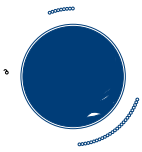
Authorized Generic Drugs:

Short-Term Effects and Long-Term Impact

Federal Trade Commission
August 2011



AUTHORIZED GENERIC DRUGS:
SHORT-TERM EFFECTS AND LONG-TERM IMPACT

A REPORT OF THE
FEDERAL TRADE COMMISSION

JON LEIBOWITZ	Chairman
WILLIAM E. KOVACIC	Commissioner
J. THOMAS ROSCH	Commissioner
EDITH RAMIREZ	Commissioner
JULIE BRILL	Commissioner
Joni Lupovitz	Chief of Staff
Eileen Harrington	Executive Director
Richard Feinstein	Director, Bureau of Competition
David Vladeck	Director, Bureau of Consumer Protection
Joseph Farrell	Director, Bureau of Economics
Willard K. Tom	General Counsel
David Vladeck	Director

[1] The Federal Trade Commission conducted this study at the request of Senators Grassley, Leahy, and Rockefeller, as well as at the request of Representative Waxman, all of whom asked the Commission to examine the competitive effects of authorized generic drugs. *See* Letter from Senators Charles Grassley, Patrick Leahy, and John Rockefeller to Deborah Platt Majoras, Chairman, Fed. Trade Comm'n (May 9, 2005) (*infra* Appendix A); Letter from Hon. Henry A. Waxman, U.E23'n (May 9aissss. d. Trade

period.[3] Brand-name companies now frequently launch an AG to compete with the first-filer.

AGs thus have been the subject of controversy. Brand-name companies that offer AGs contend that they are procompetitive – that they make valuable products available to consumers at lower prices than those of brand-name products and provide competition that leads to lower generic prices overall. Some in the generic drug industry, in contrast, contend that AGs harm competition by drawing revenues away from generic firms during the 180-day exclusivity period provided for first-filers that challenge a brand-name company's patents. They caution that this reduces the potential reward available to generics that challenge patents, thereby discouraging patent challenges that facilitate earlier generic competition and reduce prices for consumers. This, the AG critics argue, undermines long-run competition and the goals of the Hatch-Waxman Amendments.

As a first step toward shedding light on this controversy, the Commission in June 2009 issued an interim report that focused on the short-term effects of AGs during the 180-day exclusivity period (the "Interim Report").[4] That report presented an initial analysis suggesting that "consumers benefit and the healthcare system saves money during the 180-day exclusivity period when an AG enters the market, due to the greater discounting that accompanies the added competition provided by the AG."[5] The Interim Report, however, also found that "AG entryeads to lower

gen Tc /18 Tents.

---

[3] *See* Teva Pharm. Indus. Ltd. v. Crawford, 410 F.3d 51, 54 (D.C. Cir. 2005).

[4] FED. TRADE COMM'N, AUTHORIZED GENERICS: AN INTERIM REPORT ("Interim Report") (2009), http://www.ftc.gov/os/2009/06/P062105authorizedgenericsreport.pdf.

[5] *Id.*, Executive Summary, at 2.

[6] *Id.*

competition and 82 percent of the pre-entry brand price when an AG competes. Similarly, the average wholesale price of a typical generic drug during exclusivity, which is 80 percent of the pre-entry brand wholesale price without an AG, falls to 70 percent of the brand price with AG competition. An analysis of authorized generic pricing over the long term provides no evidence that AG prices are higher than prices of other generics, allaying concerns that AGs might be less aggressive competitors.

The new analysis also confirms the Interim Report's finding that authorized generics have a substantial effect on the revenues of competing, generic firms during the 180-day exclusivity period; depending on how the models are specified, they estimate that the presence of authorized generic competition reduces the first-filer generic's revenues by 40 to 52 percent, on average. Moreover, the impact of AG competition on first-filer revenues persists outside of exclusivity. Revenues of the first-filer generic manufacturer in the 30 months following exclusivity are between 53 percent and 62 percent lower when facing an AG.

With regard to long-term incentive effects, the analysis concludes that the reduced revenue stemming from authorized generic competition during 180-day exclusivity has not affected the generic's incentives in a way that has measurably reduced the number of patent challenges by generic firms. Any disincentive effects would likely be experienced in small markets or in situations where the generic had little chance of winning the patent suit anyway. The Report examines a variety of evidence to reach these conclusions.

- Based on economic analysis, revenue lost from authorized generic competition would be most likely to affect decisions to challenge patents on products with small sales.

  " If a challenger anticipates a 50 percent chance of success, an expectation of AG competition could tilt the balance against bringing a patent challenge in markets with brand sales between $12 million and $27 million, a range that accounts for 13 percent of drugs, but given their low sales, approximately one percent of total prescription drug expenditures. AGs, however, are rarely introduced for these small drugs. For the drugs with higher sales that frequently do attract AG competition, AGs may conceivably deter only a narrow range of challenges that the generic believes it will rarely win, meaning that the challenges are unlikely to result in early generic entry even if pursued.[7]

[7] For instance, for a drug with brand sales of $130 million, a generic that does not anticipate AG competition will expect a patent challenge to be profitable if it has at least a 4 percent chance of winning; with AG competition, that generic would need at least a 10 percent chance of winning to expect a patent challenge to be profitable. Under this mode of analysis, the AG might discourage a challenge only if the generic thinks the chance of winning is between 4 and 10 percent, i.e., when the challenge is unlikely to be successful. For larger drugs, the presence of an AG is critical to the patent-challenge decision only when the expected likelihood of success is even less than 10 percent.

9

generic competitor. Over the longer term, lower expected profits could affect a generic company's decision to challenge a patent on products with low sales, and one company provided a few examples where it claimed the expectation of an authorized generic led it to reject or delay such a challenge. Overall, however, patent challenges, even on drugs with low sales, remain robust and, by most measures, have increased despite the prevalence of authorized generic competition. Moreover, as a consequence of an authorized generic's significant negative impact on a generic's revenues, some brand-name companies have used agreements not to launch an authorized generic as a way to compensate an independent generic in exchange for the generic's agreement to delay its entry. The frequency of this practice and its profitability may make it an attractive way to structure a pay-for-delay settlement, a practice that causes substantial consumer harm.

AUTHORIZED GENERIC DRUGS:
SHORT-TERM EFFECTS AND LONG-TERM IMPACT

A REPORT OF THE
FEDERAL TRADE COMMISSION

CHAPTER 1 INTRODUCTION

This Report presents the results of a study undertaken by the Federal Trade Commission on the effects of authorized generic drugs[1] ("AGs") on competition in the prescription drug marketplace. The Commission undertook this study at the request of Senators Grassley, Leahy, and Rockefeller, who asked the Commission to examine "the short term and long term effects on competition of the practice of 'authorized generics'"[2] as well as Representative Waxman, one of the co-authors of the Hatch-Waxman Amendments,[3] who requested the FTC to study "the impact of so-called 'authorized generics' on competition in the prescription drug marketplace."[4]

Since their marketing surged beginning in 2003,[5] AGs have been the subject of controversy. Brand-name companies that offer AGs contend that they are procompetitive – that they make valuable products available to consumers at substantially lower prices than those of branded products and provide competition that leads to lower generic prices overall. Some companies in the generic drug industry, in contrast, contend that AGs harm competition by drawing revenues away from generic firms during the 180-day exclusivity period provided by governing statutes for first-filers that challenge a brand-name company's patents, thus discouraging future challenges that would allow earlier generic competition and reduce prices for consumers. Opposition to AG marketing during the 180-day exclusivity period has been voiced in citizen petitions filed with the FDA[6] and raised in litigation.[7] This study seeks to shed

---

1 Authorized generic drugs (often referred to in this Report as "AGs") are drugs that are approved as brand-name drugs but are marketed as generic drugs. AGs do not bear the brand-name or trademark of the brand-name drug or manufacturer, but the brand name and AG products are chemically identical.

2 See Letter from Senators Charles Grassley, Patrick Leahy, and John Rockefeller to Deborah Platt Majoras, Chairman, Fed. Trade Comm'n (May 9, 2005) (Appendix A).

3 Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified in scattered sections of 15, 21, 28 & 35 U.S.C.).

4 See Letter from Hon. Henry A. Waxman, U.S. House of Representatives, to Deborah Platt Majoras, Chairman, Fed. Trade Comm'n (Sept. 13, 2005) (Appendix B). Then-Commissioner Leibowitz also requested the FTC to study "the competitive implications of authorized generics." Jon Leibowitz, Commissioner, Fed. Trade Comm'n, Health Care and the FTC: The Agency as Prosecutor and Policy Wonk, Remarks at the Antitrust in HealthCare Conference 9–10 (May 12, 2005), http://www.ftc.gov/speeches/leibowitz/050512healthcare.pdf

5 See infra Chapter 2.

6 See Andrx Citizen Petition, FDA Docket No. 2004P-0563/CP1 (Dec. 27, 2004), http://www.fda.gov/ohrms/dockets/dockets/04p0563/04p-0563-cp0000-01-vol1.pdf (urging the FDA to "inform McNeil Specialty Pharmaceuticals that any authorized version of Concerta® that is introduced and marketed as a 'generic' drug before or during the initial product launch of the first ANDA-approved version will be regarded as misbranded and subject to regulatory action"); Teva

[11] Under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a generic manufacturer certifies that each relevant patent is "invalid or will not be infringed by the manufacture, use, or sale of the new [ANDA] drug for which the application is submitted."

[12] OFFICE OF G

[16] See CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 27 (1998), http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf

[17] Public Comment from the GPhA to the Fed. Trade Comm'n 2 (June 27, 2006), http://www.ftc.gov/os/comments/genericdrugstudy3/062806gpha.pdf

[18] See Teva Pharm. Indus. Ltd. v. Crawford, 410 F.3d 51, 54 (D.C. Cir. 2005).

[19] See, e.g., Fair Prescription Drug Competition Act, S. 373, 112th Cong. (2011); H.R. 741, 112th Cong. (2011).

[20] In recent years, the Commission has undertaken two other major empirical studies to address competition policy issues affecting the pharmaceutical industry. See FED. TRADE COMM'N, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES (2005), www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf; FED.

[21] IMS CONSULTING, IMS HEALTH, ASSESSMENT OF AUTHORIZED GENERICS IN THE U.S. (2006) (written for PhRMA), http://replay.web.archive.org/20061009134405/http://www.phrma.org/files/IMS%20Authorized%20Generics%20Report_6-22-06.pdf. See infra Chapter 3.

[22] Aidan Hollis & Bryan A. Liang, An Assessment of the Effect of Authorized Generics on Consumer Prices, 10 J. BIOLAW & BUS. 10, 16 (2007) (written for GPhA) (an earlier version of this paper was made available by GPhA in July 2006, available at http://www.gphaonline.org/sites/default/files/GPhA_AG_Study.pdf). See infra Chapter 3.

[23] Ernst R. Berndt, Richard Mortimer & Andrew Parece, Do Authorized Generic Drugs Deter Paragraph IV Certifications? Recent Evidence (2007) (working paper written for PhRMA), http://www.analysisgroup.com/uploadedFiles/Publishing/Articles/PhRMA_Authorized_Generic_Entry.pdf; see also Ernst R. Berndt et al., Authorized Generic Drugs, Price Competition, and Consumers' Welfare, 26 HEALTH AFF. 790 (2007), available at http://content.healthaffairs.org/cgi/reprint/26/3/790.pdf. See infra Chapter 7, Section II.B.

[24] e, See infra .pdf

e,

challenges; and information regarding the frequency and context of Paragraph IV challenges. Each piece of evidence provides insights from a different perspective regarding AGs' potential

[25] OMB approval was obtained pursuant to requirements of the Paperwork Reduction Act, 44 U.S.C. §§ 3501-21 (2007). See Agency Information Collection Activities; Comment Request, 72 Fed. Reg. 25,304 (FTC May 4, 2007); Agency Information Collection Activities; Comment Request, 71 Fed. Reg. 16,779 (FTC Apr. 4, 2006).

[26] 15 U.S.C. § 46(b) (2010).

[27] Special Orders list the information that each company must provide to the FTC.

Fifty-nine brand-name[28] and 59 generic[29] companies, including all the major firms involved in marketing AG products, were included in the study. Additionally, two AG-only companies – firms that market AGs but do not file ANDAs – also were included. Appendix C lists all companies included in the study. The Commission's Special Orders for the Brand-Name Companies, the Generic Companies, and the Authorized Generic Companies are set out in Appendices D, E, and F, respectively.

Staff identified 119 different oral-solid (tablet/capsule) AG products that were first marketed between January 1, 2001, and December 31, 2008.[30] The Special Orders required the companies to provide detailed data submissions on AGs, as well as the brand-name drugs and ANDA-generics related to the AGs, and information on relevant Paragraph IV filings and 180-day exclusivity periods.[31] As described more fully in Chapter 3 and Appendices H and I, staff supplemented this quantitative data with pricing and sales information purchased from commercial sources and also relied heavily on information culled from FDA databases.[32]

Additionally, the Special Orders required the brand-name companies to produce certain categories of preexisting "planning, decisional, or strategy documents" that "evaluated, considered, or analyzed . . . the marketing or possible marketing of an AG or AGs (as a response to current or future generic competition or for other reasons)."[33] The generic companies were subject to a similar request, as well as an additional request for documents reflecting the effects of AGs on the decision to file an ANDA or to make a Paragraph IV certification or on the

---

[28] Brand-name companies were included in the study if they marketed an AG or had a brand-name drug subject to a Paragraph IV certification that was included in the study. See infra note 31.

[29] These are companies that marketed ANDA-generic versions of brand-name drugs subject to a Paragraph IV certification, ANDA-generic drugs bioequivalent to an AG, or an AG not based on the company's or parent company's NDA. Thus, the generic companies included ANDA-generic subsidiaries of brand-name companies, but not subsidiaries that market only AGs on behalf of the parent.

[30] See infra Appendix G. The final count of 119 relevant AGs treats different dosage forms as separate AGs. Injectables and solutions were excluded to provide a more uniform data set.

[31] In general the Special Orders sought information (i) AGs launched after January 1, 2001 and all drugs related to them, i.e., brand-name versions of AG drugs and all bioequivalent generic drugs; (ii) brand-name drugs that first faced generic competition after January 1, 2001, for which at least one ANDA with a Paragraph IV certification was filed, and all bioequivalent generic drugs; and (iii) brand-name drugs for which at least one ANDA with a Paragraph IV certification was filed after January 1, 2001, but for which generic entry had not yet occurred. There was substantial overlap between the first two categories.

[32] The time periods covered by the Report's analyses vary due to the availability of information from diverse sources. See infra Appendix H.

[33] See infra Appendix D, ¶ 27, at D-6 (Brand-Name Drug Company Special Order covering the period from January 1, 2002 through April 3, 2006); see also infra Appendix F, ¶ 10, at F-3 (Authorized Generic Drug Company Special Order requesting similar information from companies that marketed AGs, but not ANDA-generic drugs).

profitability of ANDA-generic marketing during 180-day exclusivity.[34]

IV. Organization of the Report

The study's detailed findings are presented in the next seven chapters:

- Chapter 2, "An Overview of AG Marketing and Its Relationship to the Exclusivity System," examines trends and industry practices in the marketing of AGs – alternative marketing strategies and key attributes of brand-generic marketing arrangements that may affect the price of an AG and the timing of its presence in the market – and presents basic facts regarding the relationship between AG marketing and exclusivity periods;

- Chapter 3, "Short-Term Impacts of Authorized Generics: Price and Revenue Effects During 180-Day Exclusivity," examines the short-term effects of AGs on retail and wholesale prices and on brand and generic revenues based on quantitative analysis of IMS data;

- Chapter 4, "The Marketing of Authorized Generics: Brand-Name Firms' Objectives and Strategies," describes the brand-name firms' interest in using AGs to maintain an income stream after generic entry has occurred as well as to reduce generic firms' incentives to enter early via patent challenges and analyzes the brand-name firms' documents and practices for consistency with revenue-enhancement and entry deterrence strategies;

- Chapter 5, "The Marketing of Authorized Generics: Generic Firm Perceptions and Decision-Making," reviews the contemporaneous documents produced by generic companies discussing their concerns with AG competition and the impact of AGs on incentives to challenge brand patents via Paragraph IV certifications;

- Chapter 6, "Long-Term Effects of Authorized Generics: Price, Revenue, and Break-Even Effects," analyzes quantitative data (i) reflecting long-term effects of AGs on retail and wholesale prices and wholesale expenditures and (ii) indicating how AG competition may affect the break-even point – measured, alternatively, in terms of market size and probability of a successful patent challenge – necessary to profitably support generic entry via a patent challenge;

- Chapter 7, "Assessing the Impact of AG Competition from Patent Challenge Data," inquires about the extent to which generic firms have continued to challenge brand-name firms' patents despite the proliferation of AG competition. It presents data on the relationship between patent challenges and sales levels. It

---

[34] See infra Appendix E, ¶¶ 18-19, at E-4, E-5 (Generic Drug Company Special Order covering the period from January 1, 2003, through April 3, 2006).

also examines generic firms' record of bringing patent challenges under circumstances where they are likely to share exclusivity with other ANDA generics, a setting analogous to sharing exclusivity with an AG; and

- Chapter 8, "The Use of Authorized Generics in Patent Litigation Settlement Agreements," describes the various roles played by AGs in settlement contexts.

CHAPTER 2 AN OVERVIEW OF AG MARKETING AND ITS RELATIONSHIP TO THE EXCLUSIVITY SYSTEM

This chapter charts the landscape of AG marketing, describing industry practices and trends that may influence AGs' competitive effects. The overview first considers the extent of brand-name industry marketing of AGs and generic industry participation in their distribution. It then focuses on a central issue regarding AGs: their relationship to the 180-day exclusivity periods granted to ANDA-generic companies.

Consistent with industry reports, the data show that AG marketing surged beginning in 2003, becoming a widespread industry practice around that time. Many brand-name companies distributed AGs, either themselves or through contracts with generic companies. Beginning in 2003, more than half of the 180-day exclusivity periods included an AG. Yet the majority of AGs were not marketed during any portion of a 180-day exclusivity period. Indeed, brand sales level, rather than whether generic entry occurred via exclusivity, appears to have been a key factor in decisions to market AGs. These findings set the stage for analysis of the short- and long-term effects of AGs presented in the chapters that follow.

I. AG Marketing: Trends and Industry Practices

A. The Scope and Time Course of AG Marketing

A total of 119 AGs, each arising from a different capsule or tablet form of a brand-name drug, were launched from 2001–2008.[1] As shown in Figure 2-1, there were few AG launches during the earliest years covered by the study, but, consistent with industry reports, launches surged in 2003 and remained high through 2006. Only seven AGs were launched per year from 2001–2002, but from 2003–2006 the number of launches ranged between 19 and 21 per year. At the same time, the marketing of AGs during 180-day exclusivity periods substantially increased, suggesting the possibility of a new rationale for AG marketing and generating the controversy

---

[1] This data set, which is the basis for much of the Report, includes all tablet and capsule dosage forms ("oral solids") of AGs that were first marketed between 2001 and 2008. Other dosage forms, such as injectables or solutions, were excluded to provide a more uniform data set. Counts reflect the number of NDAs (individual brand-name drugs) rather than the number of strengths ("products"), avoiding multiple counts for drugs with more than one strength. AGs were identified from information provided by the FDA, company responses to the Special Orders, and other sources. The time periods covered by the Report's analyses vary due to the availability of information from diverse sources. See infra Appendix H for more information on the definition and identification of AGs, criteria for inclusion in the study, and how they were counted. See infra Appendix G for a list of all AGs covered by the study.

[2] See infra Figures 2-7 and 2-8, and accompanying discussion.

[3] See, e.g., See, e.g., JOHN R. THOMAS, CONG. RESEARCH SERV., AUTHORIZED GENERIC PHARMACEUTICALS: EFFECTS ON INNOVATION 8–9 (2008); Letter from William K. Hubbard, FDA, to Stuart A. Williams, Mylan Pharmaceuticals Inc. and James N. Czaban, Heller Ehrman, Re: Docket Nos. 2004P-0075/CP1 & 2004P-0261/CP1, at n.9 (July 2, 2004), http://www.fda.gov/ohrms/DOCKETS/dailys/04/july04/070704/04p-0075-pdn0001-list.pdf (listing authorized generic drugs launched as long ago as 1992); Kurt R. Karst, Authorized Generics—Historical Overview and Current Issues, REG. AFF. FOCUS, Mar. 2005.

[4] During the 1990s, AGs were not marketed during 180-day exclusivity, because there were almost no exclusivity periods as a result of the requirement that the first generic applicant defend successfully against a brand-name company's patent infringement lawsuit. When this requirement was eliminated, exclusivities began to increase and the opportunity for marketing during the valuable exclusivity period grew.

[7] See, e.g., Leila Abboud, *Drug Makers Use New Tactic to Ding Generic-Drug Firms*, WALL ST. J., Jan. 27, 2004, at B1; Lewis Krauskopf, *Generic Drug Companies Fighting Threat from Big Brands*, THE RECORD, Aug. 22, 2004.

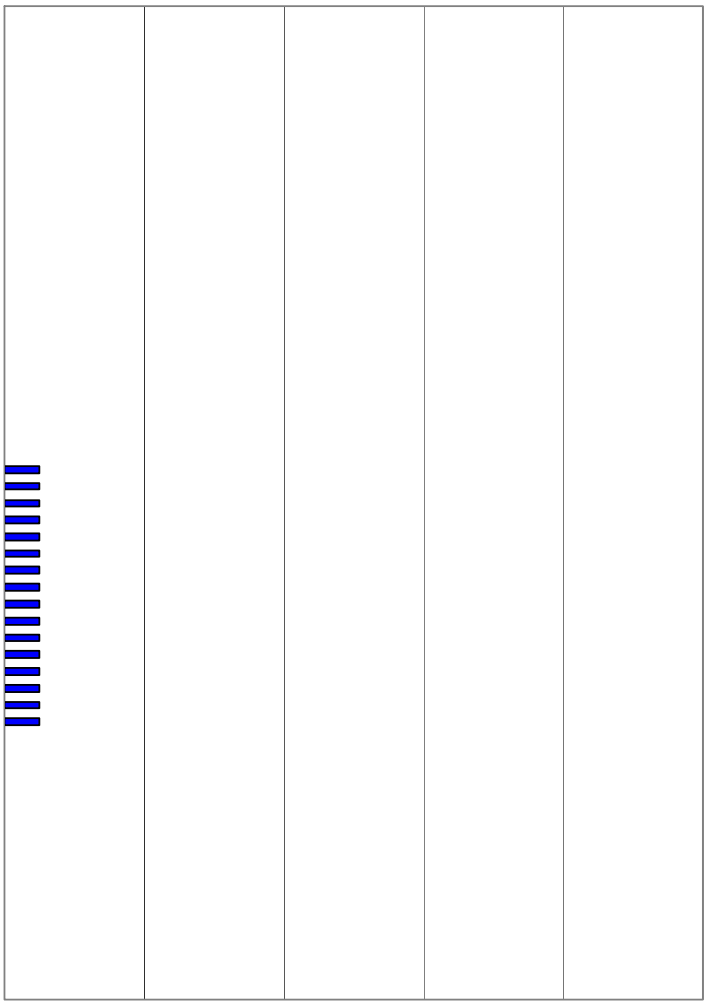
[8] See

between the brand and the generic.[14]

[14] Also, a "No AG" agreement for one drug prohibited the launch of an AG for part of 2007, and no AG was launched thereafter. For a few other drugs, "No AG" agreements prohibited the launch of AGs only during exclusivity or for some strengths, but because an AG version of the drug was launched, the AG count in Figure 2-1 was unaffected.

[15] This issue is explored in Chapter 3, Section III.B.3.

[16] These were companies that had rights to the NDA for a brand-name drug that was included in the study because it was related to an AG, a paragraph IV certification, or first generic entry (with or



[18] See infra text accompanying note 28 (agreements usually provide for AG launch upon ANDA-generic entry or the date of expected ANDA-generic entry); Chapter 4, Section III.A (AG launch usually occurs at ANDA-generic entry).

[19] See infra Chapter 3, Section III.C.2; Chapter 4, Section III.A. Brand strategies to address the loss of revenue at generic entry by promoting sales of a patent-protected drug at the expense of a product for which generic entry has occurred (a "product hop") could be less effective or even incompatible with an AG, e.g., if the brand discontinues the NDA for the product experiencing generic entry.

[20] See, e.g., FED. TRADE COMM'N & U.S. DEP'T OF JUSTICE, IMPROVING HEALTH C

A breakdown of how the NDA-holding companies distributed AGs is shown below in Figures 2-3 and 2-4. Of the 43 companies listed in Figure 2-2 that had AGs, about a third, listed in Figure 2-3, marketed AGs internally. About two-thirds, shown in Figure 2-4, entered into agreements with outside parties. A few companies marketed AGs both internally and externally, and thus appear in both figures.

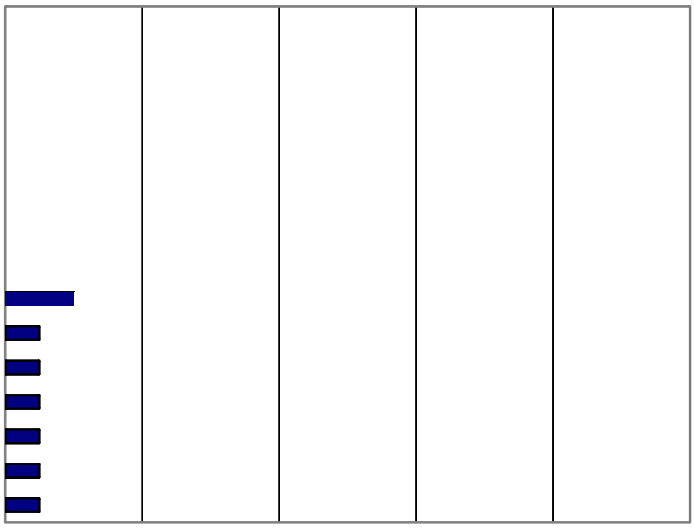
a. In-House Marketing

Figure 2-3 shows that a total of fifteen companies marketed in-house 52 AGs arising from the NDAs of their brand-name drugs, approximately 44 percent of the 119 AGs in the study. Ten of these companies were brand-name companies that had generic marketing expertise, usually in a subsidiary or division. These companies marketed 42 AGs arising from the NDAs of their brand-name drugs. Almost half of all AGs marketed in-house were distributed by two brand subsidiaries, Greenstone and Sandoz.[23] Figure 2-3 also includes five primarily generic or mixed brand/generic companies that self-marketed ten AGs for which they held the NDA.[24]

---

[23] The business model for the brand subsidiaries varied. From 2001–2008, the period covered by Figure 2-3, Greenstone, a subsidiary of Pfizer, was the primary example of a brand subsidiary with a generic portfolio limited to AGs of the parent's brand-name drugs. Beginning in 2009, however, Greenstone expanded its portfolio to include ANDA-generics and AGs for which the applications are held by other companies. See, e.g., Lisa Lucarelli Chandler & Harry Dutt Samaroo, Pfizer and the Greenstone Brand: A Sustainable Competitive Advantage?, 17 J. MED. MARKETING 155, 157, 161 (2009), available at http://mmj.sagepub.com/content/10/2/155 ("The Greenstone subsidiary has morphed from a unit that marketed only Pfizer legacy products to a full line generic company" as a result of agreements with Aurobindo Ltd. and Claris Lifesciences Ltd. to market a variety of their generic products); Greenstone LLC, Press Release, Greenstone Selected as Eisai Partner to Launch Authorized Generic of Aricept® (Donepezil Hcl) Tablets (Sept. 8, 2010), http://www.greenstonellc.com/press-release-1.aspx. Other brand subsidiaries listed in Figure 2-3 also offered ANDA-generic or AG versions of other companies' brand-name drugs. Sandoz, a subsidiary of Novartis, and Roxane, a subsidiary of Boehringer Ingelheim, are examples.

[24] These include Watson, Teva, Barr, Mallinckrodt, and K-V Pharma. AGs marketed in-house represented a small fraction of the generic business of these companies, the bulk of which was ANDA-generic drugs, but also included AGs arising from agreements with brand-name companies. Although Barr merged with Teva and became Teva's subsidiary, Barr is treated as a separate company for purposes of this study because the merger did not become effective until December 23, 2008, close to the end of the period covered by the study. For more information on the study's treatment of companies that merged, see infra Appendix H.



[25] This addresses AGs marketed between January 1, 2001 and December 31, 2008. See Appendix H, Section (Appendix) J, Appendix H, Section (Appendix) J.

Agreements between a brand-name company and its generic licensee typically are exclusive: the brand agrees that the generic company is the exclusive marketer of the AG. Exclusivity terms may bar competing AG sales by the brand-name firm itself, as well as by other generic marketers.[27] In such cases, the brand may retain the right to market the AG through its subsidiary after the 180-day exclusivity period expires.

The agreements also establish the timing of AG launch. Many agreements provide for launch only after ANDA-generic entry or the date of expected ANDA-generic launch. To ensure that brand sales are not eroded before ANDA-generic competition begins, penalty provisions often apply if the AG marketer launches before generic entry.[28]

ii. External Generic Licensees of Brand-Name Companies

Most ANDA-generic companies do not market AGs. As shown in Figure 2-5, only 21 generic companies, about one-third of the 59 ANDA-generic and two AG companies in the study, entered into agreements with the brand-name companies shown in Figure 2-4 to distribute 67 AGs. Of the 21 companies, three were responsible for more than half of the AGs marketed pursuant to agreement.

---

revenues. Such agreements are one form of settlement in which the brand agrees to refrain from offering a competing AG. See infra Chapter 8.

[27] Exclusive supply and distribution agreements that authorize the marketing of an AG by the first-filer can raise competitive concerns. They are unlikely to affect "No AG" agreements, because, although the AG is marketed, there is no competing ANDA-generic. See infra Chapter 8.

[28] See infra Chapter 4, note 40 and accompanying text.

[31] See, e.g., CD, May 18, 2004.

[32] See, e.g., Agreement, 2007 ("[Generic Co.] acknowledges and agrees that during the Term, it shall not . . . file an ANDA . . . with the FDA or manufacture, market, sell or distribute any Competing Equivalent Product."); Agreement, 2006 (similar).

[33] See, e.g., Agreement, 2007 (generic may manufacture and market an ANDA-generic product after the exclusivity period but is required to pay the same profit split on its ANDA-generic product as on the AG). Some settlement agreements also call for a profit split on ANDA-generic products. See, Settlement Agreement, 2005 (marketing of ANDA-generic version); id. (royalty of 5% of net sales of the ANDA-generic); Settlement Agreement, 2005 (option to market ANDA-generic instead of AG); id. (requiring the generic to pay 20% of its profits on the ANDA-generic product). This Report cites all agreements arising from settlements or patent litigation, including settlements, licenses and supply and distribution agreements, as settlement agreements.

[34] See infra Chapter 4, note 46; cf. Settlement Agreement, 2001 ("Buyer may discount . . . Generic Products or sell . . . Generic Products at a loss without compensation . . . after negotiation of terms acceptable to [brand] to compensate [brand] for any loss of Net Profit distribution . . . incurred by [brand] as a result of such actions by Buyer").

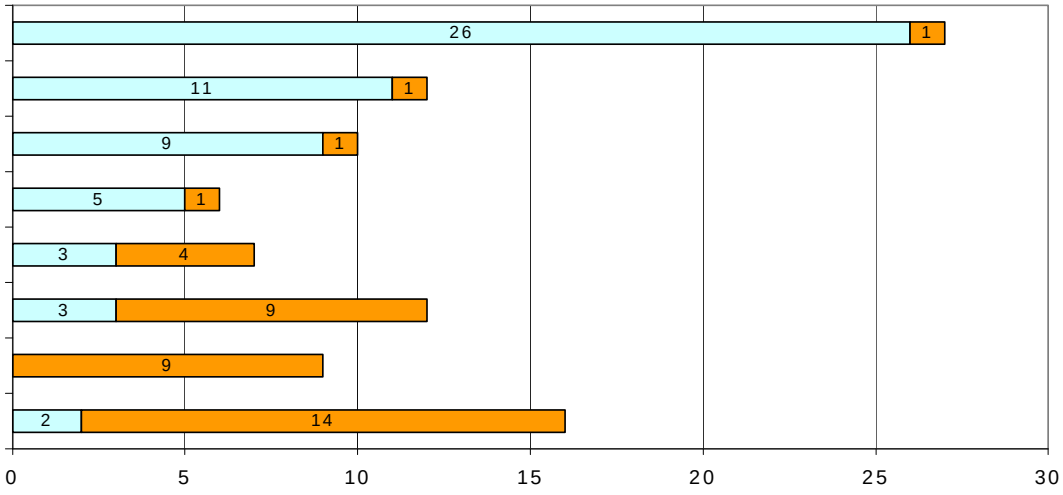
[35] See, e.g.,

company that was not the first filer the benefit of being able to market during the 180-day exclusivity period, first-filing status provides the possibility of

[37] The inverse relationship between exclusivities and AGs could also arise from brand-name company preferences; as discussed above, some brand-name companies will not contract with generic firms that have filed an ANDA or made a Paragraph IV certification for a bioequivalent product. See supra text accompanying note 31.

[38] Generic companies may tap the high revenues available during 180-day exclusivity by marketing AGs. The top four companies for marketing AGs by contract (Fig. 2-6) sold about one-third of such AGs during 180-day exclusivity, about the same fraction as for AGs overall (Fig. 2-8). Generic company documents discussing plans to market AGs highlighted their value during 180-day exclusivity. See generally CD, Jan. 15, 2006 ("Strategic Rationale" for entering into an agreement to market two AGs: "Accelerates path to profitability . . . by accessing profit share during exclusivity period . . . ."); CD, May 6, 2005 (favorable AG opportunities include "Paragraph IV exclusivities (key value drivers)").

Figure 2-6: Top Companies for 180-Day Exclusivity Periods and Authorized Generic Drugs by Contract



[39] Data regarding recent trends in the timing of generic entry and the length of brand-name firm exclusivity are presented in Appendix K.

[40] For example, the Prescription Access Litigation Project argued that "the intent [of marketing an AG] is not to foster true competition but merely to sabotage the ability of the ANDA filer to take

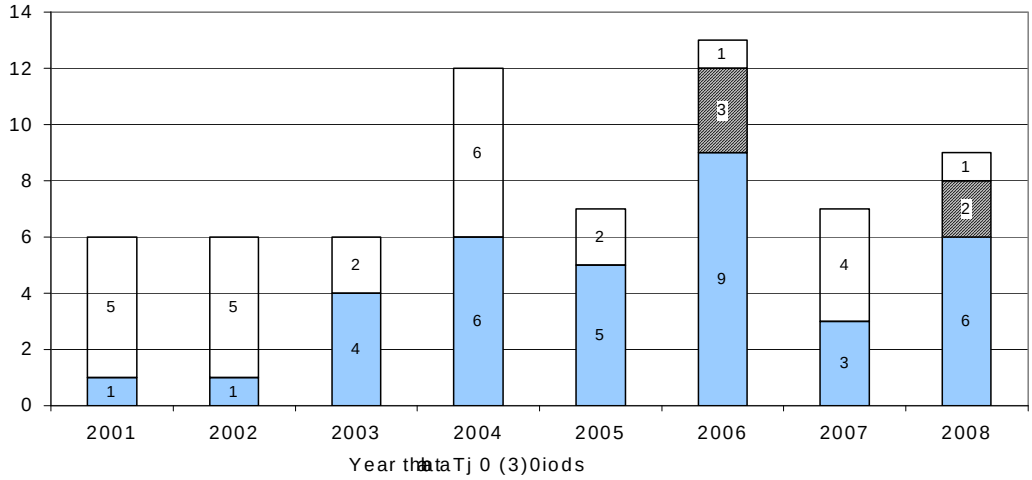
advantage of the 180-day exclusivity period provided for by Hatch Waxman." Public Comment from the Prescription Access Litig. Project et al. to the Fed. Trade Comm'n 4 (June 5, 2006), http://www.ftc.gov/os/comments/genericdrugstudy3/060605pal.pdf. Similarly, the Generic Pharmaceutical Association ("GPhA") stated, "Authorized generics occur when a brand company introduces or licenses a 'generic' version of its product to compete with the true generic during the 180-day exclusivity period, awarded to the first generic manufacturer to challenge the patent." Public Comment from the GPhA to the Fed. Trade Comm'n 1 n.2 (June 27, 2006), http://www.ftc.gov/os/comments/genericdrugstudy3/062806gpha.pdf.

[41] See supra note 4 and accompanying text.

[42] Although subject to fluctuation from year to year, the number of exclusivity periods generally has grown during the period analyzed; whereas nineteen exclusivity periods started in 2001–2003, twenty-

"no AG" agreements, 70% of exclusivity periods from 2003–2008 might have had AGs.

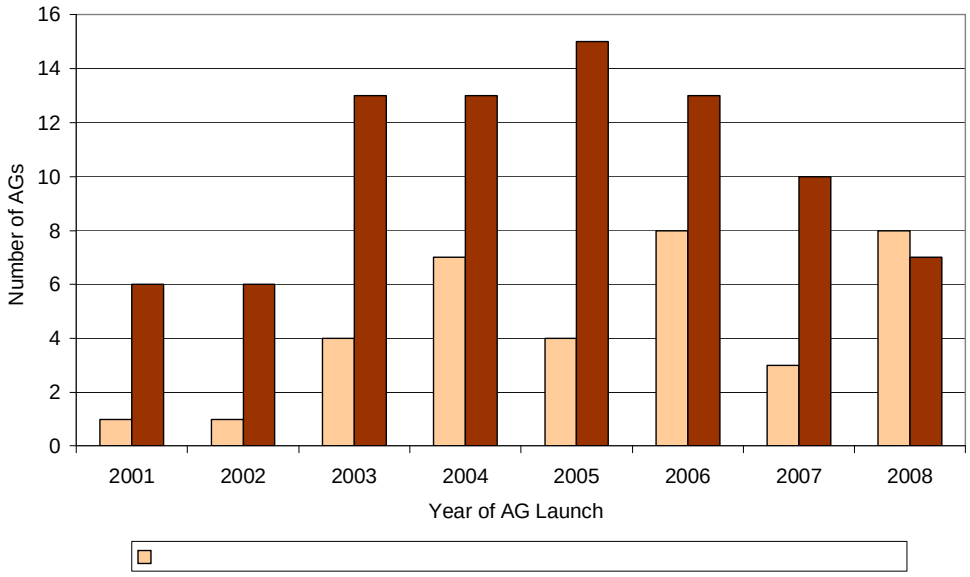
Figure 2-7: Number of 180-Day Exclusivity Periods
With and Without Authorized Generic Drugs



[44] AGs marketed outside or without exclusivity included those launched after conclusion of an exclusivity period as well as AGs for drugs for which there was no exclusivity period. (Also, in one instance the first-filer marketed, and discontinued, an AG before its 180-day exclusivity period began.) This calculation excludes AGs launched during exclusivity that the brand continued to market after the exclusivity period expired. Nor does it include drugs for which first generic entry occurred prior to January 1, 2001.

more than half of the AGs launched were marketed during a 180-day exclusivity period. It remains to be seen whether this shift, which followed a year in which almost all AGs were marketed apart from 180-day exclusivity, has continued.

Figure 2-8: Number of Authorized Generic Drugs Marketed During and Apart from Exclusivity



[45] AGs "[n]ot marketed during an exclusivity period" include four AGs that were marketed by the ANDA-generic that was the first-filer for the relevant drug. These AGs, like others marketed apart from exclusivity, likely would not have created disincentive for patent challenges; indeed, they contributed to the first-filers' revenues. Each first-filer AG was marketed during a 180-day exclusivity period shared by two competitors, which, under the circumstances, likely would have anticipated a third competitor during the exclusivity period.

launched[46] – was higher when generic entry occurred without exclusivity than with exclusivity.[47] Indeed, because of the high revenues potentially available to an AG during exclusivity,[48] and the potential disincentive to future patent challenges, brands might prefer to market AGs during exclusivity.

As shown in Figure 2-9, however, the rate of AG entry is correlated with pre-entry brand sales, rather than with the nature of generic entry. While the rate of AG entry increases with pre-entry brand sales, there was no consistent pattern as to the relative magnitude of the rates of AG entry for generic entry with and without exclusivity. And within most sales levels, the percentage of drugs with AGs was similar for ANDA-generic entry with and without exclusivity. These data suggest that during the period when AGs have been common, the anticipated sales level, on average, has had greater bearing on brands' decisions to launch AGs than whether generic entry occurred via 180-day exclusivity.

---

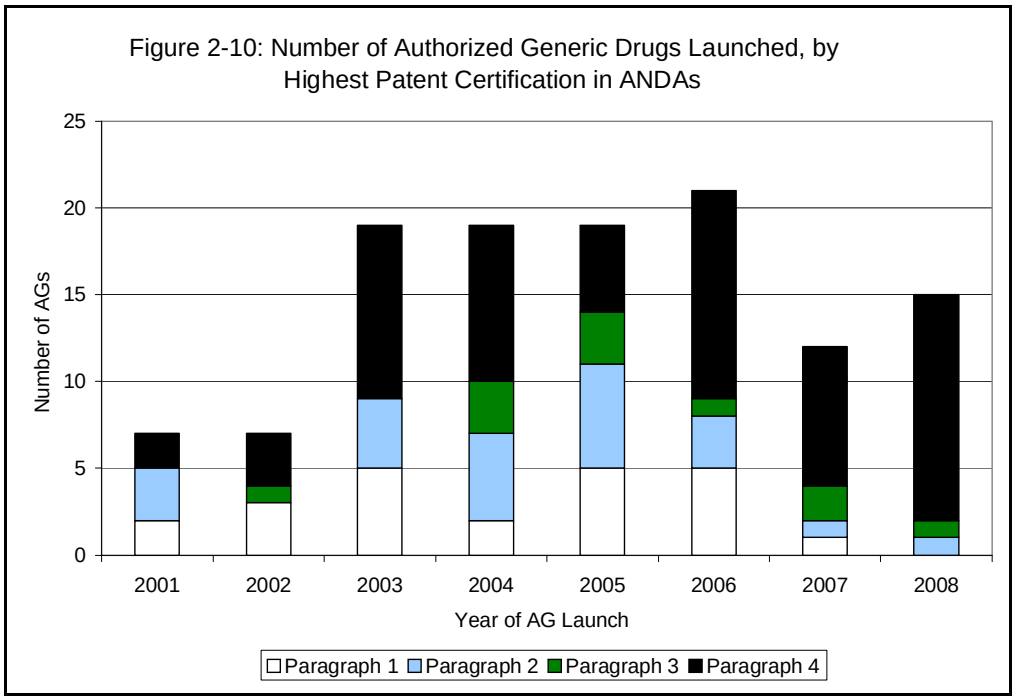
[46] Figure 2-9 examines the rate of AG launch by pre-entry market size for drugs for which first generic entry occurred during the April 2003–December 2008 period analyzed. Because the purpose of that figure is to examine whether 180-day exclusivity affects the propensity to launch an AG, the appropriate comparison is between first generic entry with and without exclusivity at similar sales levels. Launches of AGs into mature markets are not included because the decision whether to launch an AG into a mature market involves consideration of an additional factor, the ability to gain share in a market with established generic competitors. By contrast, other figures in this chapter include AGs launched into mature markets as well as those launched at first generic entry because the analyses are intended to show the circumstances of launch of all AGs.

[47] First generic entry may occur without 180-day exclusivity because no ANDA included a Paragraph IV certification, e.g., all generic applicants may have certified to the FDA that they would wait for patent expiration before entering. Moreover, even when an ANDA included a Paragraph IV certification, entry occurs without exclusivity under a number of circumstances, e.g., if the first-filer loses the infringement litigation and obtains FDA approval of its ANDA after patent expiration; launches its ANDA-generic product more than 180-days after exclusivity was triggered by a court decision; or relinquishes or forfeits its exclusivity. See, e.g., David E. Korn, Erika Lietzan & Shaw W. Scott, New History and Discussion of 180-Day Exclusivity, 64 FOOD & DRUG L.J. 335 (2009); Shashank Upadhye, GENERIC PHARMACEUTICAL PATENT AND FDA LAW ch. 13, 14 (2010).

[48] See infra Chapter 4, Section I.A.

[49] A Paragraph I certification requires an ANDA applicant to state that "patent information has not been filed," while a Paragraph II certification requires an applicant to state that "such patent has expired." 21 U.S.C. §§ 355(j)(2)(A)(vii)(I), (II). Certification under Paragraph III identifies the date on which the patent will expire, 21 U.S.C. § 355(j)(2)(A)(vii)(III), and indicates that the applicant is seeking ANDA approval only after patent expiration.

Twelve AGs were "old antibiotics" that originally were approved under 21 U.S.C. § 357, and thus



The graph shows the highest patent certification by ANDAs filed with respect to the NDA pursuant to which the AG was marketed, i.e., the NDA for the reference-listed brand-name drug. The number of AGs for which the brand-name drug was subject to an ANDA with a PIV certification is higher than the number shown in Figure 2-8 of AGs marketed during an exclusivity period because not all patent challenges result in an exclusivity period. This figure includes Paragraph IV certifications for five drugs, the same as those discussed in footnote 45, for which an AG was marketed by the first-filer.

Nonetheless, beginning in 2003 there was a substantial increase in the number of AG launches for drugs that were subject to a Paragraph IV certification, and by 2007–2008 most AGs were versions of drugs for which there had been a Paragraph IV certification. The predominance of AG launches associated with a Paragraph IV certification in 2007–2008 appears to arise more from a decrease in AGs for drugs subject to ANDAs with Paragraph I, II, or III certifications, than from an increase in those subject to PIV. Figure 2-8 similarly shows a decrease in 2007 and 2008 of the number of AGs that were not marketed during a 180-day exclusivity period. Various factors could have contributed to the decrease.[50] In any event, it

---

marketed from 2001–2006. Even if the 11 "old antibiotics" were excluded from the analysis of those years, about half of the AGs from 2001–2006 (40 out of 81) arose from NDAs of drugs for which there was no patent challenge.

[50] One possibility is that they could reflect a decline in the prevalence of drugs that were not subject to patent challenges, rather than a shift in the reasons for AG launches. See Chapter 7, Section I; see also AARON GAL & NIKHIL R. CHARI, BERNSTEIN RESEARCH, THE LONG VIEW: U.S. GENERIC PHARMACEUTICALS - A BOTTOM-UP MODEL OF THE U.S. COMMODITY GENERICS MARKET IN 2009, at 3, 7, 13, 14 (by dollar or prescription volume, Paragraph IV drugs increased in prevalence from 2004

through 2008 and comprised the bulk of generic market entry beginning in 2006). Another possibility is that the drop in AGs marketed apart from exclusivity and Paragraph IV certifications could have arisen from decisions not to market less profitabl

CHAPTER 3 SHORT-TERM IMPACTS OF AUTHORIZED GENERICS: PRICE AND REVENUE EFFECTS DURING 180-DAY EXCLUSIVITY

This chapter analyzes the effects of AG drug competition on several market outcomes during FDA-granted 180-day exclusivity periods. The market outcomes that are the focus of the analysis are prices and revenues. Preliminary analysis of these data appeared in the Interim Report.[1] This chapter employs more sophisticated tools to account for market characteristics that may systematically differ between AG and non-AG markets, in order to better isolate the effect of the AG.

As discussed in Chapter 1, an important consequence of competition from AGs may be that purchasers face lower prices. This chapter confirms the Interim Report's finding that the presence of an AG during a 180-day exclusivity period is associated with lower retail and wholesale prices. The analysis in this chapter finds that the presence of an AG during an exclusivity period was associated with lower generic prices – ranging from slightly, but not significantly,[2] lower to as much as 14% lower. The estimated impact generally was smaller for retail prices than for wholesale prices.

Another key finding of the Interim Report was that revenues of first-filer generic manufacturers were substantially lower in the presence of AG competition. Again, the more sophisticated analysis in this chapter confirms the findings of the Interim Report, that AG introduction significantly diminishes first-filer revenues during the exclusivity period. This chapter finds that the wholesale expenditures on the first-filer's generic drug – a proxy for revenues – were 40 to 52 percent lower, on average, when an AG was present. AGs could have material long-term effects if their impact on first-filer revenues is large enough to substantially alter the incentives to file Paragraph IV challenges or even to file an ANDA at all. Discussion of the impact on incentives to pursue Paragraph IV challenges is a topic of Chapter 6, where the effects of AGs beyond the exclusivity period are estimated.

---

[1] FED. TRADE COMM'N, AUTHORIZED GENERICS AN INTERIM REPORT ("Interim Report") (2009), http://www.ftc.gov/os/2009/06/P062105authorizedgenericsreport.pdf

[2] The analysis performed in this chapter allows for careful consideration of the statistical properties of the estimates. The analysis of price effects, for instance, often yields estimated effects that would not be unlikely to have been observed even if the effect was zero, in which case the estimated effects are characterized as not statistically different from zero or "statistically insignificant." Just how unlikely the estimated effect would be if the true effect actually was zero is often referred to as the level of significance. For instance, if the significance level associated with an estimated effect is 10%, that would generally be considered weaker evidence that the observed data was inconsistent with a true average effect of zero than if the significance level is 5%.

[3] IMS CONSULTING, IMS HEALTH, ASSESSMENT OF AUTHORIZED GENERICS IN THE U.S. (2006) (written for the Pharm. Research and Mfrs. of Am. ("PhRMA")), http://replay.web.archive.org/20061009134405/http://www.phrma.org/files/IMS%20Authorized%20Generics%20Report_6-22-06.pdf ("the IMS Study").

[4] Id. at 9–11.

[5] Aidan Hollis & Bryan A. Liang, An Assessment of the Effect of Authorized Generics on Consumer Prices, 10 J. BIOLAW & BUS. 10, 20–21 (2007) (written for the Generic Pharm. Ass'n ("GPhA")) (an earlier version of this article was made available by GPhA in July 2006, available at http://www.gphaonline.org/sites/default/files/GPhA_AG_Study.pdf) ("Hollis and Liang").

[6] Id. at 11–12.

[7] Id. at 14.

[8] For example, the authors contend that minor drugs such as Ganciclovir should not be weighted as heavily as major drugs such as Fluoxetine. Id. at14.

[9] PHRMA, HOWREY LLP & CAPANALYSIS, AUTHORIZED GENERICS

[12] Estimating the impact on consumers in pharmaceutical markets is indeed a very difficult task, due not only to the prevalence of private health insurance, but also government programs. The Centers for Medicare and Medicaid Services estimate that in 2007, consumers' out-of-pocket payments accounted

finished goods.[15] Whether a product faced a Paragraph IV challenge[16] and the dates of any exclusivity period arising from the challenge were determined using information obtained from the FDA.[17] AGs were identified based on information from the FDA, supplemented and verified using information subpoenaed from the pharmaceutical firms. Among other things, the subpoenaed information reports on whether the brand issued an AG and, if so, the identity of the AG distributor. The study thus builds upon and supplements the data used in prior research regarding the impact of AGs, including the IMS Study sponsored by brand-name manufacturers and the Hollis and Liang study released by the generic manufacturers. Using the combined data, the sample covers 312 products that first faced generic competition during the period between April 2003 and December 2008.[18]

The relationships depicted in Figure 2-9 and Figure I-1 in Appendix I show that AGs tend to be introduced on relatively higher sales products,[19] and suggest that market size may influence decisions about both whether to attempt generic entry through a Paragraph IV challenge and whether to launch an AG. One concern is that market size also may be correlated with the amount of discounting that happens following generic entry, which may make it difficult to separate the price effect of AG presence from the hypothesized price effect of market size. Furthermore, market size may not be the only variable that helps explain the competitive environment.

---

[15] The monthly Producer Price Index (PPI) for finished goods (WPSSOP3000) over the period of our data (January 2003 through December 2008) is obtained from the Bureau of Labor Statistics. See Producer Price Indexes, BUREAU OF LABOR STATISTICS, http://www.bls.gov/ppi/data.htm.

[16] Throughout this chapter and Chapter 6, the term "product" refers to a full specification of active ingredient(s), dosage form, and strength. The term "molecule" refers to the set of active ingredients that are included in a single tablet or capsule. The definition of a "product" using IMS data, for purposes of this chapter and Chapter 6, differs from the definition of a "drug" used elsewhere in this Report in describing data from the FDA. FDA drug information is provided at the NDA and ANDA level, whereas IMS product information is provided at the level of the molecule-dosage-form-strength-therapeutic class.

[17] Sales of a generic or AG product prior to the end of an FDA-granted exclusivity period are treated as occurring during an exclusivity period.

[18] The analysis in this chapter compares prices and expenditures before and shortly after first generic entry. In order to ensure availability of at least six months' data prior to generic entry, the analysis is limited to products with first generic entry no earlier than April 2003. Chapters 3 and 6 do not cover introductions of AGs that occurred from 2003 through 2008 if another generic entered prior to April of 2003. As such, this should be seen as an analysis of the impact of AGs on recently genericized markets.

[19] For instance, among products with 180-day exclusivity, the average market size for products with an AG was more than twice that when no AG was launched ($381 million versus $178 million). The difference was even more pronounced for products that were not subject to a Paragraph IV challenge. As was the case for Figure 2-9, market size is calculated throughout this chapter as the annualized retail sales of the brand-name product based on the three months prior to generic entry, measured in December 2008 dollars.

The regressions in this chapter attempt to control for many of these issues by including product-characteristic controls in the analysis of the effect of AG competition on market outcomes. Therapeutic class indicator variables represent an important subset of these product-characteristic controls. Therapeutic classindicators, as defined by the data vendor, IMS, are used to group together similar products that treat similar conditions. The condition treated by the product is the single most important characteristic relating the products in a category together. Therefore, the regression analysis of this chapter uses the therapeutic class indicators to help control for potential differences between products that have an AG and products that do not.[20] The use of these controls is discussed further in Appendix I.

III. The Effect of Authorized Generic Competition During the Exclusivity Period

The introduction of an AG can affect consumers in several ways. Some of these effects may be beneficial, but others could be harmful.For example, in the short-run, consumers may benefit from lower prices associated with additional competition from an AG. However, in the long-run, the expectation of an AG may deter ANDA-generic firms from challenging questionable patents using a Paragraph IV certification. If there were deterrence, consumers would not have the opportunity to choose the generic alternative until the (potentially invalid or not-infringed) patent of the brand had expired.[21] Furthermore, the anticipation of revenues from an AG version of a drug in addition to the brand sales of the drug could potentially provide added incentive for the brand-name company to develop the drugs in the first place, which could also benefit consumers. Whether an AG is, on net, beneficial to consumers depends on the relative size of the beneficial and harmful effects.

Although the analysis will not be able to address the full welfare implications of the introduction of an AG, the empirical analysis attempts to estimate many of the effects that AG competition may have on market outcomes that are relevant in both the short- and long-run. We begin by considering how AG competition affectsgeneric and brand prices and revenues during the exclusivity period.

---

[20] The endogeneity of the decision to issue an AG was also addressed by using instrumental variables regression analysis. These regressions used either market size, brand-name firm identity, or both to predict whether an AG would be launched, and then estimated the impact of the predicted presence of an AG on prices. The results of this analysis did not differ substantively from the results reported here.

[21] In addition, AG competitors might replace potentially more aggressive ANDA-generic competitors outside of the 180-day exclusivity period. In this way, consumers could face higher prices for generic products outside of exclusivity. Chapter 6 explores this issue.

[22] Other competitive environments are possible due to legal provisions that allow for shared exclusivity;

[23] Of the 40 molecules observed during exclusivity, seven (16.7%) have at least one strength or dosage form that faces an AG competitor and one that does not. For the typical molecule in the sample, either all or none of the strengths face AG competition.

[24] Because the sample is limited to oral solid dosage forms, the extended units are equivalent to molecule-strength-dosage-form combinations. In other words, the analysis is done at the 9-digit National Drug Code level.

[25] For both the retail and wholesale analysis, the monthly generic market price for a product is calculated as the total sales dollars of all generic products divided by the extended units sold by

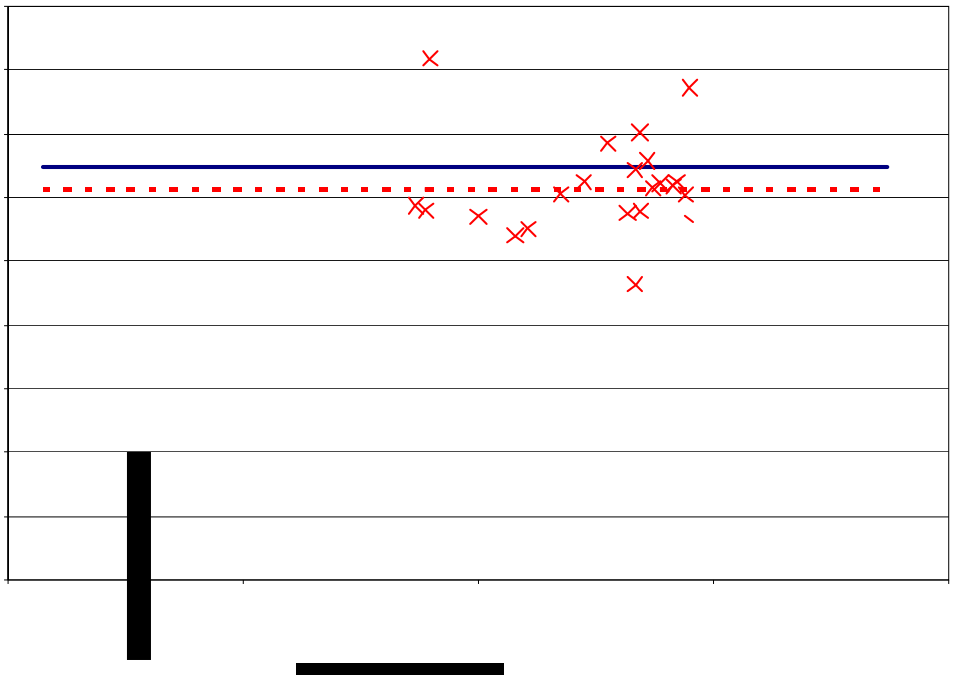
1. Generic Retail Market Prices

This section reports on estimated percent changes in average retail relative prices of

[27] See infra Appendix L for details regarding the exact specification of the model.

[28] These prices are plotted for one month only, so that all data points reflect markets that have had the same amount of time to adjust to generic entry. Month four data reflect conditions after the markets have had some time to adjust to generic entry, but before the end of exclusivity was imminent. Corresponding graphs for other months are not substantially different.

Figure 3-1: Generic Retail Relative Market Prices in Month Four of Exclusivity



[29] The manufacturers are included in the regression as a set of indicator variables that describe the competitive environment. For example, all of the models include dummy variable indicators (variables that take the value of one if true and zero if false) representing each possible number of manufacturers, whether an AG is present, and interactions between the two. The dependent variable is the generic relative price. Logarithmic transformations of the relative price result in nearly identical AG effects in all pricing models. See infra Appendix L for a more detailed description of the model employed and its assumptions.

products. Furthermore, an ANDA-generic firm may find it necessary to offer deeper than average discounts for the product in order to entice consumers to switch. In this circumstance, it would be errant to conclude that the lack of an AG caused the deep discount.

Controlling for product characteristics may allow the AG effect to be estimated in a way that accounts for unobserved factors, such as a consumer's reluctance to switch from brand-name products to generic products. For example, if consumers are equally as reluctant to switch to generic alternatives for all products within the same therapeutic class, then the inclusion of iers

---

[30] Similarly, controlling for other product attributes, such as dosage form and the months since entry, can help control for factors that could be related to the presence of an AG and price. For example, a consumer may be more reluctant to switch to generic forms of a product with an extended release formula, and producing generic versions of extended-release drugs may be relatively more costly than for typical drugs, making those products both less attractive as AG markets and likely to experience higher relative generic prices. Controlling for the number of months since entry can take separate account of any market dynamics associated with a product's life cycle, such as the decline of advertising's influence over time.

[31] The Interim Report, supra note 1, estimated the difference in the discounts between markets with an AG and markets without an AG. In order to convert the differences from that report to a percentage change in the generic price as reported here, they would to be divided by the average price of the generic. For example, the Interim Report found that the unweighted average difference between retail discounts in ANDA+AG and ANDA-Only markets was -4.2%. Dividing that by the ANDA-Only Mean Relative Price of 0.86 from the unweighted analysis in Table 3-1 would yield -4.8%, which is very close to what is reported here, given that the standard error of the estimated effect is reported in

both weighted and unweighted models, the price decreases are statistically significant at the 5% level only when the full controls are included. The AG effect in the model without controls is insignificant (i.e. not different from zero) at standard confidence levels, suggesting that the hypothesis that AG competition had no effect during the exclusivity period cannot be rejected. Another way to characterize the statistical precision of this analysis is with a confidence interval.[33] For the unweighted regression without controls in column (i) of Table 3-1, the 95%

e s 9 i m i n s i c o n f fairectaubignitisttdistephrnottfe

[33] A 95% Confidence interval indicates that if the data generating process were repeated many times, and the estimations were performed on each instance of the data generating process, roughly 95% of the confidence intervals would contain the true average AG effect. The 95% confidence intervals for these AG effects can be calculated using the estimated AG effect and their standard errors, where the interval is (Estimated AG Effect)±1.96×(Standard Error). As a rule of thumb, similar confidence intervals can be calculated for all such estimates by doubling the standard error and adding and subtracting that from the estimated effect.

[34] Clustering the standard errors has a big impact on the estimated standard errors. If the regression in column (i) is performed without clustering, the estimated effect does not change (-3.8%), but the estimated standard error drops from 2.8% to 0.7%, which would imply a 95% confidence interval of [-5.2%, -2.4%]. Incorrectly treating all the observations as if they were independent would cause the statistical significance of the analysis to be greatly overstated.

Table 3-1: Effect of AG Introduction on Generic Retail Market Prices

[35] Although the estimated effects of AG competition are larger using wholesale prices rather than retail prices, this is partially explained by the fact that base wholesale prices are lower. Averaged across

Controlling for product characteristics in the wholesale data has larger effects in both the sales-weighted and unweighted models than in the analogous retail data. For unweighted models, the AG effect, measured as the percentage change in relative price, increases from -6.9% to -12.8% when full controls are included. Although the two effects are not statistically different from each other, inclusion of product characteristics increases the precision of the AG effect, and allows the hypothesis that the AG effect is zero to be rejected with greater confidence. In the sales-weighted models, the inclusion of the product characteristics also increases the magnitude of the AG effect from -6.6% to -13.5%. Again, the estimate from the model with controls is more precise and significantly different from zero with greater confidence. Weighting the data by pre-entry brand sales had very little impact on the magnitude of the AG effect estimates.

Table 3-2: Effect of AG Introduction on Generic Wholesale Market Prices

	Unweighted		Sales Weighted	
	(i) No Controls	(ii) Full Controls	(iii) No Controls	(iv) Full Controls
Effect of Adding an AG to ANDA-Only	-6.9%	-12.8%***	-6.6%	-13.5%***
(Standard Error)	(4.8%)	(2.8%)	(5.7%)	(2.4%)
ANDA-Only Mean Relative Price	0.80		0.83	
Sample Size	673	673	673	673

***Statistically different from zero at the 1% level

3. Generic Firm Level Pricing Analysis

The analysis above considered the impact of AG entry on the average price paid for a generic version of a product, regardless of whether the product was an AG or an ANDA-generic. This section looks more deeply at pricing within markets for products that have experienced AG entry by comparing the prices for the ANDA products to the AG prices. This sheds light on the possibility that the relationship between the AG and the brand could make the AG a less aggressive price competitor than an ANDA-generic. In addition, understanding the relationship between ANDA-generic and AG prices may provide insight into the mechanism by which the presence of an AG affects market prices.

Table 3-3 presents estimates, at both retail and wholesale levels, of the differences in prices charged for an AG relative to the prices charged for a competing ANDA product. Both model specifications include the full set of controls that were included in columns (ii) and (iv) of Tables 3-1 and 3-2.[36]

[36] The results are remarkably stable with regard to model specification: they are nearly identical in sign and magnitude whether the model includes no product characteristics or a full set of indicators.

This analysis shows that retail prices for the AG tend to be lower than the retail prices for corresponding ANDA-generics, and this difference is statistically significant at the 1% level. The value of -11.4% reported as the "AG Firm Effect" estimate in column (i) implies that retail prices for the AG product are 11.4% lower, on average, than retail prices of competing ANDA-generic products, which average 0.86 in the retail data.[37] The analysis of wholesale prices discussed below suggests that this effect is a result of pricing decisions made by pharmacies, which are not a focus of this study, so this difference is not explored further here, though it could be an interesting topic for further research.

The wholesale data tell a different story. This evidence suggests the AG does not price

identifying the product of interest.

[37] Another way to address this question would be to compare generic prices in markets with one ANDA competitor and one AG to generic prices in markets with only two ANDA competitors. Unfortunately, the number of observations of the latter type of market condition was insufficient to allow for meaningful statistical analysis.

prices of AGs were similar regardless of whether they were being marketed by a subsidiary of the brand or by an independent licensee, so these results are omitted. The impact of this vertical relationship on brand pricing will be considered below.

B. Market Prices of Brand-Name Products

The pricing analysis, thus far, has focused on the effect that an AG has on the prices of generic products. However, whether a brand-name firm issues an AG may also affect the optimal pricing strategy for its brand-name product. This section considers the impact of an AG on brand-name product prices using both wholesale and retail data. Brand prices directly affect purchasers of the brand-name product, and they influence the long-run incentives of brand-name firms. How the decision to market an AG affects brand prices is therefore both directly relevant to current consumers and useful for understanding the long-run incentives of the brand-name firm.

Much of the analysis of brand prices is analogous to that of generic prices.[38] It covers the same set of products, employs the same data, and continues to use extended units of the product as the analytical unit. It derives estimates from linear regressions relating brand prices to the competitive environment. The models that examine the impact of an AG on brand prices during exclusivity are nearly identical to those that considered generic prices. These models include the same set of controls and normalize contemporaneous brand prices by pre-entry brand prices. However, because brand prices are also observed prior to generic entry, the analysis can be extended to look at pricing strategies prior to exclusivity.

1. Brand Retail Prices

The regression estimates of the change in relative retail prices for brand-name products due to AG entry can be foreshadowed by consideration of a graph of a time series of retail real price changes over the 18 months[39] relevant to the with and without an AG.

---

[38] A word of caution with respect to the measurement of brand prices and revenues in this chapter and Chapter 6 is warranted. Rebates paid by brand-name companies are not included in our data. Rebates can be substantially scaled back upon generic entry, and the impact of such practices will not be reflected in the brand prices or revenues reported here. This may cause the levels of both brand prices and revenues following generic entry to be understated in our data. Since this impact would be present regardless of whether an AG is launched, we have no reason to believe it biases our estimate of AG impacts on either brand prices or revenues.

[39] These prices are for the same set of products used in the generic product analysis during exclusivity. All of the products considered eventually face an FDA-granted exclusivity period. Price changes are measured relative to the month of generic entry.

[40] The model that produces these percentage changes regresses the logarithm of brand price against product fixed-effects and time dummy variables. The models are estimated separately for the sample with and without an AG. Both series plotted in Figure 3-3 represent the coefficient estimates on the

For most of the period prior to generic entry the two series track each other closely. Prices for products that eventually experience AG entry increase at a rate that appears linear over time, and is very similar to that for products that never experience AG entry. This real rate of price increase is consistent with price increases observed across all brand-name products over this time. Beginning roughly five months before generic entry, the time path for products that never face an AG becomes steeper relative to brand drug prices in AG markets, but any apparent differences in the rates (or the levels) are not statistically different from each other. Finally, during exclusivity, the prices of products with an AG change course and begin to fall, while prices for products without an AG continue to rise at roughly the same rate as prior to generic entry. Although the graph shows an abrupt change of course in the direction of prices, the differences are not statistically different from each other.

Figure 3-3: Average Brand Retail Price Changes Over Time

month-since-entry dummy variables. Dummy variable coefficients in log-linear models are approximations of the average percent change.

Table 3-4 reports the results of regression analysis estimating the impact of introducing an AG on brand prices during the exclusivity period. It does not show statistically significant evidence of an effect. These results are consistent with what is observed in Figure 3-3. During exclusivity, the presence of an AG lowers estimated relative brand retail prices by between 4.2% and 7.2% relative to pre-entry brand prices depending on the controls that are included in the regression model, but these estimates are generally not statistically different from zero at any reasonable significance level. The magnitude of these estimated effects is similar across all four models.

Table 3-4: Effect of AG Introduction on Brand Retail Prices During Exclusivity

	Unweighted		Sales Weighted	
	(i) No Controls	(ii) Full Controls	(iii) No Controls	(iv) Full Controls
Effect of Adding an AG to ANDA-Only	-4.2%	-4.8%*	-7.2%	-6.5%
(Standard Error)	(4.1%)	(2.4%)	(6.8%)	(4.1%)
ANDA-Only Mean Relative Price	1.05		1.01	
Sample Size	666	666	666	666

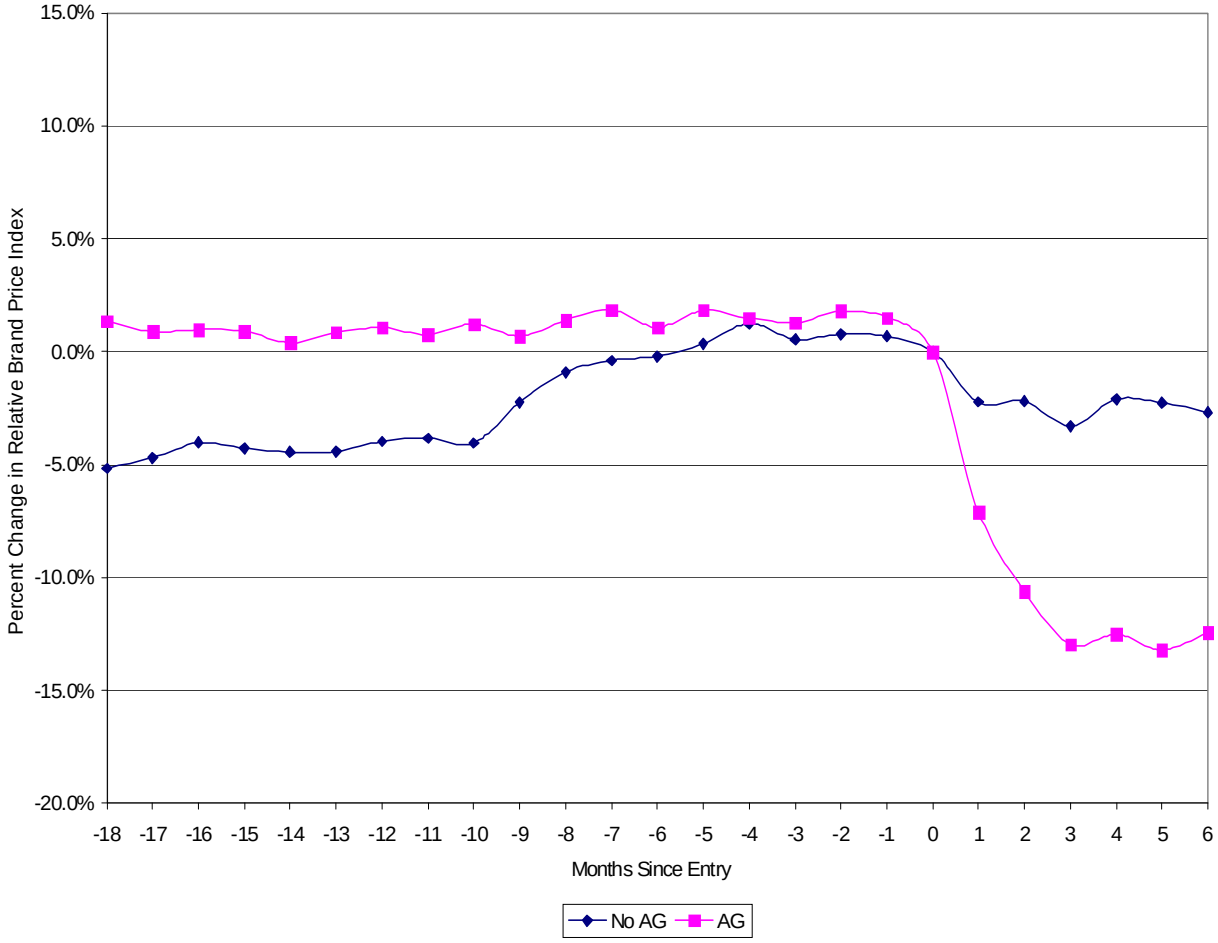
*Statistically different from zero at the 10% level

2. Brand Wholesale Prices

This section presents analysis parallel to that of the brand retail prices, except that wholesale data rather than the retail data are employed. Figure 3-4 shows the time series of wholesale relative prices for products that will eventually face an AG and products that will not. The figure is exactly analogous to Figure 3-3 except that it uses wholesale prices rather than retail.

The wholesale data reveal price patterns nearly identical to those shown by the retail data. Prior to generic entry, the two time series of prices are very similar. As in the retail data, the slopes of the two price series are not statistically significantly different from each other. wTJ 0.00foty, the presge0.0-3 excep significant

Figure 3-4: Average Wholesale Brand Price Changes Over Time



The relationship between AGs and wholesale prices is investigated further using regression models. Table 3-5 presents estimates of the impact of an AG on relative brand wholesale prices. These results are exactly analogous to those presented in Table 3-4, except that the relationships are estimated using wholesale data rather than retail data. That qualit relao CS ons by between 7.7% and 12.2%, depending on the controls that are included i

The average ANDA-Only contemporaneous brand price is 4% lower than the pre-entry brand prices in the unweighted sample and 11% lower than pre-entry brand prices in the sales-weighted sample[41]. During exclusivity, the presence of an AG lowers relative brand wholesale

[41] In contrast, the average retail relative prices for brand name products were slightly higher than the pre-entry brand prices.

twice as large in magnitude. Moreover, the estimates from all four models are statistically significant at the 5% confidence level.[42] These results are explored further below.

Table 3-5: Effect of AG Introduction on Brand Wholesale Prices During Exclusivity

	Unweighted		Sales Weighted	
	(i) No Controls	(ii) Full Controls	(iii) No Controls	(iv) Full Controls
Effect of Adding AG to ANDA-Only	-9.5%**	-10.6%***	-12.2%**	-7.7%**
(Standard Error)	(3.1%)	(2.4%)	(5-7.e z30((78 Tm3(icant at the 5%	

[42] This result may be surprising in light of economic research dating back to Frank and Salkever (1997), which shows that brands generally cut their prices upon generic entry. See Richard G. Frank & David S. Salkever, Generic Entry and the Pricing of Pharmaceuticals, 6 J. ECON. & MGMT. STRATEGY 75 (1997). However, this new finding only appears in the context of 180-day exclusivity periods, and we know of no published study that restricts attention to brand pricing during 180-day exclusivity periods. A report submitted to the FTC by Howrey LLP on behalf of Ph RMA, supra note 9, at 23, also found brand that wholesale prices dropped following generic entry in markets with an AG.

[43] See infra Chapter 8.

deferred entry by the ANDA-generic firm. Consequently, the brand-name firm's strategy may differ in these settings from the standard scenario described in the previous paragraph.

This relationship is investigated further by considering how different competitive environments affect brand pricing strategy. Table 3-6 provides the pricing results for two market scenarios chosen to describe the nature of competition in the market.[44]

One factor to consider is whether the AG is distributed by a subsidiary or by an independent licensee. Depending on specific licensing terms, the brand-name firm may retain more of the profits from customers who switch from the brand to the AG following a brand price increase when the AG is distributed by a subsidiary rather than a licensee. Analysis of AG ... [illegible]
incrediary or ts rep, byurandts repistrarket.lletheserket.gnft]TJpe0.0003 Td [(Thi(Anothan r to connclu

[44] The price effects reported in Table 3-6 are the reported results from a regression model that includes the full set of controls employed in Tables 3-1 and 3-2.

45

47

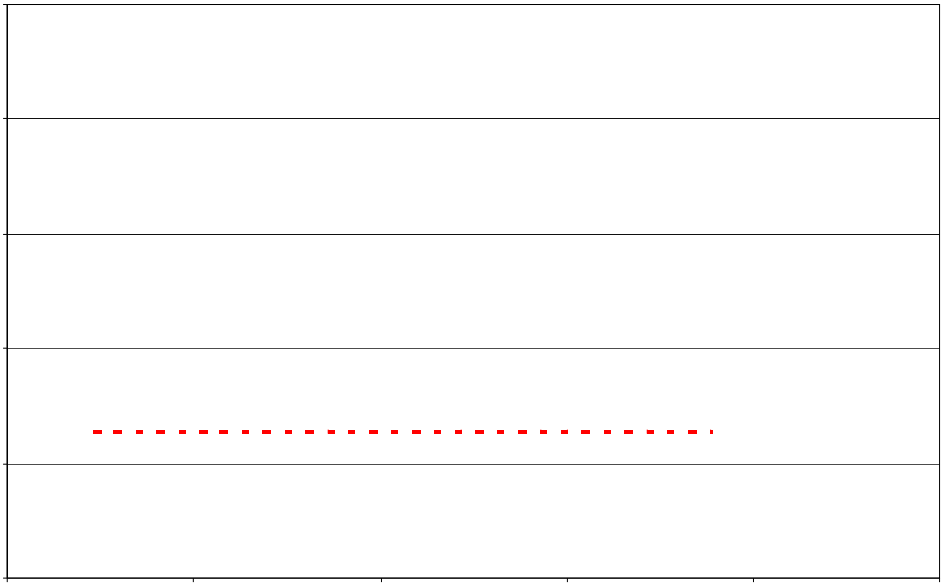
[49] Differences in the sample sizes reported in Tables 3-2 and 3-7 reflect the fact that some of the products considered in the price analysis do not have an ANDA firm present in the market and therefore would not be included in the analysis of AG effects on ANDA revenues. These products represent "AG Only" markets, discussed earlier.

[50] Table 3-7 reports results from four model specifications that are very similar to those used in

As shown in Table 3-7, introducing an AG has a large and negative effect on ANDA revenues in every model specification. All of the models predict effects that are statistically significant at the 1% confidence level. The magnitude of the AG entry effect is between -39.6% and -52.0%, depending on whether the model sales-weights observations and includes full controls. However, the differences across model specifications are small relative to the estimated AG effects, and none of the estimates is statistically different from the others.

Regardless of which of the four models one favors, the estimated impact of AG entry on wholesale expenditures on the first filer's product is quite a bit larger than the estimated price effects reported in Table 3-2. Revenue impacts depend on both prices and quantities. The evidence so far suggests that increased pricing pressure from AGs only partially explains the

Figure 3-6: Revenue Share of Brand-Name Product in Month Four of Exclusivity



[51] A note of caution is appropriate in interpreting these results: a failure to control for unobserved characteristics relevant to the decision to market an AG is virtually certain to bias the estimates of changes in brand expenditures. The point has particular relevance here. In the pricing context, unobserved market characteristics that influence the decision to launch an AG may or may not be

Table 3-8: Effect of AG Entry on Brand-Name Product Revenues

	Unweighted		Sales Weighted	
	(i) No Controls	(ii) Full Controls	(iii) No Controls	(iv) Full Controls
Effect of Adding an AG to ANDA-Only	-26.8%***	-49.0%***	-27.8%***	-47.2%***
(Standard Error)	(6.8%)	(7.9%)	(9.2%)	(9.6%)
ANDA-Only Mean Relative Expenditures	0.49		0.44	
Sample Size	673	673	673	673

***Statistically different from zero at the 1% level

Reduced revenues for the brand-name product, however, do not equate to reduced revenues for the brand-name firm. As discussed in the next section, the brand-name firm receives revenue from the AG as well as from the brand-name product, and both revenue streams contribute to the firm's overall revenues.

3. Wholesale Revenues of Brand-Name Firms

Brand-name companies earn revenues not only from the sale of the brand-name product, but also from the AG, when one is launched.[52] The effect of AG marketing on brand-name company revenues provides some insight into the strategy of the brand-name firm. Because brand-name product sales during exclusivity are more heavily cannibalized in markets with AGs, as shown in Table 3-8, an important question is whether the brand-name company is able to recoup those lost sales with AG sales. If so, the launch of an AG is in the short-term interest of the brand-name company. If not, perhaps the introduction of an AG is part of a long-term strategy. Long-term strategies might include settlements that designate an ANDA-generic firm as the AG marketer in exchange for delayed generic entry, or they might involve deterring Paragraph IV certifications with respect to other products in the portfolio that are likely to face generic entry at a later date.

---

correlated with generic pricing. However, market characteristics that explain the decision to launch an AG almost certainly are strongly correlated with the amount of revenue that the brand expects to lose when facing generic competition.

[52] Here, all AGs are treated as if they are marketed by a subsidiary of the brand-name company. Sometimes the brand-name firm will license the right to distribute an AG to an independent marketer, in which case, the brand-name firm will not receive all of the revenue associated with sales of the AG. The brand-name firm, however, typically receives both a transfer price and a share of any profits – usually a large share, unless a patent litigation settlement is involved. See supra Chapter 2, Section I.B.2.b.ii; infra Chapter 4, Section III.B; Company Document, Oct. 12, 2004 (stating that the share of profits awarded to generic firms in AG marketing arrangements had fallen to 10 percent or less).

Table 3-9 presents the estimated effect that introducing an AG has on the brand-name firm's revenues during exclusivity. The regressions control for how the number of manufacturers and their type affect the relative expenditures on both products of the brand-name firm (the brand-name product and the AG). The model specifications are very similar to those in Table 3-8.

Table 3-9 reports how the introduction of an AG affects the revenues of the brand-name firm as a percentage of what it would have earned had the AG not been introduced. For example, the "Effect of Adding an AG to ANDA-Only" figure reported in column (i), 21.0%, implies that introducing an AG to a market with only an ANDA-generic competitor increases the brand-name firm's revenues by 21%, compared to what it would have earned without introducing an AG. All four models in Table 3-9 report that revenues of brand-name firms that introduce AGs are higher on average than revenues of brand-name firms that do not. The estimated AG effects range between slightly less than 6% and 21%. However, despite the large magnitude of some of the estimates, the results are not always statistically significant.[53] Although not all of our specifications allow us to conclude that brand-name firms earn more revenues in markets with an AG than in markets without an AG, none of the estimates provides evidence that brand-name firms lose revenues as a result of introducing an AG. Consequently, based on the quantitative data, brand-name firms may be introducing an AG either as part of a short-run strategy or a long-term strategy. The long-term strategy may include an entry-deterrence element, as well as more benign, revenue-maximizing activities. Chapter 4 explores the brand-name firms' objectives and strategy from additional perspectives.

Table 3-9: Effect of AG Entry on Brand-Name Firm Revenues (Brand-Name Product and AG)

	Unweighted		Sales Weighted	
	(i) No Controls	(ii) Full Controls	(iii) No Controls	(iv) Full Controls
For				

[53] All of the estimates are imprecisely estimated, and neither model that controls for product characteristics can reject the hypothesis that introducing an AG has no effect on brand-name firm revenues.

IV. Conclusion

The analyses presented in this chapter establish several important points. First, firms' decisions to enter, or attempt to enter, markets for specific products can depend on the characteristics of those markets; specifically, Paragraph IV challenges and AG launches are significantly more common with respect to large-market products than small-market products. Second, the introduction of an AG into a market is associated with lower retail and wholesale prices for generic versions of that product. Third, based on estimates of wholesale expenditures first-filer generics make considerably less revenue when an AG enters the market. Finally, while sales of brand-name products are lower when an AG is launched, revenue losses on brand-name products may be offset by revenues from AGs. That is, data do not suggest that brand-name firms' overall revenues are diminished.

These results paint a very important part of the picture, but leave some portions blank. Empirical analysis in Chapter 6 will demonstrate that the impact of an AG extends beyond the exclusivity period. Those post-exclusivity results play a part in the analysis, and any overall quantitative assessment of the impact of AGs on generic firms' decisions must be deferred until that later discussion.

1

expectation that AGs will increase brand-name firm revenues after generic entry but also recognize that launching an AG during the exclusivity period may undermine generic incentives to challenge questionable patents.

This chapter explores the facts surrounding branded companies' marketing Ahts surrounding br

---

[3] See Henry Grabowski, Competition between Generic and Branded Drugs, in PHARMACEUTICAL INNOVATION: INCENTIVES, COMPETITION, AND COST-BENEFIT ANALYSIS IN INTERNATIONAL PERSPECTIVE 153, 154–58 (Frank A. Sloan & Chee-Ruey Hsieh eds., 2007) (generic share increased from 19% in 1984 to 51% in 2002).

[4] See PHARM. RESEARCH AND MFRS. OF AM. ("PhRMA"), PHARMACEUTICAL INDUSTRY PROFILE (2010), http://www.phrma.org/sites/default/files/159/profile_2010_final.pdf (citing IMS Health data); see also GPHA, 2010 ANNUAL REPORT 23 (2010), http://www.gphaonline.org/sites/default/files/GPhA%202010%20Anual%20Report.pdf (also citing IMS Health data); Company Document ("CD"), tbl. 10, 2007 ("Generic revenue & Rx penetration is at an all time high and continues to out pace branded product growth.").

[5] See, e.g., Tracy L. Regan, Generic Entry, Price Competition, and Market Segmentation in the Prescription Drug Market, 26 INT'L J. INDUS. ORG. 930, 939–940 (2008) (reporting brand share six months after entry of approximately 40 percent, based on generic entries from 1998–2001); see also Grabowski, supra note 3, at 158–59 (citing Atanu Saha et al., Generic Competition in the U.S. Pharmaceutical Industry, 13 INT'L J. ECON. BUS. 15 (2006)) (finding brand share six months after entry of about 60 percent, based on generic entry in the 1990s); CD, May 25, 2006 (showing brand market share at 26 weeks of approximately 70 percent, based on 1991–1993 CBO data).

[6] See, e.g., CD, May 25, 2006 (in 2005, brand share 26 weeks after entry was less than 20 percent, based on IMS data); CD, Mar. 31, 2006 (indicating that a single generic product sold during 180-day exclusivity can be expected to erode branded share

[12] CD, Dec. 1, 2006.

analysis. Wholesale expenditures during 180-day exclusivity on the brand-name firm's combined products (brand plus any AG) were higher under all models when an AG was present than when only the brand-name product and an ANDA generic competed.[18] This is consistent with a brand-name firm objective of maintaining a revenue stream following generic entry.

B. The Use of Brand-Name Discounting to Maintain a Revenue Stream

In theory, instead of marketing an AG, a brand-name company might try to retain market share after generic entry by cutting the price of its brand-name product to a level directly competitive with generic drugs. Typically, however, brand-name firms have not employed full "price equalization" strategies.[19] This section explores possible reasons why brand-name companies that seek to defend their revenues after generic entry might turn to AGs.

Selling AGs at the ANDA-generic price and brand-name products at a higher price is a form of price discrimination. If customers can be segmented by their willingness to pay a premium for a branded product, such price discrimination affords an opportunity for the brand-name manufacturer to reap greater revenues.[20] Market segmentation indeed appears possible.

---

that "Authorized Generics Do Not Negatively Impact Brand Share"); CD, Feb. 8, 2002 ("the substitution of brand to generic on this product will occur at the same rate irrespective of [an AG] launch or not"); CD, Nov. 2004 (stating that when an AG is launched in response to generic entry, there is "[n]o acceleration of brand erosion" because there is "no incentive for customer to accelerate substitution"). This is consistent with firm analyses finding that so long as one generic substitute is available, presence of a second generic product does not accelerate substitution. See, e.g., CD, Mar. 23, 2005 ("No correlation between brand erosion and the number of generic entrants."). In contrast, the expectation that brand sales are not eroded by AGs might conflict with the empirical findings of Table 3-8, which show lower expenditures on brand-name products with AG introduction. However, as previously suggested, the analysis that underlies that table cannot distinguish between an AG increasing brand erosion and brands having greater incentives to introduce AGs for products that would rapidly lose sales to generics regardless of whether an AG is introduced. See supra Chapter 3, note 51. The documentary evidence points toward the latter explanation.

[18] See supra Chapter 3, Table 3-9 (showing statistical significance for models without controls but not for models with controls). Similarly, analysis of the post-exclusivity data shows a positive average effect on brand-name firm wholesale relative expenditures from marketing an AG. See infra Chapter 6, Table 6-6. Results for the latter period, however, were not statistically significant.

[19] Other than when AGs were introduced, brands cut price only 20% as much as the ANDA-generics during the 180-day exclusivity period (based on unweighted prices). Weighting showed brand price reductions that were 65% of those of ANDA-generics. Compare supra Chapter 3, Table 3-12 with Chapter 3, Table 3-5.

[20] See CD, undated (indicating that AGs are preferable to price equalization because AGs "allow for market segmentation," i.e., they "[m]aintain brand price for patients with low price sensitivity"); CD, undated (powerpoint prepared for June 2005 presentation listing as the first benefit of an AG strategy, "Segment the market"). The technique of selling both low- and high-priced versions of the same product is not unique to pharmaceutical drugs; price discrimination has long been recognized as a potential means for enhancing a firm's total revenues. See, e.g., ROBERT S. PINDYCK & DANIEL L.

RUBINFELD, MICROECONOMICS381–82 (4th ed. 1997) (explaining that a company that sells the same product in different bottles at different prices to di

drug plans encourage generic substitution through their co-payment schedules.[27] and that

[27] CD, undated.

[28] See CD, undated (discussing retail chains); CD, undated (“PBM’s will substitute with a generic regardless of how much the branded price is discounted”).

[29] The documents add insight regarding the implications of our finding that “first-filer generics make considerably less revenue when an AG enters the market,” see Chapter 3, Section IV, with the magnitude of the AG-entry effect during exclusivity ranging between -39.6% and -52.0%, depending on the model employed. See supra Chapter 3, Tables 3-7, 3-8; CD, Oct. 6, 2005 (projecting that a first-filer generic’s product would lose 29–32% of its net present value over roughly a five-year time frame if faced with AG competition).

[30] CD, June 7, 2003; see also CD, 2006 (denoted “DRAFT”) (“AGs have had a significant impact on market pricing especially during the 180-day exclusivity period. . . . The increased competition has led to significant price erosion and reduced revenue for generic companies.”).

[31] CD, Oct. 2005. The same document, however, lists above the quoted entry the point that AGs “[m]aximize profits for brands facing generic competitors.” Id.

[32] CD, Apr. 25 (year unspecified).

[33] CD, Mar. 27, 2006.

[34] See supra Chapter 2, Section II.B.

[35] See supra Chapter 2, Figure 2-10.

[36] See CD, Nov. 2004 (AG's share is enhanced by launching before the brand loses exclusivity because

placed on appropriate formularies"); Cheu, supra note 21, at 478–79 (arguing that pharmacies' tendency to stock only one generic confers a substantial advantage on first generic to enter).

[37] CD, Mar. 31, 2004 (considering whether the brand's AG subsidiary should adopt a strategy of early launch to deter patent challenges); id. (however, another brand-name firm that considered launching an

[42] The figure does not include three instances where the second settled with the first-filer and made the

during exclusivity continue to be marketed for an extended period, often for many years. Indeed, of the 25 oral-solid AGs launched between 2001 and 2006 and associated with a 180-day exclusivity period, 23 continued to be marketed two years after the beginning of exclusivity; by the end of 2009, three to eight years after the start of the exclusivity periods, 16 remained on the market.[44] This is consistent with brand-name firms' statements that they continue to market AGs "after the 180-day period expires, if it is commercially desirable to do so."[45]

In sum, quantitative information shows that brand-name firms market AGs both with and without exclusivity; typically launch AGs on schedules that forgo maximum impact on ANDA-generic rivals while avoiding cannibalization of brand sales; and generally continue marketing AGs after 180-day exclusivity has ended. These facts all point to use of AGs as a revenue-enhancing technique, but the data are also consistent with the use of some AGs as a disincentive to patent challenges by generic firms.

B. Pricing, Market Share, and Profit-Splits

As described above in Chapter 2, AG marketing follows two principal routes; brand-name companies or their subsidiaries distributed 44 percent of the AGs covered by this study; independent licensees distributed the remaining 56 percent. When AG marketing is handled in-house, the brand-name company can exercise direct control. In contrast, pricing decisions by outside licensees typically are independent of the brand.[46] In both cases, however, material produced for this study suggests that brand-name firms shy away from maximizing impact on generic competitors, while enhancing brand-name firm revenues.

Brands that market in-house generally do not appear to aggressively reduce the price of AGs during 180-day exclusivity, even though such discounting might capture a larger share of the market and thereby diminish generic firms' incentives to challenge patents. At least one major brand-name company recognized that lowering AG prices would tend to "[r]educe[] financial incentives to file Para IV ANDAS"[47] but rejected that approach.[48] Indeed, documents

---

most authorized generics disappear from the market after the 180 days shows that they are neither intended to promote competition nor in fact do so.").

[44] For 2001–2007, discontinuation dates were based on company responses to the Special Orders. The 2010 Red Book, company websites, and other sources were used to determine whether AGs were marketed through the end of 2009.

[45] CD, July 26, 2004 ("working draft").

[46] See, e.g., Agreement, 2006 ("Distributor shall have sole discretion over Distributor's price for the Product"); Agreement, 2004 (distributor "has sole authority and discretion to implement pricing changes"); Agreement, 2005 (distributor solely responsible for pricing).

[47] CD, Mar. 31, 2004 ("Potential [Company] Strategy" of "Substantially Reduc[ing] Generic Price of All [Brand-Name Co.] LOEs During the 180-day Exclusive Period").

[48] As of 2003, the brand-name firm noted that its AG subsidiary "historically follows pricing down (never leads) . . . . Customers expect [AG subsidiary] to follow competitor price changes (both up and

[54] See

Analysis of brand-name firms' documents and marketing practices consequently provides a mixed picture, one consistent with both revenue-generating and entry-deterring objectives. In subsequent chapters we look to additional sources of evidence in order to examine AGs' likely effects on generics' long-run incentives.

CHAPTER 5 THE MARKETING OF AUTHORIZED GENERICS: GENERIC FIRM PERCEPTIONS AND DECISION-MAKING

In Chapter 4 we examined AGs from the perspective of brand-name companies. In this chapter we consider AGs from the perspective of generic pharmaceutical firms, based largely on the documents they submitted in response to the Commission's Generic Company Special Order.[1] In Section I we discuss what the documents reveal about generic company concerns regarding, and reactions to, AGs' effects on their revenues. In Section II we turn to the central issue: the extent to which AGs may create disincentives to patent challenges by generic firms, thereby potentially delaying generic entry and diminishing generic competition.

The generic company documents confirm Chapter 3's empirical finding that the sale of an AG during the exclusivity period substantially reduces the revenue of the ANDA generic, thereby reducing the value of the exclusivity gained through a patent challenge. Yet the documents do not reflect consensus on the longer-term impact of AGs. Although some documents express concern with the potential long-run impact of AGs on generic firm incentives and the financial health of the generic industry, these were largely

---

[1] See infra Appendix E, ¶¶ 18–19, at E-4, E-5. Request 18 sought documents on the impact of AGs on ANDA-generic profitability and the decision of whether to file a Paragraph III or Paragraph IV ANDA. Request 19 focused on documents relating to the marketing of AGs by generic companies. Of the 57 generic companies that received the Order, 16 provided some documents in response to one or both specifications, although several of the submissions were minimal, and several of the largest generic companies produced no documents in response to either Request. Subsequently, one large generic company supplemented its production with company documents and a third-party, interpretive analysis.

[2] See, e.g., Public Comment from the Generic Pharm. Ass'n ("GPhA") to the Fed. Trade Comm'n (June 27, 2006), http://www.ftc.gov/os/comments/genericdrugstudy3/062806gpha.pdf ("The sale of authorized generics during the generic exclusivity period reduces the value of the 180-day exclusivity and consequently reduces the incentive for generic drug companies to challenge questionable patents.").

At the same time the internal company documents submitted by a number of generic companies raise questions regarding contentions that AGs create significant disincentives to patent challenges and seriously threaten the industry's continued ability to develop generic drugs, as some in the industry have argued. As discussed in Chapter 2, different generic companies have adopted different business strategies in the face of AG competition,[3] and those strategies, not surprisingly, appear to be reflected in how they view AGs and their potential long-term impact.

I. The Impact of AGs on Generic Firm Revenues and Profits: Generic Company Concerns and Responses

A. The Nature of Generic Company Concerns

Generic company concerns about AGs are most clearly set out in advocacy documents submitted by several of the generic companies. These materials focus largely on revenue losses experienced by generic firms due to AG marketing during the 180-day exclusivity period. For example, in one generic firm's 2004 powerpoint presentation to the FTC, entitled "The Anticompetitive Threat of Authorized Generics," the firm referenced the example of another generic company that reportedly lost approximately $400 million of expected revenues due to AG competition during the exclusivity period for one drug, which represented as much as three-times its entire annual R&D budget.[4] In another example, the firm contended that it had lost revenues of over $32 million on one drug during the 180-day exclusivity period alone and that that amounted to over 32% of the firm's entire R&D budget for fiscal year 2004.[5] The presentation estimated that, industry-wide, AGs reduced generic revenues by $700 million to $1.2 billion.[6] Thus, it argued, "[a]uthorized generics harm consumers by impairing the ability of generic companies to continue innovating and developing new generic drugs."[7]

Similar concerns about the impact of AGs on exclusivity, using the same examples of lost revenues, are reflected in other advocacy documents produced by the generic firms,

---

[3] See supra Chapter 2, Section I.B.2.b.ii.

[4] Company Document ("CD"), July 15, 2004.

[5] Id. A later analysis submitted to the FTC asserted that the firm "typically forecasts that an AG will reduce its revenue during the [180-day] exclusivity period by roughly 70%" and that "[d]epending on the drug, upwards of 60% of total lifetime revenues and profits come during this exclusivity period." CD, Apr. 2011.

[6] CD, July 15, 2004.

[7] Id.

strategies in the face of widespread AG marketing.[22] Some have continued to emphasize Paragraph IV certifications and pursuit of 180-day exclusivities. Others instead have sought to partner with brand-name firms in marketing AGs.[23] Still other generic companies pursue a mix

---

[22] See supra Chapter 2, Figure 2-6 and accompanying text.

[23] At one end of the spectrum, Prasco markets itself as "The Authorized Generics Company," and explains that it is "not structured to compete with brand companies," but rather focuses on "providing Pharma companies access into the generic marketplace." See Our Business: Authorized Generics, PRASCO, http://www.prasco.com/default.asp?contentid=12&img=ourbusiness.jpg

[24] CD, July 14, 2005 (proposing to "[p]ursue PIV ANDAs; [p]ursue authorized generics . . . If you can't beat-em join-em"); see also CD, Dec. 8, 2004 (stating that "most major generic companies have participated in authorized generic opportunities").

[25] See CD, Mar. 26, 2004 (providing Leila Abboud, "Authorized" Generics Are Under Fire, WALL ST. J., March 25, 2004, at D4) (e-mail attaching Wall St. Journal article reporting that "[a]uthorized-generic deals are dividing the generic-drug industry. Some companies such as Watson Pharmaceuticals and Pharmaceutical Resources Inc.'s Par Pharmaceuticals unit think partnering with brands is a good strategy. But generic industry heavyweights Teva Pharmaceutical Industries Ltd., Mylan Laboratories and Barr Pharmaceuticals Inc. say authorized generics threaten the profitability and long-term health of the industry."); CD, undated (chart entitled "Generic Manufacturers Differ in Strategic Approach," showing Teva, Mylan and Barr "Against" AGs and Sandoz, Watson and Ivax "For").

[26] See supra notes 4-7 and accompanying text.

[27] See, e.g., CD, Jan. 9, 2006 (noting "authorized generic/piggybacking" as one objective); CD, Dec. 8, 2004 (detailing five "near term authorized generic opportunities actively pursued"); CD, June 18, 2004 (e-mail from company CEO stating "I believe we should approach the innovators about authorized generics").

[28] See, e.g., CD, Dec. 21, 2005 (e-mail asking brand-name companies to consider generic company as AG distributor).

arrangements reportedly became important sources of profits for some generic firms.[29]

At the same time, some documents also suggest that AG distribution opportunities for generic firms even as early as 2004 were becoming more difficult to obtain, thereby prompting some to re-visit their AG strategies.[30] As one generic firm document explains:

> AGx opportunities and expected returns have both been substantially reduced in recent months, due to the decision of various brand companies to market more of their products through their own AGx subsidiaries, and increased competition among generic companies for available AGx deals.
> . . . .
> Revenue and earnings shortfalls by many publicly-traded generic companies due to severe pricing competition has made AGs one of the only ways to maintain growth in the short term; The resulting intense competitive bidding for remaining opportunities has made brand companies realize they are in a position to retain most of the economic value of authorized generic versions of their intellectual property; Historically, generic partners received 20–35% of the economics, but this has now been driven down to 10% or less; The reduced value of AG deals for generic companies will hurt the business models of some companies[31] . . . .

In sum, the documents produced by the generic firms reflect different perspectives on AGs depending in large part on their differing business strategies. With this foundation, the following section examines what the generic company document submissions reveal about the long-term impact of AGs on the incentives of generic firms to challenge patents via Paragraph IV filings.

II. The Long-Term Impact of AGs on Generic Firm Incentives to Bring Generic Products to Market via Patent Challenges

Although a few documents register concern with AGs at a general, strategic level,[32] and suggest an increased need to manage the product selection and litigation processes, none of the

---

[29] See CD, Dec. 8, 2004 (chart showing that AGs contribute significantly to the bottom lines of certain generic companies and explaining for two different firms that "authorized generic growth covers base business erosion" and "two authorized generics cover base business erosion").

[30] See CD, May 6, 2005 (describing options as "Stay the course . . . ; Limiting to High Barrier to Entry (HBE), including PIV exclusive opportunities . . . ; Limiting to HBE, not including PIV exclusive opportunities unless they are HBE post exclusivity; [and] Terminate AG activities").

[31] CD, Oct. 12, 2004; see also CD, Dec. 8, 2004 ("Authorized generics will be a continued focus as blockbusters reach the end of exclusivity;" while "[s]ingle product deals open the door to additional opportunities," "the deal value continues to shrink in the US.").

[32] See supra Section I.A.

[33] One document includes a one-sentence statement memorializing a decision to drop a generic project "[d]ue to launch of the authorized generic." CAD Aug. 9, 2005. The context, however, did not involve

strategy," noting that the "Generic Landscape has changed: No More True Exclusivity (Authorized Generics); Probability of Success (POS) of litigation may have changed" and "Market Pricing & Share assumptions have changed."[37] The outcome in that instance, however, was not to cease or shift away from Paragraph IV filings. Rather, the document suggests that the company's mix of Paragraph III and Paragraph IV filings be reviewed and that a more rigorous, systematic selection process be implemented ("[w]e must realign cost/risk against potential upsides in our PIV strategy"), with the goal of placing "Increased Focus on Formulation and

[37] CD, Oct. 27, 2005. In particular, it noted that Paragraph III pricing had declined "from over 10% of brand to under 2% of brand" and that Paragraph IV pricing had declined "from ~60% of brand to ~40% of brand." Id.

[38] Id.

[39] See id. (noting that one AG deal alone "[c]ould add $6M[million]–$24M margin potential in FY06–07").

[40] CD, Jan. 12, 2005.

[41] CD, undated (noting that the "loophole [that] allows the brand manufacturer's 'authorized generic' to immediately compete with the generic manufacturer's product that was granted 180 day exclusivity

. . . is significant because the company that was granted market exclusivity must lower its price to compete with the authorized generic, resulting in reduced profits. Over time, this strategy will lower

think we'd be more selective.[44]

Finally, some of the financial forecasts produced by generic companies support assertions that the expectation of AG competition has tipped the balance against proceeding with a Paragraph IV challenge for certain small-market drugs. One generic company produced contemporaneous "new product forecasts" for four drugs,[45] and explained these forecasts in a subsequent interpretive analysis submitted to the FTC.[46] Combining the contemporaneous data with some additional assumptions and assertions regarding the firm's assessment methodology,

[44] Id.

[45] CDs, Sept. 14, 2007 & May 8, 2008 (new product forecasts).

[46] CD, Apr. 2011.

[47] Id.

[48] Id. The firm's quantitative analysis, however, shows that a generic version of a third drug (with annual sales of $36 million) would have been profitable with or without an AG competitor and finds generic entry for a fourth drug (with annual sales of $20 million) unprofitable under both circumstances. Id.

> the price that the holder of an exclusive generic sells the product for, i.e. say 20% less than the brand. A great profit. If there were an "authorized" generic also, perhaps they will have to discount 30–40% – still a great profit. A profit well worth the expense of the Paragraph IV suit![49]

Moreover, the general counsel shared his concerns with GPhA:

> While I do not wish to be seen as a "rabble rouser" or a malcontent, I do have a few concerns and questions regarding the GPHA position on "Authorized Generics" . . . . [W]hile it is obvious to me that the authorized generic would "skim" some of the profits the first to file would get during a period of generic exclusivity, is there proof that the GPHA position, in the real world, is true, i.e., would many, if not most, Paragraph IV filings not be undertaken if the Paragraph IV filer thought that an authorized generic would be marketed before or during a period of generic marketing exclusivity. Actually I do not believe that is true. . . . I believe that there are many members that are "suspicious" of the GPHA position.[50]

Similarly, a 2004 document produced by a generic company that is a subsidiary of a brand-name company questions the seriousness of the AG threat. After setting out the basic arguments for and against AGs,[51] that document catalogues the benefits of AGs to both brand-name companies and generic companies.[52] It notes that "[g]enerics are perceived as pro-consumer and part of the solution to increasing drug costs,"[53] but questions whether "the generic industry [is] entitled to have the value of 180-day exclusivity frozen in time as a matter of

---

[49] CD, Apr. 9, 2004 (exclamation marks in original); see also CD, July 9, 2005 (deciding to launch an ANDA-generic despite anticipated presence of AG).

[50] CD, Mar. 26, 2004.

[51] CD, Dec. 8, 2004. In support of AGs, the document cites "Increased competition; Decreased prices; Pro-consumer; Additional tool for generic companies to fill 'holes' in their pipeline or to enter new treatment areas; Respects innovator marketing rights; Support generic industry reputation of access to lower cost pharmaceuticals." The points cited in opposition are: "Potential disincentive to file Paragraph IV's; Long term financial impact on generic industry; Abuse of law not in 'spirit' of Hatch-Waxman; Reduced value of 180-day exclusivity to those who have it."

[52] Id. ("Brand companies may choose to launch an authorized generic via a generic partner to: Settle patent litigation; Maximize profits by participating in the generic market once generic competition starts; Solve a manufacturing capacity issue." "Generic companies may choose to launch an authorized generic to: Settle litigation; Compete in a market they otherwise could not have entered; Quickly add additional products to portfolio; Add new source of business.").

[53] Id.

CHAPTER 6 LONG-TERM EFFECTS OF AUTHORIZED GENERICS: PRICE, REVENUE, AND BREAK-EVEN EFFECTS

This chapter extends the analysis of Chapter 3, which considered the impact of authorized generic drugs during the exclusivity period, to time periods in which generic versions of the drug are on the market but no exclusivity applies. The analysis in this chapter is based on two samples of market outcomes: one drawn from drugs for which an exclusivity period was granted but has expired and another based on drugs for which no exclusivity was ever granted. These two scenarios will collectively be referred to as non-exclusivity situations.

The principal difference between the competitive environment outside of exclusivity, as compared to during exclusivity, is the potential for entry by ANDA-generic firms. Firms with tentative FDA approval that are not first-filers are barred from entry during exclusivity. However, firms with approved ANDAs are free to enter at any time outside the exclusivity period. Only one or two generics are typically on the market during exclusivity. In contrast, the number of manufacturers actively selling a generic version of a drug can range from one to more than fifteen outside of exclusivity. Consequently, one may expect an AG to have a greater impact during exclusivity, when it can be one of only a few competitors, rather than one of many.

Chapter 3 showed that introduction of an AG during exclusivity tended to be associated with lower prices, decreased first-filer revenues, and increased brand-name firm revenues. This chapter presents similar analysis using market data from non-exclusivity situations. In general, the results of the analysis of drugs with expired exclusivity periods are remarkably consistent with the exclusivity-period analysis: prices for generic drugs tend to be lower in markets where an AG was launched than in markets without AGs. For markets in which no generic manufacturer was granted an exclusivity period, the estimated effect on generic price of entry by an AG is not consistently different from the effect of entry by an additional ANDA-generic.

In Chapter 3, the analysis of wholesale expenditures demonstrated that introduction of an AG can substantially reduce the revenue of the first-filer generic manufacturer during exclusivity. The new evidence in this chapter suggests that early generic entrants, whether first-filers or AGs, are able to retain a large portion of their market shares even after potentially many other ANDA-generics enter following the 180-day exclusivity period. This first-mover advantage seems to be an important benefit of introducing a product during the exclusivity period. Because the average first-filer who faced an AG during exclusivity begins post-exclusivity competition with a smaller market share, and thus holds on to a portion of this smaller share, the impact of the AG on first-filer revenues persists beyond the 180 days. This result is important because it will be utilized, along with similar estimates from the exclusivity analysis, to calibrate a simple analysis of how the anticipation of facing AG competition may impact the incentives of ANDA-generic manufacturers to pursue Paragraph IV challenges.

This chapter first reviews prior studies that address some of these same issues. It next discusses data sources and analytical methodology, explaining that the data derive from the same sources as in Chapter 3 but that the analysis needs to be tailored to account for differences between exclusivity and non-exclusivity periods. The chapter then presents an econometric analysis of prices and expenditures. It concludes with analysis focused directly on the impact of AGs on the profitability of filing Paragraph IV challenges.

I. Prior Studies

As summarized below, two studies examined the impact of additional generic competitors on price levels after the 180-day exclusivity period. Both show that the marginal impact of an additional generic, whether an ANDA-generic or an AG, is small when more than four or five generics are already on the market. Furthermore, two additional studies considered the impact of AGs on Paragraph IV challenges. Taken together, they suggest that the increased popularity of AG launches has not substantially deterred Paragraph IV challenges and that whatever effects do exist are likely most important with regard to decisions on relatively small-market drugs.

As discussed in Chapter 3, an IMS Study finds that AGs have large price effects during 180-day exclusivity.[1] It extends analysis beyond the exclusivity period by dividing its 18-drug sample into two groups: one comprised of drugs that had 2–5 generics post exclusivity and another for drugs with six or more generic competitors, post exclusivity. The study finds that when 2–5 generics compete, discounts are larger when an AG is also in the market. However, the study finds no long-term price impact from the presence of an AG in markets with six or more competitors.[2]

Using IMS wholesale price data for all drugs that faced new generic competition between January 1999 and December 2003, Berndt et al.[3] plot the relationship between the ratio of contemporaneous generic to brand prices and the number of competitors at 24 months following initial generic entry. Consistent with earlier literature, the authors discover that at 24 months after generic entry ". . . the impact of an additional generic [entrant] is negligible after the fourth or fifth entrant . . . ."[4] While this does not directly address the specific competitive influence of

---

[1] IMS CONSULTING, IMS HEALTH, ASSESSMENT OF AUTHORIZED GENERICS IN THE U.S. 11 ("IMS Study") (2006) (written for the Pharm. Research and Mfrs. of Am. ("PhRMA")), http://replay.web.archive.org/20061009134405/http://www.phrma.org/files/IMS%20Authorized%20Generics%20Report_6-22-06.pdf

[2] Id. at 14–15.

[3] Ernst R. Berndt et al., Authorized Generic Drugs, Price Competition and Consumers' Welfare, 26 HEALTH AFF. 790 (2007).

[4] Id. at 792–93. The study did not distinguish AGs from other generic competitors.

authorized generics, it does suggest that an AG's long-term impact on prices may be small once regulatory restrictions on entry lapse, and conditions are such that many competitors enter.

To the extent that an AG takes sales away from a first-filer generic, expectations about the likelihood of facing AG competition may impact decisions by ANDA-generics about whether to attempt Paragraph IV challenges. One study summarized here finds no support for this hypothesis when analyzing the number of Paragraph IV challenges over time, while AG launches were becoming more prevalent. A second study, using a break-even analysis, finds that the expectation of AG entry may deter Paragraph IV challenges for small-market drugs.

Berndt, et al.[5] analyze whether the upward trend in AG launches over time has had any apparent impact on the number of Paragraph IV certifications. The authors note: "If incentives to file paragraph IV certifications are reduced to the point that no generic manufacturer files a paragraph IV certification against a drug that otherwise would have been successfully challenged, then generic entry could be delayed."[6] However, the authors go on to note that while the "prevalence of authorized generic entry has increased, there has been little overall change in the number of drugs facing paragraph IV certifications, the number of paragraph IV certifications filed per drug, or the timing of paragraph IV certifications relative to NCE [new chemical entity] approval."[7] The authors, therefore, infer that consumers have not borne higher costs as a result of forgone Paragraph IV challenges.

Another analysis conducted by Morgan Stanley[8] attempted to infer how AGs would alter the minimum market size in which it would be profitable to successfully pursue a Paragraph IV challenge. The analysis concludes that the anticipated introduction of an AG would increase the break-even market from one in which the brand had pre-generic-entry sales of $48 million to one in which pre-entry brand sales were $110 million.[9] Hence, the study concludes that to the extent that AGs discourage first entry, they would tend to do so in moderately sized markets. This is

---

5 Ernst R. Berndt, Richard Mortimer & Andrew Parece, Do Authorized Generic Drugs Deter Paragraph IV Certifications? Recent Evidence (2007) (working paper written for PhRMA), http://www.analysisgroup.com/uploadedFiles/Publishing/Articles/PhRMA_Authorized_Generic_Entry.pdf.

6 Id. at 4.

7 Id. at 4. Chapter 7, infra, presents findings based on our own analysis of Paragraph IV certifications.

8 MARC GOODMAN, GARY NACHMAN & LOUISE CHEN, MORGAN STANLEY, QUANTIFYING THE IMPACT FROM AUTHORIZED GENERICS (2004).

9 Id. at 8–9.

10 David Reiffen & Michael R. Ward, Branded Generics as a Strategy to Limit Cannibalization of Pharmaceutical Markets, 28 MAN. & DEC. ECON. 251, 263 (2007).

II. Data and Methodological Approach

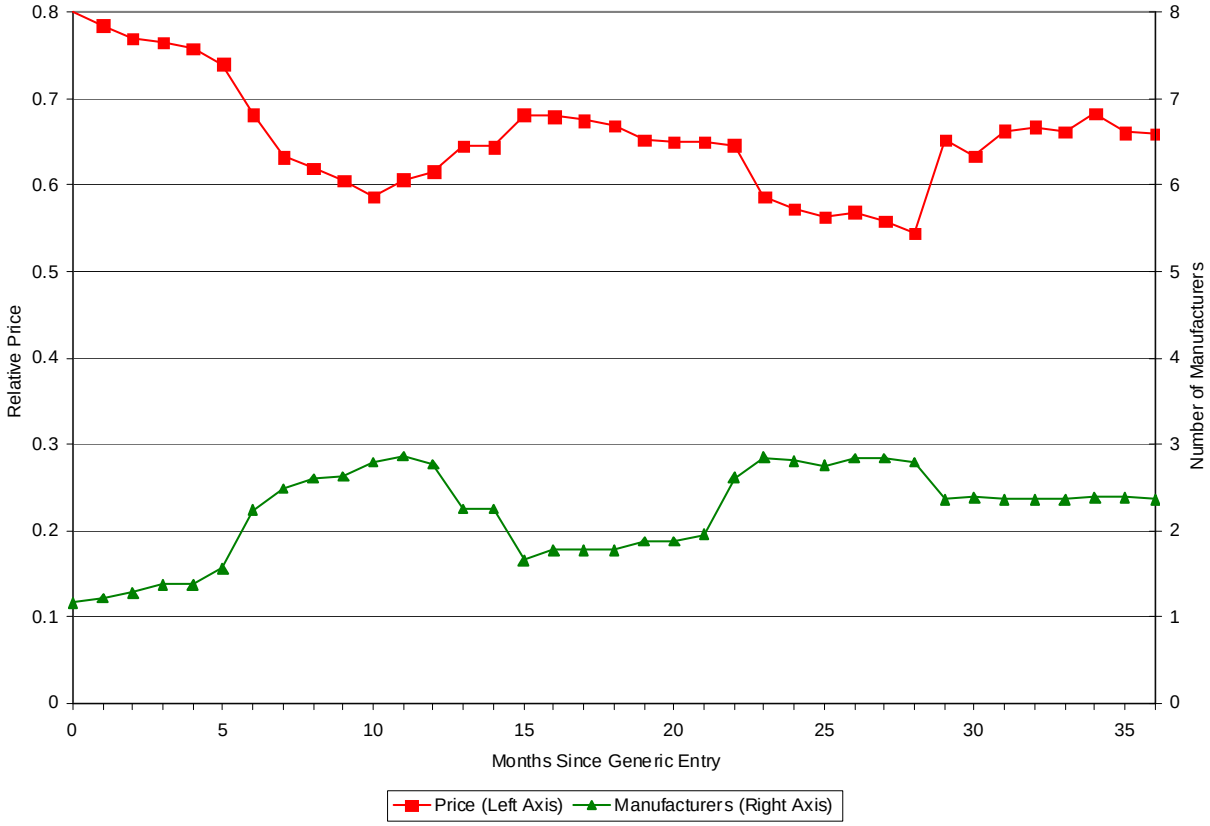
The data analysis presented below has two main goals. First, it seeks to determine the impact of AGs on important market outcomes, such as prices, in situations where market conditions rather than regulatory constraints (apart from FDA ANDA approval) are likely to be the key determinant of the number of competitors in the market. Second, it picks up where Chapter 3 left off, by determining the impact of AGs on first-filer generics in the months following an exclusivity period.

Because markets for drugs that once had an exclusivity period may evolve very differently from markets that never had an exclusivity period, the analysis separately considers the effect of AG entry for drugs that had an exclusivity period at some point and drugs that never had an exclusivity period. In the first instance, the period of study begins immediately following expiration of the exclusivity period (typically six months after initial entry), and includes the same set of products investigated in Chapter 3. In the second instance, analysis begins on the date that any generic competitor entered the market with positive sales, and includes any products that first faced generic competition from 2003 to 2008, and on which no generic

[11] As in Chapter 3, the data analyzed in this chapter consist of monthly observations of market outcomes for "products," which are defined as a full specification of active ingredient(s), dosage form, and strength. Each product accounts for a number of observations equal to the number of months the product is observed in the data, so the results reported may differ substantially from a listing that combined all observations for the same drug. For instance, suppose 600mg Gabapentin tablets account for an observation in the three-manufacturer row of Table 6-1 in a particular month. Then if another manufacturer enters, that product accounts for one of the observations in the four-manufacturer row for the next month. If the number of manufacturers stays at four for several months, each of those months counts as another observation in the four-manufacturer row. In some of those months, there are also four manufacturers selling 800mg Gabapentin tablets, which also would be counted in the four-manufacturer row.

[12] This decline does not necessarily indicate that firms exit the market; it is in part due to some of the products with a relatively high number of competitors experiencing first generic entry with less than 30 months left in our data window, so that we do not observe the 30th month of generic competition for these products.

Figure 6-2: Average Generic Wholesale Relative Price and Number of Generic Manufacturers: Products That Had Exclusivity Without an AG



These graphs also suggest that the question about the impact of an AG needs to be framed somewhat differently in the non-exclusivity analysis. In Figure 6-1, the number of manufacturers in the first several months was a little above two, whereas in Figure 6-2, it was just greater than one. This difference is easily explained b-5551tAG it2s4

---

[13] Some of the steps leading up to generic entry often occur years in advance of actual entry. Therefore, some of the costs associated with entry will have been sunk long before the entry actually occurs. Potential entrants presumably use their expectations about the competitive environment before sinking these costs for a particular product, but they may not know with certainty whether an AG will enter when making some of these decisions.

[14] In technical terms, the problem is that both the decision to issue an AG and the entry decisions of ANDA-generic manufacturers are endogenous, i.e., they have causal links with other variables in the model. An instrumental variables regression analysis utilizing market size and brand-name firm identity as instruments to control for this endogeneity was investigated. The results suggested that

these instruments did not control well for the endogeneity of the number of ANDA-generic manufacturers, so the results are not reported here.

[15] For concreteness, the effect of an AG during exclusivity typically was characterized as the impact of going from just one ANDA-generic competitor to an ANDA-generic plus an AG. Outside of exclusivity, the analysis will estimate the impact of switching from five ANDA-generic competitors, for example, to four ANDA-generics plus an AG. One piece of evidence supporting this approach is provided by an examination of market shares of generic competitors in the first several months following generic entry in "No Exclusivity" markets

A. Retail Prices

Table 6-2 displays estimates of the effect of an AG on relative generic retail price outside of the exclusivity period. This table reports the percentage change in relative price due to substitution of an AG for an ANDA. The first two columns, labeled (i) and (ii), report estimates based on products that never had an exclusivity period; the last two columns, (iii) and (iv), report estimates based on data for products that previously had an exclusivity period. Two regressions are run on each of these data sets. The Unweighted regression treats each monthly observation of an average generic price equally. The Sales Weighted regression weights each observation proportionate to the sales of the brand-name product prior to generic entry.

The estimated effect is the percentage change in generic relative prices due to substituting an AG for an ANDA-generic competitor. A concern that might arise from the relationship between the brand and the AG is that the AG may be a less fierce competitor than an ANDA-generic firm. In such a case, the price of generic products would be higher in markets where an ANDA-generic is replaced by an AG. The results provide little evidence supporting this concern. The AG effect estimates are negative in three of the four models, implying that prices would be lower in a market with an AG than in a market without an AG, holding the total number of generics on the market fixed. For products that had exclusivity, the estimates are

IV. Wholesale Expenditures

This section presents an analysis of wholesale expenditures, which, as discussed in Chapter 3, serve as a proxy for firm revenues. This analysis extends Chapter 3's discussion of the impact of AG launches on the revenues of first-filer generic companies and brand-name manufacturers beyond the exclusivity period. It starts by looking at the dynamics of expenditure shares as additional generic competitors enter the market. It then presents econometric analysis of the impact of AG entry on post-exclusivity expenditures on first-filer generics, on the brand-name product, and on the brand-name and AG products combined. Because this section primarily focuses on the long-term impact of decisions to launch an AG during exclusivity, it considers only the set of products that had an exclusivity period.

A. Evolution of Revenue Shares in Markets with and without AGs

Figure 6-1 shows that AG markets experience a great deal of generic entry at the end of the exclusivity period. If the first-filer becomes just one typical generic manufacturer in a market filled with many such competitors, it is possible that the short-term effects of AG entry on first-filer revenues reported in Chapter 3 will dissipate after the exclusivity period, as the markets quickly become much more competitive. Another possibility is that the added competition causes the first-filer to lose some proportion of its current sales, and that having faced competition from an AG during exclusivity, the first-filer is simply competing to hold on to an initially smaller share of the pie.

Initial insights flow from considering the dynamics of expenditure shares in markets with and without AGs. Shares of wholesale expenditures are calculated for up to four types of manufacturers – first-filer generic(s); other ANDA generic(s); an AG, when appropriate; and the brand -- for each product in each month. Then these shares are averaged across products for each month. Figure 6-3 shows the shares of wholesale expenditures for products with an AG from the first month of generic entry through the third year of generic competition.

The average first-filer quickly takes a share of 40%, but that share falls to just over 30% in the months following the end of the exclusivity period, as the share of other generics increases. As seen in Figure 6-1, the number of generic competitors increases from just over two to almost seven roughly two years after first generic entry. In that light, it is perhaps surprising that the first filer retains as much expenditure share as indicated. Apparently, the first-filer has a first-mover advantage, which may derive from establishing itself as the incumbent supplier to purchasers while facing relatively little competition during the exclusivity period.[17]

[17] See Company Document ("CD"), undated ("historically the first generic to market . . . gains a significant foothold in market share"). Cf. supra Chapter 4, note 36 and accompanying text (discussing potential first-mover advantages in connection with AG launch timing).

The average AG also quickly captures significant expenditure share, and holds onto a significant part of it up through month 36. The brand's share, which was obviously 100% prior to

[18] Because these are shares of current-month expenditures, and as shown in Figure 6-1, the generic price is declining, these are shares of a pie that typically is shrinking over time.

Figure 6-4: Wholesale Expenditure Shares in Markets Without an AG

Taken together, Figures 6-3 and 6-4 indicate that the expenditure shares obtained by generic manufacturers that enter during the exclusivity period, whether first-filer ANDA generics or AGs, tend not to dissipate quickly when the end of exclusivity allows additional generic entry. Consequently, it is possible that AG effects on first-filer and brand expenditures during exclusivity, as estimated in Chapter 3, may extend beyond the exclusivity period. The remainder of this section presents estimates of those effects.

B. Wholesale Expenditures on the First-Filer's Product

This analysis begins by considering the effect of an AG on first-filer revenues.[19] Although the extra revenue earned during 6(a)-wr-20(e)43(t)-wriuQf15(i)35(n)20(6(e)-26(x)-c(e)-10(lu2-33(s)-ivited.)

exclusivity thatg thueswflcli alt mihtain f tl 7irst1ohadv8(1)42(an)38(t)-age.10(t)-19(h)20(i)38(s)9d0(ev)

[19] The sample is limited to first-filer firms. A firm is identified in the data as a first-filer for a product if it is an ANDA-generic firm and had positive sales during exclusivity. The sample of products is therefore implicitly limited to products with an exclusivity period. In the uncommon case in which the product has multiple first-filers, expenditures on the products produced by these firms are aggregated. Revenues of known re-packagers are excluded.

The analysis focuses on the relative wholesale expenditure on the products of first-filers, which are calculated as the expenditures on the first-filer product in a given month divided by the average expenditures on the corresponding brand-name product in the three months prior to generic entry. This is the same measure of relative expenditures utilized and described in Chapter 3. The average AG impact on relative expenditures is estimated using the same model

C. Wholesale Expenditures on The Brand-Name Firm's Products

The analysis now shifts to consideration of the brand-name firm, first estimating the effect of an AG launch on expenditures on the brand-name product itself, then considering the combined impact on the brand and the AG. This enables exploration of whether there is evidence that launching an AG is in the near-term interest of the brand-name company. If combined revenues declined, one explanation might be that the brand-name company is pursuing an unprofitable strategy in order to punish generic companies that pursue Paragraph IV challenges and thereby deter future challenges.

Table 6-5 reports the estimates for brand-name product revenues. The AG Effect estimates are negative, and large in magnitude, but smaller than the estimated impact on first-filer revenues. The estimates range from -21.8% to -15.9%, though the standard errors are quite large, so that one cannot conclude that the impact is different from zero at any reasonable level of significance. The very large standard errors on the estimated AG Effect imply that brand-name product wholesale relative expenditures vary substantially, and that controlling for the presence of an AG does not consistently account for this variation. Although the estimated impact of negative 21.8% reported in column (I) may appear large, the estimate implies that rather than earning revenues equivalent to 11% of pre-entry brand revenues when no AG was launched, the brand-name product earned revenues equivalent to 8.6% of pre-entry brand revenues when an AG was launched. The main finding here is that brand-name product revenues are much lower than they were prior to generic entry, and the presence of an AG has no statistically significant impact on that result.

Table 6-5: Average Effect of Substituting an AG for an ANDA on Brand-Name Product Wholesale Relative Expenditures

	(I) Unweighted	(ii) Sales Weighted
AG Effect	-21.8%	-15.9%
(Standard Error)	(23.9%)	(23.0%)
ANDA-Only Mean Relative Expenditure	0.11	0.07
Sample Size	2,077	2,077

Table 6-6 shows the estimates of AG effects on brand-name firm revenues, i.e., the combined revenues from brand-name products and AGs. Average AG effects are large and positive, ranging from 33.3% to 54.1%, though they are not precisely estimated and are not statistically different from zero. The positive results suggest that marketing an AG that substitutes for an ANDA-generic increases the brand-name firm's revenue on average, but the large standard errors suggest that this impact varies substantially across products. This is in line with our prior analysis of brand-name firm wholesale expenditures during exclusivity, which

also found positive, but sometimes statistically insignificant, effects of AG introduction.[20]

Table 6-6: Average Effect of Substituting an AG for an ANDA on Brand-Name Firm (Brand plus AG) Wholesale Relative Expenditures

	(I) Unweighted	(ii) Sales Weighted
AG Effect	54.1%	33.3%
(Standard Error)	(34.4%)	(38.1%)
ANDA-Only Mean Relative Expenditure	0.11	0.07
Sample Size	2,077	2,077

Neither effect is statistically different from zero at the 10% level

This analysis, along with corresponding results from the exclusivity period presented in Chapter 3, allows for a very rough approximation of the magnitude of the impact of AG introduction on brand-name company revenues relative to the revenue stream generated over the life-span of a brand-name drug. Figure K-3 in Appendix K demonstrates that the average number of years between NDA approval and the first generic entry for brand-name drugs that experienced generic entry by 180-day exclusivity from 2001 through 2008 was roughly ten years, during which time the brand-name company would earn relative expenditures of 1.0 per year. When a brand-name drug faces generic competition during a 180-day exclusivity period, it has the option to launch an AG. Table 3-9 reported that the brand-name firm's relative expenditure averages 0.49 when no AG is launched and increases by 5.9% to 0.52 with an AG. Following exclusivity, Table 6-6 reports the brand-name firm's average relative expenditure in ANDA-Only markets is 0.11 and increases by 54.1% to 0.17 with the introduction of an AG. This effect was estimated using only 0.172605 dou004 d [(dG.)i3e 3, Talts fr 3,n Cth the i8(a)-1(tion ts the brand-05 Tc -0.0005 Tw 0 -1.1Aefff1h pthe inh an onlcally dcef years bion A

[20] See supra Chapter 3, Table 3-9.

[21] This rough calculation assumes that drug prices increase at a rate consistent with the rate at which the brand-name company discounts future revenue streams.

Table 6-7: Impact of AG Introduction on Brand-Name Firm Revenues

Year:	1	2	3	4	5	6	7	8	9	10	11	12	13	Total
No-AG	1	1	1	1	1	1	1	1	1	1	0.49/2 + 0.11/2	0.11	0.11	10.52
AG	1	1	1	1	1	1	1	1	1	1	0.52/2 + 0.17/2	0.17	0.17	10.68
											Generic Competition			

V. Incentives to File Paragraph IV Challenges

The estimated effects of AG launches on first-filer generic expenditures, presented above and in Chapter 3, suggest that anticipation of AG competition during exclusivity might substantially impact a generic company's calculus about whether to pursue a Paragraph IV challenge. This section uses those estimates in a simple break-even analysis to gauge that potential impact. It first presents a calculation of the expected profits for a first-filer from pursuing a Paragraph IV challenge. This is a model of whether to pursue a Paragraph IV challenge when the only resolution of such a challenge is via litigation; agreements to settle the dispute are not considered. This model is calibrated using the estimates from this chapter and Chapter 3 to investigate the impact of AG entry on the decision to file a Paragraph IV challenge. Such decisions, however, are highly idiosyncratic, and it will never be possible to identify from averages and regression estimates how changed expectations regarding the launch of an AG would have affected decisions regarding any particular drug.

A. The Profit Calculation

The model assumes that the potential Paragraph IV challenger expects that if it spends a certain amount of money to pursue a patent challenge on a particular drug, it will win the challenge with some probability, where a win means that the generic is given approval to immediately market a generic version of the drug during a 180-day exclusivity period. The level of anticipated legal expenses and the probability of winning the challenge could certainly vary across drugs, but this analysis will start by thinking in terms of a given drug for which these numbers could readily be estimated by the generic company. Independent of the legal costs, the company also must pursue research and development in order to be in position to file and win approval of its ANDA. In the event that the Paragraph IV challenge fails, this R&D will still allow the challenger to enter, only not with an exclusivity period, and not until the brand no longer has patent protection.

The expected profit of a Paragraph IV challenger can be written as follows:

(Profit of Challenge) = P(win)[(Profit during Exclusivity)+(Profit Post-Exclusivity)]
+ [1-P(win)](Profit ofNon-Exclusive Entry)
- (Legal Costs) - (ANDA Costs)

Each of the profit terms on the right side of this equation needs to be estimated. One potential

Similar algebra yields the following estimate for the first filer's profit during the 2.5 years[26] after the exclusivity period:

$$2.5 \times \frac{(\bar{p}_g - 0.1) \times \bar{r}_g \times r_b}{\bar{p}_g}$$

where variables covered with a bar represent estimated relative statistics from outside of exclusivity, which were estimated previously in this chapter.

Finally, the profitability of entering the market without an exclusivity cannot easily be derived from statistics estimated in this Report. Initially, it is assumed that the patent challenge succeeds with certainty, so this term drops out of the expected profit calculation. However, some of the analysis that follows considers the possibility of unsuccessful challenges. For those situations, a zero-profit entry condition is employed, meaning that outside of exclusivity, generic firms enter until the net present value of the profits from entering equals the costs of obtaining the ANDA, which may include opportunity costs of the manufacturer's time and effort in addition to actual R&D and regulatory filing expenditures. This assumption implies that the expectation of the (Profit of Non-Exclusive Entry) term is equal to the (ANDA Costs) term.

With regard to the cost of Paragraph IV challenges, many respondents to the Special Orders indicated that they did not track these costs on a drug-by-drug basis or could not report the information for similar reasons. For responses that were provided at the drug level, the mean expenditure on a Paragraph IV challenge was approximately $5 million. Expenditures ranged from very low amounts to many multiples of the $5 million mean, and the inter-quartile range was roughly $2 million to $6 million. Similarly, responses to information requests regarding expenditures on R&D and other expenses related to filing an ANDA often were not sufficiently detailed to be useful. However, the responses that did lend themselves to this analysis showed relatively little variation. The inter-quartile range goes from $900,000 to $1.2 million, with a mean of approximately $1 million. Estimates of these costs can vary. An analysis submitted to the FTC by Howrey LLP on behalf of PhRMA utilized an estimate of $5.5 million for litigation costs and $2.5 million in development costs.[27] The robustness of the results to different cost

---

[26] Because it was not possible to reliably estimate effects more than three years after first generic entry, analysis is truncated at the three-year mark. This almost certainly causes some understatement of the profits associated with generic entry. However, the bulk of the AG effect likely is recognized during the exclusivity period and the few years that follow, so ignoring the impact past three years probably is not a significant source of error. Furthermore, future profits are not discounted: assuming that the inflation rate in a given drug market will roughly equal the discount rate of market participants, the use of current dollars in the analysis is appropriate.

[27] HOWREY LLP, THE SHORT-TERM AND LONG-TERM COMPETITIVE IMPACT OF AUTHORIZED GENERICS 22–23 (2009) (written for PhRMA), http://www.ftc.gov/os/comments/genericdrugstudy3/091028pharmresearch.pdf. Also, Morgan Stanley used an estimate of $10 million per challenge, which includes $1–2 million in costs associated with the ANDA approval process. See GOODMAN ET AL., supra note 8, at 8. That is within the range of expenditures observed in the data, and, given the relatively low rate of usable responses, the evidence does not suggest that Morgan Stanley's estimated $8–9 million of challenge expenses was inaccurate.

estimates will be explored.

Given estimates of the legal challenge and ANDA costs and the relative prices and relative expenditures estimated previously in this Report, the expected profitability of a Paragraph IV challenge can be expressed entirely in terms of the pre-generic-entry brand sales of the drug and the probability of winning the Paragraph IV challenge. The next section presents break-even analyses focused on these variables.

B. Break-Even Analysis

Suppose a potential Paragraph IV challenger knew with certainty that a challenge would succeed and an exclusivity period would be granted if the company invested $5 million on the challenge in addition to $1 million on developing the ANDA. How big would the market for the drug need to be to make such a challenge profitable? How would that market size change depending on whether or not the challenger expected to face AG competition? To start to answer these questions, the profit function developed above is calibrated with estimates based on the expectation of no AG entry.

1. Markets without an AG

The first step is to insert estimates derived from the regression analyses of this chapter and Chapter 3 into the expression representing profit during exclusivity.[28] Table 3-2 reported that the average wholesale generic relative price for a drug in a non-AG market during exclusivity is 0.80; which will serve as the estimate of the relative price of the generic during exclusivity, p_g. Similarly, Table 3-7 reports that, without an AG, the average wholesale relative expenditure on the first-filer's product during exclusivity is 0.70. Plugging these numbers into the expression for profit during the exclusivity period yields

$$\frac{(0.80 - 0.1) - 0.70 \times r_b}{2 \times 0.80} \times r_b \times 0.31 \times r_b \times .$$

As reported in Table 6-3, the average ANDA-Only wholesale relative price post-exclusivity is 0.39, and the average ANDA-Only wholesale relative expenditure post-exclusivity is reported to be 0.31 in Table 6-4. Thus, the profits of the first-filer in the 2.5 years following the exclusivity period are

---

However, there is no apparent reason to believe that any accounting idiosyncrasies that may have affected responses to the Special Orders predict a biased sample, so the $5 million estimate of typical expenditures on a Paragraph IV challenge will be used as the baseline here.

[28] Because this analysis is meant to apply to small drugs as well as large drugs, it relies on estimates from unweighted regressions from Chapter 3 and earlier in this chapter.

$$2.5 \times \frac{(0.39 - 0.1) \times 0.31 \times r_b}{0.39} = 0.58 \times r_b.$$

This implies that the first filer revenues in the exclusivity period are a little over half of the sum of their revenues over the 30 months that follow.

The expected profit calculation can now be expressed entirely in terms of the pre-entry brand sales:

(Profit of Challenge) = P(win)[(Profit during Exclusivity)+(Profit Post-Exclusivity)]
+ [1-P(win)](Profit of Non-Exclusive Entry)
- (Legal Costs) - (ANDA Costs)
$=1.0\times(0.31 \times r_b + 0.58 \times r_b) - \$5 \text{ million} - \$1 \text{ million}$
$=0.88 \times r_b - \$6 \text{ million}.$

If the challenger is expected to just break even on the patent challenge, the annual revenues of the brand-name drug would need to be $6.8 million. If instead of the $5 million estimate of the cost of pursuing a Paragraph IV challenge a $10 million estimate was used, expected profits of the first filer would need to total $11 million instead of $6 million, and the break-even brand market size would be $12.5 million.

2. Markets with an AG

Alternatively, a Paragraph IV challenger might expect to face AG competition, both during the exclusivity period and in the years that follow. Table 3-2 reports that the addition of an AG causes average generic wholesale relative prices to fall by 12.8%, so the average relative price during the exclusivity period would be the 0.80 used above times (1 - 0.128), or 0.70. Table 3-7 estimates that average relative expenditures fall by 52.0% when an AG is launched, so the average relative expenditure during exclusivity would be the 0.70 used above times (1 - 0.52), or 0.34.

Similarly, the presence of an AG causes the post-exclusivity relative price to fall by 13.0%, according to Table 6-3, so the mean relative price falls to 0.34. Table 6-4 indicates that the post-exclusivity relative expenditures on the first-filer's drug fall by 52.5% when an AG is present, so relative expenditures fall to 0.15. Plugging these estimates into the expected profit formulas yields:

(Profit of Challenge) $=1.0\times(0.14 \times r_b + 0.26 \times r_b) - \$5 \text{ million} - \$1 \text{ million}$
$= 0.40 \times r_b - \$6 \text{ million}.$

The pre-entry brand revenues would need to be $14.9 million in order for the challenger to have expected profit of exactly zero. Using the $10 million estimate of challenge expenses, break-even market size increases to $27.3 million.

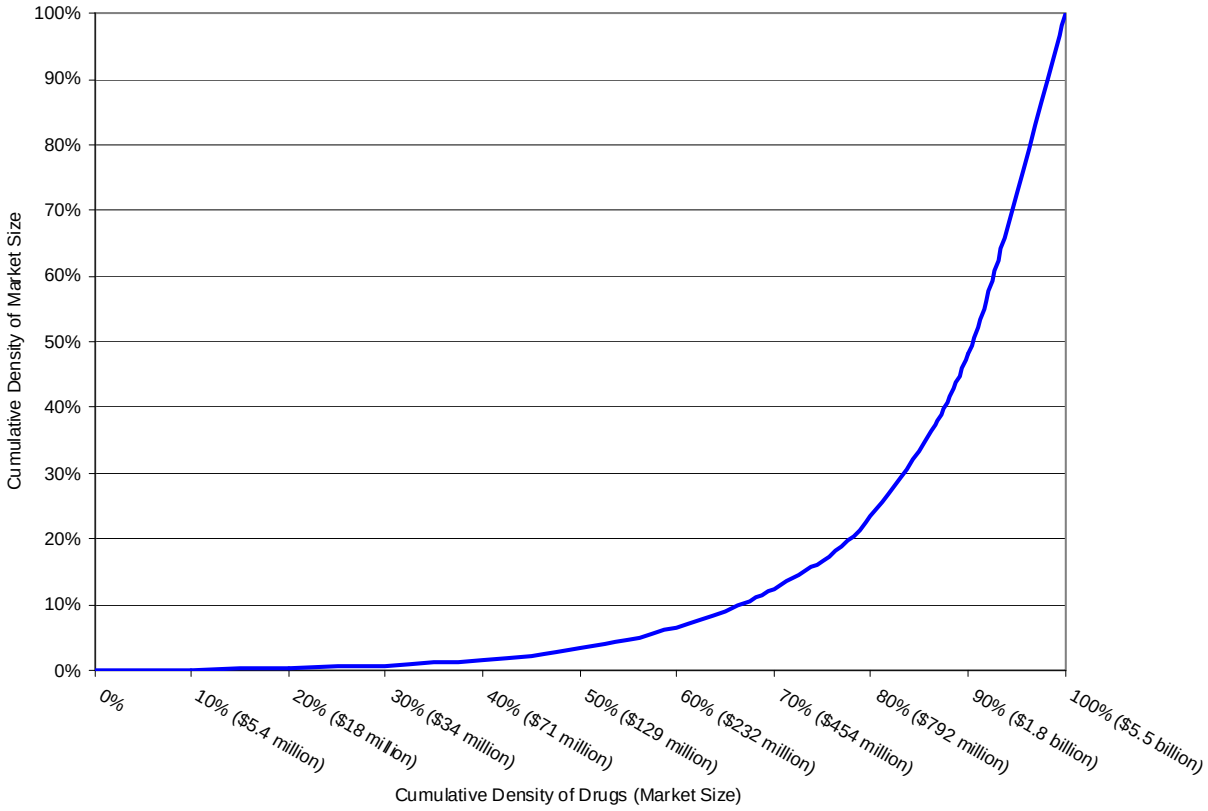
Two observations warrant emphasis. First, the estimated break-even market is more than

twice as large when the first filer must compete with an AG. This is not surprising: the AG takes share from the first filer during the exclusivity period, that effect persists after exclusivity, and prices are lower in the presence of an AG. Second, break-even levels are satisfied by very low-sales drugs. The break-even market sizes reported here are much smaller than the break-even

[29] The lower break-even market sizes reported here are consistent with evidence presented in Chapter 7, that drugs with market sizes smaller than $50 million do attract Paragraph IV challenges.

[30] The market sizes reported here are aggregated over strength and dosage form. In other words, market size is calculated for all strengths and forms of a particular combination of active ingredients.

Figure 6-5: Cumulative Share of Pre-Entry Wholesale Sales For Drugs Experiencing First Generic Entry from 2003 through 2008



Using the higher cost estimates, the break-even analysis above identifies drugs with sales below $27.3 million as those for which an expectation of an AG would deter a Paragraph IV challenge. Figure 6-5 indicates that drugs of this magnitude constitute between 20% and 30% of the drugs in the sample, but account for less than 1% of the total sales. Using the lower cost estimates, expected AG entry would deter Paragraph IV challenges affecting drugs with sales below roughly $15 million, representing a little under 20% of the drugs in the sample but less than 1% of total sales.[31] However, this analysis was based on the presumption that the Paragraph IV challenge will succeed with certainty. Challengers, of course, almost never are 100% certain to succeed. The analysis below further explores the relationship between market size and probability of winning the Paragraph IV challenge.

3. Effect on Threshold Probability of a Successful Challenge

Another way to think about the effect of AG competition on the decision to bring a Paragraph IV challenge is to fix the drug's market size and to consider how the probability of winning the challenge necessary to justify pursuing it changes when an AG is launched. As

[31] Some drugs, with very small market sizes, may have drawn Paragraph IV challenges even if there had been no prospect of AG competition.

noted above, this analysis must account for the impact on profits when the challenge is unsuccessful and the generic enters only in a non-exclusivity situation. Given that any generic

[32] Again, the calculation of market size aggregates all strengths and dosage forms associated with a particular combination of active ingredients. See supra note 30.

the challenge would depend on the likelihood of AG entry. More generally, the area between these two curves depicts the situations where the perceived likelihood of AG entry can impact whether or not a Paragraph IV challenge can be expected to be profitable.

Without data on how generic companies perceive their probabilities of success for Paragraph IV challenges, it is not possible to determine how many additional challenges would be pursued if expectations shifted from expecting an AG to not expecting one, though consideration of a few examples can be instructive. For the median drug, it was shown above that the range of probabilities over which an AG could impact whether a challenge is expected to be profitable or not is narrow. However, for some drugs just below the median, the range can be quite substantial. For instance, the 30th percentile drug shown in Figure 6-5 has $34 million in annual sales. For a drug of that size, Figure 6-6 shows that expectation of an AG launch can be pivotal for success probabilities from 17% to 39%. Although a substantial number of drugs of this approximate size are on the market, Figure 6-5 indicates that these drugs account for less than 1% of the dollars. On the other hand, drugs the size of the 70th percentile drug or larger, with annual sales in excess of $454 million, account for 87% of the expenditures. For this 70th percentile drug, the AG is pivotal only for success probabilities between 1.3% and 2.7%, and that range shrinks for even larger drugs. For these bigger drugs, the 180-day exclusivity period is so profitable, even if shared with the AG, that the probability of success need not be very high for a challenge to be profitable in expectation.

At stake, however, is not the number of generic challenges but an authorized generic's potential to reduce or delay actual competition. Although many factors affect a decision to file a Paragraph IV ANDA, Figure 6-6 provides a rough sense of when the expectation of an

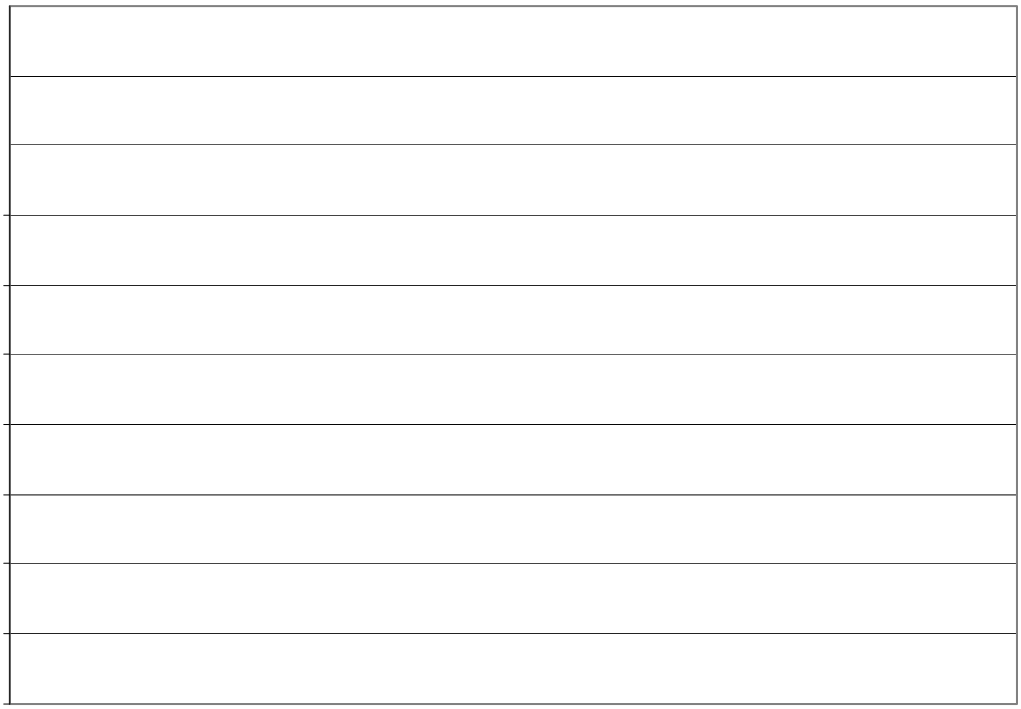
---

[33] To the degree a generic company is overly optimistic about its challenge, however, AG competition would deter challenges when the generic's actual chance of winning was even lower than four to ten percent. Conversely, if the generic were overly pessimistic about its chances, AG competition would deter challenges when the real chance of success was higher than the subjective assessments shown in Figure 6-6.

[34] In this analysis, future profits are not discounted. Firms do not typically use the same discount rates when making entry decisions, and therefore the choice of any specific discount rate is admittedly arbitrary. The effects of a higher discount rate would likely shift the profiles of the break-even drugs towards larger drugs. However, changing the discount rate by any reasonable amount would not drastically alter the basic conclusions of the analysis: an AG would affect the profitability of a paragraph IV filing only where the brand sales are small.

bringing a patent challenge in markets with brand sales between $12 million and $27 million, a range that accounts for 13 percent of drugs, but, given their low sales, approximately one percent of total prescription drug expenditures.

Figure 6-6: Break-Even Market Sizes for Varying Probabilities of Successful Paragraph IV Challenge



These effects appear unlikely to impact decisions on high-sales drugs, but could potentially play a role in decisions to challenge small and medium market drugs. The only challenges that would be deterred by expectation of an AG and have a reasonably large probability of being successful are on the relatively small drugs.

CHAPTER 7 ASSESSING THE IMPACT OF AG COMPETITION FROM PATENT CHALLENGE DATA

The financial analyses of Chapters 3 and 6 show that AG marketing during exclusivity

[1] Unlike Chapter 3 and Chapter 6, where analysis examined different "products," see supra Chapter 3, note 16 and Chapter 6, note 11, this chapter focuses on "drugs," which include all strengths covered by an NDA. This unit of observation is most appropriate for an analysis of patent challenge data because Paragraph IV challenges typically target all strengths of a drug. In addition, ANDA records in the relevant FDA database were organized by application number, and usually included all strengths of a drug in a single application. The chief consequence is that different strengths, which had been treated as separate observations in Chapters 3 and 6, are treated together as a single observation.

[2] See supra Chapter 6, Section V.

[3] See, e.g., David Reiffen & Michael R. Ward, Branded Generics as a Strategy to Limit Cannibalization of Pharmaceutical Markets, 28 MAN. & DEC. ECON. 251, 263 (2007) (concluding that the introduction of AGs is "least problematic . . . in relatively large markets").

[4] The dates of the first Paragraph IV certifications made in ANDAs for a particular drug (i.e., for a particular dosage form and NDA) were obtained from the U.S. Food and Drug Administration's ("FDA") Paragraph IV Patent Certifications website. See Paragraph IV Patent Certifications, FDA,

Table 7-1: Number of Drugs Subject to First Patent Challenges, by Sales Level

Year	<$50M	$50-100M	$100-500M	>$500M
2003	2	1	7	10
2004	2	3	10	8
2005	6	3	11	7
2006	6	7	9	6
2007	8	5	19	9
2008	6	11	15	7
SUM	30	30	71	47

The table shows, by sales level, the number of drugs for which the first Paragraph IV certification was made from 2003–2008.

[6] See HOWREY LLP, THE SHORT-TERM AND LONG-TERM COMPETITIVE IMPACT OF AUTHORIZED GENERICS 26 (2009) (written for Pharm. Research and Mfrs. of Am. ("PhRMA")), http://www.ftc.gov/os/comments/genericdrugstudy3/091028pharmresearch.pdf (finding break-even points of $50.2 million without an AG and $110 million with an AG); ARC GOODMAN, GARY NACHMAN, & LOUISE CHEN, MORGAN STANLEY, QUANTIFYING THE IMPACT FROM AUTHORIZED

with the finding in Chapter 6 that break-even levels for entry via a patent challenge that the generic believes it has a 50% probability of winning may be satisfied in markets with annual sales of $27.3 million when an AG is anticipated, and $12.4 million without an AG.[7] AGs have been very uncommon for drugs with sales of less than $50 million,[8] and consequently may have played a reduced role in decisions regarding patent challenges for such drugs.

The sales-level data thus suggest that many low-sales drugs receive patent challenges, notwithstanding potential AG competition. This is not to say that patent-challenge incentives are adequate for all small-market drugs. Nor does it suggest that patent challenges are likely for small-revenue drugs as for large-revenue drugs.[9] Indeed, as a general matter, the reverse is true.[10] The challenges to some small-revenue drugs could be explained by factors that made the drug more valuable to the company than the brand's sales level would suggest. For example, challenges may have occurred in settings where the generic company anticipated a future increase in the drug's sales,[11] or had a special interest in a particular drug because of its therapeutic class, or where the generic company was already challenging the same patent with respect to another drug or perceived infringement litigation (or successful infringement litigation) to be unlikely.

GENERICS 6–9 (2004) (break-even point of $48 million without an AG and $110 million with an AG); see also Pfizer, Do Authorized Generics Benefit Consumers? (2005) (presentation slides showing break-even points of $48 million without an AG and $89 million with an AG). The analysis in Chapter 6 suggests that for a drug with $50 million in pre-entry brand-name sales, a generic firm that does not expect AG competition would expect that a patent challenge would be profitable if it anticipated a 12% probability of winning; however, if the firm expected to face an AG, it would require at least a 26% probability of winning to expect profitability. See supra Chapter 6, Figure 6-6.

[7] See supra Chapter 6, Figure 6-6. For higher probabilities of winning, the break-even level is even lower, e.g., $6.8–$14.9 million when the generic believes it has a 100% probability of winning, depending on whether or not it anticipates AG competition.

[8] See supra Chapter 2, Figure 2-9 and accompanying text. Between April 2003 and December 2008, there were six exclusivity periods on products with sales below $50 million; in none of those situations did the brand launch an authorized generic during the exclusivity period. But cf. supra Chapter 5, note 14 and accompanying text (noting that some generic companies produced documents indicating that the firms always assume AG competition).

[9] Even assuming companies are less likely to challenge patents on low-sales drugs, similar numbers of low- and high-sales drugs subject to a first patent challenge could arise if there are more low-sales drugs available for first challenge than high-sales drugs.

[10] See infra Appendix I, Figure I-1 (frequency of Paragraph IV challenges increases as pre-entry brand sales increase).

[11] The data are based on sales at the time of certification rather than at generic entry. (Because the length of time between certification and generic entry is often many years, generic entry has not yet occurred for many of the drugs with first patent challenges in 2003–2008.) It is possible that a company might have challenged a patent on a low-sales drug because it anticipated an increase in sales by the time of generic entry. If so, a low sales level at certification might not represent the company's view of the financial incentive underlying its challenge.

To explore this issue, we examined the circumstances for challenges regarding the twelve drugs during the 2003–2008 time frame for which sales were under $20 million. For eight of the twelve low-sales drugs, the first ANDA with a Paragraph IV certification was filed within three years of NDA approval, and anticipated growth in sales might have been a factor.[12] For three drugs, the therapeutic class of the low-sales drugs may have contributed to the companies' interest in pursuing a challenge.[13] In several instances economy of litigation appears to have been a factor: the generic company challenged the same patents with regard to a related drug with a larger market, thus reflecting an overall financial incentive greater than that of the smaller drug.[14] In other instances, the generic company might have believed that it was unlikely to be sued. Thus, for one low-sales drug, the generic company might have thought that litigation was unlikely because the brand-name company had not filed an infringement suit when another generic firm challenged the same patent with regard to a different product.

Together, these facts suggest that generic companies may be more selective with regard to low-sales drugs, bringing challenges under conditions that they consider favorable. The combination of factors in such cases supports patent challenges even in small markets. But that may not always be the case, and it is possible that a perception that AG competition is likely could tilt the balance against a patent challenge in some instances.

B. Trends in Sales Levels of Drugs Subject to Challenge

The trends in 2003–2008 sales levels of brand-name drugs for which patent challenges were made provide no suggestion that AG marketing has inhibited challenges with regard to low-sales drugs. Table 7-2 shows the mean, median, and range of the sales of brand-name drugs subject to a first patent challenge from 2003 through 2008. While there is some year-to-year variation, during this period the mean and median sales level of drugs subject to a first challenge clearly show no increase. Rather, in 2003, the mean sales level of drugs subject to a first patent challenge was $844 million; in 2008, the mean was $358 million. The median sales level

---

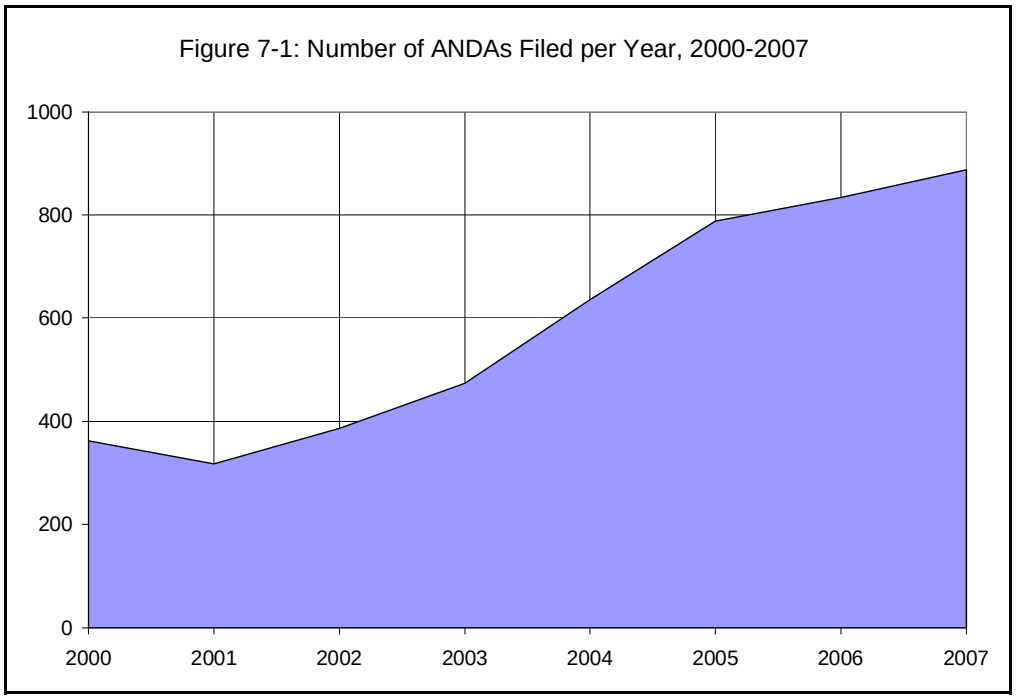
[12] For example, patent challenges for a new formulation of a blockbuster drug (sales greater than $2 billion) began less than a year after approval of the new formulation, when annualized sales were about $14 million. Five years later, the year before generic entry, sales of the new formulation had risen to about $90 million. See infra Appendix H, Section IX, regarding annualization of sales.

[13] This might have contributed to two companies' patent challenges regarding three contraceptives; the companies offer a number of estrogen hormone-related drugs.

[14] The most dramatic example of such a strategy concerned a company's challenge to patents on a drug with sales under $1 million, which could be expected by its simultaneous challenge to the same patents listed for an older dosage form of the drug with sales of nearly $2 billion. The low-sales drug was a line extension of the high-sales drug, i.e., it contained the same active ingredient, and was part of the same "franchise" as the high-sales drug. Five other low-sales drugs involved challenges to patents that covered other drugs with substantially higher sales.

[15] The declines were statistically significant for comparisons of 2003 sales with 2007 and 2008 (5% statistical significance level, using a two-tailed t-test, variances not assumed equal). Other pair-wise comparisons were not statistically significant. The observed declines in the mean and median sales levels of drugs subject to a first patent challenge could be explained by an increase in challenges to small-market drugs or by a decrease in the market size of drugs available for challenge; the data do not distinguish between the possibilities.

[16] These graphs are based on the patent certifications entered in ANDA records maintained in the FDA's application database. Although patent certifications must be made with respect to every patent listed in the Orange Book, the FDA application database lists only the highest certification made. Thus, if an ANDA contains a Paragraph IV certification for any patent, the database shows a Paragraph IV certification even if the applicant also made Paragraph II (the patent is expired) or Paragraph III certifications for other patents. Changes in the FDA's application database precluded compiling the



Number of ANDAs filed per year, including all dosage forms.

The trends in ANDAs filed with respect to patent-protected drugs are similar to the overall increase in ANDAs. As explained above, a company that files an ANDA for a drug for which patents are listed in the Orange Book must certify whether it intends to wait until patent expiration to market its generic product (a "Paragraph III" or "PIII" certification) or whether it seeks entry before patent expiration by challenging the patent on the basis of invalidity or non-infringement (a "Paragraph IV" or "PIV" certification).[19] As shown in Figure 7-2, Paragraph III and IV ANDAs increased roughly in parallel from 2000–2007, although the total increase in PIV certifications was somewhat greater than that of PIIIs. The substantial increase in PIVs after 2004, when AGs had become common, is another piece of evidence consistent with the conclusion that authorized generics have not noticeably deterred Paragraph IV challenges.

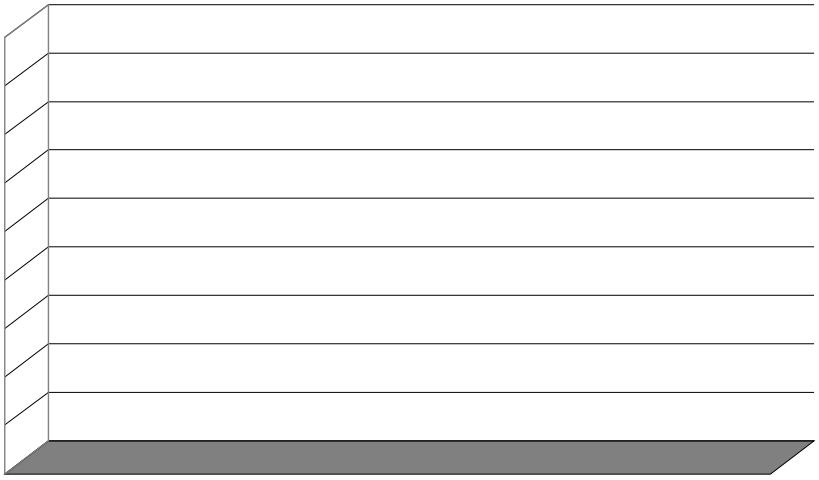
---

increase from the years 2000 to 2007 in ANDA filings, including those with patent challenges, does not appear to arise from an increase in NDAs. The number of NDA approvals varied from year to year but did not exhibit an upward trend in this period and the years preceded it. See U.S. GOV'T ACCOUNTABILITY OFFICE, NEW DRUG DEVELOPMENT: SCIENCE, BUSINESS, REGULATORY, AND INTELLECTUAL PROPERTY ISSUES CITED AS HAMPERING DRUG DEVELOPMENT EFFORTS 24 (2006), http://www.gao.org/new.items/d0749.pdf; CTR. FOR DRUG EVAL. AND RESEARCH ("CDER"), FDA, 2007 UPDATE: IMPROVING PUBLIC HEALTH THROUGH HUMAN DRUGS 12–15 (2007), http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/WhatWeDo/UCM121704.pdf

[19] See 21 C.F.R. § 314.94(a)(12) (2010).

20

2003 and 2006 and a large increase in 2007.[22]



[22] Data on yearly patent challenges were obtained from the FDA's Paragraph IV website. See supra note 4. A previous study that examined the number of drugs facing a first Paragraph IV certification observed little change from 2004 through May 2006. See Ernst R. Berndt et al., Authorized Generic Drugs, Price Competition, and Consumers' Welfare, 26 HEALTH AFF. 790, 794 (2007).

[23] Staff examined the FDA's application database to determine whether a particular ANDA contained the first PIII certification for a given drug (i.e., for a particular dosage form and NDA), and whether any previous or subsequent ANDAs for the same drug contained a PIV certification. This allowed staff to identify PIII drugs, for which no ANDAs with PIV certifications were filed, either before or after the first PIII certification. Because complete PIII ANDA filing information for 2008 was unavailable, staff limited the analysis to 2003–07.

[24] Of the 286 ANDAs with PIII certifications filed in 2006 and 2007, only four were first PIII certifications; rather, the bulk of the ANDAs with PIII certifications were either filed after a first PIII certification in a previous year, or were filed with regard to a drug for which another applicant made a PIV certification.

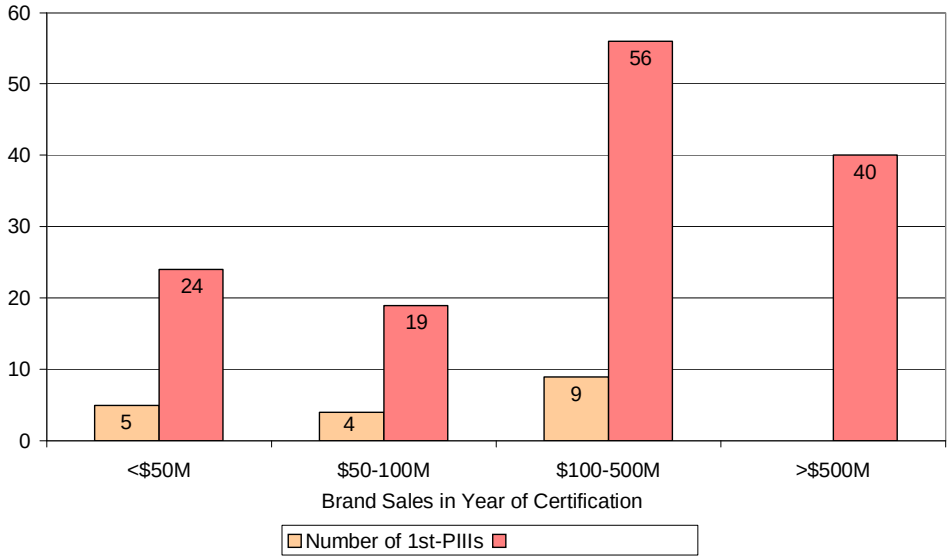
[25] This percentage could fall if a "first PIII filer" amends its certification to PIV, or if a subsequent ANDA makes a PIV certification for any of the four drugs.

[26] These findings are consistent with a recent industry study that concluded that "the vast majority of

OF THE U.S. COMMODITY GENERICS MARKET IN 2009–2013, at 3 (2009); see also id. 7, 14 (by dollar or prescription volume, Paragraph IV drugs comprise the bulk of generic market entry).

[27] The difference between the mean sales of PIII drugs ($136,245,673) and PIV drugs ($541,720,294) was statistically significant at the 1% level, using a two-tailed t-test, variances not assumed equal.

Figure 7-4: Number of Drugs with First Paragraph III and Paragraph IV Certifications from 2003-2007, by Brand Sales



[29] In addition to an increased likelihood of sharing exclusivity with another generic competitor in the NCE context, there is also the possibility of an authorized generic, further reducing the expected profits from a successful Paragraph IV certification.

[30] See 21 C.F.R. § 314.108 (2010). The percentages were calculated from New Molecular Entity (NME) and NDA approvals from 2000–07, as reported by the FDA. See Summary of NDA Approvals & Receipts, 1938 to the present, FDA, http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/SummaryofNDAApprovalsReceipts1938tothepresent/default.htm (last updated Feb 16, 2011); NME Drug and New Biologic Approvals, FDA, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/ucm121136.htm (last updated Feb 23, 2011); CDER, supra note 18, at 11.

[31] See JOHN THOMAS, PHARMACEUTICAL PATENT LAW 432-35 (2d ed. 2010). ANDAs with PIV certifications cannot be filed until four years and six months have elapsed if the FDA has granted pediatric exclusivity.

[32] See id.; CDER & CTR. FOR BIOLOGICS EVAL. AND R

[33] SeeCDER,FDA,

[36] The increase in first-day challenges may reflect that, under the certainty, with shared exclusivity, that any given first-day filer will be permitted to participate in the exclusivity period. The gradual nature of the

increase likely reflects the time required for generic companies to take advantage of the broadened opportunity for sharing exclusivity by developing and filing ANDAs for NCE drugs for which first-day filing opportunities were approaching.

[37] The number of first-day ANDAs with a PIV certification is based on the number of apparent first-day ANDAs in the FDA's application databases. Because the FDA may not deem all such filings as "substantially complete" or approvable, these numbers should be considered estimates of the number of companies that will compete during exclusivity. See infra Appendix H, Section X.

[38] The companies likely anticipated that they would share 180-day exclusivity with several other first-day filers. Although ANDA filings are confidential, firms would be aware of the prospect of sharing exclusivity, both because of such sharing for a few NCEs for which generic entry already has occurred (e.g., Protonix), and because of court documents and other sources that indicate that many companies

willing to undertake patent challenges despite the prospect of sharing exclusivity with an AG.

IV. Conclusion

Analysis of a number of measures of the frequency and scope of challenges to pharmaceutical patents suggests that patent challenges continue to be induced for most drugs, even though AGs substantially diminish generic revenues during 180-day exclusivity. Despite concerns that challenges to patents on small-market drugs might be inhibited, such challenges do occur, and the surge in AG marketing has not been accompanied by any observed increase in the sales level of drugs for which patents are challenged.

In addition, the number of ANDAs with Paragraph IV certifications rose dramatically in recent years, and the number of drugs with such certifications also increased. By contrast, generic companies rarely have chosen to wait until patent expiration to enter the market; drugs for which only ANDAs with Paragraph III certifications are filed have been very uncommon in recent years. And even at the lowest sales levels, the number of Paragraph IV drugs greatly exceeds the number of Paragraph III drugs. Moreover, examination of the analogous situation posed by first-day Paragraph IV certifications for new chemical entities, for which the generic company is likely to share exclusivity with other ANDA applicants, suggests that generic companies are nonetheless willing to undertake patent challenges. Thus, a variety of findings point to the conclusion that generic firms continue to bring patent challenges for most drugs, even though AGs are now common.

---

now have shared exclusivity in most cases"); Sara Stefanini, The Best and Worst Patents for Generics To Fight, IP Law360, at 1, 4, May 6, 2008 ("People are going to be filing on that four-year date, and everybody knows that everybody is going to file . . . .").

CHAPTER 8: THE USE OF AUTHORIZED GENERICS IN PATENT LITIGATION SETTLEMENT AGREEMENTS

As reported in Chapter 3, AG competition typically reduces an ANDA-generic's revenues during the 180 days of marketing exclusivity by approximately 50 percent. To prevent this loss of revenue, the ANDA-generic may be willing to delay its entry in return for a brand's agreement to launch an authorized generic during the generic's 180 days of marketing exclusivity.

Such agreements can harm consumers in two ways:

- First, generic entry, and the accompanying discounts, would not be

[1] See, e.g., CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 31 (1998), http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf

[2] In some cases, the brand appoints the generic to distribute the brand's AG during the 180-day period of marketing exclusivity. In such circumstances, there is still no competition between an ANDA-generic's product and a brand's AG.

first-filer generics[3]. About one-quarter (39 out of 157) of those involved (1) an explicit agreement by the brand not to launch an AG to compete against the first-filer, combined with (2) an agreement by the first-filer generic to defer its entry. On average, the entry date specified in the agreement was 37.9 months after the settlement date.

" Annual brand sales of the affected products ranged from $7.1 million to $5.3 billion, with an average market size of $616 million and a median market size of $245 million. Seven settlements covered products with annual brand sales between $1 billion and $5.3 billion.

" Over the seven years studied, settlements that combined deferred entry with "No AG" promises governed the sales of drugs with a total market exceeding $23 billion.

This chapter describes and analyzes the various types of agreements that involved AGs in ways that raised potential competitive concerns.

I. The Problem of Anticompetitive Brand-Generic Patent Settlement Agreements

Under Hatch-Waxman, patent litigation between a brand and a generic typically occurs when a generic seeks entry *prior* to expiration of the patents on a corresponding brand-name drug by alleging that such patents are invalid or *not* infringed by the generic's drug product. The parties often settle rather than litigate the case to its conclusion. Such settlements do not necessarily raise concerns under the antitrust law. For example, if the brand and generic settle the litigation simply by agreeing on a time for generic entry that is prior to patent expiration but later than immediate entry without any compensation, such a settlement most likely reflects the parties' views on the likelihood of success of their respective patent challenges and patent defenses, as well as their respective tolerances for risk. These types of simple settlements, with no other provisions, generally do not raise competition concerns.

Settlements in this context can raise serious competition concerns, however, when they involve compensation from the brand to the generic to delay generic entry beyond the time of a simple compromise date along the lines described above (hereinafter, the "simple compromise date"). The FTC has challenged a number of these settlements as anticompetitive. Such

---

[3] In this chapter, when used in the context of categorization of an agreement, a "first-filer" is defined as a generic entitled to 180 days of marketing exclusivity *at the time* of the settlement agreement. Under some circumstances, there can be competition from other first-filers during the 180-day exclusivity period. See 21 U.S.C. § 355(j)(5)(B)(iv)(II)(bb) (2010) (providing that exclusivity may be shared by applicants filing on the same day).

settlements, known as "exclusion payment" or "pay-for-delay" settlements,[4] thwart the goal of the Hatch-Waxman Amendments to encourage generic companies to challenge questionable patents and promptly "make available more low cost generic drugs," while simultaneously protecting legitimate patent claims covering innovator drugs.[5] Settlements potentially raising "exclusion payment" issues are now common.[6] Congress is now considering a variety of legislative proposals regarding "pay-for-delay" settlements, and the Commission supports restricting such settlements.

In recent years, a number of brand-generic patent settlement agreements filed under the MMA appear to use provisions relating to authorized generics – instead of direct monetary payments – to compensate a generic in return for a generic's agreement to delay its entry beyond the simple compromise date. Moreover, material produced in connection with the FTC's study of authorized generics confirms that a brand-name company may agree to refrain from offering a competing AG to maximize the net present value of both the brand-name and generic products. Documents from a brand-name firm show how an agreement not to compete with an AG increases the revenues of both the brand-name and generic companies. The brand-name company's revenues increase because generic entry and the accompanying drop in brand revenues occur later than they would without the brand's promise not to market an AG; the generic's revenues increase

---

[4] Pursuant to settlement, a generic company may pay a royalty to the brand to gain an earlier entry date than it would get by compromising on the date alone, while an exclusion payment – a payment from the brand to the generic – buys a later entry date. See Alden F. Abbott & Suzanne T. Michel, The Right Balance of Competition Policy and Intellectual Property Law: A Perspective on Settlements of Pharmaceutical Patent Litigation, 46 IDEA 1, 14 (2005).

[5] H.R. Rep. No. 98-857(I), at 14, 28 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647, 2661. Although initial judicial reactions reflected concern with such arrangements, see, e.g., In re Cardizem CD Antitrust Litig., 332 F.3d 896, 908 (6th Cir. 2003), subsequent appellate rulings adopted a far more permissive position. See Ark. Carpenters Health & Welfare Fund v. Bayer AG (In re Ciprofloxacin Hydrochloride Antitrust Litig.), 544 F.3d 1323, 1336 (Fed. Cir. 2008), cert. denied, 129 S.Ct. 2828 (2009); Ark. Carpenters Health & Welfare Fund v. Bayer AG, 604 F.3d 98 (2d Cir. 2010), cert. denied, 131 S.Ct. 1606 (2011); Joblove v. Barr Labs., Inc. (In re Tamoxifen Citrate Antitrust Litig.), 429 F.3d 370 (2d Cir. 2005), amended by, 466 F.3d 187 (2d Cir. 2006); Schering Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005). Other cases remain in litigation. See, e.g., King Drug Co. of Florence v. Cephalon, Inc., 702 F. Supp. 2d 514 (E.D. Pa. 2010) (denial of motion to dismiss); FTC v. Watson Pharms., Inc., No. 10-12729-DD (11th Cir. first notice of appeal of dismissal filed June 10, 2010); In re K-Dur Antitrust Litig., Nos. 10-2077, -2078, -2079, -4571 (3d Cir. first notice of appeal filed Apr. 30, 2010).

[6] In FY 2010 there were 31 final settlements filed under the MMA that involved compensation to the generic patent challenger and an agreement by the generic firm to refrain from launching its product for some period of time. BUREAU OF COMPETITION, FED. TRADE COMM'N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF AGREEMENTS FILED IN FY 2010 (2011), http://www.ftc.gov/os/2011/05/1105mmaagreements.pdf. These agreements involved 22 different brand-name drugs with combined annual U.S. sales of $9.3 billion. Id.

[7] This reflects the fact that competition typically destroys total profits accruing to suppliers so that the sum of duopoly profits is less than monopoly profits. See, e.g, Mark A. Lemley & Carl Shapiro,

for a period of time, and the generic agrees to defer entry (39 agreements);

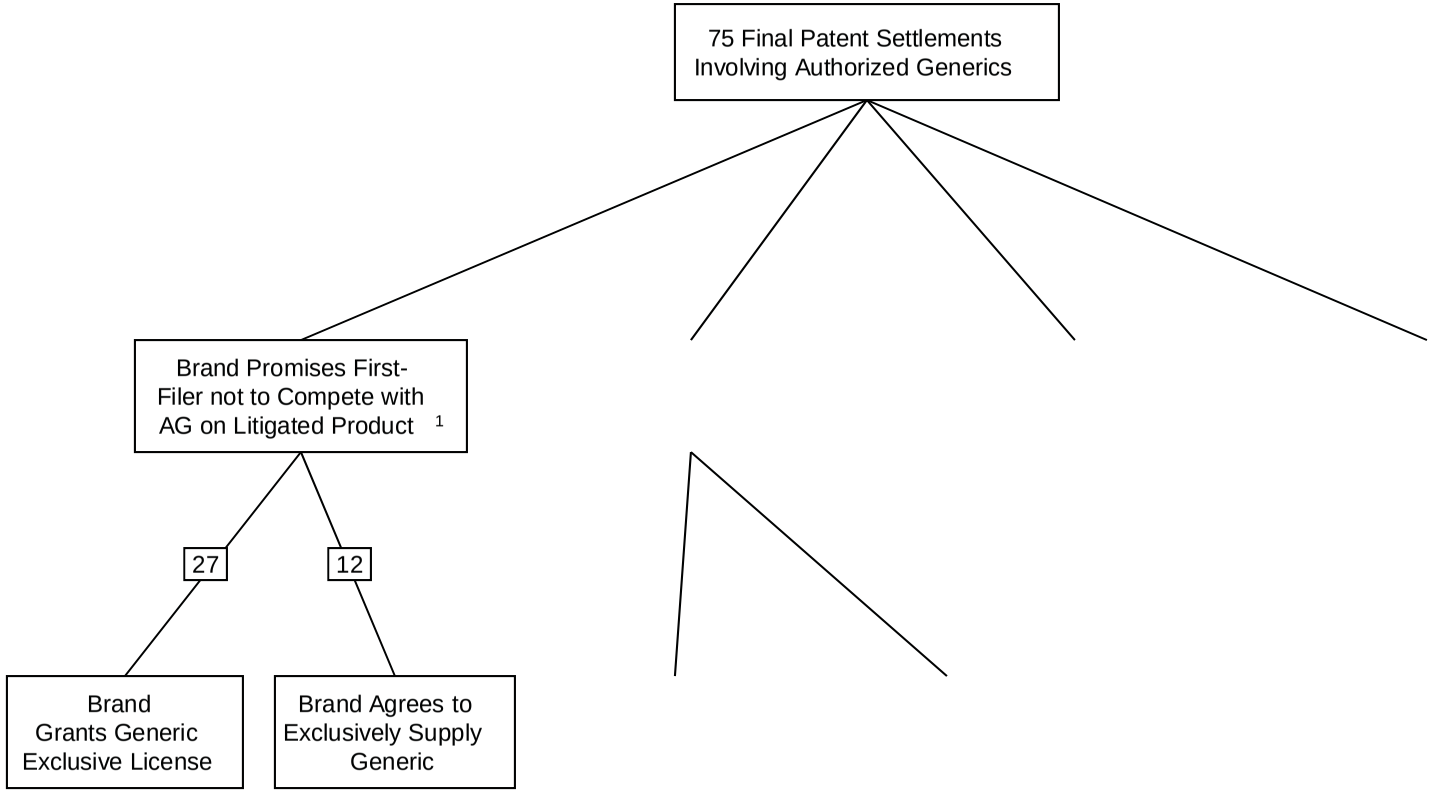
(2) For the litigated product, either (a) there is no explicit promise not to compete, but the agreement creates incentives discouraging the brand from launching an AG that would compete against the first-filer (11 agreements), or (b) the brand explicitly agrees not to engage in AG competition, but the generic is not eligible for the 180-day exclusivity period (5 agreements);

(3) For the litigated product, the brand appoints a subsequent-filer generic as an AG marketer in competition with the first-filer (8 agreements); or

(4) For adifferentproduct – one that was not the subject of the underlying patent litigation – the brand appoints the generic as the AG marketer (12 agreements).

Figure 8-1 breaks down these agreements by type of AG provision.

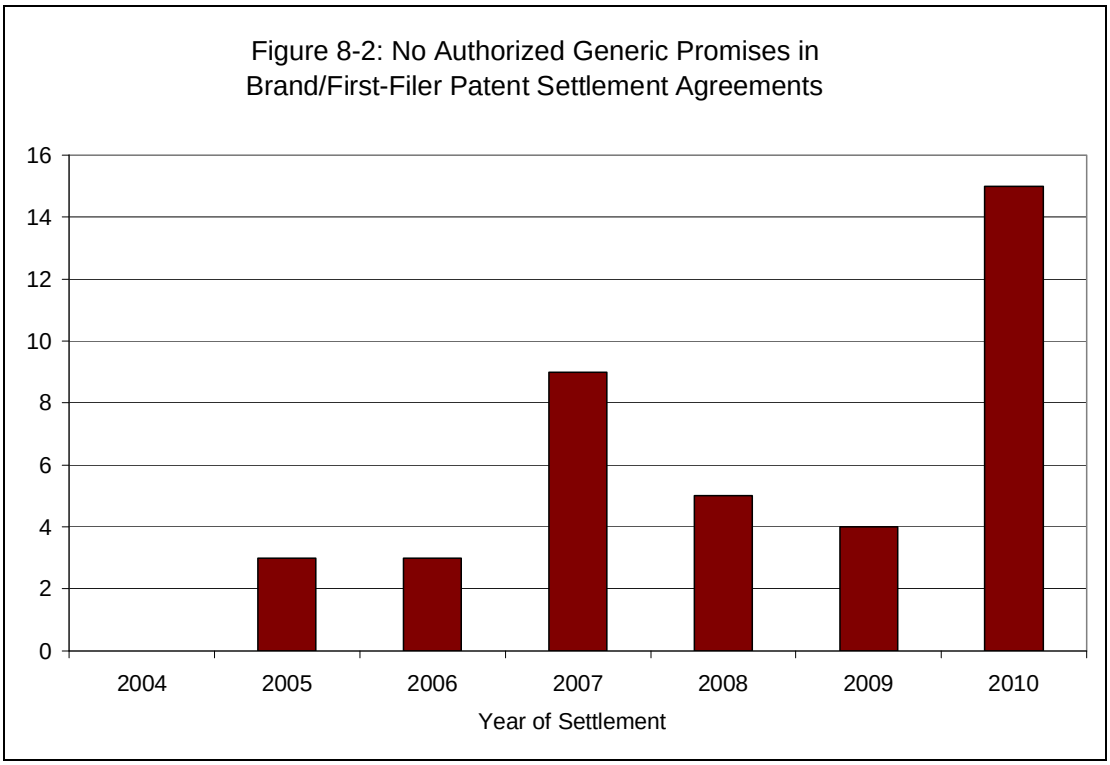
Figure 8-1: Overall Breakdown of Final Patent Settlement Agreements Involving Provisions on Authorized Generics: Fiscal Years 2004-2010



[12] A brand can compete with an AG either by launching it on its own or by authorizing another firm to market the AG. See supra Chapter 2, Sec. I.B.2. An explicit commitment not to compete can take different forms, for example, the brand company's granting the first-filer an exclusive license to a generic version of the brand. In these settlements, the brand agreed not to launch or sponsor its AG in competition with the first-filer's generic product for some period of time.

[13] Hatch-Waxman rewards the first-filer to challenge a brand-name drug patent with 180 days of market exclusivity, and bars the FDA from approving any later applicants until the period has expired or been forfeited. Thus, an agreement with a first-filer that defers entry may create a "bottleneck," blocking the approval of subsequently filed ANDAs. See FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION ch. 5 (2002),

recognized mode of compensation to generics for restrictions on entry. Figure 8-2 presents the data for each fiscal year.



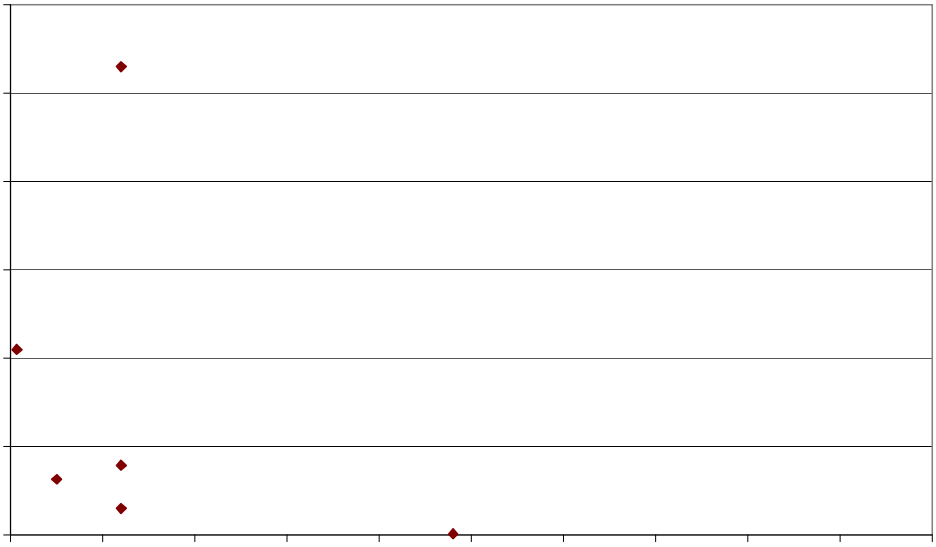
The detailed terms of settlements involving a restriction on the first-filer's ability to market its product and an explicit promise by the brand not to launch or sponsor an authorized generic varied.

- Slightly more than two-thirds – 27 out of 39 – allowed the generic to offer its own product without facing competition from the brand's AG for some period of time. In the other twelve cases, either the brand agreed exclusively to supply the generic with the AG, or the generic could choose whether to market its own product or the AG. In either case, the result would be no competition between an AG and the first-filer's generic product for a certain period of time.

- The length of time during which the brand agreed not to launch or sponsor an AG ranged from 10 days to 45.5 months. The average length of the restriction on the brand's ability to offer a competing AG was 9.6 months, and the median was six months. Indeed, for about half of the agreements (20 out of 39), the restriction was six months, i.e., the length of the 180-day exclusivity period.[14]

[14] See infra note 16 (discussing why restrictions on AG marketing usually do not exceed 180 days).

[15] All sales figures are for the full calendar year prior to the settlement agreement or for the last full year prior to generic entry. The annual sales data are from IMS Health, IMS National Prescription Audit Plus 7™, Years 2003 to 2008, Data Extracted January 2009; and from Top 200 Drugs for 2009 by Sales,



[17] Under four such settlements, the agreed-upon entry date gave the brand the entire length or nearly the entire length of a composition of matter patent covering the drug. Another provided for entry six months before expiration of the only listed patent, which had claimed a method of use. Another settlement barred entry until 6–8 months before expiration of late-issued patents confined to a single form of the drug's active ingredient.

brand would not market a competing AG for the strengths for which the generic was the first-filer. This agreement ensured that the generic would have sole 180-day exclusivity on the two strengths for which it was the first-filer and that it could compete with the company that was the first-filer on the third strength during that first-filer's 180-day exclusivity. Thus, the settling generic would be able to enter at the time of generic entry for each of the three strengths, giving it a competitive advantage relative to the first-filer on the third strength, which was required to wait until 181 days after generic entry to launch the two strengths for which it was not the first-filer.

Another arrangement found in several Type (1) agreements involves drugs with two dosage forms; the generic is allowed to enter shortly after settlement with an AG or ANDA-generic version of one product, but entry is deferred on the other. The second product usually has much higher sales.[18] Such a package of commitments could induce the generic to defer entry on the higher-sales product by promptly providing it with revenues on the lower-sales product and shielding it from a competing AG with respect to one or both of the products.

C. Type (2) Agreements: Other Promises by Brands Limiting AG Competition on the Litigated Product

Type (2) agreements encompass two categories of AG provisions that in some cases may operate in a manner similar to Type (1) "No AG" arrangements. The effect of these agreements, however, is more difficult to determine from the face of the agreement alone. First, in eleven agreements there was no explicit brand promise to a first-filer to refrain from marketing a competing AG, but there were provisions that could create an incentive for the brand not to market a competing AG. These provisions either provided that royalties due to the brand would drop significantly if the generic faced competition on the drug at issue within a specified period of time or appeared otherwise to discourage the brand from offering a competing AG.[19] These agreements effectively could operate as promises by the brand not to launch or sponsor an AG for a period of time.

The second category of Type (2) agreements consists of five agreements that contain an explicit promise by the brand not to compete with an AG, but (unlike the Type (1) agreements) at the time of settlement the generic did not have the right to 180-day exclusivity. In some instances, the generic was pursuing approval under a regulatory framework that does not provide a 180-day

---

[18] See, e.g., Settlement Agreement, 2005 (entry on low-sales product, about 2 months after settlement; on blockbuster product, more than 3 years later); Settlement Agreement, 2005 (entry on low-sales product, about 7 months after agreement; on blockbuster product, nearly 5 years); Settlement Agreement, 2008 (products with similar sales, one with entry about one week after execution of the agreement, the other about 3 years). For these agreements, both products contain the same active ingredient, i.e., one is a line extension of the other, and the generic was the first-filer for both products.

[19] To avoid double counting, four agreements with tiering royalties after expiration of an explicit "No AG" provision are not included in the eleven Type (2) agreements.

[20] One ANDA was ineligible for 180-day exclusivity

infringement that would trigger the first-filer's exclusivity period or its forfeiture.[23] The Federal Circuit has recognized that brand-name companies may seek to settle with subsequent filers because brand-name firms "have a strong incentive to avoid litigation that would trigger the first Paragraph IV ANDA filer's exclusivity period and allow the FDA to approve subsequent . . . ANDAs 181 days" thereafter.[24]

Agreements with subsequent filers also might affect the timing of generic entry through provisions that make the subsequent filer's right to market an AG during the first-filer's 180-day exclusivity contingent on whether the first-filer launches at risk or has not settled its litigation with the brand. Such agreements allow the subsequent filer to market an AG for the litigated product during the first-filer's exclusivity, but only if the first-filer launched at risk or had not settled its litigation. Otherwise, the subsequent filer can market the AG 181 days after the first-filer's launch. By ensuring that the relevant terms, though normally kept confidential, become known by the first-filer, the brand-name firm may induce the first-filer to delay entry, in order to avoid triggering the subsequent filer's right to enter as an AG during the first-filer's 180 days of marketing exclusivity.[25] The first-filer could settle the lawsuit, accepting delayed entry to avoid AG competition, or it could refrain from launching at risk.

Four of the eight Type (3) agreements with subsequent filers were of this type. For example, one agreement provided that if the first-filer launched its ANDA-generic product without settling with the brand, the subsequent filer would be allowed to market the AG during the first-filer's 180-day exclusivity.[26] However, if the first-filer settled with the brand and launched its ANDA-generic pursuant to a license under the brand's patents, the subsequent filer could not market the AG until 181 days after the first-filer's launch. The brand and the first-filer subsequently entered a settlement that deferred ANDA-generic entry for about three years and confirmed that the first-filer would not face a competing AG during its 180-day exclusivity.[27]

Firms can make the terms of agreements with subsequent filers known to the first-filer through a variety of means – by publicly announcing the relevant terms of the agreement; by using

---

[23] Pursuant to amendments contained in the MMA, a final court decision is a forfeiture event: if the first-filer does not launch its product within 75 days of a court decision, it forfeits its exclusivity, and the FDA is permitted to approve subsequent filers. See 21 U.S.C. § 355(j)(5)(D); Caraco Pharm. Labs. v. Forest Labs., 527 F.3d 1278, 1284–88 (Fed. Cir. 2008).

[24] Caraco, 527 F.3d at 1284.

[25] Under these agreements, the brand retains the ability to offer a "No AG" promise to the first-filer, which could act as an incentive for the first-filer to settle and defer entry.

[26] Absent a settlement between the first-filer and the brand, the agreement allows the subsequent filer to launch the AG on the day the first-filer launches its ANDA-generic product following a final court decision of patent invalidity, unenforceability, or non-infringement. See Settlement Agreement, 2006.

[27] See Settlement Agreement, 2006 (appointing the first-filer the exclusive AG distributor for 180-days but requiring the brand to supply the AG only if the first-filer was unable to obtain final FDA approval of its ANDA).

[28] See infra note 30 and accompanying text.

[29] For most of these agreements, the other product is a different drug (NDA), but for three agreements, the other products are dosage strengths of the litigated drug that were not at issue in the litigation. For two other agreements, the other products are further dosage strengths of the litigated drugs for which the brand had requested FDA approval. In addition to the twelve Type (4) agreements appointing the generic as the AG for another product, four Type (1) agreements and one Type (3) also contained such provisions.

[30] See Settlement Agreement, 2008 (allowing launch during 180-day exclusivity if the first-filer launches at risk, but not if the first-filer defers entry until after a decision by a court of appeals). This agreement was made publicly available in the brand-name's 8-K filing with the Securities and Exchange Commission. For further discussion of these issues, see F

first-filer; negotiations over terms may be particularly easy because the cost to the brand and the benefit to the generic are proportional to the size of the market and estimable by both. However, numerous alternative forms of compensation exist, so it is likely that alternative settlement terms could be reached in many circumstances, even if the parties could not have used a “No AG” clause as a form of compensation. Any restrictions on pay-for-delay agreements should account for all viable forms of brand-generic payments to delay entry, including an agreement not to compete with an AG.

APPENDIX A LETTER FROM SENATORS LEAHY, GRASSLEY, AND ROCKEFELLER

May 9, 2005

Chairman Deborah Platt Majoras
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Dear Chairman Majoras and Commissioners:

It has come to our attention that the practice of "authorized" generic drugs may produce anti-competitive results and, thus, present an issue worthy of study by the Federal Trade Commission.

The amendments to the Hatch-Waxman Act of 1984, enacted as part of the Medicare Modernization Act (Title XI, PL 108-173), provide that, in general, a generic company that successfully challenges the patent of a name brand pharmaceutical company earns 180 days of marketing exclusivity on that generic drug. The legislation was designed to strengthen incentives for generic manufacturers to bring generic drugs quickly to market, and thus promote competition and lower prices for consumers.

We have heard concerns that the practice of "authorized" generics could have a negative impact on competition for both blockbuster and smaller drugs, because the generic industry would be less inclined to invest in their production. Consequently, if the generic industry were to be less incentivized to produce such generic drugs to compete with name brand drugs, it is possible that fewer generic drugs would come to market and the prices for certain drugs would remain high for consumers.

We are interested in determining the short term and long term effects on competition of the practice of "authorized" generics. Consequently, we request, pursuant to § 6(b) of the Federal Trade Commission Act, that the Commission conduct a study on this issue. We ask that this study look into the short term competitive benefits of introduction of "authorized" generics during the 180 day market exclusivity period. We also ask that the study look

into the long term impact of the practice of “authorized” generics on competition in the drug market and on the price of drugs, as well as on the viability of the generic drug industry.

If such a study were to prove unfeasible, we hope the FTC will be able to conduct a workshop on this issue in the near future. If you have any questions about this request, please feel free to contact Susan Davies of Senator Leahy's office, Rita Lari Jochum of Senator Grassley's office, or Jocelyn Moore of Senator Rockefeller's office. They can be reached at (202) 224-7703 (Sen. Leahy), (202) 224-5564 (Sen. Grassley), or (202) 224-6472 (Sen. Rockefeller), respectively.

Sincerely,

PATRICK LEAHY
United States Senator

CHUCK GRASSLEY
United States Senator

JOHN ROCKEFELLER
United States Senator

cc: Commissioner Pamela Jones Harbour
Commissioner Thomas Leary
Commissioner Jon Leibowitz
Commissioner Orson Swindle

APPENDIX B LETTER FROM REPRESENTATIVE WAXMAN

September 13, 2005

Deborah Majoras
Chairman
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580-0002

Dear Chairman Majoras:

I am writing to request that the Federal Trade Commission conduct a study pursuant to section 6(b) of the Federal Trade Commission Act on the impact of so-called "authorized generics" on competition in the prescription drug marketplace. I recognize that the Commission may also be considering a workshop on this subject, but rise of authorized generics raises serious competitive issues and requires a full study.

As you know, authorized generics are generic drugs that enter the market under aegis of the brand name drug manufacturer. There is evidence that brand name drug companies are increasingly using authorized generics to undermine one of the incentives to increase competition created by The Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments).

The Hatch-Waxman Amendments provide a special incentive to generic companies that challenge patents on the brand name drug – in exchange for undertaking the costs and risks of patent litigation, the successful challenger is given 6 months of marketing without any other generic competition. The purpose of this incentive is to encourage challenges to patents that otherwise would inappropriately block competition. Brand name companies, however, are now increasingly arranging for authorized generics to enter the market during the 6-month period of generic exclusivity, substantially reducing the value of that exclusivity to the generic drug manufacturer who challenged the patent.

As the Commission has documented, there have been a large number

APPENDIX C LIST OF COMPANIES COVERED BY THE STUDY

Brand Companies

3M Company
Abbott Laboratories
Aqua Pharmaceuticals, LLC
Astellas Pharma US, Inc.
AstraZeneca Pharmaceuticals LP
Bayer HealthCare Pharmaceuticals
Biovail Pharmaceuticals Inc.
Blansett Pharmacal Co., Inc.
Boehringer Ingelheim Corp
Bradley Pharmaceuticals
Bristol-Myers Squibb Company
Celgene Corporation
Cephalon, Inc.
Duramed Pharmaceuticals, Inc. (Barr)
Eisai Corporation of North America
Elan Corporation
Eli Lilly and Company
Forest Laboratories, Inc.
Gate Pharmaceuticals (Teva)
GlaxoSmithKline
Hi-Tech Pharmacal Co., Inc.
Hoffmann-La Roche Inc.
Jerome Stevens Pharmaceuticals
Johnson & Johnson
King Pharmaceuticals, Inc.
K-V Pharmaceutical Co.*
Lannett Company, Inc.
Merck & Co. Inc.
MGI Pharma Inc.
Mission Pharmacal Company, Inc.
Novartis Corporation
Novo Nordisk, Inc.
Organon Inc.
Otsuka America, Inc.
PDL BioPharma, Inc.*
Pfizer Inc.
Procter & Gamble Company, The
Purdue Pharma L.P.
Reliant Pharmaceuticals, Inc.
Salix Pharmaceuticals, Inc.*
Sankyo Pharma Inc. [Daiichi Sankyo, Inc.]
Sanofi-Aventis US LLC
Savient Pharmaceuticals, Inc.
Schering-Plough Corporation
Schwarz Pharma Inc. (UCB)
Sciele Pharma, Inc.
Shire PLC
Sigma-Tau Pharmaceuticals, Inc.*
Solvay America, Inc.
Somerset Pharmaceuticals, Inc.
Stat-Trade, Inc.
Takeda America Holdings, Inc.
Tyco Healthcare Group LP [Covidien]
UCB Pharma Inc.
Valeant Pharmaceuticals International
Warner Chilcott Holdings Company III, Limited
Watson Pharmaceuticals, Inc.
Wyeth
X-Gen Pharmaceuticals, Inc.

Generic Companies

Actavis U.S.
Akyma Pharmaceuticals LLC
Anchen Pharmaceuticals, Inc.
Andrx Corporation (Watson)
Apotex, Inc.
Aurobindo Pharma USA, Inc.
Barr Pharmaceuticals, Inc.
Biovail Pharmaceuticals, Inc.
Blu Pharmaceuticals, LLC
Boca Pharmacal, Inc.
Breckenridge Pharmaceutical, Inc.
Caraco Pharmaceutical Laboratories
Carlsbad Technology, Inc.
Cobalt Laboratories, Inc.
CorePharma LLC
DAVA Pharmaceuticals, Inc.
Deca Pharmaceuticals, LLC
Dr. Reddy's Laboratories, Inc.
Endo Pharmaceuticals
Eurand N.V.
Gedeon Richter USA, Inc
Glades Pharma (Stiefel Labs)*
Glenmark Pharmaceuticals, Inc.
Golden State Medical Supply, Inc.
Hikma Pharmaceuticals Ltd.
Hi-Tech Pharmacal Co., Inc.*
Impax Laboratories, Inc.
Interpharm Holdings, Inc.
Invagen Pharmaceuticals, Inc.
Ivax Pharmaceuticals, Inc. (Teva)
K-V Pharmaceutical Co.
Lannett Company, Inc.
Lupin Pharmaceuticals, Inc.
Major Pharmaceuticals, Inc.
Mallinckrodt Pharmaceuticals (Covidien)
Martec Pharmaceutical, Inc.
Mylan Inc.
Paddock Laboratories, Inc.
Par Pharmaceutical Companies, Inc.
Perrigo Company
Prometheus Laboratories, Inc.
Qualitest Pharmaceutical, Inc. & Vintage Pharmaceutical, Inc.
Ranbaxy Pharmaceuticals, Inc.
Rising Pharmaceuticals
Roxane Laboratories, Inc. (Boehringer)
Sandoz, Inc. (Novartis)
Spectrum Pharmaceuticals Inc.
Sun Pharmaceutical Industries Inc.
Taro Pharmaceuticals U.S.A. Inc.
Teva Pharmaceuticals USA, Inc.
Three Rivers Pharmaceuticals, LLC
Trigen Laboratories Inc.
UCB, Inc.
United Research Laboratories, Inc. & Mutual Pharmaceutical Co., Inc.
Upsher-Smith Laboratories, Inc.
Versapharm Inc.
Watson Pharmaceuticals, Inc.
Wockhardt USA Inc.
Zydus Pharmaceuticals (USA) Inc.

Authorized Generic Companies

Heritage Pharmaceuticals, Inc.
Prasco Laboratories

*did not receive a Special Order

APPENDIX D BRAND-NAME DRUG COMPANY SPECIAL ORDER

OMB Control No. 3084-0140
Expires 8/31/2010[1]

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: Deborah Platt Majoras, Chairman
Pamela Jones Harbour
Jon Leibowitz
William E. Kovacic
J. Thomas Rosch

FTC Matter No. P062105

[1] Under the Paperwork Reduction Act, as amended, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

2. State whether the Company is a subsidiary company; whether the Company has subsidiary companies; and report the same information specified in Item 1 regarding each parent or subsidiary engaged in research and development, planning and design, production and manufacturing, distribution, or sales and marketing of any drug product.

3. Submit one copy of each organization chart and personnel directory in effect on January 1 of each year since January 1, 2001, (a) for the Company as a whole and, (b) for each of the Company's subsidiaries or divisions involved in the AG drug business, if any.

4. For each drug on "List A" provided by the FTC, state whether any orally administered capsule or tablet form of the drug, at any strength, has been marketed in the United States as an AG drug product (either currently or previously), with a launch date after Jan. 1, 2001, under an NDA for which the Company holds rights or held rights at the time of launch or any time thereafter.

5. For each drug on "List B" provided by the FTC, state whether the specified dosage form and strength of the drug has been marketed in the United States as an AG drug product (either currently or previously), with a launch date after Jan. 1, 2001, under an NDA for which the Company holds rights or held rights at the time of launch or any time thereafter.

6. Submit a list of all of the Company's orally administered prescription AG drug products of any capsule or tablet form launched in the United States after Jan. 1, 2001 (either currently or previously marketed under a NDA for which the Company holds or held the rights), including but not limited to the drugs on the lists provided by the FTC, and provide the following information regarding marketing in the United States: (a) proprietary/trade name of the AG, if any; (b) proprietary/trade name of the brand-name drug for which the NDA authorizes the marketing of the AG; (c) active ingredient; (d) dosage form; (e) NDA number of the brand-name drug that authorizes the marketing of the AG (5 digits, no letter); (f) dosage strength; (g) date of approval of the NDA for each strength; (h) the AG's 9-digit National Drug Code (NDC) number for each strength (labeler and product code separated by a hyphen); (i) the date of launch for each NDC number; (j) the date of discontinuance for each NDC number, if any; (k) the name of the firm/business entity associated with each NDC labeler code; (l) the relationship (or former relationship) of each labeler code firm/entity to the Company, e.g., current or former division, subsidiary, affiliate, licensee, contractor; (m) the address and phone number of the firm/business entity associated with each NDC labeler code.

7. For each AG on the list provided by the Company in response to Item 6, state whether the marketing entity is part of the Company, so that the Company will coordinate with the marketing entity in providing complete answers to the

13. For all strengths of brand-name drugs on “List B” that were not covered in the

19. Total sales: brand-name drugs (AG version marketed). For each brand-name drug on the list the Company provided to the FTC in response to Item 12 (brand-name versions of AGs), for sales in the United States from Jan. 1, 2001-March 31, 2007, state the (a) applicable month and year; (b) the drug identifying information described in the second paragraph of Instruction (D); (c) the Company's total monthly sales attributable to all strengths and package sizes of the dosage form of the brand-name drug under consideration, net of discounts, rebates, promotions, returns and chargebacks, in dollars; and (d) the total monthly sales in prescriptions.

20. Total sales: brand-name drugs (no AG marketed). For all brand-name drugs on "List B" that were not covered in the response to Item 19 (i.e., brand-name drugs listed in response to Item 13, for which no AG was marketed), provide the information requested in Item 19.

and (d) the average manufacturer price ("AMP") as defined by, and reported to, the Centers for Medicare and Medicaid Services (CMS).

25. Price of brand-name drugs (AG version marketed): For each brand-name drug on the list the Company provided to the FTC in response to Item 12 (brand-name versions of AGs), for sales in the United States from Jan. 1, 2001-March 31, 2007, state the (a) applicable quarter and year; (b) the drug identifying information described in the second paragraph of Instruction (D); (c) 9-digit NDC number (including labeler and product codes separated by a hyphen); and (d) the AMP as defined by, and reported to, the CMS.

26. Prices of brand-name drugs (no AG marketed): For all brand-name drugs listed in the response to Item 13 that have been subject to ANDA-generic competition (i.e., brand-name drugs for which a date of ANDA-generic entry was entered in Item 13(m)), provide the information requested in Item 25 (for the period from Jan. 1, 2001-March 31, 2007).

27. Submit all documents that were prepared by or for any officer(s) or director(s) of the Company and/or, if applicable, the marketing entity, or that are in the files of any current or prior Company (and/or marketing entity) senior vice president (or equivalent position) with product line responsibility (during all or part of the period from January 1, 2003-April 3, 2006) for an AG and/or a brand-name drug in the list the Company provided to the FTC in response to Item 6 (or, in the case of unincorporated entities, individuals exercising similar functions), as follows. Tc - .0irTm

[2] Section 6003 of the Deficit Reduction Act of 2005, P.L. 109-171, which became effective on Jan. 1, 2007, amends Section 1927(b)(3)(A) of the Social Security Act (42 U.S.C. § 1396r-B8(b)(3)(A)) to

[3] *See* FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS v, 2-2 (27th

(4) "Authorized generic ("AG") drug" means any drug sold, licensed or marketed under an NDA approved by the FDA under 21 U.S.C. § 355(c); and marketed, sold or distributed (directly or indirectly) without using the listed drug's brand-name and with a different NDC product number or labeler number (or both).[4]

(5) "Brand-name" drug means an innovator drug product marketed pursuant to an approved NDA under a proprietary, trademark-protected name.

(6) "Capsule" means all dosage forms of capsules as set forth in Appendix C of the Orange Book, including capsule; capsule, delayed release (DR); capsule, delayed release pellets (DRP); and capsule, extended release (XR).

(7) "Company" means 3M Company, its domestic and foreign parents, predecessors, divisions, subsidiaries, affiliates, partnerships and joint ventures, and all directors, officers, employees, agents and representatives of the foregoing. The terms "subsidiary," "affiliate," and "joint venture" refer to any person in which there is partial (50 percent or more) or total ownership or control between the company and any other person. As used in this definition, the term "person" includes the company and means any natural person, corporate entity, partnership, association, joint venture, government entity, or trust.

(8) "Documents" means all computer files and written, recorded, and graphic materials of every kind in the possession, custody or control of the Company.

(9) "NDA" means a New Drug Application, as set forth in 21 U.S.C. § 355(b) and approved under 21 U.S.C. § 355(c).

(10) "Tablet" means all dosage forms of tablets as set forth in Appendix C of the Orange Book, including tablet; tablet, chewable (CT); tablet, coated particles (CP); tablet, delayed release (DR); tablet, delayed release, orally disintegrating (DR OD); tablet, extended release (XR); tablet, orally disintegrating (OD).

D. Data Submissions

Unless modified by agreement in writing with the staff of the Federal Trade Commission, all numerical data submitted in response to Items 15-26 must be submitted in a spreadsheet

---

[4] Generally, AGs are marketed under a different product code, labeler code, trade name, trademark, and/or packaging (other than repackaging the listed drug for use in institutions) than the listed drug. *See* Medicaid Program; Prescription Drugs, 71 Fed. Reg. 77,174, 77,183-84, 77,198 (Dec. 22, 2006). Typically, the name of an AG is the nonproprietary established name of its active ingredients, but in some cases a trade name different from the brand-name of the listed drug is used. Also, AGs are usually marketed by a subsidiary or division of the brand-name manufacturer or a third party in a manner equivalent to the marketing practices of holders of an approved ANDA for a drug. *See* Letter from William K. Hubbard, FDA, to Stuart A. Williams, Mylan Pharmaceuticals, Inc., and James N. Czaban, Heller Ehrman White & McAuliffe 2 n.2 (July 2, 2004) (responding to the citizen petitions of Mylan and Teva regarding AG drugs and 180-day exclusivity).

format both on paper and on machine-readable CDs or DVDs. The Commission will accept database and spreadsheet data in the following formats: MS Excel, MS Access, tab-delimited or fixed width text files. All financial information required to be submitted by this Order should be in whole dollar amounts. For Items 15-26, the applicable month (quarter) and year requested refers to each month and year for which the Company provides the information called for by the given Item. If the information is not kept in the form requested, the Company is encouraged to contact the Commission representative to discuss alternative formats in which the information may be provided.

To identify the drug for which data is being provided, for those Items requesting data on AGs (Items 15, 18, 21, and 24) state on the applicable row or page the (b)(1) proprietary/trade name of the AG, if any; (b)(2) proprietary/trade name of the brand-name drug; (b)(3) active ingredient; (b)(4) dosage form; (b)(5) NDA number (5 digits, no letter); and the (b)(6) dosage strength (except for Item 18). For Items requesting data on brand-name drugs (Items 16-17, 19-20, 22-23, and 25-26), state the previously listed identifying information (b)(1)-(6), omitting (6) for Items 19 and 20.

E. Document Submissions

This Special Order covers documents in the Company's possession, custody or control, wherever the documents are located. However, unless or until the Commission notifies Company otherwise in writing, the Commission will not seek to enforce the Special Order to compel the production of documents that were located outside the United States at the time Company received the Special Order. In order to expedite the receipt of documents reflecting the views of all recipients of Special Orders, the Commission requests your cooperation in producing any such documents on a voluntary basis by the date specified in this Special Order.

Provide two paper copies of each document. All documentary responses should be Bates-stamped.

F. Responsibilities of Company and AG-Marketing Entity Officials

1. Companies that market AGs via entities that are part of the Company as defined in definition (7) are required to coordinate with those marketing entities in the submission of certain information on AGs in Part III, as described in the instructions to individual Items. If the marketing entity identified in Item 6(k) is not part of the Company, the FTC will also contact the marketing entity, and require it to submit certain information on the AGs it markets.The Company's response to Item 7 merely notifies the FTC, on a drug-by-drug, entity-by-entity basis, whether the Company will contact the marketing entity and coordinate with it, because it is part of the Company or whether the FTC will contact the marketing entity, because the marketing entity is not part of the Company. For most Items, however, the Company and any independent marketing entity (which the FTC will contact separately) will be required to respond. The Company's response to Item 7 does NOT eliminate the Company's requirement to respond to each Item, unless expressly stated in the instructions for an Item.

2. The Special Report is required to be subscribed and sworn to by an official of the Company who has prepared or supervised the preparation of the Special Report from books, records, documents, correspondence, and other data and material in the Company=s possession. In addition, if the Company indicates in response to Item 7 that it will coordinate with its AG marketing entity, then Items 10, 15, 18, 21, 24, 27-28, and 30 must be subscribed and sworn to by an official of the subsidiary, or other entity of the Company that markets AGs. Each subscriber to the Special Report is to give his or her full name, title, and contact ilclgtclghYHfto gies a ncde, an0,w a certii the

5. “List B” is a list of the Company’s orally administered capsule and tablet dosage forms of drugs for which at least one ANDA with a paragraph IV certification was filed and generic competition began after Jan. 1, 2001, or for which generic competition has not yet begun and at least one ANDA with a paragraph IV certification was filed after Jan. 1, 2001. The list contains only those strengths for which a paragraph IV certification has been m3t04 Tc -0.000t least Tw -18.iat begunaw -1e.iata paragrh Tw -18.iat begs conts fileins

contractor or licensee, the Company must enter “no,” and the marketing entity will be contacted by the FTC and asked to provide certain information. A Company’s response of “no” to Item 7 does NOT eliminate the Company’s requirement to respond to each Item below, unless expressly stated in the instructions for an Item.

Because some manufacturers of brand-name pharmaceuticals also manufacture ANDA-generic drugs, the FTC reserves the right to request additional information from the Company, and directly from marketing entities that are part of the Company, even if the Company has responded to this request or provided a coordinated response to an Item.

Part II

8. This Item requests the basic information in Item 6 on any AGs launched in the United States by Dec. 31, 2007 pursuant to a NDA for which the Company holds rights that were not included in the Company’s initial response to that Item. For the purposes of this study, the FTC will not require any information beyond that requested in Item 6 for these AGs.

9. This Item requests updated information on AGs identified by the Company in its initial response to Item 6, including but not limited to, whether the marketing of the AG has

Item 12(j), (k). State the therapeutic category and pharmacological class as set forth in the U.S. Pharmacopeial Convention, Inc., U.S.P. Medicare Model Guidelines, Version 2, Feb. 6, 2006[5].

Item 12(l). When entering the 14-digit GPI, separate the two-digit fields with dashes.

Items 12(m), (n), (o). If the brand-name drug has not been subject to ANDA-generic competition, enter "none" in response to Item 12(m), and do not respond to Items 12(n) and (o).

13. Enter the required information for each brand-name drug on "List B" that was not covered in the response to Item 12 on the spreadsheet provided by the FTC. Enter the specific dosage form, e.g., capsule DR, capsule XR, tablet DR, or tablet XR. Enter each strength, and each 9-digit NDC number related to a particular strength, in a different row. If the NDCs associated with the drug have changed, provide all NDC numbers that have been used. With respect to therapeutic category and pharmacological class, follow the instructions in Item 12. If the brand-name drug has not been subject to ANDA-generic competition, enter "none" in response to Item 13(m), and do not respond to Items 13(n) and (o).

14. On the applicable spreadsheet and column, enter "yes" if a litigation settlement agreement between the Company and an ANDA-generic company provided that an AG would not be marketed, and i 9h008 Toespovolumn,ve

[5] *See* http://www.usp.org/pdf/EN/mmg/modelGuidelinesV2.0-2006-02-06.pdf. *See also* Drug List Table, at http://www.usp.org/pdf/EN/mmg/drugListingV2.0-2006-02-06.pdf

18. Responses to this Item represent the Company's combined sales or revenues from all strengths and NDC numbers.

If the Company answered "yes" to Item 7 with respect to a particular drug, the Company must coordinate with its marketing entity and provide the net sales for the Company (including the marketing entity) with respect to that drug. However, the Company must respond to Item 18 even if the Company answered "no" to Item 7 and is not coordinating with the marketing entity. In such cases, the Company should provide its revenues (including royalties, license fees, and transfer payments) arising from sales in the United States, not the sales of the independent marketing entity. In calculating its net revenues, the Company should include its own discounts, rebates, promotions, returns and chargebacks (if any), not those of the independent marketing entity.

19, 20. Responses to these Items represent the Company's combined sales from all strengths and NDC numbers.

21. The referenced 11-digit NDCs should have been listed in response to Item 15(c).

22. The referenced 11-digit NDCs should have been listed in response to Item 16(c).

23. The 11-digit NDCs should be a subset of those listed in response to Item 17. Provide data for the entire requested period, regardless of whether the drug was subject to ANDA-generic competition for the entire time.

24. Item 24 requests the quarterly Average Manufacturer Price ("AMP," 42 U.S.C. § 1396r-8(k)(1)), for each AG listed by the Company in response to Item 6, for all 9-digit NDCs provided in response to Item 6(h).

If the Company answered "yes" to Item 7 with respect to a particular drug, the Company must coordinate with its marketing entity in providing the information requested in Item 24. If the Company is not coordinating with its marketing entity with respect to a particular drug, i.e., it answered "no" in response to Item 7 for that drug, the Company should not respond to this Item. In such cases, the FTC will ask the independent marketing entity to provide the AMP.

25. The Company must provide the information requested in Item 25, regardless of its response to Item 7 and whether it is coordinating with the marketing entity.

26. The 11-digit NDCs should be those listed in response to Item 23. Provide data for the entire requested period, regardless of whether the drug was subject to ANDA-generic competition for the entire time.

27. When responding to Item 27(b), do not duplicate documents provided in response to Item 27(a).

If the Company answered "yes" to Item 7 with respect to a particular drug, the Company must coordinate with its marketing entity in responding to Item 27(a) with respect to that drug. In responding to Item 27(b) in regard to documents generally about AG drugs, the Company must coordinate with its marketing entity if it answered "yes" to Item 7 with respect to any drug. However, the Company must respond to Items 27(a) and 27(b) even if it answered "no" in response to Item 7 and is not coordinating with the marketing entity. In such cases, the marketing entity will be asked to respond to Items 27(a) and 27(b), in addition to the Company.

Group the documents by drug product, and if applicable, segregate the documents obtained from the Company from the documents obtained from the marketing entity. For each document, indicate the name of the person from whose files the document came and whether the document was generated within the Company or externally; if generated externally, provide the name of the source of the document.

28. If the Company answered "yes" to Item 7 with respect to a particular drug, the Company must coordinate with its marketing entity in responding to this Item with respect to that drug. Group the documents by drug product.

29. The Company must respond to Item 29 with respect to all AGs for which the Company answered "no" in response to Item 7, and is not coordinating with the marketing entity. Group the documents by drug product, and indicate the name of the person from whose files the document came.

If an agreement authorizing the marketing of an AG was previously submitted to the FTC pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,[6] do not provide another copy of the agreement. Provide the names of the parties, the date of the agreement, and the date that the agreement was submitted to the FTC.

30. The Company must respond to this Item, and if the Company answered "yes" to Item 7 with respect to any drug, the Company must coordinate with its marketing entity in responding to this Item. For each document, indicate the name of the person from whose files the document came.

[6] *See* P.L. 108-173, tit. XI, Subtit. B, § 1112, 117 Stat. 2066, 2461-2 (2003).

APPENDIX B

Certification

This Special Report, together with any and all appendices and attachments thereto, was prepared and assembled under my supervision in accordance with instructions issued by the Federal Trade Commission in its Special Orders for the Authorized Generic Drug Study. Subject to the recognition that, where so indicated, reasonable estimates have been made because books and records do not provide the required information, the information is, to the best of my knowledge, true, correct, and complete. Where copies rather than original documents have been submitted, the copies are true, correct, and complete.

_____

TYPE OR PRINT NAME AND TITLE

_____

TYPE OR PRINT COMPANY NAME AND ADDRESS

_____

TYPE OR PRINT PHONE NUMBER AND E-MAIL ADDRESS

_____

(Signature)

*Subscribed and sworn to before me at the City of*_____,

State of _____, *this*_____ *day*

*of*_____, *20*____.

_____

(Notary Public)

My Commission Expires: _____

APPENDIX E GENERIC DRUG COMPANY SPECIAL ORDER

OMB Control No. 3084-0140
Expires 8/31/2010[1]

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: Deborah Platt Majoras, Chairman
Pamela Jones Harbour
Jon Leibowitz
William E. Kovacic
J. Thomas Rosch

FTC Matter No. P062105

ORDER TO FILE SPECIAL REPORT

Pursuant to a resolution of the Federal Trade Commission dated March 28, 2006, entitled "Resolution Directing The Use Of Compulsory Process," a copy of which is enclosed, Company A, hereinafter referred to as the "Company," is ordered to file a Special Report with the Commission containing the information specified herein. The enclosed Authorized Generic Drug Study Federal Register Notice describes the purpose and scope of the information collection.

Please supply the following information, data, and documents, consistent with the Definitions and Instructions contained in Appendix A:

1. State the full name of the Company and its official address, and its state of incorporation.

2. State whether the Company is a subsidiary company; whether the Company has subsidiary companies; and report the same information specified in Item 1 regarding each parent or subsidiary engaged in research and development,

[1] Under the Paperwork Reduction Act, as amended, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

8. For each ANDA-generic drug addressed in Item 7, state the (a) active ingredient; (b) dosage form; (c) ANDA number (5 digits, no letter); (d) dosage strength; (e) date of ANDA filing; (f) date of ANDA approval for each dosage strength; (g) 14-digit GPI (Medi-Span's Generic Product Identifier); (h) patent numbers of patents for which the Company made a patent certification under 21 U.S.C. § 355(j)(2)(A)(vii); (i) paragraph number of the certification for each patent number; (j) date of each patent certification; (k) paragraph number of any amended patent certifications; and the (l) date of amendment of the patent certification.

9. Sales of AG drugs, by NDC. For each AG drug addressed in Items 4 and 5, for sales in the United States from Jan. 1, 2001-March 31, 2007, state the (a) applicable month and year; (b) the drug identifying information described in the second paragraph of Instruction (D); (c) the 11-digit NDC number (including labeler, product, and package size codes separated by hyphens); (d) package size; (e) package type; total sales to all customers, net of discounts, rebates, promotions, returns and chargebacks, in (f) units (as represented by the NDC's package size code), and in (g) dollars.

10. Sales and costs of ANDA-generic drugs, by NDC. For each ANDA-generic drug addressed in Item 7, for sales in the United States from Jan. 1, 2001-March 31, 2007, provide the information requested in Item 9, and (h) the cost to or sto

(e) package type; (f) wholesale acquisition cost (AWAC, *see*, 42 U.S.C. § 1395w-3a(b)(6)(B)); and (g) the average wholesale price ("AWP").

14. Prices of ANDA-generic drugs: WAC and AWP. For each drug on the list of ANDA-generic drugs addressed in Item 7, for sales in the United States from Jan. 1, 2001-March 31, 2007, provide the information requested in Item 13.

15. Prices of AG drugs: AMP. For each AG drug addressed in Items 4 and 5, for the period from Jan. 1, 2001-March 31, 2007, state the (a) applicable quarter and

paragraph III or IV certifications, and/or the possible impact of AGs on the profitability of ANDA-generic drugs during 180-day exclusivity or otherwise.

19. For the AG drugs addressed in Items 4 and 5: Submit planning, decisional, or strategy documents, including studies, surveys, analyses, and reports (both internal and external), that were prepared from Jan. 1, 2003 to April 3, 2006, by or for any officer(s) or director(s) of the Company, or that are in the files of any current or prior Company (or marketing entity) senior vice president (or equivalent position) with product line responsibility (during all or part of the period from January 1, 2003-April 3, 2006) for the specified AG drug (or, in the case of unincorporated entities, individuals exercising similar functions), that evaluated, considered, or analyzed the marketing or possible marketing of the AG; the timing of AG launch relative to any anticipated 180-day exclusivity period; the effect or potential effect of the AG on ANDA-generic competition; the marketing of the AG in the context of settlements of patent-related litigation; the profitability or other benefits of marketing the AG; and/or whether to market an ANDA-generic drug or an AG.

20. For the AG drugs addressed in Items 4 and 5: (a) If the Company and the brand-name company entered into an agreement that licensed or otherwise authorized the marketing of the identified drug product as an AG, submit the agreement. (b) Submit copies of any public announcements, e.g., press release(s), of the planned marketing or launch of each AG.

By direction of the Commission.

Deborah Platt Majoras
Chairman

SEAL

Date of Order: December 10, 2007

[3] Generally, AGs are marketed under a different product code, labeler code, trade name, trademark, and/or packaging (other than repackaging the listed drug for use in institutions) than the listed drug. *See*

Each subscriber to the Special Report is to give his or her full name, title, and contact information in a notarized certification at the end of the Special Report, as set forth in Appendix B.

G. Questions

Any questions you have relating to the scope or meaning of this Order, or suggestions for possible modifications thereto, should be directed to Karen A. Goldman, Federal Trade Commission, Office of General Counsel, 600 Pennsylvania Ave., N.W., Washington, DC 20580,

6. On the applicable spreadsheet and column, enter “yes” if the marketing of the AG occurred pursuant to a settlement agreement, “no” if it did not. If “yes,” restate Item 6 in a separate document, identify the AG, and provide the required information about the litigation.

7. The second list provided by the FTC is a list of ANDA-generic drugs marketed by the Company (i) any (tem 6 in

17. Self-explanatory.

18. The documents requested by this Item are not limited to those that consider drugs marketed or previously marketed by the Company, nor are they limited to those that discuss drugs identified in the lists provided by the FTC. For example, responsive documents might consider drugs for which the Company filed an ANDA that has not yet been approved; drugs for which the Company considered making a paragraph IV certification, but the ANDA that was filed did not contain a paragraph IV certification; or drugs for which the Company considered filing an ANDA, but ultimately did not.

    Do not duplicate documents when responding to Items 18(a), (b), and (c).

19. Do not duplicate documents submitted in response to Item 18.

20. For press releases, the source of the document need not be provided.

    If an agreement authorizing the marketing of an AG was previously submitted to the FTC pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,[4] do not provide another copy of the agreement. Provide the names of the parties, the date of the agreement, and the date that the agreement was submitted to the FTC.

[4] *See* P.L. 108-173, tit. XI, Subtit. B, § 1112, 117 Stat. 2066, 2461-2 (2003).

APPENDIX B

Certification

This Special Report, together with any and all appendices and attachments thereto, was prepared and assembled under my supervision in accordance with instructions issued by the Federal Trade Commission in its Special Orders for the Authorized Generic Drug Study. Subject to the recognition that, where so indicated, reasonable estimates have been made because books and records do not provide the required information, the information is, to the best of my knowledge, true, correct, and complete. Where copies rather than original documents have been submitted, the copies are true, correct, and complete.

_____

TYPE OR PRINT NAME AND TITLE

_____

TYPE OR PRINT COMPANY NAME AND ADDRESS

_____

TYPE OR PRINT PHONE NUMBER AND E-MAIL ADDRESS

_____

(Signature)

Subscribed and sworn to before me at the City of _____,

State of _____, *this* _____*day*

of _____, *20*___.

_____

(Notary Public)

My Commission Expires: _____

APPENDIX F AUTHORIZED GENERIC DRUG COMPANY SPECIAL ORDER

OMB Control No. 3084-0140
Expires 8/31/2010[1]

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: Deborah Platt Majoras, Chairman
Pamela Jones Harbour
Jon Leibowitz
William E. Kovacic
J. Thomas Rosch

FTC Matter No. P062105

ORDER TO FILE SPECIAL REPORT

Pursuant to a resolution of the Federal Trade Commission dated March 28, 2006, entitled "Resolution Directing The Use Of Compulsory Process," a copy of which is enclosed, Company A, hereinafter referred to as the "Company," is ordered to file a Special Report with the Commission containing the information specified herein. The enclosed Authorized Generic

[1] Under the Paperwork Reduction Act, as amended, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

subsidiary companies; and report the same information specified in Item 1 regarding each parent or subsidiary engaged in research and development, planning and design, production and manufacturing, distribution, or sales and marketing of any drug product.

3. Submit one copy of each organization chart and personnel directory in effect on January 1 of each year since January 1, 2001, (a) for the Company as a whole and, (b) for each of the Company's subsidiaries or divisions involved in the AG drug business, if any.

4. For each AG drug on the list of AG drugs provided by the FTC, state the (a) proprietary/trade name of the AG, if any; (b) proprietary/trade name of the brand-name drug for which the NDA authorizes the marketing of the AG; (c) active ingredient; (d) dosage form; (e) NDA number of the brand-name drug that authorizes the marketing of the AG (5 digits, no letter); (f) dosage strength; (g) 14-digit GPI (Medi-Span's Generic Product Identifier); (h) the AG's 10-digit National Drug Code (NDC) number for each strength (labeler and product code separated by a hyphen); (i) name of the firm/business entity associated with each NDC labeler code; (j) date of launch for each NDC number; (k) date of discontinuance for each NDC number, if any; and (l) date of the first public announcement of the marketing or intended marketing of the AG.

5. Submit a list of the Company's orally administered prescription AG drug products of any capsule or tablet form that were launched after Jan. 1, 2001, but are not on the FTC's list of AG drugs (if any), and provide the information requested in Item 4.

6. Sales of AG drugs, by NDC. For each AG drug addressed in Items 4 and 5, for sales in the United States from Jan. 1, 2001-March 31, 2007, state the (a) applicable month and year; (b) the drug identifying information described in the second paragraph of Instruction (D); (c) the AG's 11-digit NDC number (including labeler, product, and package size codes separated by hyphens); (d) package size; (e) package type; total sales to all customers, net of discounts, rebates, promotions, returns and chargebacks, in (f) units (as represented by the NDC's package size code), and in (g) dollars.

7. Total sales of AG drugs. For each AG drug addressed in Items 4 and 5, for sales in the United States from Jan. 1, 2001-March 31, 2007, state the (a) applicable month and year; (b) the drug identifying information described in the second paragraph of Instruction (D); (c) the Company's total sales attributable to all strengths and package sizes of the dosage form under consideration, net of discounts, rebates, promotions, returns and chargebacks, in dollars; and (d) the total sales in prescriptions.

8. Prices of AG drugs: WAC and AWP. For each AG drug addressed in Items 4 and 5, for sales the United States from Jan. 1, 2001-March 31, 2007, state the (a) applicable month and year; (b) the drug identifying information described in the second paragraph of Instruction (D); (c) the AG's 11-digit NDC number (including labeler, product, and package size codes separated by hyphens); (d) package size; (e) package type; (f) wholesale acquisition cost ("WAC," see 42 U.S.C. § 1395w-3a(b)(6)(B)); and (g) the average wholesale price ("AWP").

9. Prices of AG drugs: AMP. For each AG drug addressed in Items 4 and 5, for the period from Jan. 1, 2001-March 31, 2007, state the (a) applicable quarter and year; (b) the drug identifying information described in the second paragraph of Instruction (D); (c) the AG's 9-digit NDC number (including labeler and product codes separated by a hyphen); and (d) the average manufacturer price ("AMP") as defined by, and reported to, the Centers for Medicare and Medicaid Services (CMS).

10. Submit all documents that were prepared by or for any officer(s) or director(s) of the Company and/or, if applicable, the marketing entity, or that are in the files of any current or prior Company (and/or marketing entity) senior vice president (or equivalent position) with product line responsibility (during all or part of the period from Jan. 1, 2002-April 3, 2006) for an AG drug addressed in Items 4 and 5 (or, in the case of unincorporated entities, individuals exercising similar functions), as follows. (a) For each AG drug addressed in Items 4 and 5, submit planning, decisional, or strategy documents prepared from January 1, 2002 to April 3, 2006, including studies, surveys, analyses, and reports (both internal and external), that evaluated, considered, or analyzed (but did not merely refer to) the marketing or possible marketing of an AG or AGs (as a response to current or future generic competition, or for other reasons), including but not limited to whether or not to license or otherwise market a brand-name drug product as an AG drug product; reasons for marketing an AG and/or refraining from marketing an AG; the timing of AG launch relative to a 180-day exclusivity period; the marketing of an AG during 180-day exclusivity; the marketing of an AG in the context of paragraph IV certifications and settlements of litigation; the marketing of AGs upon expiration of patents or marketing exclusivities claiming a brand-name drug product or its use; and the profitability or other benefits of marketing an AG drug. (b) With respect to AGs in general, submit documents as described in (a) of this Item.

11. For the AG drugs addressed in Items 4 and 5: (a) If the Company and the brand-name company entered into an agreement that licensed or otherwise authorized the marketing of the identified drug product as an AG, submit the agreement. (b) Submit copies of any public announcements, e.g., press release(s), of the planned marketing or launch of each AG.

12. Submit planning, decisional, or strategy documents dated Jan. 1, 2006-April 29, 2007 that discuss the effect(s) or possible effect(s) of the enactment of Section

6003 of the Deficit Reduction Act of 2005, P.L. 109-171,[2] the marketing of AGs after Jan. 1, 2007.

By direction of the Commission.

Deborah Platt Majoras
Chairman

SEAL

Date of Order: December 10, 2007

[2] Section 6003 of the Deficit Reduction Act of 2005, P.L. 109-171, which became effective on Jan. 1, 2007, amends Section 1927(b)(3)(A) of the Social Security Act (42 U.S.C. § 1396r-8(b)(3)(A)) to include all drugs approved pursuant to 21 U.S.C. § 355(c), including AGs, in Medicaid best price calculations.

APPENDIX A

GENERAL INSTRUCTIONS

A. Organization of Responses and Due Dates of Parts

The Company's Special Report must be filed by March 19, 2008.

B. Responses to Questions

The Special Report should be entered into the Excel spreadsheets provided with this Order whenever possible. The FTC has entered the question numbers and the information that must be provided in the header row of each column. To efficiently enter the requested information, companies may wish to electronically "copy and paste" drug identifying or other information that must be entered on more than one row or worksheet. When it is not possible to enter the required answer or information into the applicable worksheet, or no worksheet has been provided, restate the Item and provide the required answer or information. If any question cannot be answered fully, give the information that is available and explain in detail in what respects and why the answer is incomplete.

All responses to Items 1-2 and 4-5 should be submitted to the FTC in both paper and in electronic form (as Excel, Word, or WordPerfect documents) on machine-readable CDs or DVDs.

C. DEFINITIONS

The following definitions apply to all Items:

(1) "Active ingredient" means a drug's nonproprietary established name, including the established names for all active ingredients, as defined at 21 C.F.R. § 299.4 and used in the Orange Book[3].

(2) "ANDA" means Abbreviated New Drug Application, as set forth in 21 U.S.C. § 355(j).

(3) "ANDA-generic drug" means a drug marketed or sought to be marketed pursuant to an

[3] *See* FDA, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS v, 2-2 (27th ed. 2007) [hereinafter Orange Book].

(directly or indirectly) without using the listed drug's brand-name and with a different NDC product number or labeler number (or both).[4]

(5) "Brand-name" drug means an innovator drug product marketed pursuant to an approved NDA under a proprietary, trademark-protected name.

(6) "Capsule" means all dosage forms of capsules as set forth in Appendix C of the Orange Book, including capsule; capsule, delayed release (DR); capsule, delayed release pellets (DRP); and capsule, extended release (XR).

(7) "Company" means Company A, its domestic and foreign parents, predecessors, divisions,

[4] Generally, AGs are marketed under a different product code, labeler code, trade name, trademark, and/or packaging (other than repackaging the listed drug for use in institutions) than the listed drug. *See* Medicaid Program; Prescription Drugs, 71 Fed. Reg. 77,174, 77,183-84, 77,198 (Dec. 22, 2006). Typically, the name of an AG is the nonproprietary established name of its active ingredients, but in some cases a trade name different from the brand-name of the listed drug is used. Also, AGs are usually marketed by a subsidiary or division of the brand-name manufacturer or a third party in a manner equivalent to the marketing practices of holders of an approved ANDA for a drug. *See* Letter from William K. Hubbard, FDA, to Stuart A. Williams, Mylan Pharmaceuticals, Inc., and James N. Czaban, Heller Ehrman White & McAuliffe 2 n.2 (July 2, 2004) (responding to the citizen petitions of Mylan and Teva regarding AG drugs and 180-day exclusivity).

D. Data Submissions

Unless modified by agreement in writing with the staff of the Federal Trade Commission, all numerical data submitted in response to Items 6-9 must be submitted in a spreadsheet format both on paper and on machine-readable CDs or DVDs. The Commission will accept database and spreadsheet data in the following formats: MS Excel, MS Access, tab-delimited or fixed width text files. All financial information required to be submitted by this Order should be in whole dollar amounts. For Items 6-9, the applicable month (quarter) and year requested refers to each month and year for which the Company provides the information called for by the given Item. If the information is not kept in the form requested, the Company is encouraged to contact the Commission representative to discuss alternative formats in which the information may be provided.

To identify the drug for which data is being provided in response to Items 6-9, state on the applicable row or page the (b)(1) proprietary/trade name of the AG, if any; (b)(2) proprietary/trade name of the brand-name drug for which the NDA authorizes the marketing of the AG; (b)(3) active ingredient; (b)(4) dosage form; (b)(5) NDA number (5 digits, no letter) of the brand-name drug that authorizes the marketing of the AG; and the (b)(6) dosage strength (except for Item 7).See the Excel spreadsheets provided by the FTC, which should be used to provide this data whenever possible.

E. Document Submissions

This Special Order covers documents in the Company's possession, custody or control, wherever the documents are located. However, unless or until the Commission notifies Company otherwise in writing, the Commission will not seek to enforce the Special Order to compel the production of documents that were located outside the United States at the time Company received the Special Order. In order to expedite the receipt of documents reflecting the views of all recipients of Special Orders, the Commission requests your cooperation in producing any such documents on a voluntary basis by the date specified in this Special Order.

Provide two paper copies of each document. Group the documents by drug product. For each document, indicate the name of the person from whose files the document came and whether the document was generated within the Company or externally; if generated externally, provide the name of the source of the document. All documentary responses should be Bates-stamped.

F. Responsibilities of Company Officials

The Special Report is required to be subscribed and sworn to by an official of the Company who has prepared or supervised the preparation of the Special Report from books, records, documents, correspondence, and other data and material in the Company's possession. Each subscriber to the Special Report is to give his or her full name, title, and contact

information in a notarized certification at the end of the Special Report, as set forth in Appendix B.

G. Questions

Any questions you have relating to the scope or meaning of this Order, or suggestions for possible modifications thereto, should be directed to Karen A. Goldman, Federal Trade Commission, Office of General Counsel, 600 Pe

6. Item 6 requests monthly net sales data for AGs for all 11-digit NDCs arising from the 9-digit NDCs provided in response to Item 4(h) and Item 5, i.e., including all package size codes for those NDCs.

7. The responses to Item 7 represents combined sales from all strengths and NDC numbers.

8. Item 8 requests monthly WAC and AWP for all 11-digit NDCs arising from the 9-digit NDCs provided in response to Items 4(h) and 5.

9. Item 9 requests the quarterly AMP (42 U.S.C. § 1396r-8(k)(1)), for all 9-digit NDCs provided in response to Items 4(h) and 5.

10. When responding to Item 10(b), do not duplicate documents provided in response to Item 10(a).

11. For press releases, the source of the document need not be provided.

12. Self-explanatory.

APPENDIX G LIST OF AUTHORIZED GENERIC DRUGS IN STUDY

BRAND NAME	ACTIVE INGREDIENT	DOSAGE FORM	NDA#
Accupril	quinapril hydrochloride	tablets	19885
Accuretic	hydrochlorothiazide; quinapril hydrochloride	tablets	20125
Actigall	ursodiol	capsules	19594
Agrylin	anagrelide	capsules	20333
Aldactazide	hydrochlorothiazide; spironolactone	tablets	12616
Aldactone	spironolactone	tablets	12151
Allegra	fexofenadine hydrochloride	tablets	20872
Amaryl	glimepiride	tablets	20496
Ambien	zolpidem tartrate	tablets	19908
Amoxil	amoxicillin	capsules	62216
Amoxil	amoxicillin	tablets	50754
Amoxil	amoxicillin	tablets, chewable	50761
Arava	leflunomide	tablets	20905
Augmentin	amoxicillin; clavulanate potassium	tablets	

Glucovance	glyburide; metformin hydrochloride	tablets	21178
Imitrex	sumatriptan	tablets	20132
Inspra	eplerenone	tablets	21437
K-Dur	potassium chloride	tablets, extended release	19439
Lamictal CD	lamotrigine	tablets, chewable	20764
Lamisil	terbinafine hydrochloride	tablets	20539
Limbitrol	amitriptyline hydrochloride; chlordiazepoxide hydrochloride	tablets	16949
Lotensin	benazepril hydrochloride	tablets	19851
Lotensin HCT	benazepril hydrochloride; hydrochlorothiazide	tablets	20033
Lotrel	amlodipine besylate; benazepril hydrochloride	capsules	20364
Macrobid	nitrofurantoin; nitrofurantoin, macrocrystalline	capsules	20064
Macrodantin	nitrofurantoin, macrocrystalline	capsules	16620
Marinol	dronabinol	capsule	18651
Mestinon	pyridostigmine bromide	tablets	9829
Micro-K	potassium chloride	capsules, extended release	18238
Microzide	hydrochlorothiazide	capsules	20504
Mobic	meloxicam	tablets	20938
Monodox	doxycycline	capsules	50641
Monopril	fosinopril sodium	tablets	19915
MS Contin	morphine sulfate	tablets, extended release	19516
Myambutol	ethambutol hydrochloride	tablets	16320
Neurontin	gabapentin	capsules	20235
Neurontin	gabapentin	tablets	20882
Nolvadex	tamoxifen citrate	tablets	17970
Nor-QD	norethindrone	tablets	17060
Norvasc	amlodipine besylate	tablets	19787
OMNICEF	cefdinir	capsules	50739
Ortho Micronor	norethindrone	tablets	16954
Ortho Tri-Cyclen	ethinyl estradiol; norgestimate	tablets	19697
Ortho-Cyclen	ethinyl estradiol; norgestimate	tablets	19653
Ortho-Novum 7/7/7	ethinyl estradiol; norethindrone	tablets	18985
Ovcon 35	ethinyl estradiol; norethindrone	tablets	17716
Oxandrin	oxandrolone	tablets	13718
OxyContin	oxycodone	tablets, extended release	20553
Pamine	methscopolamine bromide	tablets	8848
Parlodel	bromocriptine	capsules	17962
Paxil	paroxetine hydrochloride	tablets	20031
Paxil CR	paroxetine hydrochloride	tablets, extended release	20936
Plendil	felodipine	tablets, extended release	19834
Pletal	cilostazol	tablets	20863
Ponstel	mefenamic acid	capsules	15034
Pravachol	pravastatin sodium	tablets	19898
Prilosec	omeprazole	capsules, delayed release	19810
Proscar	finasteride	tablets	20180

Protonix	pantoprazole sodium	tablets, delayed release	20987
Purinethol	mercaptopurine	tablets	9053
Razadyne	galantamine hydrobromide	tablets	21169
Razadyne ER	galantamine hydrobromide	capsule, extended release	21615
Rebetol	ribavirin	capsules	20903
Remeron SolTab	mirtazapine	tablets, orally disintegrating	21208
Restoril	temazepam	capsules	18163
Retrovir	zidovudine	tablets	20518
Risperdal	risperidone	tablets	20272
Ritalin SR	methylphenidate hydrochloride	tablets	18029
Robinul	glycopyrolate	tablets	12827
Rv1.073sren Ttsantoilocarg			l

APPENDIX H METHODS

I. General

A. Definition of Authorized Generic Drug

For purposes of the study, "authorized generic ("AG") drug" means any drug sold, licensed or marketed under a New Drug Application ("NDA") approved by the FDA under 21 U.S.C. § 355(c) and marketed, sold or distributed (directly or indirectly) without using the listed drug's brand-name and with a different National Drug Code ("NDC") product number or labeler number (or both).[1]

Typically, the name of an AG is the nonproprietary established name of its active ingredients,[2] but in some cases a trade name different from the brand-name of the listed drug is used.

B. Timing and Dates

All chronological information is reported by calendar year.

C. Reporting by Drug

In Chapters 2 and 7, data are presented by drug (NDA), rather than by strength; a drug is counted as having only one AG, one first patent challenge, and one entry by 180-day exclusivity even if these conditions occur for multiple strengths. Also, a drug is counted as having an AG if at least one strength had an AG, as having a first patent challenge if one strength had a challenge, and as having entry by 180-day exclusivity if such entry occurs for one strength. In addition, chronological information about AGs, patent challenges, and 180-day exclusivity is generally presented in terms of the timing of the first such event for each drug. For example, Figure 2-1 reports AG launches by the year of the first launch of any strength. Counting by drug is consistent with the perception that decisions about whether to launch an AG or bring a patent challenge are usually made on a drug basis,[3] presumably because the economic incentives for

---

[1] This definition, which was used in the Special Orders, is very similar to the definitions of authorized generic drug in the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(t)(3), and in Centers for Medicare and Medicaid regulations, 42 C.F.R. § 447.506.

[2] *See* 21 C.F.R. § 299.4 ("Established names for drugs.").

[3] Generally, drugs that have AGs have them for all multisource strengths. Exceptions may involve settlement agreements in which the generic markets its ANDA-generic product for some strengths and AGs for others. Similarly, most ANDAs filed during the period covered by the study include all

strengths of a drug. *See* CTR. FOR DRUG EVAL. AND RESEARCH, U.S. FOOD AND DRUG ADMIN., GUIDANCE FOR INDUSTRY: VARIATIONS IN DRUG PRODUCTS THAT MAY BE INCLUDED IN A SINGLE ANDA 1 (Dec. 28, 1998), http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072892.pdf.

[4] OFFICE OF GENERIC DRUGS, U.S. F

series for finished goods.[6]

II. Identification of AGs, their NDA-holders, and Distributors

A. Sources of Information

We developed a list of AGs that meet the above definition based on information from the following sources. (1) *FDA National Drug Code (NDC) database, cumulative and current (online) Directory*.[7] The NDC database was used because it provides information on two numerical codes that are key aspects of the definition of an AG, the product and labeler numbers. Thus, we searched the FDA's historical NDC database and current online information for NDAs with some NDC numbers for which the tradename was an active ingredient or other name different from that of the brand-name drug, and the "product code" or "labeler code" was different from those of the brand-name drug.[8] NDC information was also used to identify the distributors of AGs when other sources identified the AG but did not provide the name of the distributor. (2) *Companies sent the Special Orders.* Companies were asked to identify AGs marketed pursuant to their NDAs and AGs distributed pursuant to other companies' NDAs. (3) *The FDA's List of Authorized Generic Drugs.*[9] After it became available, we included AGs from the FDA's List of Authorized Generic Drugs. Because the *List* does not include information on the distributor of the AG, and its launch and discontinuance dates are often unknown or approximate, we used other sources for this information. (4) *RED BOOK.*[10] The RED BOOK includes AGs but does not identify them as such; it was used primarily to confirm information from other sources on AGs and their distributors. In addition, since the RED BOOK provides prices of marketed drugs, it was used to confirm that drugs identified on the basis of NDCs or pre-launch information had entered the market. (5) *Internet Information.* AGs were identified from a variety of internet sources, such as press releases, Securities and Exchange Commission (SEC) reports, and pharmacy benefit manager lists of new generic drugs.

---

[6] The monthly Producer Price Index (PPI) for finished goods, seasonally adjusted (WPSSOP3000), over the period of our data (January 2003 through December 2008) is obtained from the Bureau of Labor Statistics. *See Producer Price Indexes*, BUREAU OF LABOR STATISTICS, http://www.bls.gov/ppi/data.htm (last updated June 14, 2011).

[7] The cumulative NDC database, provided by the FDA, contains all NDC records available when it was compiled, whereas the online NDC Directory contains current but not discontinued NDC records. *National Drug Code Directory*, U.S. FOOD AND DRUG ADMIN., http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm (last updated June 15, 2011).

[8] The nature of the "labeler" also helped identify AGs; NDA products with active ingredient names and labeler codes for generic companies (including generic subsidiaries of brand-name parent companies) or authorized generic companies were usually AGs.

[9] *See FDA Listing of Authorized Generics*, U.S. FOOD AND DRUG ADMIN., http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm126391.htm (last updated Mar. 25, 2011). This list became available on June 27, 2008. Because the list is based on annual reports provided by companies to the FDA, it may not identify all recent AGs.

[10] THOMPSON HEALTHCARE, RED BOOK (2010 ed. 2010).

[11] Also, one AG launched before 2001 was included in the study because a new strength was launched after 2001.

[12] One such AG was included because of competitive implications – it had been distributed by a generic company pursuant to settlement, but not long before generic entry (including the settling generic's ANDA-generic) the brand-name company became the AG distributor.

[13] *See* ILL. DEPT. OF PUBLIC HEALTH, ILLINOIS FORMULARY FOR THE DRUG PRODUCT SELECTION PROGRAM x–xii (21st ed. 2003), http://www.idph.state.il.us/about/fdd/Formulary21st_edition.pdf. The 21st edition was the last edition of the Illinois Formulary. Since the list of AGs in the Illinois Formulary is cumulative, editions 14–20 (1994–2002, provided by the Division of Food, Drugs and

Generally, companies with rights in relevant NDAs were sent Brand-Name (or Authorized Generic) Special Orders, and companies with rights in relevant ANDAs were sent Generic Special Orders.[18] Because some companies had rights in both relevant NDAs and ANDAs, they were sent Special Orders for both brand-name and generic companies.

1. Brand-Name Company Special Orders

Companies received Brand-name Special Orders if they held the NDA for (i) the brand-name version of an AG included in the study or (ii) a brand-name drug that first faced generic competition after January 1, 2001, for which at least one ANDA with a paragraph IV certification was filed; or (iii) a brand-name drug for which at least one ANDA with a paragraph IV certification was filed after January 1, 2001, and generic entry had not yet occurred.

2. Generic Company Special Orders

Companies received Generic Special Orders if they held an ANDA for (i) a bioequivalent generic version of an AG included the study; or (ii) a bioequivalent generic version of a brand-name drug that first faced generic competition after January 1, 2001, for which at least one ANDA with a paragraph IV certification was filed.[19]

3. Authorized Generic Company Orders

Two companies received AG Special Orders because they distributed an AG included in the study, but did not hold any NDA or ANDA described in (1) or (2) above.

4. Licenses and Assignments of NDAs and ANDAs

In addition, some companies that did not hold the relevant NDAs or ANDAs received Special Orders based on apparent licenses regarding the brand-name and generic drugs approved under the FDA applications described above.[20] Licenses were inferred from comparisons of the

---

[18] For a description of the drugs covered by each type of Order, *see* Appendix D, at D-11, D-12 (Brand-Name Drug Company Special Order, *Instructions for Specific Items*, ¶¶ 4-6); Appendix E, at E-9, E-10 (Generic Drug Company Special Order, *Instructions for Specific Items*, ¶¶ 4, 5 and 7); and Appendix F, at F-8 (Authorized Generic Drug Company Special Order, *Instructions for Specific Items*, ¶¶ 4 and 5).

[19] Generic companies were also asked to provide information on any AGs that they distributed, but companies were categorized as generic companies on the basis of their ANDAs, not AGs.

[20] For example, licensee relationships include situations in which one company develops a drug and holds the NDA or ANDA, and another, contractually-related company, sells or promotes the brand-name or ANDA-generic drug. Assignments involve the sale of the NDA or ANDA from one company to another. Although AGs often are distributed via licenses or assignments (e.g., an external generic company enters into a license with the NDA holder to distribute an AG, or distributes an AG pursuant to a mature NDA purchased from an innovator company), the licenses and assignments discussed in

this section refer to arrangements for the distribution and sale of brand-name and ANDA-generic drugs by a company other than the original developer, not arrangements for distribution of an AG.

[21] The RED B

[28] Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, 117 Stat. 2066 (codified in scattered sections).

[29] Rarely, the first strength with generic entry via exclusivity lacks an AG, but AGs of all strengths are launched later, and are marketed

[32] Rarely, the first strength of an AG is launched at the time of generic entry without exclusivity, but subsequently AGs for other strengths enter during exclusivity periods.

[33]

[35] COMIS was used by the FDA "to track information about the receipt and review status of investigational new drug applications (INDs), new drug applications (NDAs), and abbreviated new drug applications (ANDAs)." *See Drugs@FDA Frequently Asked Questions*, U.S. FOOD AND DRUG ADMIN., http://www.fda.gov/Drugs/InformationOnDrugs/ucm075234.htm. The FDA provided information from the database to the FTC in 2008, including applications filed by May 13, 2008. Beginning in 2009, the FDA tracked applications in its Document Archiving, Reporting, and Regulatory Tracking System (DARRTS). Because of difficulties in working with 2008 information that arose from two different systems, we were unable to extend most of our analyses based on application data past the end of 2007.

[36] *Paragraph IV Patent Certifications*, U.S.

Similar to other analyses, the dates of first patent challenge are presented by drug (NDA), rather than by strength. This is consistent with the observation that in most cases, the same patents are listed for each strength of a drug, and most ANDAs include all strengths of a drug. When the first PIV certifications for different strengths were made on different dates, as occasionally occurs, the earliest date was used. The use of a single PIV certification date for a drug simplifies the determination of the sales level of a drug at the time of patent challenge, by ensuring that the sales of a single year are used.[38]

VIII. Drugs Subject to a First Paragraph III Certification

To evaluate the extent to which generic companies chose to make PIII rather than PIV certifications and wait until patent expiration to enter the market, we examined trends in "first PIII certifications" for drugs for which the first PIII was between 2003 and 2007 (Table 7-3). We define "first PIII" drugs as those for which the highest certification in all ANDAs was a PIII. Thus, if an ANDA with a first PIII is amended to include a PIV certification, or if a prior or subsequent ANDA for the same drug includes a PIV certification, the drug is categorized as a first PIV rather than a first PIII. In essence, the first PIII and first PIV drugs represent the population of patent-protected drugs that generic companies viewed as available for patent challenge.[39]

The year of the "first PIII certification" for a given drug (i.e., for a particular dosage form and NDA) was estimated from ANDA filing dates in the FDA's application database.[40] Using the database, we identified all ANDAs filed from 2003–2007 for which the highest certification was a PIII certification. Based on the established name, dosage form, and strengths, we determined the reference-listed drug for each ANDA, and excluded those for which the drug was listed on the FDA's Paragraph IV Patent Certification website as of February 7, 2011. We excluded from the remaining ANDAs those for drugs for which an earlier-filed ANDA made a PIII certification, and thus determined, for each brand-name drug not subject to a PIV certification, the year of filing of the first ANDA with a PIII certification.

IX. Sales Levels of Drugs Subject to a First Paragraph III or IV Certification

To assess the financial incentives underlying decisions to attempt to enter the market before patent expiration by making a PIV certification, or to make a PIII certification and wait to enter after patent expiration (Tables 7-1, 7-2, 7-4; Figure 7-4), we determined the sales level of brand-name drugs subject to first PIII or PIV certifications. The sales level used was that of the year of the first PIII or PIV certification, according to IMS Health NPA data.

---

[38] Analysis by drug also avoids counting repeated "first PIVs" in anomalous situations such as when the brand adds a new strength many years after initial NDA approval, or a generic company files an ANDA with a PIV certification for a strength not approved under an NDA.

[39] Drugs *not* subject to a PIII or PIV may lack patent protection or may be covered by regulatory exclusivities that extend beyond the drug's patent protection or prohibit a challenge.

[40] Unlike PIV patent certifications, no website reports PIII patent certifications.

A

[41] The first PIV certifications for these drugs occurred 2–11 months after NDA approval, and the length of time from NDA approval to the end of the year ranged from 6.5–11.3 months.

[42] *See* 21 C.F.R. § 314.108.

[43] For the few instances in which more than one dosage form of the same active ingredient had NCE exclusivity, the figure includes only the first dosage form (NDA) that was approved, for which ANDAs with PIV certifications cannot be filed for four years after NDA approval. The figure does not include later-approved dosage forms of the same active ingredient because NCE exclusivity for all dosage forms of the same active ingredient ends on the same date, and the period for which ANDAs with PIV certifications cannot be filed is less than four years for the later approved dosages forms. *See* Abbreviated New Drug Application Regulations, 54 Fed. Reg. 28,872, 28,897 (July 10, 1989) (NCE exclusivity applies to active moiety, not specific drug product).

[44] Lists of NCEs with approval dates from 1998–2004 (first PIV dates from 2002–2008) were obtained8y16.213ONDAwe

NDAs that were not available for patent challenge or for which a patent challenge would not advance entry, including those that lacked listed patents on the first day on which a patent could be challenged, or lacked patent protection after the expiration of regulatory exclusivity (e.g., after the expiration of NCE exclusivity or Orphan Drug Exclusivity). The remaining NCEs were used to determine the number and percentage for which an ANDA with a paragraph IV certification had been filed on the first possible day (Figure 7-5).

B. Number of ANDAs Filed on the First Possible Day

We used information from the FDA's application databases to determine the number of ANDAs filed on the first possible day.[45] Only NCEs with first-day ANDAs were included in calculations of the mean number of first-day ANDAs per NCE (Table 7-5), so that the results reflect the likely number of competitors during any 180-day exclusivity with respect to NCEs that received a first-day patent challenge. Similarly, although companies occasionally submitted multiple first-day ANDAs for the same drug (e.g., for different strengths), we counted only one ANDA per company to ensure that the count reflects the likely number of competitors during 180-day exclusivity. However, because the FDA may not deem all such filings as "substantially complete" or approvable, or a company may withdraw an application or decide not to market an approved ANDA product (e.g., because of a merger of two filers), these numbers should be considered only estimates of the number of companies that will compete during exclusivity.

---

through 2008: No NCE with an NDA approved during the last six months of 1997 had pediatric exclusivity that made the first possible day for a patent challenge occur in the first half of 2002 instead of the last half of 2001. Similarly, no NCE with an NDA approved during the last six months of 2004 had pediatric exclusivity that extended the first possible day for a challenge from the last half of 2008 to the first half of 2009.

[45] For ANDAs filed Jan. 1, 2002–May 13, 2008, we used the COMIS database, while the DARRTS database was used for ANDAs filed May 14, 2008–Dec. 31, 2008. *See supra* note 35. ANDA filings determined with the DARRTS database were cross-checked against publicly available litigation filings and other documents.

APPENDIX I TECHNICAL DATA APPENDIX

This appendix describes the sources of data used in the analysis of Chapters 3 and 6 and details the criteria used to construct the data sample. Additionally, it summarizes characteristics of the sample, and discusses how the analysis was tailored to account for some of these characteristics.

I. Data Sources

The data for this Report were acquired from several sources. The retail and wholesale price, expenditure, and quantity data were licensed from IMS Health, Inc. Authorized generic products and their distributors were identified based on information produced by pharmaceutical companies pursuant to the Commission's information requests ("Special Orders"), press releases, and information provided by the FDA.[1] The following sections describe, in detail, the data obtained from each of these sources and how they have been combined for use in the Report.

A. IMS Health Inc.

The FTC purchased a license from IMS Health for information representing nationally aggregated, monthly sales information for each non-injectable prescription medication distributed in the United States over the period from January 2003 through December 2008. This information included: (1) the National Sales Perspective (NSP) Survey, which represents wholesale level quantity and dollar sales[2] information for products purchased by retail and non-

---

[1] The Federal Trade Commission received prescription sales information from over 100 drug firms representing product-level sales information over the period 1/1/2000–3/31/2007. Unfortunately, much of the firm data proved intractable due in part to inconsistencies across firms, and sometimes across products within a firm. For example, the firms often applied discounts, charge-backs, returns, drug expirations and other product flow information as periodic accounting adjustments. These adjustments were made on irregular bases over time and could differ in timing across dollar and quantity sales of the same product. As a consequence, the sales adjustments frequently led to negative sales dollars and quantities, which made calculation of meaningful prices problematic. These issues led us to purchase sales information from a data vendor.

[2] Certain discounts may not be accounted for in this data. IMS CONSULTING, IMS HEALTH, ASSESSMENT OF AUTHORIZED GENERICS IN THE U.S. 19 (2006) (written for the Pharm. Research and Mfrs. of Am. ("PhRMA")), http://replay.web.archive.org/20061009134405/http://www.phrma.org/files/IMS%20Authorized%20Generics%20Report_6-22-06.pdf ("[P]rompt-payment cash discounts and bottom-line invoice discounts are not reflected in the dollar purchase amounts. Also, it should be noted that volume purchase estimates may not always reflect drop shipment activity.") As long as these omitted discounts do not vary systematically between authorized and ANDA-generic products, the absence of information on

these discounts should not bias the analysis.

[3] Most molecules were assigned to the most prevalently observed therapeutic class observed in the data. However, the molecule, Bupropion, represents an important exception. The molecule Bupropion must be distinguished by whether it is used to treat smoking addiction or depression. Nitrofurantoin was excluded from the analysis because it is associated with several molecular names in the FDA data.

[4] Dosage forms were defined using the "three-lettered" code defined by IMS. The mapping of this variable into dosage forms used in the analysis is provided in Table I-4. This mapping was necessary in order to match the IMS and FDA data.

[5] Several market outcomes, such as prices, have been normalized based on the market conditions that existed prior to generic entry. Consequently, even though data for the first three months of 2003 were available, that information was used only to calculate pre-generic entry market characteristics for products that experienced generic entry early in 2003.

[6] This process dropped Clopidogrel 75mg tablets, Ondansetron 24mg tablets, Fenofibrate 160mg tablets, Fenofibrate 54mg tablets, Trimethobenzamide 300mg capsules, and Amantadine 100mg tablets.

Products were defined as beginning to face generic competition during the period on the basis of the manufacturer, brand status, and sales information provided by IMS. The manufacturer and brand status information were used to classify each product into one of two types: brand and generic. A product was treated as facing generic competition if at least one generic manufacturer (including the AG distributor) of the product had positive sales prior to the end of the sample. The product was treated as having begun to face generic competition during the sample period if it faced(end of the sam)9(p)1(le. The product was tri.-201 Tm a8h3NAG1ki.385 -1.15 Td [

---

[7] On occasion, positive but small sales figures were observed for a generic firm earlier than other reliable information suggests it could be on the market. Therefore, generic sales that occurred prior to the FDA-defined exclusivity period and that represented less than 0.5% of pre-entry brand sales were excluded.

[8] The six-month limitation on the length of the exclusivity period affects only products in "AG Only" markets. The three-year window considered outside exclusivity is a maximum length. The analysis considers drugs with shorter time horizons. The three-year mark was chosen because less than half of the drugs in the sample were observed for more than three years.

[9] The IMS data do not always differentiate between manufacturers and repackagers. Although repackagers were not included in the count of manufacturers, the sales associated with them were used to construct price and sales figures. A list of companies treated as repackagers is provided in Table I-5. Incorrect identification of the repackagers could cause over- or under-statement of the number of active generic manufacturers of a product.

[10] *See* FED. TRADE COMM'N, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES ch. VI (2005), http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf (providing additional information on repackagers).

including whether the product faced a Paragraph IV challenge and the end date of exclusivity periods associated with Paragraph IV challenges.

AGs were identified using information produced by pharmaceutical companies pursuant to the Special Orders and information provided by the FDA.[11] The Special Orders requested the proprietary/trade name of the AG, the proprietary name of the brand-name drug for which the NDA authorizes the marketing of the AG, the active ingredient, the dosage form, the NDA number of the brand-name drug that authorizes the marketing of the AG, and the strength of the AG. This information was collected from both the generic and brand-name manufacturers. In addition, brand-name manufacturers were requested to provide the name of the entity associated with each NDC labeler code, enabling identification of the AG distributor.

The most relevant Hatch-Waxman related information was whether the product faced a Paragraph IV patent challenge and whether a generic manufacturer was granted exclusivity related to a Paragraph IV challenge. A list of drugs facing Paragraph IV challenges was downloaded from the FDA website.[12] For each drug associated with a 180-day exclusivity period, the date that generic exclusivity ended was determined from information provided by the FDA. A month was treated as part of the exclusivity period if the 28

---

[11] *See, e.g., FDA Listing of Authorized Generics*, U.S. FOOD AND DRUG ADMIN., http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm126391.htm (last updated Mar. 25, 2011).

[12] *See Paragraph IV Patent Certifications*, U.S. FOOD AND DRUG ADMIN., http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm047676.htm (last updated June 10, 2011) (list updated twice a month).

[13] For example, if the exclusivity period as identified by the FDA ended on June 15, 2005, then the exclusivity would include the months December 2004 through May 2005 but would exclude June. However, if the end date of the exclusivity was June 29th, then the month of June would also be included in the exclusivity period.

the period of our data (January 2003 through December 2008). These data were obtained from the Bureau of Labor Statistics.[14]

II. Properties of the Data

As detailed above, this Report considers a very wide range of drugs, from pain killers to anti-cholesterol drugs to antibiotics. The benefit of this approach is that the analysis can be informed by a large sample size. A potential danger is that the analysis could produce misleading results by comparing apples to oranges. This section describes the heterogeneity observed in the sample and the steps that were taken to tailor the analysis accordingly.

A. Sample Characteristics

Table I-1 presents product-level information describing the variables used to construct the regression samples. More than 60% of the products in the sample face a Paragraph IV certification. However, less than 40% of all products, and 63% of products facing a Paragraph IV certification, were observed with an exclusivity period. AGs were observed for roughly half of the products in the sample, with half distributed through a licensee and half through a subsidiary of the brand-name firm.

Settlements between brand-name and ANDA-generic firms can be important determinants of whether an AG is observed for a product. Table I-1 reports that 14% of products in the sample are involved in a settlement involving an AG. Nearly two-thirds of these settlements named the litigant as the AG distributor, whereas the rest restricted the ability of the brand to issue an AG.

Table I-1: Hatch-Waxman Act and Authorized Generic Statistics

Variable	Obs.	Mean
Hatch-Waxman and Authorized Generic Information		
Paragraph IV	312	0.625
Exclusivity	312	0.394
Authorized Generic	312	0.535
AG is Distributed by a Licensee	312	0.272
AG is Distributed by a Subsidiary	312	0.263
Settlements Involving an AG		
Settlements Involving an AG	312	0.138
Litigant Named the AG Distributor	312	0.087
Settlement Terms Require no AG	312	0.051

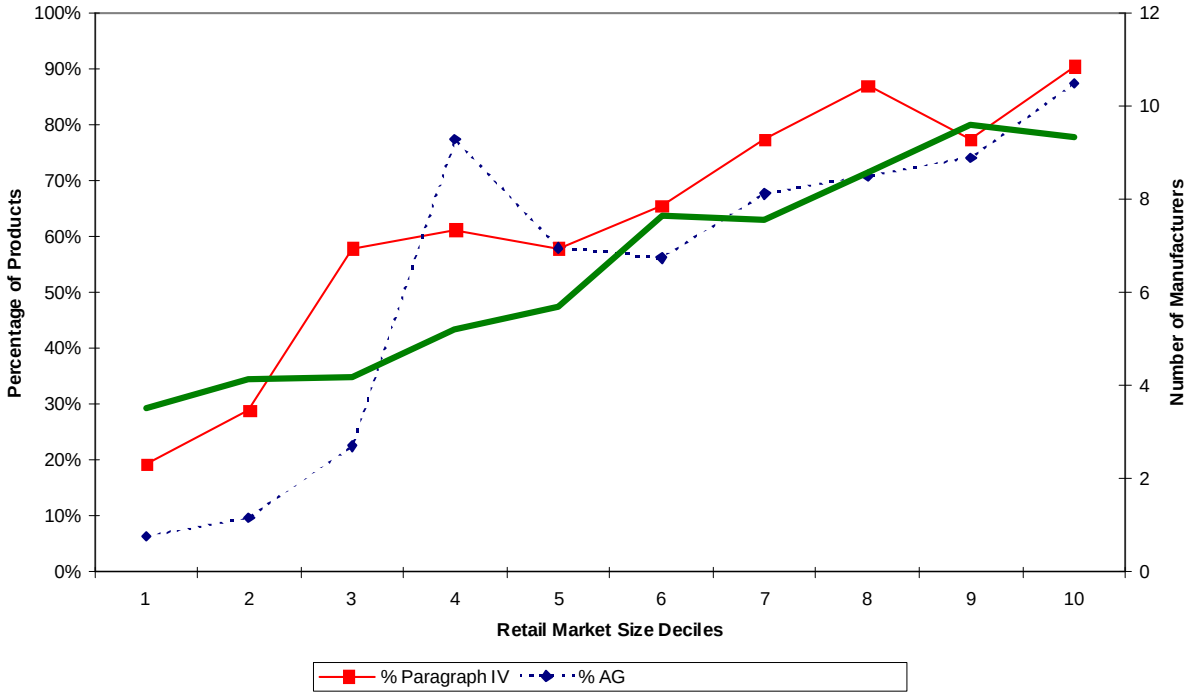
[14] *See Producer Price Indexes*, BUREAU OF LABOR STATISTICS, http://www.bls.gov/ppi/data.htm.

B. Heterogeneity of Products Based on Market Size

The regression analyses in Chapters 3 and 6 often include product-characteristic controls in an attempt to control for the non-random determinants of the competitive environment, such as the presence of an AG. The importance of controlling for the determinants of the competitive environment can be seen in Figure I-1, which plots the pre-entry retail sales of the brand-name product against the relative frequencies of Paragraph IV challenges, AG entry, and the maximum number of generic competitors observed for that product in any month in our sample.

This figure shows that all three of these competition measures are generally increasing in pre-entry retail dollar sales. The horizontal axis measures retail sales of the brand-name product just prior to generic entry, grouped in deciles. So, for example, the first point on the Paragraph IV line shows that about 20% of the smallest 10% of products faced Paragraph IV challenges. The frequency of Paragraph IV challenges increases as the pre-entry brand sales grow (moving to the right on the graph), with over 90% of the largest 10% of products getting challenged. The presence of AG competitors follows a similar pattern. Less than ten percent of products in the lowest sales deciles have an AG competitor, but nearly 90% of the products in the highest sales decile have an AG competitor. The third statistic counts the maximum number of manufacturers observed for each product (measured on the vertical axis to the right) over the entire sample. Figure I-1 shows that products with larger pre-entry brand sales tend to attract more generic competitors. The average number of generic competitors in the lowest sales deciles is slightly more than three per product, but products in the highest sales decile have an average of over nine generic competitors per product by the end of the sample period.

Figure I-1: The Influence of Market Size



[15] Another way to group products would be by chemical properties of the active ingredients, but the condition treated by the product is, arguably, the single most important characteristic relating the products in a category. For example, the molecule Bupropion is used to treat two conditions, smoking addiction and clinical depression. Bupropion is categorized into two therapeutic codes that represent the treatment of these conditions, despite being the exact same molecule and thus having identical chemical properties.

differences, between products with and without AGs, that are constant across the condition treated. The drugs in the sample are classified into 31 different therapeutic classes. Of these 31

Table I-2 : Product Characteristics Summary Statistics

Variable	Obs.	Mean	Std. Dev.
Dosage Form			
Tablet	312	0.679	0.467
Capsule	312	0.115	0.320
Chewable	312	0.006	0.080
Orally Disintegrating	312	0.038	0.193
Extended Release Capsule	312	0.035	0.185
Extended Release Tablet	312	0.112	0.316
Sustained-Release Tablet	312	0.013	0.113
Therapeutic Class			
Allergy/Cold Preps*	312	0.013	0.113
Amebacide/Antibacterial Agent	312	0.006	0.080
Analgesics*	312	0.035	0.185
Anti-arthritics	312	0.013	0.113
Anti-Fungal Agents*	312	0.019	0.138
Anti-hyperlipidemic Agent*	312	0.032	0.176
Anti-Infectives Systemic*	312	0.074	0.262
Anti-nauseant*	312	0.016	0.126
Antineoplastic Agents	312	0.003	0.057
Anti-Obesity	312	0.003	0.057
Anti-viral*	312	0.035	0.185
Cardiac Agents	312	0.010	0.098
Contraceptives	312	0.003	0.057
Dermatologicals	312	0.003	0.057
Diabetes Therapy*	312	0.054	0.227
Diuretics & Aquaretics	312	0.010	0.098
Gastrointestinal*	312	0.022	0.148
Genitourinary*	312	0.019	0.138
Hemostatic Modifiers	312	0.013	0.113
Hormones*	312	0.026	0.158
Miscellaneous Preps	312	0.003	0.057
Musculoskeletal*	312	0.035	0.185
Neurological Disorders*	312	0.131	0.338
Ophthalmic Preparations	312	0.003	0.057
Parasympathetics	312	0.003	0.057
Psychotherapeutics*	312	0.163	0.370
Sedatives & Hypnotics	312	0.022	0.148
Smoking Deterrents	312	0.003	0.057
Thyroid Therapy	312	0.013	0.113
Tuberculosis Therapy	312	0.003	0.057
Vascular Agents*	312	0.208	0.407

*At least one drug in the therapeutic class is observed during exclusivity.

[16] Even without considering dollars sold, some therapeutic classes may represent a large fraction of total products sold in the market, but represent a small number of products beginning to face generic

[18] For example, some of the products in the sample are ineligible to face a Paragraph IV challenge.

Table I-3: Products Used in the Analysis by Therapeutic Class

Allergy/Cold Preps
- Cetirizine, 10mg Tablet
- Fexofenadine, 180mg, 30mg, 60mg Tablets

Amebacide/Antibacterial Agent
- Metronidazole, 375mg Capsule
- Metronidazole, 750mg Extended-Release Tablet

Analgesics
- Acetaminophen/Propoxyphene, 100-500mg Tablet
- Acetaminophen/Tramadol, 37.5-325mg Tablet
- Hydrocodone/Ibuprofen, 7.5-200mg Tablet
- Ibuprofen/Oxycodone, 5-400mg Tablet
- Oxycodone, 10mg, 20mg, 40mg, 80mg Extended-Release Tablets
- Sumatriptan, 100mg, 25mg, 50mg Tablets

Antiarthritics
- Leflunomide, 10mg, 20mg Tablets
- Meloxicam, 15mg, 7.5mg Tablets

Anti-Fungal Agents
- Fluconazole, 100mg, 150mg, 200mg, 50mg Tablets
- Itraconazole, 100mg Capsule
- Terbinafine, 250mg Tablet

Antihyperlipidemic Agent
- Colestipol, 1000mg Tablet
- Pravastatin, 10mg, 20mg, 40mg, 80mg Tablets
- Simvastatin, 10mg, 20mg, 40mg, 5mg, 80mg Tablets

Anti-Infectives Systemic
- Amoxicillin/Clavulanic Acid, 250-125mg Tablet
- Azithromycin, 250mg, 500mg, 600mg Tablets
- Cefdinir, 300mg Capsule
- Cefpodoxime Proxetil, 100mg, 200mg Tablets
- Cefprozil, 250mg, 500mg Tablets
- Ciprofloxacin, 1000mg, 500mg Extended-Release Tablets
- Ciprofloxacin, 100mg, 250mg, 500mg, 750mg Tablets
- Clarithromycin, 500mg Extended-Release Tablet
- Clarithromycin, 250mg, 500mg Tablets
- Demeclocycline, 150mg, 300mg Tablets
- Ofloxacin, 200mg, 300mg, 400mg Tablets

Antinauseant
- Granisetron, 1mg Tablet
- Ondansetron, 4mg, 8mg Orally Disintegrating/Ecteric Coateds
- Ondansetron, 4mg, 8mg Tablets

Antineoplastic Agents
- Mercaptopurine, 50mg Tablet

Table I-3: Products Used in the Analysis by Therapeutic Class *(continued)*

Anti-Obesity
- Benzphetamine, 50mg Tablet

Antiviral
- Didanosine, 200mg, 250mg, 400mg Extended-Release Capsules
- Famciclovir, 125mg, 250mg, 500mg Tablets
- Ganciclovir, 250mg, 500mg Capsules
- Ribavirin, 200mg Capsule
- Zidovudine, 100mg Capsule
- Zidovudine, 300mg Tablet

Cardiac Agents
- Midodrine, 10mg, 2.5mg, 5mg Tablets

Contraceptives
- Drospirenone/Ethinylestradiol, 3-0.03mg Tablet

Dermatologicals
- Tretinoin, 10mg Capsule

Diabetes Therapy
- Acarbose, 100mg, 25mg, 50mg Tablets
- Glimepiride, 1mg, 2mg, 4mg Tablets
- Glipizide, 10mg, 2.5mg, 5mg Extended-Release Tablets
- Glipizide/Metformin, 2.5-250mg, 2.5-500mg, 5-500mg Tablets
- Glyburide/Metformin, 1.25-250mg, 2.5-500mg, 5-500mg Tablets
- Metformin, 500mg, 750mg Extended-Release Tablets

Diuretics and Aquaretics
- Metolazone, 10mg, 2.5mg, 5mg Tablets

Gastrointestinal
- Balsalazide, 750mg Capsule
- Glycopyrrolate, 1mg, 2mg Tablets
- Omeprazole, 10mg, 40mg Extended-Release Capsules
- Pantoprazole, 20mg, 40mg Orally Disintegrating/Ecteric Coateds

Genitourinary
- Butabarbital/Hyoscyamine/Phenazopyridine, 150-0.3-15mg Tablet
- Finasteride, 5mg Tablet
- Flavoxate, 100mg Tablet
- Oxybutynin, 10mg, 15mg, 5mg Extended-Release Tablets

Hemostatic Modifiers
- Anagrelide, 0.5mg, 1mg Capsules
- Cilostazol, 100mg, 50mg Tablets

Hormones
- Desmopressin, 0.1mg, 0.2mg Tablets
- Estrogenic Sub,Conjugated, 0.45mg Tablet
- Hydrocortisone, 5mg Tablet
- Methylprednisolone, 16mg, 32mg Tablets
- Oxandrolone, 10mg, 2.5mg Tablets

Table I-3: Products Used in the Analysis by Therapeutic Class *(continued)*

Miscellaneous Preps
- Cabergoline, 0.5mg Tablet

Musculoskeletal
- Alendronate, 10mg, 35mg, 40mg, 5mg, 70mg Tablets
- Cyclobenzaprine, 5mg Tablet
- Dantrolene, 100mg, 25mg, 50mg Capsules
- Etidronic Acid, 200mg, 400mg Tablets

Neurological Disorder
- Clonazepam, 0.125mg, 0.25mg, 0.5mg, 1mg, 2mg Orally Disintegrating/Ecteric Coateds
- Divalproex, 125mg, 250mg, 500mg Tablets
- Gabapentin, 100mg, 300mg, 400mg Capsules
- Gabapentin, 600mg, 800mg Tablets
- Galantamine, 16mg, 24mg, 8mg Extended-Release Capsules
- Galantamine, 12mg, 4mg, 8mg Tablets
- Lamotrigine, 25mg, 5mg Chewables
- Lamotrigine, 100mg, 150mg, 200mg, 25mg Tablets
- Levetiracetam, 250mg, 500mg, 750mg Tablets
- Oxcarbazepine, 150mg, 300mg, 600mg Tablets

Table I-3: Products Used in the Analysis by Therapeutic Class *(continued)*

Sedatives and Hypnotics
- Methylphenobarbital, 100mg, 32mg, 50mg Tablets
- Zaleplon, 10mg, 5mg Capsules
- Zolpidem, 10mg, 5mg Tablets

Smoking Deterrents
- Bupropion, 150mg Sustained-release Tablet

Thyroid Therapy
- Thyroid Gland, 15mg, 240mg, 300mg, 90mg Tablets

Tuberculosis Therapy
- Isoniazid/Rifampin, 300-150mg Capsule

Vascular Agents
- Amlodipine, 10mg, 2.5mg, 5mg Tablets
- Amlodipine/Benazepril, 10-20mg, 2.5-10mg, 5-10mg, 5-20mg Capsules
- Benazepril, 10mg, 20mg, 40mg, 5mg Tablets
- Benazepril/Hydrochlorothiazide, 10-12.5mg, 20-12.5mg, 20-25mg, 5-6.25mg Tablets
- Bendroflumethiazide/Nadolol, 40-5mg, 80-5mg Tablets
- Carvedilol, 12.5mg, 25mg, 3.125mg, 6.25mg Tablets
- Diltiazem, 360mg, 420mg Extended-Release Capsules
- Eplerenone, 25mg, 50mg Tablets
- Felodipine, 10mg, 2.5mg, 5mg Extended-Release Tablets
- Fosinopril, 10mg, 20mg, 40mg Tablets
- Fosinopril/Hydrochlorothiazide, 10-12.5mg, 20-12.5mg Tablets
- Hydrochlorothiazide/Metoprolol, 100-25mg, 100-50mg, 50-25mg Tablets
- Hydrochlorothiazide/Moexipril, 15-12.5mg, 15-25mg, 7.5-12.5mg Tablets
- Hydrochlorothiazide/Quinapril, 10-12.5mg, 20-12.5mg, 20-25mg Tablets
- Isradipine, 2.5mg, 5mg Capsules
- Metoprolol, 100mg, 200mg, 25mg, 50mg Extended-Release Tablets
- Moexipril, 15mg, 7.5mg Tablets
- Nimodipine, 30mg Capsule
- Nisoldipine, 20mg, 30mg, 40mg Extended-Release Tablets
- Quinapril, 10mg, 20mg, 40mg, 5mg Tablets
- Ramipril, 1.25mg, 10mg, 2.5mg, 5mg Capsules

Table I-4: Mapping from IMS Data to Dosage Form

Three-Lettered Code (as provided by IMS)	Analysis Dosage Form
ABA Tablets Uncoat Regular Ordinary Tablet	Tablet
ACA Tablets Coated Regular Ordinary Tablet	Tablet
AAA Capsules Regular Ordinary	Capsule
AAE Capsules Regular Soluble	Capsule
AAF Capsules Regular Sprinkle	Capsule
ABC Tablets Uncoat Regular Chewable	Chewable
ACC Tablets Coat Regular Chewable	Chewable
ABD Tablets Uncoat Regular	Buccal/Sublingual
BBD Tab Uncoat Long Acting Buccal/Sub-Lingual	Buccal/Sublingual
AGD Lozenge Reg Buccal/Sub-Lingual	Buccal/Sublingual
ABE Tablets Uncoat Regular Sol	Orally Disintegrating/Ecteric Coated
ABZ Tablets Uncoat Regular Other	Orally Disintegrating/Ecteric Coated
ACZ Tab Coated Regular Other	Orally Disintegrating/Ecteric Coated
BAA Capsules Long Acting Ordinary	Extended-Release Capsule
BAZ Capsules Long Acting Other	Extended-Release Capsule
AAZ Capsules Regular Other	Extended-Release Capsule
BBA Tablets Uncoat Long Acting Ordinary	Extended-Release Tablet
BBE Tablets Uncoat Long Acting Solution	Extended-Release Tablet
BBZ Tablets Uncoat Long Acting Other	Extended-Release Tablet
BCA Tablets Coated Long Acting Ordinary	Extended-Release Tablet
BCZ Tablets Coated Long Acting Other	Extended-Release Tablet
AGA Lozenge Regular Ordinary Lozenge	Lozenge
RB Mouth Throat Lozenges Lozenge	Lozenge
BGA Lozenge Long Acting Ordinary	Extended-Release Lozenge
BDA Granulate Long Acting Ordinary	Extended-Release Granule
Doseform=Tablet/Capsule	Other

Table I-5: Firms Counted as Repackagers

Allscripts Pharmaceuticals
Altura Pharmaceuticals
American Generic
American Health Packager
American Pharmaceuticals
American Pref Pharmaceuticals
American Regent
American Therapeutical
American Urologic
AQ Pharmaceuticals
Blenheim Pharmacal
Blu Pharmaceuticals
Bryant Ranch Pre-packager
DHS
Dispensexpress
Dispensing Solution
Dr.X
GSMS
Keltman Pharmaceuticals
Major Pharmaceuticals
Marlex Pharmaceuticals
Mckesson Packaging Services
Nucare Pharmaceuticals
Palmetto Pharmaceuticals
PD-RX Pharmaceuticals
Pharma Medical
Pharma Pac
Pharmpak
Physicians Total Care
Physician Partner
Physician Therapeutics
Prepak Systems
Quality Care Pharmaceuticals
Repackager
Rxpak Division
Southwood Pharmaceuticals
St Marys Mpp
Stat Rx
UDL Laboratories
Vibranta

Table I-6: List of USC5 Decongestant Therapeutic Classes Excluded

14310 Anti-histamine/Decongestant
14330 Anti-histamine/Decongestant/Analgesic
14390 Comb W/O Expectorant,Other
14510 Expectorant/Decongestant
14560 Expectorant/Decongestant/Analgesic
34380 Narcotic Cough/Expectorant
34510 Non-Narcotic Cough/Decongestant
34520 Non-Narcotic Cough/Anti-histamine
34540 Non-Narcotic Cough/Decongestant/Anti-histamine
34560 Non-Narcotic Cough/Anti-histamine/Analgesic
34570 Non-Narcotic Cough/Decongestant/Anti-histamine/Anal
34590 Non-Narcotic Cough Comb W/O Expectorant,Other
34610 Non-Narcotic Cough/Decongestant/Expectorant
34650 Non-Narcotic Cough/Decongestant/Analgesic/Expectorant
34680 Non-Narcotic Cough/Expectorant

Table I-7: List of USC5 Vitamin Therapeutic Classes Excluded

11420 Vitamin K & Related, Oral
32200 Lipotropics
37340 Emollients & Protectives
43100 Enzymes, Local/Topical
48111 Ferrous, Iron Alone
48112 Ferrous, Iron Combination
48120 Liver
48130 Vitamin B12
48190 Hematinics, Other
60500 Calcium Supplements
60600 Complete Food Supplement
60700 Nutrients & Supplements
73000 Tonics
76110 Multivitamin Prenatal
76121 Multivitamin-Pediatric Chewable W/Fluoride
76122 Multivitamin-Pediatric Drops W/Fluoride
76123 Multivitamin-Pediatric Liquid W/Fluoride
76131 Multivitamin-Pediatric Chew without Fluoride
76132 Multivitamin-Pediatric Drops without Fluoride
76133 Multivitamin-Pediatric Liq without Fluoride
76140 Multivitamin General
76212 B-Complex, Plain, Oral
76222 B-Complex, W/C, Oral
76230 B-Complex, Other Combination
76310 Ascorbic Acid
76320 Vitamin A
76330 Vitamin A & D
76340 Vitamin D
76350 Niacin
76380 Vitamin E
76390 Vitamins,Other
84210 Natural Medicine Other, Herbals
84220 Natural Medicine Other, Nutritn
84230 Natural Medicine Other, Topical

[1] *See* Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, Title IV, § 4401 (a)(3), 104 Stat. 1388-143 (codified at 42 U.S.C. § 1396r-8 (2010)).

[2] The program is administered by the Centers for Medicare & Medicaid Services ("CMS") in the Department of Health and Human Services.

[3] *See, e.g.*, Company Document ("CD"), undated (contending that "the failure of the Department of Health and Human Services (HHS) to enforce the inclusion of authorized generics in the Medicaid rebate calculation for the brand product is . . . depriving state Medicaid programs of hundreds of millions of dollars in rebates").

[4] Deficit Reduction Act of 2005 ("DRA"), Pub. L. No. 109-171, 120 Stat. 4 (codified at 42 U.S.C. § 1396r (2010)).

B. The DRA and the Treatment of Authorized Generics

Section 6003 of the DRA specifically requires brand manufacturers to include authorized generic sales in their calculations of both the AMP and best price when they report these prices for covered outpatient drugs to the Secretary.[5] The DRA also required CMS to promulgate regulations detailing precisely how the AMP was to be calculated. The effective date of the law was January 1, 2007.

On December 22, 2006, CMS published proposed regulations, including rules on the inclusion of AG prices in the calculation of AMP and best price.[6] The proposed rule would have required the brand manufacturer to factor into its calculation of the AMP and Best Price for a given drug all the sales of the corresponding AG, even if the AG were manufactured or marketed by a different company.[7]

This drew significant adverse comments. Among other things, commenters argued that the rule as proposed would require brand companies (the NDA holders) to obtain pricing data

---

5 *See id.* §§ 1396r-8 (b)(3)(A), (c)(1)(C)(i)(ii).

6 *See* Medicaid Program; Prescription Drugs, 71 Fed. Reg. 77,174 (Dec. 22, 2006).

7 *Id.* at 77,183–84, 77,198.

8 *See* Medicaid Program; Prescription Drugs, 72 Fed. Reg. 39,142, 39,151, 39,199 (July 17, 2007).

9 *See id.* at 39,199–200; *id.* at 39,243 (final rule § 447.506).

10 *See, e.g.*, CD, July 13, 2007.

11 *See* Public Comment from Ronald W. Davis, Attorney, to the Fed. Trade Comm'n 3 ("Davis Comment") (June 4, 2006), http://www.ftc.gov/os/comments/genericdrugstudy3/060604davis.pdf (submitted on behalf of an undisclosed client) ("Among other things, the new provision, effective in

comment asserted that the DRA provisions would so greatly discourage the marketing of AGs that this study, to the extent that it would be based on historical data, would not be useful.[13]

These concerns appear overstated. As discussed in Chapter 2, although the number of AG launches fell off in 2007–2008 from the high levels observed in 2003–2006, substantial numbers of AGs continue to be introduced. The DRA clearly did not bring a halt to the introduction of AGs.[14]

In order to help examine this issue further, the Commission's Special Orders required the brand-name companies and the specialized AG companies to produce "planning, decisional or strategy documents . . . that discuss the effect(s) or possible effect(s) of the enactment of Section 6003 of the Deficit Reduction Act of 2005, P.L. 109-171 on the marketing of AGs after Jan. 1, 2007."[15] The documents that were submitted, combined with the data regarding the

---

2007, amends the definition of 'best price,' for purposes of calculating the Medicaid rebate, to include prices charged for authorized generics sold by an affiliate or other licensee of the NDA holder. The purpose, and the likely effect, of this amendment is to fundamentally reduce the incentives of branded firms to introduce authorized generics."); Public Comment from the Pharm. Research and Mfrs. of Am. ("PhRMA") to the Fed. Trade Comm'n 10 n.17 (June 5, 2006), http://www.ftc.gov/os/comments/genericdrugstudy3/060605pharma.pdf (cautioning that the inclusion of AGs in the calculation of best price "could impact . . . the incentives for brand drug companies to introduce authorized generics").

[12] *See* CD, Oct. 5, 2006 (DRA a "[b]ig win for generic lobbyists . . . ; [c]ould cost [Brand Co.] approximately $25–50 million a year in additional Medicaid rebates"); CD, Feb. 5, 2007 (DRA provisions are "intended to discourage AG's by increasing the Medicaid rebate liability of the brand drugs"; "AG provisions may discourage some brand companies on some products from entering into AG agreements due to increased Medicaid rebates on their brand sales and increased complexity of AMP/BP price reporting requirements for AG's."); CD, Mar. 3, 2006 (law firm analysis predicting that the "new [DRA] provision may significantly complicate the ability of manufacturers to enter the generic market by use of an authorized generic"); *see also* CD, Sept. 28, 2006 (DRA "designed to discourage authorized generic introduction during the Hatch Waxman 180 day generic exclusivity period, also penalizes innovators launching authorized generics during the first quarter of generic sales").

[13] Davis Comment, *supra* note 11, at 3 ("[T]he purported 'problem' that gave rise to the proposed study will likely disappear, or be substantially reduced, without any further regulatory or legislative action. And the regulatory environment will be materially altered, so that the information sought will be of little practical utility to any possible Commission action or change in statutory law.").

[14] The DRA became effective on January 1, 2007. As reported in Chapter 2, twelve AGs were launched that year, and fifteen were launched in 2008. *See supra* Chapter 2, Section I.A.

[15] *See supra* Appendix D, ¶ 30, at D-7 (Brand-Name Drug Company Special Order); *see supra* Appendix F, ¶ 12, at F-3 to -4 (Authorized Generic Drug Company Special Order).

[16] The DRA changes were signed into law in February 2006, and had an effective date of January 1, 2007. The proposed rule was issued on December 22, 2006, but the final rule was not issued until July 17, 2007. The document request applied to documents dated January 1, 2006 to April 29, 2007. Accordingly, most of the financial and analytical documents that the companies produced were based on the proposed rule rather than the final rule, which, as noted above, likely imposed significantly higher Medicaid rebates than the proposed rule.

[17] Eighteen brand companies and one specialized AG firm that received the Special Orders provided

The documents also reveal two companies that decided to discontinue marketing a total of three AGs largely because of the DRA. One company decided to stop marketing two AGs (both in the same therapeutic category) when the AGs had not been profitable for the past two years and the expected impact of the DRA changes on the amount of Medicaid rebates was expected to be significant.[27] The other case was similar: the brand company and its AG distributor agreed to terminate their contract for the AG several days prior to the effective date of the DRA final rule when the AG had been only marginally profitable in any event and the additional Medicaid rebate liability would have made future marketing unprofitable.[28] It thus

[27] *See* CD, undated.

[28] *See* CD, Sept. 25, 2007 (agreeing to "suspend" their AG contract "as a result of [the DRA] final rule").

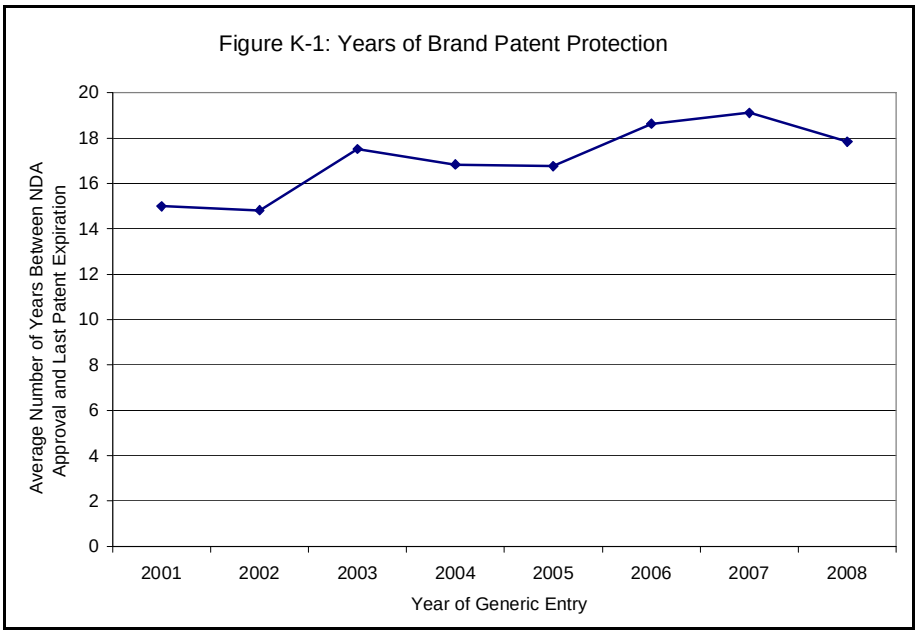
[29] *See, e.g.*, CD, undated; CD, Jan. 9, 2006; CD, Mar. 2007; *see also*, CD, Jan. 5, 2007 (deciding to launch two AGs shortly before issuance of the final rule when AG revenues were expected to offset increased rebates).

[30] *See* CD, Jan. 5, 2007 ("Consider strategic implications in addition to financials (customer expectations, inventory and production capacity utilization)").

APPENDIX K PATENT CHALLENGES: IMPACT ON GENERIC ENTRY AND BRAND EXCLUSIVITY

The length of brand exclusivity – the period when generics are not available, from NDA approval to generic entry – depends on both the length of patent protection obtained by a brand-name company and the extent to which patent challenges reduce the protected period. The following figures, which are based on the set of drugs for which generic entry took place via 180-day exclusivity from 2001–2008,[1] suggest that both factors contributed to variations in the length of brand exclusivity.

As shown in Figure K-1, the length of patent protection obtained by brand-name companies increased from 2001–2008: the period between NDA approval and expiration of the last-to-expire patent gradually rose by about 3–4 years.

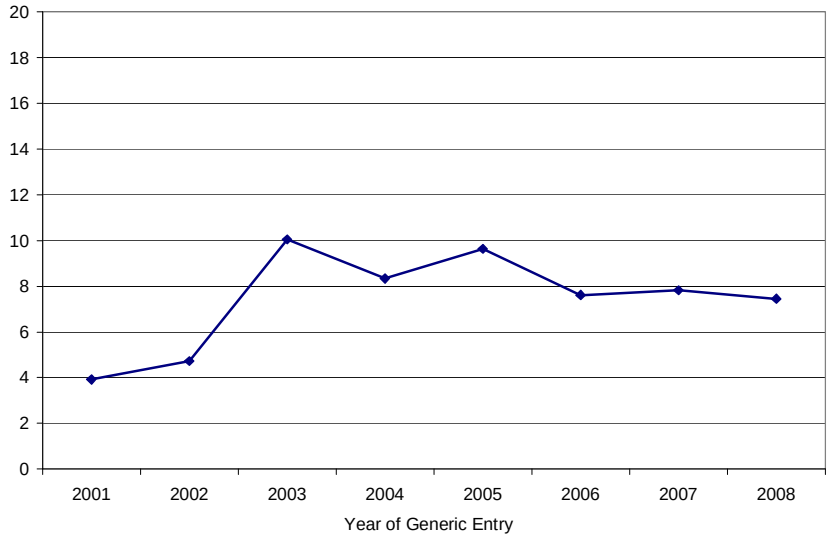


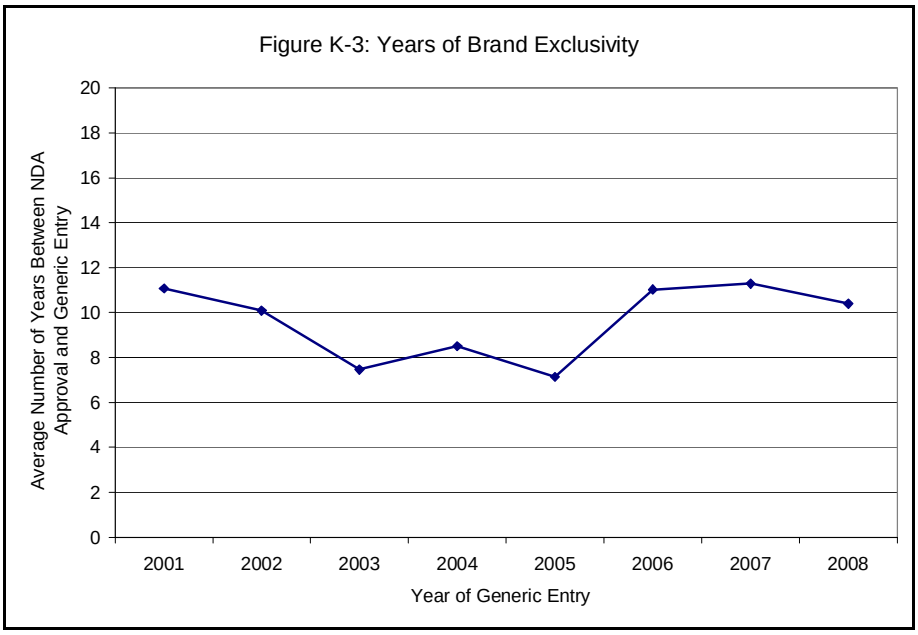
The figure shows, by year of generic entry, the average number of years between the NDA approval date and the last patent expiration date for 66 brand-name drugs that experienced generic entry by 180-day exclusivity from 2001–2008. The drugs are limited to tablet and capsule dosage forms. See supra Appendix H, Section I.D.

[1] Entry by 180-day exclusivity could occur following a successful patent challenge with a court determination of invalidity, non-infringement, or unenforceability or when a brand fails to sue the generic or the parties enter a settlement.

At the same time, generic companies sought to reduce the period of brand exclusivity by challenging patents. As shown in Figure K-2, the number of years by which patent challenges reduced the period of patent protection varied. On average, generic entry first occurred about four years before expiration of the last patent in 2001. This average rose to about 8–10 years before expiration from 2003–2005 but then fell back to about seven and one-half years during 2006–2008.

Figure K-2: Years Generic Entered Before Brand Patent Expiration





The figure shows, by year of generic entry, the average number of years between the NDA approval date and the first generic launch date for 66 brand-name drugs that experienced generic entry by 180-day exclusivity from 2001–2008. The drugs are limited to tablet and capsule dosage forms. See supra Appendix H, Section I.D.

APPENDIX L TECHNICAL MODELING APPENDIX

The discussion throughout Chapters 3 and 6 refers to regression models that relate competition variables (such as the presence of an AG) to measures of specific market outcomes, such as generic prices and first-filer revenues. This appendix presents the details of those regression models. The appendix begins with a detailed presentation of the models used within the exclusivity period. The models estimated outside of exclusivity are modifications of these initial models, and the discussion of them simply highlights the changes.

I. Models Applied During the 180-Day Exclusivity Period

---

[1] The count of generic manufacturers in the market includes the AG and was constructed, separately, for wholesale and retail data. Manufacturers were considered to have exited if they experienced three consecutive months of zero sales. Discrepancies in manufacturer counts between the NSP and NPA data were allowed to remain.

[2] Pre-entry sales of the brand-name product refer to the sum total of brand-name product sales three months prior to generic entry.

$$\left(\frac{p}{p_{b_0}}\right)_{mdft} = D_1 ag_{mdft} + E_2 man2_{mdft} + E_3 man3_{mdft} + E_4 man4_{mdft} + E_5 (ag \times man2)_{mdft} + E_6 (ag \times man3)_{mdft} + E_7 (ag \times man4)_{mdft} + \sum E_t year_{df} + \sum tc_{G_{mdft}} + \tilde{}$$

where,

Variables

p: monthly price of the product (various prices are used depending on the analysis[3])

p_{b0}: Pre-entry price of the brand-name product (three-month average)

ag: An indicator of whether an AG has positive sales during the month

man2-man4: Dummy variable indicators representing the count of generic manufacturers 2-4

and,

Estimated Coefficients

. : Regression constant

$_1$ - $_7$: Competition variable coefficients

l_t : Vector of five month-since-entry indicator variables (month 0 is excluded[4])

l_{df} : Vector of six dosage form indicator variables (tablets are excluded)

l_{year} : Vector of five calendar year indicator variables (year 2008 is excluded)

l_{tc} :Vector of fourteen therapeutic class indicator variables (analgesics are excluded)

0 : Error term.

The left-hand side of the equation is the relative price for each product (note the subscript *mdft* refers to the molecule, dosage-form-strength, and month-since-entry). For the

---

[3] For the analysis reported in Table 3-1, this price, p, is the average retail price of all generic versions of the product, including the AG. Table 3-2 is based on the same model; the only difference is that p is the average wholesale price of all generic versions of the product. In Table 3-3, the average ANDA price and the AG price in a given month are treated as two separate observations instead of being combined in a weighted average, and the AG indicator is turned on when the observation is an AG price. Tables 3-4 and 3-5 report analysis very similar to that in Tables 3-1 and 3-2, except that p is the price of the brand-name product in the month as opposed to an average generic price.

[4] Although the indicator variable for month 0 was excluded, data from month 0 were not excluded. When estimating a regression model that has a constant, such as this model, it is necessary to have indicator variables for all but one of the possible categories. The effect of the omitted category is picked up by the constant.

The right-hand side of the equation includes the competition and product characteristic variables. The competition variables include an indicator for whether an AG is present (ag), indicators for the total number of manufacturers in the market (man2-man4), and interactions of the AG with the total number of manufacturers. The product characteristic variables control for the months since generic entry, the dosage form, and the therapeutic class. The indicator for whether an AG is present is set to equal one if the AG manufacturer has positive sales during the month, and zero otherwise. Similarly, the manufacturer count and product characteristic indicators equal one if the market conditions are true, and zero otherwise. For example, man2 is equal to one if the market has exactly two generic manufacturers, and is zero otherwise. Similarly, the capsule indicator is set to one if the product is a capsule, and is zero otherwise. The estimation equation for the models with "no controls" is identical to the model above, but excludes the product characteristic controls represented by the vectors $/_{t}$, $/_{df}$, $/_{year}$, and $/_{tc}$.

The competition variable coefficient estimates from the regressions were used to estimate the AG effect on price. For the exclusivity analysis in Chapter 3, the estimated AG price effect represents the percentage change due to adding an AG to an ANDA-Only market. The percentage price change was evaluated at the constant using the following equation:[5]

$$\%' P \quad \frac{P^{*}_{AG} \quad P^{*}_{ANDA}}{P^{*}_{ANDA}} \quad (\ _{1} \quad E_{2} \quad _{5}) E \ , \qquad E \qquad D$$

[5] The results of this prediction are not very sensitive to the specification or to the point of evaluation. For example, estimation of a model with a log-linear specification that imposes a constant AG effect at any point in the data produces effects of similar magnitudes.

[6] The mdft subscripts have been suppressed for the sake of exposition.

[7] The pre-entry brand revenue, R_0, is constructed to be the total expenditures on the brand-name product

$$\% \Delta R_{FF} \quad \frac{Rg^{*}_{AG} \quad Rg^{*}_{ANDA}}{Rg^{*}_{ANDA}} \quad (\ _{1} \quad E_{4}) / \quad E \qquad D$$

The same naming conventions used for the pricing regressions were also used for the revenue equation. R* represents the predicted revenues from the regression. The predicted revenue for markets with one ANDA and an AG is represented by $R^{*}_{AG,}$ whereas the predicted revenue for a market with one ANDA manufacturer but no AG is represented by Rg^{*}_{ANDA}. The above equation calculates the predicted revenue change from adding an AG to an ANDA-Only market.

2. Brand-Name Firm Revenues

The brand-name product revenue and the brand-name firm (brand-name product + AG) revenue equations are analogous to the first-filer equation, and appear identical to each other. They are represented below:

$$\frac{R_{b}}{R_{0}} \qquad D_{1}ag \quad E_{2}man2 \quad E_{3}mas3 \quad _{4}\ mE4 \qquad E$$

$$_{5}ag \quad man2 \quad E_{6}\ ãg \quad mas3 \quad _{7}\ ag \quad man4 E_{t}\tilde{} \quad _{year} \quad _{df} \quad _{tc} \qquad E\tilde{} \qquad G$$

The above equation regresses relative brand revenues against product characteristic controls and a set of competition variables that are very sims 0 0 12evenues-/<r racteroduore i65>26<

rHq•¶9 ,˜Òƒ HD1g”™ Q*VJÚ ! XÒˆ!2Ú¥ É %dáVdEÚ¡Ô ÉsE3 ` !œ—e„ 1! “1 ZQ‘1

[9] The effect of the AG may depend on the number of manufacturers in the market. Interacting the AG indicator with the number of manufacturers captures these differential effects. Because some markets involve many manufacturers, the number of interaction terms in this model is large, producing many estimates of the impact of an AG (one for each interaction). The effects from this model are difficult to interpret, unstable across specifications, and difficult to estimate because products facing large

The price at which these effects are measured can be especially important outside of exclusivity because average prices with ten manufacturers can be much lower than average prices with two manufacturers. In exclusivity, markets were relatively homogeneous, so these effects were evaluated at the average price for a market with only one ANDA competitor, which happened to be estimated by the intercept term,