

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

Overview of Agreements Filed in FY 2011 A Report by the Bureau of Competition

During the fiscal year 2011 (October 1, 2010 to September 30, 2011), the Federal Trade Commission received 156 final resolutions of patent disputes between a brand and a generic. This preliminary assessment summarizes the types of final settlements received in FY 2011 and describes how the FY 2011 results compare to filings in other recent years.

Overview of Final Settlements

- 28 final settlements contain both compensation to the generic manufacturer and a restriction on the generic manufacturer's ability to market its product.
 - These settlements involve 25 different branded pharmaceutical products with combined annual U.S. sales of more than \$9 billion.
- 100 final settlements restrict the generic manufacturer's ability to market its product, but contain no explicit compensation.
- 28 final settlements have no restrictions on entry.

Final Settlements Involving First Filers

- 54 settlements involve generics eligible for 180-day first-filer exclusivity.
 - 18 settlements contain both compensation to the generic manufacturer and a restriction on the generic manufacturer's ability to market its product. 10 of these settlements include an agreement by the brand not to compete with an authorized generic or an exclusive license for the generic to market an authorized generic.
 - 29 settlements restrict the generic manufacturer's ability to market its product, but contain no explicit compensation.

Comparing FY 2011 to Prior Years

FY 2011 witnessed the continued trends of (a) record numbers of brands and generics resolving patent litigation prior to a final court decision on the merits and (b) significant numbers of such settlements potentially involving pay-for-delay. In fiscal years 2010 and 2011, the FTC received 59 potential pay-for-delay settlement agreements, almost equal to the total number of potential pay-for-delay agreements identified in the preceding six years combined. This trend similarly applies to potential pay-for-delay settlements between brands and generics eligible for 180-day first-filer exclusivity.

	FY2004	FY2005	FY2006	FY2007	FY2008	FY2009	FY2010	FY 2011
Final Settlements	14	11	28	33	66	68	113	156
Potential Pay-for-Delay	0	3	14	14	16	19	31	28
Potential Pay-for-Delay Involving First Filers	0	2	9	11	13	15	26	18