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

Summary of Agreements Filed in FY 2005
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 2005 (October 1, 2004 to September 30, 2005) and compare those settlements with the ones reported in FY 2004 and with the findings of the Commission's 2002 study entitled "Generic Drug Entry Prior to Patent Expiration"[2] (the Generic Drug Study).

This summary provides information about the settlements using criteria similar to those in the Generic Drug Study. 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 or an interim agreement that did not resolve the patent litigation;
- 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.[3]

In FY 2005, the Commission received 20 agreements under the MMA involving 16 different products (see Fig. I).

- Eleven of the agreements were final settlements of patent litigation between a

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

[2] "Generic Drug Entry Prior to Patent Expiration: An FTC Study," Federal Trade Commission, July 2002. The report for FY 2004 is available at http://www.ftc.gov/os/2005/01/050107medicareactrpt.pdf.

[3] 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. For a more detailed description of the regulatory process, see "The Generic Drug Study," at 3-9, *supra* n. 1.

brand and a generic company.

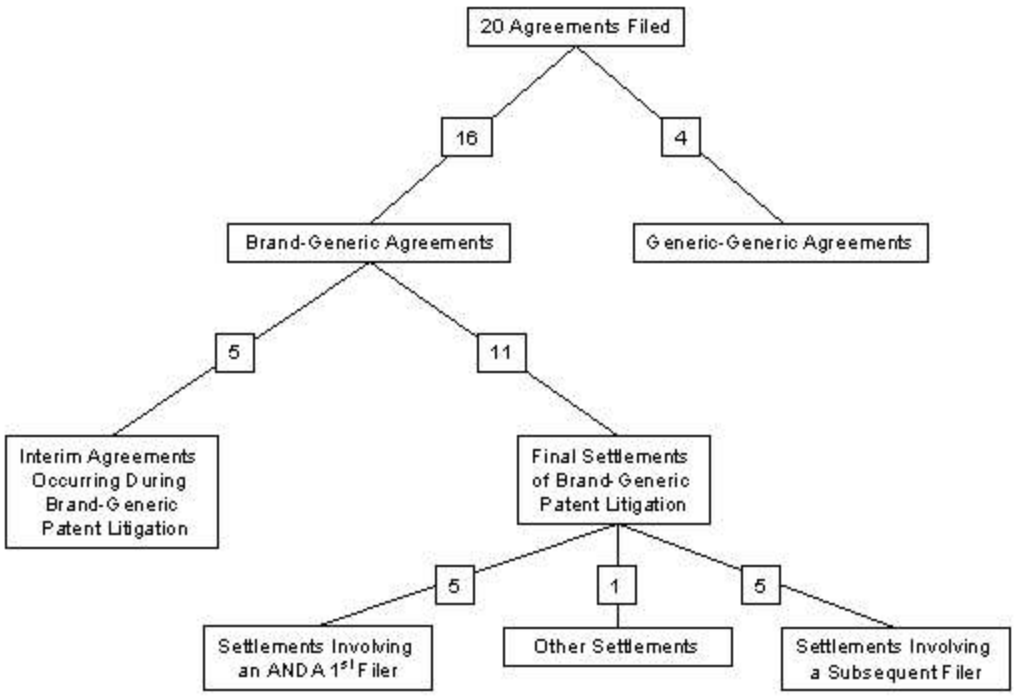
- Five were interim agreements that occurred during patent litigation between a brand and a generic company but did not resolve the litigation.

- The remaining four agreements were between a first-filer generic company and a subsequent generic filer.

I. Final Settlements

We categorized 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 (see Fig. II). None of the final settlements reported under the MMA in FY 2005 included a restriction on the generic's marketing a form of the brand-name company's product not at issue in the litigation.

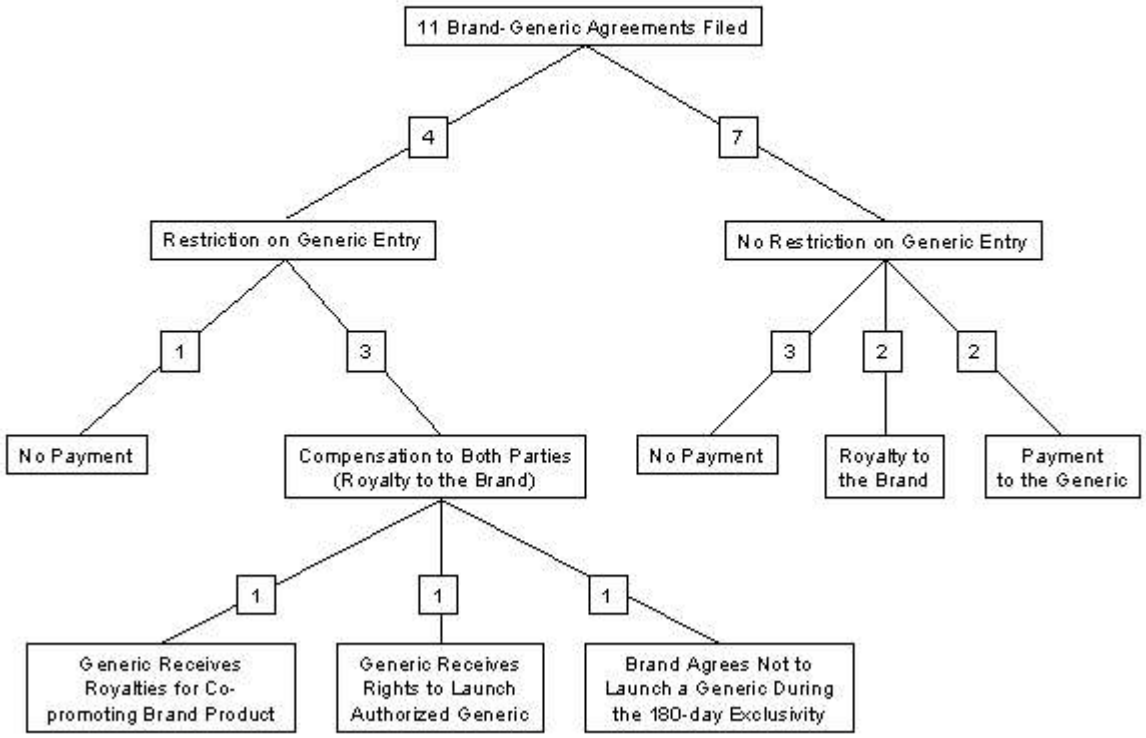
Figure I:
Overall Breakdown of Agreements Provided under the MMA in Fiscal Year 2005



A. Three of the eleven final settlements included both compensation to the generic manufacturer and a restriction on the generic manufacturer's ability to market its product.

For the first time since the Commission's investigations into pharmaceutical patents settlements became public and based on the information available to the Commission, pharmaceutical companies entered into settlement agreements that included both compensation to the generic and a restriction on the generic's ability to market its product.[4] The Generic Drug

Figure II:
Breakdown of Final Settlements by Type of Payment



[4] The Commission lacks data for the approximately three year period between the end of the Generic Drug Study and the beginning of the MMA reporting period. The Generic Drug Study included all settlements in which the generic filed its paragraph IV certification between January 1, 1992 and January 1, 2001 and the settlement occurred before June 1, 2002. *See* Generic Drug Study, *supra* n. 1, at 10, 13. The MMA reporting requirements began on January 07, 2004. *See* Medicare Prescription and Drug Improvement Act Requires Drug Companies to File Certain Agreements with the Federal Trade Commission and the U.S. Department of Justice, available at http://www.ftc.gov/os/2004/01/040106pharmrules.pdf.

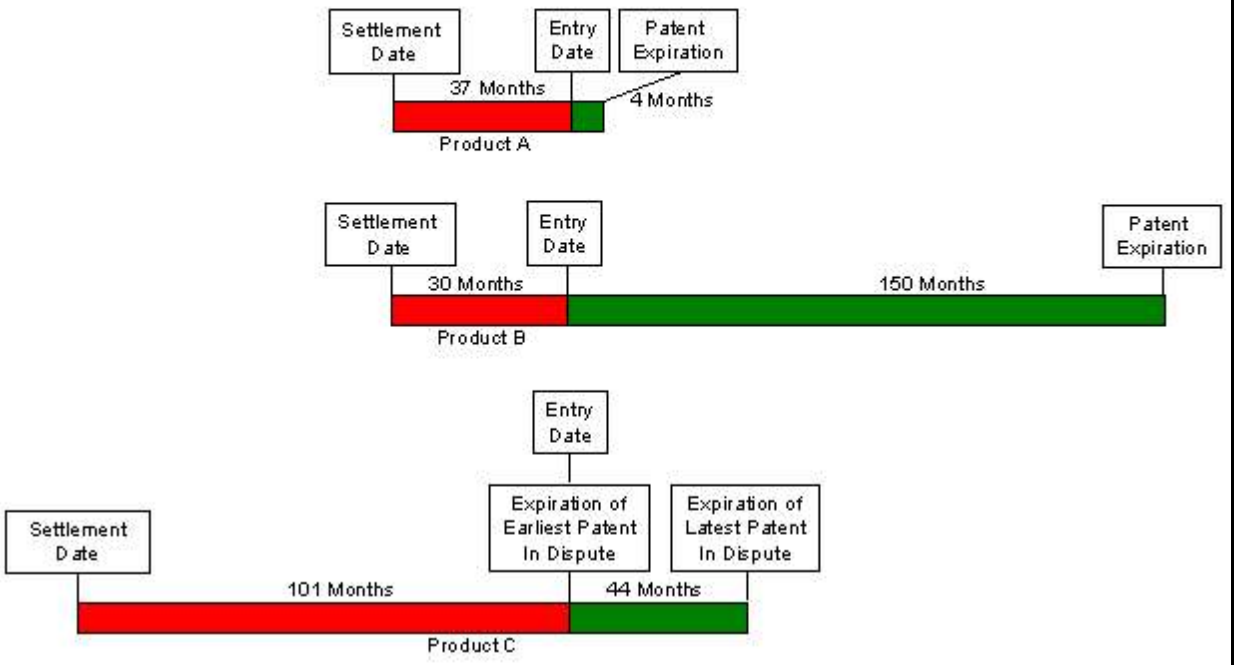
Study reported that between 1992 and 1999, over half (eight) of the settlements between brand and generic first-filers included those provisions. In 1999, it was reported that the Federal Trade Commission was investigating agreements involving such payments. Neither the six settlements entered in 2000 and 2001 nor the fourteen settlements reported in FY 2004 under the MMA contained payments to the generic and a restriction on the generic's ability to market its product.

In FY 2005, however, the Commission received three agreements, which covered five products, that included both compensation to the generic and a restriction on the generic's ability to market the product. In all three settlements, both the brand and generic company received compensation. The brand, in each case, received a royalty in exchange for granting the generic a license to the patent at issue in the litigation. The compensation to the generic took different forms. Two of the three settlements included side deals for other products unrelated to the alleged infringing product. Both side-deal settlements occurred after the 11th Circuit decision in *Schering-Plough v. Federal Trade Commission*, reversing the Commission's decision that a settlement involving a side deal was anticompetitive. In one agreement, the brand allowed the generic to co-promote the brand product, and the generic received royalties on the branded product's total sales. In the other side-deal settlement, the generic received licenses to sell authorized generic versions of unrelated products for which the generic company had not filed an ANDA. In a third agreement, which did not involve a side deal, the brand company agreed not to launch an authorized generic during the first-filer generic company's 180-day exclusivity period

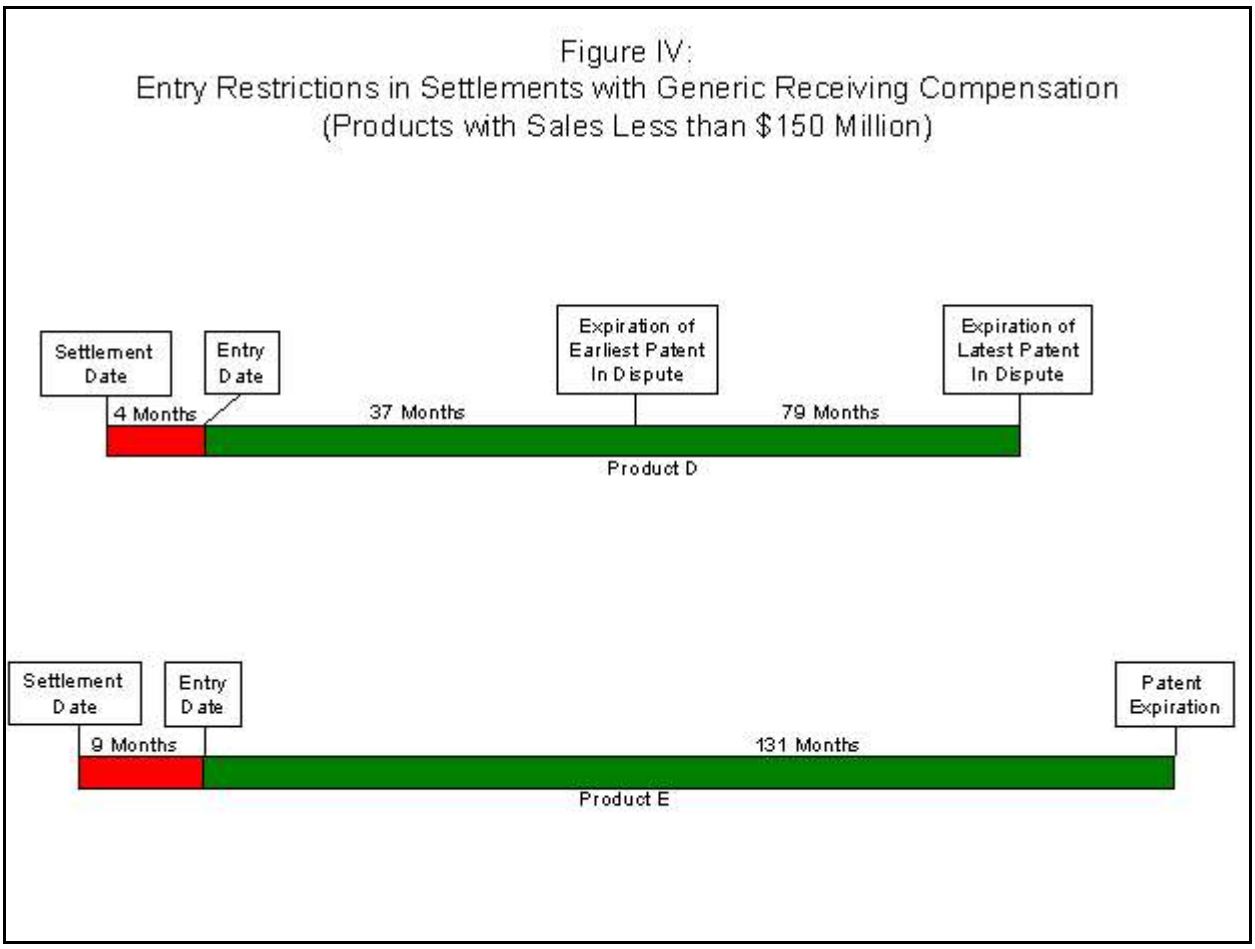
There are at least two ways to measure the restriction on generic entry: the amount of time from the settlement to generic entry or how early the entry date is compared to the expiration of the patent at issue. *See* Generic Drug Study at 29 (Table 3-2) and 32 (Table 3-3). In some of the FY 2005 settlements involving compensation and a restriction on the generic's entry, multiple patents were at issue with different expiration dates. Thus, where possible, this report identifies (1) the length of time from the settlement to the entry date, (2) the length of time between the entry date and the expiration date of the patent with the earliest expiration date, and (3) the length of time between the entry date and the expiration date of the patent with the latest expiration date.

The restriction on the generic's entry varied with the size of product (See Figs. III and IV). For the three products with annual sales exceeding $150 million, the agreed entry date varied from 30 to 100 months after the settlement. The lengths of these restrictions are consistent with the restrictions in settlements with compensation to the generic that were reported in the Generic Drug Study. *Compare* Fig. III with Generic Drug Study at 32 (Table 3-3).

Figure III:
Entry Restrictions in Settlements with Generic Receiving Compensation
(Products with Sales Greater than $150 Million)



In contrast, for the two products with sales below $150 million, entry occurred much sooner, from four to ten months after the settlement. Compared to the patent expiration dates, the amount of time between the agreed entry date and patent expiration varied significantly. In one agreement, entry occurred four months before the last patent expired, while in another agreement, entry occurred 150 months before patent expiration.



B. One settlement included a restriction on the generic's entry and no compensation to either party.

The number of settlements in which the parties simply split the remaining patent term fell from five in FY '04 to one in FY '05. That settlement allowed entry after the patents at issue expired but prior to the expiration of the pediatric exclusivity period. The parties reached the settlement after the generic manufacturer lost a decision on infringement before the trial court.

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

Seven of the 11 final settlements did not restrict generic entry either because (a) the generic was already on the market and the settlement did not require the generic to withdraw its product, (b) the agreement included a license to the brand's intellectual property, or (c) the brand gave a covenant not to sue the generic over the product at issue. Three of these seven agreements included no compensation to either party, two required the generic to pay a royalty on its sales to

the brand, and two included small payments (less than $2 million) from the brand to the generic.

D. Final settlements involving first-filer generic companies

In five of the eleven final settlements discussed above, the generic manufacturer was the first filer. Two of those five agreements were agreements with both a restriction on generic entry and a payment to the generic.[5] The lone settlement with a restriction on entry and no payment also involved a first-filer generic company. The other two settlements imposed no restriction on entry. One included a payment to the brand, and the other included a payment to the generic.

II. Interim Agreements

The number of interim agreements increased from two in FY 2004 to five in FY 2005. None of these settlements included compensation to either party. In one agreement, the first-filer generic company agreed not to market its product until the district court ruled on a motion for a preliminary injunction. In the remaining four settlements, a subsequent generic filer and the brand agreed to stay the litigation and be bound, in whole (including infringement) or in part (for example solely on the issues of validity and enforceability), by the results of patent litigation between the brand and the first-filer generic company involving the same patent or patents.

III. Generic-Generic Agreements

In all four generic-generic agreements, the first-filer generic company agreed to either waive or relinquish its exclusivity, thereby eliminating the 180-day exclusivity. In three of the agreements, the subsequent generic filer either supplied the first filer with product or paid a royalty to the first filer on the subsequent filer's sales. One of the three agreements also included a provision whereby the parties shared the risk of a future infringement finding; the party relinquishing its exclusivity and receiving a royalty agreed to pay a share of any infringement damages. In the other generic-generic agreement, the first-filer waived exclusivity as of a certain date but received no compensation. Consistent with the generic-generic agreements filed in FY 04, none of the agreements prohibited a party from competing after the expiration of the 180-day exclusivity.

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[5] The remaining agreement that included both compensation to the generic and a restriction on the generic's entry involved a product not eligible for either the 30-month stay or the 180-day exclusivity period under the Hatch-Waxman Act. The generic in that settlement, however, was the first company to seek approval to sell a generic version of the branded product.