

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

**Overview of Agreements Filed in FY 2013
A Report by the Bureau of Competition**

During fiscal year 2013 (October 1, 2012 to September 30, 2013), pharmaceutical companies filed 145 agreements constituting final resolutions of patent disputes between brand and generic pharmaceutical manufacturers.¹ This preliminary assessment summarizes the types of final settlements received in FY 2013 and describes how the FY 2013 results compare to filings in other recent years.

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The 13 potential pay-for-delay settlements involving first filers was the lowest number since 2008, and represented a substantial decrease from the previous three years (23 in FY 2012, 18 in FY 2011, and 26 in FY 2010).

In FY 2013, the number of potential pay-for-delay settlements involving a no-AG commitment as a form of compensation (4) was significantly lower than in previous years (19 in FY 2012, 11 in FY 2011, and 15 in FY 2010).

As has been the case in recent years, despite the existence of a substantial number of potential pay-for delay settlements in FY 2013, the vast majority (at least 73%, and up to 80%)⁴ of patent disputes were resolved without compensation to the generic manufacturer and/or without restrictions on generic competition.

A table summarizing some key figures regarding settlements filed since 2004 is attached as Exhibit 1.

⁴ The high end of the range includes as potential pay-for-delay settlements only the 29 final settlements with both compensation and a restriction on generic entry, while the low end of this range also includes the 10 settlements categorized as having “possible” compensation.

