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

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

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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

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).

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.

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