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

Overview of Agreements Filed in FY 2018
A Report by the Bureau of Competition

During fiscal year 2018 (October 1, 2017 to September 30, 2018), pharmaceutical companies filed 245 agreements constituting final resolution of patent disputes between brand and generic pharmaceutical manufacturers. This figure represents the most final settlements in any year since enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA").[1]

Overview of FY 2018 Final Settlements—In FY 2018, the FTC received 245 final settlements relating to 111 distinct branded products. For 44 of those products, the FTC received its first final settlement covering that product in FY 2018; for the other 67 products, the FTC had received a final settlement relating to the product in one or more previous fiscal years.

- 38 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.
    - 36 of these 38 agreements include explicit compensation solely in the form of litigation fees. 1 of the 38 agreements includes litigation fees and another type of explicit compensation (discussed below).
        - The brand manufacturer's payment to the generic manufacturer ranges from $150,000 to $7 million. The average payment is $2.017 million.
        - 9 of these 37 agreements also involve a form of possible compensation (discussed below).
    - 2 of these 38 agreements include explicit compensation apart from litigation fees. One agreement is between the brand and a first filer and includes a no-AG provision allowing the first filer to sell AG product 180 days before the brand's AG or other generics enter. The other agreement is between the brand and a non-first filer that appoints the generic manufacturer as the exclusive distributor of the brand's authorized generic product.
- 5 final settlements (in addition to 9 settlements referenced above that also contain explicit compensation, totaling 14 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

[1] This report summarizes the types of final settlements filed in FY 2018. A table summarizing certain key figures regarding settlements filed since 2004 is attached as Exhibit 1.

settlements also contains a restriction on generic entry. Common forms of possible compensation include:

- 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. This type of provision appears in 4 agreements in FY 2018.

- A declining royalty structure, in which the generic's obligation to pay royalties is reduced or eliminated if the brand launches an authorized generic product. This type of provision may achieve the same effect as an explicit no-AG commitment and appears in 4 agreements in FY 2018.

- An agreement that restricts the quantity the settling generic can sell for a period of time. This type of arrangement will likely not create the same level of competition and price reductions for consumers we would expect to see if the settling generic's ability to sell competing products was unrestricted. This type of provision appears in 7 agreements in FY 2018.

- 169 of the 245 final settlements restrict the generic manufacturer's ability to market its product but contain no explicit or possible compensation.

- 33 final settlements contain no restriction on generic entry. None of these agreements involve compensation to the generic manufacturer.

Final Settlements Involving First Filers

- Of the 245 final settlements filed in FY 2018, 110 involve "first-filer" generics—*i.e.*, generic manufacturers that 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 110 first-filer settlements:

  - 18 contain explicit compensation to the generic and a restriction on generic sales.

    - 17 of these 18 agreements include explicit compensation in the form of litigation fees.

    - 1 of these 18 agreements includes explicit compensation in the form of a no-AG provision allowing the first filer to sell AG product 180 days before the brand's AG or other generics enter.

    - 5 of these 18 agreements also include forms of possible compensation.

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

- 73 restrict the generic manufacturer's ability to market its product but contain no explicit or possible compensation.

- 15 do not restrict the generic manufacturer's ability to market its product and do not contain compensation to the generic manufacturer.

Features of Final Settlements

- *Scope of Patent License*—In the vast majority of the 245 final settlements, the generic receives patent rights beyond just the litigated patents:

    - 214 of the 245 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 193 of these final settlements, the generic manufacturer receives licenses or covenants not to sue covering all patents that the brand manufacturer owns at settlement or at any time in the future that could be alleged to cover the generic product.

        - In 21 other final settlements, the generic manufacturer receives licenses or covenants not to sue covering some, but not all, such additional patents.

    - In 5 final settlements, the generic manufacturer only receives a license to the litigated patents.

    - In the remaining 26 final settlements, the generic manufacturer does not receive the right to any patents, including the litigated patents, because the agreements involve a Paragraph III conversion, the withdrawal of the ANDA, a dismissal in which the generic did not obtain the right to enter until the patent(s) expired, or a dismissal where the generic obtained the right to enter immediately.

- *Acceleration Clauses*—179 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).

    - 174 of these 179 agreements contain provisions that accelerate the effective date of the licenses or covenants not to sue based on other events. The other 5 agreements do not contain any acceleration provisions.

    - 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*—3 of the final settlements occurred after the generic manufacturer had launched its product at risk.
    - Each of these settlements permit the generic manufacturer to continue selling the generic product and do not require the generic manufacturer to pay the brand manufacturer damages for the at-risk sales.
- *PTAB Settlements*—At least 11 of the final settlements involve simultaneous resolution of federal court litigation and an *inter partes* review or a post-grant review initiated by the generic manufacturer.
    - 7 of these settlements involve explicit compensation to the generic manufacturer. 2 of the 7 agreements also include possible compensation.

Additional Features of Agreements—In FY 2018, the FTC received 1 interim agreement in which the generic manufacturer receives a cash payment in exchange for agreeing not to launch its generic product while waiting for a decision from the Federal Circuit. The amount of the payment depended on the outcome at the Federal Circuit. At the time of the agreement, the district court had already found in favor of the generic on all but one patent (the remaining patent terminated during the pending appeal). Even though the size of the payment in this agreement is contingent, the agreement raises competitive concerns because it disincentivizes the generic manufacturer from launching its competing product following the favorable district court decision. Under the agreement, if the generic manufacturer prevails at the Federal Circuit, it would be made "whole," but consumers would have been harmed by the lack of access to the generic's product.

EXHIBIT 1

	FY2004	FY2005	FY2006	FY2007	FY2008	FY2009	FY2010	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017	FY2018
Final Settlements	14	11	28	33	66	68	113	156	140	145	160	170	232	226	245
w/ Restriction on Generic Entry and Compensation	0	3	14	14	16	19	31	28	40	29	21	14	30	20	38
w/ Restriction on Generic Entry and Compensation (excluding Solely Litigation Fees ≤ $7 million)	0	3	13	14	15	11	17	25	33	15	11	5	1	3	2
w/ Restriction on Generic Entry and Compensation Involving First Filers	0	2	9	11	13	15	26	18	23	13	11	7	16	6	18