

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

## Overview of Agreements Filed in FY 2017 A Report by the Bureau of Competition

During fiscal year 2017 (October 1, 2016 to September 30, 2017), pharmaceutical companies filed 226 agreements constituting final resolution of patent disputes between brand and generic pharmaceutical manufacturers. This figure represents a slight decline from the 232 in FY 2016, which remains the most final settlements in any year since enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”).<sup>1</sup>

**Overview of FY 2017 Final Settlements**—In FY 2017, the FTC received 226 final settlements relating to 114 distinct branded products. For 46 of those products, the FTC received its first final settlement covering that product in FY 2017; for the other 68 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.
  - 17 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 \$500,000 to \$6.5 million. The average payment is \$2.78 million.
    - 2 of these 17 agreements also involve a form of possible compensation (discussed below).
  - 3 of these 20 agreements include explicit compensation beyond solely litigation fees.
    - One involves a side deal in which the brand manufacturer assigned the generic manufacturer five patents unrelated to the litigated product at no cost.
    - One involves a side deal in which the generic sold intellectual property related to the litigated product to the brand manufacturer. This settlement also includes litigation fees and a form of possible compensation (discussed below).

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<sup>1</sup> This report summarizes the types of final settlements filed in FY 2017. A table summarizing certain key figures regarding settlements filed since 2004 is attached as Exhibit 1.

- One involves the brand manufacturer acquiring the generic manufacturer's potentially competing 505(b)(2)<sup>2</sup> product that was the subject of the patent litigation.
- 8 final settlements (in addition to the 3 settlements referenced above that also contain explicit compensation, totaling 11 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 commitment, for example, if the brand company does not market generics in the United States; this provision appears in 5 agreements in FY 2017.
  - A declining royalty structure, in which the generic's obligation to pay royalties is reduced or eliminated if a 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 2017.
  - 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 2017.
- 169 of the 226 final settlements restrict the generic manufacturer's ability to market its product but contain no explicit or possible compensation.
- 29 final settlements contain no restrictions on generic entry.
  - 2 of these agreements involve explicit compensation to the generic manufacturer.

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<sup>2</sup> The 505(b)(2) NDA pathway is a streamlined drug approval process that allows applicants to rely on existing literature or clinical data. It can be used to seek approval of a brand product and may also be used to seek approval of a generic product in situations where the ANDA pathway is not appropriate. *See* 21 U.S.C. § 355(b)(2).

- One provides compensation in the form of litigation fees.
- One provides compensation in the form of a supply deal for a dosage strength of the litigated product that was not covered by the generic manufacturer's ANDA.

### **Final Settlements Involving First Filers**

- Of the 226 final settlements filed in FY 2017, 72 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 72 first-filer settlements:
  - 6 contain explicit compensation to the generic and a restriction on generic sales. All 6 of these agreements include compensation in the form of litigation fees.
    - 1 of these 6 agreements also includes explicit compensation in the form of a side deal in which the generic sold intellectual property related to the litigated product to the brand manufacturer and a form of possible compensation.
    - 2 of these 6 agreements (in addition to the agreement referenced in the bullet above, totaling 3 agreements) also include a form of possible compensation.
  - 5 contain possible compensation to the generic and a restriction on generic sales, but no explicit compensation.
  - 55 restrict the generic manufacturer's ability to market its product but contain no explicit or possible compensation.
  - 6 do not restrict the generic manufacturer's ability to market its product.
    - 1 of these 6 agreements provides compensation in the form of litigation fees.

### **Features of Final Settlements**

- *Scope of Patent License*—205 of the 226 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. None of the 226 final settlements involved a generic company receiving an exclusive license to any patent.
  - In 177 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 28 other final settlements, the generic manufacturer receives licenses or covenants not to sue covering some, but not all, such additional patents.
- In 10 final settlements the generic manufacturer only received a license to the litigated patents.
- In the remaining 11 final settlements, the generic manufacturer did not receive the right to any patents, including the litigated patents, because the agreements involved the withdrawal of the ANDA or a dismissal in which the generic did not obtain the right to enter until the patent expired.
- *Acceleration Clauses*—192 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 that would allow the generic manufacturer to begin selling the generic product prior to the expiration of the relevant patent(s).
  - 181 of these 192 agreements contain provisions that accelerate the effective date of the licenses or covenants not to sue based on other events.
  - 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 company had launched its product at risk. Each of these settlements permitted the generic manufacturer to continue selling the generic product and require the generic company to pay the brand manufacturer damages up to \$250,000 for the at-risk sales.
- *PTAB Settlements*—11 of the final settlements involve the resolution of an *inter partes* review or a post-grant review initiated by the generic manufacturer.
  - 5 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.
    - 2 of these settlements involve explicit compensation to the generic manufacturer in the form of litigation fees.

- 6 of these final settlements involve resolution of an *inter partes* review initiated by the generic manufacturer prior to its ANDA being filed, avoiding federal litigation entirely.
  - 4 of these 6 settlements involve explicit compensation to the generic manufacturer in the form of litigation fees.
  - 1 involves explicit compensation in the form of a side deal in which the brand manufacturer assigned the generic manufacturer five patents unrelated to the litigated product at no cost.

**EXHIBIT 1**

|   | FY2004 | FY2005 | FY2006 | FY2007 | FY2008 | FY2009 | FY2010 | FY2011 | FY2012 | FY2013 | FY2014 | FY2015 | FY2016 | FY2017 |
|---|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|
| Final Settlements   | 14     | 11     | 28     | 33     | 66     | 68     | 113    | 156    | 140    | 145    | 160    | 170    | 232    | 226    |
| w/ Restriction on Generic Entry and Compensation  | 0      | 3      | 14     | 14     | 16     | 19     | 31     | 28     | 40     | 29     | 21     | 14     | 30     | 20     |
| 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      |
| w/ Restriction on Generic Entry and Compensation Involving First Filers                           | 0      | 2      | 9      | 11     | 13     | 15     | 26     | 18     | 23     | 13     | 11     | 7      | 16     | 6      |