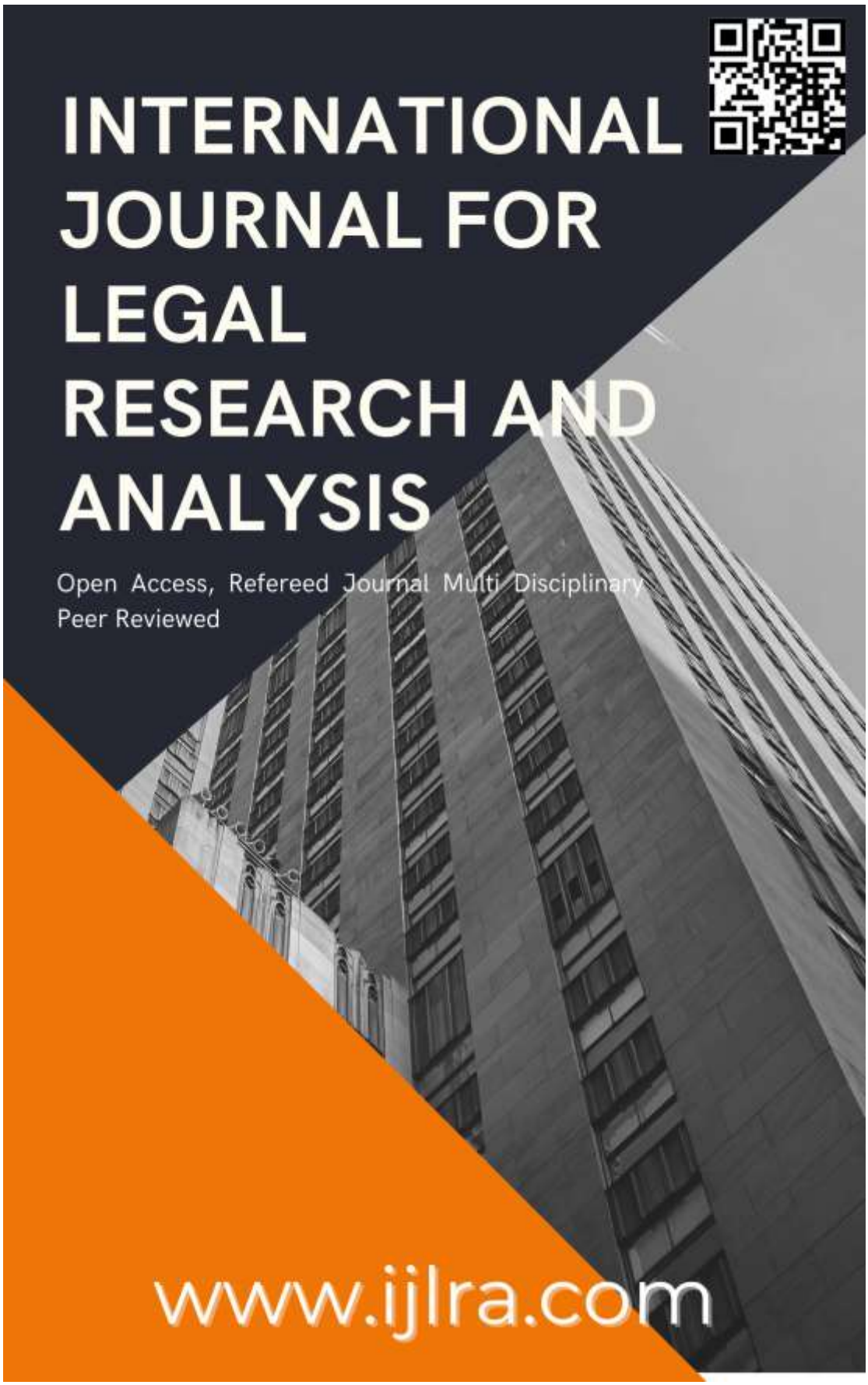

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RESEARCH ARTICLE

Pharmaceutical Trademarks & Confusingly Similar Drug Names

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Abstract

Pharmaceutical brand names carry two burdens at once. As trademarks they identify commercial origin and protect goodwill; as clinical identifiers they are written, spoken, typed and scanned by prescribers, pharmacists, nurses and patients, often under time pressure, so that one mistaken syllable can lead to the wrong drug being dispensed. This paper asks whether Indian law reconciles these functions. It examines the Trade Marks Act 1999, the Drugs and Cosmetics Act 1940 and Rules 1945 (including the 2019 brand-name undertaking in Form 51), and the case law on deceptive similarity from Amritdhara to Cadila Health Care and recent High Court decisions, and it compares India with the United States and the European Union, where clinical regulators review proposed names before launch. Drawing on Hannah Brennan's study of pharmaceutical trademarks, it also shows that confusion in this field has a second dimension: branding can lead patients to treat identical branded and generic drugs as different products. The paper argues that confusion between different medicines calls for a stricter, severity-sensitive standard, that India has begun to build preventive machinery but has not yet given it a workable similarity methodology or clinical review, and that litigation after launch remains an inadequate substitute. It proposes verified pre-registration screening, integration of the Trade Marks Registry and drug-licensing databases, risk-tiered scrutiny and post-market correction.

Keywords: pharmaceutical trademarks; look-alike sound-alike (LASA) drugs; deceptive similarity; medication errors; Trade Marks Act 1999; Form 51; patient safety.

I. Introduction

A. Background

A prescription is a short instruction, and the name of the drug is often the only information on which a dispenser can act. A brand name therefore performs the ordinary trademark function of indicating origin,1 but it is also the working vocabulary of clinical practice. One US study found that physicians prescribed by brand name in every case where no generic was available and in 79 per cent of cases where one was.2 In India, a large share of off-patent medicines is sold as 'branded generics', that is, products sold under company-specific brand names.3 Many names must therefore coexist in the same therapeutic space. The result is the look-alike, sound-alike (LASA) problem: two drug names resemble each other closely enough in spelling or pronunciation that one may be mistaken for the other. The phenomenon is well documented. In 2015 the US Food and Drug Administration (FDA) warned that the names of the antidepressant Brintellix and the antiplatelet Brilinta were being confused in prescribing and dispensing, and by May 2016 it had received 55 such reports; the antidepressant was renamed Trintellix.4 The Alzheimer's drug Reminyl was likewise renamed Razadyne in 2005 after dispensing errors involving the antidiabetic Amaryl, including at least one reported death.5 Medication safety is a global concern: the World Health Organization (WHO) estimates the global cost of medication errors at US$42 billion a year and in 2017 launched a Global Patient Safety Challenge to halve severe avoidable medication-related harm in five years.6

B. Research Problem

Trademark law requires a mark to be distinctive enough to identify a single commercial source. Drug regulation requires a name to be dissimilar enough from every other drug name that it cannot be confused when prescribed, dispensed or administered. These requirements overlap but are not identical: a name may be registrable and yet unsafe, and a name may be clinically safe yet infringe an earlier mark. Brennan adds a further complication: pharmaceutical branding and trade dress can mislead patients into thinking that equivalent branded and generic medicines differ, with consequences for cost and adherence.7

C. Research Questions

1. What legal standards govern pharmaceutical trademarks and the control of confusing drug names in India? 2. How have Indian courts assessed deceptive similarity between medicinal marks, and how far has the risk of patient harm shaped that assessment? 3. How do the United States and the European Union address the problem, and what can India learn from them? 4. What reforms would better reconcile trademark protection with medication safety? 1Hannah Brennan, 'The Cost of Confusion: The Paradox of Trademarked Pharmaceuticals' (2015) 22 Mich Telecomm & Tech L Rev 1 (Brennan) 4–8. 2Michael A Steinman, Mary-Margaret Chren and C Seth Landefeld, 'What's in a Name? Use of Brand versus Generic Drug Names in United States Outpatient Practice' (2007) 22 J Gen Intern Med 645, cited in Brennan (n 1) 18 n 110. 3Economic Laws Practice, 'Regulating Medical Practice: The Key Reforms Introduced by the Registered Medical Practitioner (Professional Conduct) Regulations, 2023' (Mondaq, 22 August 2023) (defining 'branded generic drugs' as off-patent drugs sold under different companies' brand names). 4US FDA, 'Drug Safety Communication: FDA warns about prescribing and dispensing errors resulting from brand name confusion with antidepressant Brintellix (vortioxetine) and antiplatelet Brilinta (ticagrelor)' (30 July 2015); US FDA, 'Drug Safety Communication: FDA approves brand name change for antidepressant drug Brintellix (vortioxetine) to avoid confusion with antiplatelet drug Brilinta (ticagrelor)' (2 May 2016). 5'Takeda renames antidepressant after name confusion leads to errors' (BioPharma Dive, 2016); '5 Notable Drug Name Changes' (Pharmacy Times, 4 May 2016). 6WHO, 'WHO launches global effort to halve medication-related errors in 5 years' (News release, 29 March 2017). 7Brennan (n 1) 3–4, 33–35.

D. Thesis

Pharmaceutical trademark disputes demand a stricter and more context-sensitive approach than ordinary trademark disputes, because confusion can produce medication errors and serious harm and not only economic loss. The Supreme Court said as much in Cadila Health Care Ltd v Cadila Pharmaceuticals Ltd.8 India has since added a regulatory layer, but a system that relies on applicants' self-declarations and on private litigation after launch cannot adequately protect patients.

E. Scope and Methodology

The study is doctrinal and comparative. It analyses statutes, delegated legislation, judgments, regulatory guidance and international standards, with India as the primary jurisdiction and the United States and the European Union as comparators. Two limits should be noted. First, Brennan's article is a US study; it is used for its evidence on how branding affects patients, not as a statement of Indian law. Secondly, several recent Indian developments (the 2024 High Court decisions, the 2026 CDSCO consultation and the 2026 Delhi High Court rulings) are reported here from law-firm, trade and press sources and, where indicated, should be checked against the primary judgments and notices.

II. Pharmaceutical Names and the Functions of a Trademark

A. The Names of a Medicine

A drug carries several names. Brennan identifies three in US practice: a chemical name describing its structure, a generic (non-proprietary) name, and a brand (proprietary) name.9 Generic names are built from

a stem that signals pharmacological class and cannot be monopolised as marks. Internationally, WHO assigns International Nonproprietary Names (INNs) and treats them as public property.10 India gives this principle statutory effect: section 13(b) of the Trade Marks Act 1999 bars registration of a word declared by WHO and notified by the Registrar as an INN, or one deceptively similar to it, and treats any such registration as an entry wrongly on the register for the purposes of section 57.11 The brand name is different in kind: it is coined to be distinctive and memorable, and it is the only one of the names that can be owned.

B. Functions and Special Character

A pharmaceutical mark performs the classic functions of identifying origin, distinguishing competing goods and embodying goodwill. It also performs functions peculiar to medicines: it lets prescribers and pharmacists communicate quickly, and it is the name patients remember and request. Pharmaceutical marks are also subject to a double system of scrutiny. In the United States, as Brennan notes following Clarke, the trademark office is concerned with confusion about commercial source whereas the FDA is concerned with the risk that prescribers or pharmacists will confuse a proposed name with another drug name, and the two agencies do not always perform this task perfectly.12 The same divided responsibility exists in India, with a significant difference discussed in Part III.

C. Competing Interests

Three interests compete. Manufacturers have invested in brand identity and are entitled to protection against free-riding. Patients and the public need names that cannot be confused. And generic competitors, together with the State as a purchaser, have an interest in preventing trademarks from extending exclusivity 8Cadila Health Care Ltd v Cadila Pharmaceuticals Ltd (2001) 5 SCC 73 (Cadila), paras 33–35. 9Brennan (n 1) 16–17. 10WHO, Guidelines on the Use of International Nonproprietary Names (INNs) for Pharmaceutical Substances (1997). 11Trade Marks Act 1999, s 13(b). The Registrar first notified a list of INNs (8,151 names) in February 2012: Nishith Desai Associates, ‘Respite for the Pharmaceutical Industry: Controller General publishes a list of International Non-Proprietary Names’ (IP Hotline, 8 May 2012). 12Brennan (n 1) 17–18 and n 106, citing Deirdre A Clarke, ‘Proprietary Drug Name Approval: Taking the Duel Out of the Dual Agency Process’ (2011) 12 Loy J Pub Int L 433, 442.

beyond patent expiry. A 1977 report of the US Federal Trade Commission suggested that the trademark, like the patent, might be given a limited life,13 and Brennan records that Indian authorities considered a ban on pharmaceutical brand names in 2012.14 A complete analysis must therefore keep both kinds of confusion in view.

III. The Indian Legal Framework

A. The Trade Marks Act 1999

Absolute grounds. Section 9(1) refuses marks that lack distinctive character, are descriptive, or have become customary in the trade, and section 9(2)(a) refuses marks of a nature likely to deceive the public or cause confusion. Section 13 is the specifically pharmaceutical ground (above). Relative grounds. Section 11(1) refuses registration where, because of identity or similarity with an earlier mark and similarity of goods, there is a likelihood of confusion on the part of the public, which includes the likelihood of association. Section 2(1)(h) defines a mark as deceptively similar if it so nearly resembles another as to be likely to deceive or cause confusion.15 Infringement and passing off. Section 29 protects the registered proprietor against use of identical or deceptively similar marks on identical or similar goods where confusion is likely. Passing off, preserved by section 27(2), protects unregistered goodwill. The two actions differ: in infringement the comparison is between the registered mark and the defendant’s mark, whereas in passing off the court looks at the whole get-up and the surrounding circumstances.16 Cadila itself was a

passing-off action.17 Rectification. Section 57 allows an aggrieved person to seek removal of an entry wrongly remaining on the register. It is the vehicle for post-registration challenges, as in the 2026 rectification of DAPLOGIN discussed in Part V.

B. The Drugs and Cosmetics Act 1940 and Rules 1945

The Drugs and Cosmetics Act regulates the manufacture, sale and distribution of drugs. Section 17B treats as spurious a drug that resembles another drug in a manner likely to deceive or bears the name of another drug, unless clearly marked to reveal its true character, and section 18 prohibits the manufacture and sale of such drugs. The provision partly captures resemblance but sets no standard for judging similarity.18 In Cadila, the Supreme Court suggested that drug licensing authorities could require applicants to check for the likelihood of confusion with existing names before approving a brand name.19 Action came only in 2019. The Drugs and Cosmetics (Thirteenth Amendment) Rules 2019, notified on 6 November 2019 (GSR 828(E)), inserted provisions in rules 71(9), 71A(5), 71B(v), 76(11) and 76A(v) requiring an applicant who intends to market a drug under a brand or trade name to furnish an undertaking in a new Form 51. The undertaking states that, to the best of the applicant's knowledge and based on a search of the trade marks registry, no similar brand name exists for any drug in the country and that the proposed name will not lead to confusion or deception in the market.20 Manufacturers are also required by rule 13Brennan (n 1) 4, quoting Federal Trade Commission, Staff Report on Sales, Promotion, and Product Differentiation in Two Prescription Drug Markets (1977). 14Brennan (n 1) 3–4 and nn 2–3. 15Trade Marks Act 1999, ss 2(1)(h), 9, 11. 16Kaviraj Pandit Durga Dutt Sharma v Navaratna Pharmaceutical Laboratories AIR 1965 SC 980. 17Cadila (n 8); see also the account in Mankind Pharma Ltd v Chandra Mani Tiwari (Delhi High Court, 9 August 2024), which recalls that the Supreme Court there refused to interfere with the refusal of interim relief and directed an expeditious trial. 18Drugs and Cosmetics Act 1940, ss 17B and 18. On the reliance placed on s 17B in Cadila see Anchal Bhatheja, 'Drug Names: a Matter of Trademarks or Patient Trust?' (BioSpectrum India, 14 July 2026) (Bhatheja). 19Cadila (n 8); Bhatheja (n 18) (reporting that the Court relied on s 17B and directed the Ministry of Health to develop a framework, and that the Delhi High Court echoed the concern in Curewell Drugs & Pharmaceuticals Pvt Ltd v Ridley Life Science Pvt Ltd (Delhi High Court, 6 February 2019)). 20Drugs and Cosmetics (Thirteenth Amendment) Rules 2019, GSR 828(E), 6 November 2019 (Form 51); Cyril Amarchand Mangaldas, Synapse vol III issue IV (2020); Rajya Sabha, reply of the Ministry of Health and Family Welfare to Unstarred

84AB to upload formulation and brand-name details on the CDSCO's SUGAM portal.21 The Drugs Consultative Committee (DCC) has since taken the matter further. At its 64th meeting (19 June 2024) it recommended that State Licensing Authorities, on receiving a Form 51, search the CDSCO database and the trade marks registry, and that where identical brand names are already in use the manufacturer who first submitted Form 51 should be allowed to continue while others are withdrawn.22 On 6 July 2026 the CDSCO invited stakeholder comments (by 17 July 2026) on the use of the same established brand name, with different extensions, for products containing different active ingredients, following concerns raised at the 67th DCC meeting.23

C. Other Regulatory Mechanisms

Professional regulation touches the issue indirectly. The Indian Medical Council's 2002 regulations encouraged prescribing by generic name. The National Medical Commission's Registered Medical Practitioner (Professional Conduct) Regulations 2023, notified on 2 August 2023, would have mandated generic prescribing with penalties, but were held in abeyance on 23 August 2023, and the 2002 regulations were restored.24 Generic prescribing reduces LASA risk by removing brand names from the prescription, but it is not currently mandatory.

D. The Interface and the Gap

Three propositions summarise the interface. First, a mark may satisfy the Trade Marks Act yet raise a regulatory concern. Secondly, regulatory clearance does not immunise a name from an infringement claim. The US case of Kos v Andrx illustrates this: the FDA had conditionally approved the name Altocor, yet the court still found it likely to be confused with Advicor.25 Thirdly, trademark registration does not certify that a name is safe in clinical use. India is no longer without a regulatory mechanism, but the mechanism is thin. Form 51 is a selfdeclaration. Neither the rules nor the DCC recommendations prescribe a method for judging similarity (for example, a phonetic and orthographic algorithm, or testing against prescribing conditions), and the DCC's 'first to submit Form 51' proposal resolves conflicts by filing order rather than by clinical risk. Commentators have observed that the SUGAM database enables browsing of existing names but offers no standard for deciding how similar is too similar.26

IV. Confusing Similarity in the Pharmaceutical Setting

A. Dimensions of Similarity

Courts compare marks visually (spelling and appearance, which matters for handwritten and printed prescriptions), phonetically (pronunciation, which matters for oral orders and for patients asking at a counter) and structurally (shared prefixes, suffixes, length and rhythm). In pharmaceuticals, shared stems or abbreviations common to the trade can leave only a short distinguishing portion, so a single syllable may separate two drugs.

B. The Average Consumer and the Pharmaceutical Consumer

The general Indian test asks how a person of average intelligence and imperfect recollection would react Question 258 (20 December 2022), listing the 6 November 2019 amendment. 21Conventus Law, 'India – Pharmaceutical Brand Extensions Under Regulatory Scrutiny: CDSCO Seeks Stakeholder Views' (July 2026) (Conventus). 22CDSCO, Minutes of the 64th Drugs Consultative Committee meeting (19 June 2024). 23Conventus (n 21); 'CDSCO calls for stakeholder comments on use of same brand name with different extensions for multiple formulations' (Pharmabiz, 7 July 2026). No final outcome had been located at the time of writing. 24'Commission puts Registered Medical Practitioner Regulations, 2023 on hold' (DT Next, 24 August 2023); 'NMC Professional Conduct Guidelines: A knee-jerk approach to medical regulation' (Bar & Bench). 25Kos Pharmaceuticals, Inc v Andrx Corp 369 F 3d 700 (3d Cir 2004). 26Bhatheja (n 18).

to the marks, looking at their overall impression rather than a side-by-side comparison. It descends from the English formulation in Re Pianotist Co's Application, under which marks are judged by their look and their sound, with regard to the goods and the kind of customer likely to buy them.27 This standard fits medicines uneasily because the relevant public is several groups: prescribers, pharmacists, nurses and other professionals, and patients and caregivers. For prescription-only drugs it is often argued that sophisticated professionals will not be confused, but medication errors usually arise from fatigue, interruptions, illegible handwriting, spoken orders and heavy workloads rather than ignorance. The Third Circuit made the point in Kos, where it reversed a refusal of an injunction and held that the district court had overemphasised the sophistication of prescribers; medical expertise is not by itself enough to lessen the likelihood of confusion in prescription drug cases.28 In India the argument is weaker still. Commentators describe outpatient consultations of about two minutes in government hospitals, pharmacists attending to over 200 patients a day while deciphering illegible prescriptions, and patients who rely on remembered brand names and self-medication.29

C. Factors and a Severity-Sensitive Standard

Cadila lists the considerations for deceptive similarity: the nature of the marks (word, label or composite); the degree of resemblance, phonetically and in idea; the nature of the goods; the similarity in nature, character and performance of the rival goods; the class of purchasers, their education, intelligence and degree of care; the mode of purchase or of placing orders; and any other surrounding circumstances.30 For medicines, further attention should be paid to the dosage form and strength, therapeutic indication and clinical setting, route of administration, prescription or over-the-counter status, labelling and, above all, the consequences of a mistake. The FDA's guidance reflects the same thinking: moderately similar names are of particular concern where the products have overlapping strengths or doses.31 Ordinary trademark law is probabilistic: the question is whether confusion is likely. Where the consequence of confusion may be death, a rational standard should weigh magnitude as well as probability, so that a smaller likelihood suffices to refuse a mark when the foreseeable harm is greater. This is the logic of the precautionary principle and of the stricter approach endorsed in Cadila.

V. The Judicial Approach

A. The Foundational Decisions

Amritdhara Pharmacy v Satya Deo Gupta concerned 'Amritdhara' and 'Lakshmandhara' for medicinal preparations. The Supreme Court held the marks deceptively similar, applying the test of the person of average intelligence and imperfect recollection and comparing the marks as wholes.32 In F Hoffmann-La Roche & Co Ltd v Geoffrey Manners & Co Pvt Ltd the Court, applying the Pianotist test, found 'Protovit' and 'Dropovit' so dissimilar that there was no reasonable probability of confusion.33 In Corn Products Refining Co v Shangrila Food Products Ltd the Court held 'Glucovita' and 'Gluvita' deceptively similar.34 These decisions show that the outcome turns heavily on the facts of each pair of marks.

B. Cadila Health Care v Cadila Pharmaceuticals

27Re Pianotist Co Ltd's Application (1906) 23 RPC 774, applied in Cadila (n 8) and, more recently, in Mankind Pharma Ltd v Chandra Mani Tiwari (Delhi High Court, 9 August 2024). 28Kos (n 25); see the summary in Olinsky and Potenza, New Jersey Law Journal (6 September 2004) 177 NJLJ 916, reporting the court's statements at 369 F 3d 716. 29Bhatheja (n 18), citing Comptroller and Auditor General audit reports on hospitals in Uttar Pradesh and Delhi; the figures are as reported there and should be checked against the CAG reports. 30Cadila (n 8) para 35. 31Kari Oakes, 'FDA's proprietary name guidance seeks to avoid medication errors' (RAPS, 9 December 2020). 32Amritdhara Pharmacy v Satya Deo Gupta AIR 1963 SC 449, as discussed in Cadila (n 8). 33F Hoffmann-La Roche & Co Ltd v Geoffrey Manners & Co Pvt Ltd AIR 1970 SC 2062, as discussed in Cadila (n 8). 34Corn Products Refining Co v Shangrila Food Products Ltd AIR 1960 SC 142, as discussed in Cadila (n 8).

Cadila concerned FALCIGO and FALCITAB, two anti-malarial products with different compositions and prices sold by companies that had emerged from the same corporate group. The trial judge refused interim relief, the High Court affirmed, and the Supreme Court declined to interfere but directed an expeditious trial, laying down principles that have since become the touchstone.35 Its main contributions are the list of factors set out above and the proposition that a stricter approach is required when judging the possibility of confusion of one medicinal product for another.36 The Court also drew attention to the role of drug regulators, as noted in Part III.

C. Recent High Court Decisions

Recent decisions apply Cadila in ways that show both its strictness and its limits. In Glenmark Pharmaceuticals Ltd v Sun Pharma Laboratories Ltd, a Delhi High Court division bench (16 April 2024) upheld an injunction restraining Glenmark's INDAMET, an asthma medicine, as deceptively similar to Sun

Pharma's ISTAMET XR CP, an anti-diabetic.37 The marks were used for different therapeutic categories, yet the court still found confusion sufficiently probable, which is the strict approach in action. In Glenmark v Gleck Pharma, the Bombay High Court (13 June 2024) granted an interim injunction against XIGAMET as deceptively similar to ZITA-MET for diabetes medication, relying on Cadila and noting that many consumers of medicines in India may not read the language of the mark well.38 The Delhi High Court has similarly restrained FEXIT as phonetically and structurally similar to PHEXIN, observing that proof of actual confusion is unnecessary.39 Two 2026 decisions, reported by Bisman Kaur, show the doctrine's limits.40 In Sun Pharma Laboratories v Intas Pharmaceuticals a division bench rejected an infringement claim by the owner of BEVETEX (paclitaxel) against BEVATAS (bevacizumab). The marks concerned different active ingredients, were Schedule H drugs prescribed by oncologists and given by trained personnel, and had coexisted from 2016 to 2026 with no recorded confusion; the court treated 'bev' and 'beva' as syllables common in anti-cancer drugs and declined to rest on phonetic resemblance alone; the Supreme Court declined to interfere on 27 July 2026. By contrast, in rectification proceedings brought by Dr Reddy's Laboratories, the Delhi High Court on 17 August 2026 ordered DAPLOGIN removed from the register: it reproduced the earlier DAPLO in full, both products contained dapagliflozin for type 2 diabetes, and third-party marks on the register without evidence of use did not make DAPLO common to the trade.41

D. Critical Evaluation

The case law has real strengths. It recognises that medicines differ from ordinary goods, it does not require proof of actual confusion, and recent decisions show courts weighing active ingredients, therapeutic use and the evidence. The 2026 commentary rightly stresses that the stricter standard is a direction to examine confusion with particular care, not a presumption that every phonetic resemblance infringes.42 Four weaknesses remain. First, outcomes are hard to predict: ISTAMET/INDAMET were held confusable across therapeutic categories, while BEVETEX/BEVATAS survived despite both being anti-cancer 35Cadila (n 8); Mankind Pharma Ltd v Chandra Mani Tiwari (Delhi High Court, 9 August 2024), citing Glenmark Pharmaceuticals Ltd v Sun Pharma Laboratories Ltd (n 37 below). 36Cadila (n 8) para 33 (stricter approach for medicinal products) and para 35 (factors), as quoted in Glenmark Pharmaceuticals Ltd v Gleck Pharma (OPC) Pvt Ltd (Bombay High Court, 13 June 2024), reported by BananaIP. 37Glenmark Pharmaceuticals Ltd v Sun Pharma Laboratories Ltd, FAO(OS)(COMM) 146/2023 (Delhi High Court, 16 April 2024); see also 'Trademark Tussle: HC bars Glenmark from using Indamet' (Medical Dialogues, 22 April 2024). 38Mondaq, 'ZITAMET vs XIGAMET: Bombay HC says no to confusing drug names that put patients at risk'; BananaIP, report on Glenmark Pharmaceuticals Ltd v Gleck Pharma (OPC) Pvt Ltd (Bombay High Court, 13 June 2024). 39GlaxoSmithKline Pharmaceuticals Ltd v Zee Laboratories Ltd (Delhi High Court, Karia J), as reported in Raw Law, 'Delhi High Court grants injunction to GlaxoSmithKline against 'FEXIT' marks' (date and citation to be confirmed from the judgment). 40Bisman Kaur, 'When similarity is not enough: two pharma mark rulings produce contrasting outcomes at the Delhi High Court' (World Trademark Review, 22 October 2026) (Kaur); the underlying judgments should be consulted. 41Kaur (n 40). 42Kaur (n 40).

products, and doctrine does not say how much weight severity of harm should carry. Secondly, the evidence is thin. In Intas, arguments about illegible prescriptions were reportedly dismissed as outside the pleadings and a generic press report on pharmacist negligence was treated as irrelevant, which shows that courts lack systematic data on how errors occur.43 Thirdly, litigation is inter partes: the patient's safety interest is represented, if at all, by a competitor's commercial interest, and a well-resourced rival may or may not choose to sue. Fourthly, it is late: by the time an injunction issues the drug is typically already in use.

VI. International Approaches

A. The United States

Trademark protection rests on the Lanham Act: registration is refused where a mark is likely to cause confusion with a registered mark, and infringement and unfair competition are actionable under 15 USC §§ 1114 and 1125(a).44 Federal circuits apply multi-factor tests; in Kos the Third Circuit applied its Lapp factors, reversed a refusal of a preliminary injunction against ALTOCOR as confusable with ADVICOR, and rejected an analysis that focused only on misdispensing or leaned too heavily on customer sophistication.45 The distinctive feature is the FDA's separate safety review. Its December 2020 final guidance, Best Practices in Developing Proprietary Names for Human Prescription Drug Products, sets out best practices to minimise proprietary-name-related medication errors and describes the framework the FDA uses to evaluate proposed names.46 The FDA uses its Phonetic and Orthographic Computer Analysis (POCA) software to assess how similar a proposed name is to existing names, and the guidance also contemplates name simulation studies.47 Screening is not infallible: Brintellix was reportedly screened before launch,48 yet the FDA later received 55 reports of confusion with Brilinta (n 4). The lesson is not that screening fails, but that it must be supported by post-market monitoring and the power to require a name change.

B. The European Union

EU trademark law applies a likelihood-of-confusion test: the Trade Mark Regulation (art 8(1)(b)) and Directive (art 5(1)(b)).49 The Court of Justice assesses confusion globally and through the eyes of a reasonably well-informed, observant and circumspect average consumer.50 The medicines-law track is separate. For centrally authorised products, the European Medicines Agency's (Invented) Name Review Group considers whether a proposed name could create a public-health concern or safety risk; among other things, the name should not mislead as to composition or therapeutic character and should not be liable to cause confusion with the invented name of an existing medicine in print, handwriting or speech.51 Crucially, the guideline states that review of trademarks is outside the EMA's remit and that intellectual property and trademark registration are not considered in the review (this appears in the guideline's earlier revision, CPMP/328/98 Rev 6 (2013), and is repeated in the EMA's 43Kaur (n 40). 44Lanham Act, 15 USC §§ 1052(d), 1114(1), 1125(a). 45Kos (n 25), applying Interpace Corp v Lapp, Inc 721 F 2d 460 (3d Cir 1983). 46US FDA, Best Practices in Developing Proprietary Names for Human Prescription Drug Products: Guidance for Industry (December 2020), Docket FDA-2014-D-0622. 47US FDA, 'FDA In Brief: FDA Provides Guidances on Proprietary Naming for Drugs, Changes to Naming Analysis Program' (8 December 2020); Oakes, 'FDA's proprietary name guidance seeks to avoid medication errors' (RAPS, 9 December 2020). 48BioPharma Dive, 'Takeda renames antidepressant after name confusion leads to errors' (2016), reporting Takeda's statement and noting that the FDA's Division of Medication Error Prevention and Analysis reviews brand names before approval. 49Regulation (EU) 2017/1001, arts 8(1)(b), 9(2)(b); Directive (EU) 2015/2436, art 5(1)(b). 50Case C-251/95 Sabel BV v Puma AG [1997] ECR I-6191; Case C-342/97 Lloyd Schuhfabrik Meyer & Co GmbH v Klijsen Handel BV [1999] ECR I-3819. 51EMA, '(Invented) Name Review Group'; EMA, Guideline on the acceptability of names for human medicinal products processed through the centralised procedure (EMA/CHMP/287710/2014, Rev 7).

consultation overview for the current revision).52 A marketing authorisation therefore does not decide trademark validity, and a trademark does not guarantee acceptance of the name by the regulator.

C. International Standards

WHO's INN programme supplies globally recognised generic names. Its guidelines treat INNs as public property and expect conflicts between proprietary and non-proprietary names to be avoided (n 10). The debate over biologics shows that even regulatory naming can generate the second type of confusion

identified by Brennan: the FTC warned that distinguishing suffixes for biosimilars could lead physicians to believe that biosimilars differ in clinically meaningful ways from their reference products.53

D. Comparative Assessment

Feature India United States European Union EMA Name Review Group (centralised products) FDA review of proprietary names using POCA and simulation studies Pre-market namesafety review Form 51 self-declaration after a registry search; no prescribed similarity method; SUGAM database Trademark examination Registry examination under s 11 against the register USPTO examination (§ 1052(d)) EUIPO and national offices (art 8(1)(b)) Separate agencies; limited coordination Trademark rights expressly outside the EMA's remit Link between the two tracks Form 51 refers to a registry search; DCC proposes licensing-authority checks of the registry Renaming after error reports (Trintellix, Razadyne) Name changes handled through regulatory variations Post-market correction Private injunction or rectification; proposals under DCC consideration

Table 1: Name control in India, the United States and the European Union (author's synthesis from sources cited in this Part and Part III).

Three lessons follow. First, in both comparators a clinically trained regulator reviews names against a stated method before launch. India now has a pre-launch filter but it rests on the applicant's own search. Secondly, both comparators keep safety review and trademark rights distinct, which avoids turning the drug regulator into an adjudicator of private disputes; India's Form 51 blurs this line by asking the applicant to certify both. Thirdly, error data feed back into the system through reporting and renaming.

VII. Public Health and Patient Safety

A. Errors across the Medication-Use Chain

Name confusion can cause error in prescribing (illegible handwriting, or selecting the wrong entry from an electronic list), in dispensing (look-alike names, a misheard order), in administration and in selfmedication. WHO notes that medication errors occur at every stage of ordering, prescribing, dispensing, preparing, administering and consuming, and that most harm arises from system failures.54 The Brintellix example shows how: the president of the Institute for Safe Medication Practices explained that clinicians typing the first three letters were selecting the first drug that appeared.55 FDA's 2016 communication 52EMA, Guideline on the acceptability of names for human medicinal products processed through the centralised procedure (CPMP/328/98 Rev 6, 2013); EMA, Overview of comments received on draft guideline (EMA/CHMP/287710/2014 – Rev 7). 53Brennan (n 1) 51–52, quoting the FTC staff comment on the FDA's 2015 draft guidance on the nonproprietary naming of biological products. 54WHO (n 6). 55'Brintellix Changed to Trintellix to Curb Brand Name Confusion with Brilinta' (Pharmacy Times, 2 May 2016) (quoting

recorded a patient whose medical staff confused the two names in the medication record and who, after taking the wrong drug for nine days, fell and was admitted to hospital.56 Comprehensive Indian data on name-related errors are not available in the sources consulted; one commentary cites a survey of 137 postgraduate residents at a tertiary hospital attributing 39 per cent of errors to LASA names, which should be treated as indicative until the underlying study is checked.57

B. Severity and the Precautionary Principle

The harm ranges from the trivial to the fatal: the wrong drug, the wrong dose, delayed treatment and adverse reactions. Where harm may be serious and irreversible, a lower probability of confusion should suffice to justify refusal. Indian constitutional law supports this approach: the Supreme Court has treated health and medical care as part of the right to life under article 21, and article 47 directs the State to raise the level of public health.58

C. The Second Paradox: Confusion between Identical Drugs

Brennan's central contention is that pharmaceutical branding and trade dress cause a different kind of confusion by leading patients to treat bioequivalent branded and generic drugs as distinct. Studies she reviews show that changes in the appearance of the same medicine can reduce adherence: one study of cardiovascular medications found a 34 per cent increase in the odds of a colour change preceding non-persistence and a 66 per cent increase in the odds of non-persistence after a shape change.59 Many people also rely on a pill's appearance as a check against error. The two forms of confusion pull in opposite directions. LASA confusion arises when different drugs are insufficiently differentiated; equivalence confusion arises when identical drugs are over-differentiated. A coherent policy must apply strict scrutiny to resemblance between different drugs while declining to treat marks as devices for separating products that contain the same molecule. This distinction shapes the reforms below.

VIII. Challenges

Crowding and extensions. Names are built from a limited stock of stems and endings. The CDSCO's 2026 consultation shows a related problem: the same established brand name, with different extensions, used for products with different active ingredients may mislead prescribers and patients about what they contain.60 Electronic systems. Autocomplete and drop-down lists create new failure modes, as the Brintellix case shows, and online sales raise search-based confusion. India's regulatory framework for e-pharmacies has been unsettled, and this paper has not examined it in detail. AI-assisted naming. Generative tools are increasingly used for brand naming. If they draw on patterns in existing names they could produce near-duplicates, but this is a plausible risk rather than a documented trend; it reinforces the case for mandatory objective screening that does not depend on the applicant's diligence.

IX. Reform Proposals

1. Replace self-declaration with verified screening. Form 51 should be supported by an objective Michael Cohen of the Institute for Safe Medication Practices). 56US FDA (n 4) (2 May 2016 communication). 57Bhatheja (n 18). 58Consumer Education and Research Centre v Union of India (1995) 3 SCC 42; Parmanand Katara v Union of India (1989) 4 SCC 286; Constitution of India, arts 21 and 47. 59Brennan (n 1) 33–34, discussing studies including Aaron S Kesselheim and others on pill appearance and non-adherence. 60Conventus (n 21); 'Why one drug brand can no longer mean one medicine: CDSCO moves to tackle confusing brand name extensions' (The South First).

similarity check, using phonetic and orthographic software of the kind the FDA uses and including Indian-language transliterations, with results recorded on SUGAM. A name-review panel drawing on the CDSCO and the Indian Pharmacopoeia Commission could give a reasoned opinion on risk.

2. Integrate the registers. The DCC has already recommended that licensing authorities search the CDSCO database and the trade marks registry. Statutory and technical integration of SUGAM and the Registry's database would make that search routine, and a Class 5 guidance note in the Registry's manual could require stricter comparison where goods share a therapeutic area, dosage form or clinical setting.

3. Resolve conflicts by risk, not only by filing order. The 'first to submit Form 51' proposal gives certainty, but a later name may be the safer one and an earlier registered trademark may exist. Conflicts should be assessed for clinical risk, with the filing date as a tie-breaker.

4. Risk tiering. Scrutiny should be strongest for high-alert and narrow-therapeutic-index medicines, for names that share strengths or doses with existing products, and for drugs likely to be dispensed without a prescriber's direct involvement.

5. Post-market correction. Name-related error reports should be collected and published through the pharmacovigilance system, and the regulator should have power to require a name change where errors

occur, as happened with Trintellix. The Trade Marks Act could allow a health authority to seek rectification in the public interest, rather than leaving that step to commercial rivals.

6. Technology with human review. Automated screening can handle large volumes but cannot replace review by pharmacists and prescribers, who understand clinical context.

7. A caution on abolishing brand names. Brennan proposes replacing brand names and trade dress with generic names plus manufacturer marks, and she notes India's 2012 consideration of a ban.61 The proposal would remove both forms of confusion, but it raises serious legal questions. In India, a bar on using a registered mark would have to satisfy article 19(6) of the Constitution as a reasonable restriction on the freedom to trade, and article 20 of the TRIPS Agreement prohibits unjustifiable encumbrances on the use of marks, although the Doha Declaration affirms that TRIPS should be interpreted so as to support public health.62 A more modest step is to give the generic name greater prominence on labels and prescriptions.

X. Critical Analysis

A. Is Trademark Law Alone Sufficient?

It is not. Trademark law protects commercial identifiers and is enforced by competitors; its remedies are private, its test probabilistic and its timing late. Patient safety requires a regulator with clinical expertise acting before launch and after error reports. India's 2019 amendments recognise this, but they implement it through a self-certification that borrows trademark vocabulary (search of the registry, 'similar' names) without a clinical method.

B. A Higher Threshold: Arguments and Costs

There are respectable objections to a stricter standard. It may raise clearance costs, especially for smaller firms. Safety arguments can be used strategically by established firms to block competitors and extend exclusivity, a concern at the centre of Brennan's analysis. And the 2026 decisions show that a rigid presumption would be unjust where products plainly differ and years of co-existence show no confusion. These objections explain why the higher standard should be confined: it should apply to resemblance 61Brennan (n 1) 3–4 and 36–40. 62Constitution of India, arts 19(1)(g) and 19(6); Agreement on Trade-Related Aspects of Intellectual Property Rights (1994), arts 8 and 20; Declaration on the TRIPS Agreement and Public Health (Doha, 2001), para 4; Brennan (n 1) 45–47.

between different drugs in the same clinical setting, be supported by evidence (error reports, phonetic analysis, expert views), and not extend to products containing the same molecule.

C. Commercial Rights and Public Health

Manufacturers' investment in brand identity deserves protection. But a mark is a monopoly in a word, justified by the public benefit of reducing consumer confusion; when a mark is itself a source of confusion that threatens health, it undermines its own rationale. Where serious confusion is reasonably foreseeable, public health should prevail.

D. A Unified Model

The Trade Marks Registry and the drug regulator should not operate in isolation. The aim is not to turn the Registrar into a drug regulator, but to design a shared process in which each body does what it does best and information flows between them before a name reaches the market.

XI. Conclusion

Pharmaceutical trademarks occupy a unique position because confusion about a drug name can have consequences far beyond commercial loss. Confusingly similar names create risk at every stage of the medication-use chain, from prescribing to dispensing, administration and self-medication, and the harm is

greatest for the drugs where error is least forgiving. Indian courts have recognised this. From Amritdhara to Cadila and the recent High Court decisions, deceptive similarity has been applied to medicines with growing care, and Cadila states clearly that a stricter approach is required. Equally, the recent cases show that the standard is contextual and evidencedriven, not a presumption. But litigation after a name enters the market is the least effective way to prevent harm. India has also taken regulatory steps: the 2019 Form 51 undertaking, the SUGAM database, and the DCC's recent recommendations and consultation. These steps are welcome, but they have not yet supplied a prescribed similarity method, clinical review of names, or a post-market power to require a change. The paper has therefore proposed verified screening, integration of the trademark and drug-licensing registers, risk-based conflict resolution, risk tiering, post-market correction and technological tools subject to human review. Drawing on Brennan, it has also argued that the stricter standard should be confined to resemblance between different drugs, since branding that separates identical drugs causes a different harm: confusion about equivalence, adherence and cost. The paper's limits should be acknowledged. It relies on doctrinal sources, on US behavioural research and, for the most recent Indian developments, on secondary reports; and India lacks published data on name-related medication errors. Empirical study of LASA incidents in Indian hospitals and pharmacies is the most valuable next step. Ultimately, pharmaceutical trademark protection should be understood not only as protection of commercial goodwill but as a component of patient safety and public health.

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