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

Overview of Agreements Filed in FY 2016
A Report by the Bureau of Competition

During fiscal year 2016 (October 1, 2015 to September 30, 2016), pharmaceutical companies filed 232 agreements constituting final resolution of patent disputes between brand and generic pharmaceutical manufacturers, significantly more than any other year since enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA").[1]

Overview of FY 2016 Final Settlements—In FY 2016, the FTC received 232 final settlements relating to 103 distinct branded products. For 40 of those products, the FTC received its first final settlement covering that product in FY 2016; for the other 63 products, the FTC had received a final settlement relating to the product in one or more previous fiscal years.

- 30 final settlements 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.
    - 29 of these 30 agreements contain payment in the form of litigation fees, with the brand manufacturer's payment to the generic manufacturer ranging from $250,000 to $7 million.
        - The average payment is $2.85 million, with 27 of the 29 agreements containing payments less than $7 million.
        - Three of these 29 agreements also involve a form of possible compensation (discussed below).
    - The single remaining final agreement involves 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.
- 14 additional final settlements are categorized as containing one or more forms of "possible compensation" because it is not clear from the face of each agreement whether certain provisions act as compensation to the generic patent challenger. 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 contains a restriction on generic entry.

[1] This report summarizes the types of final settlements filed in FY 2016. A table summarizing certain key figures regarding settlements filed since 2004 is attached as Exhibit 1.

- The most common form of possible compensation—appearing in 9 final settlements—is a commitment from the brand manufacturer not to use a third party to distribute an authorized generic for a period of time, such as during first-filer exclusivity. This type of commitment could have the same effect as an explicit no-AG commitment, for example, if the brand company does not market generics in the United States.

- Another common form of possible compensation is 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. This type of provision may achieve the same effect as an explicit no-AG commitment, and appear in 3 agreements in FY 2016.

- 151 of the 232 final settlements restrict the generic manufacturer's ability to market its product but contain no explicit or possible compensation.

- 37 final settlements contain no restrictions on generic entry. None of these involve explicit or possible compensation to the generic manufacturer.

Final Settlements Involving First Filers

- Of the 232 final settlements filed under the MMA in FY 2016, 76 involve "first-filer" generics—*i.e.*, those generic manufacturers 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 these 76 first-filer settlements:

    - 16 contain explicit compensation to the generic—all in the form of payment for litigation costs—and a restriction on generic sales;[2]

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

    - 48 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.

Features of Final Settlements

- *Scope of Patent License*—215 of the 232 final settlements involve the generic manufacturer receiving rights to patents that were not the subject of any litigation between the brand manufacturer and that generic manufacturer.

    - In 191 of these final settlements, the generic manufacturer receives licenses or covenants not to sue covering all patents that the brand

[2] Two of these 16 agreements also include possible compensation.

manufacturer owns at settlement or at any time in the future that could be alleged to cover the generic product.

- In 24 other final settlements, the generic manufacturer receives licenses or covenants not to sue covering some, but not all, such additional patents.

- *Acceleration Clauses*—187 final settlements contain a restriction on the generic manufacturer selling its product for some period of time, but also provide the generic manufacturer a license or covenant not to sue to begin selling the generic product prior to the expiration of the relevant patent(s).

    - 177 of these 187 agreements contain provisions that accelerate the effective date of the licenses or covenants not to sue based on other events.

    - Some of the most common events that accelerate a licensed entry date are: (i) another company selling a generic version of the branded product, (ii) another company obtaining a final court decision of patent invalidity or unenforceability or of non-infringement, (iii) the brand manufacturer licensing a third party with an earlier entry date, (iv) sales of the branded product falling below specified thresholds, or (v) the brand manufacturer obtaining FDA approval for another product with the same active ingredient.

- *At-Risk Launch*—13 of the final settlements occurred after the generic company had launched its product at risk. Each of these settlements permitted the generic manufacturer to continue selling the generic product and required the generic company to pay the brand manufacturer damages for the at-risk sales, with approximately $12.5 million as the average amount of damages.[3]

- *PTAB Settlements*—At least two final settlements involve simultaneous resolution of federal court litigation and an *inter partes* review or a post-grant review initiated by the generic manufacturer. One of those settlements involves compensation to the generic manufacturer.

[3] This calculation likely overstates the amount of damages, because in most cases the dollar totals reflected damages for past at-risk sales and a lump-sum royalty for future sales of the generic product. Because the amount for future sales is not apportioned separately, the whole amount is included as damages for at-risk sales for purposes of this calculation.

EXHIBIT 1

	FY2004	FY2005	FY2006	FY2007	FY2008	FY2009	FY2010	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016
Final Settlements	14	11	28	33	66	68	113	156	140	145	160	170	232
w/ Restriction on Generic Entry and Compensation	0	3	14	14	16	19	31	28	40	29	21	14	30
w/ Restriction on Generic Entry and Compensation (excluding Solely Litigation Fees $\leq$ $7 million)	0	3	13	14	15	11	17	25	33	15	11	5	1
w/ Restriction on Generic Entry and Compensation Involving First Filers	0	2	9	11	13	15	26	18	23	13	11	7	16