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THE "DOCTRINE OF GREATER CARE": PHARMACEUTICAL TRADEMARKS IN INDIA*

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ABSTRACT

The Indian pharmaceutical market is filled with "sound-alike" and "look-alike" drugs, that is, different pharmaceutical companies using the same or similar name to market and sell different drugs. Not only do such confusingly similar trademarks co-exist in the market, but they also co-exist on the Trade Marks Register (under Class 5). This practice has emerged in India due to the growth of a pharmaceutical industry heavily oriented toward generics, where it is often assumed that generic medicines are interchangeable substitutes for the innovator's brand. Regulatory and clinical considerations, however, reveal that Indian generic drugs may not be interchangeable. Still, the industry has developed a distinct branding language, relying on prefixes, suffixes, and sound-alike elements that signal therapeutic class or function. This reality has led to a proliferation of ambiguous terminology within the pharmaceutical market, fostering confusion that poses significant risks to public health and safety. At the same time, the absence of a clear regulatory framework for approval of pharmaceutical trademarks, combined with the Trade Marks Registry's lax enforcement of Section 13 requirements, has enabled the registration of numerous similar marks. These overlapping market and regulatory factors have created an environment in which confusingly similar pharmaceutical trademarks proliferate, heightening the risk of medication errors and undermining the public safety objectives of trademark law. In the absence of a robust regulatory framework, courts and the Trade Marks Registry have grappled with challenges in addressing issues of confusion and potential harm to public health and safety in pharmaceutical trademark infringement cases and registration proceedings. While the Supreme Court of India has applied the doctrine of "greater care" to prevent confusion between pharmaceuticals in India, inconsistencies prevail nevertheless. This article explores the evolution of the doctrine of "greater care" in India. It provides a comprehensive definition of its application, and drawing from scholarship in the United States, it proposes an expansion to the doctrine suitable for the Indian context, along with practical and implementable solutions.

I. INTRODUCTION

The Indian Trade Marks Act, 1999 (the "ITMA") allows owners of trademarks to register their marks with the Trade Marks Registry (the "ITMR") while also recognizing the rights associated with unregistered marks based on their use in commerce.[1] Registration is advantageous, as it provides nationwide rights and

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[1] The Trade Marks Act, No. 47 of 1999, § 27(2) & ch. II, India Code.

is *prima facie* evidence of a trademark's validity.[2] But registration is not automatic, and the ITMR can deny or cancel a registration in certain circumstances.[3] Such actions may arise from initiatives taken by the ITMR or by a third-party. Furthermore, the owner of a mark (whether registered or unregistered) can challenge the use of another mark through infringement or passing-off actions.[4] In both registration and infringement proceedings, the primary test is whether the marks are "likely to cause confusion on the part of the public."[5] If confusion is likely, registration will be denied and usage enjoined.

Courts apply various factors in determining whether a "likelihood of confusion" exists between conflicting marks. The key factors include visual, phonetic, and structural similarities between the marks, the nature of the marks (words, labels, or composite marks), the nature of the goods or services, the similarity of the goods or services, the channels of trade, evidence of actual confusion, the sophistication of consumers, and other surrounding circumstances.[6] These factors are collectively weighed; no one factor is dispositive.[7] Given the large number of variables, the test of confusion is inherently subjective—or at least fact specific. Consequently, the value of precedent in trademark law is not found solely in the outcomes of specific cases but is found instead in the principles applied to determine what is likely to cause confusion.

Courts in India have developed two standards for assessing confusion: one, which applies to non-pharmaceutical goods, and the other, a stricter standard, for pharmaceuticals. The stricter standard, reflecting the doctrine of "greater care" for pharmaceuticals, is based on the theory that mistakes due to confusion in this market can lead to harmful physical consequences (not just economic). Although this doctrine originated in the United States,[8] Indian courts have adapted and refined these principles to align with the domestic Indian context. In 2001, the Supreme Court of India in *Cadila Healthcare Ltd. v. Cadila Pharmaceuticals Ltd.* recognized that the use of the wrong medicine due to confusing brand names transcends economic harm and can result in physical

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2 *Id.* §§ 28, 31.

3 *Id.* §§ 9, 11, 47, 57.

4 *Id.* §§ 27(2), 29.

5 *Id.* §§ 11(1), 29(2).

6 Cadila Healthcare Ltd. v. Cadila Pharm. Ltd., (2001) 5 S.C.C. 73 at 95 (India).

7 *Id.* at 95.

8 David Simon, *Trademark Law and Consumer Safety*, 72 Fla. L. Rev. 673, 694–712 (2020) (citing authorities that note the doctrine of greater care and discussing its development in the United States); *Trademarks and the Concept of Greater Care - Glenwood Laboratories, Inc. v. American Home Products Corp.*, 14 Wm. & Mary L. Rev. 441 (1972) (noting the development and implications of the "doctrine of greater care" in the United States).

or psychological harm.[9] In doing so, the Supreme Court has acknowledged that Indian trademark law aims to promote consumer protection and safety. Despite the Supreme Court's ruling, however, lower courts and the ITMR apply this doctrine inconsistently.[10]

Furthermore, the doctrine of "greater care" has evolved in India primarily in relation to the test of confusion, which is a relative standard that necessitates comparison with other marks. As David Simon has argued in the context of the United States, this idea of exercising greater caution when dealing with pharmaceutical trademarks should also extend to assessing the suitability of a name for trademark protection.[11] The ITMA allows for an expanded interpretation, as it prohibits the use and registration of names, descriptions, or indications that are materially false or misleading.[12] These provisions can effectively prevent the use and registration of deceptive trade descriptions and misleading names.

In light of this framework, this article will examine the circumstances under which the doctrine of "greater care" has been invoked in India, define the doctrine within the Indian context, and propose guidelines for its expansion and application in both infringement and registration proceedings. To provide context, the article will also briefly discuss the regulatory framework governing pharmaceutical trademarks in India.

II. THE PHARMACEUTICAL MARKET AND REGULATORY CONTEXT IN INDIA

The Indian market for pharmaceuticals is unique in many respects. Unlike non-prescription medicines in the United States, no medicines can be purchased off-the-shelf in India. Rather, as of October, 2025, all medicines, whether prescription or non-prescription, are sold through intermediaries who are licensed to sell and distribute medicines. Certain drugs listed in specific schedules of the Drugs and Cosmetics Act, 1940 are prescription-only drugs (e.g., Schedule H, X). These drugs can be sold only based on a prescription by a licensed pharmacy/chemist. Some drugs can only be sold to hospitals and are not available at pharmacies meant for the public. The remaining non-prescription medicines such as vitamin, cough syrups, paracetamol, etc. also cannot be sold anywhere in India such as in grocery shops or general stores.

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9 *Cadila Healthcare Ltd.*, 5 S.C.C. at 93.

10 *See infra* Part III, which discusses the varying approaches taken by courts and the ITMR.

11 Simon, *supra* note 8 at 713 (deception and description in trademark law).

12 Trade Marks Act § 103 (penalty for applying false trade descriptions is imprisonment and a fine) & § 9(2)(a) (absolute grounds of refusal).

A dangerous peculiarity of this market is that it is replete with "sound-alike" and "look-alike" medicines wherein[13] different pharmaceutical companies use the same or similar names for different drugs, including:[14]

S. No.	Brand name	Indication
1.	ZITAL VITAL	Zita vitamin (premium nutrition for 28-40–week pregnancy)
	ZITA (100 mg)	Treatment for type 2 diabetes
2.	AZ	Antihistamine
	AZ PLUS Suspension	Treatment for infections caused by worms

[13] Dinesh Thakur & Prashant Reddy, The Truth Pill: The Myth of Drug Regulation in India, 406–08 (2022) [hereinafter "Truth Pill"]; Aparajita Lath, *Pharmaceutical Trademark Confusion: Poison Pill or Public Health?*, SpicyIP (Nov. 16, 2022), https://spicyip.com/2022/11/pharmaceutical-trademark-confusion-poison-pill-or-public-health.html; Prashant Reddy, *Same Same but Different! The Menace of Different Drugs with Similar Trade Names*, SpicyIP (Jan. 30, 2024), http://spicyip.com/2024/01/same-same-but-different-the-menace-of-different-drugs-with-similar-trade-names.html; Murali Neelakantan *et al*., *Look-Alike, Sound-Alike (LASA) Drugs in India,* Lancet Reg. Health Southeast Asia (May 2024), https://www.thelancet.com/journals/lansea/article/PIIS2772-3682(24)00075-1/fulltext; Lokesh Vyas & Praharsh Gour, *SITARA-D & SITARED Are Not Similar, Says the Delhi High Court: What About Consumers, Confusions, & Contradictions*?, SpicyIP (Dec. 13, 2022), https://spicyip.com/2022/12/sitara-d-and-sitaret-are-not-similar-says-the-delhi-high-court-what-about-consumers-confusions-and-contradictions.html.

[14] Truth Pill, *supra* note 13; *see, e.g.*, Optrex India Ltd. v. Dey's Med. Stores Ltd., MANU/TM/0002/1987 (Trade Marks Registry, Delhi) (trademark registration case concerning the marks DELONE used for the treatment of tuberculosis and DELOPAN used for respiratory and gastro-intestinal conditions); Johann A. Wulfing v. Chem. Indus. & Pharm. Labs. Ltd. & Ors., A.I.R 1984 Bom 281 (Bombay High Ct.) (trademark infringement case concerning the marks COMPLAMINA for vascular disorders and CIPLAMINA as anti-leprosy treatment); Charak Pharm. v. Deepharma Ltd., AIR 1999 Del 15 (Delhi High Ct.) (trademark infringement case concerning the marks ALSAREX and ULCAREX both used to treat ulcers); Aviat Chemicals Pvt. Ltd. & Ors. v. Intas Pharm. Ltd., (2001) 93 DLT 247 (Delhi High Ct.) (trademark infringement case concerning marks LIPICARD and LIPICOR both used to lower cholesterol levels); Sanat Prods. Ltd. v. Glade Drugs & Nutraceuticals Pvt. Ltd., (2003) 27 PTC 525 (Delhi High Ct.) (trademark infringement case concerning marks REFIRM and REFORM both used for osteoporosis); Sun Pharma Labs. Ltd v. Psycoremedies Ltd., 2015 (63) PTC 493 (Madras High Ct.) (trademark infringement case concerning the marks SIZOPIN and SYZOPIN for treating depression and schizophrenia); Sun Pharm. Indus. Ltd. v. Protrition Prods. LLP, 2024 (97) PTC 527 (Delhi High Ct.) (trademark infringement case concerning marks ABZORB an anti-fungal medicine and ABBZORB for a whey protein).

S. No.	Brand name	Indication
3.	MEDZOLE 400	Treatment for infections caused by worms
	MEDZOLE-40	Acidity tablets
	MEDZOL (1 mg) injection	Sedative and anaesthesia
4.	DILANTIN	Anti-convulsant
	DILCONTIN	Anti-hypertensive
5.	ROKCIN	Anti-microbial
	ROXIN	Hormone

Not only do these trademarks coexist in the market, but they also coexist on the Trade Marks Register (under Class 5).[15] The number of pharmaceutical trademark applications have increased over the years, with Class 5 (pharmaceuticals) consistently having the largest number of applications.[16] In 2022–2023, there were 32,320 trademarks registered in Class 5, as compared with 384 medicines listed by the government of India in the National List of Essential Medicines in 2022.[17] Despite the Supreme Court ruling in *Vishnudas Trading*, it is common practice for marks to be registered under Class 5 for "pharmaceuticals" in general without specifying the particular ailment or indication.[18]

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[15] *See, e.g.*, Registered trademarks on the Trade Marks Register under Class 5: TRIMOX (No. 292222 for "pharmaceutical and medical preparations"); IMOX (No. 461167 for "medicinal and pharmaceutical preparations"); ULTIMOX (No. 389473 for "medicinal and pharmaceutical preparations for human use"); PRIMOX (No. 452812 for "medicinal and pharmaceutical preparations"); MEDZAL-100GM (No. 4112387 for "pharmaceutical, veterinary and sanitary preparations; dietetic substances adapted for medical use, food for babies"); MEDZEAL (No. 1749246 for "medicines for human use"); MEDZEE (No. 1763100 for "medicinal and pharmaceutical preparations").

[16] Office of the Controller Gen. of Patents, Designs, Trademarks & Geographical Indications, *Annual Report 2022-23*, at 65 (2023), https://ipindia.gov.in/writereaddata/Portal/IPOAnnualReport/1_114_1_ANNUAL_REPORT_202223_English.pdf (India).

[17] *Id*. at 68; Cent. Drugs Standard Control Org., *List of Essential Medicines*, at 100 (2022), https://cdsco.gov.in/opencms/opencms/en/consumer/Essential-Medicines/ (India).

[18] Vishnudas Trading v. Vazir Sultan Tobacco Co. Ltd., (1997) 4 S.C.C. 201 at 223, 224 ("In our view, if a trader or manufacturer actually trades in or manufactures only one or some of the articles coming under a broad classification and such trader or manufacturer has no bona fide intention to trade in or manufacture other goods or articles which also fall under the said broad classification, such trader or manufacturer should not be permitted to enjoy monopoly in respect of all the articles which may come under such broad classification and by that process preclude the other traders or manufacturers to get registration of separate and distinct goods which may also be grouped under the broad classification.").

This common practice can be attributed to the development of a pharmaceutical industry in India that specializes in generic drugs. Until 2005, India maintained a clear policy that prohibited the grant of product patents for pharmaceuticals, allowing the same medicine to be manufactured using different processes. The public domain status of pharmaceutical products fostered the creation of a competitive generic pharmaceutical industry, leading to the marketing of identical medicines under many names. While legislative changes in 2005 allowed for product patents to align with international obligations,[19] the generic pharmaceutical industry continued to thrive by manufacturing off-patent medicines or by inventing alternative formulations.

Because much of the public presumes that generic medicines are substitutes for the innovator's brand, the Indian pharmaceutical industry has developed a unique branding language for generic products, wherein brand names often incorporate common suffixes or prefixes, commonly referred to as "stems."[20] Stems are derived from the name of the ailment, the active ingredient of the medication, or the target organ. For example, FALCIGO and FALCITAB are trademarks for medicines sold by different companies for the treatment of cerebral malaria commonly known as "Falciparum." The prefix "FALCI" indicates the purpose of the medicine to prescribers, dispensers, and patients.[21] Such names are easy to remember and use. The names also qualify as "trade descriptions," providing insight into the drug's fitness for a certain purpose, strength, performance, or behavior.[22]

But the assumption of interchangeability of generic medicines upon which this naming technique has developed has come under significant scrutiny. While generic medicines may contain the same active ingredients, they can differ in other ingredients—such as binders, stabilizers, disintegrating agents, flavoring agents, and manufacturing techniques.[23] These differences can affect the way

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19 Shamnad Basheer, *India's Tryst with TRIPS: The Patents (Amendment) Act, 2005*, 1 Indian J.L. & Tech. 22 (2005), https://repository.nls.ac.in/ijlt/vol1/iss1/2/ (India).

20 *See* S.B.L. Ltd. v. Himalaya Drug Co., I.L.R. (1997) 2 Del. 168 at 181 (Delhi High Ct.) ("In the field of medicines and pharmaceuticals, it is common practice that the drugs are named either by the name of the organ which it treats or by the principal ingredients or the name of the ailment. This enables a doctor to associate a particular trade name with the organ, ingredient or ailment, thereby reducing chances of error."); Usv Ltd. v. Systopic Labs. Ltd., (2004) 1 CTC 418 (Madras High Ct.) (citing S.B.L. v Himalaya Drug Co. Ltd., I.L.R. (1997) 2 Del. 168). Companies also use family names with prefixes common across various products sold by the same company. For example, Ciba-Geigy Ltd. uses the brand names CIBA, CIBAZOL and CIBALGIN, which indicate that all these medicines are made by Ciba-Geigy (Ciba-Geigy Ltd. v. Torrent Labs. Pvt. Ltd., (1993) 1 GLR 325 (Gujarat High Ct.)).

21 *Cadila Healthcare Ltd.*, 5 S.C.C. at 79.

22 Trade Marks Act § 2(za).

23 Thakur & Reddy, *supra* note 13 at ch. 6.

that the drug is absorbed by the body (bioavailability), subsequently affecting therapeutic results, including toxicity, efficacy, and side effects.[24]

It was not until 2017 that India enacted legislation mandating bioavailability testing to establish bioequivalence of generic medicines.[25] But this 2017 legislation did not apply retroactively to drugs approved prior to 2017.[26] As a result, generic medicines may still not be interchangeable given differences in bioavailability and stability. Compounding this issue is the tendency of pharmaceutical companies to adopt similar names for different drugs. Given this reality, the language prevalent in the pharmaceutical market has increased confusion, posing serious risks to patient safety.

Another major reason for the proliferation of confusingly similar pharmaceutical trademarks in India is the limited enforcement of Section 13 of the ITMA by the ITMR. Section 13, which bars registration of marks that are identical or deceptively similar to existing trademarks or International Non-Proprietary Names ("INNs"), was designed to protect public safety by preventing sound-alike or look-alike drug names. The INN system offers a list of approved names for identification of pharmaceutical substances.[27] INNs provide a standardized, generic designation for active ingredients, ensuring that drugs containing the same substance are clearly identifiable regardless of brand. Its roots can be traced back to earlier trademark legislation and international best practices emphasizing that pharmaceutical marks should not endanger consumers through confusion.

However, instead of marketing pharmaceutical products under generic names, many companies seek to use and register trademarks derived from an INN and including an INN common stem.[28] In practice, the ITMR has often failed to rigorously apply these standards, sometimes overlooking similarities with existing INNs or previously registered marks. Combined with delays in the notification of INNs and insufficient coordination with drug regulators, this lax enforcement has allowed multiple brands with similar names to coexist in the market, heightening the risk of medication errors and undermining the protective purpose of

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[24] *Id*.

[25] Drugs & Cosmetics (Ninth Amendment) Rules, 2017, Gazette of India, pt. II, sec. 3(i) (Apr. 3, 2017); Prashant Reddy, *India Makes a Long Overdue Move to Ensure Better Drug Safety*, Scroll.in (Apr. 12, 2017), https://scroll.in/pulse/834356/india-makes-a-long-overdue-move-to-ensure-better-drug-safety (India).

[26] *Id*.

[27] *See generally* Lionel Bently, *Limitations on Pharmaceutical Trade Marks in Britain in the Twentieth Century*, *in* Research Handbook on Trademark Limitations and Exceptions, ch. 7 at 151 (Barton Beebe & Haochen Sun eds., Edward Elgar 2023) (UK).

[28] K.M. Gopakumar and Nirmalya Syam, *A Study on the Use of International Nonproprietary Names in India*, Centre for Trade and Development, at 10 (2007).

Section 13. The table below contains examples of the use of INN stems for coining brand names for pharmaceuticals:[29]

INN	Stem	Brand name
glimepiride	gli-	GLIRIDE
alprazolam	-zolam	ALZOLAM
epirubicin	-rubicin	ALRUBICIN

Courts have held generic names of medicines (including INNs) to be commonly used words in the trade. Therefore, the adoption of a generic name of a drug or part of such a name, as a brand name, cannot result in exclusive trademark rights. These rulings have indirectly led to a proliferation of similar trademarks.

For instance, in *Griffon Laboratories (P) Ltd. v. Indian National Drug Co. P. Ltd.*,[30] the dispute concerned the trademarks SORBILINE and SORBITONE, both derived from the generic name "sorbitol." The Calcutta High Court held that since many medicines were already being manufactured with the prefix "sorbi," its use was a common practice in the medical field and could not, by itself, be said to cause confusion. Building on this reasoning, the Delhi High Court in *Panacea Biotech Ltd. v. Recon Ltd.*[31] reaffirmed that no party can claim exclusive rights over generic terms. Thus, the trademark NIMULID, derived from "nimesulide," could not prevent the registration of REMULIDE, also derived from the same generic name. Similarly, the Bombay High Court in *Schering Corporation v. United Biotech (P) Ltd.,*[32] held that exclusivity cannot be claimed over a trademark that is derived from a generic drug name or its ingredient. By adopting such a mark, the proprietor must reasonably expect that others producing medicines based on the same generic drug may also use similar names. And where two marks are coined from the same generic drug, similarities are inevitable, and minor differences between them cannot ordinarily justify an injunction, at least at the *prima facie* stage.

These cases illustrate a consistent judicial stance—trademarks derived from generic terms or INNs cannot confer exclusivity. This makes strict enforcement of Section 13 of the ITMA by the ITMR critical. Without proactive refusal of marks that resemble or incorporate INNs, the legal safeguard remains largely ineffective, and risks of consumer confusion and patient harm persist.

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29 *Id* at 13.

30 (1989) IPLR 9 (Calcutta High Ct.).

31 A.I.R 1997 Del 244 (Delhi High Ct.).

32 2011 (1) Bom. C.R. 89 (Bombay High Ct.),

In order to mitigate these risks, regulatory solutions have been proposed, *albeit* with limited success. For instance, doctors were directed to prescribe using the medicine's INN rather than the brand name.[33] Since generic medicines are not necessarily substitutes, however, prescribers prefer prescribing brands that they have "tried and tested." Also, practically, chemical/ pharmacopeial names are not as usable and memorable as trademarks. For example, CROCIN is easier to remember than "paracetamol." In practice, most medicines are marketed under both brand names and generic names.[34]

Other proposals include the mandatory approval of brand names by drug regulators. The Drugs and Cosmetics Act, 1940, prohibits the sale of spurious drugs.[35] A drug is spurious if it is deceptively similar to another drug.[36] The Supreme Court of India has interpreted this provision to include medicines sold under similar trademarks.[37] However, the current regulatory framework does not require drug regulators to pre-approve brand names for pharmaceuticals. To fix this, the government has been urged to evaluate brand names for drugs before granting manufacturing licenses.[38] These suggestions remain unimplemented. As it stands, pharmaceutical companies are required only to self-certify that their chosen names are not similar, to the best of their knowledge, to any existing drug being sold in India with no regulatory oversight.[39]

Due to the lack of regulations, pharmaceutical companies frequently engage in litigation over trademark disputes. As a result, the burden of resolving issues of confusion from similar pharmaceutical trademarks often falls upon courts and the ITMR.

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33 Press Release, Ministry of Health & Family Welfare, *Doctors Exhorted to Prescribe Generic Medicines* (July 28, 2023), https://www.pib.gov.in/PressReleasePage.aspx?PRID=1943658 (noting that the Medical Council of India had issued circulars dated Nov. 22, 2012, Jan. 18, 2013, and Apr. 21, 2017, directing registered medical practitioners to prescribe drugs with generic names as per the Indian Medical Council Regulations, 2002, regulation 6.3).

34 *See* Indian Med. Council (Prof'l Conduct, Etiquette & Ethics) Reguls., 2002, reg. 6.3, Gazette of India, pt. III, sec. 4 (Apr. 6, 2002).

35 Drugs and Cosmetics Act, § 17B.

36 Drugs and Cosmetics Act, § 17B(b).

37 *Cadila Healthcare Ltd.*, 5 S.C.C. at 94.

38 *Id*. ("keeping in view the provisions of Section 17-B of the Drugs and Cosmetics Act, 1940 which *inter alia* indicates an imitation or resemblance of another drug in a manner likely to deceive being regarded as a spurious drug it is but proper that before granting permission to manufacture a drug under a brand name the authority under that Act is satisfied that there will be no confusion or deception in the market. The authorities should consider requiring such an applicant to submit an official search report from the Trade Mark office pertaining to the trade mark in question which will enable the drug authority to arrive at a correct conclusion.")

39 Drugs & Cosmetics (13th Amendment) Rules, 2019, Gazette of India, G.S.R. 828(E), pt. II, sec. 3(i) (Nov. 06, 2019).

Thus, the legal framework for pharmaceutical trademarks in India requires urgent reform to enhance clarity, protect consumer safety, and uphold the integrity of the pharmaceutical market.

III. THE EVOLUTION OF THE DOCTRINE OF GREATER CARE IN INDIA

Prior to the Supreme Court decision in *Cadila Healthcare Ltd. v. Cadila Pharmaceuticals Ltd.* in 2001 ("Cadila"), the law governing the standards of confusion for pharmaceutical trademarks lacked consistency. In the absence of clear statutory guidance, courts adopted varying approaches. Two marked approaches emerged. One was a strict approach that presumed harm due to confusion from similar trademarks and the other approach pushed back on such a presumption.

A. First Approach: The Idea of "Greater Care"

A defining moment in the evolution of trademark law in the pharmaceutical sector occurred in 1962 when a three-judge bench of the Supreme Court of India decided *Amritdhara Pharmacy v. Satyadeo Gupta* ("Amritdhara").[40] The applicant (respondent) sought to register the trademark LAKSHMANDHARA for pharmaceutical preparations in Class 5. The appellant (opponent) opposed this application and argued that LAKSHMANDHARA was deceptively similar to its prior registered mark—AMRITDHARA in Class 5. The matter was litigated all the way to the Supreme Court of India, which ultimately agreed with the appellant and held that the two marks were similar and likely to cause confusion in the market.

The decision was predicated on a nuanced understanding of the pharmaceutical market and purchasing habits of Indian consumers. The Court noted that medicines are often acquired without prescriptions "for quick alleviation of their suffering."[41] Furthermore, the Court recognized that many Indian consumers, who may lack proficiency in English, may not understand the etymological or ideological differences between trademarks. According to the Court, consumers take trademarks as a whole and do not split names into their component parts. Therefore, consumers would not distinguish between the uncommon parts of the trademarks such as "Amrit," which means "nectar," and

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40 A.I.R. 1963 S.C. 449 (Supreme Ct.).

41 *Id.*, ¶ 7 ("It is not disputed before use that the two names 'Amritdhara' and 'Lakahmandhara' are in use in respect of the same description of goods, namely, a medicinal preparation for the alleviation of various ailments. Such medicinal preparation will be purchased mostly by people who instead of going to a doctor wish to purchase a medicine for the quick alleviation of their suffering, both villagers and townsfolk, literate as well as illiterate.").

"Lakshman," which is the name of a god. Instead, they would go by the overall structural and phonetic similarity. In its view, AMRITDHARA and LAKSHMANDHARA, taken as a whole, were phonetically and structurally similar.[42]

Interestingly, the Supreme Court found a possibility of confusion in the marketplace but allowed the application to be registered with a limitation.[43] The Court allowed the limitation on equitable grounds, since the opponent had delayed in bringing action. Although this decision did not explicitly invoke the doctrine of greater care for pharmaceuticals, it implied that greater care is required in assessing similarities of marks to protect the interest of the public.

Subsequent High Court decisions followed this case, and the contours of the doctrine of greater care started to evolve. For example, *Himalaya Drug Co. v. Warner-Lambert Pharmaceutical Co.* concerned drugs with opposite clinical effects.[44] NARDYL is a tranquilizer, sold over the counter, and the other, NARDELZINE is a stimulant, sold by prescription. The potential for confusion between these two medicines could result in serious bodily harm.

In ruling on this matter, the Bombay High Court held that while the marks were phonetically and visually distinct, special circumstances warranted a stricter standard to prevent confusion. The special nature of goods such as pharmaceuticals that are unlike "articles like toys or combs or shoes or the like, in which cases confusing one mark for the other would not result in some appreciable harm, if any at all" warrant this standard.[45] For pharmaceutical products, whether prescription based or over-the-counter, "the public" requires a "greater degree of protection," as confusion could have disastrous consequences on health.[46] The court established a presumption of harm inherent in pharmaceuticals, highlighting the vital need for clarity in this industry.

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42 *Id.*, ¶ 7 ("Where the trade relates to goods largely sold to illiterate or badly educated persons, it is no answer to say that a person educated in the Hindi language would go by the etymological or ideological meaning and, see the difference between 'current of nectar' and [']current of Lakshman'. 'Current of Lakshman' in a literal sense has no meaning; to give it meaning one must further make the inference that the 'current or stream' is as pure and strong as Lakshman of the Ramayana. An ordinary Indian villager or townsmen will perhaps know Lakshman, the story of the Ramayana being familiar to him but we doubt if he would etymologise to the extent of seeing the so called ideological difference between 'Amritdhara' and 'Lakshmandhara'.")

43 *Id.*, ¶ 13 (limitation of use only in the State of Uttar Pradesh).

44 (1970) 72 BOMLR 528 (Bombay High Ct.).

45 *Id.*, ¶ 15.

46 *Id.*, ¶ 15 ("The discretion has been granted by the statute for the protection of the public. In the case of drugs and pharmaceutical products the public, the ailing public, requires a very great degree of protection and particularly so when the result of a confusion occurring would be disastrous.")

Other High Courts mirrored this heightened standard,[47] emphasizing that phonetic similarity is the most crucial factor in determining confusion. Even a low degree of similarity warrants a presumption of harm. This strict standard of confusion is applied automatically to all pharmaceuticals, whether over-the-counter or prescribed, since prescribers and dispensers can make mistakes.[48] Courts also acknowledged that prescription medicines are often sold without written prescriptions.[49] In such cases, even for trained dispensers, visual and structural differences between words would be of little consequence.[50] Some courts applied the same standard to encompass all pharmaceuticals, regardless of their compositions or the severity of the ailments that they addressed.[51]

Thus, even where pharmaceutical products did not compete, courts viewed the safety risk as too high to permit any possibility of confusion. Without any damage to the plaintiff, the remedies granted were typically rooted in a concern for potential harm to the public rather than specific injury to the plaintiff. Also, this approach reduced potential harm to the ultimate consumer that confusion could have caused. Ultimately, reducing the risk to public safety was

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47 *See, e.g.*, Anglo-French Drug Co. (E.) Ltd. v. Belco Pharma, 1984 S.C.C. Online P&H 205 at ¶ 17 (Punjab High Ct.) (holding that BEPLEX and BELPLEX for vitamins are visually and phonetically similar and stating, "Therefore, once the two names are deceptively similar, whether visually or phonetically, then the matter of sale of medicines on the prescription of doctors loses its significance."); Win-Medicare Ltd. v. Dua Pharm. (P) Ltd., MANU/DE/1496/1997 at ¶ 20 (Delhi High Ct.) (holding that DICAMOL and DICLOMOL for anti-inflammatory medicines are deceptively similar and that the "point of difference is so insignificant that only a person with extraordinary memory and recollection of a most meticulous and careful person would be in a position to notice the distinction or difference."); Charak Pharm. v. Deepharma Ltd., MANU/DE/0106/1998 at ¶ 10 (Delhi High Ct.) (holding ALSAREX and ULCEREX medicines for treatment of ulcers to be phonetically similar and stating, "It is not uncommon that both allopathic and ayurvedic medicines are available across the same counter in various shops of the chemists and even schedule drugs are sold by some chemists without prescription slips of the physicians. Thus, an unwary customer who goes to purchase medicine can make mistake in purchasing the medicine of the defendant under the aforesaid trade mark as that of the plaintiff because of phonetical similarity between the said two trade marks.").

48 Dinesh Thakur, Prashant Reddy, *India's problem—different drugs, identical brand names*, Hindu, Jan. 25, 2024 (noting the reality that many pharmacists are not adequately trained or registered with the Pharmacy Council of India.)

49 *See, e.g.*, *Charak Pharm.*, MANU/DE/0106/1998 at ¶ 10 (Delhi High Ct.); Himalaya Drug Co. v. Warner-Lambert Pharm. Co., (1970) 72 BOMLR 528 at ¶ 15 (Bombay High Ct.).

50 *Id.*

51 Wyeth Holdings Corp. & Anr. v. Burnet Pharm. (P) Ltd., A.I.R. 2008 Bom. 100 at ¶ 14A ("A less than strict standard cannot be applied on the hypothesis that the ailment which the drug is intended to treat is not life threatening, nor for that matter can the application of a lower standard be justified merely on the ground that the composition of the Plaintiff's product is the same as that of the Defendant and the confusion caused by mistaking one for the other would not result in a danger to health. Undoubtedly, where the competing drugs are meant to cure the same ailment but the compositions are different, mistaking one for the other may result in deleterious consequences.")

of vital importance.[52] Despite many courts' willingness to leverage trademark law to protect consumers, instances remained where such protective measures were not uniformly applied. The next section discusses the counterarguments to the doctrine of "greater care" relative to pharmaceutical trademarks.

B. Second Approach: Pushback to the Idea of Greater Care

Seven years after the decision in *Amritdhara,* a two-judge bench of the Supreme Court addressed the issue of trademark confusion in *F. Hoffman-La Roche & Co. v. Geoffrey Manners & Co. (P.) Ltd.*[53] The *Roche* Court held that the trademarks PROTOVIT and DROPOVIT, both used in connection with vitamin preparations, were not similar and not likely to cause confusion among consumers.

The principles applied by the *Roche* Court differed from those in *Amritdhara.* The *Roche* Court split the marks into their component parts—"PROTO" and "VIT"; "DROPO" and "VIT." The Court observed that the common element "VIT" was commonly used in the trade for vitamins. Accordingly, consumers would focus on the "uncommon elements." Also, since there were several marks registered with the suffix "VIT," the Court presumed that consumers "would naturally be on his guard and take special care."[54] On the nature of the goods, the Court held that since vitamins could be sold only by licensed dealers, the possibility of confusion was reduced to a "considerable extent."[55]

A line of High Court decisions follows *Roche.* These courts were unwilling to find similarity even where marks were evidently confusingly similar. For example, the trademarks LIV-52 and LIV-T,[56] ENERJEX and ENERJASE,[57] DISPRIN and MEDISPRIN,[58] XYMEX and XENEX,[59] and ANAFRANIL and CLOFRANIL[60] were all held to be visually and phonetically dissimilar. The courts

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52 *See* Simon, *supra* note 8 (discussing public safety aspects of trademark law in the United States).

53 (1969) 2 S.C.C. 716 (Supreme Ct.).

54 *Id.*, ¶ 9 (evidence showed that there were as many as 57 trademarks on the Register with the suffix "VIT.")

55 *Id.*, ¶ 9 ("The fact that the vendor would be a licensed dealer also reduces the possibility of confusion to a considerable extent.")

56 S.B.L. Ltd. v. Himalaya Drug Co. Ltd., MANU/DE/0311/1997 (Delhi High Ct.).

57 Indo-Pharma Pharm. Works Ltd. v. Citadel Fine Pharm. Ltd., A.I.R. 1998 Mad. 347 (Madras High Ct.).

58 Reckitt D Colman of India Ltd. v. Medicross Pharm. (P) Ltd., (1992) 3 BOMCR 408 (Bombay High Ct.).

59 Sami Khatib & Ors. V. Seagull Labs (I) (P) Ltd. & Ors., MANU/DE/1014/2001 (Delhi High Ct.).

60 Ciba Geigy Ltd. v. Sun Pharm. Indus., MANU/GJ/0002/1992 (Gujarat High Ct.).

reasoned that common features of the marks, such as "LIV" for liver; "ENER" for energy; "SPRIN" derived from aspirin; and "X" for enzyme, were considered to be generic terms prevalent in the industry. Consequently, similarity was assessed by comparing the "uncommon elements," such as "52" and "T," "JEX" and "JASE," and "ANA" and "CLO."

High Courts also attached significant weight to the expertise of prescribers and dispensers of prescription medications, presuming that harm was unlikely for prescription medicines or medicines sold by licensed dealers. These courts applied this reasoning broadly, encompassing drugs that treated similar conditions, to drugs that treated different conditions, and to different types of medications, including ayurvedic, homeopathic, and allopathic.[61] Rather than presuming harm, the courts required a showing of serious consequences before establishing that confusion was likely. Similar outcomes were observed in trademark registration proceedings.[62]

Courts and the ITMR appeared to operate under the presumption that customers know their medicines by experience or that they were accustomed to using a particular brand. However, this perspective did not address the complexities of the pharmaceutical market, including the challenges faced by first-time users, lack of brand awareness, dependency on pharmacists to recommend medicines, and the practice of purchasing medications without prescriptions often over the phone or based on poorly written prescriptions.

C. Supreme Court Clarifies: The Doctrine of Greater Care for Pharmaceuticals

In 2001, a three-judge bench of the Supreme Court in *Cadila* resolved the tension between the two approaches. *Cadila* clarified the principles to be used to assess "likelihood of confusion" for pharmaceutical trademarks.

In *Cadila*, the two trademarks in question were FALCITAB and FALCIGO. Both medicines were used in the treatment of cerebral malaria, also known as Falciparum. The appellant sued for trademark infringement. The respondent argued that the prefix "falci" is derived from the name of the disease and has been used to

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61 *See, e.g.*, *Indo-Pharma Works,* A.I.R. 1998 Mad. 347 (finding chance of confusion remote since the parties' prescription medications were different where plaintiff's product ENERJEX was an allopathic syrup administered to growing children and pregnant women and defendant's product ENERJASE was an ayurvedic medicine used as anti-stress treatment).

62 Samir Pharm. (P) Ltd. v. P & B Labs. (P) Ltd., MANU/TM/0012/1989 (Trade Marks Registry) (case concerning registration of the marks DOXETAR and DOXYTERA in Class 5. The Trade Marks Registrar held that the marks were visually and phonetically confusingly similar. However, since both medicines were prescription medicines and it was held that this would act as a safeguard against confusion in the market.)

indicate the product's intended purpose. Since the products were sold exclusively to hospitals and clinics, the respondent argued that there was no risk of confusion or deception because the hospitals and clinics were trained experts in dispensing medicines. The appellant lost both at the Trial Court and the High Court.

The Supreme Court, however, remanded the case back to the lower court for trial and introduced the "doctrine of greater care." The Court emphasized that public interest necessitates greater care when assessing likelihood of confusion involving pharmaceutical products.[63] Unlike non-medicinal products, harm arising from confusion between medicines could have "disastrous effects on health and in some cases life itself" since "[d]rugs are poisons, not sweets."[64] Therefore, "[e]xacting judicial scrutiny is required if there is a possibility of confusion over marks on medicinal products because the potential harm may be far more dire than that in confusion over ordinary consumer products."[65]

These principles trace the line of cases that followed *Amritdhara*. The Court held that marks should be assessed as a whole. The decision disagreed with the approach of splitting marks and focusing on "uncommon elements." It recognized that the public lacks awareness and education and has limited ability to distinguish between brand names. Furthermore, the court acknowledged that prescribers and dispensers may make mistakes "[n]oting the frailty of human nature and the pressures placed by society."[66] The Court also emphasized that the realities of the market must be taken into consideration. Average consumers often purchased medicines without prescriptions and do so verbally, which increases the risk of confusion. For these reasons, the court directed lower courts and the ITMR to apply a strict standard aimed at preventing any "possibility" of confusion. While the Court clarified the likelihood of confusion assessment, it did not address the risks associated with trade descriptions or deceptive trademarks.

*D. Inconsistencies Continue Post-*Cadila

Even after the landmark ruling in *Cadila*, many courts still require a showing of serious consequences rather than presuming harm in cases of alleged trademark confusion. For example, in

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[63] *Cadila Healthcare Ltd.*, 5 S.C.C. at 94. (Holding that a stricter approach to assessing confusion was to be used for medicines as compared to other products and stating "While confusion in the case of non-medicinal products may only cause economic loss to the plaintiff, confusion between the two medicinal products may have disastrous effects on health and in some cases life itself.")

[64] *Id.*, 93.

[65] *Id.*

[66] *Id.*

Schering Corporation v. United Biotech (P) Ltd.,[67] the court examined the marks NETROMYCIN and NETMICIN, both of which contained the same active ingredient and served the same purpose as antibiotics. Even without a showing of equivalence or substitutability, the Court held that mistaken consumption of one for the other would not result in serious harm. This reasoning has been similarly applied in other cases involving medicines derived from the same active ingredient and used for the same purpose.[68]

More worryingly, some courts have refused to presume harm even where the medicines in question are used to treat different conditions. For example, in *Sun Pharmaceutical Industries Ltd. v. Anglo French Drugs Ltd.*,[69] the court found the marks OXETOL and EXITOL to be dissimilar and unlikely to cause confusion. Although the marks were similar, they were used to treat different conditions—one as an anticonvulsant and mood stabilizing drug and the other as a laxative. According to the court, the medicines were meant for different patient populations, which rendered confusion unlikely. Several courts have applied the same reasoning.[70]

In contrast, several other cases have applied *Cadila* strictly. They have applied a presumption of harm where drugs treat the same condition and even where they do not.[71]

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67 2011 (1) Bom. C.R. 89 (Bombay High Ct.).

68 *See e.g.*, Usv Ltd. v. Systopic Labs. Ltd., (2004) 1 C.T.C. 418 (Mad. Div. Bench) (where the marks PIOZ and PIO-15 both contained the active ingredient pioglitazone to treat diabetes, the court found no serious harm could result from mistaken consumption of one for the other), and Sun Pharm. Labs. Ltd. v. Hetero Healthcare Ltd., 2022 (92) PTC 536 (Delhi High Ct.) (held against a finding of confusion between LETERO and LETROZ both second—line treatments for advanced breast cancer).

69 2015 (63) PTC 580 (Delhi High Ct. (Div. Bench)).

70 *See, e.g.*, Sun Pharm. Indus. Ltd. v. West Coast Pharm. Works Ltd. & Anr., 2012 S.C.C. OnLine Guj 6290 at ¶ 23-30 (Gujarat High Ct.) (While dealing with the trademarks ACICAL and ACUCAL, the Gujarat High Court ruled that the user of the two drugs was different, even the relevant material and ingredients were different, the chemical composition was different, and so were the modes of taking them, one being a chewable tablet while the other a swallowable tablet. Applying the principal laid down in *Cadila*, the court held that *prima facie* there was no similarity in both the drugs ACUCAL and ACICAL so that the same may cause confusion in the mind of the chemist or the consumer.); Ranbaxy Labs. Ltd. v. Intas Pharm. Ltd. & Ors., (2011) 47 P.T.C. 433 (Delhi High Ct.) (holding that if a drug is ordered by hospital, there is no reasonable likelihood that NIFTAS would be passed off as NIFTRAN since the nurses and doctors in the hospital are always in a position to distinguish the drugs not only on account of difference in the name but also on account of packaging, price of the drugs and the form in which they are sold.).

71 *See e.g.*, Glenmark Pharm. Ltd v. Sun Pharma Labs., FAO (OS) COMM 146/2023 (Delhi High Ct., Div. Ben.) (holding ISTAMET for diabetes and INDAMET for asthma as likely to cause confusion and emphasizing the holding of *Cadila*); Macleods Pharm. Ltd. v. Union of India, WP 1517 of 2022 (Bombay High Ct., Div. Ben) (holding OFLOMAC and OFRAMAX medicines with different ingredients and administration methods for treating respiratory tract infections as likely to cause confusion. Public interest would support lesser degree of proof showing confusing similarity for medicinal products.); Reddy's Labs. Ltd. v. Smart Labs. (P) Ltd., CS (COMM) 744/2023 (Delhi High Ct.)

IV. "GREATER CARE" AND THE UNITED STATES: A COMPARATIVE PERSPECTIVE

Developments in the United States have influenced the Indian doctrine of "greater care" for pharmaceutical products. In *Cadila*, the Supreme Court of India cited several U.S. cases where courts applied a lower standard of confusion to prevent harm in pharmaceutical disputes. In the United States, however, the Food and Drugs Administration ("FDA") strictly regulates pharmaceutical brand names, which has reduced the situations in which courts need to invoke this doctrine in trademark disputes.

The doctrine of greater care was adopted early by the U.S. Court of Customs and Patent Appeals ("CCPA") (the predecessor of the Federal Circuit), in *Campbell Products, Inc. v. John Wyeth & Bro., Inc.*[72] In that case, the applicant had sought to register the mark ALUTROPIN for an oral medication, packaged in a clear glass bottle, intended to treat ulcers and gastric acidity. The opposer, owner of the registered mark ALULOTION for a lotion sold in a blue bottle for the treatment of impetigo, challenged the application on the grounds of likely confusion. The products were sold in different bottles of distinct colors and shapes, and both required a prescription. Further, FDA labelling rules also made clear distinctions between the two, and the products did not compete in the marketplace—one addressed stomach ailments, the other skin infections. Nevertheless, the CCPA denied registration, holding the marks to be confusingly similar. Central to its reasoning was the potential risk of physical harm if consumers or pharmacists confused the products: "[I]t seems to us that where ethical goods are sold and careless use is dangerous, greater care should be taken in the use and registration of trademarks to assure that no harmful confusion results."[73] This case established the principle that where confusion carries a risk of physical harm, the threshold for finding confusing similarity, both in registration and infringement, is lowered.

After *Campbell*, U.S. courts increasingly applied what became known as the doctrine of "greater care," lowering the threshold for confusing similarity where public health was at risk. For example, in *Moore v. Procter & Gamble*, confusion by intermediaries such as store clerks was enough to block registration in pharmaceutical

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(holding AZIWOK and AZIWAKE both azithromycin formulations to be similar and likely to cause confusion); Abbott Healthcare (P) Ltd. v. Glensmith Labs. (P) Ltd, CS (COMM) 430/2020 (Delhi High Ct.) (holding LIMCEE and LIMCEE PLUS for vitamin C tablets to be likely to cause confusion); FDC Ltd. v. Nilrise Pharm. (P) Ltd., CS(COMM) 427/2022 (Delhi High Ct.) (holding ZIPOD and ZOYPOD for cefpodoxime based antibiotic and antibacterial preparations as similar and likely to cause confusion).

72 143 F.2d 977 (C.C.P.A. 1944); *See also* Simon, *supra* note 8 (discussing the evolution of the doctrine of greater care in the United States).

73 143 F.2d 977 at 979 (C.C.P.A. 1944).

trademark cases.[74] Courts in prescription drug cases, such as *R.J. Strasenburgh Co. v. Kenwood Laboratories, Inc.*[75] and *Morgenstern Chemical Co. v. G.D. Searle & Co.*,[76] expanded the definition of "consumer" to include doctors and pharmacists, recognizing that even trained professionals were not infallible.

These decisions influenced the Indian Supreme Court in *Cadila*. In formulating the Indian doctrine of "greater care" for pharmaceutical trademarks, the Supreme Court cited *Morgenstern*, noting the U.S. position that even doctors and pharmacists, though highly trained, are not infallible, and that any possibility of confusion in medicines must be enjoined to prevent harm. Similarly, it cited *Syntex Laboratories Inc. v. Norwich Pharmacal Co.*[77] to show that U.S. courts recognized confusion among intermediaries such as physicians and pharmacists as actionable because the ultimate risk of harm fell on patients. Further, the court relied upon *Strasenburgh* to stress that differences in ailments treated did not eliminate the dangers of confusion in prescribing or dispensing. Persuaded by these holdings, the Supreme Court underscored that in India too, courts must apply a stricter standard of scrutiny in pharmaceutical cases.

Like in India, however, over time in the United States, courts have pushed back against this expansive approach. For instance, in *American Cyanamid v. Connaught Labs*,[78] the court compared HIB-IMUNE and HibVAX (chemically identical vaccines). The court found that mistakes could occur only through "spectacular incompetence," and therefore refused to lower the similarity threshold where the risk of harm was minimal.[79] A few courts have rejected the doctrine outright, insisting that the Lanham Act provides no basis for heightened standards.[80] Courts and scholars, however, state that such a conclusion is false both in history and doctrine.[81]

Importantly, the FDA's increased oversight in regulating pharmaceutical trademarks stands in contrast to India's lax regulatory framework. The current Indian regulatory framework does not require drug regulators to pre-approve brand names for pharmaceuticals. As it stands, pharmaceutical companies are only required to self-certify that their chosen names are not similar, to the best of their knowledge, to any existing drug being sold in India,

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74 193 F.2d 194 (C.C.P.A. 1951).

75 437 F.2d 566 (2d Cir. 1971).

76 253 F.2d 390 (3d Cir. 1958).

77 315 F. Supp. 45, 49 (S.D.N.Y. 1970).

78 800 F.2d 306 (2d Cir. 1986).

79 *Id.*, 301.

80 Pharmacia Corp. v. Alcon Labs., Inc., 201 F. Supp. 2d 335, 371 (D.N.J. 2002).

81 Simon, *supra* note 8 (footnotes 199 and 200).

with no regulatory oversight. In contrast, the FDA's strict review and monitoring of brand names for drugs reduces the potential risk of similar brand names reaching the market.

The FDA's Division of Medication Error Prevention and Analysis ("DMEPA") plays a central role in this process, reviewing drug names both pre- and post-marketing to ensure that they are not likely to be confused by consumers, physicians, pharmacists, or nurses.[82] In evaluating proposed names, DMEPA considers similarities in sound, spelling, and handwritten forms, as well as the potential consequences of errors, the prescription status of the drugs, and their relationship to existing trademarks or the company's own product line. Prescription drugs receive more rigorous evaluation than over-the-counter products, given the added risk of misinterpretation in handwritten prescriptions or verbal orders. The FDA also conducts internal testing with volunteers to assess potential confusion and issues guidance based on phonetic, visual, and handwriting factors.

Further, for generic drugs, the FDA requires evidence of therapeutic equivalence to the brand-name reference product before approval.[83] Generic drug names are carefully selected to avoid confusion with both the reference product and other drugs on the market. While the generic label typically includes the established or chemical name, proprietary (brand) names may still be proposed in some cases, and these undergo DMEPA review to prevent sound-alike or look-alike errors. This rigorous process, by filtering out high-risk names early, has limited the circumstances of confusingly similar pharmaceutical brand names.

V. PRACTICAL AND IMPLEMENTABLE SOLUTIONS

To ensure proper implementation of *Cadila*, courts, the ITMR, and the drug regulator in India should implement the following changes:

A. Likelihood of Confusion and Presumption of Harm in Trademark Registration and Infringement Cases

The proper application of *Cadila* requires courts and the ITMR to take greater care to prevent "any possibility" of confusion. Instead of shifting the burden of proving serious consequences, courts and the ITMR should presume harm. This presumption is important

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82 Medication Errors Related to CDER-Regulated Drug Products (FDA), https://www.fda.gov/drugs/drug-safety-and-availability/medication-errors-related-cder-regulated-drug-products.

83 Generic Drugs: Questions & Answers (FDA), https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers.

given the realities of the pharmaceutical market in India, where regulation over drug names is poor and where drugs may not be substitutable.[84]

The presumption should be rebuttable for drugs with the same active ingredient that also treat the same condition. If it can be proven that no harmful consequences would result from the mistaken consumption of the drug, then the presumption would be rebutted and a standard likelihood of confusion analysis would govern the use and registration of the trademark.

To rebut the presumption, evidence of bioequivalence and stability should be submitted to the court or the ITMR, as appropriate. The manufacturing and sale of generic medicines requires regulatory approvals.[85] A "no-objection certificate" obtained from the drug regulator certifying bioequivalence can serve as evidence to rebut the presumption of harm. Evidence of other factors, such as disclaimers on product packaging stating that the drug has been tested for bioequivalence and stability under the law, could also be submitted.[86]

For medicines that do not treat the same condition or are contra-indicated, the presumption of harm due to the use of similar names should be deemed to be conclusive. In such situations, public health demands the greatest care to prevent any possibility of confusion.

B. Greater Care in Evaluating Suitability of a Name for Trademark Protection

The ITMR should exercise caution while evaluating the suitability of a name for trademark protection. In this context, the application of the doctrine of greater care should apply even to trademark registration.[87] Since the Indian drug regulator is not legally obligated to approve brand names for pharmaceuticals, the responsibility to prevent confusion falls on the ITMR:

1. Deceptive Names and False Trade Descriptions

While courts and the ITMR have considered "likelihood of confusion," they have often failed to consider whether pharmaceutical trademarks are "false trade descriptions" or

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84 *Supra* Part II.

85 Drugs and Cosmetics (Ninth Amendment) Rules, 2017, Gazette of India, pt. II, sec. 3(i) (Apr. 3, 2017).

86 *See* Dinesh Thakur & Prashant Reddy, *India's Problem—Different Drugs, Identical Brand Names*, Hindu (Jan. 25, 2024) (noting that regulatory changes should be implemented to require pharmaceutical companies to disclose bioequivalence and stability testing on labels and packaging).

87 *Amritdhara* and *Roche* (applying the same standards of confusion both to registration and infringement proceedings in order to protect consumers from harmful consequences).

deceptively misleading trademarks. Under the ITMA, any description or indication[88] that is materially untrue or misleading as to the purpose, strength, performance, or behavior of any drug or food qualifies as a "false trade description."[89] Several pharmaceutical brand names that use similar suffixes or prefixes may mislead consumers regarding the medicine's particular purpose. For example, LIV-X may suggest that the drug is used to treat liver ailments when it may treat heart ailments.[90] In such cases, names should be evaluated strictly to ensure that they are not "false" or "deceptive." Greater care is warranted in these situations as well.[91]

2. Strictly Enforcing the Bar on Registering Marks Similar to INNs

The ITMR should enforce Section 13 of the ITMA strictly and reject trademarks that are similar to INNs.[92] INNs provide a standardized, generic designation for active ingredients, ensuring that drugs containing the same substance are clearly identifiable regardless of brand. The requirements of Section 13 are important to safeguard the public against sound-alike marks that could pose a risk to patient health. To enhance protection, the ITMR should exercise its *suo-moto* powers under the ITMA[93] to issue notices to trademark holders and give them an opportunity to justify why their marks are not deceptively similar to an INN or are not false or deceptively misleading.

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88 Trade Marks Act § 2(za)(iii) ("trade description" means any description, statement or other indication, direct or indirect, [. . .] (iii) as to fitness for the purpose, strength, performance or behavior of any goods, being "drug" as defined in the Drugs and Cosmetics Act, 1940 (23 of 1940), or "food" as defined in the Prevention of Food Adulteration Act, 1954 (37 of 1954)).

89 Trade Marks Act § 2(i)(I) ("false trade description" means "(I) a trade description which is untrue or misleading in a material respect as regards the goods or services to which it is applied").

90 LIV-X is a fictitious brand name used for illustrative purposes only. In the absence of Indian discussions on materiality thresholds, materiality discussions in the United States may be instructive. *See* Mark A. Lemley & Mark McKenna, *Irrelevant Confusion*, 62 Stan. L. Rev. 413, 415–16, 428, 433, 448, 453–54 (2010); Mark P. McKenna, *Testing Modern Trademark Law's Theory of Harm*, 95 Iowa L. Rev. 63, 67–68 (2009); Rebecca Tushnet, *Running the Gamut from A to B: Federal Trademark and False Advertising Law*, 159 U. Pa. L. Rev. 1305, 1305 (2011).

91 Simon, *supra* note 8; Trade Marks Act § 103 (penalty for applying false trade descriptions is imprisonment and fine).

92 Trade Marks Act § 13(b) ("[N]o word . . . which is declared by the World Health Organisation and notified in the prescribed manner by the Registrar from time to time, as an international non-proprietary name or which is deceptively similar to such name, shall be registered as a trade mark and any such registration shall be deemed for the purpose of section 57 to be an entry made in the register without sufficient cause or an entry wrongly remaining on the register, as the circumstances may require.").

93 Trade Marks Act § 57(4).

Despite the protective intent of Section 13, a persistent challenge in India is that up-to-date listings of INNs are not provided in a timely manner. Delays in the publication of INNs mean that trademark examiners and applicants lack up-to-date guidance on which names are already recognized, increasing the risk that new pharmaceutical trademarks could inadvertently resemble existing INNs. Timely notification and integration of INNs into the trademark examination process would strengthen the preventive function of Section 13 and better align Indian practice with international standards for pharmaceutical safety.

3. Regulatory Review of Drug Names and Coordination Between Agencies

The approval of drug brand names by the drug regulator is extremely essential to prevent the marketing of spurious or misleading drugs, as highlighted in cases such as *Cadila*. The drug regulator must be required to pre-approve drug names rather than the existing framework of self-certification. Further, a centralized database of approved drug brand names, maintained by the drug regulator, would facilitate coordination with the ITMR, ensuring that trademarks for pharmaceutical products do not conflict with existing names. The drug regulator should also maintain and publish an online list of medicines that have passed bioequivalence and stability tests along with the corresponding brand name medicines.[94] This system would function similarly to the coordination between company names and trademark registration under the Companies Act, 2013, allowing for comprehensive oversight of both commercial identity and public safety. Such a mechanism would help prevent confusion in the market, reinforce consumer protection, and strengthen the regulatory framework for pharmaceuticals in India.

C. Updating the Trade Marks Manual

To guide practitioners and applicants, the Trade Marks Manual should clarify that pharmaceutical trademarks will be reviewed with greater care. Even a low degree of similarity between marks should result in objections, thereby shifting the burden onto the applicant to prove otherwise. To overcome objections, the applicant should provide evidence of bioequivalence such as laboratory certificates confirming bioequivalence. Moreover, the ITMR must reject marks that are similar but treat different conditions. For marks that indicate a drug's purpose, strength, or performance, especially those derived from active ingredients, ailments, or organ names, the ITMR must evaluate their accuracy. If a name is likely

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[94] *See* Truth Pill, *supra* note 13 at ch. 10.

to mislead the public, the ITMR should reject it as deceptive or false. The manual should also clarify that applicants must provide a detailed description of the drug's purpose and indications. This will correct the existing practice of applying for marks with catch-all descriptions like "pharmaceuticals and medicinal products" in Class 5.[95] Furthermore, the ITMR should enforce Section 13 strictly and reject trademarks that are similar to INNs.[96]

D. Labelling

In India, proper labelling and advertising of pharmaceuticals play a critical role in protecting patient safety, particularly with regard to bioequivalence. Manufacturers must be required to disclose whether a generic drug is therapeutically equivalent to the reference product, helping healthcare providers and consumers make informed decisions. Clear disclosure on labels and advertisements ensures that prescribers, pharmacists, and patients can distinguish between bioequivalent and non-bioequivalent products, minimizing the risk of therapeutic errors.

VI. CONCLUSION

The development of the doctrine of "greater care" in India to assess likelihood of confusion between pharmaceutical trademarks is relatively recent and has been marked by inconsistencies. Until 2001, Indian courts occasionally applied the idea of "greater care" in infringement and registration proceedings for pharmaceutical trademarks. While some courts applied a stricter standard to prevent confusion in this market, others refused to do so, leading to differences in perception of purchasing habits, awareness, education levels, and market realities. In 2001, the Supreme Court of India ironed out these tensions by ruling in favor of a stricter standard or "greater care" for assessing confusion between pharmaceutical trademarks. However, inconsistencies in applying *Cadila* continue even today.

The proper application of *Cadila* requires several changes. Courts, the ITMR, and the drug regulator need to take greater care to prevent "any possibility" of confusion in the pharmaceutical market. This heightened level of care is important and necessary given the complexities of the pharmaceutical market in India. Even today, it is possible that generic medicines are not in fact substitutable. Furthermore, the use of similar names for medicines that treat different conditions warrants robust protective measures.

In addition, not only should greater care apply to assessing likelihood of confusion, but it should also extend to evaluating the

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95 *Vishnudas Trading*, A.I.R. (1997) 4 S.C.C. 201 at 224.

96 Trade Marks Act § 13(b).

suitability of a mark for trademark protection. Given the naming conventions adopted by the pharmaceutical industry, names routinely indicate the drug's purpose, strength, or performance. If these indications are materially false or misleading, they should not be registered and their use should carry penalties as prescribed under the ITMA.

Courts and the ITMR should implement these principles of greater care by presuming harm for pharmaceutical trademarks that are even slightly similar. The presumption should be a rebuttable one for drugs that treat the same condition and conclusive for drugs that are meant for different purposes. Changes in evidentiary requirements and the Trade Marks Manual can be made to implement this doctrine. These changes are in line with the spirit of the ITMA, which focuses not only on protecting commercial interests but also on public health and safety.