


2023

Renewing Faith in Antitrust: Unveiling the Hidden Network Behind Pharmaceutical Product Hopping

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Recommended Citation

Victoria Field, Note, Renewing Faith in Antitrust: Unveiling the Hidden Network Behind Pharmaceutical Product Hopping, 28 Fordham J. Corp. & Fin. L. 149 (2023).

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RENEWING FAITH IN ANTITRUST: UNVEILING THE HIDDEN NETWORK BEHIND PHARMACEUTICAL PRODUCT HOPPING

*Victoria Field**

ABSTRACT

Patents grant time-limited market exclusivity to drug manufacturers, meaning that other companies are prohibited from copying and selling the patented pharmaceutical. This allows manufacturers to lawfully charge monopoly prices. Generic competition starts at the expiration of the patent. To maintain coveted monopoly power, manufacturers often release an alternative formulation of the drug with a fresh patent that enjoys continued market exclusivity. Manufacturers who can convert their consumer base to the new formulation can continue charging peak prices. This process, called “product hopping,” has been the target of significant antitrust inquiry, with mixed results.

A product hop may be the result of legitimate innovation if a manufacturer releases a superior product and consumers voluntarily switch, or it may involve steering consumers to the new formulation through artificial means. A product hop that is not based purely on the merits of the product requires a web of anticompetitive agreements involving Pharmacy Benefit Managers (“PBM”s), insurance companies, pharmacies, and prescribers. Manufacturers use these secret agreements to keep generic competitors at bay by steering patients towards newly patented formulations. This Note shows that pharmaceutical product hopping sits at the center of a network of antitrust violations: it is anticompetitive by association when combined with tying, exclusive dealing, market foreclosure, and other anticompetitive agreements, regardless of the nature of the product hop itself.

* J.D. Candidate, Fordham University School of Law, 2023. I would like to thank Professor Richard Steuer for his mentorship, guidance, and encouragement. I would also like to thank the *Fordham Journal of Corporate and Financial Law* for editing and polishing this work. Finally, I would like to thank my husband for his seemingly endless patience and enthusiasm about my research.

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INTRODUCTION

Between 1996 and 2019, the monthly retail cost of Humalog, a synthetic insulin for treating type 1 diabetes, rose from \$21 to \$275.¹ This 1,300 percent increase was far above actual inflation in the United States, which was only about 62 percent during that same period.² While this increase may look like price gouging to the average consumer, the increase is legal under U.S. federal antitrust law.³ America’s foundational antitrust statutes, the Sherman Antitrust Act of 1890 (“Sherman Act”)⁴ and the Clayton Antitrust Act of 1914 (“Clayton Act”),⁵ prohibit monopolization and attempted monopolization through anticompetitive means but place no restrictions on an existing, lawful monopoly’s right to

1. Danielle K. Roberts, *The Deadly Costs of Insulin*, AM. J. MANAGED CARE (June 10, 2019), <https://www.ajmc.com/view/the-deadly-costs-of-insulin> [<https://perma.cc/7PNG-VLH7>].

2. *Id.*

3. *See* 15 U.S.C. §§ 1-2.

4. §§ 1-2.

5. §§ 12-27.

raise prices. As Justice Scalia wrote in *Verizon Communications v. Law Offices of Trinko*, “The mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an important element of the free-market system.”⁶ Under this reasoning, by being successful and making a profit, monopolists encourage new entry to the market by firms that aim to share in that success.⁷ Therefore, the high price of drugs like Humalog is facially legal under the holding of *Trinko*.⁸ There is no antitrust cause of action against a drug manufacturer that uses lawful monopoly power to charge a high price.⁹

However, when manufacturers set drug prices, they are not acting alone; these prices are the result of contracts, negotiations, and fees involving many players in a highly complex market. Generally, the highest-priced products are patented drugs without generic alternatives.¹⁰ Manufacturers are motivated to keep consumers purchasing these high-priced drugs rather than cede market power and profits to lower cost generics that enter the market after patent protection expires.¹¹ Therefore, through a process popularly known as “product hopping,” manufacturers convert patients from a formulation that is about to come off patent (such as a capsule) to a newly patented alternative formulation (such as a tablet).¹² Although product hopping keeps the price of drugs elevated, courts are divided on whether the practice is illegal under federal antitrust law.¹³

6. *Verizon Commc’ns, Inc. v. Law Offs. of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004).

7. *See id.*

8. *See id.*

9. *See id.*

10. Ananya Mandal, *Drug Patents and Generic Pharmaceutical Drugs*, NEWS MED. LIFE SCI. (Feb. 26, 2019), <https://www.news-medical.net/health/Drug-Patents-and-Generics.aspx> [<https://perma.cc/438V-B36J>].

11. *See* Olivier J. Wouters, Martin McKee & Jeroen Luyten, *Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018, 2020* JAMA 844, <https://jamanetwork.com/journals/jama/fullarticle/2762311> [<https://perma.cc/3P9T-HRY8>] (mean cost of developing a new drug may be as much as \$2.8 billion); *see also* Mandal, *supra* note 10 (“Once the generic drug is on the market, the monopoly of the patent holder is removed. This encourages competition and results in a significant drop in drug costs” and thereby decreased revenues for the manufacturer.).

12. *See* Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 168 (2016).

13. *See, e.g., Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 415 (D. Del. 2006) (finding that the product hop triggered antitrust liability); *cf. Mylan Pharm.*

Product hopping motivates a complex web of deals involving every level of the pharmaceutical market including Insurers, pharmacy benefit managers (“PBMs”), and pharmacies.¹⁴ PBMs play a central role in these agreements. They serve as the contractual middlemen and gatekeepers who control the flow of money between and among manufacturers, Insurers, and pharmacies.¹⁵ Many of the underlying deals they strike involve market foreclosure,¹⁶ tying,¹⁷ exclusive dealing,¹⁸ and other anticompetitive behaviors all connected to product hopping.¹⁹ Through a tangle of anticompetitive conduct (largely orchestrated between manufacturers and PBMs via drug formulary negotiations), product hopping raises prescription drug prices and restricts access to low-cost generic alternatives.²⁰

This Note explains how the anticompetitive effects of product hopping are manifested by a web of agreements involving every level of the pharmaceutical market and considers different ways to lower drug

Inc. v. Warner Chilcott Pub. Ltd. Co., 838 F.3d 421, 429-30 (3d Cir. 2016) (finding that a product hop did not trigger antitrust liability).

14. H.R. COMM. ON OVERSIGHT & REFORM, 117TH CONG., DRUG PRICING INVESTIGATION MAJORITY STAFF REPORT 8-9 (2021), <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/DRUG%20PRICING%20REPORT%20WITH%20APPENDIX%20v3.pdf> [hereinafter MAJORITY REPORT].

15. See generally *id.*

16. See Jonathan M. Jacobson, *Exclusive Dealing, “Foreclosure,” and Consumer Harm*, 70 ANTITRUST L.J. 311, 320 (2002) (noting that market foreclosure occurs when a firm commands a significant portion of the relevant market to substantially lessen competition).

17. Richard M. Steuer, *Musthavedness*, 81 ANTITRUST L.J. 447, 450 (2017) (explaining that “tying” is “conditioning the sale of one product on the purchase of another, [or] conditioning a discount on one product on the purchase of another.”).

18. FED. TRADE COMM’N, EXCLUSIVE DEALING OR REQUIREMENTS CONTRACTS, <https://www.ftc.gov/advice-guidance/competition-guidance/guide-antitrust-laws/dealings-supply-chain/exclusive-dealing-or-requirements-contracts> (last visited Aug. 10, 2022) (“In simple terms, an exclusive dealing contract prevents a distributor from selling the products of a different manufacturer.”).

19. See generally MAJORITY REPORT, *supra* note 14.

20. See Gregory H. Jones et al., *Strategies that Delay or Prevent the Timely Availability of Affordable Generic Drugs in the United States*, BLOOD (Mar. 17, 2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4915805/> [<https://perma.cc/TD8Q-A4V8>] (explaining that the Actavis product hop involving Namenda “would have led to consumers ‘pay[ing] almost \$300 million more,’ third-party payors ‘pay[ing] almost \$1.4 billion more,’ and Medicare and its beneficiaries paying ‘a minimum of \$6 billion over the next [10] years.’”).

prices through antitrust enforcement. Part I explains drug patenting and pricing. Part II describes the financial and contractual relationships between manufacturers, PBMs, Insurers, pharmacies, and other members of the pharmaceutical supply chain. Part III identifies potentially anticompetitive activities related to product hopping and analyze those behaviors according to antitrust statutes and caselaw. Part IV discusses legislative proposals to address product hopping by amending antitrust law and increasing transparency in the pharmaceutical market.

I. BRAND DRUGS, PATENTS, AND PRODUCT HOPPING

Pharmaceutical research is a gamble. From 1991 to 2010, only 19 percent of drugs succeeded from Phase I clinical trials to final Food and Drug Administration (FDA) approval, meaning that over 80 percent of pharmaceutical research never made it to production.²¹ Average cost estimates for bringing a new drug to production range from \$314 million to \$2.8 billion.²² Drug manufacturers may recoup the cost of research by maximizing profits when a drug is successful.

Patent protection excludes other companies from manufacturing or selling competing generic versions of the patented drug during a limited period.²³ Upon expiration of the patent, other manufacturers may introduce generic alternatives and the price of the drug subsequently drops dramatically.²⁴

Every drug is subject to multiple patents: a drug's "primary patent" is the patent on the original compound, giving protection for a period of 20 years.²⁵ Much of that 20-year period goes into drug development and application for FDA approval.²⁶ On average, there are 7 to 10 years

21. Tohru Takebe, Ryoka Imai & Shunsuke Ono, *The Current Status of Drug Discovery and Development as Originated in United States Academia: The Influence of Industrial and Academic Collaboration on Drug Discovery and Development*, 11 CLINICAL & TRANSLATIONAL SCI. 597, 606 (2018), <https://ascpt.onlinelibrary.wiley.com/doi/10.1111/cts.12577>.

22. Wouters et al., *supra* note 11.

23. See CDER SMALL BUS. AND INDUS. ASSISTANCE DIV. OF DRUG INFO. OFF. OF COMM'NS, PATENTS AND EXCLUSIVITY 1 (2015), <https://www.fda.gov/media/92548/download> [<https://perma.cc/4MFM-7UX3>] [hereinafter CDER].

24. See U.S. FOOD & DRUG ADMIN., GENERIC DRUGS: QUESTIONS AND ANSWERS (2021), <https://www.fda.gov/drugs/questions-answers/generic-drugs-questions-answers> [<https://perma.cc/YA9X-8MFY>].

25. CDER, *supra* note 23, at 1.

26. Mandal, *supra* note 10.

remaining on the primary patent for patent-protected sales after receiving regulatory approval.²⁷ “Secondary patents” provide more comprehensive protection, covering every other aspect of the drug, from manufacturing and inactive ingredients to administration and dosage.²⁸ Judicious use of secondary patents provides a means to extend the profitability and market exclusivity of a drug long after the expiration of the primary patent through product hopping (also called “evergreening”).²⁹ Product hopping occurs when a manufacturer releases a new formulation of a drug with new secondary patents just as the old patent is about to expire.³⁰

However, simply patenting a new formula does not ensure a successful product hop. Success hinges on a manufacturer’s ability to convert consumers to the new formulation before the patent on the old formulation expires.³¹ If healthcare providers prescribe the off-patent formulation, pharmacies may fill the prescription with their choice of either the branded product or a generic alternative (if a generic exists). On the other hand, if healthcare providers specifically prescribe the new formulation, there will be no generic alternative to the new formulation and the pharmacist will have to dispense the higher-cost brand name drug.³² To accomplish this conversion from the off-patent drug to the new formulation, brand manufacturers must collaborate with players at every level of the drug distribution chain. By transitioning consumers from one patented drug to another, these collaborations foreclose generic competition from the market. As detailed below, product hopping (and the resulting high drug price) is more than a simple switch; rather, it is the culmination of a web of anticompetitive behaviors that have an aggregate anticompetitive effect. To understand how product hopping sits at the

27. *Id.*

28. Julian W. Marrs, *Forever Green? An Examination of Pharmaceutical Patent Extensions*, 18 OR. REV. INT’L L. 81, 82 (2016) (distinguishing between “primary patents, which protect an active ingredient directly” and “secondary patents” that “protect a range of chemicals related to an active ingredient, methods of use, alternate formulations, or dosages.”).

29. Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLA. L. REV. 1009, 1016 (2010).

30. Carrier & Shadowen, *supra* note 12, at 168. Product hopping is defined by two behaviors: (1) reformulating the product “in a way that makes the generic [version of the original product] not substitutable”; and (2) “encourag[ing] doctors to write prescriptions for the reformulated product rather than the original[,]” i.e., switching the prescription base from the original to the reformulated product. *Id.*

31. *Id.*

32. *See id.*

center of this web, we must first understand how the money flows. To that end, the following section will map out the pharmaceutical market and explain how drug prices are negotiated.

II. FOLLOWING THE MONEY

A. DRUG PRICES AND FORMULARIES

Drug prices start with manufacturers who research, patent, and produce brand name drugs (“brand drugs”). The manufacturers’ “list price” or baseline, non-discounted price tag for each drug, is used to establish copayments and insurance premiums.³³ However, insurance companies and employers who sponsor health plans (collectively “Insurers”) almost never pay the full list price.³⁴ Instead, Insurers contract with PBMs to negotiate rebates for the purpose of achieving a lower “net cost.”³⁵

In exchange for manufacturer rebates, PBMs grant preferential placement on the formulary, which is the list of prescription drugs covered by an insurer, often sorted into tiers according to the amount of the copayment, coinsurance, or patient rebate.³⁶ This list of covered drugs is intended to promote the highest quality of care at the lowest cost.³⁷ While the drugs are generally selected by a PBM’s Pharmaceutical and

33. H.R. COMM. ON OVERSIGHT AND REFORM MINORITY STAFF, A VIEW FROM CONGRESS: ROLE OF PHARMACY BENEFIT MANAGERS IN PHARMACEUTICAL MARKETS 4 (2021) [hereinafter MINORITY REPORT].

34. *Id.*

35. *See* MAJORITY REPORT, *supra* note 14, at 9:

PBMs leverage their aggregated demand to offer preferential access to patients through formularies, which function as lists of drugs covered by a plan, in exchange for discounts and rebates from the drug manufacturer that partially offset the drug’s list price. The cost of a drug after applying all of the manufacturer’s rebates and discounts is referred to as a drug’s net price.

36. *See* PATRICK J. KENNEDY ET AL., THE KENNEDY FORUM, A CONSUMER GUIDE TO DRUG FORMULARIES: UNDERSTANDING THE FUNDAMENTALS OF BEHAVIORAL HEALTH MEDICATIONS 3 (Judy Behm et al. eds., 2017) https://www.thekennedyforum.org/app/uploads/2017/09/170824-KF-Consumer-Guide-Drug-Form-Issue-Brief-0817_4.pdf [<https://perma.cc/JG7G-YJQ7>] [hereinafter THE KENNEDY FORUM].

37. *Id.* at 1 (“By establishing coverage limitations for prescription drugs, formulary guides are intended to make sure patients receive the most appropriate medications and reduce the utilization of unnecessary medical resources.”).

Therapeutics team composed of medical experts,³⁸ the final formulary is the result of negotiations between the PBM and drug manufacturers. In these negotiations, rebates are offered by the manufacturers in exchange for favorable placement on formulary lists.³⁹

Formularies may incorporate certain “utilization management protocols” to “promote appropriate use . . . of medical resources.”⁴⁰ These protocols may include: quantity limits on the number of units a patient may receive in a given period; “fail first protocols,” which require a medical provider to try a generic before prescribing a more expensive brand drug; requirements for prior authorization before a prescription will be covered; and mail-order criteria that set a higher copay for prescriptions filled at a retail pharmacy than through the PBM’s own mail-order pharmacy.⁴¹ On the other hand, formularies may also have a “preferred drug list” of brands and medications which are exempt from such prior authorization requirements.⁴² Medications on the preferred drug list are easier for patients to access.⁴³

Formularies are the arenas in which brand manufacturers vie for access to consumers and compete with generic alternatives. Low copayments and a spot on the preferred drug list mean low out-of-pocket cost and easier access for consumers, which in turn increases the volume of sales.⁴⁴ Ultimately, brand manufacturer profits depend upon advantageous placement on formulary lists.⁴⁵

38. *Id.* at 3 (“PBMs may also design and manage the prescription drug benefit for health plans via a Pharmacy and Therapeutics (P&T) committee, which typically consists of a group of doctors, nurses, and pharmacists tasked with selecting the medications included within a formulary.”).

39. MINORITY REPORT, *supra* note 33, at 4.

40. THE KENNEDY FORUM, *supra* note 36, at 4.

41. *Id.*

42. *Id.*

43. *Id.*

44. *See* Jones et al., *supra* note 20. Given that “[a]pproximately 1 in 5 Americans do not fill prescriptions because of prohibitive cost[.]” cost is a factor in prescription drug sales. *Id.*

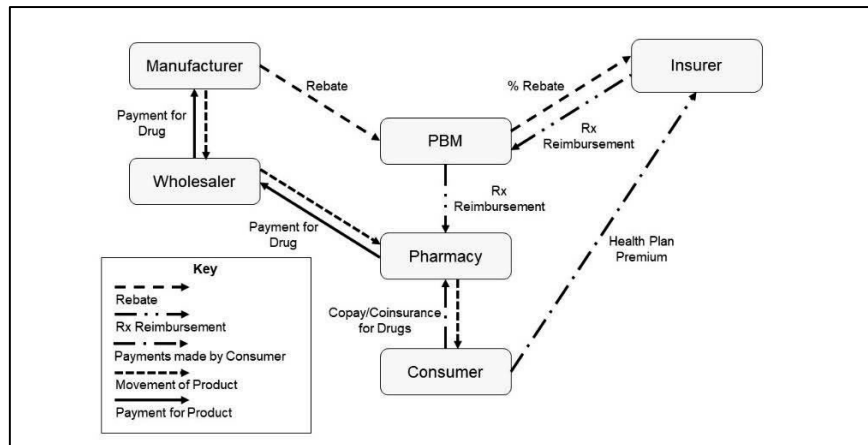
45. *See* CHRISTOPHER STOMBERG, THE ROLE OF REBATES IN THE PHARMACEUTICAL INDUSTRY 2 (2021) https://www.nera.com/content/dam/nera/publications/2021/The_Role_of_Rebates_in_the_Pharmaceutical_Industry.pdf [<https://perma.cc/9NW8-T2FJ>]. “[PBMs] can steer pharmaceutical demand for large numbers of beneficiaries. A relatively small handful of PBMs serve as gatekeepers to a large percentage of the insurance-covered beneficiaries in the United States.” *Id.*

B. THE PHARMACEUTICAL SUPPLY CHAIN

PBMs have three primary roles in which they act as contractual and financial middlemen: PBMs work with manufacturers to develop formularies on behalf of Insurers; negotiate rebates and discounts from manufacturers on behalf of Insurers; and reimburse pharmacies for drugs dispensed to consumers with prescription insurance.⁴⁶

While drugs themselves move through a relatively straightforward pipeline from manufacturer to consumer, pharmaceutical finances move in a more complex network of transactions involving multiple levels of the supply chain with the PBM as the central actor.⁴⁷ Figure 1 below depicts the flow of products and money throughout the pharmaceutical market.

Figure 1: The Pharmaceutical Supply Chain (Simplified)⁴⁸



Prescription drugs (the physical product) are created by the manufacturer and sold to the wholesaler, which in turn sells the drugs to the pharmacy.⁴⁹ These medications are ultimately dispensed to the consumer with a physician's prescription.⁵⁰ If the consumer has prescription insurance and is not paying out of pocket, then the consumer

46. SHAWN BISHOP, THE COMMONWEALTH FUND, PHARMACY BENEFIT MANAGERS AND THEIR ROLE IN DRUG SPENDING 1 (2019), https://www.commonwealthfund.org/sites/default/files/2019-04/Explainer_PBMs_1.pdf [<https://perma.cc/5CV3-T7PU>].

47. MINORITY REPORT, *supra* note 33, at 6.

48. *See id.*

49. *See id.*

50. *See id.*

pays a pre-determined copayment or coinsurance.⁵¹ The pharmacy recoups additional costs for covered drugs via reimbursements from the PBM (rather than receiving reimbursement directly from the insurer).⁵² PBMs in turn receive an agreed-upon payment from Insurers which may be more than the amount actually paid to the pharmacy (with the PBM keeping the difference).⁵³ Thus, PBMs act as financial middlemen between Insurers and pharmacies for covered prescriptions.

PBMs are also financial middlemen in rebate transactions between pharmaceutical manufacturers and Insurers. In formulary negotiations between manufacturers and PBMs, manufacturers offer rebates in exchange for favorable placement on formulary lists.⁵⁴ Upon sale, the manufacturer pays the rebate to the PBM.⁵⁵ These rebates may account for 40 percent or more of the drug's list price.⁵⁶ The PBM retains a percentage of the rebate as profit and passes the rest on to the insurer.⁵⁷

For example, consider a hypothetical PBM which represents Insurers X, Y, and Z in negotiating for Drug A. If the manufacturer's list price of Drug A is \$1,000 and the PBM negotiates a \$500 rebate, then the manufacturer will pay the PBM a \$500 rebate for every unit of Drug A delivered to consumers who are insured by Insurers X, Y, and Z. Assuming for simplicity's sake that there is only a rebate and no other discount, copayment, or coinsurance, each insurer pays the full list price of \$1,000. The PBM then sends a percentage of the rebate to the Insurers and retains a percentage for itself.⁵⁸ Therefore, if the PBM sends 90 percent of the rebate to the Insurers, then Insurers X, Y, and Z each receive \$450 per unit of Drug A dispensed to their beneficiaries, leaving them paying a net cost of \$550 for the drug while the PBM retains \$50 from the rebate.

51. *See id.*

52. *See id.*

53. BISHOP, *supra* note 46, at 1-2.

54. MINORITY REPORT, *supra* note 33, at 4.

55. ELIZABETH SEELEY & AARON S. KESSELHEIM, COMMONWEALTH FUND, THE COMMONWEALTH FUND PHARMACY BENEFIT MANAGERS: PRACTICES, CONTROVERSIES, AND WHAT LIES AHEAD 2-3 (2019) https://www.commonwealthfund.org/sites/default/files/2019-03/Seeley_pharmacy_benefit_managers_ib_v2.pdf [<https://perma.cc/9QLA-9CE5>].

56. *Id.* at 3.

57. *See id.* at 2-3.

58. *See* BISHOP, *supra* note 46, at 1.

C. MONEY FOR THE MIDDLEMEN

According to PBMs' business models, details of pharmacy reimbursements or rebates from formulary negotiations are confidential.⁵⁹ This cloak of secrecy, coupled with the PBM's central role in moving money among manufacturers, Insurers, and pharmacies presents unique opportunities for PBM profit and anticompetitive abuse.

The confidential nature of contracts between manufacturers and PBMs means that neither government regulators nor the Insurers who employ the PBMs can learn the details of the contracts or materially contribute to the negotiation process.⁶⁰ Insurers are unable to identify exactly how much of negotiated rebates they receive and how much is retained by the PBM.⁶¹ While PBMs report that 90 percent of rebates are passed on to Insurers and consumers, some recipients (especially small Insurers) report that they are not receiving that amount.⁶² In the hypothetical case of Drug A above, if Insurer Z is a small company and the PBM sends them only 80 percent of the \$500 rebate, they would receive only \$400 compared to the \$450 received by Insurers X and Y. This would leave them paying a net price of \$600 as compared to their larger competitors' net price of only \$550.

In addition to the disparate impact on small Insurers, rebates can actually increase prescription costs for consumers across the board. This is because manufacturers may increase the list price of drugs to recoup profits lost to rebates, leading to rising prices over time.⁶³

59. See *id.* at 1 (rebates received from drug manufacturers are generally not disclosed); see also Catherine Candisky, *State Report: Pharmacy Middlemen Reap Millions From Tax-Funded Medicaid*, USA TODAY: COLUMBUS DISPATCH (2018), <https://stories.usatodaynetwork.com/sideeffects/state-report-pharmacy-middlemen-reap-millions-from-tax-funded-medicaid/> [<https://perma.cc/8G6N-T54X>] (“[I]t is not clear how much of the price difference, known as the price spread, is profit and how much goes to administrative costs.”).

60. See Robin Feldman, *Perverse Incentives: Why Everyone Prefers High Drug Prices—Except for Those Who Pay the Bills*, 57 HARV. J. ON LEGIS. 303, 306-07 (2020).

61. See *id.* at 316 (“[T]hese price concessions are a closely-guarded secret, and it is difficult to tease out the actual net price different entities pay along the drug chain.”).

62. SEELEY & KESSELHEIM, *supra* note 55, at 3.

63. NEERAJ SOOD ET AL., USC LEONARD D. SCHAEFFER CENTER FOR HEALTH POL’Y & ECON., THE ASSOCIATION BETWEEN DRUG REBATES AND LIST PRICES 1, 3 (2020), <https://healthpolicy.usc.edu/research/the-association-between-drug-rebates-and-list-prices/> [<https://perma.cc/Q3WT-Y8SR>]:

Lack of transparency also presents opportunity for PBMs to profit when they reimburse pharmacies for drugs. Through a practice known as “spread pricing,” PBMs reimburse pharmacies for a lower dollar amount and negotiate higher payments from Insurers, pocketing the difference as “spread.”⁶⁴ While some of this price difference may reasonably be attributable to administrative costs, a lack of transparency makes it unclear how much of the price spread accounts for administrative costs and how much is additional profits for PBMs.⁶⁵ PBMs also monetize their position by charging fees to pharmacies.⁶⁶ These fees reduce and may even surpass the reimbursement that the pharmacy would otherwise receive from the PBM, causing them to lose money on prescriptions.⁶⁷ For a typical retail pharmacy, these fees may include administrative fees charged to the pharmacy ranging from \$1.25 to \$3.50 per prescription

[A] \$1 increase in rebates is associated with a \$1.17 (95[percent] CI [0.69, 1.66] P<0.001) increase in list price. . . . [R]educing or eliminating rebates could result in lower list prices, thereby decreasing out-of-pocket costs for uninsured patients and for insured patients with deductibles or coinsurance.

64. See *In re Lidoderm Antitrust Litig.*, No. 14-md-02521-WHO, 2017 U.S. Dist. LEXIS 24097, at *48-49 (N.D. Cal. Feb. 21, 2017) (“PBMs use ‘spread pricing’ and ‘rebates’ as part their [sic] business operations. PBMs typically negotiate prices for drugs directly with retail pharmacies and earn profits on the ‘spread’ between the prices they pay the pharmacies and the price they charge [insurers].”); see also Candisky, *supra* note 59 at 2 (“[A]n investigation by The Dispatch . . . found that CVS Caremark, which has most of Ohio’s Medicaid business, was billing the state more than it paid pharmacies and often reimbursed them less than the cost of the medication.”).

65. See Candisky, *supra* note 59, at 2-3.

66. DENNIS TUMMINIA, EDGEWOOD PARTNERS INSURANCE CENTER, HOW YOUR PHARMACY BENEFIT MANAGER MAKES MONEY 1 (2013) <http://cdn.sparkart.net/edgewoodins/content/pdfs/Pharmacy.pdf>.

67. See MINORITY REPORT, *supra* note 33, at 4:

These retroactive fees can be for just participating in the network, or they can be tied to performance metrics, such as pharmacy refill rates, error rates, or audit rates, which the PBM establishes. These retroactive fees add up—sometimes it costs a pharmacy more to fill a prescription than it is reimbursed.

filled and transaction fees ranging from \$0.10 to \$0.15 per insurance claim.⁶⁸

PBMs are immensely profitable.⁶⁹ However, PBM profit depends on the price of drugs and number of prescriptions filled.⁷⁰ With PBMs receiving a share of rebates, their profits are directly proportional to the dollar amount of each rebate. PBMs earn profits per prescription based on the number and amount of administrative and transactional fees.⁷¹ PBMs are therefore motivated to negotiate higher rebates (which indirectly lead to higher drug prices) and encourage a high volume of fee-generating prescriptions.

D. POTENTIAL MARKET DISRUPTERS: COUPONS AND DISCOUNT CARDS

In the 2000s,⁷² brand drug manufacturers began distributing prescription coupons to reduce the out-of-pocket cost of their drugs for consumers.⁷³ While including a drug in a formulary connects the manufacturer to an insurer, coupons are a way of marketing certain brand drugs directly to consumers and building brand identity. By attracting consumers to the brand drugs rather than generics, manufacturer coupons increase brand sales without the manufacturer having to vie for (or pay for) preferential placement on formularies.⁷⁴ Copay coupons reduce the price of the product by offsetting the copay, though insurance generally

68. TUMMINIA, *supra* note 66, at 1.

69. See, e.g., Robin Townsend, *What Are the Biggest Health Insurance Companies?*, VALUEPENGUIN (Feb. 11, 2022) <https://www.valuepenguin.com/largest-health-insurance-companies> [<https://perma.cc/FJ32-HCHZ>] (explaining that in 2021, UnitedHealth Group's revenue was \$286 billion and CVS's revenue was \$61 billion).

70. See SOOD ET AL., *supra* note 63, at 1, 3.

71. See *id.*

72. Scott Wooldridge, *Drug Coupons: A Hidden Driver of Rising Pharmaceutical Costs*, BENEFITS PRO (Feb. 21, 2022) <https://www.benefitspro.com/2022/02/21/drug-coupons-a-hidden-driver-of-rising-pharmaceutical-costs/> Prescription coupon use has accelerated rapidly since being introduced in the 2000s, such that the “share of branded drug spending with a coupon increased from 26 [percent] to 54 [percent] between 2007 and 2010.” *Id.*

73. See Shawn Radcliffe, *Big Pharma, Insurance Giants in Heated Battle Over Drug Coupons*, HEALTHLINE (Apr. 17, 2018) <https://www.healthline.com/health-news/big-pharma-insurance-giants-battle-over-drug-coupons> [<https://perma.cc/BR93-JBGX>].

74. See Wooldridge, *supra* note 72 (explaining that manufacturer coupons “driv[e] consumers to more expensive branded drugs”).

picks up the rest of the tab.⁷⁵ The discounted drugs are more attractive for consumers but much less attractive to Insurers due to increased costs.⁷⁶ Therefore, some Insurers will not allow payments made with coupons to apply to the consumer's insurance deductible or will increase premiums overall to recoup costs.⁷⁷ Thus, while coupons offer savings outside of the formulary framework, concerted pushback from Insurers undermines the efficacy of coupons as a cost-saving model.

Prescription Discount Cards ("PDCs") are another source of discounts for consumers outside of the insurance and drug formulary framework. Through PDCs, PBMs negotiate discounts of up to 85 percent on brand and generic drug prices on behalf of pharmacies rather than Insurers.⁷⁸ PBMs then advertise these cards to consumers who may be drawn to lower-cost prescriptions.⁷⁹ Thus, in exchange for offering discounts, pharmacies benefit from increased visibility. Although participation in PDC programs may reduce a pharmacy's prescription drug revenues, offering cheaper prescriptions may build customer loyalty and increase sales of other products at the pharmacy.⁸⁰

While PDCs may lower the cost of certain drugs, they also present certain challenges and inefficiencies for consumers. A consumer using a PDC generally cannot apply any insurance to their prescription purchase because the savings are negotiated outside of the formulary framework, but may find that the coupon price is lower than their copayment would otherwise have been.⁸¹ However, PDC users may not know the final

75. See Radcliffe, *supra* note 73 ("[T]otal monthly costs—what the consumer and insurance company paid combined—were about the same for both groups. Copay coupons just reduced the consumers' out-of-pocket spending.").

76. See *id.*

77. See *id.* (UnitedHealthcare and Express Scripts introduced a "copay accumulator program" prevents manufacturer coupon savings from being applied to a deductible.)

78. Olga Hilas, *A Pharmacist's Primer on Prescription Discount Cards*, U.S. PHARMACIST (Oct. 15, 2021), <https://www.uspharmacist.com/article/a-pharmacists-primer-on-prescription-discount-cards> [<https://perma.cc/Q8TY-QN5F>].

79. See *id.*

80. See *id.*

81. See *id.*:

It is important to note that these discount cards cannot be combined with prescription coverage; therefore, any medication costs would not be applied toward insurance deductibles or out-of-pocket maximums. [However,] [p]atients can compare medication prices offered by the

prescription price until they present the card at the pharmacy counter, which makes PDCs unpredictable compared to insurance.⁸² Even with prior research, it is difficult for a consumer to determine whether insurance or PDCs provide the better deal.⁸³

Formularies and PDCs are competing platforms on which manufacturers exchange discounts for access to consumers with PBMs acting as contractual middlemen. While formularies are the only way for manufacturers to access consumers paying with insurance, PDCs are a way to connect with consumers who are paying out-of-pocket, which may include insured consumers who are seeking a better deal outside of their prescription coverage. If manufacturers want to access consumers without paying into the expensive formulary system, PDCs present an attractive alternative. However, PDCs may not be equally attractive to consumers because pricing through PDCs is more complicated and unpredictable than pricing through prescription insurance.⁸⁴ Insured consumers may also be disincentivized to pay out-of-pocket through a PDC if the payment will not count toward their deductible.⁸⁵ Therefore, PDCs are not poised to threaten insurance formularies as the primary gateway to prescription drug consumers.

Furthermore, while formularies and PDCs connect manufacturers with different members of the pharmaceutical supply chain (Insurers and pharmacies respectively), they use the same middlemen: PBMs.⁸⁶ Therefore, PDCs cement the power of PBMs as price-makers rather than disrupting the market. Even with the existence of PDCs as an alternative savings model, manufacturers are still motivated to direct consumers to patented drugs, and formularies remain the primary tool for making that happen.

various free prescription discount cards either online or via mobile apps to determine the most cost-effective option.

82. *Id.*

83. *See id.*

84. *See Hilas, supra* note 78.

85. *See id.*

86. *See* THE KENNEDY FORUM, *supra* note 36 (drug formularies are the result of negotiations between PBMs and Insurers); *see also* Hilas, *supra* note 78 (PDC discounts are negotiated between PBMs and pharmacies).

III. THE ANTICOMPETITIVE NETWORK

A. OVERVIEW OF APPLICABLE LAW

The Sherman Act⁸⁷ and the Clayton Act⁸⁸ are the foundations of federal antitrust law. Section 1 of the Sherman Act prohibits contracts and combinations in unreasonable restraint of trade such that “every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce . . . is declared to be illegal.”⁸⁹ Section 2 of the Sherman Act prohibits monopolization and attempted monopolization.⁹⁰ Antitrust law does not confer liability to products or business practices that gain monopoly power naturally by chance or their own merits; rather, monopolization is defined by the Supreme Court as “(1) possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of superior product, business acumen, or historic accident.”⁹¹ Attempted monopolization under Section 2 of the Sherman Act requires proof of “(1) . . . anticompetitive conduct with, (2) a specific intent to monopolize, and (3) a dangerous probability of achieving monopoly power.”⁹²

The Clayton Act supplements the Sherman Act by prohibiting particular anticompetitive behavior such as tying and exclusive dealing.⁹³ One provision of the Clayton Act declares that it is unlawful for a seller to require a buyer to agree to not deal with the seller’s competitors, if such a deal would substantially lessen competition.⁹⁴ The Clayton Act also

87. 15 U.S.C. §§ 1-2.

88. §§ 12-27.

89. § 1.

90. *See id.*

91. § 2; *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966).

92. *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 456 (1993).

93. 15 U.S.C. § 14.

94. *Id.*:

That it shall be unlawful for any person engaged in commerce, in the course of such commerce, to lease or make a sale or contract for sale of goods, wares, merchandise, machinery, supplies or other commodities, whether patented or unpatented, for use, consumption or resale within the United States or any Territory thereof or the District of Columbia or any insular possession or other place under the jurisdiction of the United States, or fix a price charged therefor, or

contains an incipency clause which extends antitrust liability to conduct which “*may* be substantially to lessen competition, or to *tend* to create a monopoly[,]” regardless of whether it contributes to or maintains monopoly power in the present.⁹⁵

Another key component of antitrust law is the Federal Trade Commission Act, which created the Federal Trade Commission (FTC) to enforce federal antitrust and consumer protection laws.⁹⁶ The Federal Trade Commission Act, which also filled gaps left by the Sherman Act, provides “[t]hat unfair methods of competition in commerce in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.”⁹⁷

Collectively, federal antitrust laws prohibit anticompetitive conduct and collusion, which is “generally defined as conduct to obtain or maintain monopoly power as a result of competition on some basis other than the merits.”⁹⁸ Monopoly power is “the ability to control prices and exclude competition in a given market.”⁹⁹ However, antitrust law does not protect individual competitors within the market. Rather, it protects the market from “conduct which unfairly tends to destroy competition itself.”¹⁰⁰

Product hopping does not necessarily constitute anticompetitive conduct. In some cases, an apparent product hop is the result of legitimate innovation through which a new, superior product takes over the market from an old, inferior formulation. In other cases, however, the conversion of consumers from one product to the other is supported and enabled by a network of tying, exclusive dealing, and other anticompetitive activities involving drug formulary negotiations between manufacturers and PBMs; pressure campaigns targeting prescribers; and exclusive dealing between

discount from, or rebate upon, such price, on the condition, agreement or understanding that the lessee or purchaser thereof shall not use or deal in the goods, wares, merchandise, machinery, supplies or other commodities of a competitor or competitors of the lessor or seller, where the effect of such lease, sale, or contract for sale or such condition, agreement or understanding may be to substantially lessen competition or tend to create a monopoly in any line of commerce.

95. *See, e.g.*, 15 U.S.C. § 14 (emphasis added).

96. Federal Trade Commission Act, ch. 311, 38 Stat. 717 (1914) (codified as amended at 15 U.S.C. § 41).

97. 15 U.S.C. § 45.

98. *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 308 (3d Cir. 2007).

99. *Id.* at 307.

100. *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993).

manufacturers and pharmacies. Regardless of whether product hopping violates antitrust laws by itself, the aggregate effect is anticompetitive when it is enabled by a tangle of antitrust violations. The following sections will explain the product hopping network and examine the anticompetitive effects of individual activities within that network.

B. REVERSE PAYMENT SETTLEMENTS

Before the legal community turned its attention to product hopping, it took aim at reverse payment settlements, a by-product of the Hatch-Waxman Act,¹⁰¹ which was designed to facilitate the introduction of generic drugs.¹⁰² Reverse payment settlements are a means of protecting patents and extending patent-monopoly profits.¹⁰³ When a brand manufacturer holds a patent for a drug, a would-be competitor might attempt to produce and sell a generic alternative before the patent expires.¹⁰⁴ In such cases, the brand manufacturer may sue for patent infringement, but the court may find that the original patent was invalid or was somehow not violated by the generic competition, allowing the competition to continue.¹⁰⁵ If the brand manufacturer cannot defend its patent, lower cost generic drugs enter the market and the manufacturer loses its erstwhile monopoly power.¹⁰⁶ To protect against such a loss of revenue, brand manufacturers may engage in “reverse payment” settlements, also called “pay-for-delay.”¹⁰⁷ When faced with a patent challenge, the patentee (the company that holds the patent) offers a substantial¹⁰⁸ “reverse payment” to the challenger (the competing

101. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417 § 101, 98 Stat. 1585.

102. Stephen J. Elliott, *Reverse Payments, ‘Actavis’ and Settlement of Hatch-Waxman Disputes*, N.Y. L. J., Sept. 8, 2015.

103. See KEVIN T. RICHARDS, KEVIN J. HICKEY & ERIN H. WARD, CONG. RSCH. SERV., R46221, DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES 28 (2020).

104. See *id.*

105. See *id.*

106. See *id.*

107. See *id.*

108. See, e.g., BRIAN COGGIO & SCOTT M. FLANZ, FISH & RICHARDSON, PATENT LITIGATION SETTLEMENTS: END OR NEW BEGINNING? (2020), <https://www.fr.com/wp-content/uploads/2020/07/Antitrust-Implications-of-Biologic-Settlements-Final.pdf>. In 2019 Endo and Impax reverse payment regarding Endo’s brand pain medication, Opana ER, involved \$10 million settlement plus \$30 million in milestone payments for joint ventures. *Id.* at 18.

company that could develop a generic alternative) in exchange for the promise to not make or sell a generic for an agreed-upon period.¹⁰⁹ While these payments may be large, they are less than the combined court costs and potential lost profits. While these settlements protect manufacturer profits, they hurt consumers by limiting consumer choice to higher-priced patented drugs when cheaper generics might otherwise be made available.¹¹⁰

Prior to 2013, reverse payment settlements were considered only under patent law, entirely shielded from antitrust scrutiny.¹¹¹ Unless the patent was invalid—in which case antitrust liability could be triggered—reverse payment settlements were treated as lawful use of “patent monopoly” power. This changed when the Court ruled in *Actavis*¹¹² that reverse payment settlements for the purpose of maintaining a monopoly were an “improper” use of patent monopoly power, and therefore “a large, unjustified reverse payment risks antitrust liability.”¹¹³

In the wake of *Actavis*, reverse payment settlements have become riskier¹¹⁴ as means of protecting drug patent monopolies because they are subject to rule of reason analysis, meaning that the court might find the activity unlawful unless the payment is relatively small, or the defendant

109. See *F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 140-41 (2013); see also *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 393-94 (3d Cir. 2015) (holding that reverse payment settlements are not limited to the exchange of cash; the patent holder may also offer valuable agreements such as permission for early entry into other markets).

110. Sean Boyle, *All Is Fair in Drugs and War: An Analysis of “Pay-For-Delay” Agreements and Product Hopping*, 53 VAL. U.L. REV. 169, 177 (2018).

111. See *Actavis*, 570 U.S. at 148; cf. *F.T.C. v. Watson Pharms., Inc.*, 677 F.3d 1298, 1315 (11th Cir. 2012) (holding that reverse payment settlements with a valid patent shall be governed by patent law).

112. COGGIO & FLANZ, *supra* note 108, at 10. Actavis agreed to not market a generic for 9 years, and Solvay paid Actavis \$19 to \$30 million annually. *Id.*

113. *Actavis*, 570 U.S. at 158.

114. See Laura Karas, *When “Pay-for-Delay” Becomes “Delay-Without-Pay”*: *Humira Antitrust Claims*, HARV. L.: BILL OF HEALTH (Feb. 1, 2021), <https://blog.petrieflom.law.harvard.edu/2021/02/01/pay-for-delay-humira-antitrust/> [<https://perma.cc/7TVN-VFF4>]. Reverse payments may, but do not always, trigger antitrust liability. The Illinois District Court dismissed a claim that AbbVie’s pay-for-delay settlement violated § 1 of the Sherman Act because the settlement “allow[ed] biosimilars to enter the U.S. market *before* the expiration of Humira patents, albeit several years into the future, and thus they increase competition and benefit consumers.” *Id.* (emphasis in original). The settlement also lacked any reverse payment or exclusivity given to the alleged infringers, “and thus no evidence of sharing of monopoly profits in exchange for delayed market entry.” *Id.*

can provide a pro-competitive justification.¹¹⁵ A valid patent no longer provides any guarantee against antitrust enforcement.

C. PRODUCT HOPPING

The new potential for reverse payment settlements to trigger antitrust liability under *Actavis* has led drug manufacturers to seek new means of ensuring profits from brand drugs such as product hopping.¹¹⁶ As noted above, product hopping occurs when a manufacturer patents a new formulation of a drug just as the old patent is about to expire and engages in various agreements with other members of the pharmaceutical supply chain to shift consumers to the new formulation instead of allowing them to choose a generic equivalent of the old formulation.¹¹⁷

Courts have varied on whether product hopping alone is a violation of antitrust law. Opinions often hinge on whether the hop is a “hard switch” (in which the manufacturer withdraws the original drug from the market prior to the introduction of the new formulation) or a “soft switch” (in which the manufacturer allows the old formulation to stay on the market alongside generic competition).¹¹⁸ Generally, hard switches are more likely to trigger antitrust liability.¹¹⁹ The court found anticompetitive activity in *Abbott Labs. v. Teva Pharmaceuticals USA, Inc.*,¹²⁰ in which drug manufacturer Teva engaged in a hard switch from TriCor capsules¹²¹ (a cholesterol medication) to a newly patented tablet formulation of TriCor.¹²² Teva did so by removing the capsule formulation from the market, buying back existing supplies of the old drug from pharmacies, and updating the TriCor capsule listing in what

115. See *Actavis*, 570 U.S. at 138.

116. See Boyle, *supra* note 110, at 182.

117. See Carrier & Shadowen, *supra* note 12, at 167-68.

118. *Id.* at 168.

119. See *id.*

120. 432 F. Supp. 2d 408 (D. Del. 2006).

121. *Uses and Important Safety Information for TriCor Fenofibrate Tablets*, ABBVIE INC., <https://tricortablets.com/> [<https://perma.cc/Q485-VY9Z>].

122. *Abbot*, 432 F. Supp. at 415.

was then the National Drug Data File (now FDB MedKnowledge)¹²³ to “obsolete.”¹²⁴

However, in *Mylan Pharmaceuticals Inc. v. Warner Chilcott Public Co.*, the court found that the manufacturer’s hard switch from a capsule to a tablet version of the unpatented acne drug Doryx¹²⁵ (generic name Doxycycline) was not anticompetitive because generic competition was not completely foreclosed from the market.¹²⁶ Defendants removed the capsule version from the market, destroyed or bought back existing capsule inventory, and made deals with retailers to fill prescriptions with the tablet version whenever the Doryx brand was prescribed.¹²⁷ However, engaging in a hard switch did not violate antitrust law in this case because defendants did not have monopoly power in the relevant market, which included all Doryx and name-brand tetracyclines prescribed to treat acne.¹²⁸ According to this broad definition of the market as including all tetracyclines, defendants’ share of the market never exceeded 18 percent, while antitrust liability would have required 55 percent.¹²⁹ In addition, there was a non-pretexual justification for the shift because the capsule form of the medication had side effects which were not caused by the tablet.¹³⁰

123. See *NDDF Source Information*, NAT’L LIBR. OF MED. (Mar. 31, 2020), <https://www.nlm.nih.gov/research/umls/rxnorm/sourcereleasedocs/nddf.html> [<https://perma.cc/LES9-ZEMJ>] “FDB MedKnowledge™, formerly National Drug Data File (NDDF) Plus™ . . . encompasses medications approved by the U.S. Food and Drug Administration, and information on commonly-used over-the-counter and alternative therapy agents such as herbals, nutraceuticals and dietary supplements.” *Id.*

124. *Abbott*, 432 F. Supp. 2d at 415, 422.

125. *Mylan Pharms. Inc. v. Warner Chilcott Pub. Co.*, 838 F.3d 421, 429-30 (3d Cir. 2016). Defendants developed a dual-scored Doryx tablet which could be broken into multiple smaller pieces for controlled self-dosing. This tablet had no approved generic alternatives which were interchangeable with the brand dual-scored Doryx. *Id.*

126. *Id.* at 438. Mylan developed its own generic version of Doryx tablets, from which they made \$146.9 million. *Id.*

127. *Id.* at 429.

128. *Id.* at 431, 435.

129. *Id.* at 437–38. However, defendants’ market share in the oral tetracycline market was relatively small: it never exceeded 18 percent. *Id.*

130. *Id.* at 438-39:

Doxycycline capsules had been linked with esophageal problems. . . . [Doryx also] experienced shelf-life stability problems, which in 2002 resulted in a largescale recall of Doryx capsules. Third, Defendants introduced different dosages for Doryx largely in response to the actions of their competitors. For instance, Defendants offered

In *Walgreen Co. v. AstraZeneca Pharmaceuticals L.P.*, which involved a soft switch of Prilosec to Nexium, the court failed to find anticompetitive activity because the introduction of Nexium increased consumer choice.¹³¹ With Prilosec still on the market after Nexium was released, consumers ostensibly could choose between the products (although consumer choice in the prescription drug market may in fact be guided by PBMs and other actors).¹³²

Regardless of whether a product hop is a hard switch or a soft switch, its goal is to foreclose or at least impede competition and keep prices high.¹³³ Furthermore, the success of a product hopping endeavor is ensured by a series of anticompetitive agreements, each of which individually forecloses competitors and steers consumers.¹³⁴ This relationship renders the product hop anticompetitive by association. The following Sections map out this web of agreements, explain how they enable product hopping, and analyze them under federal antitrust law.

D. HOW FORMULARY NEGOTIATIONS SUPPORT PRODUCT HOPPING

Theoretically, formularies are intended to ensure quality of care and promote efficient use of medical resources.¹³⁵ The emphasis on cost and efficiency means that the formulary should generally prioritize low-cost drugs such as generics.¹³⁶ Less favorable drugs will not be covered, or will be locked behind higher pricing tiers and utilization management protocols, such as prior authorization or quantity limits.¹³⁷ For example, some formularies do not include certain drugs for behavioral health

evidence that their decision to introduce the 150mg tablet was in response to the fact that both Adoxa and Solodyn, tetracyclines prescribed to treat acne, were offered in a variety of dosages.

131. See 534 F. Supp. 2d 146, 151 (D.D.C. 2008).

132. See *id.*

133. See Phebe Hong, *Stopping the Pharmaceutical "Product Hop"*, HARV. L.: BILL OF HEALTH (Oct. 11, 2019), <https://blog.petrieflom.law.harvard.edu/2019/10/11/stopping-the-pharmaceutical-product-hop/> [<https://perma.cc/4L9M-FRLU>].

134. See generally MAJORITY REPORT, *supra* note 14.

135. See THE KENNEDY FORUM, *supra* note 36, at 3.

136. *Id.* at 1 (“Consumer advocates argue that formulary design is overly focused on cost control, resulting in formulary structures that impose substantial barriers to necessary medications.”).

137. *Id.* at 3-5; see also Mathematica Policy Research, THE ROLE OF PBMS IN MANAGING DRUG COSTS: IMPLICATIONS FOR A MEDICARE DRUG BENEFIT 15 (Jan. 2000).

disorders, especially antipsychotics and medication-assisted treatment for substance abuse disorders.¹³⁸ In other cases, low quantity limits such as a 14-day supply, may lead to skipped doses if patients do not refill short-term prescriptions promptly.¹³⁹ While these restrictions are intended to keep premiums competitive, direct patients toward more affordable treatments, and limit abuse of medications, they may also impose barriers to care and make certain drugs inaccessible.¹⁴⁰

At the same time, the prioritization of cost also makes formularies susceptible to manipulation via rebates; a manufacturer may use rebates as bargaining chips to put a patented drug on a more advantageous tier with a lower copayment or place it on a preferred drug list to circumvent administrative barriers.¹⁴¹ Placement on a more advantageous tier or a preferred drug list will have the effect of potentially preferencing the drug above other drugs for treating the same diagnoses, even if the alternatives could have the same efficacy at a lower cost.¹⁴²

Following a three-year investigation into the pharmaceutical industry, the House Committee on Oversight and Reform published a report¹⁴³ (the “House Report”), which included examples of potentially anticompetitive agreements related to formulary negotiations. The House Report unveiled many formulary negotiation tactics which enabled broader product hopping endeavors and kept drug prices from falling.¹⁴⁴ For example, it was reported that when Pfizer embarked on a product hopping campaign in 2018 to transition consumers from an off-patent version of Lyrica to a newly patented formulation, the manufacturer offered PBMs a higher rebate on the newer drug in exchange for preferential formulary placement.¹⁴⁵ Internal documents showed evidence that the rebate was specifically intended to drive conversion of consumers from the original formulation to the newer patent-protected version.¹⁴⁶

138. *Id.* at 7.

139. *Id.* at 9.

140. *Id.* at 7.

141. See MAJORITY REPORT, *supra* note 14, at 9; see also THE KENNEDY FORUM, *supra* note 36, at 7-9.

142. See MAJORITY REPORT, *supra* note 14, at 9; see also THE KENNEDY FORUM, *supra* note 36, at 7-9.

143. See generally MAJORITY REPORT, *supra* note 14.

144. *Id.*

145. See *id.* at 117.

146. See *id.* “Documents show that, to drive conversion, Pfizer planned to strategically contract with health plans and PBMs to prefer the patent-protected CR

Brand drugs are generally (though not always)¹⁴⁷ more expensive than generic alternatives. By directing consumers to brand drugs, product hopping encourages sale of higher-cost products.¹⁴⁸ Rebates related to product hopping and formulary negotiation can bring down the price of brand drugs for Insurers and consumers in the short term, but may actually increase the price of drugs over time as manufacturers raise the list prices to compensate.¹⁴⁹ Therefore the cost-saving effects of rebates may be only situational and temporary. Worse yet, as out-of-pocket costs increase, patients are more likely to abandon prescriptions, leading to non-adherence to treatment plans.¹⁵⁰

Another anticompetitive formulary negotiation tactic is tying. Tying is “conditioning the sale of one product on the purchase of another, [or] conditioning a discount on one product on the purchase of another.”¹⁵¹ In formulary negotiations, a manufacturer may condition a rebate for a desired drug on preferential inclusion of a newly patented drug in the formulary.

In *Jefferson Parish Hospital District v. Hyde*, the Court held that tying may violate antitrust law under rule of reason analysis when there is “market power in the tying product, a substantial threat of market power in the tied product, and a coherent economic basis for treating the products

formulation over the original Lyrica formulation by offering significant rebates on the CR formulation as soon as the original formulation lost exclusivity.” *Id.*

147. See, e.g., *Mylan Pharm. Inc. v. Warner Chilcott Pub. Co.*, 838 F.3d 421, 438 (3d Cir. 2016). Mylan developed a formulation of generic doxycycline that was briefly sold at a higher cost than the brand Doryx. *Id.*

148. See *id.*

149. See SOOD ET AL., *supra* note 63, at 3.

150. See Jalpa A. Doshi et al., *Association of Patient Out-of-Pocket Costs with Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents*, 36 J. CLINICAL ONCOLOGY 476, 478 (2018) (finding that patients who abandoned prescriptions had higher out-of-pocket costs than patients who filled them).

151. Steuer, *supra* note 17, at 450; see also 15 U.S.C. § 12(3), which states:

[I]t shall be unlawful for any person engaged in commerce, in the course of such commerce, to lease or make a sale or contract for sale of goods . . . or fix a price charged therefor, or discount from, or rebate upon, such price on the condition, agreement or understanding that the lessee or purchaser thereof shall not use or deal in the goods . . . or other commodities of a competitor . . . where the effect . . . may be to substantially lessen competition or tend to create a monopoly in any line of commerce.

as distinct.”¹⁵² A seller possesses market power in the tying product if its tying product commands a large share of the market or is a uniquely desirable “must have” product which the customer cannot easily acquire elsewhere.¹⁵³ These tied and tying products are distinct if consumers might naturally purchase them separately from one another.¹⁵⁴ However, by “forcing” the buyer to purchase the two products together when they might otherwise have purchased only one, “competition on the merits in the market for the tied item is restrained and the Sherman Act is violated.”¹⁵⁵ Therefore, a pharmaceutical tying arrangement may constitute a violation of the Sherman Act when a manufacturer possesses market power for a “must-have” drug which it uses to force a PBM to include a second tied drug in the formulary.¹⁵⁶

The House Report found that in mid-2014 (approximately one year after the *Actavis* decision), Teva Pharmaceuticals patented Copaxone 40 mg/mL, a treatment for multiple sclerosis, after the patent expired on another formulation, Copaxone 20 mg/mL.¹⁵⁷ The two formulations were largely interchangeable, with 20 mg/mL taken once a day and 40 mg/mL

152. *Jefferson Par. Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 41 (1984).

153. *Steuer*, *supra* note 17, at 453. Asserting that conditional pricing cases that include tying require leverage of a “must have” product, which is defined by multiple factors including: (1) whether the customer is an end user or a reseller; (2) who is imposing the conditional pricing (supplier or intermediary); (3) whether demand is based on customer “preference or inescapable necessity”; (4) whether the product is always or only partially a “must-have”; (5) how difficult it would be to replicate the “must-have” product or bundle; and (6) who instigated the conditional pricing (supplier or customer). *Id.*

154. *See Jefferson Par. Hosp. Dist.*, 466 U.S. at 39 (“[T]he tied product must, at a minimum, be one that some consumers might wish to purchase separately without also purchasing the tying product.”).

155. *See id.* at 12:

[T]he essential characteristic of an invalid tying arrangement lies in the seller’s exploitation of its control over the tying product to force the buyer into the purchase of a tied product that the buyer either did not want at all, or might have preferred to purchase elsewhere on different terms. When such “forcing” is present, competition on the merits in the market for the tied item is restrained and the Sherman Act is violated.

156. *Id.*

157. *See MAJORITY REPORT*, *supra* note 14, at 111.

taken three times per week.¹⁵⁸ Internal documents stated: “We want a rapid transition of COPAXONE 20 mg to 40 mg prior to expected generics in mid-2014.”¹⁵⁹ To this end, Teva engaged in tying arrangements, conditioning rebates on Copaxone 20 mg/mL (a popular, “must-have”¹⁶⁰ product which PBMs wanted to include on drug formulary lists) on the inclusion of the new Copaxone 40 mg/mL on formularies.¹⁶¹ By December of 2015, 76.9 percent of Copaxone patients had been converted to Copaxone 40 mg/mL prescriptions, and only 19.3 percent were taking Copaxone 20 mg/mL or a generic alternative.¹⁶²

Another arrangement involved Sanofi’s long-acting basal insulin products, Lantus and Toujeo. When Lantus was about to come off patent, Sanofi converted consumers to Toujeo via product hopping supported by tying.¹⁶³ If Toujeo was not included on a formulary, Lantus was also pulled.¹⁶⁴ This tying of products¹⁶⁵ resulted in inclusion of Toujeo in 76 percent of commercial formularies.¹⁶⁶ Additionally, Sanofi leveraged market power from Lantus to make Toujeo a preferred drug, exempting it from prior authorization requirements.¹⁶⁷

These tying arrangements by Teva and Sanofi may violate Section 1 of the Sherman Act if there is demonstration of “the size of the company owning the tying product; the volume of sales of the tied product; a

158. Patricia Silva, *New 3-Times-Per-Week Regimen for Teva’s Copaxone Safe, Effective & Increases Patient Compliance #ECTRIMS2015*, MULTIPLE SCLEROSIS NEWS TODAY (Oct. 9, 2015), <https://multiplesclerosisnewstoday.com/multiple-sclerosis-news/2015/10/09/new-3-times-per-week-regimen-tevas-copaxone-safe-effective-increases-patient-compliance-ectrims2015/> [<https://perma.cc/LG7Q-BG8U>].

159. See MAJORITY REPORT, *supra* note 14, at 112.

160. See Steuer, *supra* note 17, at 453.

161. See *id.* at 112-13.

162. *Id.* at 113.

163. See H.R. COMM. ON OVERSIGHT & REFORM, DRUG PRICING INVESTIGATION SELECTED INVESTIGATION DOCUMENTS 225 (2021) <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/final-copy-packet-release.pdf> [<https://perma.cc/G8L4-T427>] [hereinafter INVESTIGATION DOCUMENTS].

164. *Id.*

165. See *id.* at 225 (noting that “value can be offered to payers by bundling the entire Insulins portfolio . . . particularly since Lantus and Toujeo are already tied together.” Lantus was “the preferred 1st generation basal insulin,” rendering it a must-have product for many formularies).

166. *Id.*

167. *Id.*

noncompetitive price for the tied product; and the uniqueness of the tying product or its desirability to consumers.”¹⁶⁸

Strategic rebates—such as Pfizer’s Lyrica rebates—and tying arrangements—such as Teva’s Copaxone tie and Sanofi’s Lantus-Toujeo bundle—guaranteed insurance coverage for the newly patented drugs, which is vital to a successful product hop. However, ensuring the inclusion of a new drug in a formulary, by itself, will not necessarily be enough to ensure patients will convert from one formulation to the next. Manufacturers may need to coordinate with PBMs, pharmacies, prescribers, or even patients themselves to complete the conversion.

E. ADDITIONAL PRODUCT HOPPING TOOLS

When a pharmaceutical company employs multiple tactics to support a product hop, it can be difficult to tell which ones are ultimately responsible for excluding generic competition. In such cases, “plaintiffs should be given the full benefit of their proof without tightly compartmentalizing the various factual components,” meaning that the individual contributing activities need not be examined in isolation from one another for determining anticompetitive effects.¹⁶⁹ Instead, an antitrust analysis of product hopping should consider the aggregate anticompetitive effect of the multiple underlying agreements and tactics.

Teva’s Copaxone product hop involved additional tools beyond the formulary negotiation, such as a “Copaxone conversion initiative.”¹⁷⁰ After Teva released the newly patented Copaxone 40 mg/mL, generic competition for Copaxone 20 mg/mL (Glatopa) entered the market.¹⁷¹ Generic competition made prescriptions for Copaxone 20 mg/mL less profitable to the manufacturer than prescriptions for Copaxone 40 mg/mL. Through the conversion initiative, Teva collaborated with Humana’s PBM to pressure prescribers to transition their patients to the more profitable version of the drug.¹⁷² Humana repeatedly contacted

168. *Fortner Enters. v. U.S. Steel Corp.*, 394 U.S. 495, 499 (1969).

169. *Cont’l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962).

170. MAJORITY REPORT, *supra* note 14, at 113.

171. *Id.*; see also *Sandoz Announces U.S. FDA Approval and Launch of Glatopa 40 mg/mL Three Times-a-Week Generic Option for Relapsing Forms of Multiple Sclerosis*, NOVARTIS (Feb. 13, 2018) <https://www.novartis.com/news/media-releases/sandoz-announces-us-fda-approval-and-launch-glatopa-40-mgml-three-times-week-generic-option-relapsing-forms-multiple-sclerosis> [<https://perma.cc/5T6X-3QME>]. Glatopa is manufactured by Sandoz, a Novartis division. *Id.*

172. MAJORITY REPORT, *supra* note 14, at 113.

prescribers on Teva's behalf with lists of their patients still on the old formulation, pressuring these prescribers to make the switch.¹⁷³

The agreement between Teva and Humana's PBM may constitute conspiracy to restrain trade in violation of Section 1 of the Sherman Act.¹⁷⁴ While the Copaxone conversion initiative alone was most likely not responsible for the success of the product hop (which also required advantageous formulary placement), it probably contributed to its success. Generic competition ultimately penetrated only 23.1 percent of the market.¹⁷⁵ In 2015, Copaxone sales in the United States amounted to \$760 million, a decrease of only 9 percent from 2014 despite the expiration of the patent on the 20 mg/mL formulation and subsequent competition from Glatopa.¹⁷⁶ Given that average brand drug prices drop 39 percent after generic entry, this minimal decrease in price suggests that the product hop was successful.¹⁷⁷

Sanofi also supported their Lantus-Toujeo product hopping endeavor with a collection of strategies that went beyond formulary negotiations. For example, Sanofi went directly to consumers, marketing itself as "a company that truly cares about patient affordability."¹⁷⁸ Sanofi also reached consumers directly by offsetting out-of-pocket costs for Toujeo with copayment coupons and pharmacy programs.¹⁷⁹ Sanofi also ceased marketing Lantus, except where Toujeo was unavailable.¹⁸⁰

F. CEMENTING BRAND NAME MARKET POWER

While the goal of product hopping is to increase sales of patented drugs, the scheme often relies on market power in off-patent drug markets. Tying arrangements hinge on a "must-have" product, without

173. *Id.*

174. *See* 15 U.S.C. § 1.

175. *Id.*

176. *Teva Reports Full Year 2015 and Fourth Quarter Financial Results*, FIERCE PHARMA (Feb. 11, 2016), <https://www.fiercepharma.com/pharma/teva-reports-full-year-2015-and-fourth-quarter-financial-results> [<https://web.archive.org/web/20220119111317/https://www.fiercepharma.com/pharma/teva-reports-full-year-2015-and-fourth-quarter-financial-results>].

177. *See Generic Competition and Drug Prices*, FOOD & DRUG ADMIN. (Dec. 13, 2019), <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices> [<https://perma.cc/NX3L-7VYG>].

178. INVESTIGATION DOCUMENTS, *supra* note 163, at 227.

179. *Id.* at 230.

180. MAJORITY REPORT, *supra* note 14, at 116.

which the product hop may be unsuccessful.¹⁸¹ To ensure their off-patent drugs are “must-have” products, manufacturers must find ways to maintain post-patent market power for key drugs. This Section explains how manufacturers use “house brand agreements” and marketing campaigns to strategically exclude generic competition, thereby turning their off-patent brand drugs into bargaining chips.

In “house brand agreements,” manufacturers contract with PBMs to make their brand name drug the only version of the drug dispensed at PBM-owned pharmacies.¹⁸² If the prescription calls for a generic, the pharmacy dispenses the brand name drug in an unmarked box and bills the patient and insurer at generic drug prices.¹⁸³ The PBM receives the full rebate from the manufacturer for every prescription filled, regardless of whether it was written for the branded drug or the generic.¹⁸⁴ While this cuts into manufacturers’ profits, it blocks generic sales and ensures that the brand name drug occupies more of the market.

In 2016, Novartis hired a consulting company to explore “ways to retain the most profitable access for Gleevec, e.g.[,] keeping the generic off formulary [sic].”¹⁸⁵ Part of this plan included a house brand agreement with a specialty pharmacy serving Medicare Part D beneficiaries.¹⁸⁶ Specialty pharmacies are owned by PBMs. Novartis’s Gleevec house brand agreement was intended to circumvent the rule that prioritized generics for Medicare Part D.¹⁸⁷

181. See Steuer, *supra* note 17, at 453.

182. MAJORITY REPORT, *supra* note 14, at 121.

183. *Id.* at 122. Teva’s Executive Vice President for North America explained how a Copaxone 20 mg/mL House Brand contract was preventing generic competition. The PBM was “getting an additional rebate to fill all ‘glatiramer’ or Copaxone scripts with Copaxone . . . if a doctor orders generic glatiramer or the pharmacy benefit mandates it to be filled as a generic, it will come in a plain box with Copaxone inside. Win-win for all.” *Id.*

184. *Id.*

185. *Id.* at 121.

186. *Id.*

187. *Id.*:

Novartis executive identified a workaround for a Part D requirement that prohibits plans from putting generics on non-preferred formulary tiers, which typically have higher out-of-pocket costs. For this particular plan, the executive suggested instead putting Gleevec and the generic on the same tier but requiring prior authorization for both drugs. The executive explained that the PBM had its own in-house specialty pharmacy and would direct the pharmacy to dispense

Section 2 of the Sherman Act prohibits the acquisition or maintenance of monopoly power through predatory or exclusionary conduct.¹⁸⁸ Conduct may be predatory or exclusionary if “it would make no economic sense for the defendant but for its tendency to eliminate or lessen competition.”¹⁸⁹ Conduct may also be exclusionary if the defendant maintains or attains monopoly power at the expense of short-term profits.¹⁹⁰ House brand agreements such as the one Novartis made for Gleevec may be anticompetitive under the no-economic-sense test because manufacturers give brand-name rebates while receiving only generic drug revenue, making less money on each unit of the brand drug for the purpose of injuring rivals.¹⁹¹

Dispense-as-written campaigns are another tactic to exclude competition from an off-patent drug. Ordinarily, pharmacies can substitute a generic if a brand name is prescribed.¹⁹² To prevent generic substitution, doctors may mark prescriptions with “dispense as written” or “DAW.”¹⁹³ Through advertising campaigns directed at prescribers and consumers, manufacturers endeavor to persuade prescribers to specify the brand name in the prescriptions and prohibit generic substitution.¹⁹⁴ For example, Novartis targeted prescribers with slogans like “multiple generics can lead to patient confusion,” and “[w]hat is worse than telling patients their cancer is back?” which implied that generics may not be as effective as the brand drug.¹⁹⁵ At the same time, Novartis also advertised directly to consumers, saying “[i]t’s your right to ask your pharmacist for

Gleevec rather than the generic. The account manager wrote, “Since they have a [specialty pharmacy] requirement, they have set it up with their network [specialty pharmacies] to ensure Gleevec is dispensed vs the generic.”

188. *See Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 602 (1985).

189. Brief for the United States and the Federal Trade Commission as Amici Curiae Supporting Petitioner at 15, *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398 (2004) (No. 02-682) <https://www.justice.gov/atr/case-document/file/515316/download>.

190. *See Aspen Skiing Co.*, 472 U.S. at 610-11.

191. *See* MAJORITY REPORT, *supra* note 14, at 122-23.

192. *Id.* at 133-36.

193. *Id.* at 134.

194. *See id.* at 135. Dispense-as-written campaigns were employed by Pfizer for Lyrica, Teva for Copaxone, and Novartis for Gleevec. *Id.*

195. *Id.* at 135-36.

branded Gleevec” and “[t]he power is in your hands—demand the brand.”¹⁹⁶

House brand agreements and dispense-as-written campaigns are ways to foreclose generic competition outside of the formulary negotiation process. With sufficient market power, manufacturers maintain the utility of off-patent drugs as “must-have” products for tying arrangements related to soft-switch product hops. By collaborating with PBM-owned pharmacies, pressuring prescribers, and advertising to consumers, house brand agreements and dispense-as-written campaigns play a key role in the web of anticompetitive activities that enables product hopping.

IV. AMENDING ANTITRUST LAW

While high drug prices alone may be facially legal, several bills have been proposed to amend the law and give antitrust enforcers tools to address drug prices. In 2020, a bipartisan bill titled “Stop Stalling Access to Affordable Medications” proposed to make reverse payment settlements presumptively anticompetitive under the Federal Trade Commission Act.¹⁹⁷ The bill would prohibit generic drug manufacturers from delaying market entry in exchange for payment or other valuable exchange.¹⁹⁸ Despite the *Actavis* holding and the potential for antitrust liability, pharmaceutical companies are still engaging in reverse payment settlements to delay generic competition.¹⁹⁹ By making all reverse payment settlements presumptively anticompetitive, the bill (or another like it) could prevent pharmaceutical companies from agreeing to delay development of generics by outlawing pay-for-delay. However, brand

196. *Id.* at 135.

197. H.R. 2375, 116th Cong. (2020):

[A]n agreement shall be presumed to have anticompetitive effects and shall be a violation of this section if . . . (i) an ANDA filer or a biosimilar biological product application filer receives anything of value, including an exclusive license; and (ii) the ANDA filer or biosimilar biological product application filer agrees to limit or forgo research, development, manufacturing, marketing, or sales of the ANDA product or biosimilar biological product, as applicable, for any period of time.

198. *Id.*

199. *See, e.g.,* COGGIO & FLANZ, *supra* note 108 (examining Endo and Impax 2019 reverse payment settlement).

manufacturers would still be able to avoid competition and keep prices high through product hopping and the network of underlying agreements.

However, as we have seen in the post-*Actavis* landscape, pay-for-delay is not the only tool for raising pharmaceutical prices.²⁰⁰ Product hopping steers consumers toward high-price patented drugs and reduces access to generics.²⁰¹ Therefore, to comprehensively protect access to affordable medication, manufacturers must also be prohibited from using anticompetitive means to engage in product hopping. This could be accomplished directly in a “top-down” approach by prohibiting product hopping directly or it could be accomplished indirectly in a “bottom-up” approach by aiding enforcement against the underlying deals that make product hopping possible.

A. A TOP-DOWN APPROACH

One approach to eliminating anticompetitive product hopping is to assign antitrust liability to product hopping itself. At this time, courts only find antitrust liability when the product hop forecloses competition.²⁰² This is far more likely in hard switches, while soft switches may be found to be pro-competitive (and therefore beyond the reach of antitrust enforcement) because they ostensibly increase consumer choice.²⁰³ Both the Copaxone and Lantus-Toujeo product hops were soft switches, with the original formula not only remaining on the market but acting as leverage for further anticompetitive behavior.²⁰⁴

The Affordable Prescriptions for Patients Through Promoting Competition Act of 2019²⁰⁵ would close the soft-switch loophole by rendering all product hopping anticompetitive through an amendment to

200. The Teva Copaxone product hop occurred approximately one year after the *Actavis* decision. MAJORITY REPORT, *supra* note 14, at 111.

201. For example, Sanofi’s Lantus-Toujeo product hop secured market power for the newly patented basal insulin product, Toujeo, and steered consumers away from the generic basal insulin product, Lantus. INVESTIGATION DOCUMENTS, *supra* note 163, at 227.

202. See Carrier & Shadowen, *supra* note 12, at 170.

203. See, e.g., *Walgreen Co. v. AstraZeneca Pharm. L.P.*, 534 F. Supp. 2d 146, 151 (D.D.C. 2008).

204. See MAJORITY REPORT, *supra* note 14, at 111; see also INVESTIGATION DOCUMENTS *supra* note 163, at 225.

205. H.R. 4398, 116th Cong. (2019).

the Federal Trade Commission Act.²⁰⁶ The bill proposes to make both hard and soft switch product hopping “an unfair method of competition” if it occurs within 180 days of applying for “an abbreviated new drug application or biosimilar biological product license application.”²⁰⁷ According to the bill, a hard switch occurs when the manufacturer requests withdrawal of approval for the “reference product” (the older version of the drug) or itself withdraws, discontinues, or destroys inventory of the reference product prior to marketing or selling a “follow-on product” (the newly patented formulation).²⁰⁸ Likewise, a soft switch occurs when the manufacturer takes actions to unfairly disadvantage the reference product relative to the follow-on product “in a manner that impedes competition from a generic drug or a biosimilar biological product that is highly similar to, and has no clinically meaningful difference with respect to safety, purity, and potency from, the reference product.”²⁰⁹

B. A BOTTOM-UP APPROACH

Despite the apparent effect of product hopping on pharmaceutical prices, assigning blanket antitrust liability to product hops may ultimately harm innovation. If a manufacturer develops a superior product, it should be able to pull the old product from the market or allow the new product to naturally take over the market without fear of antitrust liability.²¹⁰ In a competitive pharmaceutical market, products must be able to compete on their merits without reprisal. However, when the success of a product hopping endeavor is engineered through anticompetitive conduct, it must be subject to antitrust liability. Thus, a “bottom-up” approach that eases detection of anticompetitive behaviors and increases antitrust enforcement against them could take away the anticompetitive means of product hopping while allowing innovation to continue.

While tying and exclusive dealing are already illegal under federal antitrust law, the confidential nature of PBM contracts makes it hard for

206. *Id.*

207. *Id.* § 27(b)(1).

208. *Id.* § 27(b)(1)(A).

209. *Id.* § 27(b)(1)(B).

210. *See, e.g.,* Mylan Pharms. Inc. v. Warner Chilcott Pub. Co., 838 F.3d 421, 438-39 (3d Cir. 2016). In the Doryx product hop, the old product had been linked with esophageal problems, experienced shelf-life stability problems, and had more limited dosage options. The court found that the new product was arguably superior and the manufacturer was justified in recalling the old product. *Id.*

enforcers to identify and address them in time.²¹¹ The House Committee on Oversight and Reform published a report in 2021 which revealed anticompetitive behaviors from 2014 and earlier.²¹² With such delays, a manufacturer who engaged in a product hop years ago might be protected by a statute of limitations.²¹³

Increased transparency would aid discovery and improve efficient enforcement of antitrust law across the pharmaceutical market. Several bills have proposed methods to improve transparency and accountability for PBMs. The Pharmacy Benefit Manager Accountability Study Act of 2021 proposed requiring the Government Accountability Office to study the role of PBMs involved in federal programs (such as Medicare and the Federal Employees Health Benefits program) in the pharmaceutical supply chain and examine the use of rebates, fees, and utilization management protocols in formulary negotiations.²¹⁴ The Improving Transparency to Lower Drug Costs Act of 2021 proposed amending the Social Security Act to require disclosure by PBMs of certain information related to rebates, discounts, and fees.²¹⁵ These bills (or others like them) might reveal antitrust violations, enable enforcement, and disincentivize future anticompetitive behavior. By prohibiting the enabling activities, transparency legislation could hinder or even stop product hopping altogether.

Another legislative solution could be to reduce the role of PBMs in establishing drug prices or take them out of the negotiation process entirely. This would greatly reduce manufacturers' ability to support product hopping through formulary manipulation. In reducing the role of PBMs, however, the role of drug price negotiation must be assigned to someone else. The Elijah E. Cummings Lower Drug Costs Now Act proposed removing PBMs from much of Medicare drug pricing.²¹⁶ Instead, the Secretary of Health and Human Services would negotiate prices directly with manufacturers for the 300 highest-cost drugs.²¹⁷

211. See BISHOP, *supra* note 46, at 1; see also Candisky, *supra* note 59.

212. See generally, MAJORITY REPORT, *supra* note 14.

213. See 18 U.S.C. § 3282(a) ("Except as otherwise expressly provided by law, no person shall be prosecuted, tried, or punished for any offense, not capital, unless the indictment is found or the information is instituted within five years next after such offense shall have been committed.").

214. S. 298, 117th Cong. (2021).

215. H.R. 3682, 117th Cong. (2021).

216. H.R. 3, 117th Cong. § 101 (2021).

217. *Id.*

While this negotiation power only extends to federal programs, the bill also proposes voluntary price matching by private Insurers, with a public list of those private Insurers who choose not to comply.²¹⁸ This tactic may encourage private insurer participation and extend the resulting cost savings to consumers covered by private insurance.²¹⁹

Transparency and a restructuring of the role of PBMs (or some combination thereof) could prevent PBMs from assisting manufacturers in converting consumers to new drug formulations that cost more without delivering greater value. Without this assistance, manufacturers may be prevented from artificially enabling product hopping endeavors that are based on market manipulation rather than the merits of the products involved.

CONCLUSION

Pharmaceutical manufacturer profits are highest when patented, brand-name drugs dominate the market. Considering the potential for financial gains, the prevalence of product hopping is unsurprising, yet the effects on competition and price are unmistakable.

Instead of ensuring quality of care for consumers, drug formularies are being co-opted as a battleground for brand manufacturers to control the drug market. While PBMs may have been created to reduce costs and increase quality of care for consumers, their role in the pharmaceutical market provides ample opportunity for profit and anticompetitive abuse. Ultimately, formularies raise barriers to health care by increasing prices and obstructing non-preferred drugs with prior authorization requirements. In so doing, formularies generate profit through rebates and fees at the expense of Insurers and consumers.

218. See H.R. 3, 117th Cong. § 1197(b) (2021):

With respect to each price applicability period and each selected drug with respect to such period, the Secretary and the Secretary of Labor and the Secretary of the Treasury, as applicable, shall make public a list of each group health plan and each health insurance issuer offering group or individual health insurance coverage, with respect to which coverage is provided under such plan or coverage for such drug, that has elected under subsection (a) not to participate under the program with respect to such period and drug.

219. H.R. 3, 117th Cong. § 1197(a) (2021).

When product hopping is enabled by anticompetitive agreements spanning every level of the pharmaceutical supply chain, it harms consumers and jeopardizes the competitive process. As a result, these product hops themselves are vicariously anticompetitive. This web of agreements is primarily centered on the contractual relationship between manufacturers and PBMs, but affects which drugs and brands are covered by Insurers, prescribed by doctors, and dispensed by pharmacies. Product hopping and related conduct all too often increase the price of drugs and block patient access to low-cost generic drugs.

A comprehensive approach is key to addressing the aggregate anticompetitive effects of product hopping. Antitrust reform could take a top-down approach by making product hopping presumptively anticompetitive or a bottom-up approach that targets the agreements that make product hopping successful. However, legislation to eliminate product hopping directly could lead to over-enforcement against legitimate innovations through which a new product takes over the market. Furthermore, a top-down focus on product hopping alone could misdirect enforcers away from the illegal, enabling behaviors. However, pairing a top-down approach to product hopping itself with a bottom-up approach that addresses related antitrust violations throughout the market would allow enforcers to halt the whole anticompetitive system in its tracks. If antitrust law considers the aggregate anticompetitive effects of the product hopping network as a whole, then antitrust enforcement could benefit the competitive process by keeping the market open for generic competition and reduce the cost of healthcare for consumers by increasing access to lower-cost generic drugs.