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).

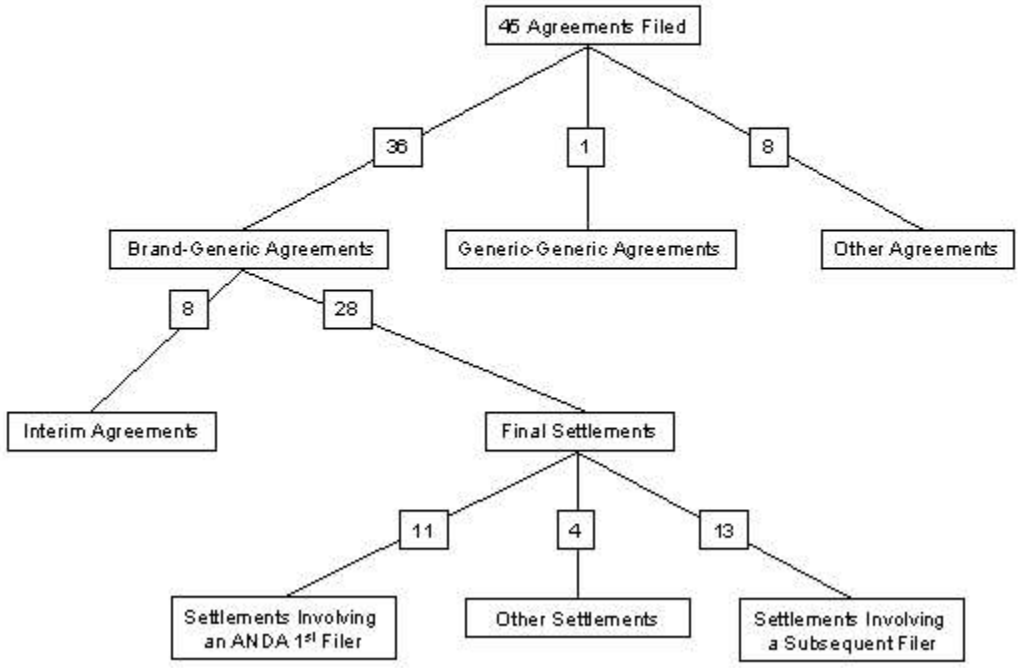
- Twenty-eight of the agreements were final settlements of patent litigation between a brand and a generic company.

- 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.

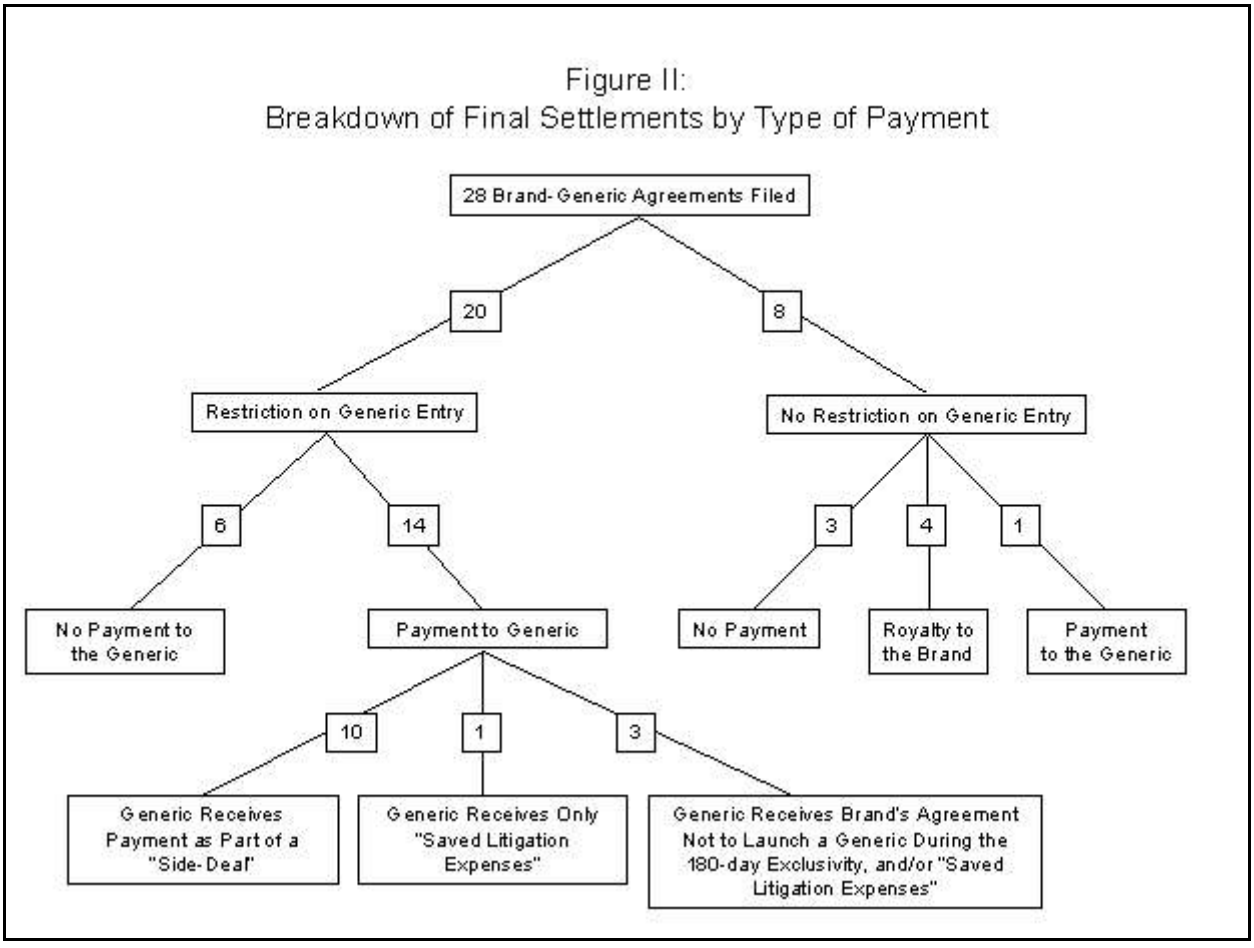
- The remaining eight agreements are brand-generic agreements (such as intellectual property licenses, supply agreements, and authorized generic deals) that do not settle patent litigation on a final or interim basis, and thus do not fall within the other three categories.

Figure I:
Overall Breakdown of Agreements Provided under the MMA in Fiscal Year 2006



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.



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

In FY 2006, fourteen of the twenty-eight final settlements that the Commission received (50%) included 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. By comparison, in FY 2005, only 3 of the 11 final settlements (27%) included both compensation to the generic and a restriction on the generic's ability to enter, and, in FY 2004, no agreements involved both compensation and a restriction.

The fourteen agreements received in FY 2006 settled patent litigation on eight different branded pharmaceutical products. Each of the agreements involved a product with 2005 U.S. annual sales exceeding $125 million; eight of the agreements involved products with 2005 U.S. annual sales of more than $450 million.

The compensation to the generic took different forms. In one agreement, the only guaranteed compensation received by the generic was a payment characterized by the parties as saved litigation expenses. In three of the agreements, the compensation received by the generic was an agreement by the brand company not to launch or sponsor an authorized generic during the 180-day exclusivity period and/or saved litigation expenses. Each of the remaining ten agreements included some sort of side-deal involving elements not directly related to the resolution of the patent litigation. In these ten "side-deal" settlements, the generic often received compensation in a combination of forms, which we summarize below:

- Intellectual property license: In five agreements, the generic manufacturer received compensation for licenses to intellectual property held by the generic. In three cases, the intellectual property related generally to the types of products at issue in the litigation; in the other two cases, the intellectual property did not relate at all to the types of products at issue in the litigation.

- Co-promotion agreement: In four agreements, the generic received payments from the brand to co-promote products; in two of the cases, the brand and the generic agreed to co-promote the product at issue in the patent litigation; in the other two cases, the co-promotion involved products unrelated to the patent litigation.

- Saved litigation expenses: In three agreements, the generic received a payment characterized by the parties as saved litigation expenses.

- Supply agreement: In three agreements, the generic received compensation in return for agreeing to supply the brand either with raw material for the

manufacture of the brand product or with finished drug product. Two of these agreements provided a minimum purchase guarantee for the generic, and the other included a payment to the generic regardless of whether the generic actually supplied product to the brand.

- No authorized generic agreement: In two cases, the brand company agreed not to launch an authorized generic during the first-filer generic company's 180-day exclusivity period for the product at issue in the litigation. In one of these cases, the brand also granted the generic a license to market a version of the product not subject to the litigation. The brand agreed not to launch an authorized generic during the period of the license with respect to this version of the product.

- Development agreement: In two cases, the brand agreed to pay the generic up-front payments, milestones, sales percentages, and/or development fees for unrelated products to be developed using the generic's technology.

In twelve 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 eleven cases, and in one case, the brand received a payment for the sale of assets not related to the patent infringement litigation.

Finally, five of the fourteen agreements included provisions that could restrict the generic's ability to enter the market with a form of the brand-name company's product not at issue in the litigation. All five of these cases involved compensation to the generic.

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

In three agreements, all involving the same branded product, the generic withdrew its patent challenge, thereby agreeing not to enter the market until patent expiry. In one case, the generic withdrew its patent challenge on a later-expiring patent after losing its challenge at the district court on the earlier-expiring patent. The brand granted the generic a license to enter the market no later than the expiration of the earlier-expiring patent (including pediatric exclusivity) in exchange for a royalty on the generic's sales of the product from entry until the expiration of the later-expiring patents. In the remaining two cases, the generic had begun selling its product "at risk" following a favorable court decision in the patent litigation and agreed to withdraw its product following an unfavorable appellate court decision in exchange for the brand dropping its damages claims.

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 agreement included a license to the brand's intellectual property or the brand gave a covenant not to sue the generic over the product at issue. Two agreements simply dismissed the litigation. Another agreement took place after the generic was already on the market. In that agreement, there is no explicit restriction on the generic company's ability to enter the market; however, the generic acquired the brand product, and therefore controls the sale of both the brand and generic versions of the product.

The remaining case also had no explicit restriction on generic entry. It involved a complex set of transactions in which the brand manufacturer granted the generic company a license to an authorized generic of the capsule form of the product that was the subject of the litigation; the brand company acquired a new tablet form of the product at issue; the brand agreed to pay the generic a royalty on the sales of the acquired product; and then the parties dismissed the litigation involving the capsule form of the product. As one of the parties has disclosed, this set of transactions is under investigation by the FTC.

D. Final settlements involving first-filer generic companies.

In eleven of the twenty-eight final settlements discussed above, the generic manufacturer was the first-filer.[4] Nine of those eleven were agreements with both a restriction on generic entry and compensation to the generic manufacturer.[5] In all but two cases, the 2005 U.S. annual sales of the products involved exceeded $250 million.

The remaining two agreements involved either an explicit restriction on the generic manufacturer's ability to market its product, or a payment to the generic manufacturer, but not both. The agreement that involves no payment to the generic contains a seven-month restriction on the generic's ability to market its product. The agreement that involves a payment to the generic manufacturer but no explicit restriction on the generic's ability to market its product, is the complex set of transactions discussed above (Part C) that is the subject of an ongoing FTC investigation.

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[4] Three additional final settlement agreements involved a generic company that had filed the first generic application. At the time of these agreements, however, the generic company had already launched its product and the 180-day exclusivity period had already expired. Because these settlements had no impact on the 180-day exclusivity period, they are not categorized as involving a "first filer." Another agreement involves a situation in which the product was not eligible for the 180-day exclusivity period. These four agreements have been categorized as "other settlements" in Figure 1.

[5] An additional 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.

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.
- One agreement amended the royalty terms of a patent settlement that occurred years before.
- In one agreement, a generic manufacturer licensed intellectual property to a brand manufacturer, and in exchange, received an up-front payment and royalties.
- One agreement involved a supply agreement between the brand and the generic, in which the generic agreed to supply the brand with product for one dosage of a product, while continuing to litigate against the brand on another dosage of the product. Additionally, under the agreement, the generic agreed to supply the brand with a different product unrelated to the patent litigation.

Figure III
Breakdown of Final Settlements by Restriction and Compensation

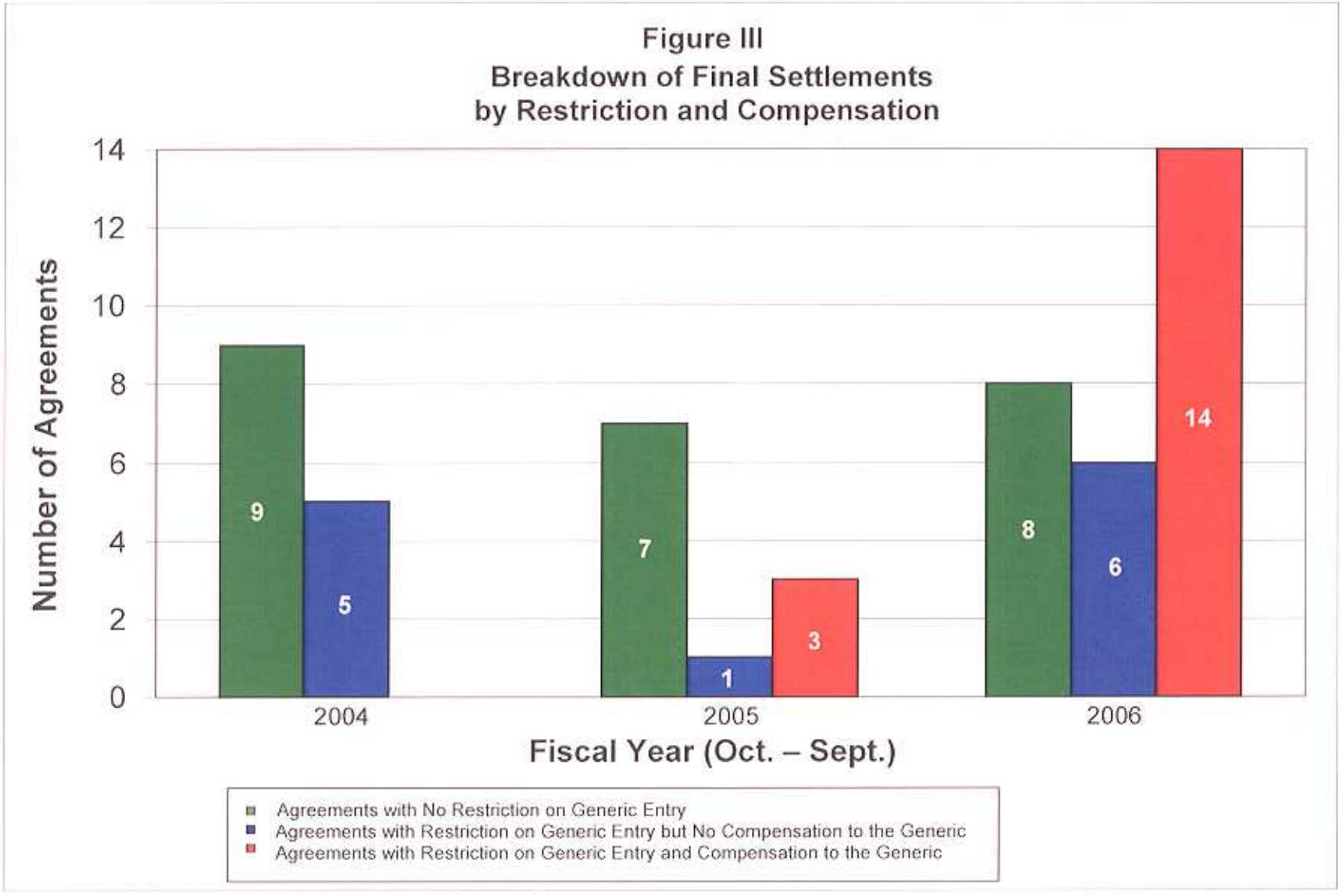

Figure IV
Breakdown of Final Settlements with First-Filers by Restriction and Compensation