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Increase Consumer Welfare?

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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

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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 concerns about “reverse payment” settlements.

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 authorities.

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, Fusun 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 and Value of Physicians' Samples under Competition," Working Paper.

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

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 Füsün 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 Communication for New Products*, Marketing Sci. (2009).

Research has also focused on promotion's role in matching patients to drugs. Bradford et al. (2005) found that the advertising for osteoarthritis drugs encouraged faster adoption among the patients who were good candidates for the treatment, and decreased the speed of adoption for less well-suited clinical candidates. Crawford and Shum (2005) showed that significant uncertainty exists in the idiosyncratic match between patients and drugs which is resolved through patients actually trying a drug.¹⁸ Joseph and Mantrala (2009) argued that free samples can reduce the cost of patients trying drugs, thereby making the process of matching drugs with patients easier and cheaper in an environment of uncertainty.¹⁹ Taken together, these studies support the view that promotional activities improve the matching process between patients and drugs.

Academic research has also found that pharmaceutical promotion may increase patients' compliance with treatment. Donohue et al. (2004) studied the effect of direct-to-consumer (DTC) advertising and detail visits on the initiation and duration of treatment for people diagnosed with depression.²⁰ They found that an increase in aggregate DTC advertising for the antidepressant category beyond a certain threshold led to an increase in the duration of antidepressant use for patients.²¹ Calfee et al. (2002) found that DTC advertising is positively associated with the proportion of cholesterol patients who have been successfully treated, which may also indicate an improved compliance with treatment.²² Promotion may thus increase total consumer welfare both by increasing the value of pills consumed due to better matching and by increasing the quantity of the drug consumed through improved compliance and by encouraging patients to seek treatment.

In contrast to the promotional efforts of brand manufacturers, generic manufacturers do not generally market their drugs to consumers or physicians. Instead, generic manufacturers rely on physicians to write prescriptions for the branded product that are then substituted at the pharmacy with a generic version.²³ Substitution laws enacted in each state either allow or mandate pharmacies to dispense generic equivalents in the place of branded drugs unless the brand is cheaper or such substitution is explicitly prohibited by the prescribing physician.²⁴ When multiple generic versions are available, the pharmacies choose which generic version to use. Because physicians and consumer have no control over which generic version is substituted for the brand, manufacturers have no incentive to promote generic drugs to physicians or consumers. As a result, the informational and other benefits of promotion are provided solely by brand manufacturers.

B. *Incremental Innovation Through Supplementary Indications*

Branded drug companies also increase the value of pharmaceutical products by conducting clinical trials to gain regulatory approval for additional indications. Although

¹⁸ Gregory Crawford & Matthew Shum, *Uncertainty and Learning in Pharmaceutical Demand*, 73 *Econometrica* 1137 (2005).

¹⁹ Kissan Joseph & Murali Mantrala, *A Model of the Role of Free Drug Samples in Physicians' Prescription Decisions*, 20 *Marketing Ltrs.* 15 (2009).

²⁰ Julie M. Donohue, Ernst R. Berndt, Meredith Rosenthal, Arnold M. Epstein & Richard G. Frank, *Effects of Pharmaceutical Promotion on Adherence to the Treatment Guidelines for Depression*, 42 *Med. Care* 1176 (2004).

²¹ The authors found that drug-specific DTC advertising did not have a statistically significant effect on the duration of use for that drug.

²² John E. Calfee, Clifford Winston & Randolph Stempki, *Direct-to-Consumer Advertising and the Demand for Cholesterol-Reducing Drugs*, 45 *J.L. & Econ. Pt. 2: The Regulation of Medical Innovation and Pharmaceutical Markets* 673 (2002).

²³ This article focuses on self-administered drugs—drugs dispensed through pharmacies—rather than drugs that are administered by physicians during office or hospital visits.

²⁴ Physicians can prevent generic substitution by writing "dispense as written" on a prescription.

physicians can prescribe drugs for indications that are not approved by the Food and Drug Administration (FDA), clinical trials for new indications and resulting FDA approval provide information to physicians about the drug's efficacy and safety for those indications.²⁵ Such efforts in turn increase the use of the drug for those indications and more consumers can benefit from the use of the drug.

Berndt, Cockburn and Grepin (2006), among other researchers, have documented the significant benefits to patients from supplemental indications.²⁶ For example, the proton pump inhibitors class of drug products, initially approved as anti-ulcer medicines, experienced greater patient utilization from their supplementary approval for gastroesophageal reflux disease. Products in the selective serotonin re-uptake inhibitors class of anti-depressants gained several supplementary indications for the treatment of associated mental disorders including panic disorder, obsessive compulsive disorder, bulimia nervosa, and generalized anxiety disorder. This pattern of incremental innovation through supplementary indications characterizes many major therapeutic classes and has resulted in significant economic and medical benefits.

C. Price Competition By Generic And Brand Manufacturers

The benefits of pharmaceutical products must be viewed in relation to their costs. The retail price—i.e., the total price charged by pharmacies including the patient's out-of-pocket costs (the copayment for insured patients) and any payments made by third party payors—of a generic product is lower than the retail price of its branded counterpart. The extent of the retail price discount offered by generics depends on the degree of generic competition—i.e., the number of manufacturers offering a generic version of the drug. A 1998 Congressional Budget Office (CBO) study has estimated that in 1994 the average retail price of a generic prescription was half the price of a prescription filled with a branded drug for which generic versions were also available on the market. The same study showed an increase in the discount offered by generic competitors as the number of generics on the market grew.²⁷ Reiffen and Ward (2005) estimated that with ten or more generic manufacturers, generic retail prices approach the cost of manufacturing and distributing a generic resulting in very low profit margins.²⁸ Grabowski and Vernon (1992) studied a sample of 18 drugs that experienced generic entry between 1983 and 1987 and had sales above \$50 million per year at the time of patent expiration.²⁹ They found that the average generic in this category offered a 39 percent retail price discount at the time of entry, and this discount increased to 54 percent one year after entry, and to 63 percent two years after entry.

For branded drugs, there are two other factors affecting price: rebates to third party payors (TPPs) and free samples. The size of discounts provided by rebates to TPPs is hard to quantify because such rebates are usually confidential. The 1998 CBO study estimated that the ratio of the best price (i.e., the lowest price to any private purchaser including TPPs) to the average price paid by wholesalers was on average equal to 0.77

²⁵ By law, pharmaceutical manufacturers can only market their drugs for the indications approved by the FDA.

²⁶ Ernst R. Berndt, Iain M. Cockburn, and Karen A. Grepin, *The Impact of Incremental Innovation in Biopharmaceuticals: Drug Utilisation in Original and Supplemental Indication*, PHARMACOECONOMICS 69 (2005).

²⁷ *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, Congressional Budget Office, July 1998, at 33.

²⁸ David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamic*, 87 Rev. Econ & Stat. 37, (2005).

²⁹ Henry G. Grabowski & John M. Vernon, *Brand Loyalty, Entry and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 35 J.L. & Econ 331 (1992).

in 1994, and for some drugs reached as low as 0.10.³⁰ This suggests that rebates can provide significant price discounts. The FTC also conducted a survey of private TPPs and estimated that the average rebate per brand drug prescription was \$5.22 in 2002 and increased to \$6.34 in 2003.³¹ These amounts combined with estimates of prescription drug prices for 2002 and 2003 suggest that rebates on average provided a 7 percent discount in these years.³² A separate review of information on rebates from the financial filings of four branded pharmaceutical companies suggests that in 2011, rebates ranged from 8 percent to 33 percent of their wholesale sales.³³

In addition to the rebates provided to private TPPs, brand manufacturers also give rebates to the Medicaid program (known as OBRA rebates after the Omnibus Budget Reconciliation Act of 1990 that introduced them). OBRA rebates are calculated based on federal formulae, and for branded drugs they are structured so that Medicaid gets the benefit of the best discount available to private TPPs. In addition to OBRA rebates, states often sign supplemental rebate agreements with drug manufacturers, which allow them to further reduce their total drug costs. The OBRA rebate for branded drugs is calculated as the greater of 23.1 percent of the average manufacturer price (AMP) or the difference between AMP and the best price offered to any private payor.³⁴ In addition, if the AMP of a drug grows faster than the consumer price index, this “extra” growth is further rebated to Medicaid. A 2005 CBO study estimated that brand manufacturers paid OBRA rebates averaging 31.4 percent of the average manufacturer’s AMP in 2003.³⁵

OBRA rebates for generic drugs are equal to 13 percent of AMP and are thus significantly smaller than OBRA rebates for branded drugs.³⁶ Generic manufacturers do not offer rebates to private TPPs because TPPs have little control over which generic version of a drug gets dispensed by a pharmacy.

Free samples also affect the total cost of branded drugs. For example, a consumer who receives a 10 day supply of free samples and whose course of treatment lasts thirty days effectively saves one third of the expenditures on the drug. The available data indicate that free samples, if valued at retail prices, were equal in value to approximately 8-9 percent of spending in the U.S. on branded drugs between 2001 and 2004.³⁷ This

³⁰ *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, Congressional Budget Office, July 1998, at Appendix B. Note that best price measures the price available to a single purchaser. Average price net of rebates across all private purchasers is likely larger than the best price.

³¹ *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies*, Federal Trade Commission, August 2005, at viii.

³² A study by Takeda found average retail price of branded drug prescriptions to be \$79.80 in 2002 and \$91.77 in 2003 (*Prescription Drug Benefit Cost and Plan Design Survey Report*, Takeda Pharmaceuticals, (2005) at 4).

³³ The companies are GlaxoSmithKline, Pfizer, Johnson & Johnson, and AstraZeneca. The percentages would be smaller if taken as a percent of retail sales. Rebates include rebates to Medicaid and other government programs and rebates to managed care and other health insurance programs. *Do more, feel better, live longer: GlaxoSmithKline Annual Report for Shareholders*, GlaxoSmithKline plc, 2011, at 59; *2011 Financial Report*, Appendix A, Pfizer, Inc., 2011, at 18–19; *Form 10-K for the fiscal year ended 01/01/12*, Johnson & Johnson, February 2012, at 34 and 56; *AstraZeneca Annual Report and Form 20-F Information 2011*, AstraZeneca plc, 2011, at 94.

³⁴ The minimum OBRA rebate for branded drugs increased to 23.1 percent from 15.1 percent of the AMP as a result of the 2010 Patient Protection and Affordable Care Act.

³⁵ *The Rebate Medicaid Receives on Brand-Name Prescription Drugs*, Congressional Budget Office, June 2005, at 5.

³⁶ Similarly to the OBRA rebates for branded drugs, rebate for generic drugs increased to 13 percent from 11 percent of the AMP as a result of the 2010 Patient Protection and Affordable Care Act.

³⁷ The retail value of samples is from IMS Health IPS data as reported in *Impact Of Direct-To-Consumer Advertising On Prescription Drug Spending*, Kaiser Family Foundation, (June 2003); *Prescription Drug Trends Update*, Kaiser Family Foundation, (October 2004); Marc-Andre Gagnon & Joel Lexchin, *The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States*, 5 PLOS

corresponds to an average effective price discount from free samples of 7-8 percent.³⁸ Generic manufacturers do not provide free samples because physicians and patients do not control which generic version a pharmacy decides to stock and dispense. There is, therefore, no corresponding sample discount on generic drugs.

IV. THE EFFECTS OF GENERIC ENTRY ON COMPETITION AND CONSUMER WELFARE

To understand how consumer welfare is affected by generic competition it is necessary to understand how generics and brands compete. A key component of this competition is how free riding by generics affects brands' incentives to continue to compete with other brands through the promotion of their products and through investments to gain FDA approval for additional indications for their products. It is also necessary to understand the price discounts provided by generics, and in particular, how generic prices compare to the price the brand would charge absent generic entry and net of rebates and discounts from samples.

A. *The Nature Of Competition In Pharmaceutical Markets*

Generic competition in U.S. pharmaceutical markets has increased dramatically since the passage of the Hatch-Waxman Act in 1984.³⁹ The Act significantly reduced generic entry barriers by allowing generic manufacturers to receive approval from the FDA without reproducing the expensive and time-consuming clinical trials required of branded drugs.⁴⁰ In addition, states have increasingly adopted pharmacy substitution laws that allow (and sometimes even mandate) pharmacies to substitute generic equivalents of branded drugs without having to receive permission from the prescribing physician. In many states, pharmacists are not required to inform patients that the prescription has been filled with a generic version. Pharmacies also typically earn higher margins on generic products and thus have a financial incentive to substitute generic equivalents.⁴¹ In addition, patients usually face lower copayments for generic products. As a result of all these factors, generic versions of self-administered prescription drugs quickly take significant sales away from their branded counterparts.

Competition between a branded pharmaceutical product and its generic equivalents ("within-brand" competition) differs from the competition that exists across branded products within the same therapeutic category ("across-brand" competition). Generic competition does not require generic manufacturers to convince physicians to prescribe the generic version of a branded drug. Instead, generics simply free ride on the prescriptions written by physicians for the branded product.

Competition across brands within the same therapeutic category differs substantially. Pharmacists cannot substitute between different branded products (or substitute a brand with a generic equivalent for a different brand) without receiving permission from the prescribing physician. Because pharmacists have little influence over which brand is

Med. (2008). U.S. sales are estimated by combining information on growth rates and 2006 U.S. sales from *Prescription Drug Trends*, Kaiser Family Foundation, (September 2008).

³⁸ If samples are 8% of sales, then the discount is equal to $.08 / (1+.08) = \sim 7\%$.

³⁹ The official name of the Hatch-Waxman Act is the Drug Price Competition and Patent Term Restoration Act of 1984.

⁴⁰ This act established the generic drug approval process such that generic companies could file abbreviated new drug applications (ANDAs) in which they were only required to demonstrate bioequivalence to the brand. The Act also allowed generic manufacturers to conduct testing to demonstrate bioequivalence prior to the expiration of the patents covering the branded product.

⁴¹ Henry G. Grabowski & John M. Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals after the 1984 Drug Act*, 35 J.L. & Econ. 331, (1992).

prescribed, brand manufacturers have little incentive to compete on prices paid by pharmacies. Instead they compete for market share within the therapeutic category through the entities that do affect drug choice, namely TPPs or their pharmacy benefit managers (PBMs),⁴² physicians, and patients. Brand manufacturers compete on price through the rebates to TPPs and PBMs discussed in the previous section. These rebates vary in size depending on how successful third party payors and PBMs are in moving share or volume. They also compete on price by providing free samples to patients via their physicians. Branded manufacturers also compete by providing information to physicians and patients on their products and by seeking FDA approval for additional indications.

Competition between generic versions of a branded drug is almost exclusively based on the prices they charge to wholesalers and large pharmacy chains because these entities choose which generic version to stock.

B. *The Effect Of Generic Entry On Brand Competition*

The economic incentives of brand manufacturers change in response to generic entry. Prior to generic entry, brand manufacturers receive returns in the form of additional prescriptions from the investments they make in their brands. In such a world, brand manufacturers have an incentive to promote their products as long as the additional prescriptions generated from such promotion justify the cost. After generic entry, promotion may still result in additional prescriptions, but because those prescriptions are largely filled with generic equivalents, brand manufacturers have no incentive to invest in promotion. The decline in promotion after generic entry is well documented in the literature.⁴³ Indeed, brand promotion tends to decrease even before generic entry as the window during which returns from promotion can be captured closes.

The importance of promotion relative to any price discounts offered by generics may be evidenced by a decline in output (in aggregate across both the brand and its generics). Such declines are often witnessed after generic entry despite the lower prices offered by generics. Indeed, Lakdawalla et al (2006) found that patent expiration does not lead to higher output, even though the within-brand average price is lower after generic entry.⁴⁴ They found that the decline in advertising undertaken by the brand caused the decrease in quantity. The authors further demonstrated that, on average, patent expiration makes consumers worse off by approximately \$400,000 a month in the short run because the price discount provided by generics cannot compensate for the decrease in value consumers receive from promotion. In the long-run, Lakdawalla et al assume a generic price discount of 90 percent resulting in a price discount that is large enough to compensate for the decrease in promotion. Lichtenberg and Duflos (2009) examined the effect of patent expiration on output using data on prescription drugs sold in the U.S. between 2000 and 2004.⁴⁵ They found that the decrease in marketing after generic entry offsets the effect of lower prices offered by generics, and the overall number of prescriptions for the drug (brand and generic combined) does not change after generic

⁴² PBMs have emerged as the main overseers of the prescription drug plans of employers and managed care organizations. PBMs have developed various strategies for controlling prescription drug consumption. These strategies include formularies, three-tier copayment schemes, drug utilization reviews, and reimbursement restrictions.

⁴³ See, for example, Ernst R. Berndt, *Pharmaceutical in U.S. Health Care: Determinants of Quantity and Price*, 16 J. Econ. Persp. 45 (2002).

⁴⁴ The measure of brand prices used by Lakdawalla et al. does not include rebates and discounts from free samples. As a result, the observed price decrease in price after generic entry may overstate the actual decrease in price.

⁴⁵ 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).

entry. However, the authors noted that because there is a reduction in the number of free samples distributed to physicians, overall drug utilization goes down after generic entry. Berndt et al (2003) studied anti-ulcer drugs and reached a similar conclusion that the quantity of within-brand prescriptions decreases after generic entry.⁴⁶

Similarly, manufacturers have no incentive to conduct R&D and seek approval for new indications for a brand after it experiences generic entry because the large majority of prescriptions for such new indications will be filled with the generic.⁴⁷ Even though the FDA can grant new use or indication exclusivity and manufacturers can obtain method of use patents for new indications, the realities of the drug distribution system make any such exclusivity provisions impossible to enforce. Physicians do not provide information on the indication for which a drug is prescribed to the pharmacist, so pharmacists have no way to limit generic substitution to certain indications. It is therefore not surprising that brand manufacturers choose not to conduct additional R&D on their products as generic entry approaches or after generic entry.⁴⁸ As a result, generic entry arguably results in suboptimal levels of investment in promotion and R&D for branded drugs.⁴⁹

While generic manufacturers compete vigorously for existing prescriptions written for the brand, the intensity of competition among branded products decreases. Unable to retain sales when faced with competition from lower-priced generics, brands no longer have economic incentives to offer free samples, educate physicians via detailing visits on the benefits of the drug, or investigate additional uses for the drug. In the presence of free riding by generics, branded pharmaceutical products (and their generic equivalents) may no longer be able to compete as effectively with other branded products that continue to provide information valued by physicians and their patients. In such a situation, actions that reduce generic competition may enhance consumer welfare despite causing higher retail prices: to the extent promotion and other forms of competition across brands are greater when brands do not face generic competition, the higher prices incurred by consumers may be justified.

C. *The Effect Of Generic Entry On Prices*

While generic entry results in a reduction in promotion and other forms of brand investment, the effect of such reductions on consumer welfare must be compared to

⁴⁶ 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). Note that for one of the drugs total within-brand quantity (without taking into account samples) increased after an over-the-counter version was introduced.

⁴⁷ When the FDA approves a drug, it approves a particular strength and form of the drug. Therefore, this observation is limited to the strengths and forms of the drug for which generic equivalents have been approved. There remain incentives to research additional uses for drugs with the same active ingredient, but different strengths and forms, for which no generic equivalents have been approved.

⁴⁸ Branded firms often attempt to develop new formulations for drugs experiencing patent expiration (e.g., extended release formulations and combination products). The effectiveness of these "life cycle management" strategies is mixed and depends on the degree of the incremental therapeutic benefits and the ability to gain favorable tier placement in managed care formularies. Henry Grabowski, *Competition between Generic and Branded Drugs*, PHARMACEUTICAL INNOVATION: INCENTIVES, COMPETITION AND COST BENEFIT ANALYSIS IN INTERNATIONAL PERSPECTIVE (Frank A. Sloan and Chee-Ruey Hsieh, eds., University Press 2007).

⁴⁹ Uncertainty over the enforceability of patents can exacerbate this issue. In addition to lowering generic entry barriers, the Hatch-Waxman Act also encouraged generic manufacturers to challenge the patents covering branded products. It did this by allowing generic manufacturers to challenge patents without launching the product, thus greatly reducing the risks associated with patent litigation; and by granting six months of exclusivity to the first generic manufacturer to challenge the patents covering a branded product. Since 1984, generic firms have not only filed increasingly more lawsuits to challenge the patents of branded products, they have also started to challenge these patents early in branded products' lifecycles. See Henry Grabowski, *Are the Economics of Pharmaceutical Research and Development Changing? Productivity, Patents and Political Pressures*, 22 *Pharmacoeconomics* 15 (2004).

the benefits resulting from the lower prices offered by generics to consumers and their TPPs.⁵⁰ Data from IMS Health on 54 branded drugs that lost patent protection between 2006 and 2008 show that wholesale generic price discounts are on average 55 percent and retail generic price discounts are on average 34 percent one year after generic entry. For drugs with more than \$750 million in sales in the year prior to generic entry, wholesale and retail generic price discounts are 82 percent and 52 percent, respectively, one year after generic entry.⁵¹

While these data provide reliable estimates of the prices paid by and charged by pharmacies for generic and branded products, they do not necessarily provide good estimates of the price discounts generics provide to patients and TPPs. This is because retail and wholesale prices do not account for rebates brand manufacturers pay to TPPs or the discounts brand manufacturers provide by distributing free samples to physicians.⁵² Wholesale price discounts also overstate the generic price discount received by patients and TPPs because pharmacies charge higher markups on generic products than they charge on branded products—i.e., pharmacies capture a portion of the price discount offered by generic manufacturers.⁵³

As already discussed, brands decrease or end their distribution of free samples after generic entry. Rebates may also decrease because they are usually dependent on market share or volume, both of which decrease substantially after generic entry. If brands do not distribute free samples or provide rebates to TPPs after generic entry, it could be argued that once generic entry occurs, retail prices (the prices charged by pharmacies) accurately measure the price discount generics provide to consumers and their TPPs. However, the relevant comparison is between generic prices and what brand prices would have been in the absence of generic entry, not what brand prices are after generic entry. Thus TPP rebates and free samples are important to include in any analysis of how generic competition affects prices.

The omission of rebates and samples from the calculation of net retail price, as well as reliance on wholesale prices may significantly inflate estimates of the price discount generics offer relative to the corresponding brand. Where brands provide large numbers of free samples and/or large rebates to TPPs, the net brand price may actually be lower than the generic price. Section IV describes an example of this situation.

D. The Effect Of Generic Entry On Consumer Welfare

The unique nature of generic competition causes it to increase within-brand competition at the expense of across-brand competition. The two effects offset each other and should be considered in determining how generic competition affects consumer welfare. Whether consumers gain more from the within-brand competition that generic entry provides than they lose from the decrease in across-brand competition caused by generic entry is likely to vary across drugs and therapeutic categories and is thus an empirical question. Such an evaluation would involve examining the true price discounts likely to be provided by generic equivalents and understanding the value to consumers of brand promotional efforts and FDA approval of new indications.

⁵⁰ Lower prices may result in non-price benefits, such as improve compliance. Improved compliance should lead to greater consumption however, and there is little evidence that generic entry increases overall consumption, at least on a systematic basis.

⁵¹ Calculations based on IMS Health Generic Spectra data.

⁵² Generics do not generally provide free samples or provide discounts to TPPs because such entities do not influence which generic version of a branded product is dispensed at the pharmacy.

⁵³ Henry G. Grabowski & John M. Vernon, *Longer Patents for Increased Generic Competition in the US: The Waxman-Hatch Act after One Decade*, 10 *Pharmacoeconomics* 110 (1996).

For example, research has shown that generic price discounts depend on the number of generic competitors available for the brand, with more generic competitors corresponding to a larger generic price discount.⁵⁴ Thus, when evaluating the effects of generic entry on consumer welfare, it is important to take into account the number of generics that are expected to compete with the brand. The number of manufacturers offering generic versions of a branded product usually increases with the size of the brand's sales, but other factors such as how difficult it is to manufacture the product or distribution challenges may also limit the number of generic competitors. Moreover, the larger the generic price discount, the larger the share of prescriptions that are captured by generics and thus the larger the proportion of consumers that is likely to benefit from any price discount offered by the generic. Saha et al. (2006) found that the average generic penetration 12 months after generic entry was 79 percent for drugs with at least 20 generics, but only 47 percent for drugs with two or fewer generics.⁵⁵ The size of brand sales may also influence the generic penetration rate because TPPs (and their PBMs) may focus more attention on encouraging generic substitution for blockbuster branded products.

The prevalence of price discounts offered by brands in the form of free samples and TPP rebates differs significantly between therapeutic categories and also across brands within a therapeutic category. Factors such as which medical conditions are treated by the drug, the number of therapeutic substitutes, the degree of product differentiation, and the order in which a drug enters into a therapeutic class can all affect the extent of price discounting and marketing efforts.⁵⁶ A study by Rosenthal (2003) found that the three-year average ratio of the value of free samples compared to the sales revenues for proton-pump inhibitors (PPI) drugs was as high as 84 percent while for cholesterol drugs this ratio was only as high as 7 percent. Within the antidepressant drug class, a few heavily promoted drugs such as Celexa have three times the number of free samples as less extensively promoted antidepressant drugs have.⁵⁷ Consistent with economic theory, the FTC has found that the size of rebates offered by brand manufacturers depends on the number of therapeutic competitors in the category.⁵⁸ The 1998 CBO study concluded that brand manufacturers offer larger rebates to TPPs when facing competition from other brands or generics in the therapeutic class.⁵⁹ Thus, the impact of samples and rebates on the true brand price will depend on factors specific to the brand and the therapeutic category in question.

The other side of the consumer welfare equation depends on factors that affect the value of the brand, such as the informational value provided by the brand's promotional efforts and the number of indications for which the brand is approved. Promotional

⁵⁴ *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, Congressional Budget Office, July 1998.

⁵⁵ Atanu T. Saha, Henry G. Grabowski, Howard Birnbaum, Paul Greenberg & Oded Bizan, *Generic Competition in the US Pharmaceutical Industry*, 13 *Int'l J. of the Econ. Of Bus.* 15 (2006).

⁵⁶ For more discussions along this line, see Ernst R. Berndt, Ashoke Bhattacharjya, David N 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 (2002); Rahul Guha, Jian Li & Andrea L. Scott, *The Economics of Commercial Success in Pharmaceutical Patent Litigation*, *Landslide* 8 (2009).

⁵⁷ Meredith B. Rosenthal, Ernst R. Berndt, Julie M. Donohue, Arnold M. Epstein & Richard G. Frank, *Demand Effects of Recent Changes in Prescription Drug Promotion*, *Frontiers in Health Pol'y Res.* 1 (2003).

⁵⁸ *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies*, Federal Trade Commission, August 2005, at ix.

⁵⁹ *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, Congressional Budget Office, July 1998, at 62. Note that this analysis relies on the "best price" estimate, which measures the best price given across all private purchasers, not the average price. The average rebate across all private purchasers will be likely smaller than the lowest price offered to a single purchaser.

efforts may be particularly valuable when it is important to correctly match patients to drugs based on patient characteristics. This is true even if only a small share of patients experience differences across drugs and thus need to be carefully matched to the correct drug. Approval for additional indications may provide substantial value to patients depending on the availability and characteristics of other treatment options for these indications. If maximizing consumer welfare is the goal of antitrust policy, the effect of generic competition on non-price competition—promotional efforts and seeking FDA approval for additional indications—should not be ignored by antitrust authorities. While in many cases the benefits of generic competition are likely to outweigh its costs, this is not always the case.

V. THE OVCON EXAMPLE

The oral contraceptive Ovcon 35 (Ovcon), produced by Warner Chilcott, provides an example where the benefits of across-brand (i.e., therapeutic) competition likely outweighed the benefits of within-brand (i.e., generic) competition. A comparison of the generic and brand price (taking into account free samples) demonstrates that a generic version of Ovcon would not have provided a lower cost option to consumers.

In January of 2000, Warner Chilcott purchased Ovcon from Bristol-Myers Squibb Co. (“BMS”), and BMS began supplying Ovcon to Warner Chilcott shortly thereafter. Ovcon had been off-patent for a number of years but no generic manufacturer had entered with a generic equivalent. Despite the lack of generic entry, BMS had stopped promoting Ovcon and its share of oral contraceptive sales was declining. Sales of Ovcon totaled \$30.6 million in 1999, corresponding to 1.6 percent of the oral contraceptive category. Starting in 2000, Warner Chilcott began promoting Ovcon to physicians through detail visits and the provision of free samples. As a result, Ovcon’s sales doubled, growing to \$61.6 million in 2003, and its market share increased to 2.0 percent.

In 2004, Barr Labs (“Barr”) received FDA approval to launch a generic equivalent of Ovcon. Following FDA approval, Barr entered into an agreement to supply Warner Chilcott with Ovcon. The supply agreement was exclusive in that it precluded Barr from supplying Ovcon to anyone other than Warner Chilcott, including itself. Subsequently, Barr and Warner Chilcott were sued by the FTC, several indirect and direct purchasers, and state attorneys general. These parties claimed that the supply agreement was anticompetitive because it delayed the entry of a lower priced generic.⁶⁰

To evaluate whether consumers⁶¹ were indeed harmed by the supply agreement, we compared the price discount that would have been provided by Barr’s generic with the price discount from the free samples provided by Warner Chilcott. The analysis shows that, had Barr entered with a generic, consumers would have paid more for the generic than they paid on average for branded Ovcon. This is because a substantial number of free samples were provided by Warner Chilcott to patients via their physicians, and Warner Chilcott would have ceased distributing free samples following the introduction of a generic version of Ovcon by Barr. For example, according to IMS data, over the relevant period (April 2004 – September 2006), Warner Chilcott distributed approximately 2.2 million packs of Ovcon in the form of free samples compared to 6.2

⁶⁰ Henry Grabowski and Tracy Lewis provided expert testimony on behalf of Warner Chilcott in these matters.

⁶¹ We use the term consumers generally to encompass both patients and the third party payors who cover a portion of the cost of the prescription.

million packs purchased by consumers. Thus, free samples provided an effective price discount of 26 percent.⁶²

Warner Chilcott provided large numbers of free samples—as do other brand manufacturers of oral contraceptives that do not yet face generic competition—precisely because across-brand competition is so vigorous in the oral contraceptive category. This is a crowded drug category with numerous branded and generic oral contraceptive products. It is not a highly differentiated category—all oral contraceptives have roughly the same efficacy and the same major risks.⁶³ Oral contraceptives do differ in terms of minor side effects but for most women, all oral contraceptives are fairly interchangeable.⁶⁴ As a result, as of 2006 no single brand or generic product dominated the category and sales were spread across a large number of products. (See Figure 1.)

We also estimated the price discount that would have been provided by Barr's generic equivalent of Ovcon. An analysis of IMS data on retail prices demonstrates that Barr's generic versions of other oral contraceptives provided retail price discounts ranging from 10 to 20 percent with an average discount of 13 percent.⁶⁵ (See Figure 2.) The discounts are substantially smaller than the effective price discounts provided by free samples of 26 percent.

⁶² This is calculated by dividing 2.2 million samples by 8.4 million packs consumed. Of the 8.4 million packs consumed, 6.2 million packs were purchased packs and 2.2 million were free samples. If not all free samples reach consumers (e.g., if physicians throw some free samples away), the discount provided by free samples would be lower. However, from our work in various pharmaceutical cases, it is our understanding that IMS data underestimates the true number of free samples distributed to physicians by as much as 50 percent. Given this, we believe the estimate of 2.2 million samples reaching patients is conservative even if not all samples distributed reach patients.

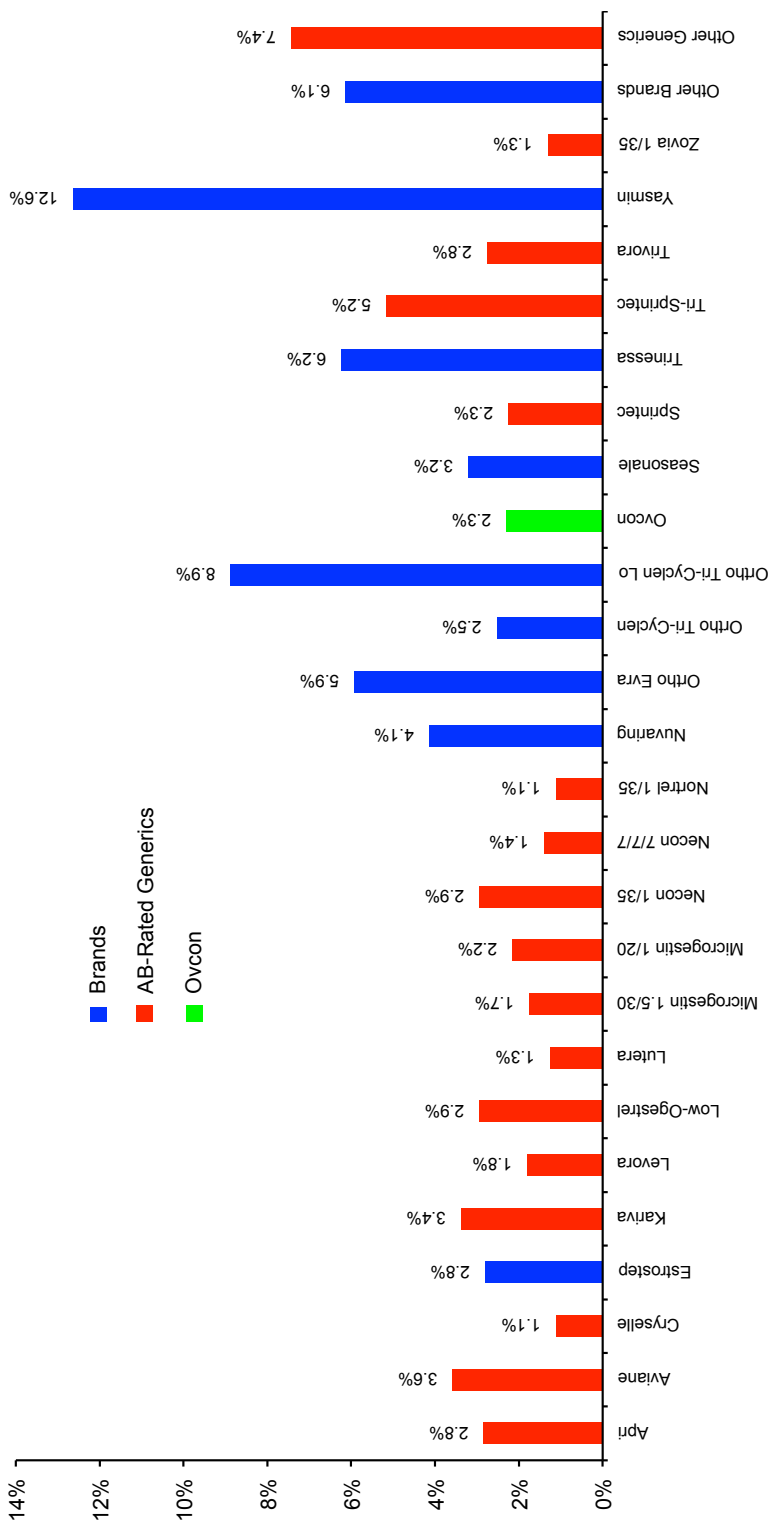
⁶³ The FDA does not allow oral contraceptive manufacturers to make claims of superior efficacy in their marketing. *Draft Guidance for Industry Labeling for Combined Oral Contraceptives*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION (March 2004).

⁶⁴ For a subset of women, the side effects can be meaningful and it is important that they are matched to the correct oral contraceptive.

⁶⁵ The discount is calculated from the time of entry of the first generic to the time of entry of the second generic, or April 2007, whichever is earlier.

Figure 1: Share of Retail Packs by Oral Contraceptive Product in 2006

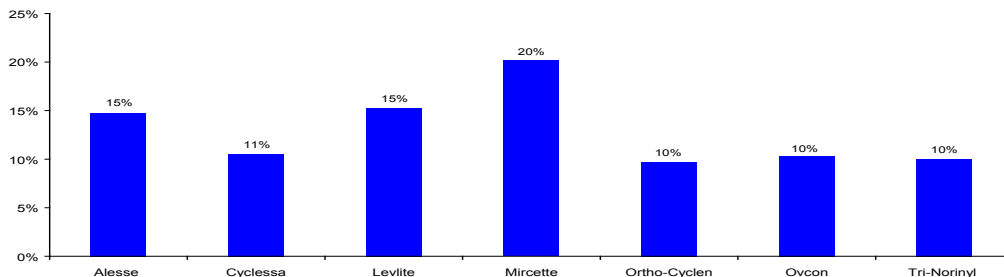
Source: IMS Health



Note: All combination hormonal contraceptives with 35 mcg or less of ethinyl estradiol are included. Analysis includes oral contraceptives, Nuvaring (vaginal ring), and Ortho Evra (patch). The data covers the period from January 2006 through September 2006. Only drugs with a share of more than 1 percent are displayed. The "Other Brands" category includes Alesse, Breviceon, Cyclessa, Demulen, Desogen, Levlen, Levite, Lo/Ovral, Loestrin 1.5/30, Loestrin 1/20, Loestrin 24, Mircette, Modicon, Nordette, Norinyl 1/35, Ortho-Cept, Ortho-Cyclen, Ortho-Novum 1/35, Ortho-Novum 10/11, Ortho-Novum 7/7/7, Seasonique, Tri-Levlen, Tri-Norinyl, and Triphasil. The "Other Generics" category includes Aranelle, Cesia, Entresse, Jolessa, Junel 1.5/30, Junel 1/20, Kelnor 1/35, Leena, Lessina, Mononessa, Necon 0.5/35, Necon 10/11, Norrel 7/7/7, Portia, Previfem, Quasense, Reclipsen, Solia, Sronyx, Tri-Previfem, Velivet, and Yaz.

Generic Retail Price Discounts for Brands with a Single Generic

Source: IMS Health; Bureau of Labor Statistics



The estimated generic price discount is relatively small because Barr was unlikely to have faced competition from any other generic manufacturer, and as a result would not have had to compete to supply pharmacies with generic versions of Ovcon.⁶⁶ Between 2004 and 2007, most off-patent oral contraceptives only faced competition from one or two generic competitors.

To determine whether consumer welfare is positively or negatively affected by generic entry in this situation, one cannot simply compare the average price of Ovcon taking into account free samples with the average price of generic Ovcon. Doing so assumes that consumers value free samples at the same level they value purchased packs. While this may be an appropriate assumption for consumers who received free samples and then went on to purchase Ovcon,⁶⁷ it may not be true for consumers who never purchased Ovcon. Indeed, patients who received free samples but never purchased Ovcon may have placed very little value on the free samples.

Instead, assessing the consumer welfare of generic entry requires understanding how much value consumers received from free samples and comparing that to the savings they would realize on their purchased packs of Ovcon were a generic to enter.^{68, 69} For purchased packs, the price discount offered by the Barr generic was likely to be approximately 13 percent. With an average brand price per pack of approximately \$44, the 13 percent discount corresponds to savings of \$5.66 for every consumer that

⁶⁶ The analysis of Barr's retail price discounts is limited to situations where Barr is the sole generic competitor for a brand. Barr would have been the only generic of Ovcon between April 2004 and September 2006, and therefore we assume that only one generic competitor would have existed during this time period. Even with two generic competitors, the price discount would not have been large enough to compensate for the loss of free samples.

⁶⁷ In contrast to many drugs for which samples may contain fewer pills than a typical prescription, a sample of an oral contraceptive generally consists of a four weeks supply (or one cycle) of the drug.

⁶⁸ Understanding changes in overall consumption of purchased packs is also important. For the Ovcon case, we believed overall consumption would decrease with generic entry because past instances of generic entry for oral contraceptives almost uniformly showed a decrease in the number of purchased packs. The analysis we present here only takes into account lost welfare from the loss of free samples and does not take into account any additional welfare decrease from a reduction in consumption of purchased packs.

⁶⁹ To the extent that Ovcon consumers' overall consumption of oral contraceptives would not have decreased had a generic of Ovcon been available, one might want to compare the value consumers received from free samples to the value they would have received had they consumed a different oral contraceptive in the place of those free samples. To the extent they would have had to purchase the alternative product, it is likely that they received far more value from the free samples. To the extent they would have received free samples of another oral contraceptive, presumably that would have resulted in other consumers not having the benefit of those free samples.

switched to the generic. For other oral contraceptive brands experiencing generic entry, on average 73 percent of sales go to generic versions in the long run. Thus consumers would have received savings equal to \$5.66 multiplied by 73 percent of 6.2 million purchased packs. This amounts to \$25.8 million in savings.⁷⁰

It is more difficult to precisely assess the value consumers received from free samples. We make two assumptions to calculate a lower bound estimate of this value. First, we assume that free samples received by patients who never purchased Ovcon had no value to consumers. Second, we assume that free samples received by patients who did go on to purchase Ovcon were valued by those patients at the price of purchased packs, i.e., \$44.⁷¹ We used IMS data on the number of Ovcon new prescriptions compared to the number of physician visits involving Ovcon to understand the likely number of samples received by patients who never filled a prescription. In total there were 2.4 million office visits and 1.7 million new prescriptions between April 2004 and September 2006. Thus there were 0.7 million office visits that did not result in a purchase of Ovcon.⁷² On average patients received 0.9 samples per visit (2.2 million samples / 2.4 million office visits). Multiplying 0.7 million office visits by 0.9 samples results in 0.63 million samples going to consumers who did not subsequently purchase Ovcon. The remaining 1.60 million samples went to consumers who did purchase Ovcon and are thus assigned a value of \$44, for a total value of \$69.8 million.⁷³ This amount far exceeds the \$25.8 million in saving consumers would receive from generic discounts on purchased packs.

Our analysis shows that, even using conservative estimates, consumer welfare would not have increased with generic entry. The analysis is also conservative because it ignores the non-monetary benefits provided by free samples such as better compliance, improved patient education, and patient convenience. It also ignores other potentially important factors such as rebates and the value to consumers of other forms of promotion.⁷⁴

In most situations, it is unlikely that an analysis of the monetary value of samples alone will lead to the conclusion that generic entry reduces consumer welfare. Even so, generic entry may very well be harmful to consumers in a substantial number of instances once all of the factors relevant for an analysis of consumer welfare are taken

⁷⁰ This analysis assumes that the price for branded Ovcon would not have been different had Barr entered with a generic version. If the brand price would have been lower (higher) than the price observed without generic entry, the value of generic entry would also have been lower (higher).

⁷¹ By making a purchase at that price, consumers have demonstrated that they value each pack of the drug at least as much.

⁷² This assumes that all new prescriptions involved an office visit. We have calculated alternative estimates assuming a portion of new prescriptions are written outside of office visits. For reasonable values of that proportion, our conclusions from this analysis do not change qualitatively.

⁷³ It may be the case that consumers who never purchased Ovcon received higher numbers of samples in their office visits than average consumers. For example, such consumers may mostly be new patients who are more likely to receive samples than continuing patients. However, even if, on average, patients who do not purchase Ovcon received two free samples in their office visits, this would still leave 0.8 million samples going to consumers who subsequently purchased Ovcon resulting in \$35.2 million in lost value were samples to disappear.

⁷⁴ With regard to rebates, the following abstract from the Iowa Medicaid list of frequently asked questions (as of 2009) is instructive: "The cost benefits of generic use are not as black and white as commonly perceived and portrayed in the media, especially for Medicaid programs. State Medicaid programs participate in a federally negotiated rebate program with drug manufacturers. This means they receive a varying percentage of the cost of every drug back from the manufacturer. This rebate is almost always 11% of the average manufacturer price (AMP) for generic drugs. The rebate for brand drugs starts at 15% of AMP and over time and due to competition (such as from state preferred drug lists), these brand rebates can go up to anywhere from 20% to 90% of a drug's AMP. Due to such disproportionately large brand rebates, the net prices of certain brand drugs are significantly less than their generic counterparts." Iowa Department of Human Services, Frequently Asked Questions, available at http://www.iowamedicaidpdl.com/uploads/Wg/2c/Wg2c0Qb84IPZw5wIjNST9A/Frequently-Asked-Questions-PDL-May-2009-_4_.pdf.

into consideration. The Ovcon example illustrates the importance of conducting an economic analysis of the trade-offs affecting consumers as a result of generic entry, in particular, in the context of litigation.

VI. IMPLICATIONS FOR THE ANALYSIS OF GENERIC COMPETITION FOR BIOLOGIC PRODUCTS

The framework to determine the impact of generic entry on consumer welfare can also be applied to biologic drugs. Generics for biologic drugs are called “biosimilars” because, unlike traditional pharmaceutical products, exact copies cannot be made.⁷⁵ Until the Biologics Price Competition and Innovation Act (BPCIA) was passed in March 2010 as part of the Patient Protection and Affordable Care Act, the U.S. did not have an abbreviated pathway for the approval of biosimilars.⁷⁶ The BPCIA provides such a pathway, but the regulatory hurdles to gain approval are likely to be much more stringent for biosimilars than they are for traditional generic drugs.⁷⁷ As a result, the approval costs of biosimilars are estimated to be as high as \$200 million, significantly more than the approval costs of traditional generic drugs, which are on average approximately \$2 million.⁷⁸ Higher approval costs are expected to result in fewer biosimilar competitors and, in turn, smaller price discounts than what is currently observed for traditional prescription drugs—in the range of 20 to 40 percent.⁷⁹

Smaller price discounts may in turn result in lower penetration rates for biosimilar products relative to what is seen for traditional generic products. Moreover, penetration rates are likely to be smaller because biosimilars are unlikely to be considered interchangeable to the corresponding biologic product, and thus pharmacists will not be able to automatically substitute the biosimilar without permission from the prescribing physician.⁸⁰ The experience of biosimilars in the European Union, which has had an approval pathway for biosimilars since 2005 and currently does not allow automatic substitution of biosimilar products,⁸¹ may provide some insight as to what we can expect in the U.S. in terms of biosimilar penetration rates.

In Europe, biosimilar entry has occurred to date in three separate classes: somatotropins (human growth hormone), erythropoiesis stimulating agents (ESAs), and granulocyte-colony stimulating factors (G-CSFs). We have analyzed the impact of biosimilars

⁷⁵ Biologic drugs consist of multiple, complex proteins and are several times larger than conventional drugs. These and other factors make the manufacturing of these drugs very difficult. It is therefore unlikely that reference and biosimilar drugs will be identical. Further, it is extremely difficult to accurately measure whether a biosimilar and its reference biologic drug are bioequivalent.

⁷⁶ The Hatch-Waxman Act limited the abbreviated approval pathway to generics for chemical entities only.

⁷⁷ It is likely that approval will require manufacturers to conduct clinical trials for most biosimilar products. The nature and extent of such trials will vary across biosimilar products, and will be determined on a case-by-case basis by the FDA. Draft Guidance for Industry, Scientific Considerations in Demonstrating Biosimilarity to a Reference Product, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION (February 2012).

⁷⁸ Henry Grabowski, David Ridley, and Kevin Schulman, *Entry and Competition in Generic Biologics*, 28 *MANAGERIAL AND DECISION ECONOMICS* 439 (2007).

⁷⁹ Henry Grabowski, Genia Long and Richard Mortimer, *Implementation of the Biosimilar Pathway: Economic and Policy Issues*, 41 *SETON HALL LAW REVIEW* 511 (2011).

⁸⁰ Reimbursement rules for physician-administered biosimilars may also reduce biosimilar penetration rates relative to those seen for traditional generic drugs. See Henry Grabowski, Genia Long and Richard Mortimer, *Implementation of the Biosimilar Pathway: Economic and Policy Issues*, 41 *SETON HALL LAW REVIEW* 511 (2011).

⁸¹ The European Medicines Agency (the European equivalent of the FDA) does not evaluate interchangeability, and questions of substitutability of biosimilars at the pharmacy level are left to member states. At this point, however, none of the member states allow automatic substitution of biosimilar products.

in Europe for two of these drug classes. For Eprex (in the ESA category), biosimilars in Germany and Sweden achieved a penetration rate (measured in daily doses) in excess of 60 percent in 2011, while the penetration rates in the United Kingdom, France, and Italy were much more modest in size (less than 20 percent).⁸² In contrast, the biosimilar penetration rate with respect to Neupogen in the G-CSF market in 2011 was between 40 and 60 percent in Germany, the United Kingdom, France, and Sweden.⁸³ Penetration rates were never as high as those seen for traditional generic drugs (typically over 90%).

Without the free-riding (and associated high penetration rates) that automatic substitution allows, brand biologic manufacturers will have a greater incentive after biosimilar entry to continue promoting their products and to continue conducting R&D on their products to identify additional indications.⁸⁴ Moreover, biosimilar manufacturers may also choose to promote their products because they will not be able to rely on generic substitution at the pharmacy to garner sales.⁸⁵ Thus, biosimilar competition is likely to resemble brand to brand competition for the foreseeable future. Correspondingly, the development of biosimilar products is attracting interest from both generic and research-intensive biopharmaceutical companies with potential implications for both cost savings and innovation incentives. The evolution of the market for biosimilars is an important issue for research and analysis.

VII. CONCLUSION

Generic competition in pharmaceutical markets has provided significant cost savings to consumers. Unfortunately, it also introduces a free rider problem that limits the ability of brand manufacturers to compete in ways that may benefit consumers. Reductions in promotion and incentives to seek regulatory approval for additional indications may significantly reduce the value consumers receive from a pharmaceutical product relative to what they would have received absent generic competition. Whether the reduction in costs provided by generic competition outweighs any reduction in value provided by a branded product will depend on the specific branded product and therapeutic category at issue.

It is tempting to focus solely on the retail price discounts provided by generics when analyzing the effects of delayed generic entry—these discounts are fairly straightforward to measure and provide concrete benefits to consumers. However, a failure to examine the broader market within which a brand competes and to analyze how generic competition affects competition within that broader market will result in a flawed assessment of the true effects of generic entry on consumer welfare and may lead to incorrect conclusions as to whether a delay in generic entry is anticompetitive.

⁸² Analysis using IMS MIDAS data.

⁸³ Analysis using IMS MIDAS data.

⁸⁴ Anecdotal evidence suggests that branded biologics in Europe have continued to be promoted after biosimilar entry.

⁸⁵ In some instances in Europe, manufacturers of biosimilars have spent significant resources on promotions geared towards overcoming physician opposition to the prescription of biosimilars. To the extent such promotions provide useful information to physicians or patients on the attributes of the biosimilar and/or its reference biologic, such promotion is procompetitive.