

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.²

Overview of Final Settlements

- 29 final settlements potentially involve pay for delay because they contain both compensation from a brand manufacturer to a generic manufacturer and a restriction on the generic manufacturer's ability to market its product in competition with the branded product.
 - These 29 potential pay-for-delay settlements involve 21 different branded pharmaceutical products with combined annual U.S. sales of approximately \$4.3 billion.
- Of the 29 potential pay-for-delay settlements:
 - Nearly half (14 out of 29) include compensation solely in the form of a cash payment from the brand to the generic that purported to reimburse some or all of the generic's litigation fees.
 - Most of the other potential pay-for-delay agreements (11) included compensation in the form of a side business deal between the brand and generic manufacturer.
 - 4 agreements included compensation in 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").

¹ FY 2013 saw the first full year of filed agreements following the Third Circuit's decision in *In re K-Dur Antitrust Litigation*, 686 F.3d 197 (3d Cir. 2012), which rejected the "scope of the patent" test and adopted a "quick look" rule of reason analysis for pay-for-delay cases.

² The United States Supreme Court decided *FTC v. Actavis, Inc.*, 133 S. Ct. 2233 (2013), on June 17, 2013, resolving a split among the courts of appeals and addressing the standards that courts should apply in pay-for-delay cases. Because this decision came nearly three quarters of the way through FY 2013, there are not yet enough post-*Actavis* settlements to draw meaningful conclusions from the data.

- In 10 of the final settlements, it is not immediately obvious from the settlement agreement whether certain provisions act as compensation to the generic patent challenger. For example, an agreement containing a declining royalty structure, in which the generic’s obligation to pay royalties is reduced or eliminated if a brand launches an authorized generic product, may achieve the same effect as an explicit no-AG commitment. The agreements are currently classified as containing “possible compensation.”³ Analysis of whether there is compensation requires inquiry into specific marketplace circumstances, which lies beyond the scope of this summary report.
 - Each of these 10 settlements also contained a restriction on generic entry.
- 75 of the 145 final settlements restrict the generic manufacturer’s ability to market its product but contain no explicit or possible compensation.
- 31 of the 145 final settlements contain no restrictions on generic entry.

Final Settlements Involving First Filers

- Of the 145 final settlements filed under the MMA, 41 involve “first-filer” generics—*i.e.*, those generic producers who were the first to file abbreviated new drug applications on the litigated product and thus were eligible for 180 days of generic exclusivity under the Hatch-Waxman Act. Of the first-filer settlements:
 - 13 are potential pay-for-delay settlements.
 - 20 restrict the generic manufacturer’s ability to market its product but contain no explicit or possible compensation.
 - 5 do not restrict the generic manufacturer’s ability to market its product.
 - 3 contain possible compensation to the generic.

Comparing FY 2013 to Prior Years

In FY 2013, the number of final settlements (145) remained about the same as the last two years – 140 in FY 2012 and 156 in FY 2011. Comparing these 145 final settlements to previous years:

- The number of potential pay-for-delay agreements in FY 2013 declined to 29, representing a substantial decrease from the record high of 40 potential pay-for-delay settlements filed in FY 2012.
 - The FY 2013 totals are in line with the total number of potential pay-for-delay agreements filed in FY 2010 (31) and FY 2011 (28).

³ For a previous, similar discussion of these types of settlements, *see, e.g.*, FY 2010 Summary Report, at 1.

- 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.

EXHIBIT 1

	FY2004	FY2005	FY2006	FY2007	FY2008	FY2009	FY2010	FY2011	FY2012	FY2013
Final Settlements	14	11	28	33	66	68	113	156	140	145
Potential Pay-for-Delay	0	3	14	14	16	19	31	28	40	29
Final Settlements Involving First Filers	8	5	11	16	29	32	49	54	43	41
Potential Pay-for-Delay Involving First Filers	0	2	9	11	13	15	26	18	23	13