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

Overview of Agreements Filed in FY 2015
A Report by the Bureau of Competition

During fiscal year 2015 (October 1, 2014 to September 30, 2015), pharmaceutical companies filed 170 agreements constituting final resolution of patent disputes between brand and generic pharmaceutical manufacturers. This report summarizes the types of final settlements filed in FY 2015 and describes how the FY 2015 results compare to filings in other recent years.

FY 2015 is the second complete year of filings 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] Consistent with FY 2014, the number of settlements potentially involving pay for delay continues to decrease significantly in the wake of the *Actavis* decision, even though the total number of settlements filed with the FTC has increased. For example, excluding settlements in which the only compensation is the payment of less than $7 million in litigation fees,[2] only 5 of the 170 final settlements in FY 2015 include compensation to the generic and a restriction on generic entry. That is the lowest proportion of potential pay-for-delay settlements relative to total final settlements since FY 2004.

Overview of FY 2015 Final Settlements

- 14 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 14 potential pay-for-delay settlements involve 11 different branded pharmaceutical products with combined annual U.S. sales of approximately $4.6 billion.
    - Of the 14 potential pay-for-delay settlements:

[1] 133 S. Ct. 2223 (2013).

[2] Recent stipulated orders for permanent injunction entered by the Commission in reverse-payment cases have not prohibited settlements that restrict a generic's entry and include a cash payment of $7 million or less in litigation fees. *See* Stipulated Order for Permanent Injunction with Endo Pharmaceuticals Inc. and Endo International PLC, at https://www.ftc.gov/system/files/documents/cases/allergan_jt_mtn_re_stip_order.pdf; and Stipulated Order for Permanent Injunction with Teikoku Seiyaku Co., Ltd., and Teikoku Pharma USA, Inc., at https://www.ftc.gov/system/files/documents/cases/160331endoorderexh1.pdf.

- 10 of 14 include compensation solely in the form of a cash payment for litigation fees. These cash payments range from $15,000 to $9.5 million, with only one including a cash payment greater than $7 million.

- 4 of the 14 agreements include compensation in the form of a brand manufacturer's promise not to market an authorized generic in competition with the generic manufacturer's product for some period of time, one of which is with a first filer. One of these four also includes a cash payment for litigation fees.

- 10 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. 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.

- 126 of the 170 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.

- At least three final settlements involve simultaneous resolution of an inter partes review or a post grant review initiated by the generic company. None of those settlements involves compensation to the generic company, although one involves possible compensation.

Final Settlements Involving First Filers

- Of the 170 final settlements filed under the MMA in FY 2015, 39 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 39 first-filer settlements:

    - 7 contain explicit compensation to the generic and a restriction on generic sales;

    - 5 contain possible compensation to the generic and a restriction on generic sales, but no explicit compensation;

    - 24 restrict the generic manufacturer's ability to market its product but contain no explicit or possible compensation; and

- 3 do not restrict the generic manufacturer's ability to market its product.

Comparing FY 2015 to Prior Years

In FY 2015, the total number of final settlements (170) was not significantly different than the last three years –140 in FY 2012, 145 in FY 2013, and 160 in FY 2014. Comparing these 170 final settlements to previous years:

- The number of potential pay-for-delay agreements in FY 2015 declined to 14, 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 2014 (21 such agreements) FY 2013 (29), FY 2011 (28), and FY 2010 (31).

- The number of potential pay-for-delay settlements involving first filers (7) in FY 2015 was the lowest since 2005, when there were only 11 total final settlements for the entire fiscal year. The FY 2015 number is significantly reduced from other recent years, including FY 2014 (11), FY 2013 (13), FY 2012 (23), and FY 2011 (18).

- As in other recent years, the number of potential pay-for-delay settlements involving a prohibition on sales of an authorized generic for a period of time as a form of compensation in FY 2015 (4, along with 5 in FY 2014 and 4 in FY 2013) was significantly lower than previous years (19 in FY 2012, 11 in FY 2011, and 15 in FY 2010).

- Building on a trend from recent years, the vast majority (at least approx. 86% and up to approx. 92%)[3] of patent disputes filed in FY 2015 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.

[3] The high end of the range includes as potential pay-for-delay settlements only the 14 final settlements with both explicit 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	FY2014	FY2015
Final Settlements	14	11	28	33	66	68	113	156	140	145	160	170
Potential Pay for Delay	0	3	14	14	16	19	31	28	40	29	21	14
Potential Pay for Delay (excluding Solely Litigation Fees < $7 million)	0	3	13	14	15	11	17	25	33	15	11	5
Potential Pay for Delay Involving First Filers	0	2	9	11	13	15	26	18	23	13	11	7