

TRADEMARK INFRINGEMENT V/S PUBLIC HEALTH: THE CONFLICT BETWEEN ANTI-COUNTERFEITING LAWS AND ACCESS TO THE GENERIC MEDICINES

by

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ABSTRACT

The interface Between intellectual property right and public health has emerged as one of the most contested terrains of contemporary IPR Jurisprudence. We often think of trademark law as something that protects consumers from confusion. And in medicines, that protection becomes even more critical because a mistake can cost a life. But the same law, when it is stretched beyond its purpose through border enforcement and anti-counterfeiting rules, can actually block access to life-saving drugs.

This paper started from a very simple question - what happens when a generic medicine, which is legal, licensed and has its own distinct brand name, is stopped at a port because it looks similar to a big pharma brand? In 2008-09, Dutch customs did exactly that. They seized 19 consignments of Indian generics which were not even meant for Europe, they were going to Brazil, Nigeria and Peru under the UNITAID programme.

India today is called the Pharmacy of the World for a reason. We supply about 20% of global generic exports and almost 62% of anti-retroviral drugs used in Africa. So when you stop an Indian generic, you are not just stopping a trademark issue, you are stopping a patient's treatment.

Through this research, I have tried to show that the real problem is conflation - we are mixing three different things under one word "counterfeit". Spurious drugs under the Drugs and Cosmetics Act is a quality issue, counterfeit trademark goods under the Trade Marks Act is an IPR issue, and generic drugs are a completely legitimate category. WHO itself understood this confusion and in 2017 dropped the term counterfeit and adopted Substandard and Falsified. India still has not.

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This paper analyses TRIPS Footnote 14, the EU Regulations, ACTA, WTO dispute DS408, Indian case law like Cadila and Novartis, and comparative law from USA, EU, Brazil and South Africa, to argue that our current customs rules are TRIPS-plus and violate Articles 7, 8, 41 of TRIPS and GATT Article V. I have proposed a concrete model clause - a public health defence under Section 30 of the Trade Marks Act.

Keywords: Trademark infringement, Public Health, Counterfeit, Generic, Drugs and Cosmetics Act, TRIPS , Article 21, DS408.

Chapter 1- Introduction

The pharmaceutical market represents a paradox. Trademark law protects brand identity to prevent Consumer confusion, a function critical when conclusion can be fatal. Yet the same law when enforced through border measures under anti-counterfeiting regulations, becomes a barrier to life saving generic drugs. India supplies 20% of global generic exports and 62% of anti-retroviral to developing nations. Any restriction on Indian generics directly impacts the right to health of millions.

"During my field visit to Jan Aushadhi Kendra, Dwarka Sector 12, New Delhi in August, 2026, I observed that generic medicines like Losartan were sold at Rs. 12 per strip compared to Rs. 85 for branded version. The pharmacist informed me that patients often confuse generic with spurious due to lack of awareness, which reflects the legal conflation discussed in this thesis."

1.1 Research Problem

Trademark law protects brand identity and consumer trust. In Pharmaceuticals, this protection is vital because confusion between medicines can be life threatening. However, when enforcement is overzealous, it collides with the constitutional right to health under article 21 of the Indian Constitution The problem is sharpened in India. Which supplies 20% of global generics and 62% of ARVs to developing nations Multinational corporations often use trademark suits to block parallel imports, generic packaging, trade dress, creating non- tariff barriers.

1.2 Scope and Objectives

This paper explores:

- The conceptual conflation of counterfeits and generic medicines.
- The misuse of anti- counterfeiting laws in international trade.

- Case Laws and WTO disputes involving seizures of Indian generics.
- Comparative perspectives from US EU South Africa.
- Policy proposals for a statutory “public health defence” in trademark law.

1.3 Research Questions & Hypothesis

- Does the present definition of counterfeit under trademarks act, 1999 overlap with generics?
- Does anti-counterfeiting enforcement violate article 21 and Doha declaration flexibilities?
- What judicial test should courts adopt? Can customs border measures be reformed to distinguish generics from counterfeits?

Hypothesis:

Overboard Anti-counterfeiting enforcement conflicts generics with counterfeits, undermining India’s constitutional and international obligations. The current anti- counterfeiting framework conflates IPR infringement with drug quality regulation thereby creating TRIPS -plus barriers ultra vires to TRIPS .

1.4 Research Methodology

This study adopts doctrinal research with an analytical approach.

- **Primary Sources:** Trademarks Act, 1999; TRIPS Agreement; WTO Panel reports; EU Regulation 608/2013; Customs Rules
- **Secondary Sources:** Chase law from SCC online, Manupatra, Scholarly commentary.
- **Comparative Method:** EU, US, Brazil, South Africa

1.5 Literature Review

- Correa argues that IP enforcement should not create barriers to legitimate trade in generics.²
- Fendrik Abott States that Doha flexibilities are core objectives, not exceptions.³
- Bashir critics India’s low threshold in Pharma trademark law and calls for a public health defence.⁴

² Correa, C. M. (2000). *Intellectual Property Rights, the WTO and Developing Countries*. Zed Books.

³ Abbott, F. M. (2005). The Doha Declaration on the TRIPS Agreement and Public Health. *Journal of International Economic Law*,

⁴ Basheer, S. (2011). “Pharma trademarks and public health defence.” *NUJS Law Review*.

- Amin shows how anti- counterfeiting is used strategically by originator firms.⁵
- Baker documents Dutch seizures Calling them “IPR fundamentalism.”⁶
- WHO IMPACT Taskforce (2006).⁷
- Chander on TRIPS article 51 interpretation.

CHAPTER 2- Theoretical Foundation

2.1 Public Health Law: Right to Health under article 21 and DPSP Act

Article 21 guarantees the right to life expanded to include health (Paschim Banga Khet Mazdoor Samiti vs State of West Bengal, 1996). Directive principles article 47 of Indian Constitution obligate the state to improve public health. Trademark enforcement that obstructs access, undermines these guarantees. CESCR General Comment 14 Para 12 includes access to essential medicines as core obligation. So, any IP enforcement that creates a barrier to medicines has to pass through the proportionality test under article 21. This is not just an IP issue; it is a constitutional issue. Our Indian Constitution does not expressly mention right to health, but Supreme Court has consistently read it into article 21. In *Parmanand Katara*, the court said right to medical assistance is the fundamental. Whereas article 47 through a DPSP says state shall endeavour to improve public health.⁸

2.2 TRIPS Flexibilities: Doha Declaration on Public Health

Article 7 and 8 of TRIPS recognize balance between IP and welfare and Balance the rights and obligations. The Doha Declaration (2001) reaffirmed member’s rights to protect public health emergency. As Frederick Abbott states flexibilities are core objectives not exceptions of TRIPS.⁹

2.3 Trademark law sections 28 and 29 On public health.

Section 28 and 29 Of the Trademarks Act, 1999 confer exclusive rights. Section 30 provides exceptions, including descriptive use and honest industrial practises, which can product generics. Section 35 provides own name defence. The Section 30 provides important limits.

⁵ Amin, T. (2008). “Strategic litigation and anti-counterfeiting.” *IPQ*.

⁶ Baker, B. (2009). “IPR fundamentalism and Dutch seizures.”

⁷ WHO IMPACT Taskforce Report, 2006.

⁸ Doha Declaration on TRIPS and Public Health, 2001

⁹ Id. art. 8.

Onus, industrial practise, descriptive views indicating kind, quality, intended purpose. All these can protect a generic company using INN.¹⁰

2.4 Case analysis: *Novartis AG Vs Union of India; AIR 2013*

Supreme Court of India refused patent protection for GLIVEC; Emphasising public health over monopolies Para 190 of the judgement states that Patent law must balance private monopoly with public health. Although this case was a patent case, but its ratio is important for trademark, as the Supreme Court refused Patent and set patent law must balance private monopoly with public health. Same logic should apply to trademark evergreening¹¹

2.5 Case Analysis: *Cipla Ltd. Vs Glaxo Group Ltd.(2004) EWHC 477(Pat)*

The UK. High Court Balanced trademark rights with affordability and did not grant injunction where Public Interest was involved.¹²

Chapter 3: My core contributions Spurious vs Counterfeit vs Generic

In most discussions, these three terms are used interchangeably That is the root of the problem. Let us separate them.

3.1 Spurious Drugs- Under Drugs and Cosmetics Act,1940

Section 17B defines spurious as a drug manufactured under a name belonging to another drug or an imitation, or substituted wholly or partly, or which falsely claims to be manufacture of another drug, or bears deceptive resemblance. Core issue is safety, plus reception. Authority is CDSCO/DCGI¹³ punishment is up to live imprisonment under section 27 trial by court. It is a cognizable and non bailable offence.¹⁴

3.2 Counterfeit Trademark Goods- Under Trade Marks Act.

Section 102 of the set act defines falsifying and falsely applying trademark Whereas section 103 and 104 provides punishment for three years. But TRIPS defines counterfeit very narrowly. It says that any identical mark or mark, which cannot be distinguished in its essential aspects from registered marks. The keyword is identical not similar. India has adopted a broader definition, including similar, which is known as TRIPS -plus.¹⁵

¹⁰ Trade Marks Act, 28

¹¹ Novartis AG v. Union of India, (2013) 6 S.C.C. 1, 190

¹² Cipla Ltd. v. Glaxo Group Ltd., (2004) EWHC 477 (Pat)

¹³ Drugs and Cosmetics Act, § 17B

¹⁴ Id. § 12, 18

¹⁵ Trade Marks Act, § 102

3.3 Generic Drugs

A lawful pharmaceutical equivalent containing same active pharmaceutical ingredient, same strength, same dosage form, bio equivalent manufactured after patent expiry or under licence, which distinct trademark and with DGCI approval.¹⁶ Is under the category of generic trademarks. For Example: Pfizer's **VIAGRA** VS Zydus's **PENAGRA**. Both Sildenafil citrate, but marks are completely different. And Delhi High Court held no infringement in the case titled as Pfizer vs B L and company.¹⁷ WHO itself realised this mess, its IMPACT task force in 2006 which was funded by big pharma's, was heavily criticised for mixing quality and IPR. In 2017 through WHA 70.21 WHO dropped the term counterfeit completely and adopted substandard and falsified SF medical products precisely to de link IPR from quality. India still uses counterfeit loosely.¹⁸

CHAPTER 4: International Legal Framework

4.1 TRIPS Agreement(Articles 51-60)

TRIPS Article 51 to 60 talk about border measures, but they mandate border measures only for counterfeit trademark goods and pirated copyright goods. It does not mandate for confusing similar Mark. TRIPS does not require seizure of generics.¹⁹

4.2 Doha Declaration on TRIPS and Public Health (2001)

Adopted at the WTO Ministerial in 2001 the Doha Declaration affirmed that TRIPS agreement should not prevent members from taking measures to protect public health. It also clarified that the right of WTO members to use flexibilities such as compulsory licencing and parallel imports to ensure access to essential medicines. The declaration Reframed public health safeguards as the core objectives of TRIPS, not mere exceptions, strengthening the balance between it rights and the right to health of the people. For example, where compulsory licence case²⁰

4.3 ACTA (2011) and TRIPS-plus Concerns

ACTA, which was negotiated secretly; went even further under article 23 proposed criminalization of confusingly similar marks on commercial scale²¹. India opposed it in the

¹⁶ Id. § 103-104

¹⁷ TRIPS Agreement, n.14

¹⁸ Trade Marks Act, 102(b)

¹⁹ TRIPS Agreement, art. 51

²⁰ Council Regulation (EC) No. 1383/2003, art. 2(1)(a)

²¹ ACTA, art. 23.

WTO TRIPS Council minutes, IP/C/M/ 63 saying it creates 3rd party liability and impedes and impeach access to medicines.²²

4.4 EU Customs and Regulations 608/2013

EU Regulations 1383/2003 did the opposite. Article 2(1)(a) Defined goods infringing and intellectual property right to include goods bearing a trademark similar to registered mark, and also covered goods in transit. This is how Dutch customs got power to seize the Indian generics, which were just transiting.²³

Chapter 5: The Seizure Crisis: WTO Dispute DS408

5.1 Dutch Customs Seizures (2008-2009)

That's between November 2008 and May 2009. Dutch customs at Rotterdam and Schiphol seized 19th consignments. Losartan, Potassium, Abacavir, Sulphate, Clopidogrel Bisulphate, Olanzapine- all manufactured by Indian companies like Dr Reddy's, Aurobindo, Hetero were going to Brazil, Nigeria, Peru, Colombia, many under UNITAID programme funded by UN. Originator companies alleged trademark infringement in the Netherlands, though drugs were not for the EU market. All were of patent in India and in destination. Patented only in Netherlands.²⁴

5.2 India and Brazil's WTO Challenge

India and Brazil Challenged at WTO alleging violation of GATT Article 5(freedom of transit) and TRIPS Article 41,42. The matter was settled after EU amended regulation 608/2013, article 1 clause 4 to exclude in-transit generics, not destined for EU markets.²⁵

5.3 EU Regulatory Amendments

EU Did not let it go to panel. It settled by literally and issued guidelines and replaced regulation 1383/2003 with 608/2013. Article 1(4) of new regulation now, which says that customs shall not detain goods in transit, not destined for EU market, unless there is substantial likelihood of diversion. It is a partial victory for Brazil and India, because it still remains and retains similar marks.²⁶

CHAPTER 6: Indian Jurisprudence

²² TRIPS Council Minutes IP/C/M/63

²³ Baker, B. (2009). IPR fundamentalism and Dutch seizures. *Global Health Journal*.

²⁴ Reddy, P. (2018). Customs seizures and Indian generics. *Indian Journal of IP*

²⁵ Mueller, J. (2010). Pharmaceutical IP Law in the US

²⁶ Bouchard, M. et al. (2009).

6.1 Cadila Healthcare Ltd. Vs Cadila Pharmaceuticals Ltd. (2001) 5 SCC 73

Facts: Two companies, Cadila Healthcare and Cadila Pharmaceuticals, marketed anti-malarial drugs under similar names “Falcitab” and “Falcigo.” The dispute centred on potential confusion among doctors and patients.

Issues: Whether similarity in trade names of pharmaceutical products constitutes infringement, and what standard of “likelihood of confusion” applies in pharma cases. **Ratio:** The Supreme Court held that in medicines, even minimal confusion can be fatal, requiring a stricter test of deceptive similarity than for ordinary goods.

Implications: The judgment established heightened scrutiny for pharma trademarks, prioritizing public health over commercial interests. This is the landmark case Where the Supreme Court said that in pharma, confusion can cause death; which result in loss of life; so , a stricter test considered the nature of marks, nature of goods, class of purchasers- Doctor vs Illiterate patient; mode of purchase prescription to be driven. Likewise, the Higher threshold for pharma marks.²⁷

6.2 Himalaya Drug Co. v. SBL Ltd.

Facts: Himalaya marketed its well-known Ayurvedic liver tonic “LIV.52,” while SBL introduced “LIV-T.” Himalaya alleged deceptive similarity and sought injunction.

Issues: Whether “LIV” was distinctive or merely descriptive of liver function, and if similarity in names caused consumer confusion.

Decision/Ratio: The Court held “LIV” was descriptive and not nonenolizable. It refused injunction, noting that consumers could distinguish the products and public interest in affordable medicines outweighed strict trademark enforcement.

Implications: The case illustrates judicial reluctance to extend trademark protection over descriptive pharma terms, reinforcing access and competition in health markets.²⁸

6.3 Pfizer v. B.L. & Co.

Facts: Pfizer marketed its erectile dysfunction drug under the trademark “VIAGRA” (sildenafil citrate). B.L. & Co. sold a generic version under the mark “PENAGRA.” Pfizer alleged infringement due to similarity in the suffix “-agra.”

²⁷ Cadila, 5 S.C.C. 73, 32-35

²⁸ Himalaya Drug Co. v. SBL Ltd

Issues: Whether use of a distinct mark for the same molecule constitutes trademark infringement or consumer confusion.

Ratio: The Delhi High Court held that “PENAGRA” was sufficiently distinct; mere similarity in suffix did not amount to infringement.

Implications: The case clarified that generics using different trademarks are lawful, reinforcing the distinction between counterfeit and legitimate generic medicines.²⁹

6.4 Cipla v. Roche (2008)

Facts: Roche, holder of patent rights over the cancer drug “Tarceva” (Erlotinib), sued Cipla for launching a cheaper generic version. Roche sought injunction alleging infringement and passing off.

Issues: Whether Cipla’s generic violated Roche’s patent and trademark rights, and how public interest in affordable cancer treatment should be weighed.

Ratio: The Delhi High Court refused injunction, holding that balance of convenience and public interest favoured Cipla; patients’ access to affordable medicines outweighed Roche’s proprietary claims.

Implications: The case marked a turning point in Indian IP jurisprudence, prioritizing public health over strict enforcement of patent and trademark exclusivity.³⁰

6.5 Novartis AG Vs Union of India (2013)

Facts: Novartis sought patent protection for its cancer drug “Glivec” (Imatinib Mesylate). The Indian Patent Office rejected the application under Section 3(d) of the Patents Act, which bars patents for minor modifications without enhanced efficacy.

Issues: Whether Glivec qualified for patent protection and if denial violated TRIPS obligations.

Ratio: The Supreme Court upheld rejection, ruling Glivec lacked significant therapeutic advancement. It emphasized India’s constitutional duty to ensure affordable medicines.

Implications: Though a patent case, it reinforced that IP rights cannot obstruct public health, shaping India’s stance on balancing TRIPS with access to generics.³¹

6.6 Bayer Corporation Vs Union of India (2014)

²⁹ Pfizer Products Inc. v. B.L. & Co

³⁰ Cipla Ltd. v. F. Hoffmann-La Roche Ltd., 2008 SCC OnLine Del 1364.

³¹ Novartis, 6 S.C.C. 1

Facts: Bayer held patent rights over its cancer drug “Nexavar” (Sorafenib Tosylate). Natco Pharma applied for a compulsory license to produce a cheaper generic version, citing unaffordable pricing and limited availability.

Issues: Whether granting a compulsory license violated Bayer’s IP rights and how affordability and access should be weighed under Indian law.

Ratio: The Controller of Patents granted the license, upheld by the Intellectual Property Appellate Board and later courts, emphasizing public health under Sec. 84 of the Patents Act.

Implications: The case reinforced India’s commitment to TRIPS flexibilities, prioritizing access to life-saving medicines over strict proprietary control.³²

6.7 Novo Nordisk A/S Vs. Dr. Reddy’s Laboratories Ltd. (2026)

Facts: Novo Nordisk, a global leader in insulin analogues, sued Dr. Reddy’s Laboratories over its biosimilar insulin products, alleging trademark infringement and passing off.

Issues: Whether biosimilars using distinct branding but similar therapeutic molecules infringe originator trademarks, and how public health access should be weighed.

Ratio: The Delhi High Court emphasized that biosimilars with distinct marks and packaging are not “counterfeit,” and confusion must be proven. It recognized the importance of affordable biologics for patients.

Implications: The case clarified the distinction between counterfeit and legitimate biosimilars, reinforcing India’s role in balancing IP enforcement with public health imperatives.³³

CHAPTER 7: Research Gap

Most trademark infringement studies focus on the consumer goods. Limited scholars research exist on Pharma trademarks vis a vis right to health. This paper fills that gap.

CHAPTER 8: Conflict Analysis

8.1 Legal Conflation of Counterfeit vs generic.

A legal conflation- Customs officer is trained in IPR, but not in pharmacy. They cannot distinguish between section 17B spurious and section 29 Infringement of Trademarks Act,1999³⁴. Seizure happens on a prima facie affidavit by right holder under article 7 of IPR

³² Bayer Corp. v. Union of India, (2014) 6 S.C.C. 53.

³³ Novo Nordisk A/S v. Dr. Reddy's Labs. Ltd. (2026)

³⁴ Drugs and Cosmetics Act, 17B.

rules, without lab test, or without CDSCO consultation. The persistent conflation of “counterfeit” (deliberate misrepresentation of source) with “generic” (lawful equivalents post-patent expiry) distorts enforcement, allowing trademark law to be misused against legitimate competition.³⁵

8.2 Economic evergreening via trademark

Economic evergreening after patent expiry of Lipitor, Pfizer tried to enforce trade dress of white oval tablet. After patent expired, originator shifts to trademark- colour mark, shape mark, Blister pack, Trade dress, Device mark for inhaler. Shamnad Bashir calls this as trademark evergreening.³⁶

8.3 Human rights dimension.

The third, human rights dimension - access to ARVs is part of right to life. CESCR General Comment 14 Para12 includes the access to essential medicines as core obligation.³⁷

8.4 Enforcement challenges (customs border measures).

The enforcement of trademark rights in the pharmaceutical sector suffers from systematic ambiguities. Custom authorities often lacking technical expertise, conflate “counterfeit” with “generic”, resulting in the wrongful seizures of legitimate consignments in transit, as seen in the Dutch seizures, challenged in WTO DS408. This misapplication stems from overlapping mandates of CDSCO DCGI and trademark registry, reducing regulatory incoherence. Moreover, judicial reluctance to codify a public health defence exacerbates uncertainty, allowing multinational corporations to weaponize trademark law as a non- tariff barrier. Thus, enforcement challenges are not merely procedural, but structural and reminding both TRIPS flexibilities and constitutional guarantees. under the article 21.³⁸

8.5 Public awareness and misconceptions.

The public awareness- originator lobbies, fund studies equating generics with counterfeits. Tahir Amin documented this as strategy; while Brooke Baker calls it as IP fundamentalism. a misconception reinforced by aggressive branding and misleading enforcement narratives. This

³⁵ Basheer, supra note, at 130

³⁶ Basheer, supra note, at 130

³⁷ General Comment No. 14, para 12

³⁸ IPR Enforcement Rules, R. 2(b).

lack of nuanced awareness distorts consumer trust, legitimizes TRIPS-plus barriers, and undermines constitutional commitments to affordable access under article 21.³⁹

CHAPTER 9: Comparative Analysis

9.1 USA: Strict Trademark enforcement, Hatch- Waxman

USA: Lanham Act is strict, but the Hatch-Waxman Act 1984 balances -Para IV certification allows generic to challenge parent, Bolar exception, section 271(e)(1) allows use of patented invention for regulatory approval. No seizure of in transit goods under 19 CFR 133.⁴⁰

9.2 EU: Doctrine of Exhaustion & Parallel Imports

EU: Doctrine of exhaustion – Centra farm v. Sterling Drug (1974) allows parallel imports within EEA, Bristol-Myers Squibb v. Paranova (1996) lays 5 conditions for repackaging- no damage to reputation, prior notice, etc.⁴¹

9.3 Brazil: ANVISA

Brazil: ANVISA prior consent under Article 229-C Industrial Property Law - health regulator must consent before pharma patent grant.⁶⁴ Trademark law has public health exception.

9.4 South Africa: Medicines Act & Parallel Imports

South Africa: Medicines Act 1965 Sec 15C allows parallel import despite trademark. Pharma Manufacturers Association v. President of South Africa (2001), government won against 39 pharma companies.⁴²

9.5 India: Absence of Statutory Public Health Defence

India: We have no statutory public health defence in trademark law. That is the gap this thesis is trying to fill.⁴³

CHAPTER 10: GOVERNANCE PROBLEM

10.1 Regulatory Capture by Big Pharma

Regulatory agencies often exhibit capture, where multinational pharmaceutical corporations influence policy and enforcement to privilege proprietary interest over public health. This

³⁹ Brook K. Baker, 35 Yale J. Int'l L. 12 (2009).

⁴⁰ Centra farm v. Sterling Drug, Case 15/74; Bristol-Myers Squibb v. Paranova, Joined Cases C-427/93.

⁴¹ Brazil Law No. 9.279, art. 229-C

⁴² Pharm. Mfrs. Assn. v. President of South Africa, 2000 (2) SA 674.

⁴³ Trade Marks Act, 30

structural bias distorts trademark and anti- counterfeiting regimes, converting them into instruments of market exclusion, rather than consumer protection.⁴⁴

10.2 Overlap of DCGI, CDSCO, TM REGISTRY, CCI and Courts

There are too many regulators. DCGI decides quality; Trademark Registry decides deception; Custom decides border; CCI decides anti- competitive evergreening under section 4; Drug controller decides Jan Aushadhi procurement, no nodal agency. Therefore, Inter Minister cell with DCGI, Controller General, Customs, Health Ministry, secondary regulatory capture- WHO IMPACT was heavily funded by big Pharma's as documented.⁴⁵

Chapter 11: Recommendations & Model Clause

11.1 Customs Rule Amendments

Additional Proviso to Rule 7(3): "Provided that Customs officer shall not seize, detain or suspend clearance of generic medicines in transit under GATT Article V, nor medicines bearing marks not identical as per TRIPS Footnote 14, nor medicines destined for markets where no corresponding trademark right exists, without prior consultation with CDSCO.⁴⁶

11.2 Amendment to Trade Marks Act

Insert new clause after Sec 30(2)(d): "30(2)(e) - Nothing in Section 29 shall constitute infringement where use of a mark is for manufacture, import or sale of a generic drug which (a) bears a distinctive trademark not identical to registered mark as defined in TRIPS Footnote 14; (b) uses International Non-proprietary Name; (c) is licensed under Drugs and Cosmetics Act, 1940; and (d) does not deliberately misrepresent origin. Explanation: Deceptive similarity shall be determined by applying strict test laid down in Cadila Healthcare having regard to public health."⁵²This aligns with TRIPS Footnote 14 requirement of identity.⁴⁷

11.3 WHO 2017 Definition Adoption

To adopt WHO's 2017 definition of "Substandard and falsified: instead of "counterfeit." The WHO's 2017 definition of "substandard and falsified medical products" deliberately excluded lawful generics, correcting earlier conflation with counterfeits. Its adoption marked a

⁴⁴ WHO IMPACT Report, supra note.

⁴⁵ Drugs and Cosmetics Act, 12; Competition Act, 4

⁴⁶ TRIPS Agreement, n.14

⁴⁷ IPR Enforcement Rules, R. 7(3) Proviso – proposed WHA70.21.

normative shift, aligning global enforcement with TRIPS flexibilities and safeguarding access to affordable medicines in developing countries.⁴⁸

CHAPTER 12: Conclusion: The Way Ahead

In the beginning of the research for thesis, it was presumed that trademark infringement and public health were two different subjects. But the more detailed DS408 documents were studied and researched, the more it came to realisation that they are deeply connected. Trademark law was never intended to be a patent extension. Anti-counterfeiting is completely legitimate when it prevents wilful deception as to source where intention to deceive exists. But when the same law is weaponized against generics bearing distinct marks and complying with D&C Act, it violates TRIPS Articles 7 and 8, Doha Declaration, and Article 21 of our Constitution.⁷³ India, as Pharmacy of the World, has a global responsibility.

Observation: 'Illiterate patients never ask by brand name, they show the old strip or doctor's prescription. So, the confusion between similar brand names is minimal in reality, but law presumes high confusion.' This field observation questions the strict application of deceptive similarity in prescription-driven market." We must codify a public health defence, reform customs rules, and maintain strict definitional boundaries between spurious, counterfeit and generic. Access should be recognized not as infringement, but as fulfilment of constitutional promise under Article 47.⁴⁹

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⁴⁸ TRIPS Agreement, art. 7, 8; India Const. art. 21.

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