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

Overview of Agreements Filed in FY 2019
A Report by the Bureau of Competition

During fiscal year 2019 (October 1, 2018 to September 30, 2019), pharmaceutical companies filed 194 agreements constituting final resolution of patent disputes between brand and generic pharmaceutical manufacturers.[1]

Overview of FY 2019 Final Settlements—In FY 2019, the FTC received 194 final settlements relating to 104 distinct branded products. For 46 of those products, the FTC received its first final settlement covering that product in FY 2019; for the other 58 products, the FTC had received a final settlement relating to the product in one or more previous fiscal years.

- 24 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.
    - 23 of these 24 agreements include explicit compensation solely in the form of litigation fees.
        - The brand manufacturer's payment to the generic manufacturer ranges from $500,000 to $9 million. 2 of these 23 agreements include a payment of litigation fees from the brand to the generic that is over $7 million. The average payment is $3.465 million.
        - 1 of these 23 agreements contains explicit compensation in the form of litigation fees in a secondary agreement by the same parties entered within 30 days of (but not on the same day as) the patent litigation settlement.
        - 5 of these 23 agreements also involve a form of possible compensation (discussed below).
    - 1 of these 23 agreements includes explicit compensation apart from litigation fees. The agreement appoints the generic manufacturer as the exclusive distributor of the brand's authorized generic product and includes a side deal in which the generic agrees to copromote the brand's product and the brand's authorized generic product.
- 5 final settlements (in addition to 5 settlements referenced above that also contain explicit compensation, totaling 10 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

[1] This report summarizes the types of final settlements filed in FY 2019. A table summarizing certain key figures regarding settlements filed since 2004 is attached as Exhibit 1.

circumstances, which lies beyond the scope of this summary report. Each of these 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.[2] This type of provision appears in 1 agreement in FY 2019.

- Similarly, an agreement where the brand gives the generic manufacturer a right of first refusal to act as the brand's third-party distributor of the brand's authorized generic product. This type of provision may act like an explicit no-AG commitment and appears in 2 agreements in FY 2019.

- 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 1 agreement in FY 2019.

- An agreement that provides AG supply to a non-first filer ANDA holder during the first filer's exclusivity period, thereby permitting the non-first filer ANDA holder to sell an authorized generic during the exclusivity period. While such an arrangement may have competitive benefits under certain circumstances, the ability to earn profits during the 180-day period when the ANDA holder would not otherwise be approved to sell could also induce the ANDA holder to abandon patent litigation that might result in earlier generic entry. This type of provision appears in 1 agreement in FY 2019.

- 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 3 agreements in FY 2019.

- An agreement that provides for a potential reduction of potentially significant infringement damages stemming from a prior at-risk launch. This type of arrangement may act as a mechanism to transfer millions of dollars from the brand to the generic manufacturer to induce the generic manufacturer to settle and exit the market without raising the specter of an explicit cash payment in the settlement agreement. This type of provision appears in 1 agreement in FY 2019.

- An agreement that gives the generic manufacturer a much earlier license date in foreign jurisdictions (as compared to the U.S. license date for the product at

[2] A no-AG commitment is where the brand commits not to sell an authorized generic, or AG, for some period. Settlements that contain this type of commitment raise antitrust concerns because potential rivals agree to avoid competition and share the resulting monopoly profits.

issue). It is possible that this structure would compensate the generic for delaying entry into the U.S. market while simultaneously limiting U.S. consumers' access to affordable pharmaceutical products. This type of provision appears in 1 agreement in FY 2019. The possible compensation in this agreement is in a secondary agreement by the same parties entered within 30 days of (but not on the same day as) the patent litigation settlement.

- 145 of the 194 final settlements restrict the generic manufacturer's ability to market its product but contain no explicit or possible compensation.

- 20 final settlements contain no restriction on generic entry.

    - 3 of these agreements involve explicit compensation to the generic manufacturer in the form of a cash payment settling claims related to the destruction of recalled product for a different product, a side deal updating the pricing for an existing supply deal for other products, and a provision appointing the generic manufacturer as the exclusive distributor of the brand's authorized generic product. 2 of these agreements contain explicit compensation in a secondary agreement by the same parties entered within 30 days of (but not on the same day as) the patent litigation settlement.

    - 17 of these agreements contain no compensation to the generic manufacturer.

Final Settlements Involving First Filers

- Of the 194 final settlements filed in FY 2019, 97 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 97 first-filer settlements:

    - 14 contain explicit compensation to the generic and a restriction on generic sales. All these agreements include compensation in the form of litigation fees.

        - 1 of these 14 agreements contains compensation in a secondary agreement by the same parties entered within 30 days of (but not on the same day as) the patent litigation settlement.

        - 1 of these 14 agreements also includes possible compensation.

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

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

    - 1 does not restrict the generic manufacturer's ability to market its product. This agreement contains explicit compensation to the generic manufacturer in the form

of a provision appointing the generic manufacturer as the exclusive distributor of the brand's authorized generic product.

Features of Final Settlements

- *Scope of Patent License*—In the vast majority of the 194 final settlements, the generic receives patent rights beyond just the litigated patents:
    - 176 of the 194 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 164 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 12 other final settlements, the generic manufacturer receives licenses or covenants not to sue covering some, but not all, such additional patents.
    - In 4 final settlements the generic manufacturer only receives a license to the litigated patents.
    - In the remaining 14 final settlements, the generic manufacturer does not receive the right to any patents, including the litigated patents, because the agreements involve the withdrawal of the ANDA or a dismissal in which the generic did not obtain the right to enter until the patent(s) expired.
- *Acceleration Clauses*—153 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).
    - 149 of these 153 agreements contain provisions that accelerate the effective date of the licenses or covenants not to sue based on other events. The other 4 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.

- 2 of these settlements permit the generic manufacturer to continue selling the generic product and require the generic manufacturer to pay the brand manufacturer royalties on the at-risk sales and future sales.

- 1 of these settlements grants the generic manufacturer a license for a future date and requires the generic manufacturer to pay the brand manufacturer damages up to $40 million for the at-risk sales.

- *PTAB Settlements*—6 of the final settlements involve the simultaneous resolution of federal court litigation and an *inter partes* review or a post-grant review initiated by the generic manufacturer.

    - 3 of these settlements involve explicit compensation to the generic manufacturer in the form of litigation fees. 1 of the 3 agreements with explicit compensation also includes possible compensation.

    - 1 of these agreements contains compensation in a secondary agreement by the same parties entered within 30 days of (but not on the same day as) the patent litigation settlement.

Additional Features of Agreements—On October 24, 2018, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") was amended to require brand and generic manufacturers to submit agreements that were entered within 30 days of an agreement subject to the MMA. Thus, FY 2019 contains the first set of agreements subject to this requirement.

- For 7 final settlements, the FTC received one or more additional agreements that the parties entered into within 30 days of the primary agreement (but not on the same day as the primary agreement).

    - For 3 of these final settlements, one or more of the additional agreements the FTC received contain explicit compensation. For 1 of these final settlements, one or more of the additional agreements the FTC received also contain possible compensation.

    - For 4 of these final settlements, none of the additional agreements the FTC received contain compensation.

EXHIBIT 1

	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
Final Settlements	14	11	28	33	66	68	113	156	140	145	160	170	232	226	245	194
w/ Restriction on Generic Entry and Compensation	0	3	14	14	16	19	31	28	40	29	21	14	30	20	38	24
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	3	2	3
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	14