

Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

Overview of Agreements Filed in FY 2012 A Report by the Bureau of Competition

During the fiscal year 2012 (October 1, 2011 to September 30, 2012), the Federal Trade Commission received 140 final resolutions of patent disputes between a brand and a generic, of which 40 settlements may involve pay-for-delay payments. This preliminary assessment summarizes the types of final settlements received in FY 2012 and describes how the FY 2012 results compare to filings in other recent years.

Overview of Final Settlements

- 40 final settlements potentially involve pay for delay because they contain both compensation to the generic manufacturer and a restriction on the generic manufacturer's ability to market its product.
 - These settlements involve 31 different branded pharmaceutical products with combined annual U.S. sales of approximately \$8.3 billion.
 - In nearly half of these potential pay-for-delay agreements (19 out of 40 such agreements), compensation took the form of a brand manufacturer's promise not to market an authorized generic ("AG") in competition with the generic manufacturer's product for some period of time (a "no-AG commitment").
 - It is not uncommon for a brand company to enter multiple settlements involving payment for the same branded product. In FY 2012, 7 branded products had multiple settlements involving compensation and restrictions on entry. Since 2004, brand companies have paid multiple generics in relation to 26 branded products. For 14 products, a brand company paid 3 or more generics, with as many as 10 generic companies receiving payment on a single branded product.¹
- 81 final settlements restrict the generic manufacturer's ability to market its product, but contain no explicit compensation.
- 19 final settlements have no restrictions on generic entry.

¹ Subsequent settlements do not necessarily involve compensation. Since 2004, 44 branded products have been involved in a potential pay-for-delay settlement followed by at least one settlement containing no compensation to the generic. As many as nine generic companies have settled for no compensation following a potential pay-for-delay deal on the same branded product.

Final Settlements Involving First Filers

- 43 settlements involve generics eligible for 180-day first-filer exclusivity.
 - 23 settlements contain both compensation to the generic manufacturer and a restriction on the generic manufacturer's ability to market its product.
 - 16 settlements restrict the generic manufacturer's ability to market its product, but contain no explicit compensation.
 - 4 settlements contain no restrictions on generic entry.

Comparing FY 2012 to Prior Years

In FY 2012, a record number of settlements involved potential pay-for-delay agreements. The 40 final settlements potentially involving pay for delay in FY 2012 represent a significant increase compared to FY 2011 (in which 28 potential pay-for-delay agreements were filed with the Commission), even though the total number of final settlements was similar in the two years.²

Further, the Commission received a record number of potential pay-for-delay settlements involving a no-AG commitment as a form of compensation. The 19 such settlements received by the Commission in FY 2012 were significantly greater than FY 2011 (in which 11 settlements had compensation in the form of a no-AG commitment) and FY 2010 (with 15 such settlements).

Despite the record number of potential pay-for delay settlements in FY 2012, the vast majority of patent settlements (greater than 70%) continued to be resolved without compensation to the generic manufacturer.

	FY2004	FY2005	FY2006	FY2007	FY2008	FY2009	FY2010	FY2011	FY2012
Final Settlements	14	11	28	33	66	68	113	156	140
Potential Pay-for-Delay	0	3	14	14	16	19	31	28	40
Potential Pay-for-Delay Involving First Filers	0	2	9	11	13	15	26	18	23

² For reports from previous fiscal years, see <http://www.ftc.gov/bc/healthcare/drug/index.htm>.