

**The Short-Term and Long-Term
Competitive Impact of Authorized Generics**

A Report for the Federal Trade Commission

October 28, 2009

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INTRODUCTION

At the request of Congress, the Federal Trade Commission is conducting an empirical study of the competitive effects of authorized generic drugs.¹ Some generic drug manufacturers have complained to Congress that brand name drug manufacturers sell authorized generics at prices that are too low, making price competition less attractive for generic drug manufacturers. The first phase of the FTC's empirical study was to measure the price effect of authorized generic drug during the 180-day marketing exclusivity period under the Hatch-Waxman Act. The FTC published a report in June focusing on the price-lowering effect of authorized generics. As our pricing analysis of this FTC report demonstrates, authorized generics led to \$880 million in consumer savings.

In the ongoing second phase the FTC is assessing whether increased price competition has caused long-term competitive harm to the detriment of consumers. The generic drug industry began complaining about foreclosure in the early 1990s. For over fifteen years, they have said that authorized generics will eliminate them from the marketplace. Yet generic drug manufacturers have enjoyed growth in sales, profits, market capitalization, and share price. These are not the characteristics of an industry experiencing anticompetitive foreclosure and in genuine need of legislative relief from price competition.

In its initial report, the FTC found that authorized generic drugs result in average prices that are 8.1% lower than prices in markets without them.² For the 2004 to 2008 time period of the FTC study, this equates to consumer savings of \$880 million. The FTC also found that authorized generics lead to a 5% output expansion, further contributing to improved health care

¹ This paper has been commissioned by and is submitted on behalf of the Pharmaceutical Researchers and Manufacturers of America (PhRMA). PhRMA represents the country's leading pharmaceutical research and biotechnology companies. Mike Cowie of Howrey LLP and Oliver Grawe of CapAnalysis prepared the report. Oliver Grawe supervised the economic analysis, particularly the analysis focusing on profitability of entry.

² FTC, Authorized Generics: An Interim Report, at 11, June 2009, www.ftc.gov (based on volume-weighted averages and wholesale pricing data).

for patients. The FTC study, the most comprehensive empirical analysis to-date, confirms that consumers receive large, measurable benefits from authorized generic drugs.

The FTC's next report will consider whether authorized generics deter patent-challenge entry or entry based on a paragraph IV certification under the Hatch-Waxman Act. The FTC's initial report suggests that there may be some single-source brand drug markets that are too small to justify patent-challenge entry in light of increased price competition from authorized generics.³ Using the FTC findings, we have identified a range of candidate markets where foreclosure or entry deterrence might be theoretically possible. Empirical analysis demonstrates that nearly all markets are large enough to support profitable entry and that there is only a very small subset of markets (less than 3% of single-source brand drug markets) in which authorized generics could possibly contribute to reduced entry.

The first step in this analysis is to identify single-source brand drug markets that are too small to support patent-challenge entry even without authorized generics. Our analysis shows that the break-even or minimum market size to support patent-challenge entry is about \$50 million in annual sales. This means that prospective entrants are unlikely to fund patent challenge entry into markets below \$50 million in annual sales regardless of price competition from authorized generics. The next step is to identify the break-even market size for competition with authorized generics. Our analysis shows that the break-even market size is about \$110 million. Markets larger than that can support profitable patent-challenge entry despite enhanced price competition from authorized generics.

³ *Id.* at 2 (“We do not directly address the impact of the presence of authorized generics on the decisions of generic companies to initiate paragraph IV challenges, or to seek approval of an ANDA from the FDA.”).

³ *Id.* at 4 n.6 (discussing past studies suggesting an “impact on challenges for drugs with relatively low sales volume” and the need for further analysis comparing “outcomes for drugs with high and low sales volumes”); *see also* Concurring Statement of Commissioner J. Thomas Rosch on the Release of the Commission’s Interim Report on Authorized Generics at 2 n.4, June 2009 (“The Report simply says that in some small markets the revenue reduction is likely to change the calculus of the ANDA generic’s decision making but it goes on to acknowledge that no analysis has been done that would suggest that ‘AG entry deters generic entry prior to patent expiration that otherwise would take place.’”).

There is a limited range of markets – about \$50 million to \$110 million in annual single-source brand drug sales – in which foreclosure of patent-challenge entry is even possible. About 97% of single-source brand drug sales occur in markets with annual sales exceeding \$110 million or below \$50 million.⁴ Thus, the speculative foreclosure claims are inapplicable to nearly all drug markets. Patent challenge entry remains unaffected in these markets and any restriction on authorized generics would deprive consumers of the large savings shown by the initial FTC report.

In its ongoing foreclosure analysis, the FTC must be careful not to discourage price competition with the onset of generic drug availability. Any plausible finding of consumer-harming foreclosure, however limited in time or product scope, must be predicated on robust factual information. Speculation about future harm or ambiguous qualitative evidence cannot match – and will almost certainly jeopardize – the known and measurable consumer savings.

DISCUSSION

I. LONG-TERM COMPETITIVE HARM IS UNLIKELY

The FTC's initial report "does not examine long-term and/or overall effects" of authorized generics and instead focused on the "short term" impact.⁵ In its ongoing report, the FTC is examining the potential long-term impact from the presence of authorized generics. The relevant marketplace data does not support any claim that authorized generics are causing or are likely to cause long-term harm to generic drug manufacturers to the detriment of consumers. Generic drug manufacturers have faced competition from authorized generics for about two decades and have thrived in the face of this additional price competition. This is not an industry suffering from foreclosure or lockout.

⁴ IMS National Sales Perspective, 2008.

⁵ FTC, Authorized Generics: An Interim Report at 1, June 2009, www.ftc.gov.

A. Unsupported Foreclosure Claims Have Been Made For Nearly Two Decades

Some generic drug manufacturers would have the FTC believe that brand drug manufacturers only recently started offering low priced authorized generics. One vocal opponent of authorized generics has stated to the FTC that “[a]uthorized generics began only 2 years ago” – referring to 2004.⁶ In 2006, the President of the Generics Pharmaceutical Association described authorized generics as “the new scam in town.”⁷

However, the sale to consumers of low priced authorized generics has been common for nearly twenty years.⁸ For example, in 1992, the Generics Pharmaceutical Association described authorized generics as “the new thing that’s happening,”⁹ and the New York Times reported that many brand drug manufacturers were marketing low priced authorized generic drugs.¹⁰ The table below identifies some of the authorized generics introduced to consumers in the 1990s.

⁶ David A. Balto on behalf of American Antitrust Institute, Consumer Federation of America et al., Comments to FTC at 6, June 6, 2006, www.ftc.gov; *see also* GPhA, Comments to FTC at 4, June 27, 2006, www.ftc.gov (stating that authorized generics “become so prevalent (circa late 2003)” and “began to proliferate” in 2003); Gilbert’s LLP on behalf of unidentified generic drug company, Comments to FTC at 2, June, 5, 2006, www.ftc.gov (referring to the “dramatic rise of authorized generics in or around 2003”).

⁷ Generic Drugs: The Window Has Loopholes, N.Y. Times, July 1, 2006.

⁸ *See, e.g.*, CRS Report for Congress, Authorized Generic Pharmaceuticals: Effects on Innovation, at 8, Aug. 8, 2006 (authorized generics can be “traced to the early 1990s”); David Reiffen & Michael R. Ward, Branded Generics, 28 Managerial and Decision Economics, May 2007, at 2 (discussing introduction of authorized generics in early 1990s); Beat the Generics By Joining Them, Medical Marketing & Media, Sept. 1992, at 110 (stating that pioneers are “arrang[ing] for a self-controlled generic introduction”).

⁹ Fending Off Generic Competition, Wash. Post, Dec. 15, 1992 (“‘The brands have always been in the generic market,’ said Jay Molishever, spokesman for the Generic Pharmaceutical Industry Association, which represents independent generic drug makers. ‘But they’ve never competed directly with their own products. This is the new thing that’s happening.’”).

¹⁰ All About Generic Pharmaceuticals; Now the Big Drug Makers Are Imitating their Imitators, N.Y. Times, Sept. 20, 1992 (identifying companies).

Authorized Generics Introduced in the 1990s¹¹

Innovator	Drug
Bayer	Ciproflaxin
Bristol-Myers Squibb	Captopril
Ciba-Geigy	Metoprolol
Ciba-Geigy	Diclofenac
GSK	Salbutamol
ICI	Atenolol
ICI	Tomofoxen
Marion Merrell Dow	Diltiazem
Marion Merrell Dow	Sucralfate
Merck	Diflunisal
Pfizer	Nifedipene
Scarle	Verapamil
Schering	Salbutamol
SmithKline Beecham	Triamterene
SmithKline Beecham	Cimetidine
Syntex	Naproxen
Upjohn	Alprazolam
Upjohn	Triazolam
Warner-Lambert	Ticlopidine HCL

Since the 1990s, some generic drug manufacturers fearing the price competition from authorized generics predicted that authorized generics would destroy the industry.¹² The chairman of Mylan Laboratories described authorized generics in 1992 as “a ploy by the brand-name companies to try to drive us out of business.”¹³ The chairman of another generic

¹¹ See CRS Report for Congress, *Authorized Generic Pharmaceuticals: Effects on Innovation*, at 8, Aug. 8, 2006; David Reiffen & Michael R. Ward, *Branded Generics*, 28 *Managerial and Decision Economics*, May 2007, at 11; *As Brand-Generic Alliances Grow, Opponents Cry Foul*, *Drug Store News*, Aug. 23, 2004; *Why Authorized Generics Are Making A Comeback*, *Drug Topics*, Nov. 3, 2002, www.drugtopics.com; CBO, *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, at 50 July 1, 1998; *Endless Motion at Mylan Despite Drug Firm’s Record Quarter*, *Pittsburgh Post-Gazette*, Oct. 27, 1994, at D7; *The Drugmakers vs. the Trustbusters*, *Bus. Week*, Sept. 4, 1994, at 67; *Drug Wars*, *Forbes*, Aug. 29, 1994; *Fending Off Generic Competition*, *Wash. Post*, Dec. 15, 1992, at Z11; *Dolobid, Early Generic Opponents*, *Drugs & Fine Chemicals*, *Chemical Marketing Reporter*, Oct. 5, 1992, at 5; *Beat the Generics by Joining Them*, *Medical Marketing & Media*, Sept. 1992, at 110; *All About Generic Pharmaceuticals; Now the Big Drug Makers Are Imitating their Imitators*, *N.Y. Times*, Sept. 20, 1992.

¹² See, e.g., *Will There Be a Generic Industry Five Years From Now?*, *Medical Marketing & Media*, Apr. 1994, at 26.

¹³ *All About Generic Pharmaceuticals; Now the Big Drug Makers Are Imitating their Imitators*, *New York Times*, Sept. 20, 1992.

manufacturer stated in 1994 that “the goal [of authorized generics] is to drive the generics out of the business.”¹⁴ An industry consultant warned in 1996 that generic drug manufacturers would be “overcome by brand name firms” as a result of authorized generics.¹⁵

A senior executive of Mylan Laboratories told Congress that authorized generics are sold at prices “that gut generic returns.”¹⁶ Other opponents have stated that authorized generics “will destroy this [generic drug] industry,”¹⁷ “could vanquish the generic drug industry,”¹⁸ threaten “to put a dagger through the heart of the generic industry,”¹⁹ will lead to “dire consequences to the generic industry,”²⁰ and “will enable brand companies to squeeze out generic competition by creating a virtual drug monopoly.”²¹ Despite claims made by generic drug manufacturers over the years regarding the potential anticompetitive or foreclosing effect of authorized generics, the marketplace performance metrics (such as sales, profitability, and market capitalization) show that the generic drug industry has been strong and vibrant.

¹⁴ The Drugmakers vs. the Trustbusters, *Bus. Week*, Sept. 4, 1994, at 67 (quoting Morton H. Katz, chairman of Clay-Park Laboratories Inc.).

¹⁵ Bryan A. Liang, *The Anticompetitive Nature of Brand-Name Firm Introduction of Generics Before Patent Expiration*, *The Antitrust Bulletin*, Fall 1996, at 634.

¹⁶ Testimony of Heather Bresch, Sr. VP of Corp. Strategic Development, Office of the CEO, Mylan Laboratories, U.S. Senate Comm. On Aging, July 20, 2006.

¹⁷ Mylan Laboratories, Q3 2006 Earnings Conference Call (Feb. 2, 2006) (quoting Mylan Laboratories’ Vice Chairman and Chief Executive Officer).

¹⁸ David Balto, *We’ll Sell Generics Too*, *Legal Times*, Mar. 20, 2006.

¹⁹ *Generic Drugs: The Window Has Loopholes*, *N.Y. Times*, July 1, 2006 (quoting Sen. Schumer).

²⁰ *The War on Generics – Part I*, the RMP Report, at 10, Sept. 2006, www.therpimreport.com (quoting Kathleen Jaeger, GPhA President).

²¹ *Feds Look Into Battle Over Authorized Generics*, *Investor’s Business Daily*, Aug. 14, 2006 (quoting Kathleen Jaeger, President of GPhA).

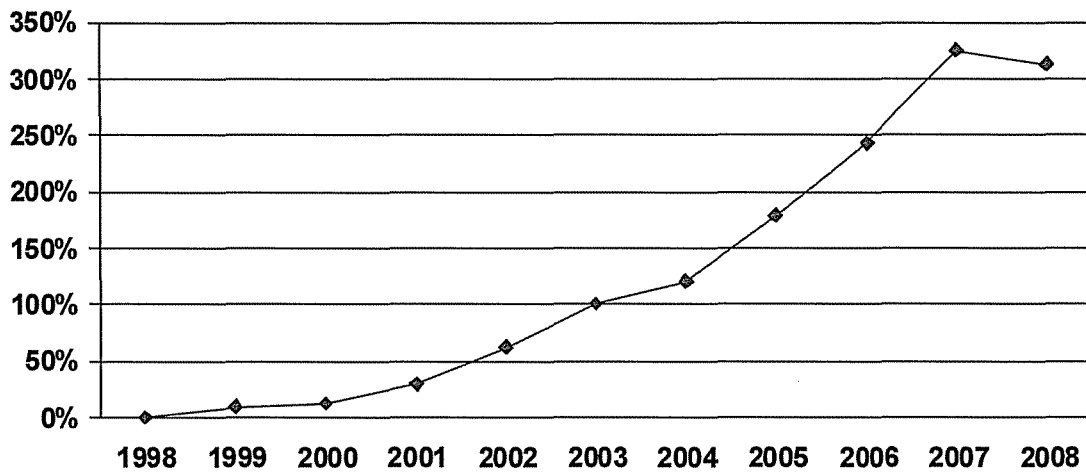
B. Marketplace Realities Undercut The Long-Term Foreclosure Theory

Over the past decade, generic drug manufacturers have enjoyed rising sales and profitability and have been the darlings of Wall Street. The evidence does not support the need for legislative relief from price competition to ensure their long-term survival.

1. Sales and Profitability Are Growing

During the period from 1998 to 2008, U.S. generic drug sales have grown over 300%.

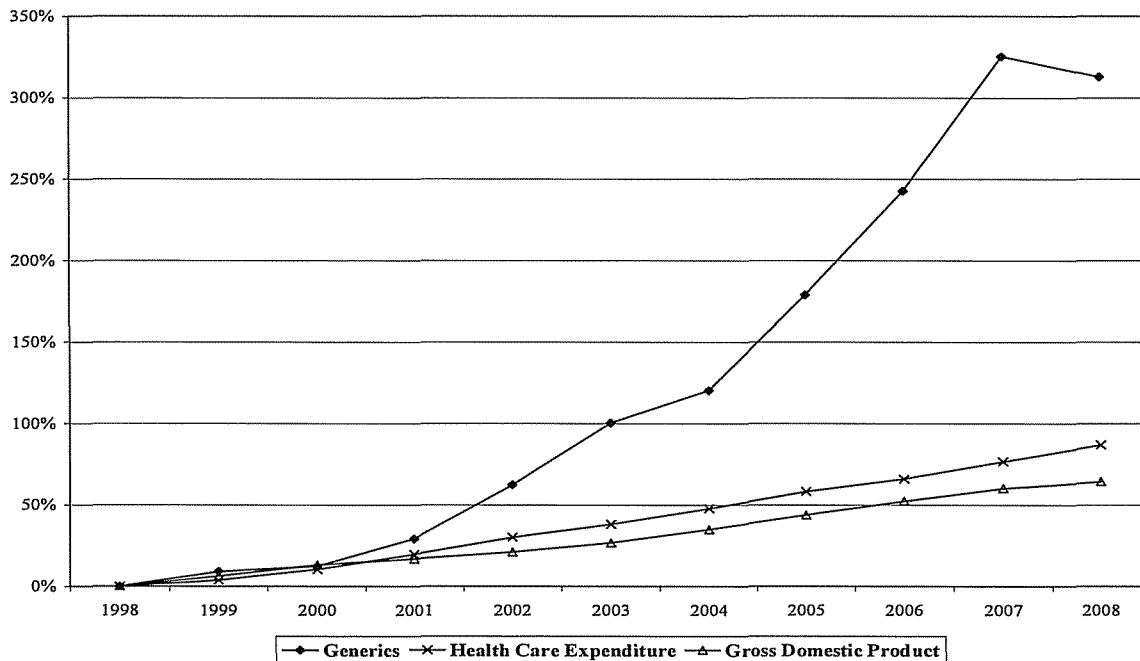
U.S. Generic Drug Sales, 1998-2008²²



The growth rate during this period far exceeds U.S. gross domestic product and national medical care spending.

²² IMS data.

Sales Growth of U.S. Generic Drugs vs. Benchmarks, 1998-2008²³



As is widely reported, generic drug sales will continue to grow as more products come off patent in the next several years.²⁴ Given the projected growth, generic drug manufacturers can be expected to expand and enter markets, not to retreat or exit.²⁵ Speculative antitrust

²³ *Id.*; U.S. Department of Commerce, Bureau of Economic Analysis (data on national medical care expenditure and gross domestic product).

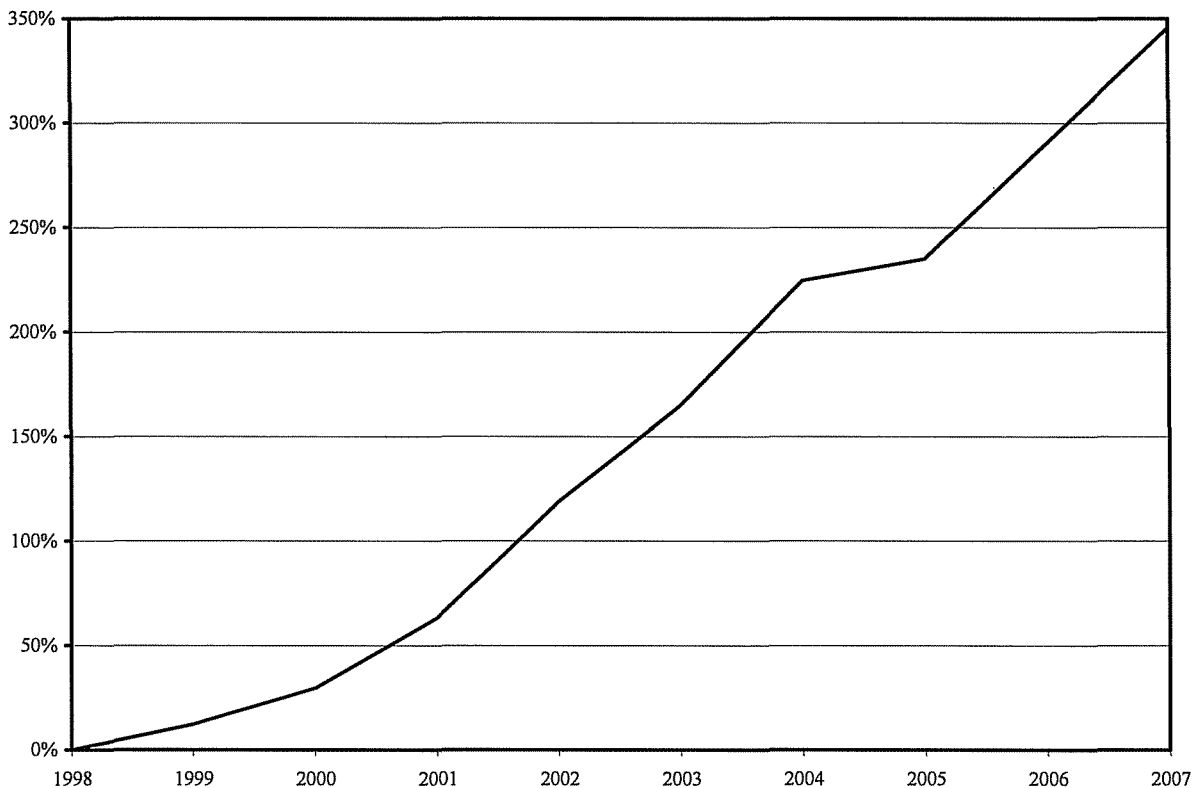
²⁴ See, e.g., Merrill Lynch, *Generic Perspectives*, Mar. 2, 2009, at 2, 4 (projecting nearly 50% growth between 2007 and 2018).

²⁵ Baker, *The Problem with Baker Hughes and Syfy: On the Role of Entry in Merger Analysis*, 65 *Antitrust L.J.* 353, 363 (1997) (entry is likely where it “would be profitable to carry out”); FTC and Justice Department, *Horizontal Merger Guidelines*, 3.3 Likelihood of Entry (1997) (the ability to “capture a share of reasonably expected growth in market demand” presents sales opportunities for new entrants, while “the prospect that an entrant will share in a reasonably expected decline in market demand” reduces sales opportunities for new entrants); *Metro Mobile CTS, Inc. v. NewVector Commc’ns, Inc.*, 892 F.2d 62, 64 (9th Cir. 1989) (“Because untapped potential provides a mouth-watering incentive for vigorous competition, it is axiomatic that monopoly power is unlikely to arise in dynamic industries marked by a rapidly expanding volume of demand and low barriers to entry.”); *United States v. Siemens Corp.*, 621 F.2d 499, 507 (2d Cir. 1980) (entry unlikely where “the period of rapid market growth has passed or at least ebbed and ... the future will be one of slow or gradual growth”); *United States v. Syfy Enters.*, 903 F.2d 659, 667 (9th Cir. 1990) (entry was likely where the market was marked by “healthy and growing demand”).

foreclosure concerns are the least plausible in industries experiencing this kind of phenomenal growth.

It is not just sales revenues that are growing. Generic drug industry profitability also is growing.

Gross Profit Growth of Top 10 Generic Drug Manufacturers, 1998-2007²⁶



²⁶ See The Future of Generic Pharmaceuticals, PCMA Presentation, Oct. 24, 2005 (listing top 10 generic drug companies based on prescription data from IMS NPA Plus, June 2005). The ten companies included in this analysis are: Alparma, Altana, Barr, Ivax, Mylan Generic, Par, Perrigo, Taro, Teva, and Watson. Profitability data for each company was collected from publicly-available annual reports and SEC filings of the companies from 1998-2007. The analysis does not include Novartis and Tyco (Mallinckrodt) because these companies do not separately report generic drug data and they have a significant amount of other business. The analysis does not include Qualitest because it is privately held and the relevant profitability data is unavailable. The analysis added Altana, Taro, and Perrigon as the next largest generic drug manufacturers with available data. For reports showing rising profit margins, see Citigroup, Specialty Pharmaceuticals, June 16, 2005 at 4 (showing “[g]eneric sector gross margins” as 49% in 2002 and 52% in 2004); Bank of America, Future of Generics: A Wall Street Perspective (showing generic “industry gross margin” increasing from 44% in 2001 Q1 to 46% in 2005 Q1).

Opponents of authorized generics have highlighted the 2002 to 2005 period as the time in which generic drug manufacturers suffered from the “Rising Tide of Authorized Generics.”²⁷ However, the data shows rising generic drug profits, as well as sales, during this time period.

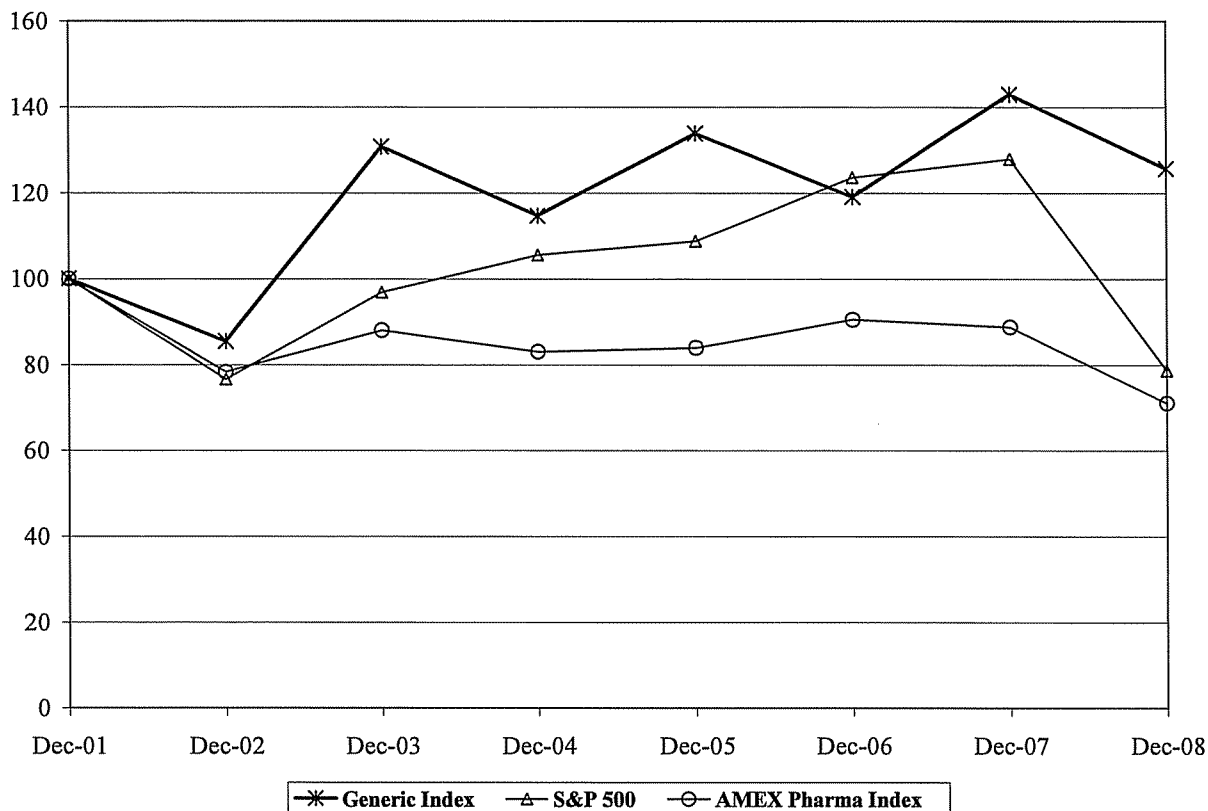
2. Wall Street Valuations Are Growing

Wall Street views the generic drug industry as well positioned to prosper. Generic drug manufacturers continue to outperform the Standard & Poor’s 500 and a leading stock index for brand drug manufacturers.²⁸

²⁷ Tim Gilbert, Gilbert’s LLP, Hatch-Waxman: Upsetting the Balance, ABA Antitrust Section (quantifying the number of authorized generic products by year and referring to 2002-05 growth as “the rising tide of authorized generics”).

²⁸ Citigroup, Specialty Pharmaceuticals, June 16, 2005 at 2 (showing generics outperforming S&P 500 from 2002-05); Bank of America Securities, Future of Generics: A Wall Street Perspective at 5-6, Mar. 2006 (shows that Bank of America Securities Generic Index or BASGI outperforming S&P 500).

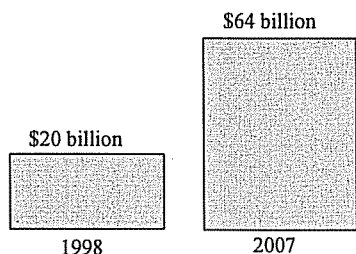
Generic Drug Stock Performance vs. Benchmarks, 2001-08²⁹



This chart shows that an investment of \$100 in 2001 would yield under \$80 for Amex Pharma Index (the brand drug manufacturer index) and the Standard & Poor's 500, and over \$120 for the generic drug manufacturer index. The continued high valuation of generic drug industry can also be measured by market capitalization – the share price multiplied by the number of outstanding shares.

²⁹ The companies included are the generic drug companies traded on the New York Stock Exchange, NASDAQ, or OTC as of December 31, 2005. Abraxis, Alpharma, Altana, Andrx, Barr, Dr. Reddy's, Impax, Ivax, KV, Mylan, Par, Perrigo, Taro, Teva, and Watson.

Market Capitalization of Generic Drug Manufacturers, 1998-2007³⁰



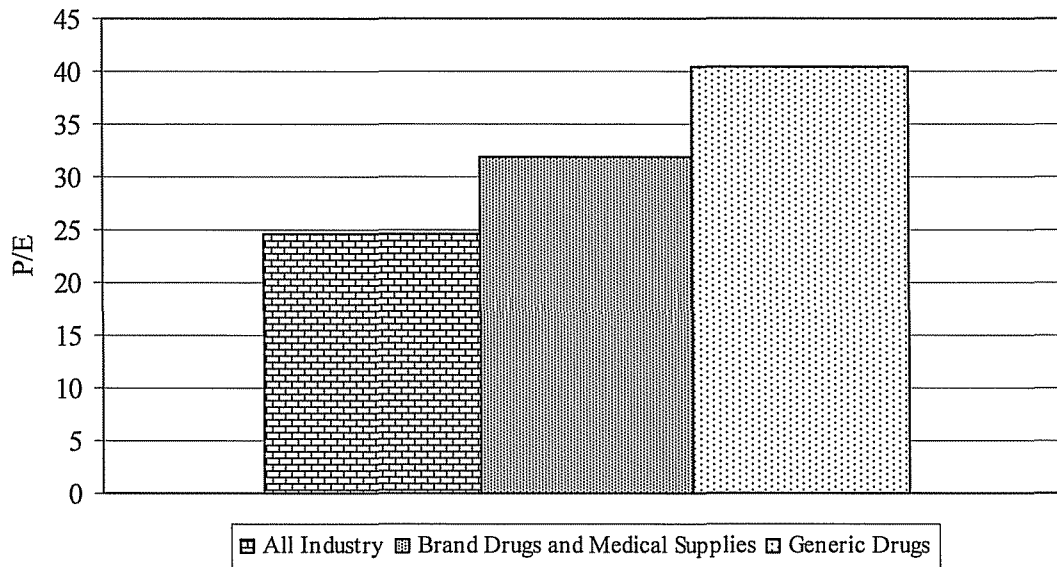
Companies and investors have spent large sums to acquire ownership and control of generic drug manufacturers. Since 2001, acquisitions of generic drug manufacturers have exceeded \$60 billion in value.³¹

For acquisitions of generic drug manufacturers, the acquisition-price-to-earnings ratios or P/E ratios, a measure of the acquiring company's expectations of future profitability for the acquired business, exceed overall industry benchmarks. This is the ratio of the price paid to acquire the generic drug company to the generic drug company's earnings or profitability. The chart below shows that the P/E ratios for acquisitions of generic drug companies far exceed those of brand name drug companies, medical device suppliers, and other industries.

³⁰ The companies included are the generic drug companies traded on the New York Stock Exchange, NASDAQ, or OTC as of December 31, 2005. Abraxis, Alparma, Altana, Andrx, Barr, Dr. Reddy's, Impax, Ivax, KV, Mylan, Par, Perrigo, Taro, Teva, and Watson. The outstanding shares data comes from the companies' publicly-available annual reports and SEC filings. The share price data comes from 10k Wizard and Yahoo Finance. Alparma's 2005 market capitalization is based on December 16, 2005 data because the company was acquired shortly thereafter.

³¹ Irving Levin & Associates; M&A database; Factset Mergerstat LLC; Bloomberg; Thompson Reuters.

**Acquisitions of Generic Drug Manufacturers:
Price-to-Earnings Ratio vs. Benchmarks, 2001-08³²**



The companies financing these acquisitions believe that the current and historical earnings of the generic drug manufacturers understate their future competitive significance. The high P/E ratios reflect the marketplace reality that generic drug manufacturers have very healthy long-term prospects.

Despite many years of competition with authorized generics, generic drug manufacturers have not suffered competitive harm of the type seen in markets characterized by actual anticompetitive foreclosure. This review of basic marketplace performance metrics – sales, profitability, market capitalization, and P/E ratios – shows that generic drug manufacturers do not need regulatory relief from price competition to bolster their long-term competitive prospects.

³² Factset Mergerstat LLC; Thompson Reuters.

II. THE FTC PRICING ANALYSIS SHOWS \$880 MILLION IN CONSUMER SAVINGS

The FTC's initial report further undermines the generic drug industry claim of harm to competition. The FTC analyzed pricing of prescription drugs in which entry occurred during a 180-day marketing exclusivity period. The review covered the time period from 2004 to 2008 and the pricing of 95 prescription drugs – 53 with authorized generics and 42 without authorized generics. The FTC measured (1) the average price of the single-source brand drug in the three months preceding generic drug entry and (2) the average drug price (both brand and generic) during the 180-day marketing exclusivity period.³³ To determine whether consumers benefitted from authorized generics, the FTC compared the price decline for drugs with authorized generics to the price decline for drugs without any authorized generics.

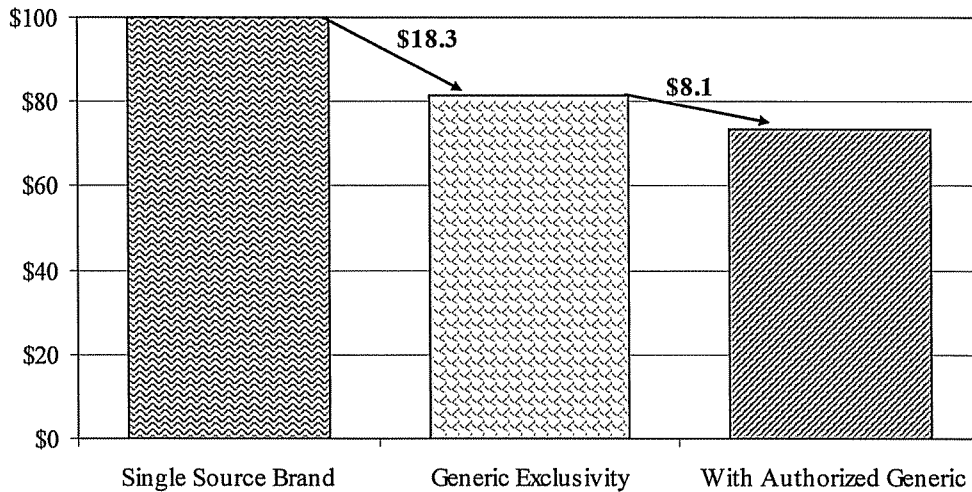
The FTC study shows that entry of a single generic drug manufacturer dropped the price of a sample \$100 prescription by \$18.3, to \$81.7.³⁴ Adding an authorized generic drove the price down another \$8.1, to \$73.6.³⁵

³³ FTC, Authorized Generics: An Interim Report, at 5-6, June 2009, www.ftc.gov.

³⁴ *Id.* at 11.

³⁵ *Id.*

**Price Impact of Authorized Generics, Weighted Avg., Wholesale Data
(sample \$100 prescription)**



On a dollar basis, the benefits to consumers found by the FTC are substantial. For the drugs in the FTC study, this 8.1% additional price decline resulted in consumer savings of \$880,220,841. The consumer savings for each drug in the FTC study is calculated by applying the FTC's 8.1% price erosion rate to the single-source brand drug revenues for the relevant time period – the six-month period preceding entry.³⁶ The FTC limited its analysis to authorized generics introduced during the 2004 to 2008 time period. The measurable consumer savings already realized are in the billions when considering the time period before 2004 as well as 2009.

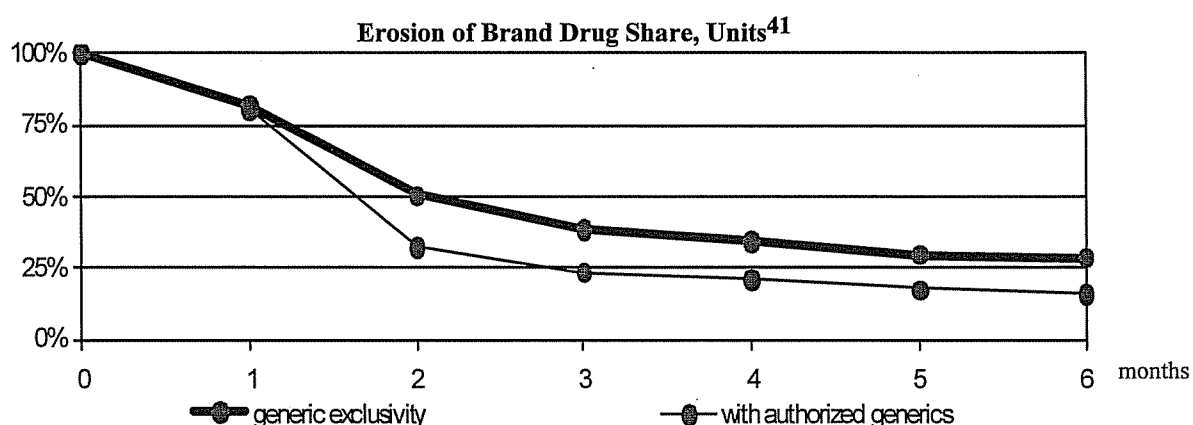
The finding of \$880 million in additional price reductions is consistent with earlier FTC analyses of generic drug competition. The FTC found ten years ago that the entry of a second generic drug drove down average prescription drug prices.³⁷ Following fact-intensive

³⁶ Consumer savings = .081*(single-source brand drug revenue for the six-month period preceding generic entry). To arrive at the \$880 million consumer savings sum, we applied this calculation for the drugs listed in table A6 of the FTC report. This is based on IMS National Sales Perspective data.

³⁷ FTC Bureau of Competition and Policy Planning, In the Matter of the 180-Day Generic Drug Exclusivity for ANDAs, Nov. 4, 1999, www.ftc.gov (“Generally, the staff has found that the more generic versions of the same drug product that are on the market, the lower the price consumers pay for a generic version, regardless of which generic company is marketing the product. For example, the entry of a second generic drug product generally doubles the price decrease introduced by the first generic product from the branded drug product’s price.”).

investigations, the FTC has also brought merger enforcement actions to preserve the benefits of the additional price competition brought about by authorized generics.³⁸

The recent FTC report highlights the important role authorized generics play in eroding brand drug sales. Patients may perceive authorized generics, often manufactured and distributed by the brand drug company, to be closer substitutes to the brand drug.³⁹ The FTC found that the added competition from authorized generics leads to “quicker and more pronounced” erosion of brand drug sales.⁴⁰



The FTC found greater and faster substitution from brand to generic drugs. By the second month, the brand drug share dropped to 51% without authorized generics and all the way down to 33% with authorized generics.⁴²

³⁸ In the Matter of Teva Pharmaceutical Industries Ltd. and Ivax Corp., Decision and Order, Jan. 2006, www.ftc.gov (requiring divestiture of 4 authorized generic licensing agreements in order to reduce “the likelihood that customers would be forced to pay higher prices”); *see also* In the Matter of Watson Pharmaceuticals, Inc. and Andrx Corp., Complaint at ¶¶ 9, 12, Oct. 2006, www.ftc.gov (treating authorized generic manufacturer as a separate and independent competitor in a generic drug market).

³⁹ Prasco, Authorized Generics, FAQs, www.authorizedgenerics.com (“Consumers also have the identical product experiences with Authorized Generics as they do with brand products in areas such as taste, color, mouth feel and shape.”).

⁴⁰ FTC, Authorized Generics: An Interim Report, at 15, June 2009, www.ftc.gov.

⁴¹ *Id.* at 15-16.

⁴² *Id.*

Moreover, the FTC found that authorized generics result in an expansion of prescription drug output, leading to additional benefits in patient health. It found that prescriptions dispensed are about 5% greater in markets with authorized generics compared to markets with generic exclusivity.⁴³ For markets with generic exclusivity, output declines to 97.6% of pre-entry output.⁴⁴ Authorized generics result in output that is 103% of pre-entry output.⁴⁵ This prescription drug output expansion associated with authorized generics improves overall health outcomes and contributes to greater patient health.

III. CONSUMER SAVINGS SHOULD BE MEASURED USING WHOLESALE DATA AND WEIGHTED AVERAGE PRICES

A. The Wholesale Data Carries Far More Weight

The FTC used both retail transaction data and wholesale transaction data to measure the price-lowering effect of authorized generics.⁴⁶ When using retail data, the FTC found that authorized generics had a price erosion effect ranging from .6% to 4.2%.⁴⁷ The retail data is based on sales by pharmacies.⁴⁸ The wholesale data includes direct sales by drug manufacturers and sales by wholesalers to all distribution channels.⁴⁹ While the FTC used both databases, it recognized that the retail data has “several limitations.”⁵⁰

⁴³ *Id.*

⁴⁴ *Id.* at 15 (setting forth data showing that “drugs tended to be dispensed somewhat less frequently” during generic exclusivity period compared to pre-entry output).

⁴⁵ *Id.* at 16.

⁴⁶ *Id.* at 3.

⁴⁷ *Id.* at 7-8 (.6% for volume weighted average retail prices and 4.2% for un-weighted average retail prices).

⁴⁸ IMS National Prescription Audit Plus, www.imshealth.org (“The *National Prescription Audit Plus* measures national prescriptions of all pharmaceutical products that are sold from the retail pharmacies to the consumer.”).

⁴⁹ IMS National Sales Perspectives, www.imshealth.org (“Advantages . . . Capture direct sales”); FTC, Authorized Generics: An Interim Report at 9 (“The wholesale level transactions in our data represent purchasers of drugs by pharmacies from manufacturers and wholesalers.”).

⁵⁰ FTC, Authorized Generics: An Interim Report at 9, June 2009, www.ftc.gov.

One of the limitations of the retail data is that it omits several distribution channels such as hospitals, clinics, other institutions (e.g., prisons and universities), home health care, and HMOs.⁵¹ As Commissioner Rosch observed, “the [FTC] Report admits that retail prices do not reflect all of the payments consumers make for prescription drugs.”⁵² The channels that are omitted from the retail pricing data represent about 23% of U.S. prescription drug sales.⁵³ In contrast, the wholesale data represents 100% of U.S. prescription drug sales.⁵⁴ The omission of non-retail channels may bias the results, as several federal agencies have found that the omitted channels have lower average prescription prices than retail pharmacies.⁵⁵

The use of retail data to study manufacturer pricing creates other problems that are well recognized by economists. Retailers make pricing decisions based on the retail service levels, retailer brand or reputation, impact on other retail sales (e.g., magazines or soda), local competition, and other competitive dynamics unique to that distribution channel. For these

⁵¹ *Id.* at 9 (“Also, the source of our retail data, IMS Health’s National Prescription Audit, only tracks sales at retail pharmacies. . . . One benefit of the wholesale data is that it contains information about purchases by more outlets, such as non-retail pharmacies, hospitals, and HMOs, for instance, than were covered by the retail data.”).

⁵² Concurring Statement of Commissioner J. Thomas Rosch on the Release of the Commission’s Interim Report on Authorized Generics at 2, June 2009”).

⁵³ Kaiser Family Foundation, Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain, at 11, Mar. 2005 (showing that the excluded channels represent 23% of U.S. prescription drug sales, based on IMS National Sales Perspectives data extracted in Feb. 2005).

⁵⁴ www.imshealth.org, IMS National Sales Perspectives (“This portfolio of services offers you insights to 100% of the total U.S. pharmaceutical market distribution channels. . . . Advantages . . . 100% channel coverage”).

⁵⁵ See Department of Health and Human Services, Report to the President: Prescription Drug Coverage: Spending Utilization and Prices, chapter 3 at 9, Apr. 2000, <http://aspe.hhs.gov> (for 100 top selling brand name drugs, the average price relative to average prices of retail pharmacies are: retail pharmacies 100%, long-term care 95%, hospitals 91%, clinics 91%, HMOs 82%, and federal facilities 58%); CBO, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry, chapter 3 at 25 (July 1998), www.cbo.gov (“hospitals and clinics paid 9 percent less than retail pharmacies in 1994, and HMOs paid 18 percent less”).

reasons, senior economists from the FTC and the Justice Department have warned about the danger of using retail data to measure or evaluate manufacturer pricing.⁵⁶

The express purpose of the FTC study is “to build on the economic literature” by providing “a robust and up-to-date analysis of the competitive effects of authorized generics based on actual company data.”⁵⁷ Reliance on incomplete retail data does not advance this important objective.

B. Average Drug Prices Should Be Volume-Weighted

Using the wholesale data, the FTC found that authorized generics led to 6.5% deeper price erosion compared to competition without authorized generics. This 6.5% sum is based on un-weighted average prices – placing equal weight on each of the drugs in the FTC study. By placing too much emphasis on limited observations or low volume products and too little weight placed on high volume products, un-weighted averages may inflate or deflate the average prices.

The FTC also calculated a volume-weighted average with greater weight placed on higher selling drugs and less weight placed on lower selling drugs.⁵⁸ The use of volume-weighted averages is the common method used by FTC economists to measure average price

⁵⁶ See Froeb, Hosken, & Pappalardo, Economics Research at the FTC: Information, Retrospectives, and Retailing, at 27-28, FTC Bureau of Economics, www.ftc.gov (expressing concern about the assumption that retailers play “the passive role” of “simply marking up the wholesale price of goods to cover their costs” without providing any additional value or services for their customers); Werden, Froeb, & Scheffman, A Daubert Discipline for Merger Simulation, Antitrust, at 18 (Feb. 16, 2004), www.ftc.gov (“The other [wrong assumption] is that of retailers following a simple rule of thumb and applying a constant percentage mark-up to the prices they pay to manufacturers.”); American Bar Association Section of Antitrust Law “Brown Bag” Program, Interview with the FTC’s New Director of the Bureau of Economics, Antitrust Source 4 (Sept. 26, 2001), www.abanet.org (it “doesn’t make any sense” to rely on retail price data when “what we’re really interested in . . . is the competition between manufacturers”); Scheffman & Coleman, FTC Perspectives on the Use of Econometric Analyses in Antitrust Cases, at 11 (2002), www.ftc.gov (“As a matter of economic theory (and common sense), there is a relationship [between manufacturer level and retail level pricing], but that relationship may be complex. Thus, it is very important to develop the relevant evidence bearing on pricing at the manufacturer level.”); Dennis Carlton Statement, FTC Empirical Industrial Organization Roundtable, at 10 (Sept. 11, 2001), www.ftc.gov (there are too many assumptions made when attempting “to use retail data to say something about a merger among manufacturers”).

⁵⁷ FTC Notice, Request for Comments on Information Requests for Authorized Generic Drug Study, at 3, Mar. 29, 2006; FTC, Congressional Budget Justification, Fiscal Year 2007, at 10, Feb. 6, 2006.

⁵⁸ FTC, Authorized Generics: An Interim Report at 8, June 2009, www.ftc.gov.

discounts or differences. The FTC uses this approach for data-intensive policy studies.⁵⁹ It also uses volume-weighted averages when evaluating pricing for purposes of antitrust enforcement.⁶⁰ When using wholesale data and volume-weighted averages, the FTC found that authorized generics led to 8.1% greater price erosion.

Price Declines: Un-weighted vs. Volume Weighted Averages

	un-weighted avg. price decline	weighted avg. price decline
with authorized generics	28.8%	26.4%
without authorized generics	22.3%	18.3%
	6.5%	8.1%

IV. THE REDUCTION IN GENERIC MANUFACTURER PROFITS IS UNLIKELY TO FORESTALL ENTRY

The FTC has yet to make any findings addressing the theory that authorized generics have resulted in anticompetitive marketplace foreclosure that has caused actual consumer harm.⁶¹ A key remaining issue is whether entry has become unprofitable in relatively small drug markets as a result of increased price competition from authorized generics.⁶²

Patent-challenge entry is far more dependent on the overall size of the single-source brand drug market than the presence or absence of authorized generics. Nearly all markets are

⁵⁹ See, e.g., FTC, Pharmacy Benefit Managers: Ownership of Mail Order Pharmacies, at 33, Aug. 2005, www.ftc.gov (“the Commission staff compared the weighted average of mail and retail prices for all prescriptions”); *id.* at D-4 (“The average price for a drug type within a given channel is calculated by taking the weighted average of the prices of all drugs, where each price is weighted according to the total number of prescriptions dispensed for that drug in both channels combined.”).

⁶⁰ In the Matter of South Georgia Health Partners LLC, Complaint at ¶ 41, Oct. 2003, www.ftc.gov (“SGHP’s price list [was] 187% of RBRVS, on a weighted average basis”).

⁶¹ FTC, Authorized Generics: An Interim Report at 2, June 2009, www.ftc.gov (“We do not directly address the impact of the presence of authorized generics on the decisions of generic companies to initiate paragraph IV challenges, or to seek approval of an ANDA from the FDA.”).

⁶² *Id.* at 4 n.6 (discussing past studies suggesting an “impact on challenges for drugs with relatively low sales volume” and the need for further analysis comparing “outcomes for drugs with high and low sales volumes”); see also Concurring Statement of Commissioner J. Thomas Rosch on the Release of the Commission’s Interim Report on Authorized Generics at 2 n.4, June 2009 (“The Report simply says that in some small markets the revenue reduction is likely to change the calculus of the ANDA generic’s decision making but it goes on to acknowledge that no analysis has been done that would suggest that ‘AG entry deters generic entry prior to patent expiration that otherwise would take place.’”).

large enough to support profitable patent-challenge entry alongside authorized generic competition. A foreclosure story can only make sense for single-source brand drug markets large enough to support profitable patent-challenge entry without any authorized generic competition and small enough so that the additional competition would make patent-challenge entry unprofitable. These markets in which foreclosure is even theoretically possible are a very small subset of drug markets (about 3%). The \$880 million in realized savings far outweigh the speculative foreclosure claims that are inapplicable to about 97% of all drug markets.

A. Markets Below \$50 Million Are Too Small To Support Patent-Challenge Entry Even Without Authorized Generics

Some drug markets are too small in profit opportunity to justify patent-challenge entry with or without price competition from authorized generics. A generic drug manufacturer considering entry must account for the costs of patent litigation and the risk of losing the patent litigation. Even if successful in the patent litigation, entry in relatively small drug markets may be unprofitable. Earlier reports have estimated that the break-even market size is about \$50 million for patent-challenge entry without authorized generics.⁶³ The implication is that entry is unlikely in markets under \$50 million in size even in the absence of price competition from authorized generics.

Using the findings of the initial FTC report, we have estimated the break-even market size needed to support profitable patent challenge entry without authorized generic competition. The first step in the analysis is to estimate the sunk costs or the costs that would be lost.⁶⁴ The

⁶³ Morgan Stanley, *Quantifying the Impact from Authorized Generics*, Dec. 9, 2004, at 8; Greenstone/Pfizer, *Do Authorized Generics Benefit Consumers?*, at 3, July 2005.

⁶⁴ Reiffen and Ward, *Branded Generics*, 28 *Managerial and Decision Economics* 251, 259, 2007 (analysis focuses on whether paragraph IV filer “can earn quasi-rents at least as high as the fixed costs of entering”); FTC, *Generic Drug Company Special Order at Request 17, Authorized Generic Study* (requesting information on the “sunk” costs of entry).

FTC focuses on sunk costs when evaluating profitability of entry in a particular market.⁶⁵

Relevant cost items to consider are as follows:

Costs of Patent-Challenge Entry⁶⁶

	Costs	Costs + Cost of Capital
Patent Litigation	\$5,500,000	\$6,552,665
Generic Drug Development/ ANDA Filing	\$2,500,000	\$3,193,835
	\$8,000,000	\$9,746,493

The American Intellectual Property Law Association recently testified before Congress that the average cost of high stakes patent litigation is \$5.5 million.⁶⁷ This \$5.5 million sum is at the high end of the range of other publicly-available estimates of patent litigation costs.⁶⁸ The expected patent litigation costs at the relevant time period of the FTC’s analysis --- 2004 to 2008 – should be used in assessing whether any actual foreclosure has occurred in the marketplace. We have assumed that the patent litigation costs are fully paid at the outset of the filing and have not attempted to spread the costs over the life of the patent litigation.

⁶⁵ FTC and Justice Department, Horizontal Merger Guidelines, at § 3, www.ftc.gov (profitability analysis focuses on the “sunk costs” of entry).

⁶⁶ In its information requests to generic drug manufacturers, the FTC asked for cost data on these particular items – generic drug development ANDA filing costs, and litigation costs. FTC, Generic Drug Company Special Order at 17. This estimate of \$9.7 million in entry costs is similar to Wall Street estimates. *See* Bear Stearns, FDLI’s Conference on Two Decades of Hatch-Waxman, Dec. 1-2, 2004, at 6 (estimating entry costs of \$10 million including “ANDA development” and litigation costs); Morgan Stanley Equity Research, Qualifying the Impact from Authorized Generics, at 8, Dec. 2004 (estimating \$10 million including “bioequivalency study” and litigation costs). The cost of litigation at \$5.5 million is assumed to be all incurred 30 months prior to entry at the end of the 30-month stay. The cost of the ANDA at \$2.5 million is all incurred 42 months prior to entry.

⁶⁷ Statement of Teresa Stanek Rea, President of American Intellectual Property Law Association, Hearing on Biologics, House Judiciary Comm., at 6, July 14, 2009 (“The median average cost of a patent infringement case involving more than \$25 million dollars was about \$5,500,000.”).

⁶⁸ R. Margiano, Cost and Duration of Patent Litigation, *Managing Intellectual Property*, Feb. 1, 2009 (“The average patent litigation lasts about two years and costs about \$3 million.”); Genetic Engineering & Biotechnology News, *Biobusiness Channel*, Vol. 26, No. 7, Apr. 1, 2006 (“In the Northern District of California . . . a good rule of thumb is to expect \$3 million in fees for the first patent in suit and \$1 million for each additional patent to be litigated.”); *Patent World*, Sept. 2004 (“the average cost of bringing a patent litigation is almost \$2 million”).

A generic drug manufacturer considering entry will have to conduct some generic drug development work or bioequivalence studies to establish to the Food and Drug Administration that it can manufacture a bioequivalent generic drug. While publicly-available cost estimates range from \$1-2 million, we have conservatively estimated \$2.5 million for the ANDA filing supported by bioequivalence studies.⁶⁹ These costs also must be considered at the relevant time period of the FTC study (2004 to 2008) before reaching any conclusions about historical foreclosure.

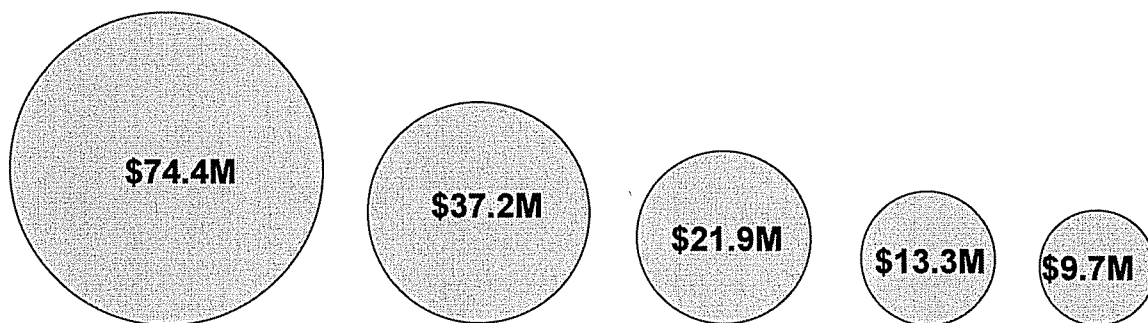
The time value of money or the cost of capital should also be accounted for when evaluating the profitability of entry. We used a weighted average cost of capital of 7.23% based on an index of generic drug manufacturers.⁷⁰ This increases the expected costs of entry from \$8 million to about \$9.7 million.⁷¹ Using the FTC findings, we have estimated the break-even market size for a patent-challenge entrant seeking to recoup \$9.7 million in entry costs.

⁶⁹Canadian Generic Pharmaceutical Association, *Generic Drugs, Same Quality, Low Price* (“Typical costs for conducting bio-equivalency studies are in the range of \$1-\$1.5 million per product.”); Morgan Stanley Equity Research, *Qualifying the Impact from Authorized Generics*, at 8, Dec. 2004 (estimating “\$1-2 million for the bioequivalency study”); Berndt et al., *Authorized Generic Drugs, Price Competition and Consumers’ Welfare*, at 793, *Health Affairs*, Vol. 26 No. 3, May/June 2007 (“Both Reiffen and Ward and Aidan Hollis place the typical cost of filing an ANDA at less than \$1 million.”).

⁷⁰ FTC and Justice Department, *Horizontal Merger Guidelines*, at § 3.3, *Likelihood of Entry*, www.ftc.gov (analysis should include “an appropriate rate of return for invested capital”).

⁷¹ The source for the cost of capital (7.23%) is Ibbotson Associates, a leading authority in this area. *See* Ibbotson Custom Valuation Analysis, Valuation Date: Sept. 30, 2009. At our request, Ibbotson measured the cost of capital for the leading generic drug manufacturers. Ibbotson used the top 18 generic drug manufacturers for which data was available. Companies not publicly traded or privately held were not included in the peer group due to data constraints. Ibbotson’s cost of capital is based on the Capital Asset Pricing Model (CAPM). The 18 companies in the generic drug industry peer group are: Covidien, Caraco Pharmaceutical Laboratories, Catalyst Pharmaceutical Partners, Elite Pharmaceuticals, Hi-Tech Pharmacal Co., Helicos BioSciences Corporation, K-V Pharmaceutical Company, Mylan Inc., Novartis, Orchid, Perrigo, Par Pharmaceutical Companies, Dr. Reddy’s, Rx for Africa, SeraCare Life Sciences, Tara Pharmaceutical Industries, Teva Pharmaceuticals USA, and Watson Pharmaceuticals.

**Break-Even Profitability, Recovery of Entry Costs,
Without Authorized Generics**



Annual Pre-Entry Brand Revenue	6-Month Pre-Entry Brand Revenue	Profitability After Price Erosion	ANDA Share	Litigation Risk
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The prospective entrant would expect to earn over \$10 million – enough to recover the expected costs of entry – in a drug market with annual sales of \$74.4 million. The above analysis, supported by the FTC findings, adjusts the revenue opportunity to focus on a six-month period, accounts for the expected decline in prices following generic drug entry,⁷² expresses the market size based on profitability of sales by accounting for the cost of product manufacturing and shipping,⁷³ adjusts the market opportunity to account for the entrant’s expected market

⁷² The FTC found 18.3% price erosion during the period of generic exclusivity. FTC Authorized Generics: An Interim Report at 11, June 2009, www.ftc.gov (based on volume-weighted wholesale data).

⁷³ We estimate that the cost of product manufacturing and shipping is 23% of revenue. This does not take into account the significant costs associated with research and development, overhead, taxes, legal and regulatory expenses, and sales and marketing costs. The 23% estimate for product manufacturing and shipping costs is based on publicly-available 2008 data from twelve leading brand drug manufacturers. See CapAnalysis Review of Profitability Data, Oct. 2009. We excluded manufacturers whose financial data is aggregated with large other business such as medical devices or animal health.

The third circle’s value is $\$37.2 \times (D-v)$, where D is the % of pre-entry price that remains after generic entry and v is the fraction of the pre-entry price that represents cost of goods. For generic entry without an authorized generic, $D = .817$ and $v = .23$. Hence the value of this third circle is: $\$37.2 \times .587 = \21.84 . The model assumes that generic drug costs for product manufacturing and shipping equates to brand drug costs for product manufacturing and shipping (23%). This may result in understatement of the profitability of entry, as some generic drug manufacturers have touted their production efficiency relative to brand drug manufacturers.

share,⁷⁴ and accounts for the litigation risk or the risk that the paragraph IV filer will lose the patent case.⁷⁵

This analysis does not account for the first-mover advantage.⁷⁶ After expiration of the six-month exclusivity period, the generic drug manufacturer that entered through a paragraph IV filing may have a competitive advantage over other generic drug manufacturers and earn relatively larger sales by virtue of its earlier entry and established marketplace presence. The break-even market size is lower (i.e., less than \$74 million) when accounting for first-mover advantage.

The break-even analysis above is based on entry costs (\$9.7 million) that are likely overstated. While we included generic drug development and ANDA filing costs, these are not sunk costs. Generic drug manufacturers would incur those costs to enter in the United States at a later time – after patent expiration. The generic product development or bioequivalence studies would be used for entry then as well. These costs are not specific to entry through a U.S. patent challenge or an FDA filing. Stated differently, these costs can be and are commonly recovered through later generic drug sales in the United States or through sales outside the United States.

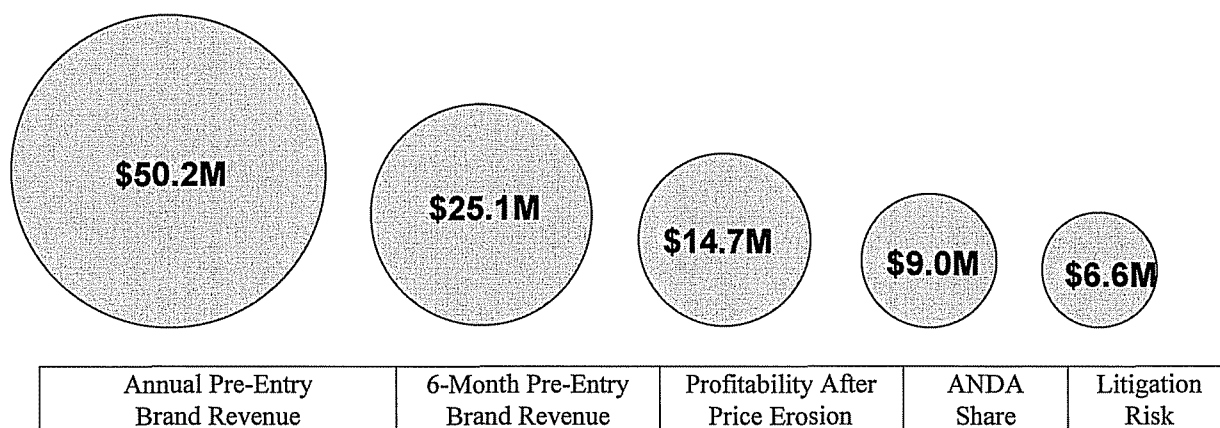
⁷⁴ The FTC found an average market share of 61.1% for generic drug manufacturers during the 180-day exclusivity period when not facing competition from an authorized generic. FTC Authorized Generics: An Interim Report at 11, June 2009, www.ftc.gov. The fourth circle's value is \$21.9*.611, or \$13.3.

⁷⁵ The fifth circle's value is \$13.3*.73, or 9.7. Manufacturers considering entry must account for the likelihood of success in the patent case. An earlier FTC study found that paragraph IV filers prevailed in 73% of court decisions. FTC, Generic Drug Entry Prior to Patent Expiration: An FTC Study, July 2002, at 19-20, www.ftc.gov (“There were court decisions on 40 different drug products. . . Generic applicants prevailed for 29 out of 40 drug products (or 73%).”). This FTC study is based on court decisions from 2002 and earlier, and thus does not reflect any court decisions from the past five years. When accounting for court decisions from the past five years, the rate at which generic drug manufacturers prevail is lower. See Covington & Burling LLP, Survey of Hatch-Waxman Litigation (2004 to 2008 cases).

⁷⁶ Reiffen and Ward, Branded Generics, 28 Managerial and Decision Economics 251, 259, 2007 (“it is commonly recognized that these first-move advantages exist and can be large”); Hesselton & Shapiro, The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals, May 2007, at 6, www.sonecon.com (“The literature shows that the advantages of being first and winning a period of exclusivity go beyond the higher prices a paragraph IV challenger can charge for the 180-day period in the absence of competition from other generics. In addition, pharmacies and other outlets often stock only one generic version of a drug, in order to reduce their administrative costs, so the first generic on the market can win long-term contracts to supply them.”).

We have also analyzed the break-even market size focusing on the true sunk costs – the \$5.5 million in patent litigation costs (\$6.55 million when accounting for the cost of capital). The break-even market size is about \$50.2 million.

**Break-Even Profitability, Recovery of Sunk Costs,
Without Authorized Generics**



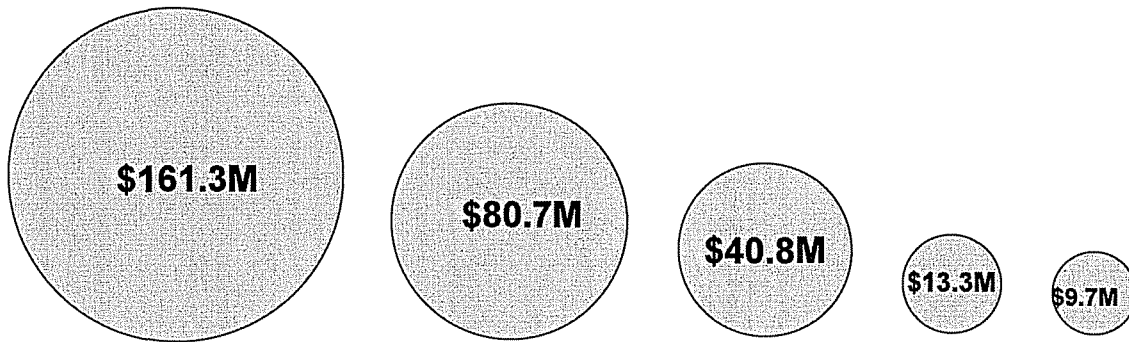
Relatively small markets are unlikely to attract patent challenges regardless of additional price competition. Our analysis, focusing on true sunk costs, indicates that the break-even market size is about \$50.2 million for patent-challenge entry without authorized generic price competition.

B. Markets Above \$110 Million Support Patent-Challenge Entry With Authorized Generics

The next step in the analysis is to identify the break-even market size for competition with authorized generics. Earlier analyses conclude that the minimum market size needed to support paragraph IV entry with authorized generic competition ranges from \$90 to \$110 million.⁷⁷ Our analysis, building off the FTC’s initial findings, shows that the break-even market size for entry with authorized generic competition is \$161.3 million when defining sunk costs broadly to include generic drug development and ANDA filing costs.

⁷⁷ Greenstone Ltd., Authorized Generics (AG), Part of the Generic Landscape, at 18, Oct. 24, 2005; Morgan Stanley Equity Research, Qualifying the Impact from Authorized Generics, Dec. 2004.

**Break-Even Profitability, Recovery of Entry Costs,
With Authorized Generics**



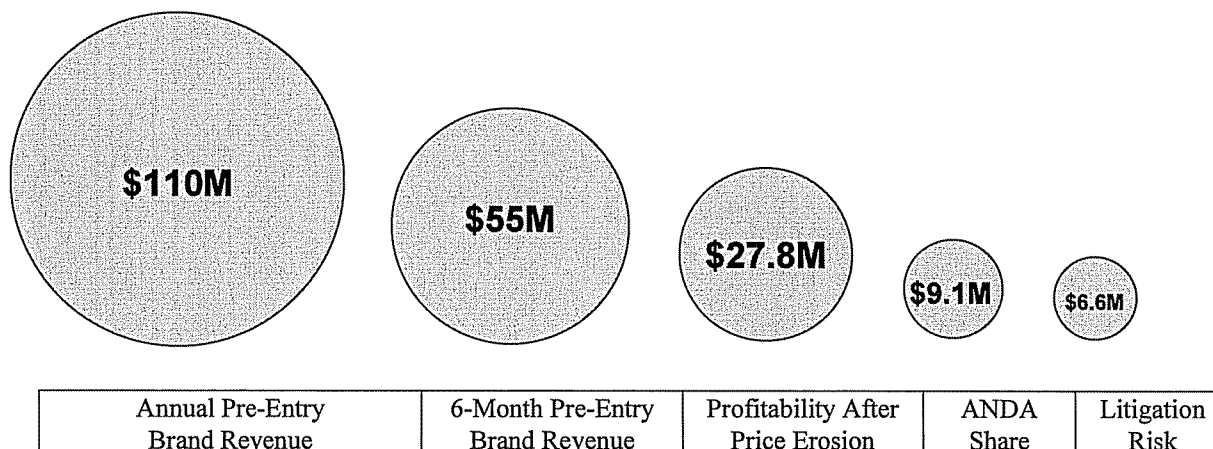
Annual Pre-Entry Brand Revenue	6-Month Pre-Entry Brand Revenue	Profitability After Price Erosion	ANDA Share	Litigation Risk
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This analysis shows that in markets over \$161 million a patent-challenge entrant would expect to recover litigation costs and additional costs (generic drug development and ANDA filing) despite added price competition from authorized generics. This overstates the break-even market size because it does not account for first-mover advantages enjoyed by the initial entrant. The FTC’s empirical findings concerning competition with authorized generics have been incorporated into this analysis.⁷⁸

The analysis above overstates the break-even market size by including costs – generic drug development and ANDA filing costs – that are not sunk. When limiting the analysis to sunk costs (i.e., patent litigation costs), the break-even market size is smaller:

⁷⁸ This is based on price erosion of 26.4%. FTC, *Authorized Generics: An Interim Report* at 11, June 2009, www.ftc.gov (based on volume-weighted wholesale data). The ANDA market share or share of the paragraph IV filer is 32.7%. *Id.* at 13. This model is based on the same cost of good sold and litigation risk estimates used earlier to model profitability of entry without authorized generics.

**Break-Even Profitability, Recovery of Sunk Costs,
With Authorized Generics**



This shows that a prospective entrant can recover expected patent litigation costs and endure price competition from authorized generics in markets above \$110 million. As indicated earlier, the break-even market size is even smaller when considering first-mover advantage or the incremental earnings outside the initial six-month period. Without accounting for any first-mover advantage, this analysis also understates the profitability of entry and overstates the break-even market size for competition with authorized generics. We have made other assumptions that may result in understating the profitability of entry into small markets.⁷⁹

There is a narrow range of candidate markets where authorized generic competition could potentially have some impact on the entry calculus. Our analysis shows that the candidate market range is \$50-\$110 million when properly focusing on the sunk costs of entry. Markets above \$110 million are large enough to support patent challenge entry despite price competition from authorized generics. Markets below \$50 million are unlikely to support patent challenge entry regardless of authorized generics.

⁷⁹ We have assumed (1) that generic drug manufacturers' average cost of goods sold is the same as brand drug manufacturers and thus generic drug manufacturers are not any more efficient in production or shipping and (2) that all patent litigation costs are incurred at the outset of litigation, resulting in greater cost of capital for prospective entrants.

C. The Large Consumer Benefits Outweigh Any Actual Foreclosure Effects In The Candidate Markets

There are very few markets in which anticompetitive foreclosure is even plausible. Since the focus is on paragraph IV or patent challenge entry, the potentially affected markets are limited to those with single-source brand drugs. These single-source brand products account for 28% of U.S. prescription drug sales.⁸⁰

Within the subset of single-source brand markets, the overwhelming majority of markets are large enough to support profitable patent-challenge entry. The break-even market size is \$110 million in annual sales when focusing properly on the sunk costs of entry. Markets exceeding \$110 million in annual sales account for 95% of single-source brand drug sales.⁸¹ Of the remaining 5%, some markets are too small (i.e., those with less than \$50 million in sales) to support profitable entry without or without authorized generics. These account for about 2% of single source brand drug sales.⁸² Thus, the candidate markets in which foreclosure is even possible (\$50 million to \$110 million in annual sales) account for only 3% of single-source brand drug sales.

A similar analysis holds when modeling profitability of entry based on a definition of sunk costs that includes generic drug development and ANDA filing costs. For that approach, the break-even markets size is \$160 million. Markets exceeding \$160 million account for 91% of single-source brand drug sales.⁸³ Of the remaining 9%, some markets are too small (i.e., those with less than \$74 million in sales) to support profitable patent-challenge entry under any circumstances. These account for about 3% of single source brand drug sales. The markets in

⁸⁰ IMS data; *see also* JP Morgan, Wall Street Perspective: The PBM Sector – Rx for Growth, Mar. 2009 at 12 (“Today, 70-75% of all U.S. prescriptions could be dispensed as generics”).

⁸¹ IMS, National Sales Perspective (wholesale data for all channels), 2008.

⁸² *Id.*

⁸³ *Id.*

which foreclosure is even possible under this model (\$74 million to \$160 million) account for only 6% of single-source brand drug sales.

While the consumer benefits caused by authorized generics are measurable and large (over \$880 million), any counterbalancing consumer harm is speculative and likely quite small given the size and range of the candidate markets or markets in which foreclosure is even possible. The theory that authorized generics harm consumers by foreclosing patent-challenge entry lacks relevance to nearly all drug markets.

D. Causation Must Be Established In The Candidate Markets Before Concluding That Foreclosure Has Actually Occurred

Even when focusing on the subset of candidate markets, the FTC should hesitate before jumping to any conclusion that actual marketplace foreclosure has occurred. Anticipated price competition will not explain all historical entry decision-making involving the candidate markets. Companies choose not to make paragraph IV filings for reasons wholly aside from the prospect of greater price competition from authorized generics.

The likelihood of success on the patent case may outweigh concerns about authorized generic price competition. A company evaluating entry into a candidate market may decide against doing so because of the relative weakness of its patent position. For example, a prospective entrant's calculus may reflect a likelihood of success in the patent case of 30%, well below the average used in the modeling above. Price competition could contribute to the decision against filing when the patent position is relatively weak. In this situation, authorized generic competition would have the effect of reducing high risk, wasteful patent litigation that is unlikely to lead to a marketing exclusivity period.⁸⁴

Another consideration is whether multiple generic drug manufacturers will be awarded marketing exclusivity. The prospect of sharing marketing exclusivity – a condition contemplated

⁸⁴ Berndt et al., *Authorized Generic Drugs, Price Competition and Consumers' Welfare*, at 794, *Health Affairs*, Vol. 26 No. 3, May/June 2007.

under the Hatch-Waxman Act – may contribute to a decision to defer entry in the candidate markets. Likewise, a prospective patent challenger must account for the fact that the FDA grants exclusivity on a dosage basis. Added price competition during the exclusivity period may come from a different dosage offered by a competing generic drug manufacturer.⁸⁵

It is also important to put in context the decision of a single generic drug manufacturer. One company's decision to forego a patent challenge, based on anticipated price competition from authorized generics, may not impact consumers. Another generic drug manufacturer may be capable of funding the patent infringement litigation and willing to undertake the litigation risk in light of the available profit opportunity.⁸⁶

CONCLUSION

Competition law serves to protect consumers, not competitors opposing price competition.⁸⁷ Because “[c]ompetition is tough ... there will always be those who, in their own self interest, seek to be relieved of the burdens of competition.”⁸⁸ That is precisely what some generic drug manufacturers seek – to be relieved of the burdens of enhanced price competition.

⁸⁵ Hessett & Shapiro, *The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals*, May 2007, at 4, www.sonecon.com (“for example, Sandoz successfully challenged the patent for Prozac and won 180-day exclusivity for the 10 mg dose while Barr Labs won simultaneous exclusivity for the 20 mg dose.”).

⁸⁶ Berndt et al., *Authorized Generic Drugs, Price Competition and Consumers' Welfare*, at 794, *Health Affairs*, Vol. 26 No. 3, May/June 2007.

⁸⁷ *Montfort of Colorado, Inc. v. Cargill, Inc.*, 479 U.S. 104, 116 (1986) (“To hold that the antitrust laws protect competitors from the loss of profits due to [vigorous] price competition would in effect, render illegal any decision by a firm to cut prices in order to increase market share. The antitrust laws require no such perverse result, for ‘[i]t is in the interest of competition to permit dominant firms to engage in vigorous competition, including price competition.’”); *see also* Concurring Statement of Commissioner J. Thomas Rosch on the Release of the Commission's Interim Report on Authorized Generics at 1, June 2009 (“To my knowledge, no one has ever condemned price competition on the ground that it will reduce another competitor's revenue (at least so long as the prices charged were not below the first competitor's cost).”).

⁸⁸ Deborah Platt Majoras, FTC Chairman, Remarks as Seminario sobre Competencia Economica, www.ftc.gov (Feb. 1, 2006).

A proclamation by a generic drug company executive illustrates this point: “The elimination of authorized generics is the most important upside potential for the whole [generic] industry.”⁸⁹

Eliminating authorized generics would benefit some competitors but would cause large, measurable consumer harm. The \$880 million in consumer savings, supported by the FTC’s analysis, far outweigh any potential anticompetitive foreclosure effects in the narrow sliver of markets in which such harm is even plausible as a theoretical matter.

⁸⁹ Mylan Laboratories, Event Brief of Q1 2007, Earnings Conference Call (July 26, 2006) (quoting Mylan Laboratories Vice Chairman and Chief Executive Officer).