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This article examines how the nature of competition between brands in a therapeutic category changes after generic entry and provides a framework for analyzing the effect of generic entry on consumer welfare that takes into account the generic free riding problem. It demonstrates that changes in competition along dimensions other than retail price – such as competition in research and development efforts and in promotional activities – may, in certain situations, result in generic entry having an overall negative impact on consumer welfare.

I. INTRODUCTION

The U.S. Court of Appeals for the Third Circuit recently ruled that so-called "reverse payment" settlements of patent infringement litigation between a branded drug manufacturer and potential generic competitors are presumptively anticompetitive.[1] In such settlements, the branded and generic drug manufacturers settle on a date of generic entry, a date that is often well before the expiration of the patent(s) at issue, and at the same time the branded manufacturer makes a payment to the generic manufacturer. The Third Circuit decision stands in stark contrast to rulings by the Appeals Courts in the Federal, Second, and Eleventh Circuits that such settlements are legal as long as the patent infringement litigation was not a sham and any restrictions on the generic company's marketing of a generic drug do not exceed the scope of the patent(s) at issue.[2]

The Third Circuit ruling shifts the burden to defendants to show that such agreements are not anticompetitive. As a result, analyses of the competitive effects of such agreements will be more important, at least in the Third Circuit, and potentially nationally if the U.S. Supreme Court hears the case and upholds the Third Circuit's decision.[3]

The Third Circuit decision represents a substantial victory for the Federal Trade Commission (FTC) which has focused significant attention on the potential anticompetitive harm arising from "reverse payment" settlements.[4] The FTC has long argued that such settlements delay generic entry because absent a "reverse payment" the settling parties

* Henry Grabowski , Department of Economics, Duke University; Tracy Lewis, The Fuqua School of Business, Duke University; Rahul Guha, Zoya Ivanova, Maria Salgado, and Sally Woodhouse, Cornerstone Research. The views expressed in this article are those of the authors only and do not necessarily represent the views of Cornerstone Research or Duke University.

[1] *In Re: K-Dur Antitrust Litigation*, Nos. 10-2077, 10-2078 and 10-2079 (3d Cir. 2012). The U.S. Court of Appeals for the Third Circuit has federal jurisdiction over Delaware, New Jersey, and Pennsylvania.

[2] *In Re: Ciprofloxacin Hydrochloride Antitrust Litigation*, No. 2008-1097 (Fed. Cir. 2008); *In Re: Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2006); *In Re: Ciprofloxacin Hydrochloride Antitrust Litigation*, 05-2851-cv(L) and 05-2852-cv(CON) (2d Cir. 2010); *Federal Trade Commission v. Watson Pharmaceuticals Inc.*, No. 10-12729 (11th Cir. 2012).

[3] Given the conflicting rulings across the different Circuit Courts, the issue is ripe for review by the U.S. Supreme Court and Merck, the defendant in the Third Circuit case, has already petitioned the Supreme Court. Merck & Co. v. Louisiana Wholesale Drug Co., Inc., U.S., No. 12-245, *petition for cert. filed* 8/24/12. At least one set of reverse payment cases was put on hold by a lower court while the Supreme Court decides whether to hear the K-Dur case and resolve the conflicting Circuit Court rulings. Federal Trade Commission v. Cephalon, Inc., No. 2:08-cv-2141 (Opinion, E.D. of Penn. 2012).

[4] In addition to the FTC, the US Department of Justice, and the European Commission have all raised

would agree on an earlier generic entry date. While there has been much debate as to whether earlier entry would occur absent "reverse payment" settlements, little attention has been paid as to whether earlier entry will actually increase consumer welfare. Instead, it has been presumed that generic competition enhances consumer welfare because when generics enter the market, drug prices fall as patients switch from high-priced branded drugs to lower-priced, therapeutically equivalent generics.

The effect of generic competition on consumer welfare is not always clear cut, however. In particular, generic competition reduces the incentives of brand manufacturers to inform physicians about the benefits of their drugs, provide price discounts in the form of free samples, and to enhance the usefulness of their drugs by seeking approval for additional indications. The reduced incentives to engage in such activities occur because generic manufacturers are able to "free ride" on brand manufacturers' promotional and research and development (R&D) efforts essentially capturing the benefits of those efforts instead of the brand manufacturer.[5] Promotional and R&D activities represent a major form of competition between branded therapeutic alternatives and generic entry can have the effect of decreasing such competition and thereby reducing the welfare benefits of generic competition to consumers.

Though certainly not always the case, the ability of generic manufacturers to free ride on the promotional and R&D efforts of brand manufacturers can result in situations where generic entry reduces consumer welfare on net. Indeed, recent academic research has demonstrated that generic competition frequently results in a reduction in prescriptions—a surprising result if generic entry were always procompetitive.[6]

An analysis of whether generic entry is likely to enhance or diminish consumer welfare requires an examination of the market within which the brand competes—i.e., the therapeutic category—and an understanding of how the nature of competition between brands in the category is likely to change with generic entry. This article provides a framework for analyzing the consumer welfare effects of generic competition to take into account the effect free riding by generics has on brand manufacturers' incentives to compete along dimensions other than price.[7]

The next section of this article discusses the factors that are important in assessing consumer welfare in pharmaceutical markets. Section III discusses the effect of generic entry on competition and consumer welfare. Section IV presents a case study in the

[5] Free riding often results in "destructive" or welfare decreasing competition, a form of competition that has long been noted as a potentially important defect of market systems. See Raymond Deneckere, Howard P. Marvel & James Peck, Demand Uncertainty, Inventories, and Resale Price Maintenance, 111 Q. J. Econ. 885 (1996), for a discussion of destructive competition in manufacturing; Thomas W. Hazlett, Rivalrous Telecommunications Networks With and Without Mandatory Sharing, 58 Federal Communications Law Journal 3 (2006), for a discussion in telecommunications; Joseph E. Stiglitz, Private Uses of Public Interests: Incentives and Institutions, 12 J. Econ. Persp. 3 (1998), for a discussion in public finance and federal policy; Michael G. Jacobides, Mortgage Banking, Unbundling: Structure, Automation and Profit, Housing Fin. Int'l. (2002), for a discussion in financial markets; and Yannis Bakos & Erik Brynjolfsson, *Aggregation and Disaggregation of Information Goods: Implications for Bundling, Site Licensing and Micropayment, Internet publishing and beyond: The Economics of Digital Information And Intellectual Property,* (Deborah Hurley, Brian Kahim & Hal Varian, eds., MIT Press 1997), for a discussion in internet markets.

[6] See Darius Lakdawalla, Thomas Philipson & Richard Wang, *Intellectual Property and Marketing* (NBER, Working Paper No. 12577, 2006); Frank R. Lichtenberg & Gautier Duflos, *Does Patent Protection Restrict U.S. Drug Use? The Impact of Patent Expiration on U.S. Drug Prices, Marketing, and Utilization*, presented at Pharmaceutical Research Development and Markets conference, Harvard Law School, (June 12-13, 2009); *Ernst R. Berndt, Margaret K. Kyle & Davina C. Ling, The Long Shadow of Patent Expiration: Generic Entry and Rx-to-OTC switches, Scanner Data and Price Indexes*, (Robert C. Feenstra & Matthew D. Shapiro, eds., 2003).

[7] While it can be argued that the relevant metric to assess whether a particular action is procompetitive is total welfare, we focus on consumer welfare in this article as it is the metric usually focused on by antitrust

oral contraceptive market to demonstrate the key economic trade-offs associated with generic entry. Section V describes the implications of this discussion for biologic drugs. Section VI concludes.

II. BENEFITS AND COSTS OF BRANDED AND GENERIC DRUGS

As a general matter, consumer welfare depends on the benefits of a product compared to its costs. With respect to pharmaceutical products, patients take drugs to prevent and treat the causes and/or symptoms of disease, illness, and other conditions. The ability of a drug to prevent or treat a condition is measured by its efficacy. Adverse reactions and interactions with other drugs or treatments affect the value of the drug as well. Convenience and ease of use—how frequently a drug needs to be taken, whether it must be taken with or without food, its form (e.g., pill, liquid, injection)—also affect a drug's value to consumers.[8]

A. *Competitive Effects Of Pharmaceutical Promotion*

Safety and efficacy are largely the same for brand and generic versions of a drug. A major difference in value provided by brand and generic drugs is in the promotional activities undertaken by brand manufacturers. Because the primary decision makers in the prescribing process are physicians, most brand promotional efforts are directed at them. Promotional activities to physicians include detailing (presentations to physicians by a salesperson), advertising in medical journals, and the provision of free samples. Such promotion can inform physicians about new drugs or approvals for new indications for existing drugs, increase awareness of the results of clinical studies, highlight differences between therapeutic competitors, and provide information on health insurance coverage.[9] Detail visits also provide an opportunity for physicians to ask questions about the drug and its competitors. Free samples can have educational, compliance, and convenience benefits.[10] Drug manufacturers also advertise directly to consumers which can encourage consumers to seek treatment and improve patient compliance.

Economists have debated whether pharmaceutical advertising serves primarily an informational role or a persuasive role. If advertising is informational—*i.e.*, it increases patient and physician awareness and knowledge of treatment options—it is welfare enhancing. In contrast, persuasive advertising may be socially wasteful if its primary goal

[8] Economists have found that drug characteristics such as efficacy, side effects, number of drug interactions, and dosing frequency affect the value of a drug to consumers. See, for example, Ernst R. Berndt, Robert S. Pindyck & Pierre Azoulay, Consumption Externalities and Diffusion in Pharmaceutical Markets: Antiulcer Drugs, 51 J. Indus. Econ. 243 (2003). Ernst R. Berndt, Linda T. Bui, David H. Reiley & Glen L. Urban, Information, Marketing and Pricing in the U.S. Anti-Ulcer Drug Market, 85 Am. Econ. Rev. 100 (1995); Ernst R. Berndt, Ashoke Bhattacharjya, David Mishol, Almudena Arcelus & Thomas Lasky, An Analysis of the Diffusion of New Antidepressants: Variety, Quality, and Marketing Efforts, 5 J. Mental Health Pol'y & Econ. 3 (2003); Charles King, III, *Marketing, Product Differentiation, and Competition in the Market for Antiulcer Drugs*, (HBS, Working Paper, 2002); Sriram Venkataraman & Stefan Stremersch, The Debate on Influencing Doctors' Decisions: Are Drug Characteristics the Missing Link? 53 Mgmt. Sci. 1688, (2007).

[9] See, for example, Füsun Gönül, Franklin Carter, Elina Petrova & Kannan Srinivasan, Promotion of Prescription Drugs and Its Impact on Physicians' Choice Behavior, 65 J. Marketing 79 (2001); Sriram Venkataraman & Stefan Stremersch, The Debate on Influencing Doctors' Decisions: Are Drug Characteristics the Missing Link? 53 Mgmt. Sci. 1688 (2007); and Kissan Joseph and Murali K. Mantrala (2003), "Prescription Drug Promotion: The Role & Value of Physicians' Samples under Competition," Working Paper.

[10] Samples can be used to demonstrate how to administer a drug and encourage patients to try a new alternative. Samples also offer added convenience to patients by eliminating the need for an immediate visit to the pharmacy. See Kissan Joseph and Murali K. Mantrala (2003), "Prescription Drug Promotion: The Role

is to create "artificial" differentiation or to cause physicians to over-prescribe a particular brand. Researchers have generally categorized promotion that expands overall sales in a therapeutic category as informational and promotion that affects drug market shares within a therapeutic category as persuasive.[11] However, to the extent that informative promotion helps physicians better match patients to drugs, promotion that affects drug market shares may also be informative. Similarly, if promotion results in overtreatment, promotion that expands the market may not necessarily be welfare enhancing.

The evidence in support of pharmaceutical promotion being either persuasive or informative is mixed. In one of the earliest articles on the topic, Leffler (1981) found empirical evidence for both the informational and persuasive roles of advertising but emphasized the welfare enhancing role of advertising by noting that "product promotion has a significant positive effect on the entry success of therapeutically important new drugs."[12] Berndt et al. (1995) found evidence that pharmaceutical promotions affect both the market size and individual market shares of anti-ulcer drugs,[13] providing evidence that pharmaceutical promotion may have both a persuasive and an informational role. Hurwitz and Caves (1988) found that pharmaceutical promotion helps to preserve brand share after generic entry and interpreted this as evidence of the persuasive role of advertising.[14]

In contrast, Iizuka and Jin (2002) found that direct-to-consumer advertising encourages outpatient office visits but has no effect on the choice of a particular brand prescribed, and Rosenthal et al. (2003) found that both detailing and direct-to-consumer advertising have a market-expanding rather than business-stealing effect. Azoulay (2002) also noted that "much advertising refers explicitly to clinical results" and concluded that published clinical studies drive both detailing and journal advertising expenditures of pharmaceutical manufacturers. Gonul et al. (2001) concluded that competition that occurs among sales representatives detailing different drugs can reduce the persuasiveness of detailing for each given drug while making more objective information available to physicians.[15] These four studies support the informational role of advertising.

Narayanan et al. (2005) analyzed the temporal aspect of the role of promotion and found that, for new drugs, the informative role dominates initially in the product life cycle with the persuasive role taking over as the uncertainty about the drug's efficacy is resolved.[16] Narayanan and Manchanda (2009) found significant heterogeneity in the impact of detailing across physicians over time, implying that the rate of change of the dominant role of promotion (from informative to persuasive) varies among physicians and that for some physicians the informative value of promotion remains for a long period of time.[17]

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[11] Keith B. Leffler, Persuasion or Information? The Economics of Prescription Drug Advertising, 24 J.L. & Econ 45, (1981). See also Mark A. Hurwitz & Richard E. Caves, Persuasion or Information? Promotion and the Shares of Brand Name and Generic Pharmaceuticals, 31 J.L. & Econ. 299 (1988).

[12] Keith B. Leffler, Persuasion or Information? The Economics of Prescription Drug Advertising, 24 J.L. & Econ. 45 (1981).

[13] Ernst R. Berndt, Linda Bui, David R. Reiley & Glen L. Urban, Information, Marketing, and Pricing in the U.S. Antiulcer Drug Market, 85 Am. Econ. Rev. 100 (1995).

[14] Mark A. Hurwitz & Richard E. Caves, Persuasion or Information? Promotion and the Shares of Brand Name and Generic Pharmaceuticals, 31 J.L. & Econ. 299 (1988).

[15] Füsun Gönül, Franklin Carter, Elina Petrova & Kannan Srinivasan, Promotion of Prescription Drugs and Its Impact on Physicians' Choice Behavior, 65 J. Marketing 79 (2001).

[16] Narayanan, Sridhar, Puneet Manchanda & Pradeep Chintagunta, Temporal Differences in the Role of Marketing Communication in New Product Categories, 42 J. Marketing Res. 278 (2005).

[17] Sridhar Narayanan & Puneet Manchanda, Heterogeneous Learning and the Targeting of Marketing

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