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

Summary of Agreements Filed in FY 2007
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 2007 (October 1, 2006 to September 30, 2007) and compare them with the ones reported in previous years.

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 2007, as in FY 2006, the Commission received 45 agreements under the MMA.

- Thirty-three of the agreements were final settlements of patent litigation brought by a brand company against a generic company.
- Nine 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.

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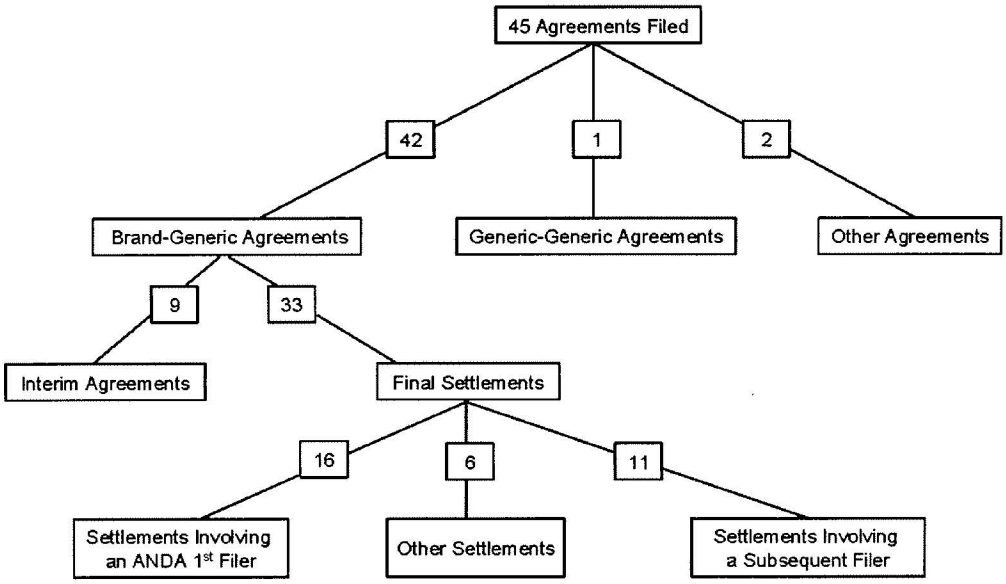
[1]For further information on the types of agreements that must be filed with the FTC, see "Pharmaceutical Agreement Filing Requirements," available at www.ftc.gov/os/2004/01/040106pharmules.pdf.

[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.

- The remaining two agreements are brand-generic agreements that do not settle patent litigation on a patent held by the branded company on a final or interim basis, and thus do not fall within the other three categories.

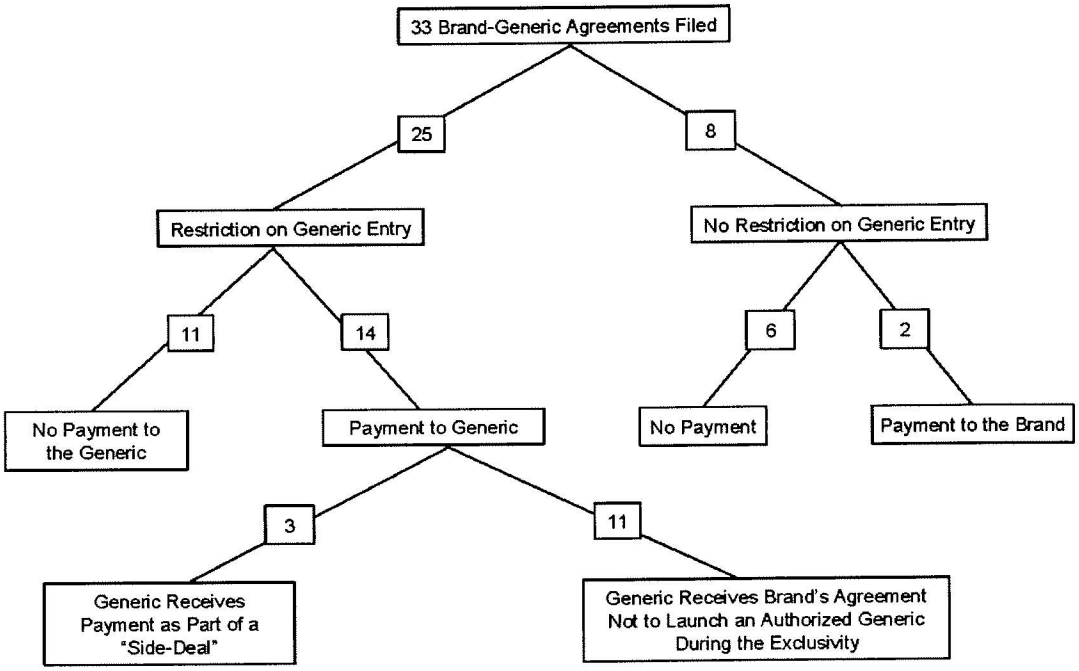
Figure I:
Overall Breakdown of Agreements Provided under the MMA in Fiscal Year 2007



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. As in FY 2006, a significant number of the final settlement agreements between a brand and a generic company (42%) included both compensation to the generic company and a restriction on the generic's ability to market its product. The vast majority of these agreements involved first filer generic companies (79%). Unlike FY 2006, however, the agreements that involved restrictions on generic entry in FY 2007 generally did not include some type of side-deal involving elements not directly related to the resolution of the patent dispute between the brand and the generic. Rather, in most of these agreements the compensation to the generic takes the form of the brand's agreement not to sponsor or compete with an authorized generic for some period of time. Also, as in FY 2006, at least one agreement received in FY 2007 included a restriction that could affect the generic's ability to market a form of the brand company's product not at issue in the litigation.

Figure II:
Breakdown of Final Settlements by Type of Payment



A. Fourteen of the thirty-three final settlements included both compensation to the generic manufacturer and a restriction on the generic manufacturer's ability to market its product.

In FY 2007, fourteen of the thirty-three final settlements that the Commission received (42%) included both provisions in which the generic manufacturer received some form of compensation from the manufacturer of the brand product at issue in the litigation and restrictions on the generic manufacturer's ability to enter with its product.

The fourteen agreements received in FY 2007 settled patent litigation on 13 different branded pharmaceutical products.[3] The compensation to the generic took different forms. In eleven of the final settlements containing compensation to the generic and a restriction on the generic company's ability to market its product, the compensation took the form of an agreement by the brand company not to launch or sponsor an authorized generic for a period of time after the entry of the generic company's product. In three instances, the compensation flowed to the generic in the form of a side-deal.

[3]By "branded pharmaceutical product" we mean pharmaceutical products sold under a particular brand name. We have not separated out branded pharmaceutical products by particular dosage types. Thus, for instance, an injectable product and a tablet product sold under the same brand name are counted as one "branded pharmaceutical product" for purposes of this report.

No Authorized Generic Agreements: The promise not to launch or sponsor an authorized generic for some period of time after the entry of the generic company's product appeared in eleven of the fourteen final settlements containing both compensation and a restriction. In one of the eleven agreements, the generic company also received compensation in the form of a payment characterized by the parties as saved litigation expenses, and potential additional payments if certain events do not occur. In another of the eleven agreements, the promise by the branded company not to launch or sponsor an authorized generic is in an ancillary agreement between the branded company and a third-party company that has rights to market the generic product. The value from the brand's "no authorized generic promise" flows through that agreement to the generic company that is party to the final settlement.

Side Deals: In three of the agreements, the compensation flowed to the generic in the form of a side-deal involving elements not directly related to the resolution of the patent litigation between the brand and the generic company. In each of these "side deal" agreements, the generic obtained a license to market a product not subject to the patent litigation between the companies. One of the agreements also provided the generic company with a license to market the products subject to the litigation under certain circumstances and potential additional compensation in the form of a percentage of the sales of the brand's products involved in the litigation.

In six of the fourteen agreements, both the brand and generic company received compensation. The brand received a royalty in exchange for granting the generic a license to the patent at issue in the litigation in three cases. In one case, the brand received a royalty on the generic company's sales of an authorized generic product, or on the generic company's sales of its ANDA product. In another case, the brand received a royalty on the generic company's sales of a particular dosage form of the product at issue in the litigation. In the remaining case, under certain circumstances, the brand could receive a percentage of the generic company's sales of the products at issue in the litigation, as well as of certain related products not subject to the litigation.

Finally, in FY 2007, none of the fourteen agreements involving both compensation to the generic and a restriction on the generic company's ability to market its product included restrictions that could reach products not at issue in the litigation.

B. Eleven settlements included a restriction on the generic's entry and no compensation to the generic.

In six of the eleven agreements that included a restriction, but no compensation to the generic, the generic withdrew its patent challenge, thereby agreeing not to enter the market until patent expiry. This includes two cases in which the generic company agreed not to appeal a district court injunction prohibiting the generic from entering prior to patent expiration. In three of the eleven settlements, the parties agreed to dismiss the patent litigation, and the brand granted the generic a license to enter as of a certain date prior to patent expiry. It is notable that in one of the three cases, the restriction on the generic company's ability to market potentially

extends beyond the product at issue in the litigation. In one of the agreements the generic agreed not to enter until patent expiry, or, to pay a set amount to the brand company if it chose to enter the market as of a certain date prior to patent expiry that was established in the agreement. The final case involved a complicated arrangement in which the generic agreed to withdraw its generic product from the market for a period of time, the brand granted a license to the generic company to reenter as of a particular date for a limited period of time after which the generic company would withdraw its product until patent expiry. Under certain circumstances, the generic could benefit from reduced generic competition during the "re-enter and license" period.

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

Eight of the thirty-three final settlements did not explicitly restrict generic entry. In five of these cases, the generic was already on the market and the settlement did not require the generic to withdraw its product. In two of the agreements, the brand gave the generic a covenant not to sue over the product at issue, which would allow the generic to enter upon receiving final approval. In the remaining case, the generic company withdrew its ANDA after the brand company prevailed at the district court against other generic challengers.

Six of the eight agreements included no compensation to either party. Two involved the generic paying the brand a fixed sum.

D. Final settlements involving first-filer generic companies.

In sixteen of the thirty-three final settlements discussed above, the generic manufacturer was the first-filer.[4] Eleven of those sixteen were agreements with both a restriction on generic entry and compensation to the generic manufacturer. In nine of the eleven cases, the compensation to the generic company was in the form of an agreement by the brand not to launch or sponsor an authorized generic for a period of time.

Five involved a restriction on generic entry but no compensation to the generic manufacturer. In two of these five cases, other generic companies that shared first-filer exclusivity rights were not blocked from entering. Another two involved a situation in which the generic had been enjoined from entering by the district court and the patent expired in the near term.

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[4]One additional final settlement agreement involved a generic company that was eligible for the 180-day exclusivity. At the time of the agreement, however, the generic company had already launched its product, triggering the 180-day exclusivity period. Because the settlement had no impact on the 180-day exclusivity period, it is not categorized as involving a "first filer." Five other final settlement agreements involved situations in which the product was not eligible for the 180-day exclusivity period. These six agreements have been categorized as "other settlements" in Figure 1.

II. Interim Agreements

There were nine interim agreements in FY 2007. Seven of theses involved either (a) an agreement to stay the litigation and be bound by the results of other litigation involving the same patents; (b) an agreement by the generic company to provide the brand manufacturer with advance notice of an "at risk" generic launch so as to provide the brand company the opportunity to seek a preliminary injunction; or (c) an agreement by the generic company not to introduce its generic product until the court ruled on a preliminary injunction motion. The remaining two interim agreements involved compensation to the generic company and some restriction on the generic's ability to enter. In one agreement the generic agreed not to market its product until the end of trial, and the brand agreed that it would not launch or sponsor an authorized generic during that time. In the other, the parties agreed that the generic company could enter with its product at a date in the future, contingent in part, on the outcome of the appeal in the patent infringement case. The brand agreed not to sponsor or compete with an authorized generic for a period of time after the generic entered.

III. Generic-Generic Agreements

In FY 2007, there was only one agreement between generic manufacturers. That agreement involved the first-filer generic company agreeing to relinquish its 180-day exclusivity period, thereby allowing the subsequent filer to obtain FDA approval for its product. During the exclusivity period, the parties agree to share profits on the sale of the generic product. In addition, the agreement provides for some form of profit sharing beyond the expiration of the exclusivity period, if the first-filer decides not to enter with its own product.

IV. Other Agreements

Two of the agreements filed in FY 2007 do not involve either a final settlement or an interim agreement arising out of patent litigation brought by the brand company. In one instance, the parties entered into a product development arrangement on different formulations of the product than those at issue in the litigation. The agreement had no impact on the pendency of the patent litigation. The second agreement involved a patent infringement lawsuit brought by a generic company against the brand. In that agreement, the parties settled their litigation, with the generic granting the brand a license to the patent at issue in the litigation in exchange for a royalty.

Figure III
Breakdown of Final Settlements
by Restriction and Compensation

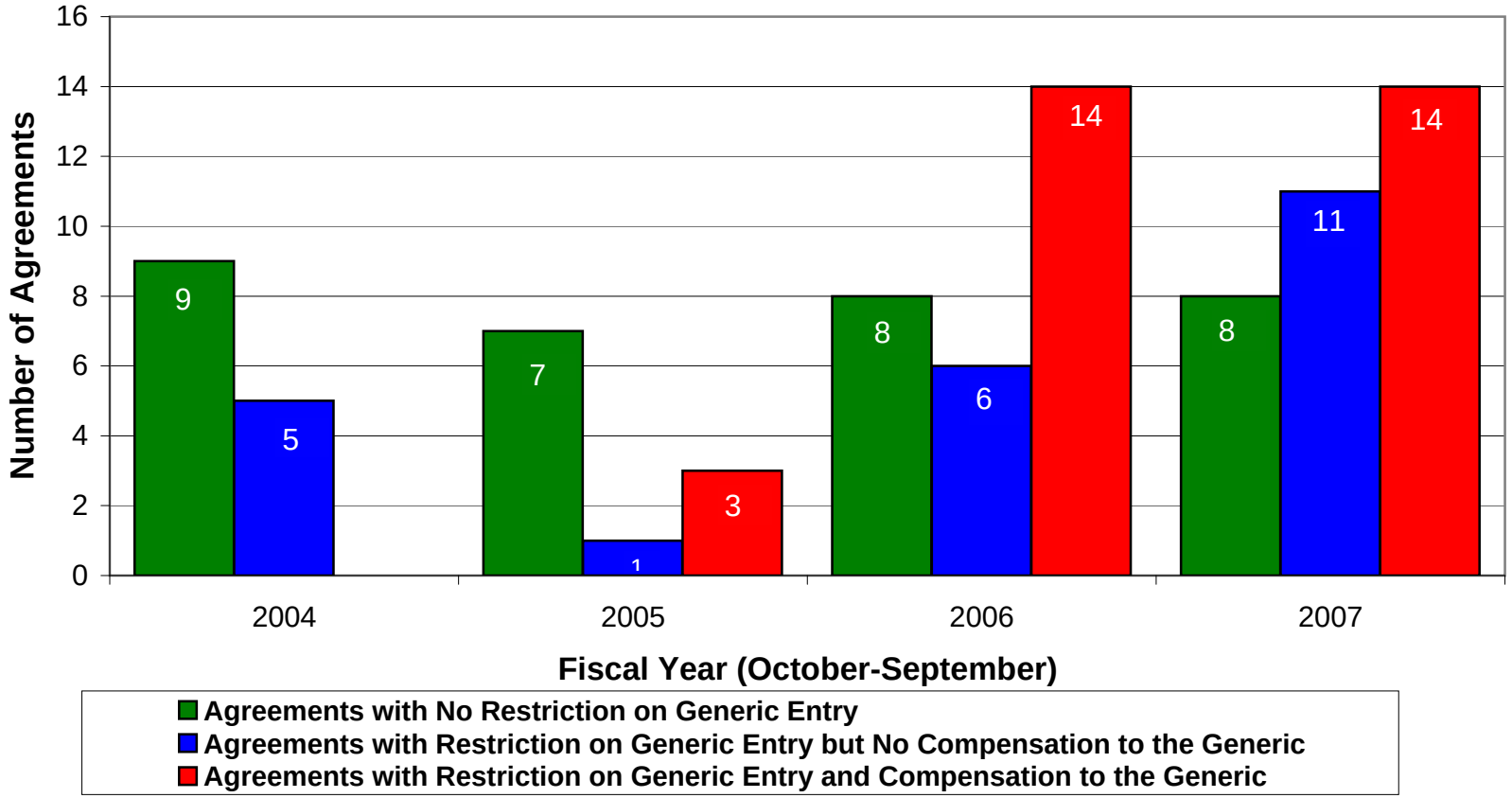

Figure IV
Breakdown of Final Settlements with First-Filers by Restriction and Compensation