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

Overview of Agreements Filed in FY 2021
A Report by the Bureau of Competition

During fiscal year 2021 (October 1, 2020 to September 30, 2021), pharmaceutical companies filed 199 agreements constituting final resolution of patent disputes between brand and generic pharmaceutical manufacturers.[1]

Overview of FY 2021 Final Settlements—In FY 2021, the FTC received 199 final settlements relating to 86 distinct branded products. For 21 of those products, the FTC received its first final settlement covering that product in FY 2021; for the other 65 products, the FTC had received a final settlement relating to the product in one or more previous fiscal years.

- 33 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.
    - All these agreements include explicit compensation solely in the form of litigation fees.
        - The brand manufacturer's payment to the generic manufacturer ranges from $100,000 to $7 million. The average payment is $3.082 million.
        - 3 of these 33 agreements contain 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.
        - 12 of these 32 agreements also involve a form of possible compensation (discussed below).
- 5 final settlements (in addition to the 12 settlements referenced above that also contain explicit compensation, totaling 17 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. 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

[1] This report summarizes the types of final settlements filed in FY 2021. A table summarizing certain key figures regarding settlements filed since 2004 is attached as Exhibit 1.

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 2021.

- 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 or authorizes a third party to launch an authorized generic product. This type of provision may achieve the same effect as an explicit no-AG commitment and appears in 2 agreements in FY 2021.

- 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 4 agreements in FY 2021.

- 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 11 agreements in FY 2021.

- 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 2021. 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.

- 152 of the 199 final settlements restrict the generic manufacturer's ability to market its product but contain no explicit or possible compensation.

- 9 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.

Final Settlements Involving First Filers

- Of the 199 final settlements filed in FY 2021, 101 involve "first-filer" generics—*i.e.*, generic manufacturers that were the first to file abbreviated new drug applications on the

[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.

litigated product and, at the time of settlement, were potentially eligible for 180 days of generic exclusivity under the Hatch-Waxman Act. Of these 101 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.
  - 2 of these 14 agreements also include possible compensation.
- 3 contain 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.
- 4 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 199 final settlements, the generic receives patent rights beyond just the litigated patents:
  - 187 of the 199 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 176 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 11 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 7 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*—167 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).

  - 166 of these 167 agreements contain provisions that accelerate the effective date of the licenses or covenants not to sue based on other events. The remaining agreement does 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*—None of the final settlements occurred after the generic manufacturer had launched its product at risk.

- *PTAB Settlements*—7 of the final settlements involve the resolution of an *inter partes* review or a post-grant review initiated by the generic manufacturer.

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

  - None of these settlements involve compensation to the generic manufacturer.

- *Additional Agreements Entered Within 30 Days*—For 22 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 in the form of litigation fees. For 1 of these final settlements, one or more of the additional agreements the FTC received also contain possible compensation.

  - For 19 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	FY 2021
Final Settlements	14	11	28	33	66	68	113	156	140	145	160	170	232	226	245	194	205	199
w/ Restriction on Generic Entry and Compensation	0	3	14	14	16	19	31	28	40	29	21	14	30	20	38	24	20	33
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	0
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	14