

Authorized Generics: An Interim Report



David Schmidt
Assistant Director
Bureau of Economics
Federal Trade Commission

The views expressed are those of the speaker and do not necessarily represent the views of the Federal Trade Commission.

Background

- ❑ Senators Grassley, Leahy, and Rockefeller asked the Commission to examine “the short term and long term effects on competition of the practice of ‘authorized’ generics.”
- ❑ Also, Representative Waxman requested the FTC to study “the impact of so-called ‘authorized generics’ on competition in the prescription drug marketplace.”
- ❑ FTC Interim Report issued June 24, 2009.
<http://www.ftc.gov/os/2009/06/P062105authorizedgenericsreport.pdf>

AG Entry During 180 Day Exclusivity

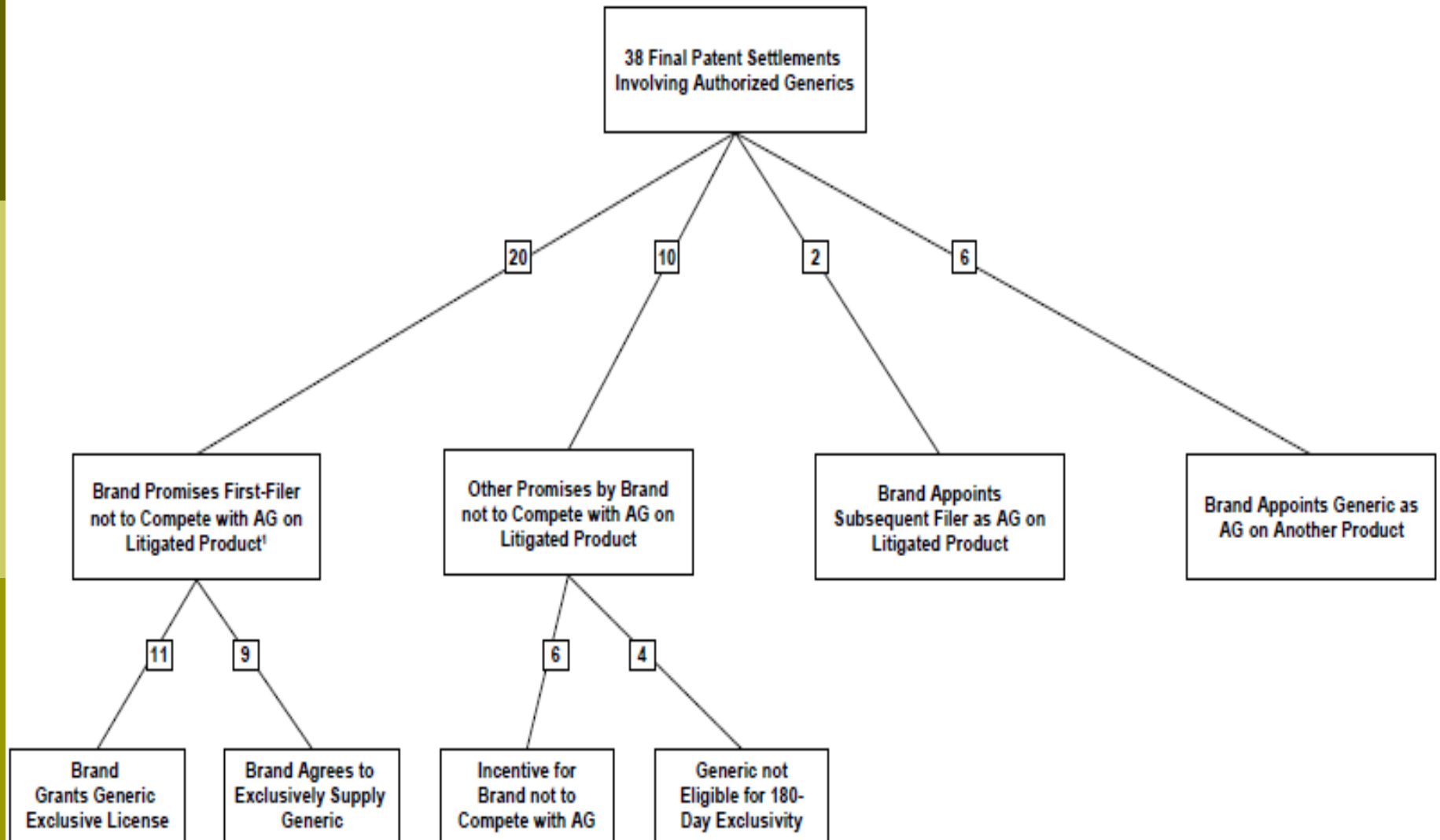
Authorized Generics (AGs) were marketed during the exclusivity period for roughly 56% of drugs that first faced generic competition via an exclusivity period between April 2003 and December 2008

Pre-Entry Market Size

	All	Big	Small
AG Enters	53	37	16
No AG	42	9	33
AG%	56%	80%	33%

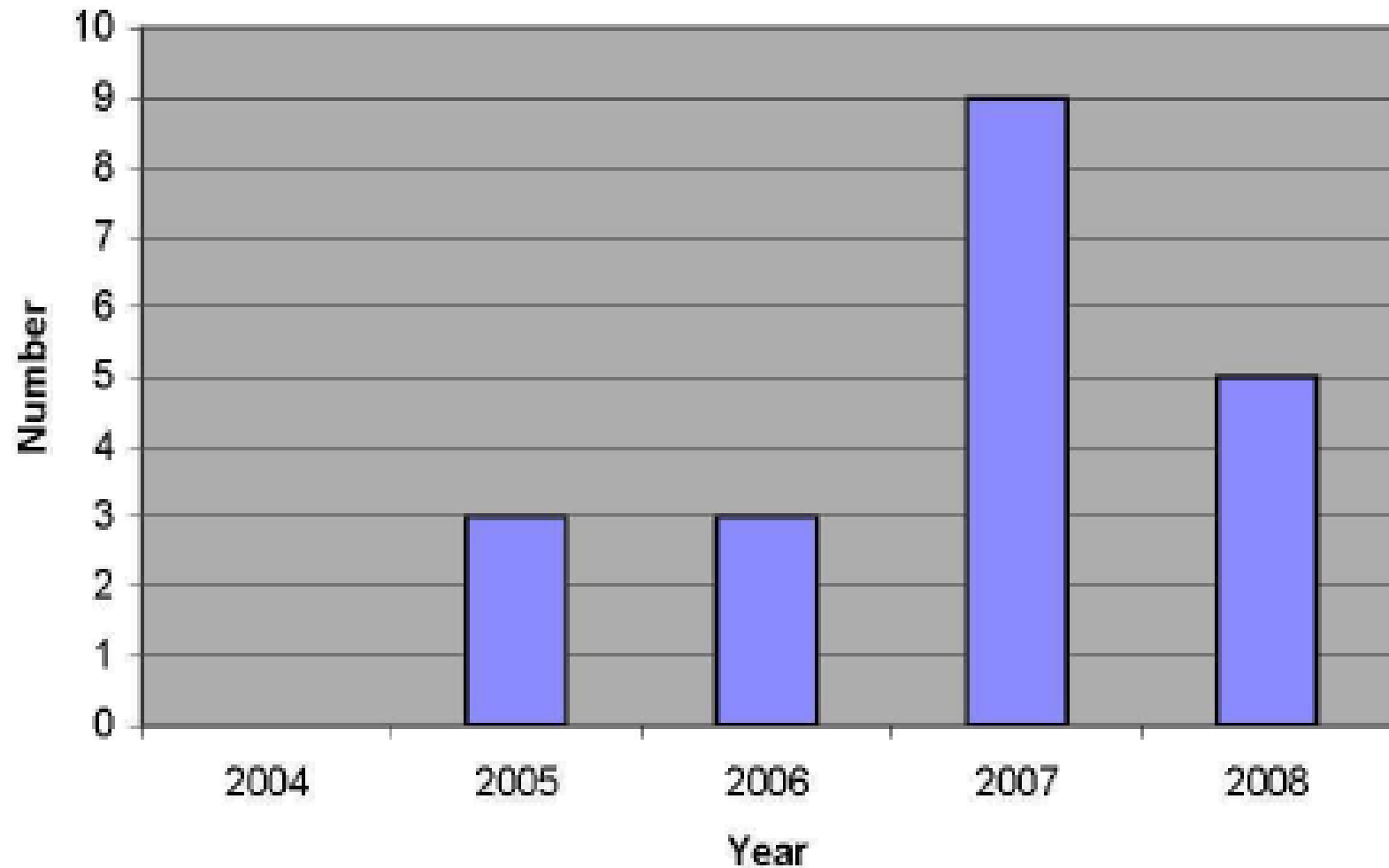
Note: For the purposes of this slide, the distinction between big and small drugs is whether the pre-generic entry brand sales are above or below the median of all drugs that first faced generic competition in the sample. See FTC Interim Report, Chapter 1, page 7.

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.

Figure 2: No Authorized Generic Promises in Brand/First-Filer Patent Settlement Agreements



Estimated Effects of AG Entry on Generic Prices

Study	Retail	Wholesale	# of Drugs
IMS		-16%	16
Hollis & Liang	-5% to 0%		16
FTC Interim Report	-4% to -1%	-8% to -7%	95

IMS CONSULTING, IMS HEALTH, [ASSESSMENT OF AUTHORIZED GENERICS IN THE U.S.](#) (2006), (prepared for PhRMA).

AIDAN HOLLIS AND BRYAN A. LIANG, [AN ASSESSMENT OF THE EFFECT OF AUTHORIZED GENERICS ON CONSUMER PRICES](#) (2006), (prepared for GPhA).

FTC Interim Report, Tables 1-A, B, C, D

Estimated Effects of AG Entry on First-Filer, AG, and Brand Product Wholesale Expenditures

The table below reports for each product the ratio of average monthly expenditures on the product during the 180 day exclusivity period to the average monthly expenditures on the brand product immediately prior to generic entry.

Markets	First-Filer	AG	Brand
ANDA-Only	61%		47%
ANDA+AG	33%	24%	33%
AG Effect	-28%	(+24%	+ -14%) = +10%

See FTC Interim Report, Tables 1-E and 1-F