Authorized Generics: An Interim Report

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EXECUTIVE SUMMARY

This Interim Report presents the first set of results from a study undertaken by the Federal Trade Commission of the effects of authorized generic drugs on competition in the prescription drug marketplace. Authorized generic drugs (referred to in this Report as "AGs") are drugs that are approved by the Food and Drug Administration ("FDA") as brand-name drugs, but that the brand subsequently chooses to market (or have marketed) as generic, as well as brand-name, drugs. The trade dress typically is different for the brand-name drug and its AG equivalent, but the drug products are chemically identical.

The study was commenced 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."[1] Representative Waxman, one of the co-authors of the Hatch-Waxman Act, also requested the FTC to study "the impact of so-called 'authorized generics' on competition in the prescription drug marketplace."[2] Aspects of these issues are relevant to current legislative debates, and this Interim Report seeks to provide pertinent information in a timely fashion.

This Interim Report provides factual information and economic analysis to date of the short-term effects of AGs on competition during the 180 days of marketing exclusivity that a generic may be awarded in certain circumstances under the Hatch-Waxman Act. This Interim Report does not examine long-term and/or overall effects of AGs on such competition.

This economic analysis is based on substantial data sets obtained from governmental and non-governmental sources and on documentary information provided by brand and generic companies in response to compulsory information requests. Specifically, our preliminary analysis addresses the following short-term effects:

- Effects on wholesale and retail generic prices from AG competition against one ANDA generic[3] during the 180 days of marketing exclusivity that an ANDA generic may be awarded after seeking entry prior to expiration of the corresponding brand-name drug's patents.

- Effects of AG competition on the revenues of, and quantities sold by, one ANDA generic during the 180 days of marketing exclusivity that an ANDA generic may be awarded after seeking entry prior to expiration of the

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[1] *See* Letter from Senators Charles Grassley, Patrick J. Leahy, and John D. Rockefeller, IV to Deborah Platt Majoras, Chairman, Fed. Trade Comm'n (May 9, 2005).

[2] *See* Letter from Hon. Henry A. Waxman, U.S. House of Representatives, to Deborah Platt Majoras, Chairman, Fed. Trade Comm'n (Sept. 13, 2005).

[3] Generic drugs approved by the FDA through the filing of an Abbreviated New Drug Application ("ANDA") will be referred to as "ANDA generic" drugs when necessary to distinguish them from AGs.

corresponding brand-name drug's patents.

- Patent settlement agreements reviewed by FTC staff in which a brand has agreed not to compete against the generic with an AG for a certain amount of time and the ANDA generic has agreed to defer its entry for a certain period of time. Such agreements have recently become more common.

Our initial analysis suggests 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. Consistent with competition to provide a relatively homogenous product, the data indicate that AG entry significantly decreases the revenues of a first-filer generic company during its 180-day exclusivity period. This revenue reduction is likely to change the calculus of business decision-making in some circumstances for both generic and branded firms, but at this stage we have not analyzed whether AG entry deters generic entry prior to patent expiration that otherwise would take place. Finally, between FY2004-FY2008, about one-quarter of final patent settlements with first-filer generics involved an explicit agreement by the brand not to launch an AG to compete against the first filer, combined with an agreement by the first-filer generic to defer its entry past the settlement date. This preliminary analysis, however, describes various brand-ANDA agreements involving AGs but does not address whether limitations on AG entry during the 180-day exclusivity period would have an effect on the incidence of reverse settlements that are harmful to consumers.

Through enactment of the Hatch-Waxman Act,[4] Congress established the regulatory framework under which a generic manufacturer may obtain approval of its drug by the Food and Drug Administration ("FDA") by filing an Abbreviated New Drug Application[5] ("ANDA") in which it is allowed to rely on the clinical data first submitted by the brand-name drug manufacturer to establish the safety and efficacy of the generic drug. To encourage generic entry as soon as warranted, that Act allows a generic drug manufacturer to file a so-called "Paragraph IV" ANDA certifying (a) its generic drug will not infringe patents listed in the FDA's "Orange Book" ("Orange Book patents") in regard to the relevant brand-name drug product, and/or (b) that the relevant Orange Book patents are invalid. Typically, patent litigation then ensues, and the FDA may not approve the generic drug until 30 months after the generic filed notice of the Paragraph IV ANDA to the brand (or after a favorable decision in the litigation, if earlier). At that point the FDA may authorize the marketing of the generic drug under the ANDA application, and the first-filed paragraph IV ANDA applicant becomes entitled to 180-days of marketing exclusivity. The 180 days of marketing exclusivity generally protect one first-filed ANDA applicant from competition with other ANDA applicants during the 180-day period. This 180 days of marketing exclusivity was intended to provide an incentive for ANDA-filers to challenge brand-name patents and seek generic entry prior to patent expiration.

[4]Drug Price Competition and Patent Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), codified as amended at 21 U.S.C. § 355.

[5]*See* 21 U.S.C. § 355(j) (2008).

The 180-day marketing exclusivity does not, however, preclude competition from an AG. The courts have determined that AGs can be marketed during that period, because they are approved under a brand-name drug's NDA rather than an ANDA.[6] As the practice has become increasingly common, it has generated increasing controversy, with generic companies contending that AGs undermine the goals of the Hatch-Waxman Act, and brand companies defending AGs as procompetitive and consistent with the Act. It is in this context that the FTC has undertaken this study.

The FTC's preliminary data analysis shows the following:

- Retail prices are on average 4.2 percent lower, relative to the pre-generic brand price, when an AG competes with one ANDA generic during the 180-day exclusivity period than when an AG does not enter.

- Wholesale prices are on average 6.5 percent lower, relative to the pre-generic brand prices, when an AG competes with one ANDA generic during the exclusivity period than when an AG does not enter.

- Revenues of a sole ANDA generic company during the180-day exclusivity period drop substantially with AG entry, with estimates of the average decline ranging from 47% to 51%. The revenue effect for generics is so much larger than the price effect for consumers primarily because the AG represents a very close substitute for the ANDA generic and therefore typically obtains significant market share at the expense of the ANDA generic. This is confirmed by an analysis of the quantities dispensed by retail pharmacies.

- To prevent this loss of revenue, a generic may be willing to delay its entry in return for a brand's agreement *not* to launch an authorized generic – that is, a brand's agreement not to compete with the generic through an AG – during the generic's 180 days of marketing exclusivity.

- Between FY2004-FY2008, about one-quarter (38 out of 152) of the final patent settlements reviewed by the FTC contained provisions relating to AGs.

- Between FY2004-FY2008, 76 final patent settlement agreements were with first-filer generics. About one-quarter (20 out of 76) of those patent settlements 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 past the settlement date by, on average, 34.7 months. With regard to these twenty settlements, branded sales of the affected products ranged from $12.6 million to $5.3 billion, with an average market size of $917 million and a median market size of $514 million. Five of the settlements covered products with annual sales of $1 billion, $1.1 billion, $2.1 billion, $2.5 billion, and $5.3 billion.

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

- Such agreements can harm consumers in two ways:

    - First, generic entry, and the accompanying discounts, would not be available to consumers as soon as otherwise would be the case. Because generic drugs often are priced substantially below the price of branded drugs, [7] overall prescription drug costs could be significantly increased by even a few additional months of branded prices in a large market.

    - Second, consumers would lose the benefit of price discounts from AG competition during the 180-day marketing exclusivity. The consumer harm in such instances arises because the brand has agreed not to compete against the independent generic during the exclusivity period. The consumer harm arises from the *absence* of AG competition against an ANDA generic, not from the *presence* of AG competition against an ANDA generic.[8]

[7] *See, e.g.*, Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998) at 31 ("Because generic drugs are priced much lower than their brand-name counterparts, they are a source of substantial savings."), *available at* http://www.cbo.gov/showdoc.cfin?index=655&seguence=0.

[8] 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.

CHAPTER 1: PRELIMINARY FINDINGS ON THE SHORT-TERM IMPACTS OF AUTHORIZED GENERICS

I. Introduction

This chapter presents the FTC's preliminary data analysis of the impact of AGs during the 180-day exclusivity period that may be granted to the first challenger of a patent covering a brand-name drug. Given the limited scope of our preliminary analysis, this chapter makes no attempt to reach any conclusions about the net impact of AGs on consumers or the economy.

The FTC's preliminary data analysis shows the following:

- Retail prices are on average 4.2 percent lower, relative to the pre-generic brand price, when an independent generic competes with an AG during the 180-day exclusivity period than when an AG does not enter.

- Wholesale prices are on average 6.5 percent lower, relative to the pre-generic brand prices, when an AG competes with one independent generic during the exclusivity period than when an AG does not enter.

- Revenues of a generic company during the 180-day exclusivity period drop substantially with AG entry, with estimates of the average decline ranging from 47 percent to 51 percent.

- The revenue effect for generics is so much larger than the price effect for consumers primarily because the AG represents a very close substitute for the independent generic and therefore typically obtains significant market share at the expense of the independent generic. This is confirmed with an analysis of the quantities dispensed by retail pharmacies.

This preliminary analysis uses the same basic methodology as two prior studies of the impact of AGs during the 180-day exclusivity period, but applies that methodology to new data that accounts for a longer period of time and more drug products than the data used in the prior studies. In 2006, IMS Consulting conducted a study commissioned by the Pharmaceutical Research and Manufacturers of America (PhRMA) to measure the impact of authorized generics upon costs to the health care system through their influence on generic pricing.[1] The study compared two sets of drugs for which generic entry occurred via 180-day exclusivity. The first group included nine drugs where an authorized generic drug competed against a single generic firm during the 180-day exclusivity period. The second group included nine drugs for which a generic drug company with 180-day exclusivity did not face AG competition. The study

[1] IMS CONSULTING, IMS HEALTH, ASSESSMENT OF AUTHORIZED GENERICS IN THE U.S. (2006), http://www.phrma.org/files/IMS%20Authorized%20Generics%20Report_6-22-06.pdf (prepared for PhRMA), referred to throughout this text as "the IMS Study".

concluded that, relative to the price of the brand drug, wholesale generic prices were about 16 percent lower when the first generic faced competition from an authorized generic.

A second study by Hollis and Liang[2] addressed similar questions using similar analysis on the same set of drugs, but with retail prices instead of wholesale prices. For reasons that will be discussed later in this chapter, they consider the price of generic drugs relative to the price of the corresponding brand drug prior to generic entry. Hollis and Liang conclude that the average retail generic discount off the pre-entry brand price was 15 percent without an AG and 20 percent with an AG, which nets out to a 5 percent impact caused by AG entry.[3]

The full description of the new analysis presented in this chapter spells out in more detail the similarities and differences between our analysis and the analysis in these two previous studies. Among other things, our study included at least twice the number of drugs or more, depending on how multiple strengths or dosage forms of the same drug are counted, than were included in the prior studies. Also, the statistical properties of the average discounts were not discussed in either prior study, while we present standard errors for all calculated averages and perform statistical tests when comparisons are being made between averages. In addition, we test our results through cross checking (e.g., comparing results for both retail and wholesale prices) and provide multiple estimates (e.g., unweighted and weighted averages). We also analyze the impact of AGs on expenditures and quantities.

II. Preliminary Empirical Results

The preliminary findings reported here will focus exclusively on the impact of AG competition within FDA- granted 180-day exclusivity periods. We do not directly address the impact of the presence of authorized generics on the decisions of generic companies to initiate paragraph IV challenges, or to seek approval of an ANDA from the FDA. However, some light will be shed on the facts relevant to such decision making through an analysis of the impact of AG entry on generic drug manufacturer revenues (as a proxy for generic manufacturer profits) during the exclusivity period. We start with a description of the data before turning to our preliminary results.

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[2] AIDAN HOLLIS AND BRYAN A. LIANG, AN ASSESSMENT OF THE EFFECT OF AUTHORIZED GENERICS ON CONSUMER PRICES (2006), http://www.gphaonline.org/sites/default/files/GPhA_AG_Study.pdf, GPhA Study, referred to throughout this text as "Hollis and Liang".

[3] *Id.* at 14. Hollis and Liang go further however, and argue that even the 5% difference overstates the immediate benefits from authorized generics. In particular, the authors argue that each of 18 drugs in their analysis should be weighted by sales. When this is done, Hollis and Liang conclude that the average generic discount off of the pre-entry brand price is virtually identical with and without AGs. *Id.* at 15.

A. Description of the Data

Our empirical analysis combines information from several different data sources. A license for both the retail[4] and wholesale[5] sales information was purchased from IMS Health Services (IMS). This is the same source of data used by virtually all of the prior research looking at the impact of AGs, including the study sponsored by branded manufacturers (IMS Consulting) and the study sponsored by the generic manufacturers (Hollis and Liang). Although these data may not account for all factors relevant to particular questions, we know of no data set that captures all of the information we would like to include in this analysis. Where possible, the final study will use additional econometric techniques to account for factors that could not be directly addressed with the available data.

Whether a drug faced a paragraph IV challenge and the dates of any 180-day exclusivity period arising from the challenge was determined from information from the Food and Drug Administration (FDA). Authorized generic drug information was based on information from the FDA and from press statements and was verified using data subpoenaed from the pharmaceutical firms. This information includes whether the brand issued an authorized generic version of the drug and the identity of the AG distributor.

A detailed description of the data and how it was processed is provided in the appendix to this chapter. To summarize, we used monthly wholesale and retail prices and quantities for all non-injectable drugs for 2003 through 2008 and limited our sample to drugs that first faced generic competition within that period. Throughout this text, the term "drug product" or "drug" refers to a full specification of active ingredient(s), dosage form, and strength. We included a monthly observation for a drug only if in that month, a generic manufacturer with 180-day exclusivity was either the only generic in the market, or was joined in the market only by an AG. When the independent generic manufacturer was the only generic on the market, we refer to that as an ANDA-Only drug. The 51 drugs that are classified as ANDA-Only drugs in our sample are listed in Table A5 in the appendix. When the independent generic was joined in the market by only an AG, the drug is referred to as an ANDA+AG drug. The 53 drugs that are classified as ANDA+AG in our sample are listed in Table A6 in the appendix.

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[4] The full reference for data that will be referred to as retail or NPA data is: IMS Health, IMS National Prescription Audit Plus 7™, Years 2003 to 2008, Data Extracted January 2009. The channels included in our IMS National Prescription Audit data are Chain Stores, Food Stores, Independents, Long-Term Care, and Mail Service.

[5] The full reference for data that will henceforth be referred to as wholesale or NSP data is: IMS Health, IMS National Sales Perspectives™, January 2003 to December 2008, Retail and Non-Retail Channels, Data Extracted February 2009. The channels included in our NSP sample are: Chain Stores, Clinics, Federal Facilities, Food Stores, HMOs, Home Health Care, Independents, Long-Term Care, Mail Service, Misc-Other, Misc-Prisons, Misc-Universities, and Non-Federal Hospitals. The analysis presented here aggregates over these channels.

B. Empirical Analysis of Market Outcomes During Exclusivity Periods

The Commission's preliminary analysis provides new evidence on two fundamental questions pertaining to the short-term impact of authorized generics. These questions are:

- Given the presence of a lone ANDA generic, what impact does AG entry have on retail and wholesale prices during the 180-day exclusivity period?
- What effect does AG entry have on the revenues of the generic and brand companies during the exclusivity period?

Although the full study will address additional market circumstances, this report shares the focus of the IMS and Hollis and Liang studies by concentrating on drugs for which one independent generic firm was granted 180-day exclusivity, and either was the lone generic on the market or was joined only by an authorized generic.[6]

As in previous studies, this analysis will focus on comparisons across groups of drugs, distinguished by whether an AG was marketed, to estimate the effect of AG entry. Because the decision whether to market an AG is a choice made by a branded drug manufacturer with a good understanding of the market for that drug, it is not appropriate to assume that drugs are randomly assigned to the group with an authorized generic (ANDA+AG) or the group without (ANDA-Only). For instance, consider a drug for which consumers are thought to be very reluctant to switch to a generic. In this situation, the branded company may choose not to issue an AG because it expects the AG to have low sales. Furthermore, an independent generic company trying to market a generic version of this drug may find it necessary to offer deeper than average discounts on this drug in order to entice consumers to switch to the generic. It would be errant to

[6] Our analysis of the prior research on AGs suggests that gaining an accurate understanding of the effect during the 180-day exclusivity period is of primary importance, yet obviously AG entry can have impacts that extend beyond the 180-day exclusivity period. For instance, the IMS Study estimated the effect of AG entry on prices after the exclusivity period, as did a second study, Ernst R. Berndt et al., *Authorized Generic Drugs, Price Competition and Consumers' Welfare*, 26 HEALTH AFFAIRS 790 (2007). Both studies found that the additional competition caused meaningfully greater discounts only when the number of independent generics who eventually enter is small, generally five or fewer. Another strand of research addresses the effect of AG entry on the decision to pursue paragraph IV challenges. The general take-away from these studies is that AG entry is most likely to have a consequential impact on challenges for drugs with relatively low sales volume. *See* MARC GOODMAN ET AL., MORGAN STANLEY, QUANTIFYING THE IMPACT FROM AUTHORIZED GENERICS (2004), and David Reiffen & Michael R. Ward, *Branded Generics as a Strategy to Limit Cannibalization of Pharmaceutical Markets*, 28 MANAGERIAL AND DECISION ECONOMICS 251 (2007). Not only do these studies point out areas for further analysis that will appear in our final report, they put into context some of the results reported in this preliminary study, particularly the comparisons made between outcomes for drugs with high and low sales volumes.

conclude that the lack of an AG *caused* the deep discount. This is just one example of how market conditions that may determine whether an AG is issued may also influence market outcomes in the generic market.[7]

Our final study will include econometric analysis that attempts to account for this problem by controlling for factors that are strong predictors of the likelihood of AG entry. For instance, we have found that when generic entry occurs via 180-day exclusivity, AGs are much more likely to enter markets with relatively large pre-generic entry brand sales than they are to enter smaller markets. The final study will contain econometric analysis that controls for the size of the pre-generic entry branded market. However, the prior literature generally did not control for factors such as this, so the analysis presented below serves primarily as an update to the results of these prior studies.

1. Price Discounts

The price of a drug is calculated as the total dollars spent on that drug divided by some measure of the quantity of the drug purchased. We obtained from IMS measures of the total dollars in both the retail and wholesale data. For this study, absolute quantities were measured in terms of extended units of the drugs. An example of an extended unit is a 200mg tablet. To the extent that we have data on different sized bottles of 200mg tablets of a drug, we aggregated over the bottle sizes to state everything in terms of the 200mg tablets.

The standard measure of price used throughout this report is the calculated monthly price for an extended unit of the drug (defined by active ingredient(s), strength, and dosage form[8])

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[7] The problem of inference in this case is that the owner of the brand has a choice to market an authorized generic; that is, the choice to market an AG is endogenous. For this reason it is difficult to determine the market impact of an AG because the firm does not randomly choose when to offer an AG. The following analogy demonstrates the difficulty in determining the causal effect. Suppose we observe that when pedestrians use umbrellas, drivers turn on their windshield wipers. It would be incorrect to conclude that the pedestrians' decisions determine the drivers' behavior because both behaviors are typically caused by rain falling from the sky. The econometric problem in estimating the effect of an AG on prices, revenues, or output is that the analogue to "rain" in the drug example cited here is the anticipated profitability of selling the authorized generic, which is not observable.

[8] Note that defining the unit of observation in this way treats blockbuster drugs and niche products equally. Also note that drugs that tend to be offered in multiple dosage forms or strengths will be more heavily represented in the data than drugs that are offered in a single strength and dosage form. Statistically, it may not be appropriate to treat the prices for a 100mg tablet of a drug and a 200mg tablet of the same drug from the same manufacturer as being independent observations. This statistical issue is not of a kind that is normally expected to bias the estimates, but it does require qualification of the calculated standard errors and statistical significance levels. The econometric analysis in the final study will account for these concerns.

divided by the average price of an extended unit of the branded version of that drug in the three months preceding generic entry. This is referred to as a relative price.[9] Normalization is necessary to allow comparisons and aggregation across drug products that may have very different nominal prices. Since differences in the competition among generics, such as may be caused by AG entry, may prompt different pricing responses from the brand, normalization by contemporaneous brand prices could confuse the brand response with differences in generic pricing. Furthermore, we follow the recent related literature and report these relative prices in terms of the percentage discount off of the pre-entry brand price, which we generally refer to as the "generic discount".[10]

a. Retail Generic Discounts

The most straightforward impact on consumers from AG entry is the effect that the additional competition has on the prices they pay for their prescriptions. Reported in Table 1-A are the mean retail generic discounts and their standard errors (abbreviated SE), throughout the six months of exclusivity for drugs of all market sizes. Note that the average discounts off of pre-entry brand prices are higher for ANDA+AG drugs than for ANDA-Only drugs in every month of exclusivity, and this difference is highly statistically significant in all but the first month.[11] Averaged across all months of exclusivity, consumers receive a 13.1 percent discount on a generic drug with exclusivity facing no AG competition. With AG competition, discounts average 17.2 percent off the pre-entry brand price. Taken together, these two discounts imply

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[9] For both the retail and wholesale analysis, the monthly generic price for an ANDA-Only drug is calculated as the total sales dollars of the generic drug divided by the extended units sold. The monthly generic price of an ANDA+AG drug is the sum of the total sales dollars from the ANDA and the AG divided by the total extended units sold of the ANDA and the AG. That is to say, in ANDA+AG markets, the generic price is a weighted average of the ANDA and the AG prices. To get relative prices, each of these are normalized by the pre-entry price per extended unit of the corresponding brand product.

[10] To be precise about how these are being calculated, let G be the average price of a generic drug in the current month, and B be the average price of the brand drug in the three months prior to generic entry. The relative price would be calculated as G/B. The discount off of the pre-entry brand price is 1-G/B.

[11] The statistical significance of these differences is reported as the p-value of a one-sided difference in means Student t-test without an assumption of equal variances. For instance, the 6.6% p-value reported for month 1 in Table 1-A means that the probability of observing the ANDA-Only sample mean discount being 3.7% lower than the ANDA+AG sample mean discount, based on the sample size and variance observed in the data, is no more than 6.6% if the null hypothesis that the ANDA-Only discount is at least equal to the ANDA+AG price is true. (In these tests, the null hypothesis is specified as the opposite of what we expect. The 1.1% p-value reported for month 2 means that it is considerably less likely that the month 2 data would be observed if the true ANDA-Only discount is higher than the true ANDA+AG discount. Put simply, the lower the p-value, the more statistically significant is the result.

that consumers receive a 4.2 percent greater discount off of the pre-entry brand price for drugs where a generic manufacturer with lone exclusivity faces competition from an AG than when no AG enters. This difference is close to the 5 percent Hollis and Liang found using a similar methodology on retail discounts for a different set of drugs over a different period of time. Also note that this difference stays relatively constant throughout the exclusivity period.

Table 1-A: Average Retail Generic Discount: Unweighted Means

		Month of Exclusivity						
Drug Group		1	2	3	4	5	6	All
ANDA-Only	Mean	12.1%	13.1%	13.2%	13.5%	14.2%	12.4%	13.1%
	SE	*2.1%*	*1.5%*	*1.4%*	*1.3%*	*1.4%*	*1.4%*	*0.7%*
ANDA+AG	Mean	15.8%	17.1%	17.6%	17.9%	17.6%	17.4%	17.2%
	SE	*1.4%*	*0.8%*	*0.8%*	*0.8%*	*0.9%*	*1.1%*	*0.4%*
Difference		-3.7%	-4.0%	-4.4%	-4.4%	-3.4%	-5.0%	-4.2%
One sided difference in means test, p-value		6.6%	1.1%	0.5%	0.3%	2.5%	0.3%	0.0%

The decision of a branded company to launch an AG depends on market characteristics, some of which may also have an impact on pricing in those markets. Of the 95 drugs in our sample—which is limited to certain drugs for which generic entry occurred by 180-day exclusivity after 2003—authorized generics entered into 53 of them. However, the decision to enter with an AG differs substantially based on the pre-generic entry sales of the branded drug. The results below suggest that consumers tend to receive deeper discounts with AG entry into higher sales drugs.

We derived this conclusion by splitting the sample of drugs into "high sales" drugs and "low sales" drugs, with the dividing line determined by whether the brand sales for the three months preceding generic entry were above or below the median of all drugs that first faced generic competition in our time window and for which at least one generic firm was granted exclusivity by the FDA. The median drug in the retail data had pre-entry brand annual sales of $130 million. Authorized generics entered for only 16 of the 49 low sales drugs (or 33 percent). Naturally, this implies that AG entry was much more common for products with high sales, where AG entry occurred for 37 out of 46 drugs in our sample (80 percent).[12]

[12] Since the median market size being used to distinguish high sales from low sales drugs is the median of all drugs that entered with exclusivity in our time frame, the number of high and low sales drugs in our restricted sample need not equal one another.

Considering only low sales drugs, the average generic discounts over all months of exclusivity were 14.1 percent (0.7 percent) and 17.6 percent (0.8 percent) in ANDA-Only and ANDA+AG markets respectively, with standard errors reported in parentheses as will be the convention henceforth. This difference is statistically significant at any standard level. On the other hand, for high sales drugs, the generic discounts are 9.4 percent (1.3 percent) and 17.1 percent (0.5 percent) in ANDA-Only and ANDA+AG markets respectively, so AGs appear to have a larger impact on discounts in high sales markets. This difference is also statistically significant at all reasonable levels.

Another way to investigate the connection between the relative size of the markets and the impact of AG entry is to calculate the average discounts with more weight being put on high sales drugs. In Table 1-A, the average discounts were calculated by putting equal weight on each drug. One way to think of what this average represents is that it is the expected discount a consumer would receive for the generic drug if one were to randomly select one of the drugs from the list of drugs in our sample. In Table 1-B, each drug/month observation is weighted by the total dollar sales of the generics for that drug/month. One interpretation of these averages is that it is the discount received for a randomly selected dollar spent on the generic drugs in our sample.

Table 1-B: Average Retail Generic Discount: Dollar Weighted Means

		Month of Exclusivity						
Drug Group		1	2	3	4	5	6	All
ANDA-Only	Mean	17.3%	14.9%	15.0%	14.9%	14.9%	15.4%	15.2%
	SE	*1.4%*	*0.8%*	*0.8%*	*0.8%*	*0.9%*	*1.1%*	*0.4%*
ANDA+AG	Mean	14.7%	15.4%	15.9%	16.1%	16.1%	15.9%	15.8%
	SE	*1.4%*	*0.8%*	*0.8%*	*0.8%*	*0.9%*	*1.1%*	*0.4%*
Difference		2.6%	-0.5%	-0.8%	-1.2%	-1.2%	-0.5%	-0.6%
One sided difference in means test, p-value		No test	36.0%	31.0%	23.0%	24.0%	41.0%	14.0%

The differences reported in Table 1-B are typically around 1% or less, and are not statistically significant. This is consistent with Hollis and Liang's analysis of similarly weighted average retail prices. One point worth mentioning is that when weighting observations in this way, one drug, clopidogrel 75mg tablets, becomes very important in the ANDA-Only calculation, accounting for over 40 percent of the weight. The weighted-average ANDA-Only discount for the six months of exclusivity falls to 11.3 percent if this drug is dropped from the

weighted average, which would bring the difference between ANDA-Only and ANDA+AG drugs back to roughly the same level as was reported for the unweighted averages.[13]

Although retail prices may reflect the most obvious measure of impact of AG entry on consumers, they have several limitations. First, retail prices may not accurately reflect all of the payments made by consumers for prescription drugs. For instance, individuals who receive prescription drug benefits as part of a health insurance plan also pay premiums, some of which should appropriately considered to be an expenditure on drugs. To the extent that insurance plans can receive lower pricing for prescription drugs, some of those savings may be passed on through lower premiums. Also, the source of our retail data, IMS Health's National Prescription Audit, only tracks sales at retail pharmacies.

b. Wholesale Price Discounts

The wholesale level transactions in our data represent purchases of drugs by pharmacies from manufacturers and wholesalers. To the extent that savings recognized by pharmacies filter through the health care system, this supplies an alternate measure of the impact of AGs on prices. As noted in the appendix, the data do not account for various types of discounts, and would also not reflect changes in the insurance premiums of consumers. To the extent that both the retail and the wholesale data do not include all relevant discounts, our analysis based on these data may overstate or understate the level of discounting. For that reason, it is particularly beneficial to have the wholesale data as a second source of information about pharmaceutical pricing with which the impact of AGs can be studied. One benefit of the wholesale data is that it contains information about purchases by more outlets, such as non-retail pharmacies, hospitals, and HMOs, for instance, than were covered by the retail data.

Reported in Table 1-C are the unweighted average wholesale generic discounts off of the pre-entry brand prices throughout the six months of exclusivity for drugs of all market sizes. As with the retail discounts, the average wholesale discount is higher in markets that experienced AG entry in each of the months, and the difference is statistically significant at any standard level for all but the first month of exclusivity. Averaged over all months, wholesale prices in ANDA+AG markets reflect a 6.5 percent deeper discount than in ANDA-Only markets. This difference is considerably smaller than what IMS Consulting found in their analysis of wholesale prices for a different set of drugs, over a different time period, using slightly different methodology. The final study will explore potential reasons for this divergence.

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[13] The circumstances surrounding the launch of generic clopidogrel are atypical. Apotex launched the generic "at risk," meaning the patent litigation was still unresolved. Subsequently, the courts upheld the patent and prevented Apotex from continuing to sell the generic. However, Apotex had managed to sell several months' supply while on the market, and these sales show up in our data. For the details of this situation, see Stephanie Saul, *Court Upholds Plavix Patent Of Bristol And Sanofi,* N.Y. TIMES, June 20, 2007, at C3.

Table 1-C: Average Wholesale Generic Discount: Unweighted Averages

		Month of Exclusivity						
Drug Group		1	2	3	4	5	6	All
ANDA-Only	Mean	21.3%	21.8%	22.4%	22.4%	22.9%	23.1%	22.3%
	SE	*1.3%*	*1.0%*	*1.1%*	*1.1%*	*1.1%*	*1.1%*	*0.5%*
ANDA+AG	Mean	22.8%	26.3%	28.9%	30.5%	32.4%	33.1%	28.8%
	SE	*2.7%*	*2.2%*	*2.3%*	*2.1%*	*2.3%*	*2.9%*	*1.0%*
Difference		-1.6%	-4.5%	-6.5%	-8.2%	-9.5%	-10%	-6.5%
One sided difference in means test, p-value		30%	3.6%	0.7%	0.1%	0.0%	0.1%	0.0%

The retail data revealed differences for discounts between high sales drugs and low sales drugs. Those differences are present, but less pronounced in the wholesale data, though the p-value for one-sided difference in means test is less than one percent for each of the comparisons. Averaged across all exclusivity months in low sales drugs, the average relative wholesale discount in ANDA-Only markets is 23.3 percent (0.6 percent), compared to 29.3 percent (2.1 percent) in ANDA+AG markets. For high sales markets, ANDA-Only discounts average 19.5 percent (0.6 percent) while average ANDA+AG discounts are 28.6 percent (1.1 percent).

Another distinction between the wholesale discounts and the retail discounts is that weighting observations by the dollar sales of the drugs caused the differences to diminish in the retail data. In the wholesale data, the weighted averages, reported in Table 1-D, reveal differences between ANDA-Only and ANDA+AG drugs that are somewhat higher than with the unweighted averages. Again, clopidogrel gets in excess of 40 percent of the weight for the ANDA-Only drugs, but dropping it from the wholesale weighted average discount calculation has little impact on the weighted average.

Table 1-D: Average Wholesale Generic Discount: Dollar Weighted Means

		Month of Exclusivity						
Drug Group		1	2	3	4	5	6	All
ANDA-Only	Mean	15.1%	18.0%	18.8%	18.2%	20.2%	20.2%	18.3%
	SE	*0.7%*	*0.8%*	*0.6%*	*0.7%*	*0.7%*	*0.7%*	*0.3%*
ANDA+AG	Mean	18.7%	24.3%	26.7%	28.7%	29.8%	29.6%	26.4%
	SE	*2.6%*	*2.0%*	*2.0%*	*2.0%*	*2.0%*	*2.4%*	*0.9%*
Difference		-3.6%	-6.3%	-7.9%	-11%	-9.6%	-9.4%	-8.1%
One sided difference in means test, p-value		9.6%	0.2%	0.0%	0.0%	0.0%	0.0%	0.0%

2. Wholesale Expenditures

We now turn to an analysis of total wholesale expenditures on this same set of drugs. The primary reason for considering these expenditures is to approximate how the revenues of a first-filer generic manufacturer are affected by competition from an AG. Of course, it would be preferable to have an estimate of the impact on profits instead of revenues, and the full study will address the impact on profits, not just revenues. However, some simple math tells us that the percentage decrease in revenues in this case understates the percentage decrease in profits.[14]

Our measure of wholesale expenditures is the total dollars reported in the IMS National Sales Perspective database. The intent of this analysis is to use wholesale level expenditures by pharmacies as a proxy for the revenues of manufacturers. Because the data represent pharmacy purchases from manufacturers and wholesalers, our proxy is imperfect to the extent that it includes wholesaler margins on the drugs that pass through wholesalers. Our results could be

[14] Revenues equal price times quantity, and in this instance, the decline in revenue is caused by a decline in both the price and the quantity of the independent generic with AG entry. To see how profits change when price and quantity drop, consider first just a price decrease. A 1% price decline, holding quantities fixed, will cause revenues to fall by 1%, and will decrease the gross margin, (price minus variable cost), and thus the incremental profits (revenues minus variable costs) by more than 1%. The nominal decline in total profit is the same as the nominal decline in incremental profit, but with positive fixed costs, this would represent an even larger percentage change in total profits (incremental profits minus fixed costs). A 1% decrease in quantity, holding price fixed, will decrease revenues by 1% and will decrease incremental profits also by 1%, assuming constant average variable costs, which will again cause a greater than 1% decline in total profits. Therefore, reporting the decline in ANDA revenues caused by AG entry understates the impact on profits.

biased if the proportions of drugs going through wholesalers are systematically different between ANDA-Only and ANDA+AG drugs, but we have no reason to believe that is the case.

Just as with prices, expenditures have been normalized by corresponding data from the branded product prior to generic entry. Relative expenditures are expressed in terms of a fraction of the pre-entry brand sales, where monthly expenditures are divided by the average monthly expenditures on the brand for the three months prior to generic entry, and are referred to as relative expenditures. Again, this normalization is employed to allow aggregation across drugs.

Table 1-E presents the relative expenditures on the ANDA generic drug for both types of markets for drugs of all sales levels. Except in the initial month, the differences are both economically large and statistically significant. Averaged over all months, monthly expenditures on the ANDA generic in ANDA-Only markets are approximately 61.1 percent of the monthly expenditures on the brand drug in the months preceding generic entry. By contrast, ANDA generic expenditures in ANDA+AG markets are only 32.7 percent of the pre-entry brand expenditures. The expenditures on the ANDA generic in ANDA+AG markets are 47 percent [15] lower than in ANDA-Only markets.

Since this data is based on calendar months, and expenditures accumulate over the month, the expenditure numbers for the first month could be misleading if, for example, the generic drug entered the market on the last day of the month. This was not a problem for prices because prices are reported per extended unit. On the other hand, generic sales may take some time to ramp up when first introduced, so there may be reason to expect first month sales to be lower than in later months, even when the generic enters on the first day of the first month. This problem cannot be resolved with the data we have, so we will estimate this important difference in expenditures a second way, by dropping the first month from the average. The average relative wholesale expenditures change to 65.6 percent and 32.1 percent for ANDA-Only and ANDA+AG markets, respectively, if the average is taken over months 2 through 6. That is, over the last five months of the exclusivity period, average relative wholesale expenditures on the ANDA generic drop by 51 percent when there is AG competition.

[15] This 47% difference is calculated as the difference between the independent generic's relative expenditures for ANDA-Only versus ANDA+AG drugs, 61.1%-32.7%, divided by ANDA-Only relative expenditures, 61.1%.

Table 1-E: Average Relative Wholesale Expenditures on the ANDA Generic

		Month of Exclusivity						
Drug Group		1	2	3	4	5	6	All
ANDA-Only	Mean	42.4%	71.1%	59.7%	62.8%	69.5%	65.0%	61.1%
	SE	*4.9%*	*10.7%*	*6.6%*	*3.9%*	*6.0%*	*4.8%*	*2.7%*
ANDA+AG	Mean	35.6%	35.0%	28.7%	32.3%	30.4%	34.4%	32.7%
	SE	*3.5%*	*3.0%*	*1.7%*	*1.7%*	*2.1%*	*2.6%*	*1.0%*
Difference		6.8%	36.1%	31.1%	30.6%	39.1%	30.7%	28.4%
One sided difference in means test, p-value		24.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

This difference may be easier to understand in the context of an example. The annualized pre-generic entry brand expenditures of the median drug in our wholesale sample were roughly $170 million, or $85 million for six months. The averages above imply that expenditures on an ANDA generic that obtains an exclusivity period for that drug would be 61.1 percent of that total over the exclusivity period if the independent manufacturer faced no AG competition; thus expenditures on the ANDA would be roughly $51.9 million. If an AG entered that market, the expenditures on the ANDA would fall to $27.8 million (32.7 percent of $85 million) assuming all else remains the same about the market for this drug. Therefore, expenditures on the ANDA generic entrant into the median sized market would be roughly $24.1 million dollars less in the ANDA+AG market.[16] If the average expenditure estimates that excluded the first month are used, the difference in expenditures on this median drug becomes $28.5 million.

The analysis of prices for high sales and low sales drugs indicated that AG entry tends to have more of an impact on generic prices of high sales drugs than low sales drugs. The same is not true of expenditures. For high sales drugs, relative expenditures on the ANDA fall from 49.7 percent (2.0 percent) in ANDA-Only markets to 31.4 percent (1.1 percent) in ANDA+AG markets, or a 32 percent decrease. In low sales markets, relative expenditures on the ANDA decrease more substantially, from 65.3 percent (3.6 percent) to 36.3 percent (2.5 percent) between ANDA-Only and ANDA+AG markets, for a 43 percent decrease.

This relative wholesale expenditure data can also shed some light on how the brand manufacturer fares in ANDA+AG markets relative to ANDA-Only markets.[17] Table 1-F reports

[16] To the extent that wholesaler margins are included in these expenditure figures, this estimate may overstate the impact on the first filer.

[17] Because these wholesale expenditures do not account for payments from brand manufacturers to third-party payers, such as pharmacy benefit managers, brand wholesale expenditures are best thought of as a proxy for brand gross revenues. *See* Chapter III of the FTC

relative expenditures on the brand drug during ANDA-Only exclusivity periods, and both brand and AG expenditures during ANDA+AG exclusivity periods. Notice that the brand expenditures drop more rapidly and to lower levels in the presence of an AG.[18] It is difficult to determine whether this is caused by the AG or is due to other differences in these markets. We will revisit this question in the next section that looks at the impact of AG entry on quantities sold. In the ANDA+AG markets, the brand expenditures decrease so substantially that in months three through six, expenditures on the AG exceed brand expenditures. It is also worth noting that in each month of exclusivity, the brand plus the AG expenditures for the ANDA+AG drugs exceed the brand expenditures for the ANDA-Only drugs. If an AG is marketed by a subsidiary of the brand company, this evidence would suggest that the parent company makes higher revenues in the ANDA+AG markets than in the ANDA-Only markets during the exclusivity period.

Table 1-F: Average Wholesale Relative Expenditures on Brand and AG

		Month of Exclusivity						
Drug Group		1	2	3	4	5	6	All
ANDA-Only	Brand-Mean	87.5%	50.3%	39.8%	34.9%	30.4%	30.0%	47.1%
	Brand-SE	*3.7%*	*3.2%*	*2.5%*	*2.7%*	*2.2%*	*3.2%*	*1.8%*
ANDA+AG	Brand-Mean	79.7%	34.4%	23.8%	23.7%	18.3%	16.7%	33.0%
	Brand-SE	*3.5%*	*2.0%*	*1.0%*	*1.4%*	*1.1%*	*1.4%*	*1.5%*
	AG-Mean	17.7%	24.9%	23.9%	24.6%	24.6%	25.9%	23.6%
	AG-SE	*2.1%*	*2.0%*	*2.0%*	*1.8%*	*1.8%*	*2.6%*	*0.8%*

Pharmacy Benefit Manager study for more information on these payments, FED. TRADE COMM'N, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES (2005), http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf.

[18] It may seem odd that the total relative expenditures for a group of drugs typically exceed one hundred percent. For instance, in month one for the ANDA-Only drugs, the independent generic's average relative expenditure is 84.9%, from Table 1-D, and the brand's average relative expenditure is 42.4%, from Table 1-F; these sum to 127.3%. We suspect that some of this increase in total expenditures at the wholesale level may be due to the filling of the supply channel with the generic. This does not indicate a problem with using this expenditure data as a proxy for revenues; sales for the purpose of filling up the supply channel still represent revenues for the manufacturer. Data presented in the next chapter show that the quantities actually dispensed by pharmacies (retail quantities) during the exclusivity period by the brand and generics are roughly equal to brand quantities prior to generic entry. Combined with the evidence above about wholesale generic discounts, an implication of the retail quantity data is that the total wholesale value of the drugs dispensed falls upon generic entry.

3. Retail Quantities

Another way to see the impact of authorized generics is to consider the quantities sold by various types of manufacturers with and without AG entry. Because wholesale quantities following generic entry can reflect the filling of the supply chain with the generic, the focus here is on quantities dispensed by pharmacies using our retail data. In order to aggregate across a wide variety of drugs, quantities need to be normalized. The normalization used here is the same as was used for prices and expenditures, dividing current quantity of extended units dispensed by the pre-entry brand quantity. This normalization allows meaningful aggregation across drugs, reveals whether the drugs were dispensed more or less than they were prior to generic entry, and gives an accurate measure of the relative market presence of the various types of drugs.

Table 1-G reports the relative quantities for the brand and the ANDA generic for ANDA-Only drugs across the six months of exclusivity. The first thing to note is that the brand relative quantities fall very quickly, with the brand losing more than half its sales by the third month, and over 70 percent by the end of exclusivity. Also note that the sum of brand and ANDA relative quantities is slightly less than 100 percent in all but the sixth month, meaning that these drugs tended to be dispensed somewhat less frequently after generic entry, though typically only by a couple of percentage points.

Table 1-G: Average Relative Retail Quantities Dispensed: ANDA-Only

		Month of Exclusivity						
Manufacturer Type		1	2	3	4	5	6	All
Brand	Mean	82.1%	50.6%	38.7%	34.4%	29.8%	28.8%	46.1%
	SE	*2.9%*	*3.1%*	*2.5%*	*2.1%*	*1.9%*	*1.7%*	*1.6%*
ANDA	Mean	13.9%	45.5%	57.3%	62.9%	67.7%	75.9%	51.5%
	SE	*2.0%*	*4.0%*	*3.8%*	*3.7%*	*3.6%*	*4.8%*	*2.0%*

Relative quantities for ANDA+AG drugs appear in Table 1-H. Just as with ANDA-Only drugs, the brand quantities drop off quickly. In fact, the decrease is quicker and more pronounced for ANDA+AG drugs. One possible explanation for this is that the added generic competition causes more severe erosion of brand sales. Another explanation is that branded companies recognize that the brand will lose relatively more sales for particular drugs, and they decide to try to regain some of those losses by issuing an AG. Nothing in these tables can distinguish between these two explanations. More sophisticated analysis in the final study will attempt to better control for the factors that make launching an AG attractive to shed more light

on this question.[19] Though this does not help distinguish between these explanations, it is interesting to note that the combined quantities of the Brand and the AG in Table 1-H exceed the Brand quantities in Table 1-G in each corresponding month. Also note that the average AG relative quantity is greater than 25 percent in all but the first month, but is always substantially lower than the relative quantity of the ANDA generic. Finally note that the ANDA generic's share drops from 51.5 percent for ANDA-Only drugs to 42.8 percent for ANDA+AG drugs, which is a 17 percent reduction in quantity. This illustrates the point discussed earlier that an important reason the independent generic makes less revenue when facing AG competition is that it loses sales to the AG.

Table 1-H: Average Relative Retail Quantities Dispensed: ANDA+AG

		Month of Exclusivity						
Manufacturer Type		1	2	3	4	5	6	All
Brand	Mean	80.6%	32.8%	23.8%	21.3%	17.7%	16.3%	32.4%
	SE	*2.8%*	*1.4%*	*1.2%*	*1.2%*	*1.2%*	*1.4%*	*1.5%*
AG	Mean	7.2%	26.7%	30.1%	33.1%	36.1%	37.5%	28.1%
	SE	*1.1%*	*1.7%*	*1.9%*	*2.3%*	*2.4%*	*3.2%*	*1.0%*
ANDA	Mean	12.8%	43.2%	47.4%	49.3%	50.4%	55.7%	42.8%
	SE	*1.9%*	*1.7%*	*1.8%*	*2.1%*	*2.2%*	*3.0%*	*1.2%*

III. Conclusion

The launch of an AG can have impacts that extend beyond the brand and generic companies to consumers and other firms. Consistent with the prior research, our initial analysis suggests that consumers benefit and that 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. These results also indicate that AG entry significantly decreases the revenues of a first-filer generic company that obtains 180-day exclusivity. The impact of AG entry likely changes the calculus of business decision-making for both the generic and brand firms. These impacts will be explored further in the final report.

[19] One such factor discussed above was the size of the market for the branded drug, prior to generic entry. However, relative retail quantities do not differ systematically between high sales and low sales drugs.

CHAPTER 2: THE USE OF AUTHORIZED GENERICS IN PATENT SETTLEMENT AGREEMENTS

As reported in the prior section, AG competition typically reduces a first-filer generic's revenues during the 180 days of marketing exclusivity by approximately 50 percent. To prevent this loss of revenue, a generic may be willing to delay its entry in return for a brand's agreement *not* to launch an authorized generic – that is, a brand's agreement not to compete with the generic through an AG – 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 available to consumers as soon as otherwise would be the case. Because generic drugs often are priced substantially below the price of branded drugs, [1] overall prescription drug costs could be significantly increased by just a few additional months of branded prices in a large market.

- Second, consumers would lose the benefit of price discounts from AG competition during the 180-day marketing exclusivity. The consumer harm in such instances arises because the brand has agreed not to compete against the independent generic during the exclusivity period. The consumer harm arises from the *absence* of AG competition against an independent generic, not from the *presence* of AG competition against an independent generic.[2]

- Between FY2004–FY2008, about one-quarter (38 out of 152) of the final patent settlements reviewed by the FTC under the MMA contained provisions relating to AGs.

- Between FY2004–FY2008, 76 final patent settlement agreements were with first-filer generics. About one-quarter (20 out of 76) of those patent settlements 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 delay its entry past the settlement date by, on average, 34.7 months. Branded sales of the affected products ranged from $12.6 million to $5.3 billion, with an average market size of $917 million and a median market size of $514 million. Five of the settlements covered products with annual sales of $1 billion, $1.1

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[1] *See, e.g.*, CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY (1998) at 31, 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 independent generic's product and a brand's AG.

billion, $2.1 billion, $2.5 billion, and $5.3 billion.

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

Patent litigation between a brand and a generic typically occurs when a generic seeks entry *prior to* expiration of the patents on a corresponding branded drug by alleging that such patents are invalid or not infringed by the generic's drug product. That litigation often is settled rather than litigated to conclusion. Such settlements do not necessarily implicate 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, 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, do not generally raise competition concerns.

Other settlements in this context can raise serious competition concerns, however, because they appear to 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 settlements, known as "exclusion payment" or "pay for delay" settlements[3], thwart the goal of the Hatch-Waxman Act to encourage generic companies to challenge questionable patents and promptly "make available more low cost generic drugs," while protecting legitimate patent claims covering innovator drugs.[4] Settlements potentially raising "exclusion payment" issues are now common.[5] Congress is now considering a variety of legislative proposals regarding "pay for

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[3] 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).

[4] 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 In re* Cardizem CD Antitrust Litig., 332 F.3d 896, 908 (6th Cir. 2003), subsequent appellate rulings adopted a far more permissive position. *See In re* Ciprofloxacin Hydrochloride Antitrust Litig., 544 F.3d 1323, 1336 (Fed. Cir. 2008); *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* FTC v. Cephalon, Inc., No. 08-cv-2141 (E.D. Pa. complaint filed Feb. 13, 2008), *available at* http://www2.ftc.gov/os/caselist/0610182/080213complaint.pdf; FTC v. Watson Pharmaceuticals, Inc., No. 09-00598 (C.D. Cal. first amended complaint filed Feb. 12, 2009), *available at* http://www2.ftc.gov/os/caselist/0710060/090212amendedcmpt.pdf.

[5] In the two most recent years for which data has been compiled, nearly half of all of the final settlements filed under the MMA involved compensation to the generic patent challenger and

delay" settlements, and the Commission supports restricting such settlements.

Most recently, some brand-generic patent settlement agreements filed under the MMA appear to use provisions relating to authorized generics – instead of monetary payments – as a means 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 Section 6(b) 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 and generic products. In one case, documents from the brand showed how an agreement not to compete with an AG increased both the brand-name and generic companies' revenues. This was true because of (1) the overall drop in brand revenues that would occur at generic entry, and (2) the generic's drop in revenues due to AG competition from the brand.[6] Indeed, the branded firm projected that if it launched an AG to compete with the first-filer generic during its 180 days of marketing exclusivity, the net present value of the generic's product would decline by nearly a third. If, however, the brand agreed not to offer an authorized generic, and the generic agreed to further delay its entry in exchange for that agreement, the combined net present value of both companies' products would be maximized, according to the brand company's documents.[7]

The combination of documents such as this, along with increased numbers of MMA filings including provisions relating to AGs, prompted staff to examine the role of AGs in Hatch-Waxman settlements.[8]

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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: SUMMARY OF AGREEMENTS FILED IN FY 2006 (2007), http://www.ftc.gov/reports/mmact/MMAreport2006.pdf (14 of 28 final settlements involved compensation to the generic patent challenger and a restriction on entry); 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: SUMMARY OF AGREEMENTS FILED IN FY 2007 (2008), http://www.ftc.gov/os/2008/05/mmaact.pdf (14 of 33 final settlements involved compensation to the generic patent challenger and a restriction on generic entry).

[6] This reflects the fact that competition typically dissipates 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, *Probabilistic Patents*, 19 J. ECON. PERSPECTIVES 75, 91 n.15 (2005).

[7] *See* Confidential Company Document (comparing forecasted net present values for early and late launches, with and without an AG).

[8] This report cites all agreements arising from settlements or patent litigation, including settlements, licenses and supply and distribution agreements as "Settlement Agreements" (SA).

II. The Possible Use of AGs to Compensate Generics for Deferring Generic Entry.

To examine the role of AGs in Hatch-Waxman settlements, staff categorized the final patent settlement agreements that the FTC has received under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") for fiscal years 2004 through 2008, along with one additional agreement received outside the MMA framework.[9] During that period, there were 38 final patent settlement agreements with provisions involving AGs.[10]

A. Agreements Involving AGs

Thirty-eight final patent settlement agreements from FY2004-FY2008 contained provisions that involved AGs. These agreements fall into four basic categories:

(1) As to the product whose patents are being litigated by the brand and the generic, the brand expressly agrees not to use an AG to compete against the first-filer generic for a period of time (20 agreements);

(2) As to the litigated product, either (a) there is no explicit promise not to compete, but the agreement incentivizes the brand not to use an AG to compete against the first-filer (6 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 (4 agreements);

(3) As to the litigated product, the brand appoints a subsequent-filer generic as the brand's AG to compete with the first filer (2 agreements); or

(4) As to a *different* product that is not the subject of litigation between the brand and the generic, the brand appoints the generic as the brand's AG (6 agreements).

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

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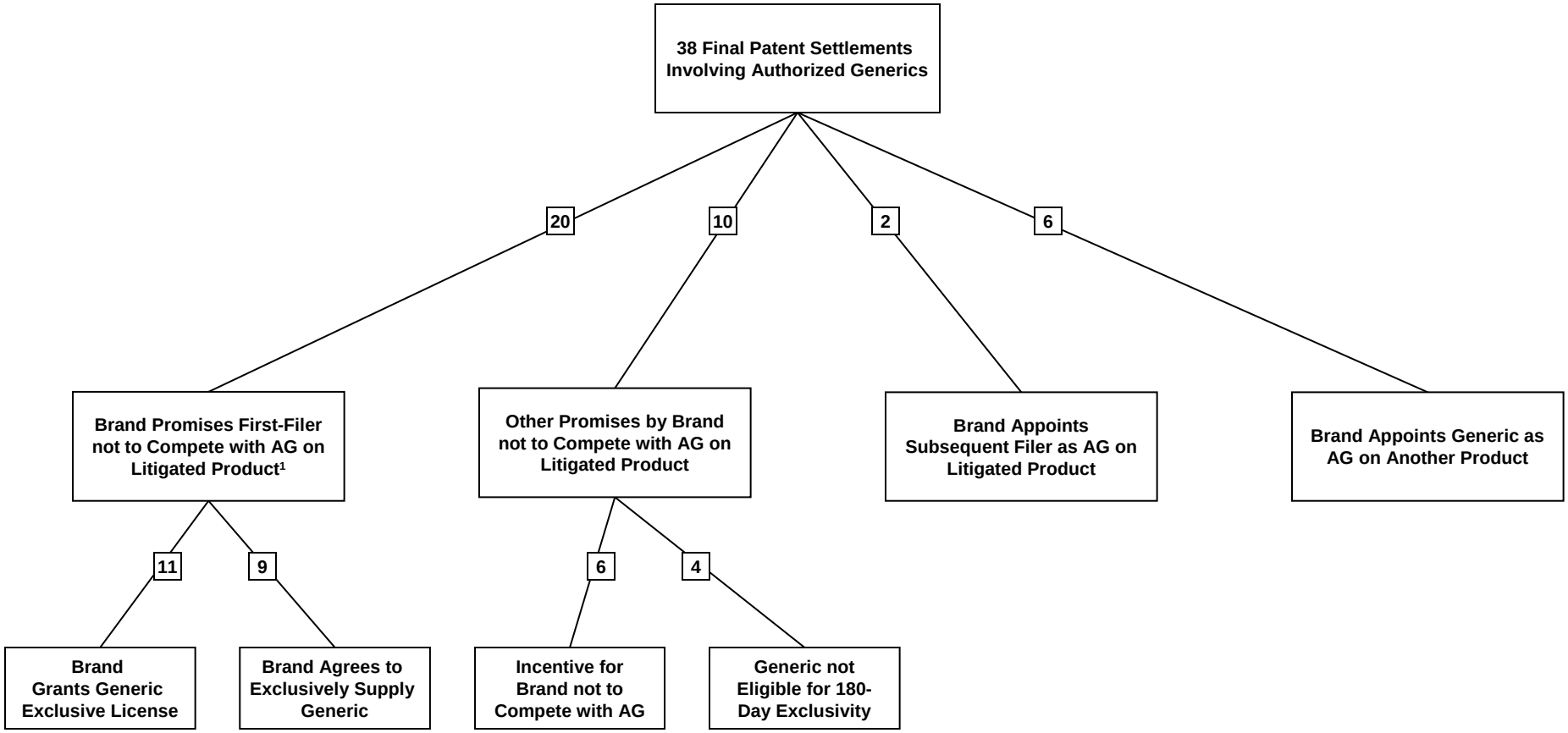
[9] The numbers set forth in this Section and in the accompanying charts reflect preliminary analysis and may be subject to minor changes.

[10] Agreements were counted based on the number of New Drug Applications involved in the litigation. For instance, if a spray formulation and a tablet formulation of a pharmaceutical involved two NDAs and both were subject to the litigation, the settlement arrangements were considered two agreements.

In one agreement included in the total, the brand and a first-filing generic settled their patent dispute without litigation, with the branded firm promising not to offer AG competition for a period of time.

Figure 1: Overall Breakdown of Final Patent Settlement Agreements Involving Provisions on Authorized Generics: Fiscal Years 2004-2008



1. Four of these agreements also involve the brand appointing the generic as an AG on another product.

A. Type (1) Agreements: Explicit Commitments Not to Compete with an AG.

Twenty settlement agreements with a first-filer involved an explicit commitment by the brand not to use an AG to compete with the first-filer for all (or at least a portion) of the first filer's 180 days of marketing exclusivity.[11] Brands explicitly agreed not to compete with an authorized generic only in patent settlements involving a first filer. A first filer is defined as a generic entitled to the 180 days of marketing exclusivity at the time of the settlement agreement.[12] Agreements with first-filers are particularly attractive because the first-filer may control generic entry.[13] As noted above, Type (1) agreements may be based on a promise by the generic to delay entry, which increases the period of time that consumers are deprived of the benefits of brand-generic competition. In addition, such agreements also deprive consumers of AG-ANDA competition whenever generic competition does begin for the litigated product.

These twenty settlements involving explicit brand promises not to compete with an AG were not evenly distributed over the five-year period. The number increased from zero in FY 2004

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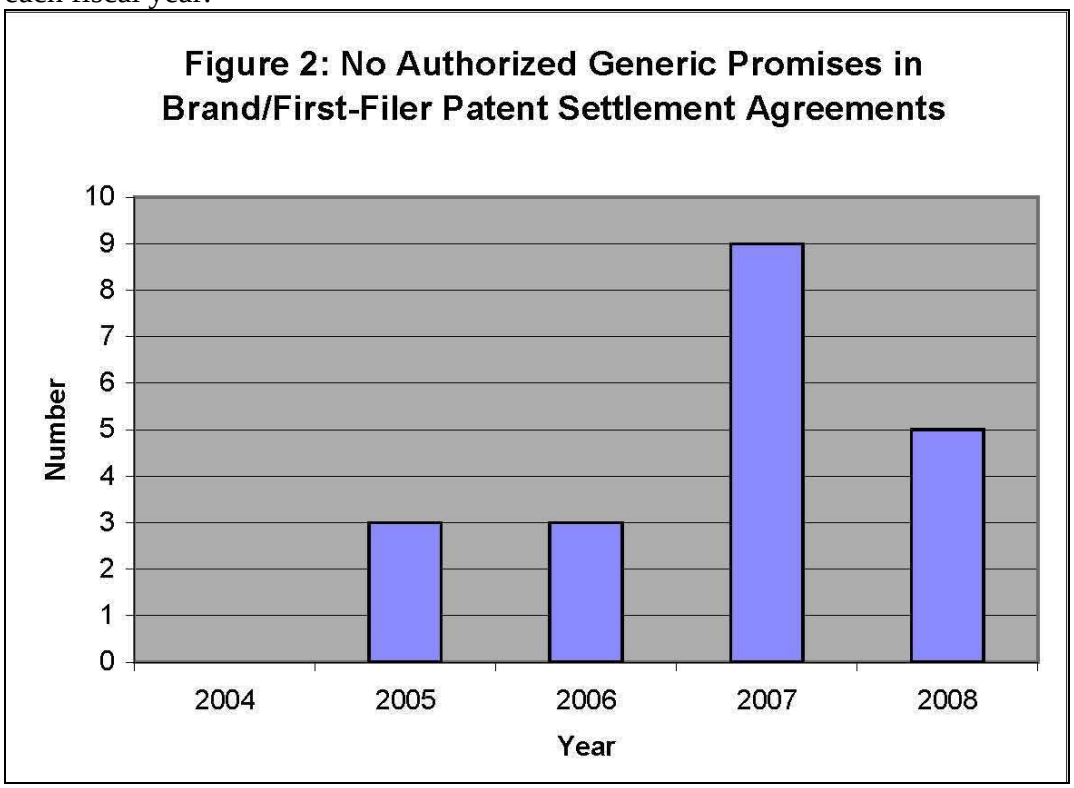
[11] A brand can compete with an AG either through launching it on its own or by authorizing another firm to market the brand's AG. In these settlements, the brand agreed not to launch or sponsor its AG in competition with the first filer's generic product for some period of time.

[12] 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) (2008) (providing that exclusivity may be shared by applicants filing on the same day).

[13] Hatch-Waxman rewards the first filer to challenge a branded 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). Although Hatch-Waxman has been amended to address this problem, by providing that first-filers forfeit their exclusivity under certain circumstances, settlement agreements still have the potential to create bottlenecks that block subsequent applicants. *See Protecting Consumer Access to Generic Drugs Act of 2009: Hearing on H.R. 1706 Before the Subcomm. on Commerce, Trade, and Consumer Protection of the H. Comm. on Energy and Commerce*, 111th Cong. (2009) (prepared statement of the Fed. Trade Comm'n) (forfeiture provisions of the MMA do not relieve bottleneck when a first generic applicant enters a settlement agreement with the brand-name company and there is no court decision of invalidity or non-infringement), *available at* http://www.ftc.gov/os/2009/03/P859910payfordelay.pdf; *see also* Letter from Gary J. Buehler, Dir., Office of Generic Drugs, U.S. Food and Drug Admin., to Marc A. Goshko, Executive Dir., Teva Parenteral Medicines, regarding Docket No. 2007N-0389, at 5 n.6 (Jan. 17, 2008) (noting that when a first-filer enters a settlement agreement without a final judgment of invalidity or non-infringement, the "inability to force a forfeiture of 180-day exclusivity could result in delays in the approval of otherwise approvable ANDAs") http://www.fda.gov/ohrms/dockets/DOCKETS/07n0389/07n-0389-let0003.pdf.

to nine in FY 2007. In FY 2008 there were five such agreements. Figure 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.

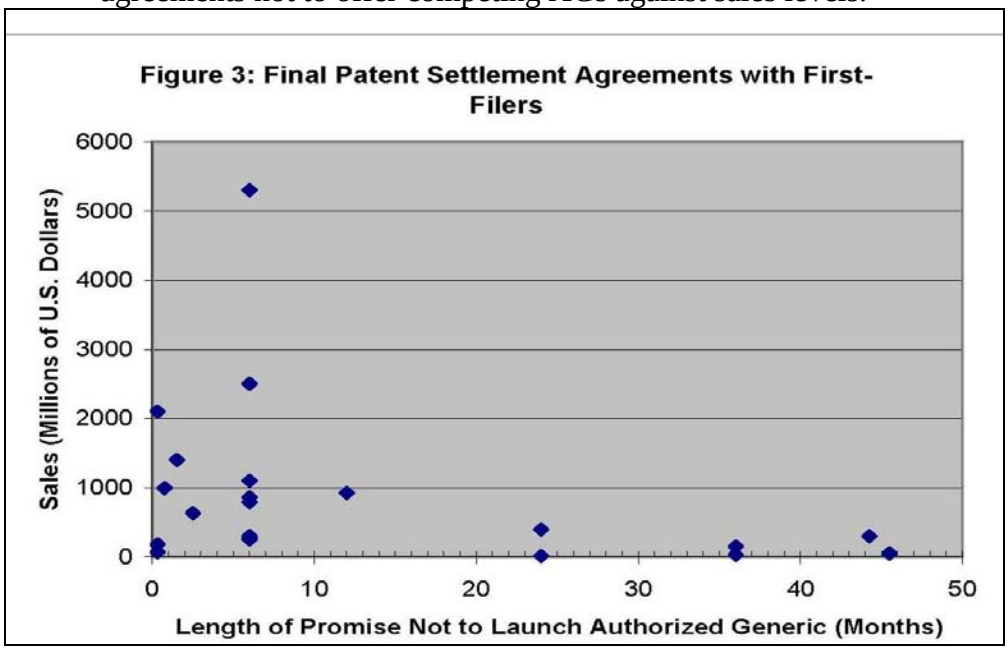
- Slightly more than half – 11 out of 20 – allowed the generic to offer its own product without facing competition from the brand's AG for some period of time. In the other nine cases, either the brand agreed exclusively to supply the generic with the brand's AG, or the generic could choose whether to market its own product or the brand's 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 13.5 months**,** and the median was six months.

- Branded sales of the affected products ranged from $12.6 million to $5.3 billion, with an average market size of $917 million and a median market size of $514

million.[14] Settlements between FY 2004 and FY 2008 included settlements covering products with annual sales of $1 billion, $1.1 billion, $2.1 billion, $2.5 billion, and $5.3 billion.

- For these particular agreements, agreements not to offer a competing AG generally governed products with relatively low sales. In larger markets, the restriction on AG competition rarely lasted more than six months. Figure 3 plots the duration of agreements not to offer competing AGs against sales levels.



- The length of time between the settlement and the date when generic entry was allowed to commence ranged from 1.75 months to 101 months. For six products, the time from settlement to allowable entry was more than four years.[15] Under the terms of eight agreements, generic entry was prohibited for at least three years. The average interval from settlement to allowable generic entry was 34.7 months, and the median was 30.1 months.

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[14] The annual sales data are from IMS Health, IMS National Prescription Audit Plus 7™, Years 2003 to 2008, Data Extracted January 2009. In one instance, when IMS data for the product at issue was unavailable, information was drawn from Top 200 Drugs for 2005 by Sales, http://www.drugs.com/top200_2005.html (last visited June 19, 2009). All sales figures are for the full calendar year prior to the settlement agreement or for the last full year prior to generic entry.

[15] One of these settlements barred entry until 6–8 months before expiration of late-issued patents confined to a single form of the drug's active ingredient. *See* [Redacted] SA (permitting entry six months before patent expiration). Under another settlement, the agreed-upon entry date gave the brand the full length of the primary composition-of-matter patent on the drug.

Four of the Type (1) agreements filed under the MMA provided for AG competition, and consumer discounts, on a *different* product, however. In these agreements, although the brand agreed not to compete with an AG against the first filer's generic product, the brand appointed that generic firm as the brand's AG to compete against a different generic product. Such agreements typically offer the generic a certain percentage of the revenues from sales of the brand's AG in the other product market, and they can provide consumer discounts through AG competition on the other product, assuming the royalties or supply price to the generic is not too high.

At the same time, such an agreement also can provide additional value to persuade a generic to delay its entry on the litigated product. For example, in one situation, a brand allowed the generic to launch the brand's AG for the product strength for which the generic was not the first-filer, in addition to agreeing that the brand would not compete with an AG for the product strengths for which the generic was the first filer. This agreement ensured that the generic would have sole 180-day exclusivity on the 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 have a full line of strengths at generic entry, giving it an advantage over the first-filer on the third strength.

A. Type (2) Agreements: Other Promises by Brand Not to Compete with AG on Litigated Product.

Type (2) agreements are difficult to categorize. In six of these agreements, there was no explicit promise by the brand not to compete with an AG. Instead, each of the agreements included provisions under which either royalties due to the brand dropped significantly if the generic faced competition within a specified period of time or some other provision discouraged the brand from offering a competing AG. These agreements actually may operate as promises by the brand not to launch or sponsor an authorized generic for a period of time, but their effect is difficult to judge.

Four of the Type (2) agreements involved an explicit promise from the brand not to compete with an AG, but the generic did not have the right to 180-day marketing exclusivity. In one of these cases, the first-filer waived its exclusivity rights to allow another generic, with which the first-filer had a contractual relationship, to market the product at issue in the litigation. The settlement agreement restricted the brand's ability to launch an AG for that product and indicated that the parties expected that the generic that was to market the product would be the only generic in the marketplace for at least the 180-day period. In a second case, the generic had been deemed by the FDA to have forfeited its exclusivity. Under the settlement, the brand granted the generic an exclusive license to market the generic's product as of a specified date. In a third case, the generic had entered "at-risk," thus triggering the exclusivity period. The settlement, which occurred after the triggering of the exclusivity period, involved the generic's promise to exit the market for a period of time. Upon re-entry by the generic, the brand agreed to exclusively supply the generic with product. The last agreement involved an explicit promise by the brand not to

compete with an AG for the life of the patent, but the generic was not eligible for the 180-day exclusivity period.

C. Type (3) Agreements: Brand Appoints Subsequent Filer as AG on Litigated Product.

Settlements with subsequent filers involving AG provisions raise complex issues. In one of the two Type (3) agreements filed under the MMA, the brand agreed to supply the subsequent filer with product to market as an AG and continued litigating with the first-filer. The other agreement would allow the subsequent filer to market the brand's AG for the litigated product during the first filer's exclusivity, but *only if* the first filer did not settle its litigation. Otherwise, the subsequent filer could market the brand's AG 181 days after the first filer's launch.

Such agreements have the potential to reduce prices to consumers through AG competition during the 180-day exclusivity period. At the same time, they might affect generic entry by eliminating a patent challenge that could have precipitated generic competition. For example, a subsequent filer may obtain a court decision of patent invalidity that would allow the first filer to market its product,[16] or a subsequent filer could obtain a court decision of invalidity or non-infringement that would trigger the first-filer's exclusivity period or its forfeiture.[17] The Federal Circuit has recognized that brand name companies may seek to settle with subsequent filers, because branded 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.[18]

D. Type (4): Brand Appoints Generic as AG on Another Product.

In six agreements, the brand appointed the generic as the brand's AG for another product. Type (4) agreements can provide AG competition, and consumer discounts, during an 180-day marketing exclusivity period for a different drug – not the drug whose patents are being litigated by the brand and generic. Consumer discounts on the second drug may result from the first-filer generic's agreement to delay its entry on the litigated product.

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[16] Under the original provisions of the Hatch-Waxman Act, a victory by a subsequent filer triggered the first-filer's exclusivity, allowing the FDA to approve the subsequent filer's ANDA 180 days later. 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2000). Although this court-judgment trigger has been eliminated and does not apply to ANDAs filed after December 2003, a judgment of invalidity won by the subsequent filer would typically speed resolution of the first-filer's case.

[17] Pursuant to amendments contained in the MMA, a court decision now triggers a forfeiture provision: 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).

[18] *Caraco*, 527 F.3d at 1284.

III. More Complex Possible Strategies to Forestall Generic Entry through Agreements Involving Authorized Generics.

Some of the patent settlement agreements reviewed by staff, and discussed in Section II above, revealed more complex strategies used in agreements involving AGs; these strategies depend on the presence of certain factors. Two types of these more complex strategies are discussed below.

A. Multiple Dosage Forms/Products and Exclusive Agreements Relating to AGs.

Several recent settlement agreements reflect terms regarding two products (including, for these purposes, two dosage forms) involving an agreement not to compete with an AG for one product and an agreement exclusively to supply an AG for the other product. The essence of these arrangements is that the generic company is permitted to market an AG or ANDA-generic for one product soon after settlement, but entry is deferred for the other product, which usually has much higher sales.[19] Such a package of commitments could induce the generic to defer entry on the high-sales product by promptly providing it with revenues on the low-sales product, and shielding it from a competing AG with respect to one or both of the products.

B. Strategic Information Disclosures.

Another category of settlements between brand-name companies and subsequent filers could operate to induce the first-filer to delay entry. In these agreements, the subsequent filer's ability to market an AG during the first-filer's 180-day exclusivity depends on whether the first filer does or does not take certain actions. By ensuring that those terms, normally kept confidential, become known by the first-filer, the branded firm may induce the first-filer to delay entry to avoid triggering the subsequent filer's right to enter as an AG during the first filer's 180 days of marketing exclusivity.

For example, one agreement provided that if the first-filer launched its ANDA-generic

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[19] *See* [Redacted] SA (entry on low-sales product, about 2 months after settlement; on blockbuster product, more than 3 years); [Redacted] SA (entry on low-sales product, about 7 months after agreement; on blockbuster product, nearly 5 years); [Redacted] SA (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. (In one case, the paragraph IV certification was made after the agreement.) A fourth agreement, involving high- and low-sales drugs that are unrelated, raises similar issues. *See* [Redacted] SA (prohibition on competing AG with respect to only the low-sales product, with ANDA entry for that product permitted upon execution of the agreement; entry of the high-sales product about 17 months from execution). There was no paragraph IV certification with regard to the high-sales product in this agreement because it is an old antibiotic.

product without entering a settlement with the brand, the subsequent filer would be allowed to market the AG during the first-filer's 180-day exclusivity.[20] 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.[21]

Another agreement allowed a subsequent filer to market the AG during the first-filer's 180-day exclusivity if the first-filer launched its ANDA-generic product "at risk," after a district court determination that the challenged patents were invalid, unenforceable, or not infringed. However, if the first-filer deferred entry until after a decision by a court of appeals, the agreement provided for launch of the AG six months after the first-filer's launch, i.e., after its 180-day exclusivity.[22] Making the relevant terms of this agreement known to the first-filer could deter it from launching "at risk" after a district court win.

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 the agreement as a tool in settlement negotiations with the first-filer; or even by making the agreement available in a public forum. Indeed, one of the described agreements was made publicly available in the branded firm's 8-K filing with the Securities and Exchange Commission.[23] If interpreted as an offer not to compete, an inappropriate disclosure could raise competition concerns.[24]

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[20] 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. [Redacted] SA. If the first-filer launches its ANDA-generic product at risk, the agreement provides that the brand and the subsequent filer will mutually decide whether to launch the AG during the first-filer's 180-day exclusivity. *Id.*

[21] *See* [Redacted] SA (appointing the first-filer the exclusive AG distributor but requiring the brand to supply the AG only if the first-filer was unable to obtain final FDA approval of its ANDA).

[22] [Redacted] SA (definition of Authorized Generic Launch Date).

[23] *See* [Redacted] SA. Most AG supply agreements are not publicly available.

[24] Invitations to collude have been judged unlawful under Section 2 of the Sherman Act, United States v. Amer. Airlines, 743 F.2d 1114 (5th Cir. 1984), and the Commission has issued consent orders in several cases involving allegations that an invitation, even when unaccepted by the competitor, violated Section 5 of the FTC Act. *See, e.g.*, *In re* Valassis Commc'ns, No. C-4160 (F.T.C. Apr. 28, 2006) (consent order resolving allegations of an invitation to collude in dividing the market made by one company during a public conference call with securities analysts); *see also* Analysis of Agreement Containing Consent Order to Aid Public Comment, In the Matter of Valassis Communications, Inc., *available at*

V. Conclusion

Review of recent brand-generic settlements reveals that agreements not to compete with authorized generics have a significant potential for use as exclusion payments in patent settlement agreements. 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.

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http://www.ftc.gov/os/caselist/0510008/060314ana0510008.pdf.

Appendix

Description of Data

Our data was acquired from several sources. The retail and wholesale price, expenditure, and quantity data were licensed from IMS Health, Inc. Authorized generic drugs 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]

1. IMS Health Inc.

The Federal Trade Commission (FTC) purchased a license for information representing nationally aggregated, monthly sales information for each non-injectable prescription medication distributed in the United States over the period 1/2003-12/2008 from IMS Health. This information included: (1) the National Sales Perspective (NSP) Survey which represents wholesale level quantity and dollar sales[2] information for drugs purchased by retail and non-retail pharmacies; and (2) the National Prescription Audit (NPA) Survey which represents retail quantity and dollar sales[3] information for prescriptions dispensed primarily at retail pharmacies. All sales information in both sets of data is reported in aggregate form within channels, and for the analysis presented here, the data have been aggregated across channels.

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[1] The Federal Trade Commission received prescription sales information from over 100 drug firms representing drug-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 drugs 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 drug. 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. Some analysis of the sales information obtained from the manufacturers will likely appear in the final study, but the sales information reported here comes entirely from the data purchased from IMS Health.

[2] It should be noted that certain discounts may not be accounted for in this data. According to the IMS Study, "Assessment of Authorized Generics in the U.S." at 19, prepared by IMS Consulting, IMS Health in 2006 for PhARMA, and available at http://www.phrma.org/files/IMS%20Authorized%20Generics%20Report_6-22-06.pdf, "However, prompt 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 generics and independent generics, not having information on these discounts should not bias our findings.

[3] IMS refers to these dollar amounts as the "cost to consumers."

In addition to monthly sales information, both surveys provided detailed information about each drug. This information included the National Drug Code (NDC), strength, dosage form, manufacturer and name of the active ingredient(s) in a single dose. Taken together, this information gave us data on each drug at the 11-digit NDC level of specificity, broken down by channel. We used this information to define a single observation in the analysis as an active ingredient(s)-dosage form-strength-manufacturer combination.[4] IMS also provided the date the drug was first recorded as having sales (dates as early as 1950 are reported), the therapeutic class of the drug, whether the medication was sold over-the-counter or as a prescription, and whether the manufacturer of the drug is a generic or a brand manufacturer.[5]

Our sample is limited to tablet and capsule dosage forms of prescription drugs. It excludes all products that are not oral solids, including syrups, ointments, liquids of any kind, over-the counter medications, vitamins and decongestants. We exclude anything that is not an oral solid because extended quantity units are difficult to compare across medications of different forms. We also excluded over-the-counter medications and vitamins because they were often sold in different venues than is collected by IMS. We excluded decongestants because the set of active ingredients included in decongestant combinations was very large, and often changes over time.[6] Finally, we excluded all drugs that did not first face generic competition during the period 4/2003 - 11/2008.[7] Drugs were defined as facing generic competition during the period if the earliest producer of the drug was a brand manufacturer as identified by IMS, and the drug was observed with positive sales of a second manufacturer who IMS indicated did not have positive sales prior to 4/2003.

We used the manufacturer and brand status information provided by IMS to classify each drug into one of two types: brand and generic. Company and FDA information was used to further classify the generic drugs as either independent generics or authorized generics. The date

[4] Dosage forms are 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 A1. This mapping was necessary in order to match the IMS and FDA data.

[5] One relevant molecule, Bupropion, is associated with multiple therapeutic classes for each strength and dosage form. We exclude it from the analysis. In addition, Nitrofurantoin had several molecular names listed in the FDA data, and was therefore excluded from the analysis.

[6] The lists of USC codes used to define whether a medication is a decongestant or a vitamin are provided in Tables A2 and A3.

[7] We normalized several market outcomes, such as prices, based on the market conditions that existed prior to generic entry. Consequently, even though we have data for the first three months of 2003, it was used only to calculate pre-generic entry market characteristics for drugs that experienced generic entry early in 2003.

of generic entry was defined as the first date in which a manufacturer other than the brand was first observed with positive sales.[8]

The number of generic manufacturers producing each drug was also constructed from the IMS data using information about the manufacturer identified therein. The number of manufacturers producing a product was defined as the count of manufacturers observed with positive sales during the month and includes the authorized generic marketer. Our IMS data does not differentiate between true pharmaceutical manufacturers and repackagers. Repackagers purchase supply from true manufacturers, and typically sell them in some alternate form of packaging, such as blister packs.[9] Our manufacturer count excluded firms that we determined were highly likely to be repackagers.[10] The indicator of whether the molecule faces an authorized generic competitor was defined by whether the authorized generic manufacturer has positive sales during the month.

The sample was then further refined to include monthly observations for a drug only if a generic manufacturer with FDA-granted exclusivity was either (i) the sole generic marketed that month or (ii) faced generic competition only from an AG. When the independent generic manufacturer was the only generic on the market, we refer to that as an ANDA-Only drug. The 51 drugs that are classified as ANDA-Only drugs in our sample are listed in Table A5. When the independent generic was joined in the market by an AG, the drug will be referred to as an ANDA+AG drug. The 53 drugs that are classified as ANDA+AG in our sample are listed in Table A6. Nine drugs[11] show up in both lists, so there are a total of 95 unique drugs in our sample.[12] A drug can show up in both lists when, for instance, the authorized generic enters several months after the independent generic. In that situation, the drug would be ANDA-Only for the first several months, then switch to ANDA+AG when the authorized generic enters.

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

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

[10] 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 we judged to be repackagers is provided in Table A4. One potential source of error in our data is incorrectly identifying the repackagers, which could cause us to overstate or understate the number of active generic manufacturers of a drug.

[11] These nine drugs are comprised of the four strengths of Amlodipine/Benazepril, two strengths each of Eplerenone and Moexipril, and one strength of Omeprazole.

[12] These 95 drugs include multiple strengths and dosage forms of some drugs. These 95 drugs represent 35 unique molecule combinations.

2. FDA and Company Data

Sales information from IMS was supplemented with data collected from the FDA and the drug manufacturers. These sources were used to identify whether a firm issued an authorized generic and the name of the authorized generic marketer when applicable. Details about relevant Hatch-Waxman related legal actions associated with each drug, including whether the drug faced a paragraph IV challenge and the end date of exclusivity periods associated with paragraph IV challenges, were collected from the FDA.

We identified AGs from information produced by pharmaceutical companies pursuant to the Special Orders and from information provided by the FDA. 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 authorized generic. This information was collected from both the generic and brand manufacturers. In addition, we requested that the brand manufacturers provide the name of the entity associated with each NDC labeler code so that we could identify the distributor of the authorized generic.

The most relevant Hatch-Waxman related information was whether the drug faced a paragraph IV patent challenge, and whether a generic manufacturer was granted exclusivity related to a paragraph IV challenge. The FDA provides a list of drugs facing paragraph IV challenges on its website.[13] For all drugs associated with a 180-day exclusivity period, we identified the date that generic exclusivity ended for the drug. These dates were determined from information provided by the FDA. We defined a month to be a part of the exclusivity period if the 28th of the month occurred prior to the exclusivity end date.[14]

[13] *See* U.S. Food and Drug Admin., Paragraph IV Patent Certifications (June 15, 2009) http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM154350.pdf (list is updated twice a month).

[14] 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–May 2005 but would exclude June from the exclusivity. However, if the end date of the exclusivity was identified as June 30th then the month of June would also be included in the exclusivity period.

Table A1: Dosage-Form Mapping

Three-Lettered Code (as provided by IMS)	Analysis Dosage Form
ABA Tablets Uncoat Regular Ordinary	Tablet
ACA Tablets Coated Regular Ordinary	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 Reg Buccal/Sub-Lingual	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 Oth	Orally Disintegrating/Ecteric Coated
ACZ Tab Coated Regular Othr	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 Sol	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
RB Mouth Throat Lozenges	Lozenge
BGA Lozenge Long Acting Ordinary	Extended-Release Lozenge
BDA Granulate Long Acting Ordinary	Extended-Release Granule
Doseform=Tablet/Capsule	Other

Table A2: USC5 Therapeutic Categories Eliminated as Decongestants

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 A3: USC5 Therapeutic Categories Eliminated as Vitamins

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

Table A4: Firms Counted as Repackagers

Allscripts Pharm
American Hlth Pkg
DHS Incorporated
Dispensexpress
Drx
Innoviant Pharmacy
Keltman Pharmaceutical
Major Pharm
Nucare Pharmaceutical
PD-RX Pharmaceutical
Pharma Pac
Pharmpak
Phys Total Care
Physician Partner
Physician Therapeutics
Quality Care Pharmaceutical
Repackager
Southwood Pharm
Unit Dose Labs (UDL)

Table A5: ANDA-Only Drugs

Alendronate 5mg, 10mg, and 40mg Tablets
Amlodipine/Benazepril 2.5-10mg, 5-10mg, 5-20mg, and 10-20mg Capsules
Ciprofloxacin 100mg Tablets
Clopidogrel 75mg Tablets
Colestipol 1000mg Tablets
Desmopressin 0.1mg, 0.2mg Tablets
Dexmethylphenidate 2.5mg, 5mg, and 10mg Tablets
Didanosine 200mg, 250mg, and 400mg Extended-Release Capsules
Eplerenone 25mg and 50mg Tablets
Famciclovir 125mg, 250mg, and 500mg Tablets
Fenofibrate 54mg and 160mg Tablets
Fosinopril/Hydrochlorothiazide 10-12.5mg Tablets
Ganciclovir 250mg and 500mg Capsules
Hydrochlorothiazide/Quinapril 10-12.5mg, 20-12.5mg, and 20-25mg Tablets
Lamotrigine 25mg, 100mg, 150mg, and 200mg Tablets
Metformin 750mg Extended/Sustained-Release Tablets
Mirtazapine 15mg and 30mg Orally Disintegrating Tablets
Moexipril 7.5mg and 15mg Tablets
Paroxetine 12.5mg and 25mg Extended/Sustained-Release Tablets
Ramipril 1.25mg, 2.5mg, 5mg, and 10mg Tablets
Venlafaxine 25mg, 37.5mg, 50mg, 75mg, and 100mg Tablets

Table A6:ANDA+AG Drugs

Acetaminophen/Tramadol 37.5-325mg Tablets
Alendronate 35mg Tablets
Amlodipine/Benazepril 2.5-10mg, 5-10mg, 5-20mg, and 10-20mg Capsules
Eplerenone 25mg and 50mg Tablets
Fexofenadine 30mg, 60mg, and 180mg Tablets
Finasteride 5mg Tablets
Fosinopril 10mg, 20mg, and 40mg Tablets
Glyburide/Metformin 1.25-250mg, 2.5-500mg, and 5-500mg Tablets
Metformin 500mg Extended/Sustained-Release Tablets
Metoprolol 100mg and 200mg Extended/Sustained-Release Tablets
Moexipril 7.5mg and 15mg Tablets
Omeprazole 40mg Extended-Release Capsules
Ondansetron 4mg and 8mg Tablets; 4mg and 8mg Orally Disintegrating Tablets
Oxybutynin 15mg Extended/Sustained-Release Tablets
Oxycodone 10mg, 20mg, and 40mg Extended/Sustained-Release Tablets
Paroxetine 10mg, 20mg, 30mg, and 40mg Tablets
Pravastatin 10mg, 20mg, 40mg, and 80mg Tablets
Risperidone 0.25mg, 1mg, 2mg, 3mg, and 4mg Tablets
Sertraline 25mg, 50mg, and 100mg Tablets
Simvastatin 5mg, 10mg, 20mg, 40mg, and 80mg Tablets

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