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

Summary of Agreements Filed in FY 2006
A Report by the Bureau of Competition

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) requires that pharmaceutical companies file certain agreements with the Federal Trade Commission and the Department of Justice within ten days of execution.[1] Below, we summarize the number and types of agreements received during fiscal year 2006 (October 1, 2005 to September 30, 2006) and compare them with the ones reported in FY 2005 and FY 2004.

This summary provides information about the agreements using criteria similar to those used in past years. Those criteria include:

- whether the agreement was between a brand and generic drug manufacturer or between two generic manufacturers;
- whether the agreement was a final settlement, an interim agreement that did not resolve the patent litigation, or another type of agreement;
- whether the agreement restricted generic entry;
- whether the agreement involved any payments between the parties; and
- whether the agreement involved the first generic to file for FDA approval (a "first-filer generic company") or a subsequent generic filer.[2]

In FY 2006, the Commission received 45 agreements under the MMA, more than double the number of agreements received in each of the two previous years. It is worth noting that all of the agreements received in FY 2006 occurred after the 11th Circuit Court of Appeals' decision in *Schering-Plough v. Federal Trade Commission*, reversing the Commission's decision that two settlements involving a restriction on generic entry and compensation to the generics violated the Federal Trade Commission Act.[3] In addition, the Eleventh Circuit rejected the Commission's determination, that in one of the settlements, a $60 million payment from the brand to the generic was substantially for delay and not for unrelated products sold to the brand.

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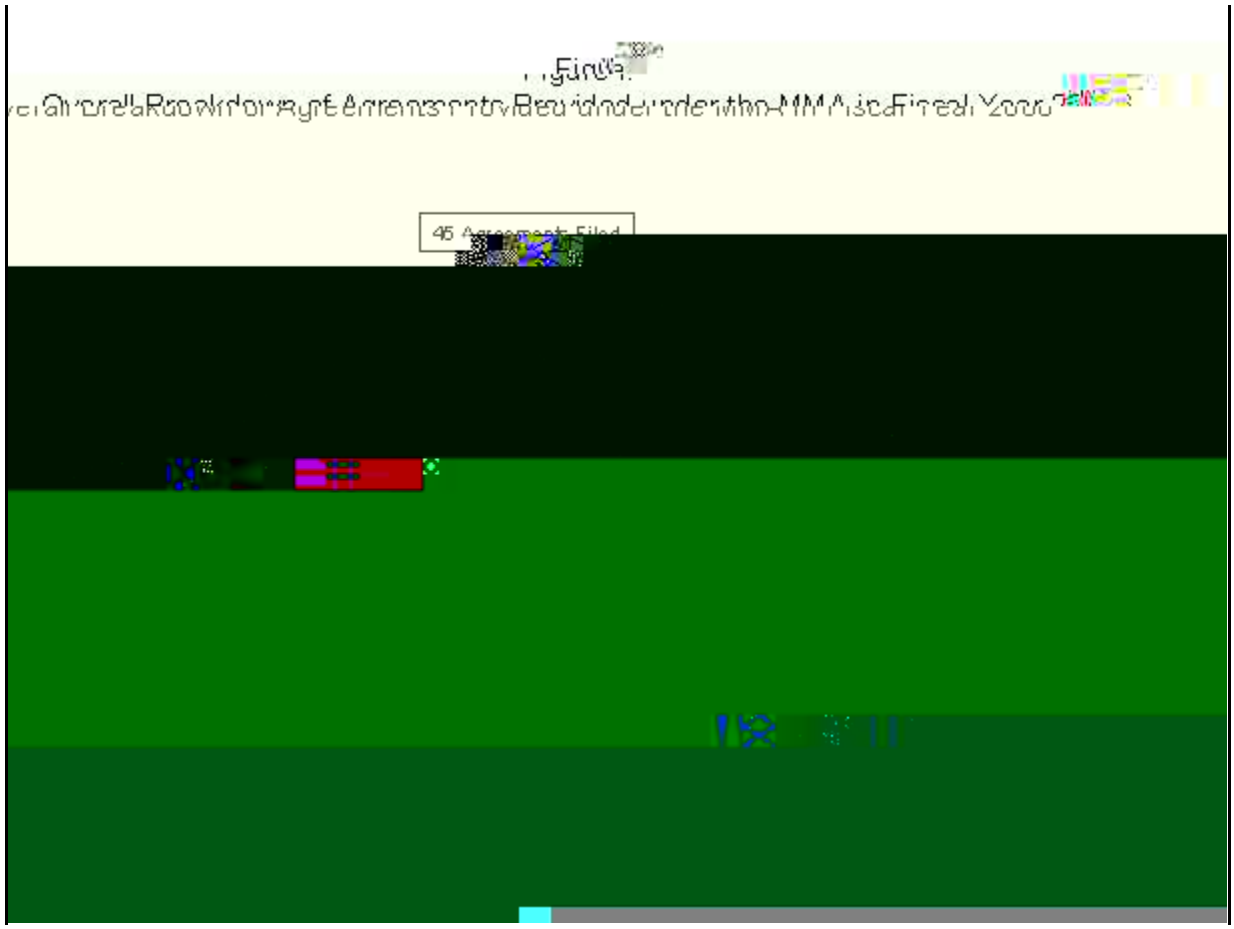
[1] For further information on the types of agreements that must be filed with the FTC, see "Pharmaceutical Agreement Filing Requirements," available at www.ftc.gov/os/2004/01/040106pharmules.pdf.

[2] A first-filer generic company refers to the generic company that is the first to file an ANDA with a Paragraph IV certification pursuant to the Hatch-Waxman Act. Under the Hatch-Waxman Act, the first filer is eligible for 180 days of market exclusivity. During that exclusivity, the FDA may not approve any additional generic filers. A subsequent generic filer means any generic filer that is not the first filer.

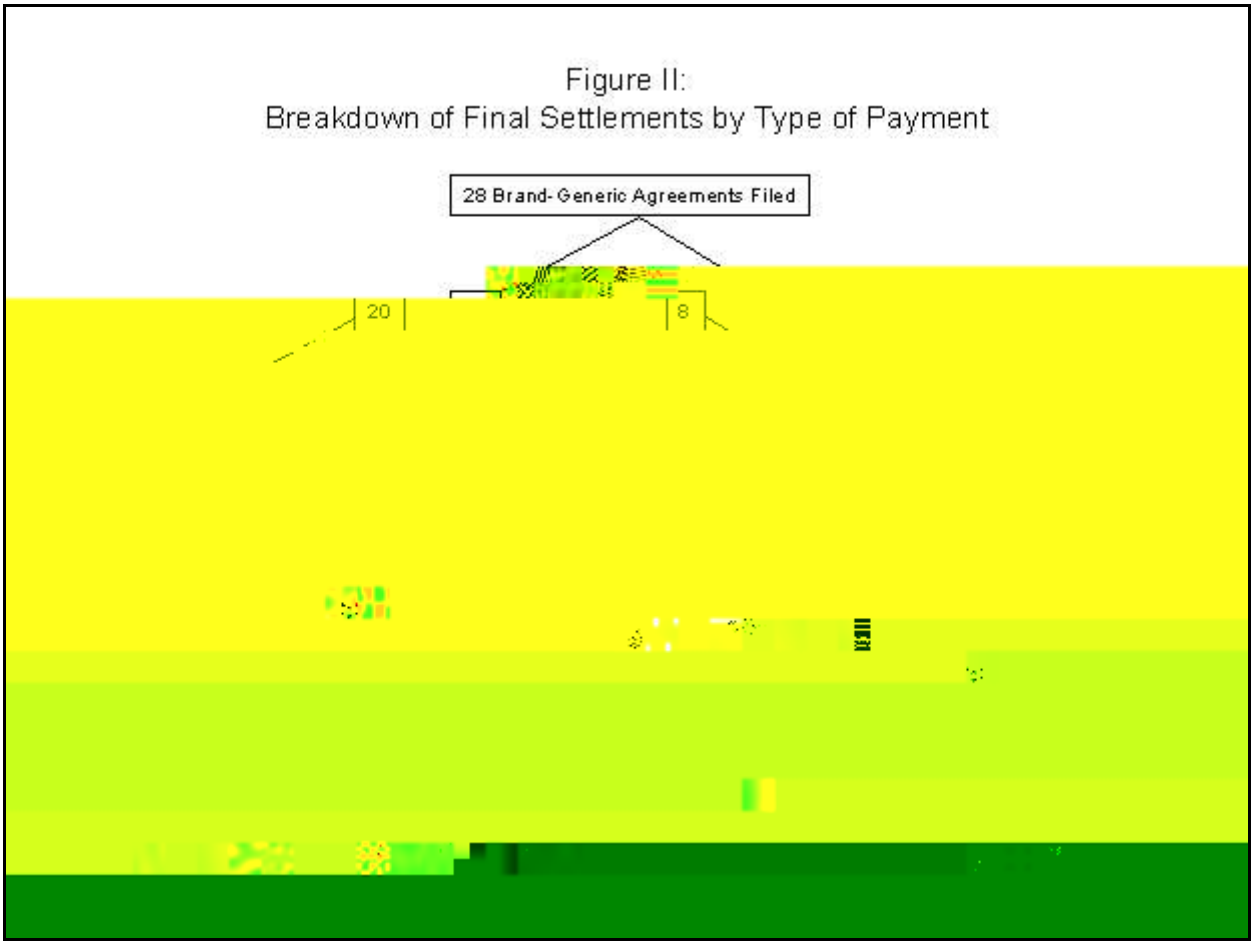
[3] *See F.T.C. v. Schering-Plough Corp.*, 402 F.3d 1056 (11th Cir. 2005).

- Twenty-eight of the agreements were final settlements of patent litigation between a brand and a generic company.
- Eight were interim agreements that occurred during patent litigation between a brand and a generic company, but did not resolve the litigation.
- One was an agreement between a first-filer generic company and a subsequent generic filer.
- The remaining eight agreements are brand-generic agreements (such as intellectual property licenses, supply agreements, and authorized generic deals) that do not settle patent litigation on a final or interim basis, and thus do not fall within the other three categories.



I. Final Settlements

The analysis below categorizes the settlements based on whether there is a restriction on the generic's ability to compete and what compensation, if any, flows between the parties. Overall, half of the final settlement agreements included both compensation to the generic company and a restriction on the generic's ability to market its product. Many of the agreements that restricted generic entry included some type of side-deal involving elements not directly related to the resolution of the patent dispute between the brand and the generic. In contrast, a side-deal occurred in only two reported agreements in which there was no explicit restriction on the generic's ability to market its product. Neither of those two agreements has resulted in competition between the brand and the generic. Moreover, for the first time since the Commission's investigations into pharmaceutical patent agreements became public, pharmaceutical companies entered into settlement agreements that included a restriction that could affect the generic's ability to market a form of the brand-name company's product not at issue in the litigation.



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C. Eight settlements included no explicit restriction on the generic's ability to market its product.

Eight of the twenty-eight final settlements did not explicitly restrict generic entry. In four of these eight cases, the ag

E. Final settlements involving side-deals.

Twelve of the twenty-eight final settlements contained some type of side-deal involving elements not directly related to the resolution of the patent litigation between the brand and the generic manufacturer. In all but one case, the 2005 U.S. annual sales of the product that was the subject of the litigation were greater than $250 million.

Ten of these twelve side-deal agreements involved both an explicit restriction on the generic's ability to market its product and a payment to the generic. Of the other two agreements, one involves the complex set of transactions that is the subject of an ongoing FTC investigation that is discussed above (Part C). In the other side-deal agreement, the generic was on the market at the time of the agreement; the generic company acquired the brand product, thus eliminating independent competition between the brand and generic; and the generic company continues to sell both the brand and generic version of the product.

II. Interim Agreements

There were eight interim agreements in FY 2006. Seven of these involved either (a) an agreement to stay the litigation and be bound in whole (including infringement) or in part (for example solely on issues of validity), by the results of other litigation involving the same patent(s); (b) a change in the parties to the litigation; or (c) an agreement on some other procedural issue (for example extending the 30-month stay through the briefing period) in the patent litigation. The remaining agreement included compensation to the brand in exchange for a license to the brand's intellectual property. This agreement neither settled the litigation between the parties nor imposed any restriction on the generic's ability to enter during the pendency of that litigation.

III. Generic-Generic Agreements

In FY 2006, there was only one agreement between generic manufacturers. That agreement involved the first-filer generic company agreeing to waive its 180-day exclusivity period, thereby allowing the subsequent filer to obtain FDA approval for its product. Consistent with the generic-generic agreements filed in FY 2004 and FY 2005, this agreement does not explicitly prohibit a party from competing after the expiration of the 180-day exclusivity, though it does provide for extra compensation to the first-filer if the first-filer decides not to compete for an additional period of time after the 180-day exclusivity period expires. In addition, the subsequent filer will make certain payments to the first-filer depending on when generic entry occurs.

IV. Other Agreements

Eight of the agreements filed in FY 2006 do not involve either a final settlement or an interim agreement arising out of patent litigation. Three of the agreements are authorized generic

deals in which the brand manufacturer licensed a generic company to sell the branded product as a generic. In two of these authorized generic deals, there was no patent litigation between the parties on the product at issue. In the other, the agreement had no impact on the pendency of the patent litigation.

Of the remaining five agreements:

- Two agreements involved proposed settlements that did not go into effect.
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