

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

Overview of Agreements Filed in FY 2010 A Report by the Bureau of Competition

During the fiscal year 2010 (October 1, 2009 to September 30, 2010), the Federal Trade Commission received 113 final resolutions of patent disputes between a brand and a generic. This preliminary assessment summarizes the types of final settlements received in FY 2010 and describes how the FY 2010 results compare to filings in other recent years.

Overview of Final Settlements

31 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 22 different branded pharmaceutical products with combined annual U.S. sales of approximately \$9.3 billion.

66 final settlements restrict the generic manufacturer's ability to market its product, but contain no explicit compensation.

- In 3 of these settlements, the brand and generic companies agreed to provisions that may provide implicit compensation to the generic in order to agree to a restriction on entry. Specifically, these agreements include a declining royalty structure in which the generic's obligation to pay royalties is reduced or eliminated if the brand launches an authorized generic product. Such a provision may achieve the same effect as an explicit agreement by the brand not to compete with an authorized generic and, thus, could be characterized as potentially involving pay-for-delay.
- 36 of these agreements involve generics not eligible for 180-day first-filer exclusivity that accept restrictions on entry in exchange for the ability to market the relevant product for some period prior to patent expiration. In 32 of these agreements, the settlement occurs with or following the brand's settlement with a first filer.

16 final settlements have no restrictions on entry.

Final Settlements Involving First Filers

49 settlements involve generics eligible for 180-day first-filer exclusivity.

- Of these 49 settlements, 26 contain both compensation to the generic manufacturer and a restriction on the generic manufacturer's ability to market its product; and
- 23 settlements restrict the generic manufacturer's ability to market its product, but contain no explicit compensation.

Comparing FY 2010 to Prior Years

FY 2010 witnessed a significant increase in the number of final settlement agreements filed, as well as the number of settlements potentially involving pay-for-delay. The number of final settlements filed in FY 2010 is almost double the amount received in any previous year. Similarly, the number of potential pay-for-delay settlements and the number of potential pay-for-delay settlements involving first filers substantially increased over any previous year.

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