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REVISITING THE JUSTIFICATION OF TRADEMARK PROTECTION FOR SINGLE DRUG COMPOSITIONS: A CRITICAL ANALYSIS FROM A REGULATORY PERSPECTIVE

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I. INTRODUCTION

Every day, the average consumer encounters trademarks through a product's or service's names, either through use or via advertisements indicating the source of origin and the product or services' quality. According to the conventional justifications for trademark protection, a trademark differentiates the products to eliminate consumer confusion and

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to assure consumers of the uniform quality of the trademarked product. Earlier, the trademarks were restricted to the word, device, label or any other visual identifier of the company. Nowadays, considering the trademark's potential to enhance the brand's equity, trademarks have expanded to include nontraditional features, such as sound, shape, smell, color, hologram, position mark, or taste mark. Hence, the trademarks not only assure consumers of good's or service's quality but are also used as a marketing tool. In this way, trademarks serve four primary functions: (1) indicating the source of origin, (2) distinguishing the goods and services from others, (3) assuring the consumers of the quality of the product, and (4) advertising the product in the market.

Like other consumer-oriented fields, pharmaceutical companies use trademarks as a brand strategy to help consumers identify their products as a familiar choice. The pharmaceutical sector is a high-technology, knowledge-intensive, and heavily regulated industry that includes the distinctive drug nomenclature system. Since a drug is identified by three names: a chemical name, generic name and proprietary name. In this sector, a brand name, or proprietary name, differentiates the product from other available alternatives in the market, thereby reducing the consumer's search cost while increasing their loyalty.

The pharmaceutical industry has a two-tier structure: branded and generic. The first and the larger tier is comprised of multinational entities and large companies that invest majorly in the research and development (R&D), allowing them to hold the majority of patents in the sector. The second tier is majorly comprised of smaller firms that manufacture off-patented products or are under license to a patent-holder and hold a smaller share in the patent segment. Through this two-tier system, final products are marketed as branded, generic, and branded-generic. Here, when a trademark is assigned to a patented drug by the innovator drug company it is referred as a branded drug, whereas a generic drug product is marketed solely by its generic name. On the contrary when trademarks are applied to generic drugs, it is known and marketed as branded-generic products.

As a marketing tool, trademarks are used as a part of sales strategy by the innovator drug companies that establish the brand name during patent protection. After a patent expires, a branded drug is substituted with a generic drug so that a prescription drug having the same active ingredient is available in the market for consumers. In the branded-medicine market, trademarks play an important role, allowing consumers to identify and differentiate between all available options. The definition of consumer changes with the nature of the medication—prescription-

based or over-the-counter (OTC). Consumers can only obtain prescription drugs by showing a prescription written by a medical practitioner, whereas consumers may purchase OTC drugs directly with no restrictions. Hence, a medical practitioner gets to choose the marketed prescription drug for their patients, whereas a consumer chooses their OTC drugs. Therefore, the availability of myriad alternative brands with similar chemical composition may create artificial product differentiation, hence confusion in product selection.

In this context, the authors of this paper have analyzed the divergent views of legal scholars on the use of trademarks for product differentiation of formulaically similar or bioequivalent products. There are two general views among these scholars: protectionist and restrictionist views. Scholars with a protectionist view support trademark protection for products that are formulaically similar or bioequivalent in nature, whereas legal scholars with a restrictionism approach have criticized its persuasive effects on consumers. For comprehensive understanding, the marketing strategies adopted by the branded drug and branded-generic manufacturers have also been studied, that reflects on how companies utilize trademarks to market a single formulation in different ways. Thereby encouraging consumers to ask for advertised medicines (branded drugs) over substitutable cheaper generic drugs. Consequently, widening the demand gap between the branded and generic drugs, especially where the marketed drug is approved by the Food and Drug Administration (FDA) on the set parameters of quality and safety. Further, this paper analyzes the effect of such trademark expansion in the branded pharmaceutical sector from the United States' market practices and regulatory perspectives. Similarly, to study the impact on market and consumer health through the lens of the branded-generic sector, this paper analyzes the regulatory interventions in India and compares them with the scholars' views.

This paper is divided into four segments—the first segment details legal scholars' views on using trademarks to differentiate chemically equivalent products. The second explains the drug nomenclature system to understand the scientific equation of branded and branded-generic with generic naming of a drug. The third highlights industry practices and regulations, if any, in the branded and branded-generic markets of the United States and India, respectively. Finally, the paper concludes with the solutions suggested by legal scholars and regulatory authorities towards resolving the challenges arising from using trademarks for similar drugs.

II. RATIONALE FOR TRADEMARK PROTECTION: DIFFERENTIATION VERSUS ARTIFICIAL DIFFERENTIATION

Trademark law has evolved from tort law, protecting consumers from unfair competition and deception.[1] As a result, the conventional justification for trademark protection is two-pronged: to ensure that trademarks minimize consumer confusion and that manufacturers maintain consistent product quality. Gradually, with the development of means of communication, trademarks' significance and subject matter of protection substantially broadened. The value of modern trademarks began to rest in their selling power. Acting as a link between the owner and the consumers, trademarks are ultimately based on the quality and merit of the goods or services.[2]

At the primary level, a trademark is a distinctive mark in the form of name, packaging, label, device, or other physical feature, that indicates a particular product's origin and distinguishes it from others.[3] In doing so, the trademark advertises the product and enables consumers to differentiate it between the alternate goods available in the market and also reduces the search cost. In this way, the trademark balances the interest of proprietors and consumers. Nevertheless, there still subsists a scholarly debate regarding the scope of trademark protection and its impact on consumers' interest.

Companies essentially use trademarks as an advertising function, which helps differentiate a product and establish its position in the competitive market. According to legal scholars, through product differentiation, companies can carve out a separate market for their products. Companies can even manipulate the demand, price, and output of a product—within legal limits—by channeling the advertising function of trademarks.[4] In the view of scholars with restrictionism approach, trademarks are being used for persuasion instead of identification.[5] Some scholars oppose this approach, arguing that consumers rely on trademarks as informational devices and nothing more. Therefore, trademarks rather

1. Mark McKenna, *The Normative Foundations of Trademark Law*, 82 NOTRE DAME L. REV. 1839 (2007).

2. Frank I. Schechter, *The Rational Basis of Trademark Protection,* 40 HARV. L. REV. 813, 830–31 (1927).

3. J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION, (Clark Boardman Callaghan 5th ed. 1996).

4. EDWARD CHAMBERLIN, THEORY OF MONOPOLISTIC COMPETITION: A RE-ORIENTATION OF THE THEORY OF VALUE (Harvard University Press 1933).

5. Ralph Brown, *Advertising and the Public Interest: Legal Protection of Trade Symbols*, 57 YALE L.J. 1165, 1171 (1948).

encourage manufactures to improve the quality of their products and deter imitators from free-riding on the goodwill of the producers.[6] It is worth noting that, while dismissing the observations of restrictionist scholars on the persuasive function and its influence on consumers' choice, the scholars with protectionist view base their arguments on the consumer rationale, i.e., the significance of trademarks from the quality perspective. Although consumers may not be interested in the chemical composition during product selection, they may be willing to pay a premium for quality assurance.[7] The scholars support trademark protection also from an economic perspective, that it reduces the consumers' "search cost" in the competitive drug market.[8]

In this instance, it is relevant to highlight the concept of the two-fold nature of trademark distinctiveness, as explained by Barton Beebe. The two-fold nature can be observed as *absolute distinctiveness*, that indicates the distinctiveness as to the source of origin, and *differential distinctiveness*, which refers to an informational effect that causes consumers to perceive a particular trademark-protected good as different from the others.[9] Considering both the producers' incentive and ability to manipulate consumers' will through advertisement, Beebe differed from Landes and Posner's economic justification, who supports the trademark protection from an economic perspective, that trademarks helps consumer by reducing their search cost.[10] In the same line, other scholars, like Dorfman and Steiner, identified that a trademark's advertising function creates product differentiation, leading to higher prices.[11]

The debate about actual and artificial product differentiation intensifies when trademarks differentiate chemically similar goods, especially by the pharmaceutical industry to differentiate a branded drug from a bioequivalent generic drug. In this context, scholars Roger Feldman and Felix Lobo observed that if trademarks reduce search costs but increase product differentiation, they may not benefit consumers.[12] When applied to pharmaceutical products, the chance of confusion due to

6. William M. Landes & Richard A. Posner, *Trademark Law: An Economic Perspective*, 30 J.L. & ECON., 265, 269 (1987).

7. *Id.* at 275.

8. Mark A. Lemley, *The Modern Lanham Act and the Death of Common Sense*, 108 YALE L.J. 1687, 1690 (1999).

9. Barton Beebe, *Search and Persuasion in Trademark Law*, 103 MICH. L. REV. 2020 (2005).

10. *Id.* at 2024

11. Robert Dorfman & Peter O. Steiner, *Optimal Advertising and Optimal Quality*, 44 AM. ECON. REV. 826 (1954).

12. Roger Feldman & Felix Lobo, *Competition in Prescription Drug Markets: The Roles of Trademarks, Advertising, and Generic Names*, 14 EUR. J. HEALTH & ECON. 667 (2013).

artificial product differentiation increases. They supported the idea of letting companies use international nonproprietary names (INN), or generic names, to minimize the search costs and product differentiation that may lead to unquestionable consumer benefits. Since, in this way, the private sector would underinvest in common nomenclature because each firm would pay attention only to the effect of language on search costs for its product. [13]

In the pharmaceutical industry, when the patent for a branded drug expires, the authorities introduce a generic name that doctors can apply to any generic equivalent of that drug. If a doctor uses the generic name on a prescription, the pharmacist is free to substitute any appropriate drug, presumably the cheapest one. However, once a doctor prescribes a drug using a brand name, the pharmacist must provide that drug and cannot substitute it with a generic alternative. [14] The influence of advertising and promotion of branded drugs generally led consumers to believe that trademarked medications were distinct from one another and superior to generic drugs. [15] While resolving this problem, Hannah Brennan proposed to replace trademarks with *manufacturers' marks,* that while performing the function of trademark as origin indicator will not be artificially differentiating the bio-equivalent drugs. [16] Following the similar argument, the scholar Jeremy Greene highlighted the negative implications of the practice of using trade-dress that visibly differentiates between the branded and generic drugs, thereby raising doubts in the mind of the patients about the quality of generic drugs. [17] Thereby he suggested to reduce artificial product differentiation by introducing a consistent and organized system of pill appearance to increase patient adherence, that will further reduce the complexity of medication errors, and thereby, he also encouraged the rational use of bioequivalent generic drugs. [18]

The later part of this paper highlights the strategies that are devised by the manufacturers to sustain upward growth and profitability through product differentiation. More and more companies, including both research-based and generic companies, are joining the race to develop differentiated drug products. Trademarks are being used as a tool for

13. *Id.* at 660

14. *Id.* at 673

15. Hannah Brennan, *The Cost of Confusion: The Paradox of Trademarked Pharmaceuticals*, 22 MICH. TELECOMM. & TECH. L. REV. 1 (2015).

16. *Id.* at 20.

17. Jeremy A. Greene, *The materiality of the brand: Form, function, and the pharmaceutical trademark,* 29(2) Int. J. Technol., 210-226 (2013*).*

18. *Id.* at 219.

artificial product differentiation: As a marketing strategy, companies use multiple trademarks to differentiate branded and generic drugs, even though both have the same composition and origin.

In marketing language, this practice is identified as product line extension that forms a part of the life cycle management of a molecule facing extinction owing to generic competition. The next section elaborates upon the nomenclature of a drug, followed by an analysis of the impact of line extension strategy adopted by the innovator drug companies and branded-generic companies that create artificial product differentiation.

III. AN OVERVIEW OF PHARMACEUTICAL NAMING SYSTEM

"A name is a necessity. It distinguishes one thing from dissimilar things. A name also distinguishes one thing from other similar things but not the same."

– Nelson M Gampfer, National Pharmaceutical Council 1961.

Therapeutic use of the same drugs for different medical conditions has been in existence since time immemorial. Until mid-nineteenth century, the drugs were dispensed by pharmacists in the form of raw materials that met pharmacopeial standards.[19] The area of activities were clearly defined, where the role of a manufacturers was restricted to the supply of bulk chemicals to the pharmacist, and after careful evaluation the final drug formulation were being prepared and dispensed by the pharmacist to the patients. Later, with the development of the synthetic dyestuffs industry, advertisement became a common practice.[20] Regulations have evolved gradually over time. Since the chemical names of these drugs were complex and difficult to remember, it was necessary to develop simple names that would help to identify the chemical composition of drugs. Hence, it led to the development of nonproprietary names.[21]

The practice of naming can be traced back to 1784 in Germany, where a pharmacopeia was created by compiling and publishing the catalogs of drugs, Subsequently, pharmacopeias were adopted for uniform

19. Alan Wayne Jones, *Early drug discovery and the rise of pharmaceutical chemistry*, 3(6) Drug Test Anal. 337-44 (2011).

20. Jan R. McTavish, *Aspirin in Germany: The Pharmaceutical Industry and the Pharmaceutical Profession*, 29 PHARM. HIST. 103 (1987).

21. WORLD HEALTH ORGANIZATION, GUIDANCE ON THE USE OF INTERNATIONAL NONPROPRIETARY NAMES (INNS) FOR PHARMACEUTICAL SUBSTANCES (2017).

identification of the medicines in many countries. Different countries published their own pharmacopeias like British Approved Names (BANs) and United States Adopted Names (USAN). Given the existence of different national nomenclature systems, the World Health Organization (WHO) harmonized the varied structure of the national nomenclature committees to standardize drug names.[22] WHO developed and formally established its nomenclature program in 1953 when its Experts Committee for the Unification of Pharmacopoeias drew up a plan to create a standard nomenclature for medicines, resulting in the publication of the first International Nonproprietary Names (INN) list for pharmaceutical substances.

INN is a foundational system that exchanges and updates information among health professionals worldwide. The names identified by INN are globally recognized and available in the public domain. WHO, together with the World Intellectual Property Organization (WIPO), encourages national offices to follow these recommendations when examining drug trademarks.[23] The goal behind the INN is to avoid a multiplicity of names and the resulting confusion and difficulty in identifying a prescribed medicine, dispensing it to the patient, and controlling drugs moving in international commerce.[24] The drug regulatory authority along with trademark authority must consider this objective behind the creation of INN and take necessary measures to avoid probable confusion that may arise from the use of similar propritiry names.

Active Pharmaceutical Ingredients (API) can be simultaneously identified by three names: a chemical, generic, and brand name. A chemical name is a scientific name based on the compound's chemical structure that is complex and lengthy, which is why they are not used for marketing purposes. A generic name refers to the nonproprietary name of API; therefore, it is public property. As a consequence, whenever a new terminology becomes an INN, it is no longer available for exclusive ownership in the form of a trademark. A trademark or proprietary name can be any word or combination of words that doesn't represent a common medicinal name.

22. Kuhu Tiwari & Niharika Sahoo Bhattacharya, *Pharmaceutical Trademarks: An Evaluation of Regulatory Intricacies and Challenges*, 15 J. INTELL. PROP. L. AND PRAC. 738 (2020).

23. World Intell. Prop. Org., Standing Comm. on the Law of Trademarks, Industrial Designs and Geographical Indications, Marks and International Nonproprietary Names for Pharmaceutical Substances (INNs), SCT/16/3 (Sept. 1, 2006).

24. Feldman & Lobo, *supra* note 14.

A proprietary name or trademark is selected by the proprietor of the product to indicate the source of origin and quality attached to it. The proprietary name differentiates the product from other available market alternatives, thereby reducing consumers' search costs. For example, Acetaminophen is marketed under the brand name Tylenol®, comprising of the chemical N-(4- Hydroxyphenyl)acetamide. Similarly, the anti-inflammatory drug Ibuprofen is identified under its brand name as Motrin®, which is comprised of the chemical 2-[4-(2-methylpropyl)phenyl]propanoic acid.

Usually, consumers first get acquainted with the drug's brand name, and once the patent for the branded drug expires, the pharmaceutical trademarks play a vital role in determining consumer choice. However, application of trademarks by the companies in a manner that leads to create artificial differentiation may deter fair market competition, ultimately affecting consumer health.[25] While conveying distinctiveness of source, a trademark also conveys, in the language of marketing, "brand differentiation."

IV. A STUDY OF BRAND PROLIFERATION FOR BRANDED AND BRANDED-GENERIC MARKET SEGMENTS

In 2020, the global pharmaceutical market revenue totaled $1.27 trillion U.S. dollars,[26] while total pharma advertising spending topped $6.58 billion.[27] Drug companies' heavy spending on marketing supports the importance of trademarks in the pharmaceutical industry across the globe. A branded drug company utilizes the exclusive period of patent protection to market its drug, and spends heavily on its promotion intending to make consumers familiar with the advertised trademark. Thereby, upon patent expiration when generic companies enter the market they use different trademarks, this in a way further leads to brand proliferation for a single drug composition. Brand proliferation can also be orchestrated by developing a new product with an existing molecule to enhance patient convenience, improve drug efficacy and safety profile, or find novel usage. The strategies and objectives of an innovator branded drug company are different from the strategies implemented by the

25. Brennan, *supra* note 17.

26. Matej Mikulic, *Global Pharmaceutical Industry—Statistics and Facts*, STATISTA (Sept. 10, 2021), https://www.statista.com/topics/1764/global-pharmaceutical-industry/#dossierKeyfigures [https://perma.cc/BF36-C4KG].

27. Beth Snyder Bulik, *The Top 10 Ad Spenders in Big Pharma for 2020*, FIERCE PHARMA (Apr. 19, 2021, 3:00 AM), https://www.fiercepharma.com/special-report/top-10-ad-spenders-big-pharma-for-2020 [https://perma.cc/54J5-27RD].

branded-generic companies. This section aims to highlight certain strategies that utilize trademarks to retain and promote brand equity for branded and branded-generic products.

A. Product Line Extension and Regulation in the United States Pharmaceutical Branded Drug Segment

During their twenty years of patent protection, patented drug, relying on trademark protection, acquires substantial consumer loyalty for a particular brand through aggressive advertising and free sampling. This may get eroded by the competitive entry of generic products. To prevent this, the innovator drug companies use different strategies that include the use of trademarks as a marketing tool, building up clientele fidelity. One of the popular strategies is launching multiple brands for a single API by extending a new product line, sometimes to address a new market segment. A few examples of such a strategy from the US pharmaceutical industry are highlighted below in Table 1.

Table 1: Examples of Line Extensions under Two Brands.

Manufacturers	Generic Name	Brand Name 1 & Indication	Brand Name 2 & Indication
Eli Lilly	Fluoxetine	Prozac- depression	Sarafem- pre-menstrual dysphoric disorder
Aventis	Triamcinolone	Nasacort- allergies	Azmacort - asthma
GlaxoSmithKline	Bupropion	Wellbutrin- depression	Zyban- smoking cessation
Merck & Co	Finasteride	Propecia- male pattern baldness	Proscar -benign prostatic hyperplasia
AstraZeneca	Budesonide	Pulmicort - asthma	Entocort/Rhinocort – allergy
Allergan	Tazarotene	Tazorac- acne	Average – facia wrinkling
Pfizer	Sildenafil Citrate	Viagra- Erectile Dysfunction	Revatio- Pulmonary arterial Hypertension (PAH)

In most cases, the new brand has a distinct value proposition (quality, functionality, etc.) that positions it above or below the existing brand for competitive purposes, if not in a different market altogether. These additional benefits are verified by the FDA, even though the active ingredients in both the products may have remained the same. For example, Eli Lilly's patent for the antidepressant drug fluoxetine (generic

name), popularly known as Prozac®,[28] was about to expire and its price was also expected to fall. Consequently, the company renamed and repackaged fluoxetine in pink and lavender capsules and launched it as Sarafem®, with the new therapeutic use of treating Premenstrual Dysphoric Disorder. The company even indicated to its shareholders that the launch of Sarafem® was entwined to the company's preparations for "Year X," the year patent protection runs out for Prozac.[29]

The extended, exclusive patent protection along with a new line of the product was created as a new application for the known API. Consequently, the price of Prozac, which would have fallen due to competition from generic versions, maintained its price stability at a higher price even though it was the same chemical. Sarafem was aggressively advertised directly to consumers and medical practitioners. It is worth noting that years after the patent expiration, the price gap between the branded and generic versions is still vast. The current price of 20 mg Sarafem® is $22.14 per unit and $18.37 per unit for Prozac®, whereas the generic version of the same composition is priced at $0.85 per unit.[30]

In another example, Merck & Co. patented Finasteride, a drug used for the treatment of benign prostate enlargement, an uncomfortable condition attributed to older males that can cause additional malaises such as kidney problems.[31] It was marketed under the brand name Proscar®. Additional patent protection and FDA approval were sought and granted when a new use of Finasteride for treating male pattern baldness was identified by the company, and thereafter marketed under the brand name Propecia®. Even after the patent's expiration in 2013, the current market

28. In 1998, the pharmaceutical companies spent $400 million to market and advertise antidepressants. Of that, $150 million was spent promoting Prozac. Terry Turner, *Cymbalta Clinical Trials & Development*, DRUGWATCH, https://www.drugwatch.com/cymbalta/clinical-trials/ [https://perma.cc/FAA2-FCZH].

29. Shankar Vedantam, *Renamed Prozac Fuels Women's Health Debate*, WASHINGTON POST, (Apr. 29, 2001), https://www.washingtonpost.com/archive/politics/2001/04/29/renamed-prozac-fuels-womens-health-debate/b05311b4-514a-4e65-aaa5-434cb2934271/ [https://perma.cc/ZYR7-539G].

30. *Fluoxetine Prices, Coupons and Patient Assistance Programs*, DRUGS.COM https://www.drugs.com/price-guide/fluoxetine#oral-tablet-10-mg [https://perma.cc/EC9B-EDBZ] (last visited Jan. 24, 2022).

31. *Benign Prostatic Hyperplasia (BPH),* MAYO CLINIC https://www.mayoclinic.org/diseases-conditions/benign-prostatic-hyperplasia/symptoms-causes/syc-20370087 [https://perma.cc/QW4F-UJJ6] (last visited Jan. 24, 2022).

price of 5 mg Proscar® is around $5 per unit,[32] and the price of 1 mg Propecia® is around $4 per unit[33]; the generic alternatives are available at prices around $1 and $0.84 for 1 mg and 5 mg respectively.[34]

A similar practice can be observed for GlaxoSmithKline's bupropion. The anti-depressant Wellbutrin® was given the additional name Zyban®, indicating its new therapeutic use to help stop smoking. The strategy of API line extension under different brand names is popular in the innovator drug industry. This is a successful commercial strategy because the wide advertisement for the new therapeutic use prompts consumers to ask for specific advertised products.

For better recognition of the advertised brands the companies also use trade dress to add a functionality of distinctive identity. One example is AstraZeneca (AZ), which introduced a new class of medication known as proton-pump inhibitors ("PPIs"), generically known as Omeprazole. After obtaining a patent, it sold the drug under the proprietary name Prilosec®. The drug was aggressively advertised under the trademark "The Purple Pill."[35] The drug promotions for "The Purple Pill" appeared in every medium—on TV, the internet, and in print ads. The pill's trade dress comprised of the purple color; it was at the heart of this effort, which is still under trademark protection.[36] In this way, potential consumers did not need to recall the drug's name. All they had to do was remember its color.[37]

In 2001, before the patent expired, the company launched a reformulated version of Prilosec® with the same therapeutic use under the trademark Nexium® (generically known as Esomeprazole) and marketed it as "The New Purple Pill." With this strategy, AZ successfully attracted

32. *Proscar Prices, Coupons and Patient Assistance Programs*, DRUGS.COM https://www.drugs.com/price-guide/proscar [https://perma.cc/WT4Q-LAPL] (last visited Jan. 24, 2022).

33. *Propecia Prices, Coupons and Patient Assistance Programs*, DRUGS.COM https://www.drugs.com/price-guide/propecia [https://perma.cc/5R6J-MQ44] (last visited Jan. 24, 2022).

34. *Finasteride Prices, Coupons and Patient Assistance Programs*, DRUGS.COM https://www.drugs.com/price-guide/finasteride#oral-tablet-1-mg [https://perma.cc/RQ6G-P26S] (last visited Jan. 24, 2022).

35. THE PURPLE PILL, Registration No. 78176056.

36. The mark consists of the color(s) purple, and gold is/are claimed as a feature of the mark, Registration No. 2980749.

37. Neil Swidey, *The Costly Case of the Purple Pill—The Story of One Blockbuster Heartburn Drug Tells You Everything You Need to Know About the High Cost of Prescription Medicine*, BOSTON GLOBE (Jan. 10, 2018) https://www.bostonglobe.com/magazine/2002/11/17/the-costly-case-purple-pill/oSiZkj5NLUWyW0elJPDdMK/story.html [https://perma.cc/J8JR-697R].

the brand loyal Prilosec® customers to Nexium®.[38] Even after the patent expiration of both Prilosec® and Nexium®, the current market price of the branded drug per unit is $1.43 and $47.56 for 20 mg and 40 mg (intravenous powder for injection), respectively, versus the generic price of around $1.19 and $2.99 per unit, respectively.

These examples permit us to see the potential impacts of such a marketing strategy, which affect medication accessibility and patient safety. Extending the period of exclusivity restricts the entry of generic drug manufacturers in the market, resulting in a lack of a of affordable medication. The cost incurred in advertising and marketing the branded drug during the exclusive period of patent protection pays off by gaining the interest and loyalty of consumers. This is a crucial observation. In the case of patent protection extension for a new use of a known drug, the entry of generic manufacturers—even for the previously patented formulation—gets restricted. As a result of brand proliferation, there is a promotion of artificial product differentiation with the trademarks in the market allowing few companies to explore the market for certain treatments, without actually offering any therapeutic difference. In this context, the primary question that arises is whether such strategies breach the legal limits?

In response to this paradigm many regulatory interventions indicated the trademark protection's effects on the pharmaceutical market. For instance, in a 1977 U.S. Federal Trade Commission (FTC) report suggested that "the trademark, like the patent, might be given a limited life" due to the social costs of trademarks in perpetuity.[39] In 2001, the concerns were also raised by the FDA's Associate Director for Medications Error, Mr. Jerry Phillips. He addressed the presence of too many "unnecessary" drug trademarks, strongly discouraged the use of multiple trademarks by the same company for the same active ingredient, and thereby declared a ban on multiple trademarks for one firm's drug on the ground of consumer safety. Though the ban was successfully

38. James G. Conley, Robert C. Wolcott & Eric Wong, *AstraZeneca, Prilosec, and Nexium: Marketing Challenges in the Launch of a Second-Generation Drug*, HARV. BUS. PUBL'G (EDUC.) (Jan. 1. 2006) https://hbsp.harvard.edu/product/KEL336-PDF-ENG.

39. FTC, Staff Report on Sales, Promotion, and Product Differentiation in Two Prescription Drug Markets 80 (Feb. 1977), https://www.ftc.gov/sites/default/files/documents/reports/sales-promotion-and-product-differentiation-two-prescription-drug-markets/197702salespromo.pdf [https://perma.cc/BCQ8-Y482].

challenged by stakeholders, it later became one of the criteria for drug name review.[40]

However, in 2002, the FDA Centre for Biologics Evaluation and Research (CBER) released the procedure related to the review of dual trademarks. The CBER Manual related to "Review of CBER Regulated Product Proprietary Names" restricted the approval of a proposed proprietary name that uses "a different name for an essentially identical product for a different indication."[41] CBER expressed concern about double dosing where healthcare practitioners and patients may not perceive the similarity of the two products with different names. It also speculated that "the use of different names for the same product may pose problems in the collection and management of adverse drug reaction reports."[42]

Thereafter, the evaluation of dual proprietary name is performed as the part of a "proprietary name review." For example, while approving Eli Lilly's drug Tadalafil under the proposed propriety name Adcirca®, the FDA conducted the proprietary name risk assessment for the use of dual names for the same API. Since Eli Lilly was marketing Tadalafil under the dual trademarks Cialis® and Adcirca®, the use of one API by a single company under different proprietary names indicated the chance of potential for concomitant administration of Cialis® and Adcirca®.[43] Errors of this type may remain undetectable because patients and practitioners may not realize that the products contain the same API. There is no past reporting of such medication error that resulted in an adverse outcome because a patient was prescribed both products.

Meanwhile, the FDA also acknowledged that the medication errors are under-reported, so a negative search does not guarantee that concomitant therapy has not occurred.[44] Based on studies conducted by medical officers, it was found that doses up to 100 mg of Tadalafil would not cause any adverse effect on the body. On this basis, the marketing of the product with two different names were allowed. Thereby it was

40. Best Practices in Developing Proprietary Names for Human Prescription Drug Products; Guidance for Industry Availability, 85 Fed. Reg. 79189 (Dec. 4, 2020) https://www.federalregister.gov/documents/2020/12/09/2020-27058/best-practices-in-developing-proprietary-names-for-human-prescription-drug-products-guidance-for.

41. FDA Limits on Dual Trademarks Tread on Patient Safety and Law, Reed Smith (Apr. 25, 2003) www.reedsmith.com/en/perspectives/2003/04/fda-limits-on-dual-trademarks-tread-on-patient-saf [https://perma.cc/B7FF-6HG7].

42. Id.

43. Center For Drug Evaluation and Research, Food and Drug Administration, Application Number: 22-332, Propritory Name Review(s) (2009).**Error! Hyperlink reference not valid.**

44. Id.

advised in the report that the applicants educate healthcare practitioners and patients to ensure substantial post-marketing education of prescribers, emergency personnel, and patients about concurrent use of their same API drugs.

Currently, the FDA allows dual proprietary names but only on a case-by-case basis. The case-by-case basis includes situations where two products are to be administered using different routes of administration or when they have different doses. Such exceptions are allowed after considering the risk of medication errors to a population taking the medication for a second indication.[45] Interestingly, the practice of brand proliferation for the same medicinal product using trademarks is not merely restricted to innovation-based companies but has become a common practice in the branded-generic segment of pharmaceutical products too.

B. Product Line Extension and Regulation in the Indian Pharmaceutical Branded-Generic Drug Segment

India is one of the largest generic drug providers in the global pharmaceutical market, and its pharmaceutical industry categorically holds a dominant position for branded generics.[46] Since India's pharmaceutical market is unstructured and lacks drug name regulation, the practice of using multiple trademarks for one drug has become a regular industry practice.[47] According to a market study on the pharmaceutical sector conducted by the Competition Commission of India (CCI), there were 47,478 brands associated with 2,871 formulations in the pharmaceutical market in India between August 2019 and July 2020, averaging 17 brands for every formulation.[48] One of the most commonly used combination-drugs from the anti-diabetes category, namely glimepiride 2mg +metformin 500 mg tablet remains the top pick in the industry, with about 137 brands from 120 companies in the market.[49] Taking cues from innovator drug companies that have adopted a similar

45. FDA Limits on Dual Trademarks Tread on Patient Safety and Law, supra note 36.

46. The Indian Pharmaceutical Industry, India Brand Equity Foundation (Jan. 23, 2022) https://www.ibef.org/industry/pharmaceutical-india.aspx [https://perma.cc/T5T6-GA4L].

47. Tiwari Kuhu & Bhattacharya S. Niharika, Judicial Navigation of Drug Name Regulation in India, 26 J. Intell. Prop. Rts. 269, 269–276 (2021).

48. Market Study on the Pharmaceutical Sector in India: Key Findings and Observations (2021), http://cci.gov.in/sites/default/files/whats_newdocument/Market-Study-on-the—Pharmaceutical—Sector-in-India.pdf [https://perma.cc/U6WA-APJP].

49. Id. at 7.

strategy of using multiple brands for one formulation, the branded-generic manufacturers seems to follow the same path.

On the other hand, one may seek to justification of brand proliferation through the lens of the rule of demand and supply. As per the rule, if the supply of drugs with brand proliferation increases and demand stays the same, the price must go down. Thus, as per this rule the consumers must gain the benefit from competitive prices. Hence to verify this hypothesis, the authors of this paper, have compared the price of certain branded generic products, represented in Table 2. We analyzed two and three brands marketed by a single drug company along with their respective prices. As shown in the table, the maximum price difference between two products from the same company is INR 37.93, which is equivalent to $0.51, a nominal difference. This shows that the practice of using multiple trademarks for a single drug formulation merely enhances the brand equity of the company that consequently creates artificial product differentiation. However, when compared with branded drugs, it can be observed that competition in the case of branded drugs is grounded on comparative quality.

Table 2: Brand Differentiation of Drugs with Price

Generic Drug Name	Company	Brand Name 1 and Price	Brand Name 2 and Price	Brand 3 and Price	Price Difference between first two brands
Cetirizine HCL	Sun Pharma Laboratory Ltd.	Cerzin®(10 mg-10 Tab) MRP - Rs. 2.31	Cetrizet® (10 mg- 10 Tab) MRP - Rs. 20.21)	Stanhist® (10 mg- 10 Tab) MRP - Rs. 15.58)	Rs. 17.9
Cetirizine HCL	Cipla Ltd.	Alerid® (10 mg- 10 Tab) MRP - Rs. 18.49)	Cetcip Tablet® (10 mg- 10 Tab) MRP - Rs. 18.50)	Okacet Tablet® (10 mg- 10 Tab) MRP - Rs. 18.50)	Nominal Difference
Lansoprazole (30 mg) (PR)	Cipla Ltd.	Lansec® (30 capsule) MRP Rs. 67.50)	Lanzol™ (30 capsule) MRP Rs. 76.50)	____	Rs. 9

Amoxycillin/ Clavulanic acid 500/125 mg	Abbott India	Fightox (625 mg Tablet 10s) MRP Rs. 149.44	Megamox Cv (625 mg Tablet 10s) MRP Rs. 157.02	Cosymoxyl (625 mg Tablet 10s) MRP 155.61	Rs. 7.58
Glimepiride/ Metformin (PR)	Lupin Ltd.	Glador M2 (15 Tab) MRP 216.95	Gluconorm G2 (15Tab) PR MRP Rs. 179.02	—	Rs. 37.93

Quality does not seem to be the ground of differentiation for the branded-generic drugs, which possess the same active ingredients as the originator medicine regardless of their brand names. Each drug also passes through the same assessment procedure and is therefore expected to be interchangeable or identical in terms of nonprice parameters, such as safety and efficacy. The market study conducted by the CCI indicated three underlying factors that contributed to the primacy of brand competition in generics: (1) elements that design information asymmetry regarding drugs vis-a-vis consumers of drugs; (2) unobservable quality of drugs; and (3) prescription of drugs by brand names rather than by generic names. In absence of technical understanding, consumers are not in a favorable position to make an informed choice and the quality and efficacy of drugs is intrinsically unobservable. Instead, consumers follow doctors' prescriptions, which are often influenced by aggressive brand promotion from pharmaceutical companies. Such brand promotion evokes the perception of the price-quality correlation, despite the lack of any quality difference between different branded-generic and unbranded generic versions of the same molecule. This ultimately affects the economic interest of consumers by reducing the price elasticity of demand.

Consequently, the use of trademarks can be observed as merely a tool for pharmaceutical companies to create artificial product differentiation to be able to command a brand premium on prices and still sustain high shares in the domestic market.[50] Since the brand names of generic drugs can hardly signal quality, several prominent players who market these brands often get their products manufactured through third–party or contract manufacturing, and the same third-party manufacturer accepts orders from multiple pharma companies. As far as the quality variance in

50. Competition Commission of India (CCI), Policy Note: Making Markets Work for Affordable Healthcare (Oct. 2018), https://www.cci.gov.in/sites/default/files/event%20document/POLICY_NOTE_0.pdf?download=1 [https://perma.cc/HXU7-JGLX].

drugs is concerned, it is attributed to the non-uniform enforcement of quality standards across states.

Therefore, the CCI report recommended certain solutions, including the introduction of an institutional quality signaling mechanism. An example is the incorporation of standard-compliance marks, providing confidence to consumers and physicians for generic name prescriptions and improving the public perception of generic drugs as a whole. There is also a need for structural modification of India's drug regulatory system to confirm a uniform and effective implementation of existing quality standards, and create a national digital drug databank for more transparency regarding the standards followed for drug approval by the authorities.

V. CONCLUSION

Thus, many questions arise among scholars regardless of their views and approaches: does branding in the pharmaceutical industry work, since marketable drugs are approved through the same regulatory process? Do trademarks help the consumers identify and differentiate the correct medication or do they just create an artificial product differentiation?

It can be concluded by the authors that the function of pharmaceutical trademarks has shifted from preventing consumer confusion to enhancing brand equity with multiple brands on the portfolio, thereby expanding the profit through product differentiation. Trademark rights gain additional importance because they offer a monopolistic way to capitalize on the brand image and recoup the substantial investment made in a medicine's creation. Since many companies, both innovator and generic drug companies, have joined the race to develop differentiated drug products, finding new clinical uses of a drug has enhanced the scope for creating a new market and extended its market life. In a way, product differentiation provides a first-line treatment to manage the life cycle of a molecule facing patent extinction owing to generic competition.

Therefore, after studying the use of trademarks in the two different segments of the pharmaceutical industry and linking the cited case studies for innovative drug industry along with scholarship on the subject matter, the economic theory of Landes and Posner[51] seems appropriate to the extent where chemically similar formulations are marketed by different proprietors. However, when one single drug composition is marketed by a single proprietor under multiple trademarks and aggressive advertising,

51. Landes & Posner, supra note 7.

it leads to artificial product differentiation, which invalidates their theory. Such differentiation may not have a fatal impact on patients' health, but using brand, rather than generic names for medications can increase health care costs by restricting the entry of the generic drugs into the market. To regulate this, trademark applications bearing multiple brand names should be subject to a strict scrutiny analysis as part of drug name regulation.

The purpose of using trademarks by the branded-generic companies seems to be only for maximizing profits on a generic drug, though the underlying intent of generics is presumably to provide better access to medicine.

Having this in mind, lessons of the renowned scholar Barton Beebe must be taken into consideration.[52] Beebe acknowledged two types of distinctiveness: brand distinctiveness and distinctiveness of origin. While the first differentiates the brands, the second indicates the origin of the product. Therefore, in this circumstance, the recommendation given by CCI towards adoption of standard-compliance marks for branded generic drugs seems well justified. As proposed by CCI, the creation of standard-compliance marks for all the branded-generic drugs will solve the problem to an extent. In that scenario, the necessity for obtaining or using a variety of trademarks would not be in existence, since the quality of all the marketable drugs would be assured by the standard-compliance marks.

52. Beebe, supra note 11.