

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

Overview of Agreements Filed in FY 2014 A Report by the Bureau of Competition

During fiscal year 2014 (October 1, 2013 to September 30, 2014), pharmaceutical companies filed 160 agreements constituting final resolution of patent disputes between brand and generic pharmaceutical manufacturers. This report summarizes the types of final settlements filed in FY 2014 and describes how the FY 2014 results compare to filings in other recent years.

FY 2014 is the first complete year since the Supreme Court decided *FTC v. Actavis, Inc.* in June 2013, holding that a branded drug manufacturer's reverse payment to a generic competitor to settle patent litigation can violate the antitrust laws.¹ Although the number of overall final settlements in FY 2014 was consistent with other recent years, the number of settlements potentially involving pay for delay decreased significantly in the wake of the *Actavis* decision. For example, the number of potential pay-for-delay settlements in FY 2014 is roughly half the number in FY 2012, the last complete year before the *Actavis* decision.

Overview of FY 2014 Final Settlements

- 21 final settlements potentially involve pay for delay because they contain both explicit 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 21 potential pay-for-delay settlements involve 20 different branded pharmaceutical products with combined annual U.S. sales of approximately \$6.2 billion.
 - Of the 21 potential pay-for-delay settlements:
 - Ten out of 21 include compensation solely in the form of a cash payment (nine purportedly covering litigation fees and one in the form of debt forgiveness).² These cash payments range from \$35,000 to \$5 million.
 - Six of the 21 agreements include compensation in the form of a side business deal between the brand and generic manufacturers.
 - Five of the 21 agreements include 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

¹ 133 S. Ct. 2223 (2013).

² Two of these agreements also include a form of "possible compensation," discussed below.

some period of time, including four no-AG commitments with first filers.

- Eight additional final settlements are categorized as containing “possible compensation” because it is not clear from the face of each settlement agreement whether certain provisions act as compensation to the generic patent challenger.³ 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. Analysis of whether there is compensation requires inquiry into specific marketplace circumstances, which lies beyond the scope of this summary report. Each of these settlements also contained a restriction on generic entry.
- 111 of the 160 final settlements restrict the generic manufacturer’s ability to market its product but contain no explicit or possible compensation.
- 20 final settlements contain no restrictions on generic entry.

Final Settlements Involving First Filers

- Of the 160 final settlements filed under the MMA in FY 2014, 53 involve “first-filer” generics—*i.e.*, those generic producers who were the first to file abbreviated new drug applications on the litigated product and, at the time of settlement, were potentially eligible for 180 days of generic exclusivity under the Hatch-Waxman Act. Of the 53 first-filer settlements:
 - 11 contain explicit compensation to the generic and a restriction on generic sales;
 - Five contain possible compensation to the generic, but no explicit compensation;
 - 36 restrict the generic manufacturer’s ability to market its product but contain no explicit or possible compensation; and
 - One does not restrict the generic manufacturer’s ability to market its product.

Comparing FY 2014 to Prior Years

In FY 2014, the total number of final settlements (160) was not significantly different than the last three years – 156 in FY 2011, 145 in FY 2012 and 140 in FY 2013. Comparing these 160 final settlements to previous years:

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

- The number of potential pay-for-delay agreements in FY 2014 declined to 21, representing a substantial decrease from the record high of 40 potential pay-for-delay settlements filed in FY 2012, and also a sizable reduction from other recent years, including FY 2013 (29 such agreements), FY 2011 (28), and FY 2010 (31).
- The number of potential pay-for-delay settlements involving first filers (11) in FY 2014 was the lowest since 2007, when there were only 33 total final settlements for the entire fiscal year. As recently as FY 2012, the number of potential pay-for-delay settlements involving first filers was more than double (23) the number seen this year. Other recent years also saw larger numbers of potential pay-for-delay settlements involving first filers, including FY 2011 (18 such agreements) and FY 2013 (13).
- As in FY 2013, the number of potential pay-for-delay settlements involving a no-AG commitment as a form of compensation in FY 2014 was significantly lower than other recent years (19 in FY 2012, 11 in FY 2011, and 15 in FY 2010). In FY 2014, there were five such settlements, and in FY 2013, there were four.
- Building on a trend from recent years, the vast majority (at least 81% and up to 87%)⁴ of patent disputes filed in FY 2014 were resolved without compensation to the generic manufacturer and/or without restrictions on generic competition.

A table summarizing certain 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 21 final settlements with both explicit compensation and a restriction on generic entry, while the low end of this range also includes the eight settlements categorized as having “possible” compensation.

EXHIBIT 1

	FY2004	FY2005	FY2006	FY2007	FY2008	FY2009	FY2010	FY2011	FY2012	FY2013	FY2014
Final Settlements	14	11	28	33	66	68	113	156	140	145	160
Potential Pay for Delay	0	3	14	14	16	19	31	28	40	29	21
Potential Pay for Delay Involving First Filers	0	2	9	11	13	15	26	18	23	13	11