

AN ANTITRUST ANALYSIS OF PRODUCT HOPPING IN THE PHARMACEUTICAL INDUSTRY

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Trinko emphasized the importance of attention to an industry's regulatory regime in determining the role of antitrust law and suggested a possible "expansion of the contours" of the Sherman Act in certain regulatory contexts. This Note explores Trinko's implications for antitrust enforcement in the pharmaceutical industry which, though heavily regulated, lacks an industry regulator that polices competition. It focuses on product hopping, a strategy launched by manufacturers of brand name drugs to undermine competition from generic substitutes. Parties have challenged product hopping as anticompetitive, and the judicial treatment thus far has hinged on the presence of consumer coercion. However, such an approach disregards the pharmaceutical industry's unique market structure and its regulatory regime. This Note inquires into the real anticompetitive harm from product hopping through the lens of Trinko. It proposes that courts undertake the antitrust analysis with an eye toward the industry's regulatory regime—particularly, state drug product selection (DPS) laws—and the legislative policy judgment it embodies, in addition to engaging such traditional antitrust concerns as promoting innovation and preserving free competition. This Note develops a framework that gives manufacturers freedom to innovate, responds to the limits of antitrust law, and punishes product hoppers that subvert the specific type of competition state legislatures sought to establish in fashioning DPS laws.

INTRODUCTION

On August 2, 2001, Eli Lilly lost its patent protection on Prozac and with it, \$2.4 billion in annual U.S. sales.¹ Eli Lilly's drop in Prozac sales and loss of market share from generic entry were the most severe Big Pharma had yet experienced.² In the prescription drug market, a patent holder—usually the brand name drug manufacturer that developed the pioneer drug, like Eli Lilly—has time-limited, exclusive rights to market

1. Bethany McLean, A Bitter Pill, *Fortune*, Aug. 13, 2001, at 118, 119; see also Eli Lilly and Co., 2001 Annual Report 1 (2001) (observing that sales fell faster than expected); John Simons, Lilly Goes Off Prozac, *Fortune*, June 28, 2004, at 179, 180 (discussing sixty-six percent drop in Prozac sales by end of fourth quarter of 2001).

2. Lilly to Miss 4Q, '02 Marks, CNN.com, Oct. 3, 2001, at <http://edition.cnn.com/2001/BUSINESS/10/03/lilly/index.html> (on file with the *Columbia Law Review*). For a discussion of severe losses from patent expiration more recently witnessed in the pharmaceutical industry, see generally Selena Class, Pharma Reformulates, 83 *Chemical & Engineering News* 15 (2005) (discussing Pfizer's antidepressant Zoloft, Merck's cholesterol reducing drug Zocor, Sanofi-Aventis's sleep aid Ambien, Bristol-Myers Squibb's cholesterol reducing drug Pravachol, Novartis's antifungal drug Lamisil, and GlaxoSmithKline's anti-nausea drug Zofran).

its patented drug,³ allowing it to realize hefty profits.⁴ Upon the patent's expiration or a finding of its invalidity,⁵ market competition replaces the previously lawful monopoly: Manufacturers of generic drugs (generic manufacturers) enter the market, and the incumbent brand name manufacturer may face a steep drop in profits and market share.⁶ State drug product selection (DPS) laws further fuel the erosion of the brand name manufacturer's market share by allowing and sometimes requiring pharmacies to fill prescriptions for brand name drugs with their rival generic equivalents.⁷

Brand name manufacturers anticipating the loss of patent protection may launch strategies to stave off competition from generic manufacturers ("generic competition") and thereby maintain their high volume of sales. This Note investigates one new tactic, product hopping, that has recently emerged among brand name manufacturers and explores its potential for manipulating the pharmaceutical industry's regulatory structure while undermining generic competition.

Product hopping brand name manufacturers ("product hoppers") make a slight alteration to their prescription drug and engage in marketing efforts to shift consumers from the old version to the new.⁸ Generic manufacturers must follow the hop to the new version in order to realize and maintain a high volume of sales.⁹ The delay to generic manufacturers from developing a new generic equivalent and obtaining FDA approval to market it allows the product hopper to insulate itself from generic competition for several years.¹⁰

Though product hopping amounts to little more than a thinly disguised scheme to manipulate the pharmaceutical industry's regulatory system and frustrate generic competition, this new and controversial strategy is not necessarily an easy target for antitrust enforcement.¹¹ While one antitrust court has denied a defendant pharmaceutical company's

3. See *infra* note 22 and accompanying text (describing protection under Patent Act).

4. See *infra* note 28 and accompanying text (reporting profit margins for drugs under patent protection).

5. See *infra* note 29 (discussing bases for patent invalidity).

6. See *infra* note 30 and accompanying text (reporting substantial discounts for generic drugs from price at which brand name drugs are typically sold).

7. See *infra* Part I.B (describing generic substitution under state DPS laws and its development).

8. See *infra* notes 99–101 and accompanying text (giving overview of basic product hopping strategy).

9. See *infra* notes 102–105 and accompanying text (describing need for generic manufacturers to follow product hoppers in order to rely on generic substitution).

10. See *infra* note 107 and accompanying text (identifying and explaining delays to generic competition from product hopping).

11. See *infra* Part II.D (framing anticompetitive harm from product hopping and challenges to antitrust enforcement); *infra* Part III.A.1 (arguing that generic manufacturers outdone by their brand name rivals in advertising cannot invoke antitrust law to condemn rivals' success); *infra* Part III.A.2 (cautioning against using antitrust to police innovation).

motion to dismiss a product hopping claim,¹² another court has granted a different alleged product hopper's motion to dismiss.¹³ Both decisions hinged on an inquiry into consumer coercion,¹⁴ which commentators have criticized as flawed given the pharmaceutical industry's unique market structure.¹⁵ Given that product hopping does not implicate any consumer coercion concerns, this Note asks the essential question: What threat to competition does product hopping pose, if any?

The courts' analysis also overlooked the complex interplay between antitrust law and the pharmaceutical industry's regulatory regime. Neither decision investigated the implications of the Supreme Court's 2004 decision in *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*.¹⁶ *Trinko's* relevance lies in its recognition of a possible expanded role for antitrust law in certain regulated industries, potentially paving an additional avenue for antitrust law to police product hopping.¹⁷ This Note undertakes the antitrust inquiry with an eye toward the pharmaceutical industry's regulatory regime, as *Trinko* instructs,¹⁸ and the possible harm to competition under the regime that product hopping might inflict.

Part I dissects the pharmaceutical industry's complex regulatory regime and the relationship it creates between brand name and generic manufacturers. It discusses the controversial strategies brand name manufacturers employ to protect their profits from generic competition and highlights the harm these tactics may inflict on market competition, as well as consumer welfare. Part II introduces product hopping as one such strategy and discusses its judicial treatment in *Abbott Laboratories v. Teva Pharmaceuticals USA, Inc.*¹⁹ and *Walgreen Co. v. AstraZeneca Pharmaceuticals L.P.*²⁰ It concludes with a critique of this judicial treatment and questions the courts' underlying assumptions. Part III pro-

12. *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408, 426 (D. Del. 2006); see *infra* notes 154–169 and accompanying text (discussing *Abbott* and rationale underlying decision to deny motion to dismiss).

13. *Walgreen Co. v. AstraZeneca Pharms. L.P.*, 534 F. Supp. 2d 146, 153 (D.D.C. 2008); see *infra* notes 170–171 and accompanying text (discussing *Walgreen* and court's distinguishing of facts from *Abbott*).

14. See *infra* notes 165–167 and accompanying text (examining *Abbott* court's finding of consumer coercion); *infra* notes 170–171 and accompanying text (discussing *Walgreen* court's conclusion that there was no consumer coercion).

15. See *infra* Part II.F (analyzing pharmaceutical industry's market structure and observing that product hopping does not jeopardize consumer free choice).

16. 540 U.S. 398 (2004).

17. See *infra* note 230 and accompanying text (noting *Trinko's* recognition of possible expansion of contours of antitrust law). But see Daniel F. Spulber & Christopher S. Yoo, *Mandating Access to Telecom and the Internet: The Hidden Side of Trinko*, 107 *Colum. L. Rev.* 1822, 1825, 1869–71 (2007) (noting disagreement among courts and commentators regarding *Trinko's* scope).

18. See *infra* notes 211, 228 and accompanying text (describing interaction between antitrust law and regulatory regime in light of *Trinko*).

19. 432 F. Supp. 2d 408 (D. Del. 2006).

20. 534 F. Supp. 2d 146 (D.D.C. 2008).

poses an analysis of product hopping's anticompetitive harm that departs from the current standard under *Abbott and Walgreen*. Its proposed framework responds to the limits of antitrust law and engages the role of antitrust law in regulated industries, as well as recognizes and reflects the pharmaceutical industry's unique market structure and regulatory regime.

I. THE PLAYING FIELD: THE PHARMACEUTICAL INDUSTRY'S REGULATORY REGIME

This Part provides an overview of the complex regulatory regime governing generic and brand name manufacturers in the pharmaceutical industry. Part I.A examines federal prescription drug regulation and the incentive structure it establishes. Part I.B traces the development of state prescription drug regulation and the generic substitution it promotes. Part I.C discusses the interaction between the pharmaceutical industry's complex regulatory structure and the competitive strategies brand name manufacturers have launched against their generic rivals.

A. Federal Regulation of Prescription Drugs

1. *Developing and Marketing Prescription Drugs.* — Brand name manufacturers supply the innovation for prescription drugs by heavily investing in research and development of new products.²¹ Patent law rewards these innovating manufacturers by granting them time-limited exclusive rights to market and sell their pioneer drug.²² However, antitrust laws,

21. Experts estimate \$500 million to \$2 billion in costs for bringing new drugs to market. Billion Dollar Pills, *Economist*, Jan. 27, 2007, at 69, 69; see also Henry G. Grabowski, John Vernon & Joseph A. DiMasi, Returns on Research and Development for 1990s New Drug Introductions, 20 *PharmacoEconomics* (Supp. 3) 11, 22–23 (2002) (noting that only about one-third of marketed drugs generate revenues that match or exceed average research and development costs); Pharm. Research & Mfrs. of Am., Innovation, at <http://www.phrma.org/innovation> (last visited Aug. 18, 2008) (on file with the *Columbia Law Review*) (“Only one of every 10,000 potential medicines investigated by America’s research-based pharmaceutical companies makes it through the research and development pipeline and is approved for patient use by the [FDA].”). But see Pub. Citizen’s Cong. Watch, Rx R&D Myths: The Case Against the Drug Industry’s R&D “Scare Card,” at i, 5–7 (2001), available at <http://www.citizen.org/documents/acfdc.pdf> (on file with the *Columbia Law Review*) (disputing Pharmaceutical Research and Manufacturers of America’s cost estimates and arguing that “the \$500 million [cost estimate] includes significant expenses that are tax deductible and unrealistic scenarios of risks” such that “actual cash outlay for a new drug is . . . as low as \$57 million per drug in [the 1990s] (including failures)”).

22. 35 U.S.C. § 271 (2000). Patent exclusivity provides the incentive to innovate, which is particularly needed where intellectual property, as a public good, tends to be underproduced and subject to free riders. Michael A. Carrier, Unraveling the Patent-Antitrust Paradox, 150 U. Pa. L. Rev. 761, 767–68 (2002); see also Frank H. Easterbrook, Foreword: The Court and the Economic System, 98 Harv. L. Rev. 4, 21–29 (1984) (describing Supreme Court’s historic treatment of ex ante perspective on intellectual property). For a contrast to ex ante justifications for patent protection, see Edmund W. Kitch, The Nature and Function of the Patent System, 20 J.L. & Econ. 265, 276 (1977)

particularly the Sherman Act,²³ prevent patent holding manufacturers from exploiting their patent-conferred monopoly to improperly harm competitors and threaten consumer welfare.²⁴

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), manufacturers must obtain market approval from the FDA before their new drugs can reach the shelves.²⁵ Brand name manufacturers may do so by submitting a new drug application (NDA) to the FDA for their pioneer drug.²⁶ The FDA grants approval upon a determination of the pioneer drug's safety and efficacy.²⁷ The brand name manufacturer may then

(justifying broad patent rights as key to efficiently coordinating invention's subsequent development). Under the Patent Act, to obtain patent protection, manufacturers must submit to the U.S. Patent and Trademark Office a specification that satisfies the statutory requirements of subject matter, utility, novelty, and nonobviousness. 35 U.S.C. §§ 101–103, 112; see also *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209–10 (Fed. Cir. 1991) (construing 35 U.S.C. § 112).

23. Antitrust's basic law, the Sherman Act, has two major provisions. Section 1 purports to condemn "[e]very contract, combination . . . or conspiracy, in restraint of trade." 15 U.S.C. § 1 (2000). Section 2 forbids a person or a combination of persons from attempting or conspiring to "monopolize." *Id.* § 2. Its goals include fostering innovation and promoting competition and consumer welfare. Antitrust Modernization Comm'n, Report and Recommendations, at ii (2007); Robert H. Bork, *The Role of the Courts in Applying Economics*, 54 *Antitrust L.J.* 21, 24 (1985); *infra* note 186 and accompanying text (identifying free and vigorous competition as focus of Sherman Act).

24. The Patent Act does not grant patentees "carte blanche" in the exercise of their rights, including immunity from antitrust laws. Louis Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*, 97 *Harv. L. Rev.* 1813, 1817–18 (1984). As the goals of the Sherman Act, see *supra* note 23, may conflict with the exercise of patent rights, courts and commentators have attempted to balance antitrust laws and the Patent Act, refusing to allow one to trump the other. See *Simpson v. Union Oil Co.*, 377 U.S. 13, 24 (1964) ("The patent laws which give a 17-year monopoly on 'making, using, or selling the invention' are *in pari materia* with the antitrust laws and modify them *pro tanto*."); *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1325 (Fed. Cir. 2000) ("Intellectual property rights do not confer a privilege to violate the antitrust laws [Nor do] antitrust laws . . . negate the patentee's right to exclude others from patent property.").

25. 21 U.S.C. §§ 355–395 (2000).

26. An NDA includes information on the drug's chemical structure, safety, efficacy, and toxicology, as well as all animal and human data for the drug and analyses of that data. Ctr. for Drug Evaluation & Research, FDA, New Drug Application (NDA) Process, available at <http://www.fda.gov/cder/regulatory/applications/NDA.htm> (last visited Aug. 18, 2008) (on file with the *Columbia Law Review*) [hereinafter FDA, New Drug Process]; see also 21 C.F.R. § 314.53(c)(2) (2008) (describing reporting requirements for new drug applications). The goal of the NDA is to provide enough information to permit the FDA to determine whether the drug is safe and effective, whether its proposed labeling is appropriate, and whether the methods used in manufacturing the drug are adequate to preserve its identity, strength, quality, and purity. FDA, New Drug Process, *supra*; see also Ctr. for Drug Evaluation & Research, FDA, NDA Review Process Application, available at <http://www.fda.gov/cder/handbook/nda.htm> (last visited Aug. 18, 2008) (on file with the *Columbia Law Review*) (providing flow chart for NDA review process).

27. An FDA review team—consisting of doctors, chemists, statisticians, microbiologists, pharmacologists, and other experts—evaluates whether the NDA establishes that the drug is safe and effective for use, where "safe" means that the drug's benefits outweigh its risks. The review team also scrutinizes the study's design, results, and

proceed to market its drug, enjoying the supercompetitive profits associated with its patent-granted market exclusivity.²⁸

However, once a drug's patent protection expires or is found to be invalid,²⁹ the brand name manufacturer loses its market exclusivity and faces competition. The most potent threat to profits comes from generic manufacturers,³⁰ who can produce equivalents of off-patent brand name drugs³¹ without incurring the high research and development costs of drug discovery.³²

conclusions. Michelle Meadows, *The FDA's Drug Review Process: Ensuring Drugs are Safe and Effective*, FDA Consumer, July–Aug. 2002, at 19, 19, 22–23.

28. Typical gross margins for drugs enjoying patent protection range from ninety to ninety-five percent. Barbara Martinez & Jacob Goldstein, *Big Pharma Faces Grim Prognosis: Industry Fails To Find New Drugs To Replace Wonders Like Lipitor*, Wall St. J., Dec. 6, 2007, at A1.

29. A patent may be found invalid for failing to comply with one or more of the requirements of 35 U.S.C. §§ 101–103, 112 (2000), namely utility, novelty, and nonobviousness.

30. The first generic entrant typically charges a price twenty to thirty percent lower than the brand name manufacturer's; as additional generic manufacturers enter the market, the price may drop to half of the brand price or less. Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements: Hearing Before the S. Comm. on the Judiciary, 107th Cong. 5 (2001) (statement of Molly Boast, Director, FTC), available at <http://judiciary.senate.gov/oldsite/te052401mb.pdf> (on file with the *Columbia Law Review*) (citing Cong. Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (1998)); see also Henry G. Grabowski & John M. Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 35 J.L. & Econ. 331, 335–36 & tbl.1 (1992) (observing that generic drugs enter at a "significant discount" to competing brand name drugs and that "there is a strong downward price dynamic over time" for generic drugs). But note a controversial type of generic product not discussed in this Note that instead helps brand name manufacturers defuse the threat of generic competition: "authorized" or "branded" generics, whereby brand name manufacturers issue, threaten to issue, or authorize a distributor to issue a generic version of their own prescription drug in order to discourage market entry by generic manufacturers. Bureau of Consumer Prot., FTC, *Drug Product Selection 48* (1979) [hereinafter *FTC, DPS*]; Saami Zain, *Sword or Shield? An Overview and Competitive Analysis of the Marketing of "Authorized Generics,"* 62 Food & Drug L.J. 739, 744–46 (2007); Leila Abboud, *Drug Makers Use New Tactic To Ding Generics*, Wall St. J., Jan. 27, 2004, at B1.

31. Generic drugs are defined as drugs that are "identical, or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use." Office of Generic Drugs, FDA, at <http://www.fda.gov/cder/ogd/#Introduction> (last visited Aug. 18, 2008) (on file with the *Columbia Law Review*). However, therapeutically equivalent drugs may still vary in characteristics such as color, shape, taste, or packaging. Therapeutically Equivalent Drugs; Availability of List, 45 Fed. Reg. 72,582, 72,586, 72,589 (Oct. 31, 1980).

32. FTC, DPS, *supra* note 30, at 13–14 ("[Generic manufacturers] do little new drug development or promotion, but usually specialize primarily in producing unbranded (i.e., not bearing a brand name) versions of . . . drugs."); see *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990) (observing that abbreviated FDA approval procedures "permit an applicant seeking approval of a generic drug to avoid the costly and time-consuming studies required for a pioneer drug"). But note that generic manufacturers must nevertheless invest time and money into developing a formulation, testing the product, and obtaining product approval, which takes multiple review cycles. Richard J. Findlay,

To enter the market as cheaper substitutes for their brand name counterparts, generic manufacturers must submit an abbreviated new drug application (ANDA) to the FDA for their generic drug.³³ Because brand name manufacturers have already demonstrated the safety and efficacy of their drug in their NDA, there is no need for generic manufacturers to undertake duplicative trials to establish their equivalent drug's safety and efficacy.³⁴ Rather, in their ANDAs, generic manufacturers need only: (1) provide information to show that the new drug is the same as its brand name counterpart (the "reference listed drug"³⁵) with respect to active ingredient or ingredients, route of administration, dosage form, strength, and labeling, with certain exceptions;³⁶ (2) establish that the generic product is the bioequivalent of the reference listed drug;³⁷ and (3) complete one of four ANDA certifications.³⁸

Originator Drug Development, 54 Food & Drug L.J. 227, 229 (1999) (describing generic product development cycle as requiring an upfront investment of \$1,000,000, six to eighteen months for product development, six to twelve months for bioequivalency testing, and eighteen to thirty months for FDA approval).

33. 21 U.S.C. § 355(a), (j) (2000); Loren Gelber, Obtaining Approval of a Generic Drug, in *The Pharmaceutical Regulatory Process* 415, 416 (Ira R. Berry ed., 2005).

34. See *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 879 (D.C. Cir. 2004) (discussing how ANDAs "piggyback" on safety and effectiveness information submitted in NDAs); *Therapeutically Equivalent Drugs; Availability of List*, 45 Fed. Reg. at 72,590 ("FDA believes it is neither in the interest of the public health nor a productive use of the nation's scarce research resources to require costly duplication of tests. A regulatory system that requires such duplicative testing is wasteful, anticompetitive, scientifically unsound, and ethically dubious."); Justina A. Molzon, *The Generic Drug Approval Process*, 5 J. Pharmacy & L. 275, 276-77 (1996) (noting that repetition of safety and effectiveness studies by generic manufacturers would "contribute little to an understanding of the safety or efficacy of the drug entity that was not already know[n]").

35. 21 C.F.R. § 314.3 (2008) ("*Reference listed drug* means the listed drug identified by FDA as the drug product upon which [a generic] applicant relies in seeking approval of its [ANDA] application."); Eric L. Cramer & Daniel Berger, *The Superiority of Direct Proof of Monopoly Power and Anticompetitive Effects in Antitrust Cases Involving Delayed Entry of Generic Drugs*, 39 U.S.F. L. Rev. 81, 119 (2004) (noting that reference listed drugs are brand name drugs approved under NDAs and to which ANDA applicants demonstrate their products are therapeutically equivalent).

36. 21 U.S.C. § 355(j)(2)(A)(ii), (iii), (v).

37. *Id.* § 355(j)(2)(A)(iv); see § 355(j)(8)(B) (defining bioequivalence); see also 21 C.F.R. § 320.1(e) (explaining that drug is bioequivalent if it shows comparable rate and extent that active ingredient is absorbed from drug and becomes available at site of action); *Therapeutically Equivalent Drugs; Availability of List*, 45 Fed. Reg. at 72,593 (discussing how bioequivalence requirement ensures that generic drugs will perform with same safety and effectiveness as their FDA-approved brand name counterparts); Ctr. for Drug Evaluation & Research, FDA, *Approved Drug Products with Therapeutic Equivalence Evaluations*, available at <http://www.fda.gov/cder/ob/docs/preface/ecpreface.htm> (last visited Aug. 18, 2008) (on file with the *Columbia Law Review*) ("A major premise underlying the [Hatch-Waxman Act] is that bioequivalent drug products are therapeutically equivalent and, therefore, interchangeable.").

38. The applicant would complete a Paragraph I certification if no patent information on the reference listed drug has been filed; Paragraph II if the patents claimed by the reference listed drug have expired; Paragraph III if the patents claimed by the reference listed drug will expire on a stated date; and Paragraph IV if the patents claimed by the

Even while a brand name manufacturer's patent is in effect, generic manufacturers may apply for FDA approval to immediately market their competing generic product. To do so, the generic manufacturer must file an ANDA with a Paragraph IV certification (an "ANDA IV") and establish that the patents claimed by the brand name manufacturer's drug are invalid or not infringed by the generic product.³⁹ The submission of an ANDA IV itself allows the brand name manufacturer to bring a suit for patent infringement and challenge the ANDA.⁴⁰ If the brand name manufacturer does not do so or if the generic manufacturer wins in litigation, the generic manufacturer may immediately enter the market upon FDA approval⁴¹ and capture a substantial portion of its brand name competitor's market share by offering an attractively cheaper but equally effective alternative.⁴²

2. *The Hatch-Waxman Act.* — The ANDA framework is a relatively recent development formally authorized by the Drug Price Competition and Patent Term Restoration Act of 1984,⁴³ usually referred to as the Hatch-Waxman Act. Congress enacted the Hatch-Waxman Act to achieve policy goals tailored to the pharmaceutical industry: (1) to increase the availability of low-cost generic drugs and (2) to create new incentives for brand name drug manufacturers to make greater investments in research and development of new drugs.⁴⁴

The Act intensifies generic competition through several mechanisms.⁴⁵ The ANDA framework streamlines the generic drug application process, facilitating market entry for generic manufacturers.⁴⁶ To further

reference listed drug are invalid or will not be infringed by the manufacture, use, or sale of the generic. 21 U.S.C. § 355(j)(2)(A)(vii). Note that while a Paragraph III certification concedes that the patents have not expired and approval is not immediately sought, a Paragraph IV certification seeks pre-expiration approval and marketing of a generic drug.

39. 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

40. 35 U.S.C. § 271(e)(2)(A) (2000).

41. 21 U.S.C. § 355(j)(5)(B)(iii) (establishing that ANDA IV certification is effective immediately if no suit is brought, or if suit is brought, it is effective at earliest of: (1) court decision that patent is invalid or not infringed, (2) patent's expiration, or (3) thirty months from the notice required by § 355(j)(2)(B)).

42. See Bruce N. Kuhlik, *The Assault on Pharmaceutical Intellectual Property*, 71 U. Chi. L. Rev. 93, 94–96 (2004) (describing factors that make competition from generic manufacturers "especially challenging" to brand name manufacturers).

43. Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271(e)).

44. H.R. Rep. No. 98-857, pt. 1, at 14–15 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647–48.

45. As compensation for its intensification of generic competition, the Act grants brand name manufacturers special patent extensions for their new drug discoveries. Molzon, *supra* note 34, at 276 n.5; see also Teresa J. Lechner-Fish, *The Hatch-Waxman System: Suffering a Plague of Bad Behavior*, 5 Hous. Bus. & Tax L.J. 372, 392 (2005) ("The patent term extension is equal to one-half the time of the investigational new drug trial (IND) period plus the NDA review period.").

46. See *supra* notes 33–39 and accompanying text (providing overview of abbreviated FDA approval process for generic drugs).

encourage generic manufacturers to enter the market and challenge invalid patents, the Hatch-Waxman Act awards time-limited exclusivity rights to the first manufacturer to file an ANDA IV.⁴⁷ For 180 days, the first filer enjoys exclusive rights to market the generic version of the prescription drug.⁴⁸ The Act's overall impact on generic competition has been significant: Consumption of generic drugs increased from 19% of prescriptions filled in 1984 when the Act was passed to 47% in 2002.⁴⁹

B. State Drug Product Selection Laws

Generic substitution under state DPS laws is also a relatively recent development.⁵⁰ Where a physician prescribes a brand name drug, generic substitution allows pharmacists to fill that prescription with a generic equivalent.⁵¹

Until the mid-1970s, nearly all states required pharmacists to dispense the exact drug specified by the prescribing physician, even if equivalent generic products were available.⁵² States had imposed this ban on generic substitution to protect the public from the flood of counterfeit drugs appearing on the market through unknowing or dishonest pharmacists.⁵³ However, as new federal laws neutralized fears of counterfeit drugs, states gradually replaced their antisubstitution laws with DPS laws in an effort to contain high drug costs.⁵⁴

47. During the exclusivity period, the FDA cannot approve "any subsequent eligible generic applicants." FTC, *Generic Drug Entry Prior to Patent Expiration* 57 (2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf> (on file with the *Columbia Law Review*) [hereinafter FTC, *Generic Drug Entry*]; see also Elizabeth Powell-Bullock, *Gaming the Hatch-Waxman System: How Pioneer Drug Makers Exploit the Law to Maintain Monopoly Power in the Prescription Drug Market*, 29 *J. Legis.* 21, 27–28 (2002) (discussing benefits of exclusivity period to generic manufacturers). For a discussion of ANDA IVs, see *supra* notes 38–39 and accompanying text.

48. 21 U.S.C. § 355(j)(5)(B)(iv). But see § 355(j)(5)(D) (listing circumstances where generic manufacturer must forfeit exclusivity period).

49. FTC, *Generic Drug Entry*, *supra* note 47, at I.

50. See generally FTC, *DPS*, *supra* note 30, at 141–55 (giving historic background on state regulation of prescription drugs).

51. *Id.* at 7.

52. *Id.* at 6–7, 150, 155 ("By 1972, virtually every jurisdiction except the District of Columbia had enacted some form of antisubstitution law or regulation."). As physicians had less familiarity with lower priced generic equivalents and were thus less likely to prescribe them by name, pharmacies rarely dispensed generics under antisubstitution laws. *Id.* at 6.

53. *Id.* at 6–7. Large manufacturers and pharmacists, fearing injury to their reputation and integrity, supported antisubstitution laws. *Id.* at 141–43.

54. *Id.* at 151, 153; see also Kenneth W. Shafermeyer, Stephen W. Schondelmeyer & G. Thomas Wilson, *The FDA Orange Book: Expectations Versus Realities*, 1 *J. Pharmacy & L.* 13, 14 (1992) ("Between 1972 and 1984, all fifty states repealed their anti-substitution laws to allow pharmacists to select generic equivalents under specified circumstances."); *infra* notes 232–237 and accompanying text (explaining means through which states intended DPS laws to control prescription drug costs).

Today, every state has passed DPS laws that allow for generic substitution,⁵⁵ though the specific provisions vary state by state.⁵⁶ Unless a prescription indicates the physician's unwillingness to permit substitution (containing such phrases as "dispense as written" or "do not substitute"), pharmacists may dispense a generic drug when the prescription calls for a brand name drug.⁵⁷ State DPS laws thus help ensure that consumers will not needlessly bear the higher cost of brand name drugs when generics will do.⁵⁸

C. *Competitive Strategies in the Pharmaceutical Industry*

By avoiding the high research and development costs of drug discovery, generic manufacturers can cause a steep drop in prescription drug prices upon market entry and chip away at the hefty profits brand name manufacturers had previously enjoyed.⁵⁹ Brand name manufacturers face a particularly grim future as their blockbuster drugs continue to go off patent, their stream of new blockbuster drugs slows to a trickle, and generic manufacturers grow more aggressive in attacking the validity of patents.⁶⁰ A financially attractive recourse for brand name manufacturers is to focus on enhancing their profits from existing blockbuster drugs, though possibly at the expense of consumer welfare. This Section investi-

55. Alison Masson & Robert L. Steiner, FTC, *Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws 1 & n.1* (1985); Norman V. Carroll, Jack E. Fincham & Fred M. Cox, *The Effects of Differences in State Drug Product Selection Laws on Pharmacists' Substitution Behavior*, 25 *Med. Care* 1069, 1069 (1987).

56. See FTC, DPS, *supra* note 30, at 155–62 (comparing major types of state DPS laws); see also Cramer & Berger, *supra* note 35, at 116 n.116 (listing examples of state DPS laws that *allow* pharmacists to substitute generics for brand name drug and others that *require* substitution).

57. FTC, DPS, *supra* note 30, at 7; James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*, 35 *Cath. U. L. Rev.* 433, 437 (1986). Physicians may disfavor generic substitution for certain "critical dose drugs," as well as medications used to treat very serious conditions. See Benjamin F. Banahan & E. M. Kolassa, *A Physician Survey on Generic Drugs and Substitution of Critical Dose Medications*, 157 *Archives of Internal Med.* 2080, 2081 (1997) (describing "critical dose drugs" as medications whose slight change in dosage could result in ineffectiveness or toxicity); Duane M. Kirking, Caroline A. Gaither, Frank J. Ascione & Lynda S. Welage, *Physicians' Individual and Organizational Views on Generic Medications*, 41 *J. Am. Pharmaceutical Ass'n* 718, 720 & tbl.2 (2001) (discussing lower support among physicians for generic substitution of drugs treating very serious conditions or with higher possibility of adverse effects).

58. See FTC, DPS, *supra* note 30, at 7 (explaining price competition fostered by state DPS laws).

59. See *supra* note 30 (reporting substantial discounts for generic drugs from price at which brand name drugs are typically sold).

60. Before 2012, brand name manufacturers are predicted to "hit a wall" and suffer a loss of \$67 billion in sales to their generic rivals. Martinez & Goldstein, *supra* note 28; see also *Beyond the Blockbuster*, *Economist*, June 30, 2007, at 73, 73 (citing IMS estimate that pharmaceutical industry in 2006 saw record \$18 billion drop in branded sales).

gates two such methods and their interaction with the pharmaceutical industry's complex regulatory structure.

1. *Direct to Consumer Advertising*. — Brand name manufacturers advertise their prescription drugs directly to the public, investing in direct to consumer (DTC) advertising.⁶¹ Initially, prescription drug advertising targeted physicians, the decisionmakers in selecting prescription drugs.⁶² However, DTC advertising grew more attractive over time as patients became increasingly involved in their treatment.⁶³ Between 1996 and 2005, spending on DTC advertising grew from \$11.4 billion to \$29.9 billion.⁶⁴

The FDA, which regulates prescription drug advertising,⁶⁵ has changed its stance toward DTC advertising several times over the years. Initially lacking a formal policy toward DTC advertising, the FDA in 1983 called for a voluntary moratorium on pharmaceutical DTC advertising.⁶⁶ Two years later, the FDA announced that “current regulations governing prescription drug advertising [to physicians] provide sufficient safeguards to protect consumers”—effectively ending the moratorium and declining

61. Only the United States and New Zealand allow advertising of prescription drugs directly to patients. Barbara Mintzes et al., *Influence of Direct to Consumer Pharmaceutical Advertising and Patients' Requests on Prescribing Decisions: Two Site Cross Sectional Survey*, 324 *BMJ* 278, 278 (2002).

62. Francis B. Palumbo & C. Daniel Mullins, *The Development of Direct-to-Consumer Prescription Drug Advertising Regulation*, 57 *Food & Drug L.J.* 423, 424 (2002); see also *infra* note 177 and accompanying text (describing physician-directed demand in prescription drug industry).

63. See Tamar V. Terzian, *Direct-to-Consumer Prescription Drug Advertising*, 25 *Am. J.L. & Med.* 149, 151 (1999) (offering reasons why pharmaceutical companies have dramatically increased their DTC advertising in recent years); Marjorie Kauffman Sherr & Donna Cutrone Hoffman, *Physicians—Gatekeepers to DTC Success*, *Pharmaceutical Executive*, Oct. 1997, at 56, 56 (describing divergence from traditional concept of only physicians as customers for pharmaceutical products).

64. Julie M. Donohue, Marisa Cevasco & Meredith B. Rosenthal, *A Decade of Direct-to-Consumer Advertising of Prescription Drugs*, 357 *New Eng. J. Med.* 673, 675–76 & tbl.1 (2007).

65. See 21 U.S.C. § 331 (2000) (prohibiting introduction or delivery for introduction into interstate commerce of any misbranded drug); see also § 352(a) (defining misbranding); § 352(n) (listing regulations for prescription drug advertisements). Note that the FTC also has authority to regulate the advertising of drugs. 15 U.S.C. §§ 45(a), 52–55 (2000); see also Paul E. Kalb, Karen O. Dunlop, Diane C. McEnroe & Scott D. Stein, *Direct-to-Consumer Marketing: The FDA is Not Alone*, 58 *Food & Drug L.J.* 25, 26, 28–29 (2003) (discussing interagency cooperation between FDA and FTC). The two agencies have entered into a quasi formal working agreement to avoid unnecessary regulatory overlap between the agencies. This liaison agreement gives the FDA primary responsibility for prescription drug advertising and the FTC primary responsibility for over-the-counter drug advertising. See Updated FTC-FDA Liaison Agreement—Advertising of Over-the-Counter Drugs, 4 *Trade Reg. Rep.* (CCH) ¶ 9,851 (1971).

66. Wayne L. Pines, *New Challenges for Medical Product Promotion and Its Regulation*, 52 *Food & Drug L.J.* 61, 62 (1997) (citing speech by Arthur Hull Hayes, Jr., Comm'r of Food and Drugs, FDA, *Direct-to-Consumer Advertising of Prescription Drugs: Moratorium* (Feb. 17, 1983)).

to establish new, specialized standards for DTC advertising.⁶⁷ In 1997, the FDA revisited the issue and promulgated new guidelines.⁶⁸ Under its more lenient requirements, broadcast (i.e., radio, television, and telephone) DTC advertisements need not disclose comprehensive risk information.⁶⁹

According to the FDA, its regulation has bite despite its looser restrictions.⁷⁰ In August 1997, it reprimanded Schering-Plough, the leading television advertiser of prescription drugs, for its Claritin DTC advertisements.⁷¹ One advertisement obscured the required disclosure information by listing it in white print against a white background. The advertisement described the drug's benefits slowly and clearly while quickly presenting its risks with interference from "competing messages."⁷² Schering-Plough immediately revised its advertisement.⁷³

DTC advertising has attracted fierce critics and supporters. One of the primary benefits touted by proponents of DTC advertising is its information value. DTC advertising "educates consumers about medical conditions and care options,"⁷⁴ enabling patients to more effectively discuss their desires and values with their physicians.⁷⁵ Armed with knowledge

67. Direct-to-Consumer Advertising of Prescription Drugs; Withdrawal of Moratorium, 50 Fed. Reg. 36,677, 36,678 (Sept. 9, 1985). Existing standards required "a brief summary of all necessary information related to side effects and contraindications in any advertisement that promotes a drug for a particular use." *Id.* at 36,677; see also 21 U.S.C. § 352(n) (listing FFDCA's requirements for prescription drug advertisements).

68. Draft Guidance for Industry; Consumer-Direct Broadcast Advertisements; Availability, 62 Fed. Reg. 43,171, 43,171 (Aug. 12, 1997). The Guidance sought to "provide consumers with adequate communication of required risk information, while facilitating the process used by sponsors to advertise their products to consumers." *Id.* at 43,172.

69. Broadcast DTC advertisements need not provide a "brief summary" of comprehensive risk information "relating to [the drug's] side effects, contraindications, and effectiveness." *Ctr. for Drug Evaluation & Research, FDA, Guidance for Industry: Consumer-Directed Broadcast Advertisements 1* (1999), available at <http://www.fda.gov/cder/guidance/1804fnl.pdf> (on file with the *Columbia Law Review*) (finalizing 1997 Draft Guidance). Broadcast DTC advertisements that do not provide this risk information must instead make "adequate provision" (provide a toll-free number, a reference to DTC print advertisements, an Internet web page address that provides the package labeling, and a statement identifying pharmacists or physicians as a source of additional product information) "in connection with the broadcast presentation." *Id.* at 1-2 (citing 21 C.F.R. § 202.1(e)(1) (2008)).

70. See Greg Borzo, *New FDA Rules for Advertising Drugs on TV Raises Questions*, *Am. Med. News*, Sept. 8, 1997, at 3, 10 ("When we issued the new guidelines, we knew there were going to be gray area, so we promised vigilance. This shows we can be vigilant and do so quickly.") (quoting FDA spokesman Don McLearn)).

71. See *id.* at 3 (noting that Schering-Plough spent about \$50 million advertising Claritin over one and a half years).

72. *Id.* at 3, 10.

73. *Id.* at 3.

74. James T. O'Donnell, *Drug Injury: Liability, Analysis, and Prevention* 37 (2005).

75. See Sherr & Hoffman, *supra* note 63, at 58 (describing overall findings as supporting effectiveness of DTC in "motivating patients to initiate brand-related discussions with their physicians").

gained from DTC advertisements, patients may become more actively involved in their own health care decisions and may more strictly comply with treatment regimens.⁷⁶

However, the information provided by DTC advertising is of questionable value, as the nature of its source is commercial, rather than unbiased and scientific.⁷⁷ By deemphasizing side effects and risks, DTC advertisements can create unreasonably high patient expectations, generate inappropriate demand for certain prescription drugs, and provide incomplete, superficial information.⁷⁸ Patients driven by promotional communications to desire certain drugs may dismiss their physician's expert advice and insist upon treatment that is more expensive and possibly riskier, but at most only marginally more effective.⁷⁹ Although physicians still make the ultimate drug prescription decision, they may relent to pressure from obstinate patients with preconceived expectations.⁸⁰

2. *"Reverse Payment" Settlements.* — Ideally for consumers, a generic manufacturer's ANDA IV would usher in generic competition and significantly lower prices prior to the scheduled expiration of the brand name manufacturer's patent.⁸¹ However, certain strategies undertaken by brand name manufacturers may thwart this possibility. The brand name manufacturer's legal challenge to the ANDA IV⁸² may end in a certain type of settlement with the generic manufacturer—a "reverse payment" settlement—under which the generic manufacturer agrees to abstain

76. See Ellen 'T Hoen, *Direct-to-Consumer Advertising: For Better Profits or for Better Health?*, 55 *Am. J. Health-Sys. Pharmacy* 594, 595 (1998) ("The belief that advertising may contribute to better use of medications seems to be one of the foundations for the [1997] FDA guidelines.").

77. See Jerry Avorn, Milton Chen & Robert Hartley, *Scientific Versus Commercial Sources of Influence on the Prescribing Behavior of Physicians*, *Am. J. of Med.*, July 1982, at 4, 8 (discussing nonscientific drug information from "visually arresting and conceptually accessible" drug advertisements and its predominance over scientific sources in DTC advertising).

78. See Sherr & Hoffman, *supra* note 63, at 64 (noting that audience of DTC advertisements generally lacks adequate education about prescription drugs and understanding of factors behind medical decisions).

79. O'Donnell, *supra* note 74, at 37 (reporting potential negative consequences of DTC advertising); see Philip R. Alper, *Letter to the Editor, Direct-to-Consumer Advertising: Education or Anathema?*, 282 *JAMA* 1226, 1227 (1999) (describing DTC advertisements as "end run around the cost-containment efforts of health managers and physicians").

80. See Elyse Tanouye, *Drug Ads Spur Patients To Demand More Prescriptions*, *Wall St. J.*, Dec. 22, 1997, at B1 (describing how patients' pushiness can overcome physician's reservations and objections to certain prescription drugs).

81. See *supra* note 30 and accompanying text (reporting substantial discounts for generic drugs from price at which brand name drugs are typically sold); see also *supra* notes 38–39 and accompanying text (describing ANDA IVs).

82. The generic manufacturer's submission of an ANDA IV itself is an act of patent infringement. 35 U.S.C. § 271(e)(2)(A) (2000).

from or postpone its market entry in exchange for a large sum from the brand name manufacturer.⁸³

Most courts have been hesitant to condemn reverse payment settlements.⁸⁴ Settlements resolve disputes in a timely manner and reduce the use of limited judicial resources, particularly where patent litigation is complex and expensive.⁸⁵ Additionally, by cutting through highly technical patent disputes, settlements may expedite generic entry.⁸⁶ However, rather than serving such desirable and procompetitive ends, reverse pay-

83. C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1557 (2006) (describing reverse payment settlements and identifying antitrust harm from them as “remov[ing] the possibility of early competition in the drug, and . . . deny[ing] consumers the allocative benefit of low prices, which would have followed with some probability had the litigation proceeded to conclusion”). Such settlements are termed “reverse payment” settlements because they are the reverse of the usual settlement structure. Settlements normally entail a payment from the defendant infringer to the plaintiff patent holder. However, in this context, infringing generic firms would be subject to minimal damages if they lose the suit, as the litigation imposes a thirty month stay on the approval of their ANDA, barring them from entering the market. 21 U.S.C. § 355(j)(5)(B)(iii) (2000). In the absence of damages and any obligation of the infringer to the patentee, any settlement here would necessarily involve a payment *from* the plaintiff patent holder *to* the defendant infringer. E.g., *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1068 (11th Cir. 2005) (describing Schering-Plough Corp.’s settlement agreement with Upsher-Smith Laboratories, Inc. for Upsher to refrain from selling generic versions of Schering’s drug, K-Dur 20, for several years); *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1300–01 (11th Cir. 2003) (discussing Abbott Laboratories’ settlement with Geneva Pharmaceuticals whereby Abbott paid Geneva \$4.5 million per month to delay introduction of its generic product); see also *FTC, Generic Drug Entry*, supra note 47, at 28–30 (providing overview of different types of settlement agreements); Thomas F. Cotter, *Antitrust Implications of Patent Settlements Involving Reverse Payments: Defending a Rebuttable Presumption of Illegality in Light of Some Recent Scholarship*, 71 *Antitrust L.J.* 1069, 1071–76 (2004) (discussing settlement situations giving rise to reverse settlement payments).

84. See, e.g., *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 202–03 (2d Cir. 2005) (describing strong public interest favoring settlement of patent claims); *Schering-Plough Corp.*, 402 F.3d at 1075 (“There is no question that settlements provide a number of private and social benefits as opposed to the inveterate and costly effects of litigation . . . [T]he caustic environment of patent litigation may actually decrease product innovation by amplifying the period of uncertainty”); *Valley Drug Co.*, 344 F.3d at 1309 (“To hold that an ostensibly reasonable settlement of patent litigation gives rise to *per se* antitrust liability if it involves any payment by the patentee would obviously chill such settlements, thereby increasing the cost of patent enforcement and decreasing the value of patent protection generally.”); *In re Ciprofloxacin*, 261 F. Supp. 2d 188, 256 (E.D.N.Y. 2003) (“[T]he American legal process encourages the settlement of lawsuits where possible”); see also Hemphill, supra note 83, at 1573–78 (discussing reasons why courts have adopted sympathetic stance toward reverse payment settlements). But see *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 906–08 (6th Cir. 2003) (condemning settlement between brand name manufacturer Hoescht Marion Roussel and generic manufacturer Andrx as anticompetitive).

85. *In re Tamoxifen*, 466 F.3d at 202.

86. *FTC, Generic Drug Entry*, supra note 47, at 25 (“[S]ettlements may provide for generic entry that might otherwise be delayed by patent disputes, and can reduce uncertainty by clarifying intellectual property rights among the parties.”).

ment settlements may instead delay generic competition through collusion and manipulate the Hatch-Waxman Act's regulatory regime to inflict harm on consumers.

The Hatch-Waxman Act grants a 180-day period of market exclusivity to the generic manufacturer that is the first to file an ANDA IV for a generic version of a brand name drug.⁸⁷ Under the Act's original provisions, the FDA could not approve any ANDA IVs for subsequent generic versions of that brand name drug until 180 days after either (1) the first filer initiates commercial marketing or (2) a court concludes that the patents claimed by the brand name manufacturer's drug are invalid or not infringed by the generic product.⁸⁸ The settlement between the brand name and generic manufacturers eliminates the immediate possibility of such a court determination.⁸⁹ The terms of the reverse payment settlement delay or foreclose the first triggering event by requiring the first filer to postpone or abstain from commercial marketing and sit on its exclusivity rights.⁹⁰ By so preventing or delaying the events that start the countdown to the exclusivity period's expiration, reverse payment settlements create a bottleneck in the approval process for subsequent eligible ANDA IV filers and allow brand name manufacturers to stave off generic competition.⁹¹

In response to reverse payment settlements and other such strategies that exploit loopholes in the Hatch-Waxman Act, Congress passed the Greater Access to Affordable Pharmaceuticals Act (GAAP), enacted

87. See *supra* notes 47–48 and accompanying text (discussing exclusivity period).

88. 21 U.S.C. § 355(j)(5)(B)(iv). But note the Greater Access to Affordable Pharmaceuticals (GAAP) Act, enacted under Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1101(a), 1102(a)(1), 117 Stat. 2066, 2448–52, 2457–61 (codified at 21 U.S.C. § 355 (Supp. IV 2004)) (amending ANDA process in response to manipulations of loopholes in Hatch-Waxman Act and to prevent certain anticompetitive abuses); see *infra* note 92 and accompanying text (describing GAAP at greater length).

89. The settlement also “secure[s] an important change in the competitive situation; it removes from consideration the most motivated challenger, and the one closest to introducing competition.” Hemphill, *supra* note 83, at 1586.

90. FTC, *Generic Drug Entry*, *supra* note 47, at 26.

91. Stephanie Greene, *A Prescription for Change: How the Medicare Act Revises Hatch-Waxman to Speed Market Entry of Generic Drugs*, 30 *J. Corp. L.* 309, 336 (2005) (“Thus, the first ANDA IV filer, by deliberately delaying, or ‘parking,’ its 180 days of exclusivity, may create a bottleneck that prevents other generic competitors from getting FDA approval.”); Elizabeth Stanley, *An Ounce of Prevention: Analysis of Drug Patent Settlements Under the Hatch-Waxman Act*, 10 *Geo. Mason L. Rev.* 345, 352–53 & n.63 (2002) (“According to the FTC . . . such settlement agreements between brand [name] and generic manufacturers act as a bottleneck that prevents any other potential competitor from entering the generic market . . .”). But see FTC, *Generic Drug Entry*, *supra* note 47, at 31 (observing that despite reverse payment settlement, 180-day exclusivity period will still begin to run if subsequent ANDA filer wins favorable court decision of noninfringement or invalidity); Hemphill, *supra* note 83, at 1587–88 (arguing that “the bottleneck [is not] a pervasive feature of pay-for-delay settlements” and cautioning against over-emphasis on this feature to demonstrate competitive concern).

under Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.⁹² It addressed reverse payment settlements by adopting a “use it or lose it” approach to the exclusivity period, requiring forfeiture of the 180-day exclusivity if the first filer fails to launch its product in a timely manner.⁹³ As a result, brand name manufacturers can no longer use reverse payment settlements to keep their generic rivals out of the market indefinitely or unreasonably postpone generic entry.

* * *

While the pharmaceutical industry’s regulatory regime leaves ample room for vigorous market competition,⁹⁴ its complexities open up avenues for manipulation that brand name manufacturers may pursue to impede generic competition.⁹⁵ Though Congress has expressed its disapproval of such manipulation and acted against one such strategy, new tactics have emerged—such as product hopping. Part II explores product hopping by brand name manufacturers and its use as a strategy to frustrate generic competition.

II. THE STRATEGY: PRODUCT HOPPING

This Part introduces the strategy of product hopping and the complex antitrust issues it presents. Part II.A explains how product hopping by brand name manufacturers undermines generic competition. Part II.B and Part II.C present two instances of product hopping.⁹⁶ To illus-

92. §§ 1101(a), 1102(a)(1), 117 Stat. at 2448–52, 2457–61. See generally Larissa Burford, *In re Cardizem & Valley Drug Co.*: The Hatch-Waxman Act, Anticompetitive Actions, and Regulatory Reform, 19 Berkeley Tech. L.J. 365 (2004) (discussing amendments to Hatch-Waxman Act and issues they address); Natalie M. Derzko, *The Impact of Recent Reforms of the Hatch-Waxman Scheme on Orange Book Strategic Behavior and Pharmaceutical Innovation*, 45 IDEA 165 (2005) (same).

93. Julia Rosenthal, *Hatch-Waxman Use or Abuse? Collusive Settlements Between Brand-Name and Generic Drug Manufacturers*, 17 Berkeley Tech. L.J. 317, 328–29 (2002) (describing structural reform of Hatch-Waxman Act that GAAP undertook); see 21 U.S.C. § 355(j)(5)(D)(i)(I) (requiring forfeiture of 180-day exclusivity period upon failure to market within defined period of time). Additionally, GAAP charged the FTC and Department of Justice with reviewing settlement agreements between parties engaged in ANDA IV litigation. 21 U.S.C. § 355(j)(5)(D)(i)(V).

94. For example, see *supra* Part I.C.1 (describing loose FDA regulations on DTC advertising).

95. For example, see *supra* Part I.C.2 (detailing reverse payment settlements and Congress’s response).

96. Not discussed in this Note is a third incidence of product hopping involving Ovcon. Generic manufacturer Barr Pharmaceuticals (Barr) filed an ANDA with the FDA for approval to market a generic version of Ovcon 35 in September 2001, expecting to enter the market by the end of 2003. *FTC v. Warner Chilcott Holdings Co.*, III, 2007-1 Trade Cas. (CCH) ¶ 75,565, at 106,942 (D.D.C. Jan. 22, 2007). Ovcon 35 is one of brand name manufacturer Warner Chilcott’s highest revenue-producing products, and Barr anticipated capturing fifty percent of its sales within the first year of production. *Id.* Warner Chilcott’s chief financial officer described generic Ovcon as the “biggest risk to the

trate the complexity of the analysis, Part II.D takes a step back and frames product hopping in terms of its anticompetitive harm and the challenges to antitrust enforcement. Part II.E discusses the only judicial opinions thus far to address product hopping and tackle these issues: *Abbott Laboratories v. Teva Pharmaceuticals USA, Inc.*⁹⁷ and *Walgreen Co. v. Astra Zeneca Pharmaceuticals L.P.*⁹⁸ Part II.F critiques this judicial treatment and highlights the features of the pharmaceutical industry's unique market structure that cast doubt on the *Abbott* and *Walgreen* courts' approach.

A. *The Basic Product Hopping Scenario*

A product hopper alters its brand name drug such that the old and new versions—that is, formulations—are no longer bioequivalent.⁹⁹ As a

company.” Id. In response, among other things, Warner Chilcott planned to introduce a chewable form of Ovcon 35 before generic entry occurred, convert its current Ovcon 35 customers to the new Ovcon Chewable, and stop selling Ovcon 35. Complaint for Injunctive and Other Equitable Relief at 8–9, *Warner Chilcott*, 2007-1 Trade Cas. (CCH) ¶ 75,565 (No. 05-2179). Under Warner Chilcott's product hopping strategy, pharmacists would be unable to fill prescriptions for Ovcon Chewable with generic versions of Ovcon 35 because the generic would not be the bioequivalent of Ovcon Chewable. Id. However, by the time generic Ovcon entry appeared imminent, Warner Chilcott had not yet obtained FDA approval to market Ovcon Chewable, jeopardizing its product hopping strategy. Press Release, FTC, *FTC Sues to Stop Anticompetitive Agreement in U.S. Drug Industry* (Nov. 7, 2005), available at <http://www.ftc.gov/opa/2005/11/galenbarr.shtm> (on file with the *Columbia Law Review*). Warner Chilcott nevertheless launched Ovcon Chewable in September 2006 and began transitioning from Ovcon 35 to Ovcon Chewable. Warner Chilcott Corp, Registration Statement (Form S-1), at 21 (Oct. 20, 2006). However, Barr announced that it expected to launch its generic version of Ovcon 35, “Balziva,” in October 2006, *Warner Chilcott*, 2007-1 Trade Cas. (CCH) at 106,945, threatening the success of Warner Chilcott's product hopping strategy, see Warner Chilcott Corp., Registration Statement (Form S-1), at 21 (Oct. 20, 2006) (“The launch of the generic version would negatively affect the migration of consumers to Ovcon Chewable and could adversely affect the longer term market acceptance of Ovcon Chewable.”). On September 25, 2006, the FTC sought to enjoin Warner Chilcott, alleging, inter alia, that its hop from Ovcon 35 to Ovcon Chewable “would impede the market for a generic version of Ovcon 35.” Id. at 30; see also *Warner Chilcott*, 2007-1 Trade Cas. (CCH) at 106,943 (“[T]he FTC filed a motion for a preliminary injunction seeking to keep regular Ovcon on the market.”). However, Warner Chilcott settled with the FTC on October 10, 2006, and the FTC withdrew its motion for a preliminary injunction. Warner Chilcott Corp, Form of Prospectus Reflecting Facts Events Constituting Substantive Change from Last Form (Form 424B3), at 25 (Nov. 22, 2006). Under the settlement agreement, Warner Chilcott would continue to fill orders for Ovcon 35 until January 23, 2007. Id.

97. 432 F. Supp. 2d 408 (D. Del. 2006).

98. 534 F. Supp. 2d 146 (D.D.C. 2008).

99. See Herbert Hovenkamp, Mark D. Janis & Mark Lemley, IP and Antitrust: An Analysis of Antitrust Principles Applied to Intellectual Property Law § 12.5 (Supp. 2007) (giving overview of product hopping strategy). Reformulation approaches include changing a drug's molecular structure, using a new delivery method, or finding a new method of use. Rebecca S. Yoshitani & Ellen S. Cooper, *Pharmaceutical Reformulation: The Growth of Life Cycle Management*, 7 Hous. J. Health L. & Pol'y 379, 389–405 (2007). Another method, combination reformulation, involves combining different drugs and patenting the new combination. See, e.g., *McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362, 1364 (Fed. Cir. 2003) (discussing combination of two drugs by manufacturer as

result, generic drugs which are the bioequivalent of the old formulation are not the bioequivalent of the new formulation. As the product hopper has just introduced the new formulation, that formulation has as yet no generic equivalents and is fully shielded from generic competition. Because generic substitution allows pharmacists to substitute brand name drugs only with their generic equivalents,¹⁰⁰ pharmacists can dispense generic versions of the product hopper's drug only when physicians prescribe the old, but not the new, formulation.¹⁰¹ The consequences may be grim for generic manufacturers, who heavily rely on generic substitution to fuel sales of their generic drugs.¹⁰² When the brand name manufacturer kills demand for its old formulation,¹⁰³ demand for rival generics dies with it.¹⁰⁴

To enjoy valuable, sales-generating generic substitution, generic manufacturers must follow the hop and develop a generic version of the new formulation.¹⁰⁵ The delay to generic manufacturers from developing a generic version of the new formulation and submitting a new ANDA IV to the FDA—which may spark a new round of patent litigation¹⁰⁶—

attempt “to extend its position as market leader”). For a discussion of bioequivalence, see *supra* note 37.

100. See Gelber, *supra* note 33, at 416–17 (explaining that pharmacists may substitute generics for brand product only if generic is bioequivalent to brand name drug and in same dosage, strength, and form—i.e., if generic is listed as “AB-rated” in FDA’s Orange Book); see also Therapeutically Equivalent Drugs; Availability of List, 45 Fed. Reg. 72,582, 72,601 (Oct. 31, 1980) (“[T]he ‘AB’ code identifies an active ingredient in a dosage form for which the submission of bioavailability data is required for approval and indicates that the firm has performed an acceptable bioequivalence study on its product.”). For a description of the Orange Book, see 21 U.S.C. § 355(b)(1), (j)(7)(A)(i) (2000) (charging FDA with publishing and regularly updating Orange Book—common name for Approved Drug Products with Therapeutic Equivalence Evaluations publication—which lists all approved drug products and their approved generic equivalents); 21 C.F.R. § 20.117(a)(3) (2007) (describing information available for public inspection); Therapeutically Equivalent Drugs; Availability of List, 45 Fed. Reg. at 72,601 (“FDA’s primary purpose in preparing the [Orange Book] is to provide to the public the agency’s information and advice on the therapeutic equivalence of approved [generics and brand name] drugs.”).

101. See Guy V. Amoresano, *Branded Drug Reformulation: The Next Brand vs. Generic Antitrust Battleground*, 62 *Food & Drug L.J.* 249, 251 (2007) (“The reformulation strategy . . . prevents [generic] drug[s] from being dispensed by pharmacists as an AB-rated substitute to fill prescriptions written for the brand drug [where the new formulation is prescribed].”).

102. See Cramer & Berger, *supra* note 35, at 125 (“Generics typically spend very little on promotional efforts, instead letting their low prices and generic substitution laws serve as the principal inducements for sales growth.”).

103. For example, see *infra* notes 115–116 and accompanying text (describing AstraZeneca’s pairing of product hopping with aggressive marketing strategy to shift physicians away from prescribing its old formulation and toward its new formulation instead).

104. For example, see *infra* notes 138–140 and accompanying text (discussing low demand for Teva’s generic product without generic substitution).

105. See Hovenkamp, Janis & Lemley, *supra* note 99, § 12.5.

106. The generic manufacturer’s submission of an ANDA IV itself is an act of patent infringement. 35 U.S.C. § 271(e)(2)(A) (2000).

allows product hoppers to enjoy several additional years of sizable profits and insulation from generic competition.¹⁰⁷ Even where the generic manufacturer has successfully made the hop to the new formulation and is on the verge of bringing its generic version to market, the product hopper may take a second hop to a third formulation and force the generic manufacturer to start from scratch again.¹⁰⁸

B. AstraZeneca's Hop from Prilosec to Nexium

Omeprazole, marketed by AstraZeneca Pharmaceuticals (AstraZeneca) under the brand name Prilosec,¹⁰⁹ is a prescription proton pump inhibitor drug used to treat heartburn.¹¹⁰ Prilosec had been AstraZeneca's best-selling drug, its U.S. sales exceeding \$4 billion by 1999.¹¹¹ Anticipating the loss of patent protection over omeprazole in

107. Hovenkamp, Janis & Lemley, *supra* note 99, § 12.5. If the brand name manufacturer launches patent infringement litigation against the generic manufacturer in a timely manner, it can trigger a thirty-month stay, barring the generic manufacturer from entering the market. 21 U.S.C. § 355(j)(5)(B)(iii); see Hemphill, *supra* note 83, at 1566 & n.50 (noting this delay can last more than three years). Even without the statutory stay, brand name manufacturers can expect to delay generic competition for several months by requiring generic manufacturers to submit a new ANDA for FDA approval. Though the FDA must either approve or reject the ANDA within 180 days of its initial receipt, 21 U.S.C. § 355(j)(5)(A), in reality the ANDA approval process takes considerably longer. Lorie Ann Morgan, *Pharmaceutical Patents and the Hatch-Waxman Act*, in 18 *Encyclopedia of Pharmaceutical Technology* 137, 146 (1998).

108. Such was Abbott and Fournier's strategy with TriCor. See *infra* notes 135–137 and accompanying text (detailing Abbott and Fournier's second hop).

109. Most prescription drugs have three names. Its "chemical name" describes the drug's chemical structure and, due to its technical nature, is "often understandable only to accomplished organic chemists." Its "generic name" refers to the drug's active chemical ingredients, a shorter and simpler version of the chemical name. The "brand name" refers to the trade name given to it by the manufacturer to distinguish it from other identical compounds produced by other firms. FTC, DPS, *supra* note 30, at 4, 26–27. In this case, Prilosec's chemical name is "5-methoxy-2-(((4-methoxy-3,5-dimethyl-2-pyridinyl)methyl)sulfinyl)-1H-benzimidazole." U.S. Patent No. 4,786,505 col.1 l.14–16 (filed Apr. 20, 1987). "Omeprazole" refers to the active ingredient, and "Prilosec" is the brand name. See *In re Omeprazole Patent Litig.*, Nos. 2007-1476, 2007-1477, 2007-1478, 2008 U.S. App. LEXIS 12390, at *1–*3 (Fed. Cir. June 10, 2008) (describing Patent No. 4,786,505, one of the patents protecting Prilosec formulation).

110. Prilosec is FDA approved for, among other things, healing erosive esophagitis and treating symptomatic gastroesophageal reflux disease. Motion to Dismiss of Defendants AstraZeneca Pharmaceuticals L.P., AstraZeneca L.P., Zeneca Inc., and Zeneca Holdings, Inc. at 1, *Walgreen Co. v. AstraZeneca Pharms. L.P.*, 534 F. Supp. 2d 146 (D.D.C. 2008) (No. 1:06-cv-02084-RWR) [hereinafter *AstraZeneca, Dismiss*].

111. First Amended Complaint and Demand for Jury Trial at 15, *Walgreen Co.*, 534 F. Supp. 2d 146 (No. 1:06 CV 02084-RWR) [hereinafter *Walgreen, First Amended Complaint*] (noting Prilosec was "top-selling drug in the world"); see also AstraZeneca, *Annual Report & Form 20-F 2000*, at 38 (2001) (reporting sales of \$6.3 billion for AstraZeneca's gastrointestinal drugs in 2000, driven by U.S. Prilosec growth); *Maker of Prilosec Under Fire from Pharmacy Chains*, *Chain Drug Rev.*, Jan. 1, 2007, at 112 [hereinafter *Prilosec Maker Under Fire*] (estimating \$6 billion in Prilosec's global sales for 2000).

2001, AstraZeneca convened a group of marketers, lawyers, and scientists (naming itself the “Shark Fin Project”) in the mid-1990s to devise strategies to frustrate generic competition.¹¹²

One tactic entailed developing another heartburn treatment with a formulation different from Prilosec’s. Prior to Prilosec’s patent expiration and the entry of generic drugs into the proton pump inhibitor drug market, AstraZeneca introduced Nexium, a prescription drug like Prilosec but with a different stereochemistry.¹¹³ This difference between Nexium and Prilosec would prevent pharmacists from substituting prescriptions for Nexium with generic versions of Prilosec.¹¹⁴

Furthermore, AstraZeneca sought to convert Prilosec prescribing physicians to Nexium, heavily promoting Nexium while drawing Prilosec promotions to a full stop.¹¹⁵ By the time generic versions of Prilosec entered the market, about ten million annual unit sales had hopped with AstraZeneca to Nexium: Nexium sales soared while Prilosec sales plum-

112. The name of the “Shark Fin Project” was based on the inverted V shape that a Prilosec sales chart would trace if no action were taken to ward off generic competition. Walgreen, First Amended Complaint, *supra* note 111, at 15.

113. Nexium, esomeprazole magnesium, is “classified as an ‘enantiomer’ of Prilosec [omeprazole].” AstraZeneca, Dismiss, *supra* note 110, at 5. The importance of this difference is debatable. The different chemical properties and biological effects of certain enantiomers—compounds that are mirror images of each other—suggest the difference between Prilosec and Nexium may be significant. Francis A. Carey, *Organic Chemistry* 310–12 (Kent A. Peterson et al. eds., 6th ed. 2006); see Jonathan J. Darrow, *The Patentability of Enantiomers: Implications for the Pharmaceutical Industry*, 2007 *Stan. Tech. L. Rev.* 2, ¶¶ 5–8, available at <http://stlr.stanford.edu/pdf/darrow-patentability.pdf> (on file with the *Columbia Law Review*) (discussing structure and characteristics of enantiomers). However, knowledge of the structure of one enantiomer necessarily suggests the structure of the other, such that an enantiomer’s corresponding mirror image may be unpatentable as obvious under the Patent Act, 35 U.S.C. § 103 (2006). See generally Darrow, *supra*, ¶¶ 17–58 (discussing modern legal framework surrounding patentability of enantiomers and identifying unique questions and issues for enantiomers within “law of chemical obviousness”). The Supreme Court’s recent decision in *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007), expanded the scope of obviousness—rejecting the Federal Circuit’s mechanical rule “that had eliminated obviousness as a meaningful basis for invalidating drug industry patents” and making enantiomer patents particularly vulnerable to challenge. Calvert D. Cray, C.D. Cray & Co., *Litigation Notes: Impact of KSR v. Teleflex on Pharmaceutical Industry* 1–2 (2007). The reluctance of patent law to recognize the difference between enantiomers and grant each patent protection suggests the difference between Prilosec and Nexium may not be significant for product hopping purposes.

114. See *supra* Part II.A (discussing how product hopping undermines generic substitution); see also *supra* Part I.B (describing generic substitution under state DPS laws).

115. Plaintiffs’ Statement of Points of Authority in Opposition to Defendants’ Motion to Dismiss at 9, *Walgreen Co.*, 534 F. Supp. 2d 146 (No. 1:06-cv-02084-RWR) [hereinafter Walgreen, Opposition].

meted.¹¹⁶ Without opportunities for generic substitution, generic Prilosec saw dismal sales as well.¹¹⁷

In December 2006, a group of pharmacies led by Walgreen Company sued AstraZeneca, alleging it illegally monopolized the market for proton pump inhibitor drugs “by switching [customers] from Prilosec, which now has generic competition, to a virtually identical drug, Nexium, which does not.”¹¹⁸

C. *Abbott and Fournier’s TriCor Product Hops*

Fenofibrate, marketed by Abbott Laboratories (Abbott) and Fournier Industrie et Sante (Fournier) under the brand name TriCor, is a cholesterol-lowering drug.¹¹⁹ Abbott and Fournier began marketing TriCor in its capsule formulation in 1998,¹²⁰ reporting TriCor sales of approximately \$750 million per year.¹²¹ By early 2000, Teva filed an ANDA IV to sell a generic version, signaling the possibility of generic competition for fenofibrate sales.¹²²

In 2001, Abbott and Fournier made their first hop from marketing TriCor in its capsule form to selling a new tablet formulation, and removed the old capsule formulation from the market.¹²³ If physicians prescribed TriCor’s new tablet formulation, pharmacists could not fill that prescription with a generic version of the old capsule formulation.¹²⁴

116. *Id.* at 3–4, 9–10 (“[B]efore generic Prilosec was even approved for marketing, AstraZeneca had succeeded in reducing annual unit sales of Prilosec from 29.6 million to 19.6 million, while increasing the annual unit sales of Nexium from 0 to 13.4 million.”).

117. See *Walgreen Co.*, 534 F. Supp. 2d at 149 (“Plaintiffs also project that if Nexium had not gone to market, the manufacturers of generic substitutes to prescription Prilosec would have far more than their current 30% of the market, and consumers would have collectively saved \$11.5 billion by the end of the year 2006.”).

118. *Walgreen*, First Amended Complaint, *supra* note 111, at 2; see also *Walgreen Co.*, 534 F. Supp. 2d at 147–49 (summarizing plaintiffs’ allegations).

119. *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408, 415 (D. Del. 2006) (describing TriCor as a treatment for high cholesterol and triglyceride levels).

120. Teva’s Answering Brief in Opposition to Abbott’s and Fournier’s Motion to Dismiss Counterclaims, at exhibit A, *Abbott Labs.*, 432 F. Supp. 2d 408 (No. 02-1512 (KAJ)) [hereinafter *Teva*, Answer].

121. Second Amended Answer, Affirmative Defenses, and Counterclaims at 21, *Abbott Labs.*, 432 F. Supp. 2d 408 (No. 02-1512 (KAJ)) [hereinafter *Teva*, Second Amended Answer]; Reply Brief in Support of Teva Pharmaceuticals USA, Inc.’s and Teva Pharmaceutical Industries Ltd.’s Motion to Supplement and Amend Their Answers to Assert Antitrust Counterclaims at 2, *Abbott Labs.*, 432 F. Supp. 2d 408 (No. 02-1512-KAJ) [hereinafter *Teva*, Reply].

122. *Teva*, Reply, *supra* note 121, at 2; see also *Abbott Labs.*, 432 F. Supp. 2d at 415 & n.1 (noting that Novopharm, Teva’s subsidiary, filed ANDA IV).

123. *Abbott Labs.*, 432 F. Supp. 2d at 416.

124. See *supra* Part II.A (discussing how product hopping undermines generic substitution); see also *supra* Part I.B (describing generic substitution under state DPS laws).

Pharmacists could not even substitute prescriptions for the old capsule formulation with *its* generic equivalent.¹²⁵ Abbott and Fournier accomplished this by allegedly changing the National Drug Data File (NDDF) code for the old capsule formulation to “obsolete.”¹²⁶ The NDDF is a private database of FDA-approved drugs¹²⁷ which pharmacists consult to identify generic substitutes for brand name drugs.¹²⁸ The NDDF links each generic drug to its reference listed drug,¹²⁹ the brand name drug to which that generic is bioequivalent according to the generic manufacturer’s ANDA.¹³⁰ Changing the code to “obsolete” eliminated the old TriCor capsule formulation’s status as a reference listed drug.¹³¹ Since Teva’s fenofibrate capsules no longer had a reference listed drug to which they were the generic equivalent, they lost their status as generic drugs¹³² and with it, the benefit of generic substitution.¹³³ By preventing pharmacists from even filling prescriptions for TriCor cap-

125. *Abbott Labs.*, 432 F. Supp. 2d at 416.

126. *Id.*; Teva, Answer, *supra* note 120, exhibit A. Note that Abbott and Fournier admitted only that “Abbott communicated the discontinuance of the TriCor capsule formulation to First DataBank.” Fournier’s Answer to First Amended Complaint at 9, *Florida v. Abbott Labs.*, No. 08-155 (SLR), 2008 WL 4107684 (D. Del. June 17, 2008) [hereinafter Fournier, Answer]; see also Abbott Laboratories’ Answer to Plaintiff States’ First Amended Complaint at 12, *Florida v. Abbott Labs.*, 2008 WL 4107684 (No. 08-155 (SLR)) [hereinafter Abbott, Answer]; Defendants’ Consolidated Opening Brief in Support of Their Consolidated Motion to Dismiss Plaintiffs’ Complaints at 5, *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408 (No. 02-1512 (KAJ)).

127. See *Schering Corp. v. First DataBank, Inc.*, No. 07-01142, 2007 U.S. Dist. LEXIS 50164, at *2 (D. Cal. Apr. 20, 2007) (“The NDDF database contains pricing and clinical information about nearly every Food and Drug Administration-approved pharmaceutical product.”).

128. *DUSA Pharms. Inc. v. River’s Edge Pharms., LLC*, No. 06-1843, 2006 U.S. Dist. LEXIS 29852, at *4 (D.N.J. May 15, 2006) (describing common use of NDDF “to identify potential substitute equivalents of branded pharmaceuticals”).

129. Teva, Answer, *supra* note 120, at 14–15.

130. See *supra* note 35 and accompanying text (defining “reference listed drug”).

131. *Abbott Labs. v. Teva Pharms USA, Inc.*, 432 F. Supp. 2d at 416; see also First Amended Complaint at 37–38, *Florida v. Abbott Labs.*, 2008 WL 4107684 (No. 08-155) [hereinafter Attorneys General, Complaint] (noting that NDDF removes “obsoleted” drugs from its database).

132. *Abbott Labs. v. Teva Pharms USA, Inc.*, 432 F. Supp. 2d at 415. The NDDF uses a “Generic Indicator” code to identify whether a drug is supplied by only one company (a “single-source product”), or whether the drug is supplied by multiple companies, including a generic manufacturer (a “multi-source product”). Attorneys General, Complaint, *supra* note 131, at 10–11. As a result of TriCor’s removal as the reference listed drug, Teva’s fenofibrate capsule became the only fenofibrate capsule listed in the NDDF and thus became “coded as a single-source drug, not a generic.” *Id.* at 20.

133. Teva, Second Amended Answer, *supra* note 121, at 44; see also Eric Stock & Robert F. Leibenluft, Antitrust Challenges to “Product Hopping”: Is the TriCor Decision an Anomaly or a Sign of Things to Come?, *Life Sci.: Competition & Antitrust Update* (Hogan & Hartson LLP, Washington, D.C.), June 29, 2006, at 4, 5 (explaining that changing drug to “obsolete” effectively prevented pharmacies from filling prescriptions for TriCor with generic capsule formulation).

sules with their generic equivalent, Abbott and Fournier successfully prevented generic substitution for TriCor formulations across the board.

However, Teva followed the hop. It developed generic TriCor tablets and applied for FDA approval in June 2002.¹³⁴ In response, Abbott and Fournier took a second hop in 2003, developing a second tablet formulation for TriCor that need not be taken with food, and again removed the old formulation from the market.¹³⁵ Abbott and Fournier claimed that patients appreciated the product change and preferred the new version, with nearly 100% of patients on its old formulation switching to the new.¹³⁶ Again Abbott and Fournier allegedly changed the NDDF code,¹³⁷ preventing generic substitution by pharmacies regardless of the generic's equivalence to the brand name drug prescribed.

As a result of Abbott and Fournier's product hopping, once Teva obtained FDA approval to market generic versions of the old formulations, it could not rely on generic substitution to fuel sales and instead marketed its fenofibrate product under its own brand name, Lofibra.¹³⁸ Without generic substitution, Teva could generate sales only when physicians prescribed Lofibra by name.¹³⁹ As a result, Lofibra sales have been modest: about \$4 million per year.¹⁴⁰

In 2005, various plaintiffs¹⁴¹ brought an antitrust suit against Abbott and Fournier claiming they schemed to monopolize the market for fenofibrate products.¹⁴² Additionally, as of July 2008, twenty-five states and the District of Columbia have filed antitrust suits against Abbott and

134. Teva, Answer, *supra* note 120, exhibit A.

135. *Abbott Labs.*, 432 F. Supp. 2d at 418; Teva, Answer, *supra* note 120, exhibit A.

136. Bruce Japsen, *Abbott Set for Battle over Generic TriCor*, Chi. Trib., May 17, 2005, at C1. Although note that Abbott and Fournier's removal of their old formulation from the market may explain this nearly unanimous shift.

137. *Abbott Labs.*, 432 F. Supp. 2d at 418; Attorneys General, Complaint, *supra* note 131, at 37–38; Teva, Answer, *supra* note 120, exhibit A; see also Abbott, Answer, *supra* note 126, at 12, 23 (admitting Abbott “notified” NDDF that TriCor capsules and 160 mg tablets were discontinued); Fournier, Answer, *supra* note 126, at 9, 15 (admitting only that Abbott “communicated” discontinuance of TriCor capsule and tablet formulations to First DataBank).

138. *Abbott Labs.*, 432 F. Supp. 2d at 416; Teva, Second Amended Answer, *supra* note 121, at 37.

139. See Amoresano, *supra* note 101, at 254 (“[T]he net effect of the reformulation strategy was that for Teva to sell its version of fenofibrate, the physician had to consciously choose Teva's product by name.”).

140. *Abbott Labs.*, 432 F. Supp. 2d at 416; Teva, Second Amended Answer, *supra* note 121, at 37.

141. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd.; Impax Laboratories, Inc.; Walgreen Co., Eckerd Corp., The Kroger Co., Maxi Drug, Inc., Albertson's, Inc., Safeway, Inc., and Hy-Vee, Inc.; CVS Pharmacy, Inc., Rite Aid Corp., and Rite Aid Headquarters Corp.; Pacificare Health Systems, Inc.; a “Class of Direct Purchasers”; and a “Class of Indirect Purchasers.” *Abbott Labs.*, 432 F. Supp. 2d at n.1.

142. Teva, Reply, *supra* note 121, at 1–2.

Fournier in Delaware District Court,¹⁴³ charging them with blocking generic competition by engaging in product hopping, among other “anti-generic strateg[ies].”¹⁴⁴ The complaint seeks, among other relief, treble damages for overcharges incurred by state public health agencies and individual consumers.¹⁴⁵

D. *The Challenges to Policing Product Hopping*

Product hopping itself amounts to little more than a thinly disguised scheme to game the pharmaceutical industry’s regulatory system. Product hopping entails introducing a product change that “ma[kes] no economic sense absent its effect of impairing generic competition”¹⁴⁶ and “unfairly reduce[s] the market place for generics.”¹⁴⁷ Brand name manufacturers engage in product hopping to improperly extend their market exclusivity, changing the formulation of their drug not to enhance the product’s effectiveness but to impair generic competition.¹⁴⁸ By so frustrating generic competition, brand name manufacturers “deny[] consumers access to a generic alternative to [brand name drug] products.”¹⁴⁹

However, brand name manufacturers are under no legal duty to help their generic competitors by curtailing formulation changes that broaden the selection of prescription drugs on the market and may better meet consumer preferences.¹⁵⁰ Nor are they obligated to continue selling

143. Arizona, Arkansas, California, Connecticut, District of Columbia, Florida, Idaho, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Nevada, New York, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, Texas, Vermont, Washington, and West Virginia. Attorneys General, Complaint, *supra* note 131, at 1.

144. *Id.* at 4–5, 15–21, 32–37, 41–43. “The wrongful actions of these drug companies increased their profits at the expense of the State of Arkansas and its consumers,” Arkansas Attorney General Dustin McDaniel commented. “At a time when drug and health costs are rapidly escalating, these practices cannot be tolerated.” Press Release, Ark. Att’y Gen. Office, Attorney General McDaniel Sues Abbott and Fournier for Illegially [sic] Blocking Generic Competition to TriCor (Mar. 19, 2008), available at http://www.ag.state.ar.us/newsroom/index.php?do:newsDetail=1&news_id=157 (on file with the *Columbia Law Review*).

145. Attorneys General, Complaint, *supra* note 131, at 72–73. According to the office of California’s Attorney General, Jerry Brown, the states seek exemplary damages due to the “willful, egregious and repeated nature of the alleged violations.” Valerie Gibbons, Brown Files 18-State Anti-trust Suit Against Abbott over TriCor, Legal News Line, Mar. 18, 2008, at <http://www.legalnewsline.com/news/contentview.asp?c=209420> (on file with the *Columbia Law Review*).

146. Walgreen, First Amended Complaint, *supra* note 111, at 23.

147. Prilosec Maker Under Fire, *supra* note 111 (quoting Walgreens spokesman Michael Polzin).

148. Walgreen, Opposition, *supra* note 115, at 5–6.

149. Press Release, Teva Pharm. Indus. Ltd., Teva’s Fenofibrate Product Receives Final Approval; Seeks Three Times Its Lost Profits in Antitrust Lawsuit Against Abbott (May 16, 2005), at http://www.tevapharm.com/pr/2005/pr_521.asp (on file with the *Columbia Law Review*).

150. See *infra* Part III.A.2 (cautioning against using antitrust to police innovation); see also *Walgreen Co. v. AstraZeneca Pharms. L.P.*, 534 F. Supp. 2d 146, 151 (D.D.C. 2008) (“[T]here is no allegation that AstraZeneca eliminated any consumer choices. Rather,

their old formulations.¹⁵¹ Most importantly, generic manufacturers remain free to enter the market and sell versions of the old formulation under their own separate brand name.¹⁵² That rival brand name manufacturers are more powerful competitors—engaging in successful advertising campaigns and directing consumers to the new formulation—falls short of an antitrust violation.¹⁵³

The challenge lies in fashioning a workable rule that preserves the ability of manufacturers to engage in beneficial product changes and legitimate market practices, but also condemns product hopping strategies that serve only to impermissibly undermine generic competition.

E. *The Abbott and Walgreen Decisions*

The Delaware District Court in *Abbott Laboratories v. Teva Pharmaceuticals USA, Inc.* issued the first court opinion to analyze product hopping.¹⁵⁴ In applying antitrust law to product hopping, the court relied on two decisions: *Berkey Photo, Inc. v. Eastman Kodak Co.*¹⁵⁵ and *United States v. Microsoft Corp.*¹⁵⁶

Microsoft addressed a monopolist's integration of two products. The court applied a balancing approach to analyze Microsoft's technological integration of its web browser and Windows operating system: Where the

AstraZeneca added choices."); supra note 136 and accompanying text (describing customer preference, asserted by Abbott and Fournier, for new formulation of TriCor).

151. Hovenkamp, Janis & Lemley, supra note 99, § 12.5. General antitrust principles have recognized a patent holder's right to refuse to sell its patented product. See, e.g., *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1326 (Fed. Cir. 2000) (holding that 35 U.S.C. § 271(d) (2000) immunizes patentees from antitrust claims for their refusals to license or use their patent rights); *Intergraph Corp. v. Intel Corp.*, 195 F.3d 1346, 1362 (Fed. Cir. 1999) (emphasizing that "antitrust laws do not negate the patentee's right to exclude others from patent property"); *Image Tech. Servs., Inc. v. Eastman Kodak Co.*, 125 F.3d 1195, 1216 (9th Cir. 1997) (finding "no reported case in which a court has imposed antitrust liability for a unilateral refusal to sell or license a patent or copyright"); cf. *W.L. Gore & Assocs., Inc. v. Carlisle Corp.*, 529 F.2d 614, 623 (3d Cir. 1976) ("The right to refuse to license is the essence of the patent holder's right under the patent law which rewards invention disclosure by the grant of a limited monopoly in the exploitation of the invention.").

152. *Infra* notes 178–180 and accompanying text (noting that product hopping does not bar generic manufacturers from bringing their drug to market); see also supra notes 138–140 and accompanying text (describing Teva's marketing of its generic fenofibrate under its own name).

153. Antitrust laws were enacted for "the protection of *competition* not *competitors*." *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962); see also *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 486–87 (1977) (holding that antitrust plaintiffs must prove more than that "they are in a worse position than they would have been in" had challenged conduct not occurred); *Walgreen Co.*, 534 F. Supp. 2d at 152 ("The fact that a new product siphoned off some of the sales from the old product and, in turn, depressed sales of the generic substitutes for the old product, does not create an antitrust cause of action.").

154. 432 F. Supp. 2d 408 (D. Del. 2006).

155. 603 F.2d 263 (2d Cir. 1979).

156. 253 F.3d 34 (D.C. Cir. 2001).

plaintiff shows anticompetitive harm from the monopolist's conduct, the monopolist may offer a "procompetitive justification" for its conduct,¹⁵⁷ and, if the plaintiff does not rebut that justification, the court will weigh the conduct's harm against its procompetitive benefits.¹⁵⁸ The government established the anticompetitive effect of Microsoft's integration, and accordingly the burden rested on Microsoft to show that its integrated product's benefits outweighed the anticompetitive harm, which it failed to do.¹⁵⁹

Berkey Photo concerned the introduction of an improved product by a monopolist. Cautious of stifling innovation, the court noted that "[t]he attempt to develop superior products is . . . an essential element of lawful competition."¹⁶⁰ Under its holding, a monopolist's introduction of a new product is per se legal if it does not remove any competitors from the market and thus does not compel consumers to purchase its product.¹⁶¹ Its per se legal approach does not weigh the benefits of the monopolist's introduction of a new product against its alleged harm, as the "weighing had already occurred in the marketplace" through the consumers' voluntary selection of the monopolist's new product over its competitors' products.¹⁶²

The *Berkey Photo* court's decision not to intervene against the monopolist's market success hinged on the preservation of consumer free choice.¹⁶³ As emphasized in dicta, "the situation might be completely different" if upon the introduction of its new product, the monopolist also engaged in conduct that "compell[ed]" purchasers to buy it.¹⁶⁴

Drawing on this distinction, the *Abbott* court opted against applying *Berkey Photo*'s per se legal approach to Abbott and Fournier's product hopping. The court noted that Abbott and Fournier had removed old formulations of TriCor from the market as they introduced new ones.¹⁶⁵ This move deprived consumers of the opportunity to freely choose between fenofibrate formulations and vote with their feet: Consumers had no choice but to follow Abbott and Fournier's hop to new TriCor formu-

157. That is, the monopolist may proffer "a nonpretextual claim that its conduct is indeed a form of competition on the merits because it involves, for example, greater efficiency or enhanced consumer appeal." *Id.* at 59.

158. *Id.*

159. *Id.* at 65–67.

160. *Berkey Photo*, 603 F.2d at 286.

161. *Id.* at 287.

162. *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408, 421 (D. Del. 2006) (citing *Berkey Photo*, 603 F.2d at 286–87).

163. *Berkey Photo*, 603 F.2d at 287 (noting that as long as consumers desired to use monopolists' products for their attractive qualities, there was no coercion and accordingly monopolist's increase in sales was due to its products' superiority).

164. *Id.* at 287 n.39.

165. *Abbott Labs.*, 432 F. Supp. 2d at 422.

lations.¹⁶⁶ The new formulations' market success accordingly failed to serve as a proxy for weighing the modification's benefits against its harms, removing the basis for applying *Berkey Photo's* per se legality to product hopping and for unequivocally exempting product hoppers from antitrust liability.¹⁶⁷

The *Abbott* court instead adopted the *Microsoft* standard. Where *Abbott* and *Fournier* took steps to prevent consumers from purchasing old formulations of *TriCor*, antitrust liability hinged on whether the modification's anticompetitive effects outweighed its benefits.¹⁶⁸ Recognizing the possibility that this could be established, the court denied *Abbott's* motion to dismiss *Teva's* antitrust claims.¹⁶⁹

Relying on *Abbott* and its identification of "elimination of choice [as] a critical factor," the court in *Walgreen Co. v. AstraZeneca Pharmaceuticals L.P.* noted that the antitrust claims against *AstraZeneca* lacked the essential consumer coercion allegation.¹⁷⁰ Rather, *AstraZeneca* had "added choices" by introducing a new drug, *Nexium*, to compete with existing proton pump inhibitor drugs.¹⁷¹ Additionally, the court observed that the Sherman Act did not prohibit *AstraZeneca* from aggressively marketing and promoting *Nexium* to channel sales away from *Prilosec*.¹⁷² Accordingly, the court granted *AstraZeneca's* motion to dismiss.¹⁷³

F. Questioning the *Abbott* and *Walgreen* Courts' Focus on Consumer Coercion

The *Abbott* court focused on the end consumer in evaluating the "free choice" that *Abbott* and *Fournier's* product hopping allegedly eliminated,¹⁷⁴ and the *Walgreen* court followed in its footsteps.¹⁷⁵ It is important to note the *Abbott* and *Walgreen* courts' underlying and unacknowledged assumption: The application of core antitrust concepts, such as

166. *Id.* at 421. But see *Amoresano*, *supra* note 101, at 254 ("Nowhere does the *Abbott Labs* court identify who the consumers are who were coerced and exactly how their choices were limited by anything *Abbott* did.").

167. *Abbott Labs.*, 432 F. Supp. 2d at 421–22.

168. *Id.* at 422.

169. *Id.*

170. *Walgreen Co. v. AstraZeneca Pharms. L.P.*, 534 F. Supp. 2d 146, 150–52 (D.D.C. 2008) (distinguishing instant case from *Microsoft* where defendant tied products to eliminate consumer choice, and from *Abbott* where defendant forced consumers to purchase new products by stopping production of old formulation and repurchasing them).

171. *Id.* at 151.

172. *Id.* at 152 ("Plaintiffs have not identified any antitrust law that prohibits market switching through sales persuasion short of false representations or fraud, or any court that has identified such conduct as exclusionary for purposes of § 2 of the Sherman Act.").

173. *Id.* at 151–53.

174. See *supra* notes 165–167 and accompanying text (examining *Abbott* court's analysis of consumer coercion).

175. See *Walgreen Co.*, 534 F. Supp. 2d at 150–51 (discussing *Abbott* and emphasizing consumer free choice).

consumer free choice, to the pharmaceutical industry is no different from their application to other industries—e.g., the photography equipment industry in *Berkey Photo* or the computer and software industries in *Microsoft*. However, the complexities of the pharmaceutical industry are unique and do not permit such an assumption, casting doubt on the *Abbott* and *Walgreen* courts' myopic focus on the end consumer in their analysis of consumer coercion.

Given that antitrust courts have recognized the physician's role in driving demand for prescription drugs and have accordingly viewed physicians as the consumer,¹⁷⁶ an antitrust analysis of "consumer free choice" in the pharmaceutical industry cannot begin with and stop at the end consumer. Physicians, acting as "gatekeepers," independently dictate the selection of prescription drugs for a patient's consumption.¹⁷⁷ Tracing demand in the pharmaceutical industry back to the prescribing physician illustrates how consumer coercion is little more than a red herring with respect to product hopping's anticompetitive harm.

Because generic manufacturers remain free to enter the market with their equivalents and to develop their own brand,¹⁷⁸ product hopping neither prevents physicians from prescribing a generic manufacturer's product, nor threatens the availability of those drugs to consumers when a physician has prescribed them.¹⁷⁹ Rather than eliminating consumer choice, product hopping merely takes advantage of an outcome of the pharmaceutical industry's regulatory regime—the pharmacist's inability

176. See, e.g., *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1063–64 (3d Cir. 1978) (determining relevant market for antitrust analysis and cross-elasticity of demand based on prescribing physician's preferences and purchasing patterns); *United States v. CIBA Geigy Corp.*, 508 F. Supp. 1118, 1152–56 (D.N.J. 1976) (focusing on challenged conduct's impact on prescribing physicians, rather than on end consumers, to determine its anticompetitive effect on market). This view of physicians as consumers of prescription drugs persists in more recent cases, though in some cases the definition has expanded beyond physicians. See, e.g., *Barr Labs., Inc. v. Abbott Labs.*, 978 F.2d 98, 115–16 (3d Cir. 1992) (analyzing whether pharmacists or physicians or both should be considered prescription drug consumers).

177. Michael E. Ernst et al., *Prescription Medication Costs: A Study of Physician Familiarity*, 9 *Archives Fam. Med.* 1002, 1004 (2000); see also Masson & Steiner, *supra* note 55, at 5 ("The institutions of the prescription drug market are markedly different from those in most other product markets. For prescription drugs, it has not been the consumer who has made the choice among brands; it has been the physician."); Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 *Mich. Telecomm. & Tech. L. Rev.* 345, 374 (2007) ("Drugs are typically prescribed by doctors, paid for by health insurers, and consumed by patients."); cf. David H. Kreling, *The Market for Pharmaceuticals: The Big Picture*, in *Handbook of Pharmaceutical Public Policy* 43, 59 (Thomas R. Fulda & Albert I. Wertheimer eds., 2007) (explaining that the law recognizes physicians as "learned intermediaries" because individual patients lack knowledge about diagnoses and prescription drugs to make complex decisions for themselves). But see *supra* notes 79–80 and accompanying text (describing influence patients may exert over physicians in drug prescription decisions).

178. For example, see *supra* notes 138–139 and accompanying text (describing generic manufacturer Teva's marketing of fenofibrate under its own brand name).

179. Amoresano, *supra* note 101, at 251, 254.

to fill a prescription for a brand name drug with a generic version of a different formulation.¹⁸⁰ As criticized by one commentator, the *Abbott* court's finding of consumer coercion "seems flawed."¹⁸¹

However, despite its flaws, the *Abbott* court's departure from *Berkey Photo*'s *per se* legality—and the *Walgreen* court's loyalty to *Abbott*—might still be justified. *Per se* legality is appropriate only if "the practice in question never—or almost never—has any negative consequences."¹⁸² Building on the criticism of the *Abbott* court's focus on consumer coercion, this Note asks the essential question: What is the real anticompetitive harm that product hopping poses, if any? This Note undertakes the antitrust inquiry with an eye toward the pharmaceutical industry's regulatory regime, as *Trinko* instructs,¹⁸³ and the possible harm to competition under the regime that product hopping might inflict.

III. THE RULES OF THE GAME: THE PROPER APPROACH TO PRODUCT HOPPING

In analyzing product hopping, antitrust courts must consider two key, unique aspects of the pharmaceutical industry: its market structure and its regulatory regime.¹⁸⁴ Part III.A analyzes the pharmaceutical industry's market dynamics and the market concerns that traditionally drive antitrust analysis, such as fostering innovation and protecting free competition ("*market* antitrust concerns"). It concludes that these market antitrust concerns do not raise any antitrust red flags for product hopping and instead encourage granting brand name manufacturers wide freedom to hop from product to product. Part III.B introduces an analysis of antitrust problems through the lens of regulatory design ("*regulatory* antitrust concerns"). It discusses the impact of the pharmaceutical industry's regulatory regime on the vigor and scope of antitrust law, focusing on

180. *Id.* at 251 (noting that product hopping "does not prevent the generic manufacturer from bringing its drug to market, but instead prevents that drug from being dispensed by pharmacists as an AB-rated substitute to fill prescriptions written for the brand drug"); see *supra* notes 99–105 and accompanying text (explaining impact of product hopping on generic substitution).

181. Amoresano, *supra* note 101, at 254.

182. Alan J. Meese, *Economic Theory, Trader Freedom, and Consumer Welfare: State Oil Co. v. Khan and the Continuing Incoherence of Antitrust Doctrine*, 84 *Cornell L. Rev.* 763, 785–86 (1999); see also *Schor v. Abbott Labs.*, 457 F.3d 608, 613 (7th Cir. 2006) ("[J]ust as rules of *per se* illegality condemn practices that almost always injure consumers, so antitrust law applies rules of *per se* legality to practices that almost never injure consumers."); Herbert Hovenkamp, *Chicago and Its Alternatives*, 1986 *Duke L.J.* 1014, 1020–21 ("Per se legality is appropriate only if we can be relatively sure that every instance of [the conduct] is competitively harmless.").

183. See *infra* notes 211, 228 and accompanying text (describing interaction between antitrust law and regulatory regime in light of *Trinko*).

184. "[A]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue." *Verizon Commc'ns., Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004).

how it carves out a role for the Sherman Act¹⁸⁵ to police anticompetitive strategies in the pharmaceutical industry. Part III.C builds on Part III.A's market analysis and Part III.B's regulatory analysis and explains how antitrust law should properly analyze product hopping, applying its proposed framework to AstraZeneca's and Abbott and Fournier's conduct. Part III.D explores and addresses possible criticisms of this framework.

A. *Market Antitrust Concerns: The Pharmaceutical Industry's Market Dynamics*

Part III.A.1 argues that product hopping does not threaten the vigorous market competition that the Sherman Act promotes¹⁸⁶ and accordingly does not implicate any market antitrust concerns. Rather, as Part III.A.2 will show, market antitrust concerns with respect to chilling valuable innovation caution against condemning product hopping as an anticompetitive product change and instead suggest that antitrust law should grant wide discretion to brand name manufacturers to hop from product to product.

1. *Product Hopping's Limited Impact on Market Competition.* — To generate market recognition of and demand for their new drugs, brand name manufacturers engage in extensive marketing and promotional efforts.¹⁸⁷ Such marketing efforts include sending sales representatives to meet with physicians, giving presentations for physicians' continuing education, holding receptions for medical students and residents, and advertising in scientific journals.¹⁸⁸

Generic manufacturers can build their sales volume by free riding off the extensive marketing efforts of brand name manufacturers.¹⁸⁹ Be-

185. For an overview of the Sherman Act and its goals, see *supra* note 23.

186. The focus of market antitrust concerns is free and vigorous competition. See, e.g., *Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 695 (1978) ("The Sherman Act reflects a legislative judgment that ultimately competition will produce not only lower prices, but also better goods and services."); *N. Pac. Ry. Co. v. United States*, 356 U.S. 1, 4 (1958) (describing Sherman Act as "designed to be a comprehensive charter of economic liberty aimed at preserving free and unfettered competition It rests on the premise that the unrestrained interaction of competitive forces will yield the best allocation of our economic resources, the lowest prices, the highest quality and the greatest material progress").

187. According to estimates, for every eleven practicing physicians in the United States, pharmaceutical companies send one drug salesperson and spend almost \$100,000. Abigail Zuger, *Fever Pitch: Getting Doctors To Prescribe Is Big Business*, N.Y. Times, Jan. 11, 1999, at A1; see also Kreling, *supra* note 177, at 44 (describing brand name manufacturers as providing not only physical drug products, but also information about them and their use through marketing and promotional efforts); *supra* note 64 and accompanying text (describing DTC advertising expenditures).

188. Alan Lyles, *Promoting Pharmaceutical Products*, in *Handbook of Pharmaceutical Public Policy*, *supra* note 177, at 371, 371; see Cramer & Berger, *supra* note 35, at 118 (listing sales calls to physicians or "detailing," journal advertising, direct to consumer advertising, and drug sampling as primary drivers of demand for brand name products).

189. A firm faces a free rider problem when it makes an investment but cannot keep its competitors from similarly taking advantage of the investments' benefits without

cause generic substitution under state DPS laws allows pharmacists to dispense generics whenever physicians prescribe a brand name drug,¹⁹⁰ marketing campaigns launched by brand name manufacturers to win over prescribing physicians may end up fueling the sales of their generic rivals instead. Able to free ride off the advertising investments of brand name manufacturers, generic manufacturers may passively wait for generic substitution to channel a stream of sales their way.¹⁹¹

Rather than foreclosing avenues of competition, product hopping merely removes generic substitution from generic manufacturers' sales-generating arsenal.¹⁹² That product hopping so prevents generic manufacturers from free riding does not raise any market antitrust concerns which call for active intervention.

First, promoting market competition is the Sherman Act's central principle, to the exclusion of advancing public policy and social welfare goals.¹⁹³ As antitrust law seeks to promote vigorous market competition

incurring any of its costs. See Herbert Hovenkamp, *Federal Antitrust Policy: The Law of Competition and Its Practice* § 11.3, at 457 (2005) (describing free rider problem in context of advertising); see also *Toys "R" Us, Inc. v. FTC*, 221 F.3d 928, 937–38 (7th Cir. 2000) (describing free riding on retailer's investment in special services or amenities); Philip E. Areeda & Herbert Hovenkamp, *Antitrust Law* ¶¶ 1611, 1613 (2006) (describing free riding in context of manufacturer-dealer relationship and of intangible image services generally); Frank H. Easterbrook, *Vertical Arrangements and the Rule of Reason*, 53 *Antitrust L.J.* 135, 148 (1984) (discussing free riding concerns in manufacturer-dealer relationship). But see *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 127 S. Ct. 2705, 2729–30 (2007) (Breyer, J., dissenting) (noting that "free riding" often takes place in the economy without any legal effort to stop it" and answering question of "how much 'free riding'" actually takes place with only "an uncertain 'sometimes'").

190. *Supra* Part I.B (describing generic substitution under state DPS laws).

191. See *infra* note 198 and accompanying text (describing refusal of generic manufacturers to invest in advertising). But note that brand name manufacturers usually do not continue to advertise their drugs upon a generic competitor's market entry, and generic manufacturers can accordingly free ride only off past marketing campaigns. See Cramer & Berger, *supra* note 35, at 124–25 (observing that "[a]s generics enter [the market], the usual response by the branded seller is to cease its marketing efforts for th[e] product [facing generic competition]" and its "efforts to build and maintain prescription volume"). However, even the free ride on a brand name manufacturer's past advertisements is valuable to generic manufacturers, as the effects of marketing campaigns do not cease when such efforts end. Past advertising leaves a lasting impression that continues to drive sales for brand name drugs and, through generic substitution, fuel sales for their generic equivalents, as well. See, e.g., *Wheaton*, *supra* note 57, at 442–43 (explaining that "a primary purpose of most pharmaceutical promotion is the creation of 'brand-name recall' in physicians" to generate "habit" of prescribing brand name drugs).

192. See *supra* notes 178–180 and accompanying text (noting that product hopping only prevents generic substitution by pharmacies and does not bar generic manufacturers from bringing their drug to market).

193. See *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 462–64 (1986) (rejecting arguments that competition was dangerous to public welfare); *Nat'l Soc'y of Prof'l Eng'rs v. United States*, 435 U.S. 679, 688, 689–90, 695 (1978) (emphasizing that competition is sole principle considered in Sherman Act rule of reason analysis and there is no room for noncommercial justifications); Maurice E. Stucke, *Morality and Antitrust*, 2006 *Colum. Bus. L. Rev.* 443, 445–46 & n.4 ("Under the continued influence of the Chicago-school's

between brand name manufacturers and their generic rivals, it should grant little sympathy to generic manufacturers who seek to temper the zeal of the competitive process by shielding themselves from the need to advertise and free riding on a competitor's marketing investments.¹⁹⁴

In line with market competition, product hopping places the onus on generic manufacturers to actively compete for the physician's prescription in order to bring in sales.¹⁹⁵ Brand name manufacturers are under no duty to serve as the sales force of generic manufacturers; rather, competitors are "expected to make their own way in the market, by advertising or other means of promotion."¹⁹⁶ Market antitrust concerns accordingly neither obligate brand name manufacturers to help their rivals nor grant generic manufacturers a right to free ride on their marketing investments.¹⁹⁷

Additionally, generic manufacturers invoke a questionable argument to support their refusal to promote their own products.¹⁹⁸ To justify anti-

neoclassical economic theories, antitrust analysis is primarily concerned with economic efficiency."); supra note 186 and accompanying text (identifying free and vigorous competition as focus of Sherman Act). Thus, public welfare goals such as cost containment for prescription drugs or minimizing negative externalities to the public from vigorous competition between brand name and generic manufacturers do not enter into the antitrust calculus. But see *United States v. Brown Univ.*, 5 F.3d 658, 678 (3d Cir. 1993) (recognizing and requiring that courts consider institution's noncommercial purposes in addition to effect of its actions on competition). Also note that in certain regulated industries, antitrust analysis would not turn a blind eye to legislative policy decisions regarding competition. See *infra* Part III.B.2 (arguing that in heavily regulated industry where regulatory regime does not police competition, Sherman Act also punishes conduct that undermines specific type of competition legislature sought to establish in fashioning regime).

194. See *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 273 (2d Cir. 1979) ("We must always be mindful lest the Sherman Act be invoked perversely in favor of those who seek protection against the rigors of competition.").

195. Advertising and product promotion "increase consumer brand identification, or create demand for new products" and are "perfectly consistent with the competitive forces that the Sherman Act was intended to foster." *Foremost Pro Color, Inc. v. Eastman Kodak Co.*, 703 F.2d 534, 546 (9th Cir. 1983), overruled on other grounds by *Chroma Lighting v. GTE Prods. Corp.*, 111 F.3d 653 (9th Cir. 1997); see also *Covad Commc'ns. Co. v. Bell Atl. Corp.*, 398 F.3d 666, 674 (D.C. Cir. 2005) (emphasizing that advertising is "essential to vigorous market rivalry" (quoting Robert H. Bork, *The Antitrust Paradox* 314 (1993))); *Olympia Equip. Leasing Co. v. W. Union Tel. Co.*, 797 F.2d 370, 378 (7th Cir. 1986) ("Advertising a competitor's products free of charge is not a form of cooperation commonly found in competitive markets; it is the antithesis of competition.").

196. *Olympia Equip. Leasing Co.*, 797 F.2d at 377.

197. *Id.* at 377-78 ("[A firm] ha[s] no right under antitrust law to take a free ride on its competitor's sales force. You cannot conscript your competitor's salesmen to sell your product even if the competitor has monopoly power and you are a struggling new entrant.").

198. See Plaintiffs' Opposition to Defendant's Motion to Supplement and Amend Its Answer to Assert Antitrust Counterclaims at 15, *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006) (No. 02-1512-KAJ) [hereinafter *Abbott, Opposition*] (discussing generic manufacturer Teva's refusal to "employ an extensive marketing department like those utilized by brand-name companies"); *Teva, Second Amended*

trust intervention to preserve their ability to free ride, they claim: “A generic firm typically cannot profitably promote a *generic* product to doctors because the firm would have no assurance that a pharmacist would dispense its generic product rather than another’s.”¹⁹⁹ Generic manufacturers thus make the questionable assertion that because generic competitors may free ride on their marketing expenditures, they are entitled to free ride on a brand name manufacturer’s promotional expenditures.

Accordingly, antitrust courts should not condemn product hopping for merely disrupting the ability of generic manufacturers to free ride on a brand name manufacturer’s marketing and promotional expenditures, nor is antitrust law the proper vehicle for generic manufacturers to claim such an entitlement to free ride. Though requiring generic manufacturers to compete for prescriptions and incur advertising costs may negate some of the cost benefits that generic drugs offer and provide questionable social value,²⁰⁰ market antitrust concerns focus on promoting robust competition and do not “inquir[e] into the question [of] whether competition is good or bad.”²⁰¹ The proper redress for such social and policy issues is better left to the legislature than to antitrust courts.²⁰²

Answer, *supra* note 121, at 37 (arguing that “Teva is a generic pharmaceutical company and does not employ . . . and should not need to employ . . . an extensive marketing department like those utilized by brand-name companies”).

199. Walgreen, First Amended Complaint, *supra* note 111, at 8; see also FTC, DPS, *supra* note 30, at 50 (discussing problem of free riding, “particularly if a non-advertising generic manufacturer offered lower prices”).

200. Though in general advertising provides valuable benefits to consumers through its information generating effect, George J. Stigler, *The Economics of Information*, 69 *J. Pol. Econ.* 213, 220 (1961), prescription drug advertising may have fewer desirable qualities than advertising in other products. For criticisms of DTC advertising, see *supra* notes 77–80 and accompanying text. For criticisms of prescription drug advertising targeted at physicians, see Kreling, *supra* note 177, at 60 (discussing physicians’ reliance on industry-provided prescription drug information); Avorn, Chen & Hartley, *supra* note 77, at 7 (criticizing predominance of commercial rather than scientific sources of drug information as problematic area in health care delivery); see also Ashley Wazana, *Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift?*, 283 *JAMA* 373, 375–78 (2000) (offering evidence suggesting that physicians are influenced by sales presentations, distributions of samples, and free gifts or food, leading to bad prescribing habits); Daniel Carlat, *Dr. Drug Rep*, *N.Y. Times Mag.*, Nov. 25, 2007, at 64, 68–69 (describing ethical issues regarding pharmaceutical detailing).

201. *Nat’l Soc’y of Prof’l Eng’rs v. United States*, 435 U.S. 679, 695 (1978). The concerns arising from vigorous market competition through advertising do not justify reining it in. The Court has rejected the argument that “an unrestrained[sic] market in which consumers are given access to the information they believe to be relevant to their choices will lead them to make unwise and even dangerous choices.” *FTC v. Ind. Fed’n of Dentists*, 476 U.S. 447, 463 (1986); see also *Nat’l Soc’y of Prof’l Eng’rs*, 435 U.S. at 696 (“[W]e may assume that competition is not entirely conducive to ethical behavior, but that is not a reason, cognizable under the Sherman Act, for doing away with competition.”).

202. See *Arizona v. Maricopa County Med. Soc’y*, 457 U.S. 332, 354–55 (1982) (recognizing “the respective roles of the Judiciary and the Congress in regulating the economy”); *United States v. Topco Assocs.*, 405 U.S. 596, 611–12 (1972) (“[D]epartures from the notion of a free-enterprise system . . . have been the product of congressional action To analyze, interpret, and evaluate the myriad of competing interests . . . and to

2. *The Resistance to Using Antitrust Law to Police Innovation.* — Market antitrust concerns with respect to chilling valuable product innovation caution against antitrust involvement in policing a product hopper's questionable product changes.²⁰³ It is not the role of antitrust courts, or within the realm of market antitrust concerns, to dictate which prescription drug innovations are desirable or which provide the optimal balance of price and quality.²⁰⁴

Also, applying antitrust law to regulate innovation in the pharmaceutical industry is rife with pitfalls. Antitrust courts should recognize their limited competence in evaluating innovation and tread cautiously when confronted with an antitrust challenge to a dominant firm's product changes, particularly in the pharmaceutical industry where innovation is complex and technical.²⁰⁵ Mistakenly condemning product changes that are driven by hopes of appealing to consumers and such competitive zeal, rather than by anticompetitive malice, would deter valuable innovation,²⁰⁶ as well as leave antitrust enforcement bereft of consistency and

make the delicate judgment on the relative values to society . . . [requires] the judgment of the elected representatives of the people . . ."); Robert H. Bork, *The Antitrust Paradox* 114–15 (1993) (discussing circumstances under which solutions lie “with the legislature rather than the judiciary”).

203. See *supra* notes 146–149 and accompanying text (observing that product hopping entails making product change of negligible consumer benefit, intended only to frustrate generic competition).

204. Evaluating product improvements risks “turn[ing] the courtroom into a colloquium on applied econometrics.” Joseph Gregory Sidak, *Debunking Predatory Innovation*, 83 *Colum. L. Rev.* 1121, 1142 (1983); see *United States v. Microsoft Corp.*, 147 F.3d 935, 948 (D.C. Cir. 1998) (“Antitrust scholars have long recognized the undesirability of having courts oversee product design . . .”); *Walgreen Co. v. AstraZeneca Pharms. L.P.*, 534 F. Supp. 2d 146, 151–52 (D.D.C. 2008) (“Courts and juries are not tasked with determining which product among several is superior. Those determinations are left to the marketplace.”); *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408, 421 (D. Del. 2006) (“If consumers are free to choose among products, then the success of a new product in the marketplace reflects consumer choice, and ‘antitrust should not intervene when an invention pleases customers.’” (quoting Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law* § 776d (2002))); Herbert Hovenkamp, *Post-Chicago Antitrust: A Review and Critique*, 2001 *Colum. Bus. L. Rev.* 257, 326–27 (arguing that antitrust should never be used to condemn legitimate product improvements where consumers freely prefer them).

205. Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition*, 39 *U.S.F. L. Rev.* 11, 11–12 (2004) [hereinafter Hovenkamp, *Sensible Antitrust Rules*] (describing pharmaceutical industry as “technologically complex” and arguing that “generalist Article III federal judges and particularly juries are not good at dealing with technological complexity”); see also Richard J. Gilbert & Stephen C. Sunshine, *Incorporating Dynamic Efficiency Concerns in Merger Analysis: The Use of Innovation Markets*, 63 *Antitrust L.J.* 569, 576 (1995) (noting difficulty of analyzing relationship between market competition and innovation).

206. See *Abbott Labs.*, 432 F. Supp. 2d at 421 (“[Because] innovation inflicts a natural and lawful harm on competitors, a court faces a difficult task when trying to distinguish harm that results from anticompetitive conduct from harm that results from innovative competition.”); Sidak, *supra* note 204, at 1146–47 (“[C]oncern over the possibility of monopolization by means of technological innovation must be traded off against the need to protect the incentive to undertake such innovation.”).

clarity.²⁰⁷ As innovation is the backbone of sales success for brand name manufacturers,²⁰⁸ the pharmaceutical industry faces heightened harm from false positives. As “the error costs of punishing technological change are rather high,” market antitrust concerns caution against active antitrust intervention to police product changes, including product hopping.²⁰⁹

B. *Regulatory Antitrust Concerns: The Pharmaceutical Industry’s Regulatory Regime*

As discussed in Parts I.A and I.B, intricate federal and state regulatory systems govern the pharmaceutical industry. An antitrust rule that blindly promotes competition while trampling over these regulatory controls would undermine the policy goals antitrust law is designed to serve.²¹⁰ Rather, “antitrust analysis must always be attuned to the particular structure and circumstances of the industry at issue,” looking not only to the industry’s market structure, but also to its coexisting regulatory regime.²¹¹

Part III.B.1 inquires into the role of antitrust law in the heavily regulated pharmaceutical industry and concludes that antitrust law still has an active competition-policing role to play. Where antitrust law applies with full force in the pharmaceutical industry, Part III.B.2 argues that the reg-

207. There are no “objective and tangible factors” to guide examination of anticompetitive product design claims—i.e., such claims are not built on “economic and antitrust factors of supply, demand, product market(s) or prices,” but instead on “more subjective factors, such as whether the product is truly superior . . . and whether there were ulterior, anticompetitive, rather than procompetitive, motives.” Kara E. Harchuck, *Microsoft IV: The Dangers to Innovation Posed by the Irresponsible Application of a Rule of Reason Analysis to Product Design Claims*, 97 *Nw. U. L. Rev.* 395, 428 (2002).

208. See Grabowski, Vernon & DiMasi, *supra* note 21, at 11 (“Competition in the research-based pharmaceutical industry centres on the introduction of new drug therapies.”); see also Thomas A. Piraino, Jr., *Identifying Monopolists’ Illegal Conduct Under the Sherman Act*, 75 *N.Y.U. L. Rev.* 809, 815 (2000) (“[C]ompetition in innovation is more critical to long-term economic efficiency than is price competition. Continuous innovation expands output, reduces prices, improves quality and productivity, and increases the range of goods available to consumers.”).

209. Hovenkamp, Janis & Lemley, *supra* note 99, § 12.1.

210. *Town of Concord v. Boston Edison Co.*, 915 F.2d 17, 22 (1st Cir. 1990); see Keith S. Watson & Thomas W. Brunner, *Monopolization by Regulated “Monopolies”: The Search for Substantive Standards*, 22 *Antitrust Bull.* 559, 560 (1977) (cautioning that “the dogmatic transposition of monopolization concepts from conventional market settings to regulated industries” may undermine goals of antitrust).

211. *Verizon Commc’ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004); see also *United States v. Citizens & S. Nat’l Bank*, 422 U.S. 86, 91 (1975) (“[C]areful account must be taken of the pervasive federal and state regulation characteristic of the industry, ‘particularly the legal restraints on entry unique to this line of commerce.’” (quoting *United States v. Marine Bancorporation, Inc.*, 418 U.S. 602 (1974))); *Town of Concord*, 915 F.2d at 22 (“[W]here regulatory and antitrust regimes coexist . . . antitrust analysis must sensitively ‘recognize and reflect the distinctive economic and legal setting’ of the regulated industry to which it applies.” (quoting Watson & Brunner, *supra* note 210, at 565)).

ulatory regime shapes the regulatory antitrust concerns courts must analyze and police.

1. *Room Enough for Antitrust Law in the Pharmaceutical Industry.* — The role of antitrust law in a heavily regulated industry depends on whether “the [regulatory] regime [i]s an effective steward of the antitrust function.”²¹² Two Supreme Court decisions represent the extremes of antitrust law’s role in a regulated industry: (1) where “unsupervised private firm discretion” dominates the market and any regulatory intervention fails to police competition, as in *Silver v. New York Stock Exchange*,²¹³ antitrust law has an active role to play, and (2) where “conduct, including anticompetitive threats, [is] thoroughly reviewed by the [industry’s] regulator,” as in *Trinko*, antitrust law has been ousted from its role as the guardian of competition.²¹⁴

The Supreme Court in *Silver* examined the relationship between antitrust law and the Securities Exchange Act of 1934. The rules adopted by the New York Stock Exchange under the Exchange Act were unconcerned with policing market competition—to the extent that the rules could inadvertently authorize and promote anticompetitive conduct.²¹⁵ The Court concluded that the Exchange’s vulnerability to manipulation for anticompetitive ends gave rise to a need for antitrust intervention to police against such harm to competition.²¹⁶ Where the industry-specific regulatory regime insufficiently “perform[ed] the antitrust function,” antitrust law existed in active interplay with the Exchange Act’s regulation.²¹⁷

Trinko’s telecommunications industry, regulated by the Telecommunications Act of 1996, stands in sharp contrast to *Silver*’s se-

212. *Trinko*, 540 U.S. at 413.

213. 373 U.S. 341 (1963).

214. Hovenkamp, *Sensible Antitrust Rules*, supra note 205, at 14–16. “The more the regulatory regime in question takes competition into account in making its decisions . . . the less room there is for antitrust in that particular market. When the regulatory agency fully considers competitive concerns in making a decision . . . antitrust is ‘ousted’ from that market to that extent.” *Id.*; see also *Credit Suisse Sec. (USA) LLC v. Billing*, 127 S. Ct. 2383, 2397 (2007) (finding antitrust ousted because challenged conduct fell within “an area of conduct squarely within the heartland of securities regulations,” securities laws gave SEC clear authority to regulate in this area, SEC in fact actively regulated challenged conduct, and overlapping antitrust and securities law regimes would result in conflicting regulation).

215. *Silver*, 373 U.S. at 347–49, 359, superseded by statute, 15 U.S.C. §§ 78c(f), 78w(a)(2) (2006), as recognized in *Friedman v. Salomon/Smith Barney, Inc.*, 313 F.3d 796, 800 (2d Cir. 2002) (“After *Silver* was decided, Congress amended the Exchange Act to require the SEC to take competition, among other things, into account in rulemaking and when reviewing rules of exchanges.”).

216. Key to the *Silver* Court’s opinion is the complete reliance on ungoverned self regulation of the market and absence of some adequate form of policing that could provide the same protection as antitrust laws. *Silver*, 373 U.S. at 352, 358–60.

217. *Id.* at 357–60.

curities exchange.²¹⁸ Though the Supreme Court acknowledged that the incumbent local telephone company, Verizon, dealt with competitors on a discriminatory basis in violation of the 1996 Act, it concluded that the complaint failed to state a claim under section 2 of the Sherman Act.²¹⁹ The Court noted that the intensive regulatory scrutiny of the Federal Communications Commission and state regulatory agencies sufficiently safeguarded the telecommunications industry from anticompetitive behavior and left little need for the Sherman Act's protections.²²⁰ Rather than strengthening antitrust claims, the existence of such an industry-specific regulatory structure—"designed to deter and remedy anticompetitive harm"—relegated antitrust law to the proverbial dustbin.²²¹

The pharmaceutical industry's regulatory regime is a far cry from the telecommunications industry in *Trinko*, where regulatory agencies actively intervened to police and promote competition. While the FDA goes to great lengths to regulate drug safety and efficacy, it deliberately avoids regulating competition in the pharmaceutical industry.²²² The FDA claims to play a purely "ministerial role" and has shied away from actively intervening to resolve issues related to competition—e.g., the scope of intellectual property rights and their conferral of monopoly power, or the manipulation of the regulatory regime for anticompetitive ends.²²³ It jus-

218. Compare *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 411 (2004) (noting "[t]he 1996 Act's extensive provision for access"), with *Silver*, 373 U.S. at 360–61 (concluding "the statutory scheme of [the Securities Exchange] Act is not sufficiently pervasive"). See John Thorne, A Categorical Rule Limiting Section 2 of the Sherman Act: *Verizon v Trinko*, 72 U. Chi. L. Rev. 289, 289–90 (2005) (describing significant impact of 1996 Act on competition in telecommunications industry).

219. *Trinko*, 540 U.S. at 404–05, 410. For a description of the Sherman Act, see *supra* note 23.

220. *Trinko*, 540 U.S. at 401–03, 411, 413; see also Thorne, *supra* note 218, at 305–06 (noting that AT&T and Verizon had state-approved agreement "saying, in effect, 'don't go to court to redress grievances,'" but instead look to agencies to resolve problems).

221. *Trinko*, 540 U.S. at 412. "Where such a [regulatory] structure exists, the additional benefit to competition provided by antitrust enforcement will tend to be small," and antitrust regulation itself is no longer "worth its sometimes considerable disadvantages." *Id.*; see Spulber & Yoo, *supra* note 17, at 1868–74 (discussing *Trinko*'s "narrow view of antitrust courts' institutional competence"); Thorne, *supra* note 218, at 297, 301 (discussing technical complexity of 1996 Act duties and explaining that "the antitrust system is not suited to the task" of enforcing them, particularly given its administration "by one-time lay juries who are not expert in the facts and economics of the industry").

222. According to the FDA's stance, "the whole point of the [Hatch-Waxman] Act's [ANDA IV] scheme is to let private parties sort out their respective intellectual property rights [and the market exclusivity they confer] through patent infringement suits while the FDA focuses on its primary task of ensuring that drugs are safe and effective." *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 241 (4th Cir. 2002).

223. *Ranbaxy Labs., Ltd. v. Leavitt*, 459 F. Supp. 2d 1, 4 (D.D.C. 2006) (noting FDA's interpretation of Hatch-Waxman Act as giving it ministerial role in listing and delisting patents in Orange Book, leaving substantive challenges to patent information in Orange Book to third parties); *Alphapharm Pty Ltd. v. Thompson*, 330 F. Supp. 2d 1, 9 (D.D.C. 2004) (upholding FDA's "ministerial role" in patent listing as "reasonable, a permissible

tifies its reliance on private parties to police anticompetitive conduct by citing its lack of resources and expertise, as well as the absence of an explicit legislative mandate.²²⁴ Thus, the FDA takes the position that if brand name manufacturers engage in anticompetitive conduct against generic manufacturers then, in short, “aggrieved parties are out of luck.”²²⁵

More closely resembling *Silver*, the pharmaceutical industry’s regulatory regime holds the door open for anticompetitive harm. Though the regime establishes rules to facilitate and reward the introduction of generic competition,²²⁶ anticompetitive conduct easily slips under the regulatory radar and escapes its scrutiny.²²⁷ The pharmaceutical industry’s regulatory system accordingly leaves ample room for antitrust law to intervene with full force, rather than squeezing it out. Where, unlike in *Trinko*’s telecommunications industry, antitrust law has a role to play here, the question becomes: *How* should antitrust law apply to a heavily regulated industry? That is, what regulatory antitrust concerns should courts consider?

2. *Enforcing the Sherman Act.* — In an industry where the regulatory regime has not ousted antitrust law, how the Sherman Act should intervene and the regulatory antitrust concerns courts must analyze depend on the regime itself, particularly “its role as a congressional judgment about the proper balance between [policy goals] and competition.”²²⁸ Such enforcement of the Sherman Act accordingly extends beyond polic-

construction of the FDCA, and neither arbitrary or capricious”); *Watson Pharms., Inc. v. Henney*, 194 F. Supp. 2d 442, 445–46 (D. Md. 2001) (“[T]he FDA ha[s] a very limited, ministerial role in patent fights between patentees and generic marketers—that of taking information from the patentee, publishing that information in the Orange Book, and awaiting the institution and/or outcome of patent litigation.”). For a description of the Orange Book, see *supra* note 100.

224. See *Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1347 (Fed. Cir. 2003) (describing FDA’s contention that it has no statutory duty to substantively review patent information); *aaPharma*, 296 F.3d at 241 (arguing that “division of labor” between private parties and FDA “is appropriate because FDA has no expertise in making patent law judgments” and reasoning that “if Congress had intended to impose any duty on the FDA to police Orange Book listings” against anticompetitive manipulation by brand name manufacturers, “it would have required the FDA” to take active steps); *Watson Pharms., Inc.*, 194 F. Supp. 2d at 445 (emphasizing that FDA “is *not* acting as a patent tribunal. It has no expertise—much less any statutory franchise—to determine matters of substantive patent law”).

225. *aaPharma*, 296 F.3d at 237.

226. See *supra* notes 45–48 and accompanying text (discussing mechanisms by which Hatch-Waxman Act intensifies generic competition).

227. See *Derzko*, *supra* note 92, at 175–212 (providing overview of strategic behavior by manufacturers to delay generic competition and response, one step behind, by antitrust courts and Congress); *Lechner-Fish*, *supra* note 45, at 407–18 (describing several ways to manipulate loopholes in Hatch-Waxman Act); Holly Soehnge, *The Drug Price Competition and Patent Term Restoration Act of 1984: Fine-Tuning the Balance Between the Interests of Pioneer and Generic Drug Manufacturers*, 58 *Food & Drug L.J.* 51, 70–78 (2003) (same).

228. *Hemphill*, *supra* note 83, at 1597. “[A]ntitrust analysis should recognize and reflect a regulated industry setting [T]he regime is a legal input, for the regime

ing ordinary market antitrust concerns²²⁹ to condemning conduct that directly undermines the specific type of competition the legislature sought to establish in fashioning the regulatory system.²³⁰

With respect to the pharmaceutical industry's regulatory regime, state DPS laws²³¹ reflect a legislative decision to contain prescription drug costs through generic substitution,²³² sacrificing even-footed competition between brand name manufacturers and their generic rivals. Disfavoring the unfettered market competition of other unregulated industries, states recognized that "the forces of competition do not work well in [the prescription drug] market where the consumer who pays does not choose, and the physician who chooses does not pay."²³³ Because the physicians who drive pharmaceutical demand²³⁴ are less price sensitive, they are unlikely candidates to lead the switch to lower cost generics upon the lifting of a brand name manufacturer's market exclusivity.²³⁵

To address this price-disconnect problem, state legislatures enacted DPS laws to promote generic substitution and thereby shift power over product selection—the choice between generic and brand name drugs for most prescriptions—from physicians to pharmacists, professionals with the incentive to lower prices.²³⁶ Driven by interpharmacy competi-

embodies a specific congressional judgment about the balance between competition and [policy goals]." *Id.* at 1560.

229. See *supra* note 186 and accompanying text (identifying free and vigorous competition as focus of Sherman Act).

230. Hemphill, *supra* note 83, at 1596–97; see also *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 412 (2004) (recognizing possible "expansion of the contours of [Sherman Act] § 2" depending on regulatory context).

231. See *supra* Part I.B (providing overview of state DPS laws regulating generic substitution).

232. See Masson & Steiner, *supra* note 55, at 1–2, 4–7 (explaining that states enacted DPS laws to promote generic substitution and thereby reduce aggregate drug expenditures by consumers); Carroll, Fincham & Cox, *supra* note 55, at 1069 ("The major impetus for enactment of DPS laws was a desire to control prescription drug costs."); see also FTC, *Generic Drug Entry*, *supra* note 47, at 9 (noting that in 1994 alone, generic substitution saved purchasers \$8 to \$10 billion).

233. FTC, DPS, *supra* note 30, at 2–3; see also Robert Pitofsky, Harvey J. Goldschmid & Diane P. Wood, *Trade Regulation Cases and Materials* 118 (2003) ("The theory underlying government intrusion is that free-market forces will . . . produce otherwise unacceptable results.").

234. See *supra* note 177 and accompanying text (identifying prescribing physician as decisionmaker in selection of prescription drugs).

235. FTC, DPS, *supra* note 30, at 3–4.

236. Masson & Steiner, *supra* note 55, at 6–7 (explaining that "physicians' incentives to choose the most cost-effective drug seem weak," whereas pharmacists "have both the power and the incentive to respond to lower prices"); see also FTC, DPS, *supra* note 30, at 68–83 (explaining that pharmacists have training and experience to competently select prescription drug products). Note that passing power of product selection to pharmacies would not interfere with physicians' control of patient therapy. See *supra* note 57 and accompanying text (observing that DPS laws do not allow generic substitution where prescriptions indicate physician's refusal to permit it).

tion, pharmacists are responsive to customer demands for lower prices and willing to engage in price competition.²³⁷

State DPS laws thus seek to control prescription drug costs by promoting generic substitution and sacrificing unfettered market competition. Regulatory antitrust concerns must accordingly punish conduct that undermines the generic substitution at the heart of state DPS laws, protecting the specific type of generics-favoring competition state legislatures sought to establish in fashioning DPS laws.

C. *A Two-Part Inquiry into Product Hopping's Anticompetitive Harm*

Where the pharmaceutical industry's regulatory regime leaves room for antitrust intervention, the regulatory system also shapes the rules of competition. Accordingly, an analysis of product hopping's anticompetitive harm must engage regulatory antitrust concerns in addition to traditional market antitrust concerns.²³⁸ While market antitrust concerns carry little weight against product hopping and instead tilt in favor of granting manufacturers wide discretion to hop from product to product,²³⁹ regulatory antitrust concerns set the boundaries of permissible market behavior for product hoppers. Once product hoppers attempt to subvert the industry's regulatory regime and the generics-favoring legislative policy judgment it embodies, antitrust courts must intervene. Parts III.C.1 and III.C.2 apply this analysis of market and regulatory antitrust concerns to AstraZeneca's and Abbott and Fournier's product hopping strategies.

1. *The First Inquiry: Market Antitrust Concerns.* — Product hopping implicates minimal market antitrust concerns, as launching new product formulations and engaging in successful advertising campaigns are consistent with the unfettered market competition that antitrust law promotes.²⁴⁰ AstraZeneca and Abbott and Fournier merely offered additional and possibly more attractive drug formulations while generic versions of the old formulations remained available—increasing the se-

237. See Masson & Steiner, *supra* note 55, at 7 (“Consumers are the ones most interested in a lower price, and pharmacists must respond to consumer demand because of direct competition with other pharmacies on prescription prices.”). Note that pharmacists have an additional incentive to dispense generic drugs: “[T]ypically the retail dollar gross margin on the generic is higher.” *Id.*; see also FTC, DPS, *supra* note 30, at 90–95 (listing different methods used by pharmacies to price prescription drugs and discussing incentives for generic substitution).

238. See *supra* Part III.B.2 (arguing that in heavily regulated industry where regulatory regime does not police competition, Sherman Act also punishes conduct that undermines specific type of competition legislature sought to establish in fashioning regime).

239. See *supra* Part III.A (arguing that loss of ability to free ride caused by product hopping is not a critical antitrust concern and cautioning that policing product changes may chill valuable innovation).

240. See *supra* notes 195–196 and accompanying text (highlighting antitrust courts' approval of advertising and product promotion efforts).

lection of products for consumers.²⁴¹ Nor is Abbott and Fournier's withdrawal of their old formulations from the market²⁴² an antitrust violation, as general antitrust principles have recognized a patent holder's right to refuse to sell its patented product.²⁴³ Finally, Teva and other generic manufacturers outdone by their brand name rivals in advertising cannot invoke antitrust law to condemn the success of their brand name rivals and compensate for their own limited marketing investments.²⁴⁴ Thus, product hopping generally does not raise any market antitrust concerns and product hoppers keep within the rules of market competition.

2. *The Second Inquiry: Regulatory Antitrust Concerns.* — Product hoppers may avoid antitrust liability as long as they do not disrupt the generic substitution at the heart of state DPS laws.²⁴⁵ Regulatory antitrust concerns recognize that when state legislatures fashioned DPS laws, they sought to establish a specific type of generics-favoring competition between brand name manufacturers and their generic rivals: Though brand name manufacturers may succeed in winning the prescription of physicians, pharmacists must be able to fill that prescription with a generic version.²⁴⁶

By taking affirmative steps to prevent such generic substitution from taking place, Abbott and Fournier subverted the legislative policy judgment that DPS laws embody. In each hop, Abbott and Fournier, without justification, contacted First Data Bank and set in motion changes that ultimately prevented pharmacists from substituting prescriptions for older formulations with their generic equivalents.²⁴⁷ This strategy pro-

241. Supra note 179 and accompanying text (observing that physicians remain free to prescribe generic manufacturer's product despite product hopping); see also supra notes 138–139 and accompanying text (describing generic manufacturer Teva's marketing of fenofibrate under its own brand name, Lofibra).

242. Supra notes 123, 135 and accompanying text (noting Abbott and Fournier's removal of old formulations after making each hop to new formulation).

243. See supra note 151 and accompanying text (discussing antitrust courts' refusal to impose legal duty on patent holders to sell their patented product).

244. See supra Part III.A.1 (arguing that loss of ability to free ride on competitor brand name manufacturer's advertising caused by product hopping does not raise antitrust concerns).

245. See supra Part III.B (arguing that in pharmaceutical industry, Sherman Act also punishes conduct that undermines specific type of competition state legislatures sought to establish in fashioning DPS laws).

246. See supra notes 236–237 and accompanying text (explaining legislative decision to pass power over drug selection from price insensitive prescribing physicians to pharmacists with incentive to respond to lower prices); see also supra Part I.B (describing generic substitution under state DPS laws).

247. See supra notes 125–133 and accompanying text (observing that Abbott and Fournier prevented generic substitution for all TriCor formulations by allegedly changing NDDF code for old formulations to obsolete). Teva claimed that Abbott and Fournier "had no legitimate business purpose for changing the codes . . . for TriCor capsules and TriCor original tablets to obsoletes." Teva, Answer, supra note 120, at 36. In response, Abbott and Fournier did not offer a justification, but merely responded that "Teva has not alleged—nor could it—that it is out of the ordinary for a pharmaceutical company to notify First

vided a safety net to catch physicians whom Abbott and Fournier's advertising campaigns failed to convert to the new formulation and who instead continued to prescribe the older formulations. As such, this tactic went beyond mere market competition and stopped generic substitution that should—and would—have taken place under state DPS laws.²⁴⁸ This obstruction is the real harm Abbott and Fournier's product hopping inflicted on competition: It impermissibly undermined the specific type of generics-favoring competition state legislatures sought to establish in fashioning DPS laws and accordingly raises compelling regulatory anti-trust concerns.

In contrast, by preserving generic substitution for prescriptions of Prilosec, AstraZeneca should escape antitrust liability. If physicians continued to prescribe Prilosec despite AstraZeneca's hop to its new product Nexium, generic substitution would still channel sales away from AstraZeneca to its generic rivals.²⁴⁹ Unlike Abbott and Fournier, AstraZeneca ate its losses from generic substitution and took no action to prevent pharmacists from dispensing generic omeprazole when they filled a Prilosec prescription.²⁵⁰ Rather than precluding generic substitution and thereby raising regulatory antitrust concerns, AstraZeneca geared its conduct toward gaining acceptance in the market²⁵¹ and stayed clear of undermining the legislative policy judgment that the industry's regulatory regime embodies.

D. Criticisms

First, one may question whether *Trinko's* attention to the industry-specific regulatory regime extends so far as to allow *state* DPS laws and unanimous *state* legislative support for generic substitution²⁵² to shape the contours of *federal* antitrust enforcement under the Sherman Act.²⁵³

Data Bank that a product was being discontinued, and for First Data Bank to subsequently remove the NDDF code from its database." Abbott, Opposition, *supra* note 198, at 17. However, Teva challenges this assertion. Teva, Reply, *supra* note 121, at 5–6 & n.3 (arguing that Abbott and Fournier's delisting is "an unreasonably exclusionary act").

248. Teva, Second Amended Answer, *supra* note 121, at 21 (explaining that Teva had satisfied all regulatory requirements for sale of its generic fenofibrate products).

249. See *supra* Part I.B (describing generic substitution under state DPS laws).

250. "At all relevant times, if a doctor chose Prilosec as the right drug for a patient, the wholesalers and retail pharmacies were ready, willing and able to provide generic omeprazole to fill that prescription." Reply Statement of Points and Authorities in Support of Defendant's Motion to Dismiss at 7, *Walgreen Co. v. AstraZeneca Pharms. L.P.*, 534 F. Supp. 2d 146 (D.D.C. 2008) (No. 1:06-cv-02084-RWR).

251. See *supra* note 115 and accompanying text (noting AstraZeneca's substantial promotional efforts for Nexium and its cessation of advertising for Prilosec).

252. See *supra* Part I.B (providing overview of state DPS laws regulating generic substitution).

253. Congress has not declared a position toward generic substitution, neither formally embracing it nor—more importantly—explicitly rejecting it. But cf. *Therapeutically Equivalent Drugs; Availability of List*, 45 Fed. Reg. 72,582, 72,596 (Oct. 31, 1980) ("FDA disagrees that the purpose of the [Orange Book] is to promote drug product

This mismatch between federal enforcement and state law is problematic only if federalism principles call for a strict demarcation that categorically forbids federal enforcement from supporting and fostering state law. However, this is not the case.²⁵⁴ *Erie* considerations of federalism require federal judges applying state law to act as state courts would act.²⁵⁵ Federal enforcement has cooperatively followed state law's lead in such areas as child support enforcement²⁵⁶ and certain criminal prosecutions.²⁵⁷ Accordingly, the influence of state DPS laws over federal antitrust enforcement neither creates an unheard of federal-state relationship nor violates federalism principles.

Additionally, one may criticize this Note's framework for its rigid structure. Certain conduct by brand name manufacturers may defy the framework's binary categorization of market and regulatory antitrust concerns, falling short of subverting the legislature's policy judgment but going beyond benign competitive strategies consistent with vigorous market

substitution.”). For a description of the Orange Book, see *supra* note 100. However, the scope of the FDA's statement is limited to the Orange Book and does not purport to reflect Congress's general policy choices. Additionally, the FDA's deliberately narrow focus on drug safety and efficacy, *supra* notes 222–225 and accompanying text, cautions against viewing it as the voice of congressional policy.

254. “‘State’ and ‘federal’ interests are not pre-existing defined sets of activities but are interactive and interdependent conceptions that vary over time.” Rory K. Little, *Myths and Principles of Federalization*, 46 *Hastings L.J.* 1029, 1032 n.12 (1995) (quoting Judith Resnik, Statement Before the Long Range Planning Committee of the United States Judicial Conference (Dec. 1994)).

255. *Guar. Trust Co. v. York*, 326 U.S. 99, 109 (1945) (“[I]n all cases where a federal court is exercising [diversity] jurisdiction . . . the outcome of the litigation in the federal court should be substantially the same, so far as legal rules determine the outcome of a litigation, as it would be if tried in a State court.”).

256. Child Support Recovery Act of 1992 (CSRA), Pub. L. No. 102-521, 106 Stat. 3403, 3403 (1992) (codified as amended in scattered sections of 18 U.S.C. and 42 U.S.C.). CSRA is “designed to aid states in their ability to enforce child support obligations in other states.” Kathleen A. Burdette, *Making Parents Pay: Interstate Child Support Enforcement After United States v. Lopez*, 144 *U. Pa. L. Rev.* 1469, 1498 (1996); see also Michael A. Simons, *Prosecutorial Discretion and Prosecution Guidelines: A Case Study in Controlling Federalization*, 75 *N.Y.U. L. Rev.* 893, 936–55 (2000) (describing problems with interstate child support that led Congress to enact CSRA and explaining how federal law enforcement under CSRA is consistent with principles of federalization).

257. See Simons, *supra* note 256, at 895 (listing murder, robbery, car theft, and failure to pay child support as examples of crimes that have been traditionally prosecuted in state court but may now be tried in federal courts); see also Sara Sun Beale, *Federalizing Crime: Assessing the Impact on the Federal Courts*, 543 *Annals Am. Acad. Pol. & Soc. Sci.* 39, 44 (1996) (“In general, . . . federal [criminal] laws supplement state law rather than nullifying or displacing it. The result is a system of dual jurisdiction where conduct that violates both federal and state law may be prosecuted by federal authorities, state authorities, or both.”). But see Simons, *supra* note 256, at 896–97 & nn.11–13 (summarizing objections to “federalization”); Maryanne Trump Barry, *Don’t Make a Federal Case of It*, *N.Y. Times*, Mar. 11, 1994, at A31 (discussing potential negative consequences of federalizing crime).

competition. For example, AstraZeneca's "Shark Fin Project"²⁵⁸ devised another strategy that entailed developing and launching an over-the-counter (OTC) version of Prilosec prior to generic entry.²⁵⁹ This strategy played on the benefits policies of managed care organizations (MCOs).²⁶⁰ MCOs generally refuse to cover prescription drugs—both brand name and generic versions—if an OTC version of the drug is available, forcing patients to bear the full cost for all versions of the prescription drug as an out-of-pocket expense.²⁶¹ Thus, among other effects,²⁶² AstraZeneca's introduction of Prilosec OTC prevented the market entry of generic Prilosec from bringing lower prescription drug prices.²⁶³

AstraZeneca's exploitation of the MCO coverage system, a private network's policy, falls short of manipulating the pharmaceutical industry's regulatory regime. At stake are discounts from third party payors rather than the generic substitution at the heart of state DPS laws. Nevertheless, AstraZeneca's OTC strategy raised prices for consumers and indi-

258. See *supra* note 112 and accompanying text (providing brief description of Shark Fin Project).

259. Walgreen, First Amended Complaint, *supra* note 111, at 36. For a discussion of additional drugs that have moved from prescription to OTC status, see generally Holly M. Spencer, The Rx-to-OTC Switch of Claritin, Allegra, and Zyrtec: An Unprecedented FDA Response to Petitioners and the Protection of Public Health, 51 Am. U. L. Rev. 999 (2002).

260. MCOs are private third party payors, like insurers. See Susan Adler Channick, The Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Will It Be Good Medicine for U.S. Health Policy?, 14 Elder L.J. 237, 253–54 (2006); Kreling, *supra* note 177, at 52; Robert F. Atlas, The Role of PBMs in Implementing the Medicare Prescription Drug Benefit, 2004 Health Aff. w4-504, w4-506–08, at <http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.504v1.pdf> (on file with the *Columbia Law Review*). In administering benefits coverage, PBMs establish formularies to list the prescription drugs that are preferred for patient use. Kimberly P. McDonough, Pharmaceutical Benefits Managers, *in* Handbook of Pharmaceutical Public Policy, *supra* note 177, at 247, 271; see also Roy Levy, FTC, The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change 31 & n.84 (1999) (explaining that for "closed formularies," only prescription drugs included in formulary will receive discount and enjoy coverage under benefits plans).

261. Walgreen, Opposition, *supra* note 115, at 10–11; Spencer, *supra* note 259, at 1023; see also Over-the-Counter Drug Coverage Changes Marketing Strategies, Drug Wk., Dec. 26, 2003, at 401, 401 (describing recent trends among MCOs and PBMs to promote OTCs instead of their prescription equivalents).

262. See, e.g., John A. Rizzo et al., Prescription to Over-the-Counter Switching of Drugs: Methodological Issues and Implications for Non-Sedating Antihistamines, Disease Mgmt. and Health Outcomes 83, 88–91 (2005) (describing implications, negative externalities, and benefits of switching nonsedating antihistamines from prescription to OTC).

263. Upon Prilosec OTC's introduction in September 2003, nearly all MCOs refused to provide coverage for prescription and generic Prilosec. Walgreen, First Amended Complaint, *supra* note 111, at 36–37; Walgreen, Opposition, *supra* note 115, at 3–4. Compare Walgreen, First Amended Complaint, *supra* note 111, at 36 (observing that as result of AstraZeneca's strategy, prescription Nexium, covered by MCOs, offered greater cost-savings for consumers than generic Prilosec), with *supra* note 30 and accompanying text (reporting substantial discounts for generic drugs from price at which brand name drugs are typically sold).

rectly undermined the legislative judgment behind state DPS laws: It stamped out the cost savings for which state DPS laws sacrificed unfettered competition between generic and brand name manufacturers.²⁶⁴ However, DPS laws do not sweepingly seek to control prescription drug costs by any and all means, but to do so specifically through generic substitution.²⁶⁵ The scope of antitrust enforcement should narrow accordingly, strictly adhering to this Note's framework to condemn only conduct that directly undermines legislative judgment and to exclude from antitrust liability gray area tactics, such as AstraZeneca's OTC strategy, that leave generic substitution intact.

* * *

The primary allure of this Note's analysis is its recognition and reflection of the pharmaceutical industry's unique market structure and complex regulatory regime. Its treatment of market antitrust concerns gives firms wide freedom to engage in beneficial and procompetitive market practices, as well as avoids the prickly issues that arise when antitrust courts attempt to police innovation. At the same time, its recognition of and approach to regulatory antitrust concerns allow courts to sternly wield the Sherman Act against manipulative conduct that undermines the specific type of generics-favoring competition state legislatures sought to establish in enacting the regulatory regime, drawing the boundaries of permissible market behavior where the industry's regulator has not.

CONCLUSION

As generic manufacturers grow more active in challenging drug patents and as the pipeline for new blockbuster drugs thins, brand name manufacturers will increasingly attempt to stretch the boundaries of patent protection and shield their existing blockbuster drugs from generic competition. Product hopping creates formidable obstacles to generic competition and may allow manufacturers to subvert the legislature's policy judgment while disguising it as legitimate market competition that provides valuable innovation. Although antitrust law must give manufacturers the freedom to innovate and thus allow them to freely hop from product to product, it need not passively watch from the sidelines while product hoppers stomp over the industry's regulatory regime and the legislative policy judgment it embodies.

264. See *supra* notes 232–235 and accompanying text (discussing state legislatures' goal of containing prescription drug costs).

265. See *supra* notes 232, 236–237 and accompanying text (explaining specific legislative policy judgment in enacting DPS laws).