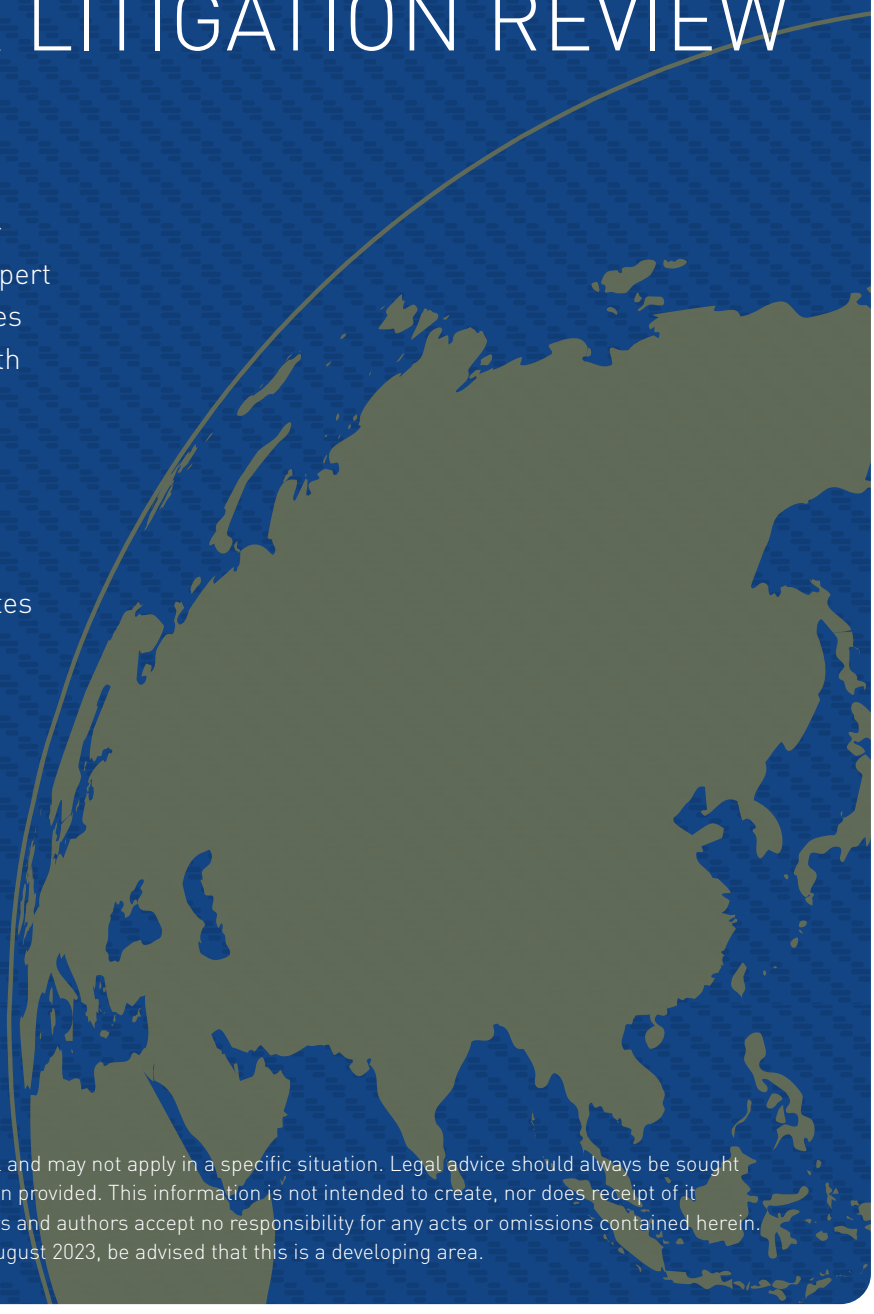

Effective litigation key to protecting trademarks in booming Indian pharmaceutical industry

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In summary

The pharmaceutical industry has witnessed tremendous growth in recent decades and accounts for a majority of the trademark registratons compared to other sectors in India. Protecting and litigating pharmaceutical trademarks presents a host of challenges; the products, the processes involved and the brand names of drugs need to be protected under trademarks and patents.

Discussion points

- Legal and regulatory framework for pharmaceutical trademarks
- Registration of pharmaceutical trademarks
- Preventive measures and existing enforcement mechanisms
- International enforcement
- Challenges in protecting and litigating pharmaceutical trademarks
- Notable judicial developments

Referenced in this article

- *Cadila Healthcare v Cadila Pharmaceuticals*
- *Cipla Limited v MK Pharmaceuticals*
- *Neon Laboratories Ltd v Medical Technologies Ltd & Ors*
- *Macleods Pharmaceuticals Limited v Union of India*
- *Sun Pharma Laboratories Limited v Bdr Pharmaceuticals International Pvt Ltd & Anr*
- *Curewell Drugs & Pharmaceuticals Pvt Ltd v Ridley Life Science Private Ltd*

Introduction

The pharmaceutical sector in India, being the third-largest manufacturer of generic medicines, constitutes about 20 per cent of total global exports in the pharmaceutical industry. India's domestic pharmaceutical market was estimated to be worth US$41 billion in 2021; it is likely to reach US$65 billion by 2024, and further expand to between US$120 billion and US$130 billion by 2030.

The Indian pharmaceutical industry has witnessed tremendous growth in recent decades and the industry accounts for the most trademark registrations of all sectors in India; therefore, the products, the processes involved and the brand names of drugs need to be protected under trademarks and patents.

Need for protecting pharmaceutical trademarks

Protecting pharmaceutical trademarks is crucial for establishing brand identity, preventing consumer confusion, combating counterfeiting, attracting investments, maintaining brand reputation and trust, and enforcing legal rights. By safeguarding trademarks, pharmaceutical companies prevent the unauthorised use of similar marks that could create confusion among consumers, leading to potential health risks, compromised treatment choices or loss of consumer trust in the industry.

Trademark protection provides pharmaceutical companies with a competitive advantage, and encourages investments in research, development and marketing. The exclusive right to use a trademark incentivises companies to invest resources in developing innovative pharmaceutical products, conducting clinical trials and bringing such products to market. The protection of trademarks helps create a favourable environment for innovation and ensures a return on investment for pharmaceutical companies.

Trademark protection further provides pharmaceutical companies with legal remedies and enforcement mechanisms against unauthorised use or infringement. Effective trademark protection helps deter potential infringers, safeguard brand value and maintain a level playing field in the market.

Legal and regulatory framework

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 that are 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, established under the Drugs and Cosmetics Act 1940 (the D&C Act).

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

In India, the regulatory provisions for manufacture and sale of medicines are covered under:

- the D&C Act;
- the D&C Rules;
- the Pharmacy Act 1948;
- the Information Technology Act, 2000;
- the Indian Medical Act 1956;
- the Code of Ethics Regulations 2002;
- the Narcotic Drug and Psychotropic Substances Act 1985; and
- the Drugs and Magic Remedies (Objectionable Advertisement) Act 1954.

Registration of pharmaceutical trademarks

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

Section 9(a) of the Trademark Act 1999 (the Act) prohibits the registration of trademarks that are descriptive, devoid of any distinctiveness (ie, not capable of distinguishing the goods or services of one source from another), or of such a nature as to deceive the public or cause confusion. Section 11 of the Act prohibits the registration of marks that are descriptive or devoid of distinctiveness, except where the mark has acquired distinctiveness or secondary significance on account of its use, publicity and popularity.

A feature particular to pharmaceutical trademarks is that these marks are often derived from the name of the ailment that the drug treats, the treatment performed by the drug, the salt composition of the drug or any other related medical term and may thus lack inherent distinctiveness. However, distinctiveness is requisite for a mark to qualify as a trademark; therefore, the deciding factor is the brand owner's evidence of secondary meaning. Another significant provision in this regard is section 13 of the Act, which prohibits the registration of names of chemical elements, compounds and international non-proprietary names that have been declared by the World Health Organization and were notified by the registrar of trademarks in 2012 or that are deceptively similar to such names.

Non-conventional trademarks

Brand owners are developing more advanced and innovative ways to distinguish their products by adopting non-conventional or non-traditional trademarks. Such marks include the shape and colour combinations of drugs as well as trade dress. Sound marks have been registered by pharmaceutical companies in India, such as the mark 'HI-SA-MI-TSU' by Hisamitsu Pharmaceutical Co, Inc of Japan. 'The Purple Pill' of AstraZeneca's Nexium and the 'Red and White' Dyazide of SK&F have been registered as colour trademarks.

Preventative measures and existing enforcement mechanisms

Preventive measures

Brand owners may consider the following points as precautionary measures:

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

Existing enforcement mechanisms

For 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 because of the misrepresentation.

For pharmaceutical trademarks, specific actions are available under the D&C Act, read with the D&C Rules. As one of the main objectives of this framework is to ensure that publicly available drugs are safe and effective, 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 D&C Act, in relation to the import and manufacture, sale and distribution of drugs, a 'spurious drug' includes counterfeit products. Amendments to the D&C Act from 2008 made

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 Indian rupees. Further, section 11(2) of the D&C 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 for between 10 years and 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 for between seven years and life and a fine of no less than the greater of 300,000 rupees or three times the value of the drugs confiscated.

In *Curewell Drugs & Pharmaceuticals Pvt Ltd v Ridley Life Science Private Ltd*,[1] the Delhi High Court scrutinised the role of the Indian drug authorities – the Drugs Controller General of India (DCGI), and the state food and drug administrations – in approving drugs that have an identical or almost identical brand name. This was also captured in the Supreme Court's judgment in *Cadila Health Care Ltd v Cadila Pharmaceutical Ltd*, which called for the need for proper coordination between the drug authorities and the Trademarks Office.

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

Border enforcement

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 the recordation of the rights with the authorities or until the expiry of the relevant IP rights registration, whichever is earlier.

International enforcement

Pharmaceutical trademarks often require protection across multiple jurisdictions due to the global nature of the industry. Inconsistencies in IP laws, varying levels of enforcement and differing legal systems across countries can make it challenging to effectively enforce trademark rights internationally.

1 2019 (77) PTC 657 (Del).

Coordinating cross-border efforts and addressing jurisdictional issues can be complex and time-consuming.

Challenges in protecting and litigating pharmaceutical trademarks

Protecting and litigating pharmaceutical trademarks presents a host of challenges. Litigation in the life sciences and pharmaceutical industries continues to be prolific due to the complex nature of the pharmaceutical industry and the importance of protecting public health.

Genericism

One common issue in pharmaceutical trademark litigation is the risk of genericism. If a trademark becomes the common name for a particular drug, it may lose its distinctiveness and legal protection. Pharmaceutical companies need to actively monitor and enforce their trademarks to prevent them from becoming genericised and maintain their exclusivity in the market.

Trademark similarity and confusion

The pharmaceutical industry often deals with many similar drug names, which can create a higher likelihood of confusion among consumers.

Regulatory approval and trademark use

The approval process for pharmaceutical products, including generic drugs and biosimilars, involves regulatory bodies such as the Central Drugs Standard Control Organisation and compliance with the D&C Act. Litigating pharmaceutical trademarks may involve determining whether the use of a particular trademark complies with regulatory requirements and whether it may cause confusion among healthcare professionals or patients.

Patents and trademark interplay

Pharmaceuticals often rely on patents to protect their inventions and exclusivity in the market. The interplay between patents and trademarks can create complex legal issues. Litigation may arise when trademarks are used to extend

patent protection or when trademarks are challenged based on the existence of overlapping patents.

Public health considerations

Litigation involving pharmaceutical trademarks must take into account public health considerations. Courts and regulatory bodies need to balance the interests of trademark owners with public access to affordable and safe medications, ensuring that trademark enforcement does not unduly hinder patient access to essential drugs.

Counterfeit and parallel import issues

The pharmaceutical industry is particularly vulnerable to counterfeit products and parallel imports, where legitimate products are imported from one market to another without the manufacturer's authorisation. Parallel imports, also called grey-market imports, are goods produced genuinely under the protection of a trademark, patent or copyright, placed into circulation in one market and then imported into a second market without the authorisation of the local owner of the IP right. These goods are authorised for original sale and are not counterfeited or pirated merchandise; thus, parallel imports are identical to legitimate products except that they may be packaged differently and may not carry the original manufacturer's warranty.

E-pharmacy

The rise of online sales and the proliferation of internet pharmacies have introduced new challenges in trademark litigation for pharmaceuticals. The DCGI issued a notification stating that the online sale of medicines must conform to the requirements laid down in the D&C Act. The chief area of concern has been the online sale of prescription drugs. The rules regarding the operation of 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 D&C Rules – including those relating to sales from licensed premises and maintaining necessary records – are not permitted. Thus, electronic and scanned copies of prescriptions are acceptable.

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 laws.

Pharmaceutical advertising

Pharmaceutical advertising plays a crucial role in promoting pharmaceutical products to healthcare professionals and consumers; however, pharmaceutical companies need to ensure that their advertising practices comply with relevant laws and regulations, including trademark laws, to avoid trademark infringement issues. The Advertising Standards Council of India is a non-governmental organisation whose main objectives include developing self-regulation guidelines for advertising content to ensure that the claims made through advertisements are true, thereby preventing the spread of dishonest and misleading content among consumers.

Under the D&C Act, a drug shall be deemed to be misbranded if it is not labelled in the prescribed manner or if the label contains anything misleading. 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 regards to drugs in general. It also prohibits false or misleading claims in advertisements and advertisements for magic remedies.

Notable judicial developments

Given the impact of the pharmaceutical industry on public health and safety, the courts adopt a stricter approach and a higher-than-usual degree of scrutiny when assessing similarities between such marks.

The Supreme Court of India, in *Cadila Healthcare v Cadila Pharmaceuticals,*[2] expressed the need for a greater level of care when dealing with pharmaceutical trademarks. The Court explained that 'drugs are poisons, not sweets'. Considering the enormous potential impact on public health, even slight confusion between two drugs may lead to detrimental consequences; thus, even if there is a minor possibility that the public may confuse one medicine for another, the courts will generally grant an injunction to restrain the use of the infringing mark given the compelling public interest. The Supreme Court established various parameters for resolving the question of misleading likeness in the case of pharmaceutical trademarks depending on the facts and circumstances of each case, as follows:

- the nature of the marks (ie, whether the marks are word marks, label marks or composite marks);
- the degree of resemblances between the marks (ie, the similarity of idea or sound);
- the nature of products;

2 2001(5) SCC 73.

- the class of purchasers, their education and intelligence, and the degree of care they are likely to exercise in purchasing or using the goods;
- the mode of buying the products or placing orders for the products; and
- any other surrounding circumstances that can be relevant to the extent of dissimilarity between the competing marks.

Another landmark case in the realm of pharmaceutical trademarks is *Cipla Limited v MK Pharmaceuticals.*[3] The plaintiff produced norfloxacin tablets in blister packaging that was oval and orange in colour under the trademark 'NORFLOX-400'. The defendant utilised an identical name, but it was not the name for which the plaintiff sued; rather, the plaintiff claimed that the defendant imitated the shape, colour and blister packing of pills, and caused confusion. The court, while deciding in favour of the defendant, held that there can be no colour monopoly because no one requests medicine based on its colour, form or packaging.

In *Neon Laboratories Ltd v Medical Technologies Ltd & Ors,*[4] the Supreme Court held that a mark should typically be an innovation and that if it is an existing word, it should not have descriptive features relating to the product.

The Bombay High Court, in *Macleods Pharmaceuticals Limited v Union of India,*[5] held that it is a settled legal position that when a particular medicinal or pharmaceutical product is involved in an impugned trademark that may deceive the public or cause confusion with respect to another trademark, it is the courts' primary duty to take utmost care to prevent any such possibility of confusion.

In *Sun Pharma Laboratories Limited v Bdr Pharmaceuticals International Pvt Ltd & Anr*, the Supreme Court laid down the following 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 an individual); and
- although one drug may be sold in one form, such as tablets or 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.

3 2008 (36) PTC 166 Del.
4 2015(64) PTC 225 (SC).
5 2023 SCC OnLine Bom 408.

Conclusion

Considering the exponential growth of India's pharmaceutical industry, the government is diligently taking steps to promote the industry by introducing and enforcing regulations that are on par with global standards. A robust trademark protection mechanism helps to prevent the entry and circulation of counterfeit medicines, ensuring that consumers receive genuine, safe and effective products. This, in turn, safeguards brand reputation and maintains consumer trust in the pharmaceutical industry. A comprehensive approach involving legal frameworks, enforcement measures, international cooperation and public awareness is required to effectively combat trademark infringement and safeguard the integrity of pharmaceutical products.

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Manisha Singh is the founder and managing partner of LexOrbis. She oversees and supervises all practice groups at the firm. Manisha is known and respected for her deep expertise in the prosecution and enforcement of all forms of IP rights, and for strategising and managing the global patents, trademarks and designs portfolios of large multinationals and domestic companies. She is also known for her sharp litigation and negotiation skills for both IP and non-IP litigation and dispute resolution. She has represented many companies in IP litigation with a focus on patent litigation covering all technical fields, particularly pharmaceuticals, telecommunications and mechanics.

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Priyanka Anand works as a senior associate in the litigation department at LexOrbis. With over six years of industry experience, Priyanka's work encompasses transaction, advisory, compliance and litigation support. She has advised and represented domestic and international clients across the technology, media, entertainment and telecommunication sectors as well as the food and beverage, infrastructure and pharmaceutical industries in connection with IP and commercial disputes, including trademark and copyright

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LexOrbis is a premier full-service IP law firm with over 260 personnel including more than 150 attorneys at its four Indian offices in New Delhi, Bengaluru, Mumbai and Chennai. The firm provides client-oriented and cost-effective solutions for the protection, enforcement, transaction and commercialisation of all forms of intellectual property in India and globally. The firm has been consistently ranked amongst the top five IP firms in India over the past decade and is well-known for managing the global patent, designs and trademark portfolios of many technology companies and brand owners. The firm has dedicated teams to cater to the IP life cycle including attorneys, engineers, scientists and specialists to deal with patent, trademark and copyright filing; research; portfolio building and management; enforcement; protection; spotting; transacting; procurement; and consultation.

The trademark practice group at the firm has over 30 attorneys experienced in partnering with brand owners and advising on the entire IP life cycle from selection to enforcement. The firm's patent practice group has over 100 patent attorneys with domain expertise in information and communication technologies, computer sciences and software including, among others, artificial intelligence and machine learning, the internet of things, blockchain, big data, mechanics, electrical and electronics, chemical and pharmaceutical, biotechnology, and energy management.

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