

# **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.<sup>1</sup> 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.<sup>2</sup>

### **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").

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<sup>1</sup> 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.

<sup>2</sup> 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.”<sup>3</sup> 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).

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<sup>3</sup> 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%)<sup>4</sup> 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.

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<sup>4</sup> 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
Potential Pay-for-Delay Involving First Filers	0	2	9	11	13	15	26	18	23	13