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

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.

issue). It is possible that this structure would compensate the generic for delaying

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
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

  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 - *i.e.*,

- 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.

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EXHIBIT 1

FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	