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Title: "Antitrust Regulations and Challenges Faced by the Pharmaceutical Sector of the US",

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I. ABSTRACT:

"Unconventional economics and an uncommon convergence of regulatory, patent, and antitrustlaws characterize the pharmaceutical sector. This paper aims to analyze and discuss the Antitrustlegal framework preventing monopolization and unjust or unfair competition in the pharmaceutical sector of The United States, with the assistance of relevant precedents and casestudies under the sub-topics of Horizontal Mergers, Potential Mergers, Vertical Mergers, Mergers in innovation markets, patent evergreening, product hopping and price discrimination".

II. INTRODUCTION:

The pharmaceutical sector is distinguished by atypical economics and a peculiar confluence of antitrust, patent, and regulatory legislation. Generic and brand-name prescription and over-the-counter (OTC) medications, wholesalers, and retail pharmacy services all make up the industry's supply side. Each of these industries has certain distinctive characteristics that influence how competition policy is applied. Due to patent protection, regulatory exclusivities, and insurance coverage, originator prescription medications have a sizable potential market share. Depending on entrance and insurance reimbursement circumstances, the generic sector, which may comprise pure generics and duplicate items, may be structurally competitive. Potentially competitive structurally are the distribution industries, which include wholesalers and retail pharmacists. Pharmaceuticals are subject to strict market access regulations worldwide since they are highly complex technology items with a significant potential for unobservable health risks. Prescription medications must prove their safety, effectiveness, and manufacturing quality to be generally supplied to consumers, according to market access regulations. Regulation and the countervailing power of both public and private insurers, who serve as third party payers and agents for patients, the ultimate customers, have a significant impact on each of these supply sectors. The way in which competition operates and the final pricing at which medications are sold reflect the combined impact of regulatory, patent, and antitrust laws as well as the compensating influence of payers.

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III. LEGAL AND REGULATORY FRAMEWORK:

Monopolization is prohibited by the Sherman Act of 1890[1]. The Act was designed for the protection of consumers and businesses from unfair corporate practices. The Federal Trade Commission of The United States addresses monopolization such that, when a business unreasonably restrains competition by establishing or preserving monopoly power, it is said to be engaging in monopolization[2]. Usually, a "rule of reason" which is a legal doctrine used to interpret the Sherman Antitrust Act, one of the cornerstones of United States antitrust law is primarily used to evaluate restraints, although price-fixing and other collusive practices are regarded as offenses.

Further, the Clayton Act of 1914[3] restricts mergers and acquisitions that have the potential to significantly decrease competitive trade or form a monopoly. Companies proposing major mergers or acquisitions must inform the antitrust authorities prior to a transaction worth more than $70 millionunder the ***Hart-Scott-Rodino (HSR)***[4] Antitrust Improvements Act of 1976[5]. This allows the authorities to examine if the transaction may breach the antitrust law. The HSR limit is modified regularly. Exclusive license to patents that convey the right to create, utilize, or sell products has also necessitated a prior notice, unless the licensor retains the right to make or usethe product. In such a situation, the license is deemed non-exclusive and no HSR file is necessary.

IV. HORIZONTAL MERGERS:

Mergers and acquisitions are a common type of transaction that the Federal Trade Commission scrutinizes for the potential to reduce competition, increase market dominance, orcreate a monopoly. The purpose is to detect and contest competitively detrimental mergers as they

[1] The Sherman Act, 1890.
[2] Federal Trade Commission. n.d. Monopolization Defined. [online] Available at: <https://www.ftc.gov/advice-guidance/competition-guidance/guide-antitrust-laws/single-firm-conduct/monopolization-defined> [Accessed 8 May 2022].
[3] The Clayton Act, 1914.
[4] The Antitrust Improvements Act, 1976.
[5] The Antitrust Improvements Act, 1976.

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happen, while preventing undue involvement with mergers that are helpful or impartial. In merger situations, typical enforcement remedies involve asset divestiture, restoring co-marketing or joint venture privileges to a participant, or wholly not proceeding with the suspect merger[6]. To assess the competition issues presented by mergers, the FTC employs a variety of statisticalapproaches to the existing facts. A merger has the power to boost market dominance merely by limiting competition between merging parties, giving the merged institution an involuntary enticement to increase prices or harm consumers, or by raising the likelihood of synchronized or interdependent behaviour among competitors. Increased seller market dominance can harmconsumers through cost rises or quasi-impacts such as lower standards or diversity of itemsor less creativity. It is typically possible to forecast the impacts of mergers. The items and geographies affected, as well as the market participants, shares, and concentration, all require market definition. Market share and concentration assessment is not a goal in and of itself, but it is useful in revealing the merger's potential competitive implications.

V. MERGERS IN THE PHARMACEUTICAL INDUSTRY:

The pharmaceutical industry in the United States is unconcentrated. However, on-patent medicines' product market definition is generally the indication, and concentration can be a serious issue at this stage. In fact, rather than seeking to assess cross-price variations, many pharmaceutical scenarios appear to apply classic merger concepts based on market shares. The FTC evaluates changes in market concentration individually for each therapeutic area in the consolidated product portfolio of large pharmaceutical companies in horizontal mergers. This has frequently led to mandates that the merging company liquidates goods in therapeutic areas where the concentration rise is considered inappropriate. For example, the FTC alleged that Pfizer's acquisition of Wyeth would limit competition in 21 US markets for animal health products and entrance into these markets would not be prompt or probable, and that price

[6] "Horizontal Merger". 2022. Corporate Finance Institute. Accessed May 8, https://corporatefinanceinstitute.com/resources/knowledge/strategy/horizontal-merger/.

increase and harm to customers would result from this. Pfizer was compelled by the consent decree to divest its Fort Dodge US animal health products company to Boehringer Ingelheim Vetmedica, Inc. in all areas of overlap, to maintain competition while empowering a future competitor[7]. As bioequivalent generics are the creator brand's nearest replacements and have a significant competitive effect on the creator, the markets for off-patent pharmaceuticals are often considered to include only bioequivalent generics. Further, in the United States, the over-the-counter and prescription medication markets are generally regarded differently since OTCs do not necessitate a physician's prescription and are usually not as potent. The cases explained below show how US merger concepts can be applied to the pharmaceutical sector.

In the case of ***Johnson & Johnson and Pfizer Inc*.[8],** Pfizer's Consumer Healthcare company was acquired by Johnson & Johnson (J&J). According to the HHI index, the H-2 blocker, hydrocortisone anti-itch, nighttime sleep-aid and diaper rash treatments markets were extremely consolidated. J&J and Pfizer were leading suppliers of all these medications, accounting for more than 70%, 55%, 45%, and 50% ofrevenue respectively with their products. The acquisition would make J&J the market'smain provider and allow it to dominate the market, in turn dramatically enhancing market consolidation even more.

The FTC argued that entering any of these four markets would not be prompt, probable, or adequate to prevent or mitigate the acquisition's anticompetitive effects as entry would entail extremely high sunk expenses, and a new competitor would have difficulty convincing retailers to undertake its goods. Now, it is noted that by stifling competition between J&J and Pfizer, enhancing the capacity of the merged firm to arbitrarily raise prices, and lowering the merged firm's motivation to encourage service or product quality, the FTC ascertained that the merger would considerably minimise competition and establish a monopoly. The FTC and J&J

[7] "Pfizer Inc., A Corporation, And Wyeth, A Corporation, In The Matter Of". 2022. Federal Trade Commission. Accessed May 8. https://www.ftc.gov/legal-library/browse/cases-proceedings/091-0053-pfizer-inc-corporation-wyeth-corporation-matter.
[8] 2022. Ftc.Gov. Accessed May 8.

agreed to divest Pfizer's Zantac assets toBoehringer, Pfizer's Cortizone, and Unisom sleep-aid products to Chattem, and J&J's Balmex diaper rash treatment product to Chattem as part of the settlement decree. A similar approach to preventing domination and encouraging and attracting new competitors could be seen in the acquisition of Sanofis Dermik Unit by Valeant Pharmaceuticals. At dispute in this case were two off-patent products with generic equivalents. The FTC characterised the relevant markets as those where BenzaClin and Topical 5FU are produced and sold in the United States, and it took into account how the proposed purchase would affect the number of competitors and market shares. Dermik, a subsidiary of Sanofi, promoted BenzaClin. Valeant earned royalties from Mylan on sale of generic BenzaClin since it owned the only ANDA and had licenced it to the company. Prior to the scheduled acquisition, Dermik's original BenzaClin and Mylan's generic BenzaClin competed for the same market.

Further, initially there were five companies competing in the market for Topical 5FU: (1) Dermik's branded Carac; (2) Spear Pharmaceuticals' generic Efudex; (3) Taro Pharmaceuticals' generic Efudex; and (4) Allergan's branded Fluoroplex. Generic Efudex had nearly eliminated the sales of Valeant's branded Efudex. After the acquisition, Valeant would control more than 50% of the market for Topical 5FU. The FTC argued that firstly, the markets were unattractive for new entrants because the markets were small; and secondly, the timeline for drug development and approval discourages competitors from entering the market in time to prevent the anti-competitive effects of the merger. The FTC claimed that competitive entry was unlikely to counteract the anti-competitive effects of the merger.

The FTC came to the conclusion that Valeant would be able to unilaterally exercise market dominance in both product areas after the merger and hike consumer costs. In accordance with the terms of the consent agreement reached between the FTC and Valeant, Valeant was compelled to sell to Mylan all rights in generic BenzaClin and also grant to Mylan, a license for the rights to the approved generic version of Efudex. Thus, in both the aforementioned cases, it is evident that the FTC evaluates the changes in market competition individually and

identifies the anti-competitive effects and their impact on new competitors. However, oftentimes it is hard to identify anti-competitive consequences. This can be seen in light of ***FTC vs. Lundbeck***[9]**.** In this case, the Eighth Circuit confirmed a District court ruling that two on-patent medications were not in a comparable industry, utilising cross-price elasticity of demand to define the market in ***Federal Trade Commission vs. Lundbeck***. According to the FTC, Lundbeck bought the licensesto Indocin IV from Merck in 2005, then purchased the rights to NeoProfen in 2006, which wasseeking FDA approval for PDA (patent ductus arteriosus), a life-threatening cardiac ailment. According to the FTC lawsuit, Lundbeck anticipated that NeoProfen might eat into Indocin's sales, so it bought NeoProfen to neutralise the risk. Lundbeck increased the cost of Indocin by1,300 percent after purchasing NeoProfen, and then introduced NeoProfen at the very same cost.

Lundbeck had been maintaining these rates for two years when the complaint was filed. The FTC claimed that Lundbeck's acquisition of NeoProfen violated the Clayton and FTC Actsby substantially raising prices, reducing competition, and maintaining its dominance in PDA therapies. The lawsuit demanded divestment and forfeiture of revenues earned illegally. The District Court found that the two products had low cross-price elasticity of demand and thus were not in the same marketplace, based on the finding that neonatologists largely decide the demand for Indocin IV and Neoprofen,' and that these treatment choices are formed without respect to price.

When patients' cost elasticities are undercut by insurance, this unexpected result shows the dangers of depending on the cross-price elasticity of demands to establish productmarketplaces. The FTC contended that the district court failed to evaluate the potential pricingsituation that would have occurred if the two items were held by different companies. This scenario demonstrates how tough it is to discover anti-competitive price consequences of a merger when

[9] 2022. Accessed May 8. https://journals.sagepub.com/doi/abs/10.1177/0003603X1405900307.

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demand already substantially prices inelastic due to insurance and medical agencies.

VI. POTENTIAL MERGERS:

One company purchasing a firm that is seeking to join its sector, or a prospective newcomer acquiring a rival in that sector, are examples of potential competition mergers. These deals could limit the real rise in competitiveness that would occur from entry, as well as the procompetitive consequences that arise when a possible foreign company's entry acts as a barrier to current firms' cost increases. The Federal Trade Commission has contested acquisitions involving pharmaceutical companies where both businesses are potential entrants, as well as mergers where one business currently possesses an FDA-approved medication on the marketplace and the other has a medication undergoing evaluation that will be a rival when approved. The following cases can be considered examples of the same. In the case of *Pfizer and Pharmacia*[10], Pfizer was among two businesses with an extended-release overactive bladder medicine, whilePharmacia was one of two businesses best placed to join the industry within the coming two years and pursuing approval from the FDA for its overactive bladder medicine.

The FTC forced Pfizer to sell its OAB-related pharmaceuticals to Novartis AG because it was likely that the acquisition would cause a delay in the commercialization of its medication. Pfizer also owned 95 percent of the erectile dysfunction market in the United States and was working on a second-generation Viagra-like medicine. With two drugs in clinical development, Pharmacia was Pfizer's sole big potential rival. Pharmacia's developmental product rights were divested to Nastech and Neurocrine Biosciences, Inc. Further, in the case of *Barr and Pilva*[11] the license on the nimodipine medicine had lapsed, and there were no generic versions

[10] Busfield, Joan. "GLOBALIZATION AND THE PHARMACEUTICAL INDUSTRY REVISITED." International Journal of Health Services 33, no. 3 (2003): 581–605. http://www.jstor.org/stable/45131310.
[11] "FTC Challenges Barrs Proposed Acquisition of Pliva". 2022. Federal Trade Commission. Accessed May 8. https://www.ftc.gov/news-events/news/press-releases/2006/10/ftc-challenges-barrs-proposed-acquisition-pliva.

available. The only firms looking for authorization for generic nimodipine included Barr and Pliva. Barr's purchase of Pliva would have eliminated possible nimodipine market rivalry. Pliva's nimodipine assets had to be divested to Banner, while Barr's had to be divested to Cardinal in the legal settlement.

VII. MERGERS IN INNOVATION MARKETS:

The Antitrust Guidelines for the Licensing of Intellectual Property were released by the FTC in 1995[12]. Innovation markets, according to such standards, are marketplaces that include research and development-oriented to certain novel or enhanced products or procedures, as well as comparable alternatives for such research and development[13]. These alternatives or 'close substitutes' as given under the guidelines are research and development initiatives, technology, and products that substantially impede the exertion of market power in the appropriate research and development. According to the guidelines, these markets are suitable targets for antitrust regulation when a firm's ability to conduct important research and development is reliant on specialized assets or traits. When five prospective innovators are present in the market, the principles imply a safe Harbour from antitrust legislation. Following the establishment of the guidelines, the FTC typically mandated intellectual property divestiture or compelled licensing in the event of innovation market mergers. The merger of Ciba-Geigy and Sandoz is an instance of the FTC's oversight of such mergers[14].

The companies' cumulative role in gene therapy research was so dominant that the other companies conducting studies in this field were required to start joint ventures or agreements with either Ciba-Geigy or Sandoz to have any chance of commercializing their research

[12] Gilbert, Richard, Carl Shapiro, Louis Kaplow, and Robert Gertner. "Antitrust Issues in the Licensing of Intellectual Property: The Nine No-No's Meet the Nineties." Brookings Papers on Economic Activity. Microeconomics 1997 (1997): 283–349. https://doi.org/10.2307/2534758.
[13] https://www.justice.gov/atr/IPguidelines/download.
[14] MORGAN, ELEANOR J. "Innovation and Merger Decisions in the Pharmaceutical Industry." Review of Industrial Organization 19, no. 2 (2001): 181–97. http://www.jstor.org/stable/41799037.

according to the FTC. A consent order compelled Novartis, the newly merged business, to offer all requesters a non-exclusive licenseto some gene therapy inventions in exchange for a $10,000 compensation and one to three percent royalty on total sales; licensing for other technologies gave Novartis more negotiation room. Another case to better explain this topic was Glaxo's purchase of BurroughsWellcome[15]. The companies were the most advanced in creating an oral migrainetreatment. The FTC barred preexisting migraine medications from the sector since they were only accessible as injectables. According to the FTC's suit, the acquisition would abolish competition among the companies in the research of oral migraine therapies and give Glaxo unilateral control over R&D for such products. Wellcome's R&D-related migraine assets werecompelled to be sold under an agreement.

VIII. VERTICAL MERGERS:

The Federal Trade Commission has delved into the vertical acquisition of three major pharmacy benefit managers by three large pharmaceutical businesses, citing the possibility for the producer to favour its own medicine on the PBM's prescriptions, foreclose rivals, and diminish the PBM's function in restricting costs. Merck and Eli Lilly signed consent orders requiring the procured PBMs to maintain and reveal an accessible formulary, establish an independent Pharmacy and Therapeutics council to factually assess medicine; and admit all offers, refunds, and other incentives provided by rival companies for incorporation in the open formulary. Despite the FTC's approval of the PBM purchases, which were subject to these and other conditions, all three were later divested. This shows that pharmaceutical corporations' ownership of PBMs undermined their usefulness as impartial price-control middlemen by markets and customers[16]. The FTC did not protest when CVS, a prominent drug store franchise and clinic service, boughtCaremark, the prominent PBM, in 2007. PBMs create preferred pharmacy networks for insured clients and manage pharmacy dispensing costs and prescription

[15] MORGAN, ELEANOR J. "Innovation and Merger Decisions in the Pharmaceutical Industry." Review of Industrial Organization 19, no. 2 (2001): 181–97. http://www.jstor.org/stable/41799037.
[16] 2022. Citeseerx.Ist.Psu.Edu. Accessed May 8. https://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.1008.6659&rep=rep1&type=pdf.

mark-ups, thus this was perhaps unexpected. In response to customer complaints, chemists, labour unions, and others, the FTC launched an inquiry into CVS Caremark's corporate operations in 2009. However, after a two-year examination, no regulatory action was taken on any of the antitrust charges. As a result, the FTC did not object to business practices common in vertically integrated companies, particularly those involving PBM-pharmacy connections. Fresenius acquired an exclusive licensing from Daiichi Sankyo to produce and supply the injectable iron medication Venofer to dialysis clinics, which was another difficult vertical acquisition. The FTC, in this case, stated that the deal would provide Fresenius, the world's largest dialysis company, the motive, and capacity to enhance Venofer's Medicare payments. The resultant consent agreement limited Fresenius' capacity to claim exorbitant costs t boost compensation, although it was eventually made moot due to changed Medicare reimbursement techniques[17].

IX. PATENT EVERGREENING:

Firms that create products have immense interest to try and extend their patent rights. The Hatch Waxman Act's paragraph IV provision encourages generic companies to contest possible defective patents, while simultaneously allowing creator companies to gain a 30-month hold on ANDA clearance while the challenged patent is being litigated. Because numerous 30-month stays were possible, companies were enticed to apply for patents for added features or pureversions of their medications, compounds, and other products. When generic businesses have been prosecuted for infringement on these rights, they have occasionally alleged that the patents are an endeavor at monopolisation, which is illegal under Section 2 of the Sherman Act. Generic firms have often been successful in filing a private antitrust case against patents that impede their capacity to compete. Under the Noerr Pennington theory, which typically safeguards the freedom to file patent infringement complaints, this possible antitrust obligation may be barred by the originator's First Amendment right to advocate for legislative orexecutive

[17] "FTC Challenges Vertical Agreement Between Fresenius And Daiichi Sankyo". 2022. Federal Trade Commission. Accessed May 8. https://www.ftc.gov/news-events/news/press-releases/2008/09/ftc-challenges-vertical-agreement-between-fresenius-daiichi-sankyo.

action. Patents are usually presumed to be valid, and the burden of proof rests with the challenger to show that they are not. Furthermore, there are no restrictions on the patent listing in the FDA Orange Book. Attorney generals frequently join monopolisation claims, requesting reimbursement for exorbitant expenses to state programmes. For example, Glaxo Smith-Kline consented to reimburse $14 million to settle accusations that it charged state government programmes artificially boosted costs for Paxil, an antidepressant narcotic, because GSK was involved in a patentscam, antitrust infringements, and futile litigation to sustain a monopoly and avoid generics from coming to market.

X. PRODUCT HOPPING:

The practise of a firm introducing modest product edits that provide patients little or no therapeutic benefit but effectively prevent generic competition merely because they are slightly different is known as "product hopping." Even before patent expiration and generic entrance on the original formulation, the originator company typically introduces a new formulation of their drug, such as a long-acting formulation. The originator then tries to persuade doctors and clients to convert to the newer version by increasing the cost of the previous medicine just above the cost of the reformed product, focusing all marketing attempts on the newer version, andeven withdrawing the original synthesis from the shelf.

Because pharmacies can only replace generic goods with identical formulation and strength as the patent-expired originator formulation under US substitution laws, a new composition and stimulated switching of prescriptions to the new composition successfully prevent pharmacy replacement and thus eradicates purposeful generic competition. In theory, a generic manufacturer could buy stock in the promotion to persuade doctors to recommend its generic drug; nevertheless, even if the prescription was written for a specific generic, pharmacies could replace other generics that would sell for less money because they had not invested in promotion. Individual generics haveno incentive to promote due to pharmacy substitution laws in the United States, and the majority of generics are non-branded, lowering expenses and

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contributing to cheap generic costs. The inventor can prohibit generics by withholding the reference product, which is an unforeseen effect of generic substitutability.

XI. DISCRIMINATION IN PRICING:

Drug stores as well as other consumers have filed private lawsuits claiming pricing collusion and price discrimination on the part of pharmaceutical manufacturers. In 1993, pharmacies filed a class action suit suing multiple pharmaceutical companies, demanding compensation and an injunction for the companies' practice of billing retail pharmacies substantially higher costs than HMOs and other 'preferred' customers, such as PBMs. Four pharmaceuticals corporations negotiated for $345 million in 1998, agreeing not to use a two-tier billing system in the future. Even though the producers are committed to providing the same prices to similarly situated clients, PBMs and HMOs can affect the utilisation and share prices of on-patent pharmaceuticals through their formulary designs, whilst pharmacies are only allowed toundertake generic substitution. Thus, compared to retail pharmacies that can simply replace amongst generics, PBMs and health plans that can affect the market share of originator goods through formulary design proceed to obtain higher discounts on on-patent pharmaceuticals in exchange for increased market share.

In 2012, a judge awarded summary judgement in favour of pharmaceutical producers in ***Drug Mart Pharmacy Corp. vs. American Home Products Corp.***[18], a price-fixing case filed by pharmacies. Under the Robinson-Patman Act, the pharmacies challenged the drug companies for fixing prices. In accordance with the act, the petitioner owes the burden of proof to prove *that "(1) the seller's sales were made in interstate commerce; (2) the seller discriminated in price between the two purchasers; (3) the product or commodity sold to the competing purchasers was of the same grade and quality; and (4) the price discrimination had a prohibited effect on competition."*[19] Regardless of the fact that the petitioners and "favored pharmacies"

[18] Drug Mart Pharmacy Corp. v. American Home Products Corp.
[19] The Robinson-Patman Act, 1936.

had different pricing, the petitioners were incapable of showing that the damage was more than minimal. Plaintiffs in price discrimination cases frequently have difficulty demonstrating damage to competition, as mandated by the Robinson-Patman Act, rather than harm to particular competitors. Consumers who do not enjoy the same rates as "preferred" customers frequently file such complaints. However, even if favoured clients pass on savings to patients and gain market share, competition is unlikely to suffer. Similarly, private claims of exclusive dealing or boycotts against PBM arrangements have typically failed. The Robinson Patman Act has also been used to deny challenges to PBM pricing.

XII. CONCLUSION:

Drug pricing is a critical concern. Although there have been advances over the years, owing to the efforts of institutions like FTC, there is still a long way to go when it comes to pharmaceutical pricing and maintaining competition in the market. For consumers who cannot afford their prescription, this is truly a life-or-death situation.

The pharmaceutical industry frequently asserts that any patent restrictions or antitrust enforcement will hamper innovation.However, not all antitrust enforcement measures would have an impact on innovation. Byending these anticompetitive practices, we can reap the benefits of decreased medicine pricingwhile still observing healthy innovation.

The FTC plays a critical role in advocating the same and must make efforts in fighting unjust practices like price discrimination and patent evergreening, cutting consumer prices in the process.