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

Overview of Agreements Filed in FY 2020
A Report by the Bureau of Competition

During fiscal year 2020 (October 1, 2019 to September 30, 2020), pharmaceutical companies filed 205 agreements constituting final resolution of patent disputes between brand and generic pharmaceutical manufacturers.[1]

Overview of FY 2020 Final Settlements—In FY 2020, the FTC received 205 final settlements relating to 111 distinct branded products. For 34 of those products, the FTC received its first final settlement covering that product in FY 2020; for the other 77 products, the FTC had received a final settlement relating to the product in one or more previous fiscal years.

- 20 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.
    - 19 of these 20 agreements include explicit compensation solely in the form of litigation fees.
        - The brand manufacturer's payment to the generic manufacturer ranges from $45,000 to $5 million. The average payment is $1.591 million.
        - 1 of these 20 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.
        - 2 of these 19 agreements also involve a form of possible compensation (discussed below).
    - 1 of these 20 agreements includes explicit compensation apart from litigation fees in the form of a side deal that transfers the rights to seven of the brand's products to the generic manufacturer. The compensation in this agreement is from a secondary agreement by the same parties entered within 30 days of (but not on the same day as) the patent litigation settlement.
- 1 final settlement (in addition to the 2 settlements referenced above that also contain explicit compensation, totaling 3 final settlements) is categorized as containing one or more forms of "possible compensation" because it is not clear from the face of the 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. This

[1] This report summarizes the types of final settlements filed in FY 2020. A table summarizing certain key figures regarding settlements filed since 2004 is attached as Exhibit 1.

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

- 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 2 agreements in FY 2020.

- 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 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 2020.

- 170 of the 205 final settlements restrict the generic manufacturer's ability to market its product but contain no explicit or possible compensation.

- 14 final settlements contain no restriction on generic entry. 1 of these agreements involves explicit compensation to the generic manufacturer in the form of a side deal requiring the brand to pay a royalty to the generic manufacturer in exchange for a license to one of the generic manufacturer's patents. The compensation in this agreement is from a secondary agreement by the same parties entered within 30 days of (but not on the same day as) the patent litigation settlement.

Final Settlements Involving First Filers

- Of the 205 final settlements filed in FY 2020, 94 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 94 first-filer settlements:

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

    - 10 of these 11 agreements include explicit compensation in the form of litigation fees.

    - 1 of these 11 agreements includes explicit compensation in the form of a side deal that transfers the rights to seven of the brand's products to the generic manufacturer. The compensation in this agreement is from 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 11 agreements also includes possible compensation.

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

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

- 2 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 205 final settlements, the generic receives patent rights beyond just the litigated patents:

    - 181 of the 205 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 167 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 14 other final settlements, the generic manufacturer receives licenses or covenants not to sue covering some, but not all, such additional patents.

    - In 12 final settlements the generic manufacturer only receives a license to the litigated patents.

    - In the remaining 12 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, 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*—157 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).

    - 154 of these 157 agreements contain provisions that accelerate the effective date of the licenses or covenants not to sue based on other events. The other 3 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 company to pay the brand manufacturer damages up to $10 million for the at-risk sales.
    - The third settlement grants the generic manufacturer a license for a future date and does not require the generic to pay the brand any damages relating to the at-risk sales.
- *PTAB Settlements*—3 of the final settlements involve the simultaneous resolution of a federal court litigation and an *inter partes* review or a post-grant review initiated by the parties. All these settlements involve explicit compensation to the generic manufacturer.
    - 2 of these agreements contain explicit compensation in the form of litigation fees. The remaining agreement contains explicit compensation in the form of a side deal requiring the brand to pay a royalty to the generic manufacturer in exchange for a license to one of the generic manufacturer's patents.
    - 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 Agreements Entered Within 30 Days*—For 20 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 to the generic manufacturer in the form of litigation fees and/or a side deal.
    - For 17 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	FY 2020
Final Settlements	14	11	28	33	66	68	113	156	140	145	160	170	232	226	245	194	205
w/ Restriction on Generic Entry and Compensation	0	3	14	14	16	19	31	28	40	29	21	14	30	20	38	24	20
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	1
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	11