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PHARMACEUTICAL TRADEMARKS AND INNS: ISSUES AND CHALLENGES IN LIGHT OF PUBLIC HEALTH

Drishti Banerjee

STUDENT, BATCH OF 2020-2025

AMITY LAW SCHOOL, AMITY UNIVERSITY, KOLKATA

Abstract

Pharmaceutical trademarks perform a role greater than product identification and goodwill protection as they have a direct nexus with public health. Deceptive similarities in such trademarks that might lead to confusion may endanger public interest at large. Naming drugs is a technically challenging process given the system of scientific non-proprietary nomenclature based on active pharmaceutical ingredients (APIs). When a drug contains more than one API, the availability of combinations becomes limited. Brand names, mostly based on generic names for their simplicity and consistency, face the challenge of limited distinctiveness. Certain practices including counterfeiting, generic substitution, or parallel imports further complicate the scenario, depriving the owners of trademarks of their fair share of protection and economic benefits. Conflicting perspectives on pharmaceutical trademarks need to be reconciled with an appropriate collaboration among the concerned departments and regulatory mechanisms in order to deal with the problem at hand.

Keywords

Pharmaceutical Trademarks, Generic Substitution, Parallel Imports, INNs, Public Health.

Correspondence Author: Drishti Banerjee

Orcid id: https://orcid.org/0009-0001-5338-0698

Introduction

Trademarks facilitate identification and distinguish between the huge multitude of products and services available in a globalized market. Pharmaceutical trademarks move ahead a step further exerting influence on the public healthcare system.[1] The question therefore becomes a constitutional one, balancing the right to

[1] Priyanka Nimje, 'The Need for Trademark in Pharmaceutical Industry' (*Sagacious IP,* 2024) < https://sagaciousresearch.com/blog/the-need-for-trademark-in-pharmaceutical-industry/> accessed 26th March 2024

freedom of trade under **Article 19(1)(g)**[2] and **Article 301**[3] on one hand, and public interest under **Article 21**[4] on the other. Pharmaceutical trademarks are usually registered under **Class 5**[5] and **Class 35,**[6] and also as certification marks and collective marks. The rights of the proprietor of a trademark in the pharmaceutical sector may be breached by giving deceptively similar names, counterfeiting, generic substitution, or parallel imports. The Hon'ble Supreme Court of India in the landmark case of **Cadila Healthcare Ltd. v. Cadila Pharmaceuticals Ltd., 2001**[7] laid down standards for disputes on pharmaceutical trademark infringement and passing off cases. The standards for assessing similarity must be strict and very high, as drugs are equivalent to poisons if misused.[8]

Every drug generally has three categories of names. First, a chemical name which indicates the chemical composition of the drug. For instance, *N-acetyl-p-aminopnrnol* is the chemical name of paracetamol. Second, a generic name or non-proprietary name. it is uniform worldwide, often based on WHO nomenclature, or nomenclature system accepted by any competent scientific body or authority. These names are often used in prescriptions as well. For instance, *paracetamol.* The proprietary name or brand name is given by the drug manufacturers. Brand names are deemed to be catchy and suggestive of the usage of the drug. Therefore, a drug with a particular composition and use may have several brand names based on the company that manufactures it. For instance, *Crocin* and *Calpol* are brand names for paracetamol.[9]

International non-proprietary names (INNs) are generic names, based on the active composition of the drugs, and can be used by all drug manufacturers. They are *publici juris,* not subjected to anybody's monopoly. Such a nomenclature has been proposed by the World Health Organization.[10] Such names cannot be trademarked, as elucidated by **section 13** of the Trade Marks Act, 1999.[11] Under the provision, the registration of names of chemical elements and compounds is also prohibited. However, what drug manufacturers often do is use the INNs as the prefix or suffix of the brand name. This does not attract infringement or passing off action in light of **section 13** but often creates confusion among the general public. This brings to light the need for greater scrutiny of pharmaceutical trademark applications. In this regard, this paper lays down the need for coordination

[2] The Constitution of India, 1950 Art. 19(1)(g)
[3] The Constitution of India, 1950, Art. 301
[4] The Constitution of India, 1950, Art. 21
[5] 'Trademark Class 5: 'Pharmaceuticals' (*India Filings,* 2018) < https://www.indiafilings.com/learn/trademark-registration-trademark-class-5/> accessed 26th March 2024
[6] Trademark Class 35: 'Business Services and Consulting' (*India Filings,* 2018) < https://www.indiafilings.com/learn/trademark-class-35-advertising-business-services/> accessed 26th March 2024
[7] *Cadila Healthcare Ltd. v. Cadila Pharmaceuticals Ltd*., 2001, AIR 2001 SUPREME COURT 1952
[8] 'Pharmaceutical Trademark Confusion: Poison Pill or Public Health?' (*Spicy IP,* 2022) <https://spicyip.com/2022/11/pharmaceutical-trademark-confusion-poison-pill-or-public-health.html> accessed 26th March 2024
[9] Karan B Thakkar, Gauri Billa, 'The concept of Generic drugs and patented drugs vs. brand name drugs and non-proprietary (generic) name drugs' (2013) Front Pharmacol < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3770914/> accessed 26th March 2024
[10] Dr. R. Balocco Mattavelli, 'International Nonproprietary Names (INN)' (*World health organization*) < https://www.who.int/teams/health-product-and-policy-standards/inn#:~:text=International%20Nonproprietary%20Names%20(INN)%20facilitate,known%20as%20a%20generic%20name .> accessed 18th March 2024
[11] Trade Marks Act, 1999 s. 13

between the Trademark Registry, the CDSCO, and the other concerned departments to ensure a smooth and efficacious solution to this problem.

There is ambiguity regarding the registration of generic names as trademarks. Pharmaceutical trademarks often derive their nomenclature from the chemical composition, organ name, or ailment. Therefore, the element of distinctiveness may often be lacking.[12] The Indian trademark law prohibits the registration of marks that are descriptive in nature, or devoid of distinctiveness unless the mark has acquired distinctiveness or secondary significance on account of popularity or publicity. The brand owner's evidence of a secondary meaning, therefore, is often the determining factor. The goodwill that a particular brand owner acquires leads to acquired distinctiveness, which is often overlooked by Courts. The Madras High Court has recently held in this regard that drug names derived from API or disease names are weaker than arbitrary and coined names, and therefore can be refused registration by the Trade Marks Registry. The Court further held that due diligence needs to be taken care of in this regard, especially with respect to 'visual, phonetic, or structural similarity'.[13]

When it comes to the protection of intellectual property, there also is the issue of generic substitution, which is a process of substitution of a branded drug by a different form of the same active substance. The generic drug industry found its origin in the Hatch-Waxman Act of the United States. This practice is more profitable, as generic drug manufacturers do not have to spend extra amounts on drug discovery, and pre-clinical and clinical trials. In India, bioequivalence studies are mandatory only for a selected number of generic drugs according to the **Drugs and Cosmetics (Ninth Amendment) Rules, 2017**. The replacement of a prescribed drug with a cheaper generic medicine has become common among pharmacists. However, the issue of generic substitution is more relevant under the ambit of Patent Law.[14]

Trademark is primarily aimed at the protection of the goodwill of a company, along with the economic benefits that come with it. However, given the socio-economic background of the country, the Indian government has always been more inclined towards generic substitution of drugs. For instance, the Medical Council of India has recommended physicians to prescribe generic names as against brand names through the amendment to the code of conduct of doctors in 2016. Further, the "Jan Aushadhi" scheme proposed by the Department of Pharmaceuticals, Government of India in 2008 also envisaged making equally efficient unbranded quality medicines available to the poor. Generic substitution becomes possible especially when the patent life of the active substance has expired. The generic drug producers also use different salts of an active pharmaceutical ingredient (API) to avoid patent-related complications.[15]

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[12] Vindhya S. Mani, Mohit Kar, 'Registrability of Trademarks Derived from Generic Names in Pharma Industry- Madras High Court Strikes a Balance', (*Lakshmikumaran and Sridharan Attorneys,* 2023) < https://www.lakshmisri.com/insights/articles/registrability-of-trademarks-derived-from-generic-names-in-pharma-industry/#> accessed March 18th 2024

[13] *Indian Immunologicals Ltd.* v. *IPCA Laboratories Pvt. Ltd. & Anr*., 2023 (T) CMA (TM) No.72.

[14] John Posner, John P. Griffin, 'Generic Substitution' (2011) PMCID < https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3243006/#:~:text=Generic%20substitution%20is%20the%20term,of%20the%20same%20active%20substance.> accessed March 18th 2024.

[15] Hannah Brenann, 'The Cost of Confusion: The Paradox of Trademarked Pharmaceuticals' (2015) Michigan Telecommunication and Technology Law Review <

This highlights the issue of parallel imports of pharmaceuticals in developing countries like India. Drugs produced under trademark protection are placed into circulation in another market of a different country at cheaper prices without the authorization of the local owner of the intellectual property right. Such dealers often take advantage of the currency fluctuations in different nations.[16] They are protected under the doctrine of exhaustion, meaning that once a product is sold, the proprietor of the intellectual property rights cannot object to its resale unless any changes are made to the product.[17] The exceptions to infringement as laid down under **section 30(3)** of the Trade Marks Act, 1999 elucidate that if a person acquires a product and deals with it by reselling it in the market, it shall not be illegal. **Section 30(4)** gives the added clause regarding distortion of the product.[18]

Review of Literature

1. **The Role of Pharmacists in the Pharmaceutical Trademark Evaluation Process**

Martha M. Rumore highlights how the process of new drug development has become costlier and time-consuming with the increase in competitive rivalry and profit measures. This shows how genuine brands undergoing cumbersome research and development procedures and approval regulations spend a lot of resources in the process. The process of trademark development is also very complicated, facilitated by the involvement of pharmacists.[19]

2. **Trademarks in Pharmaceuticals Infringement and Ethical Issues in Retail Outlets: The Case of Addis Ababa, Bole Sub city**

Girma and Bemnet highlight that deceptive trademark infringement affects the ethical valuation of drugs. Jurisdictions such as Ethiopia have therefore placed sound policy guidelines to control the infringed pharmaceutical products. However, in order to check the generic substitution of drugs, branded drugs must introduce fair pricing.[20]

3. **Pharmaceutical trademarks: an evaluation of regulatory intricacies and challenges**

Tiwari and Bhattacharya propose that trademark regulation is aimed at protecting consumers from deception and confusion. It also protects the goodwill of the company and the rights of the proprietors. With the increasing

https://repository.law.umich.edu/cgi/viewcontent.cgi?referer=&httpsredir=1&article=1207&context=mttlr> accessed March 26th 2024

[16] Keith E. Maskus, 'Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries'(2001) *WIPO* < https://www.wipo.int/export/sites/www/about-ip/en/studies/pdf/ssa_maskus_pi.pdf> accessed march 18th 2024

[17] Priya Adlakha, Shilpi Saurav Sharan, 'The Doctrine of Exhaustion of IPR', (*Bar and Bench,* 2022) < https://www.barandbench.com/law-firms/view-point/the-doctrine-of-exhaustion-of-iprs-in-india> accessed March 18th 2024

[18] The Trade Marks Act, 1999, s. 30

[19] Martha M. Rumore, 'The Role of Pharmacists in the Pharmaceutical Trademark Evaluation Process', (1996-97) J. Pharmacy & L. < https://heinonline.org/HOL/LandingPage?handle=hein.journals/jpharm6&div=13&id=&page=> accessed March 26th, 2024

[20] Bemnet Girma, 'Trademarks in Pharmaceuticals Infringement and Ethical Issues in Retail Outlets: The Case of Addis Ababa, Bole Sub-city', (2016) St. Mary's University Repository, < http://repository.smuc.edu.et/bitstream/123456789/1644/1/Bemnet%20Girma.pdf> accessed March 26th, 2024

size of the markets, the importance of trademarks has increased. Further, given its direct nexus with the healthcare system, pharmaceutical trademarks are given more prominence.[21]

Methodology

The research methodology adopted in this paper is predominantly interpretive and analytical. Doctrinal sources such as books, journals, articles, and blogs related to the vast subject area have been referred to. Reference has also been made to various cases and judgments of the Indian Courts. The provisions of several statutes have been interpreted, including the Trade Marks Act, 1999, Drugs and Cosmetics Act, 1940, the Lanham Act, etc.

Results

The issues dealt with by this paper have been taken up for consideration by the Judiciary. However, the primary concerns of the proprietors of trademarks still remain unaddressed. The Courts have given varying opinions regarding deceptive similarity. For instance, in **Sun Pharma Laboratories Limited v. Bdr Pharmaceuticals International Pvt Ltd & Anr.,**[22] the names *Lulibet* and *Labelet* were held to be deceptively similar, even though the products were used to treat different ailments. In **Curewell Drugs & Pharmaceuticals Pvt Ltd v. Ridley Life Science Private Ltd.,**[23] the Court passed a permanent injunction along with costs against products having an identical trademark and packaging. It further held that the Drug Controller General of India along with the state food and drug administrators must take an active role.

The Hon'ble Supreme Court of India in **Cadila Health Care Ltd v Cadila Pharmaceutical Ltd.**[24] also called for proper coordination between the Trademark Registry and drug authorities, as pharmaceutical trademarks require added specialization. In **Wyeth Holdings Corporation v. Burnet Pharmaceuticals (P) Ltd 2008,**[25] the plaintiffs used the name *FOLVITE* which they had used since 1949. They objected to the defendants registering their mark named *FOLV*. The Court held that although FOL (signifying folic acid) and VIT (signifying vitamin) are generic terms, the name *FOLVITE* would be valid so long as it remains on the Register and that the name *FOLV* would potentially confuse the consumers.

In the abovementioned cases, stricter rules of interpretation of similarity have been applied. However, several judgments that followed diverted from this principle. For instance, in **Schering Corporation v. Alkem Laboratories**,[26] the Court held that the marks *TEMOKEM* and *TEMOGET* are dissimilar. In **Sun Pharmaceutical Laboratories v. Hetero Healthcare Ltd.**,[27] *LETERO* and *LETEROZ* were held to be

[21] Kuhu Tiwari, Niharika Sahoo Bhattacharya, 'Pharmaceutical trade marks: an evaluation of regulatory intricacies and challenges,' (2020) Journal of Intellectual Property Law & Practice < https://academic.oup.com/jiplp/article-abstract/15/9/738/5899472> accessed March 25th 2024

[22] *Sun Pharma Laboratories Limited v. Bdr. Pharmaceuticals International Pvt Ltd & Anr.* AIR ONLINE 2020 DEL 796

[23] *Curewell Drugs & Pharmaceuticals Pvt Ltd v Ridley Life Science Private Ltd*., AIR 2018

[24] *Cadila Healthcare Ltd. v. Cadila Pharmaceuticals Ltd*., 2001, AIR 2001 SUPREME COURT 1952

[25] *Wyeth Holdings Corporation v. Burnet Pharmaceuticals (P) Ltd*. AIR 2008 Bom 100

[26] *Schering Corporation v. Alkem Laboratories*, AIR 2009

[27] *Sun Pharmaceutical Laboratories v. Hetero Healthcare Ltd*., FAO (COMM) 96/2022, CM APPL. 29651/2022, CM APPL. 29652/2022, and CM APPL. 29653/2022.

dissimilar. Similarly, in **AstraZeneca UK Ltd. & Anr. v. Orchid Chemicals & Pharmaceuticals Ltd.,**[28] the names *MEROMER* and *MERONEM* were considered to be dissimilar. All these decisions came in light of the fact that the "STEMs" of these names are derived from INNs, which are *publici juris* and hence not subjected to the proprietorship of one person or company. It is argued that this logic often overlooks the acquired goodwill of the company.

The stare decisis on parallel imports also do not favour trademark owners. The Delhi High Court in **Kapil Wadhwa v. Samsung Electronics, 2012**[29] held that parallel imports in India are not technically illegal if they comply with the provisions of the Trade Marks Act, 1999. Products may be resold in India once sold anywhere else in the world, following the doctrine of International Exhaustion. However, the cover must contain a disclaimer that the product is not from an authorized dealer and that the original proprietor would be free from liability. A similar question arose regarding customs clearance in **Western Digital Technologies Inc. vs Mr. Ashish Kumar & Anr.,**[30] where the defendant amicably agreed to affix such a labelling.

Discussion

The World Health Organization prohibits the acquisition of proprietary rights over INNs, which is in consonance with **section 13** of the Trade Marks Act, 1999.[31] As discussed, this system overlooks the possibility of considering possibilities of acquired distinctiveness. The anti-dissection rule is widely applied in the case of trademarks, which states that a trademark must be analyzed in its entirety and not by breaking it into parts based on the underlying logic that a layman would remember the whole name of the drug and not its parts. It has been codified under the provisions of the Trade Marks Act under **sections 15**[32] and **17.**[33]

However, deceptively similar drugs in the market may lead to injury to public health. It must be noted that the judiciary has also evolved the Dominant Mark Test through precedents. Infringement action may be brought under it if another trader uses some essential part of the registered trademark. It is suggested that in order to deal with the issue of registration of generic names, the Dominant Mark Test must be made applicable so that the question of acquired distinctiveness of branded drugs is duly addressed.[34]

The issue of generic substitution and parallel imports genuinely affect the rights of proprietors of trademarks. In the first case, **section 27** of the **Drugs and Cosmetics Act, 1940**[35] may be resorted to, which lays down punishment for the manufacture or sale of adulterated drugs. **Chapter IV** of the Drugs and Cosmetics Act also

[28] *AstraZeneca UK Ltd. & Anr. v. Orchid Chemicals & Pharmaceuticals Ltd.*, AIR 2016
[29] *Kapil Wadhwa v. Samsung Electronics*, 2012, C.S. (OS) No.1155/2011
[30] *Western Digital Technologies Inc. vs Mr. Ashish Kumar & Anr.,* 2016 (Del) 1155.
[31] Trade Marks Act, 1999, s. 13
[32] Trade Marks Act, 1999, s. 15
[33] Trade Marks Act, 1999, s. 17
[34] 'Rule of Anti-Dissection in Trademark Law', (*K Analysis*) < https://blog.kanalysis.com/rule-of-anti-dissection-in-trademark-law/#:~:text=Having%20noted%20the%20%E2%80%9Canti%2Ddissection,defendant%20has%20infringed%20on%20that> accessed 26th March, 2024
[35] Drugs and Cosmetics Act, 1940, s. 27

regulates the manufacture, sale, and distribution of drugs and cosmetics. It lays down penalties regarding adulterated drugs, misbranded drugs, spurious drugs, etc. These provisions may partially address the problem, as correctly labelled cheaper generic drugs are not counterfeit per se and are under the protection of government regulations.

Parallel imports undeniably lead to unfair competition. The **Customs Act** to some extent protects intellectual property rights including trademarks. Under **section 11,** import and export of goods that violate trademarks and other intellectual property rights is prohibited,[36] and the **Notification No. 51/2010-Cus. (NT)** under the provision furthers the cause. Applications are submitted to prevent the import or export of counterfeit products, but it does not actually address the issue of parallel imports. The imposition of strict contractual conditions is perhaps the best way to deal with this grey area of marketing.

However, it is pertinent to question the doctrine of exhaustion and first sale, especially in cases of trademarks, when unauthorized users make use of the duly registered trademarks. Such claims may be raised by proprietors under jurisdictions like the United States (under the **Lanham Act).**[37] The European Union also first analyses whether the use of trademark by the parallel importer was fair. The usage of valid trademarks for commerce without consent is in itself a violation of the ethos of intellectual property laws, and requisite regulations in this regard would not be uncalled for.

Conclusion

It is high time that coordination is established among the drug agencies and trademark registry so that the questions of requirement of use, acquisition of reputation, etc. are duly addressed. The nuances of drug development are resource-consuming, and there remains a substantial question of to what extent the rights of proprietors are actually protected under the current system. The regulatory conundrum therefore hinges on a deliberative determination of the authorities. It should be done with due regard to the larger societal interest of public health at stake in this regard.

[36] The Customs Act, 1962, s. 11
[37] The Trademark Act, 1946, USA