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

Summary of Agreements Filed in FY 2009
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] We summarize below the number and types of agreements received during fiscal year 2009 (October 1, 2008 to September 30, 2009).

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 patent litigation, or another type of agreement;
- whether the agreement restricted generic entry;
- whether the agreement involved any payments from the brand to the generic;[2] and
- whether the agreement involved a generic company eligible for 180-day exclusivity rights.[3]

In FY 2009, the Commission received 83 agreements under the MMA. This is similar to FY 2008 when drug companies filed 82 agreements. The number of agreements companies filed in both FY 2008 and FY 2009 easily topped the 45 agreements that companies filed in each of FY 2007 and FY 2006.

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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] For purposes of this report, "payments" include only explicit promises by the brand to the generic drug company to provide some form of compensation. As detailed in Part I.B below, some agreements without explicit compensation may nonetheless provide incentives that could lead to increased profits for one of the parties. For example, agreements with incentives for a branded drug company not to launch an authorized generic product, thereby reducing competition, could effectively compensate a generic company.

[3] Under the Hatch-Waxman Act, the first generic drug company to file an ANDA with a Paragraph IV certification is eligible for 180 days of generic marketing exclusivity. During that exclusivity, the FDA may not approve any additional generic filers. Generic companies holding potential 180-day exclusivity rights are often referred to as "first filers." There can be more than one first-filer if multiple generics filed their ANDAs on the same day.

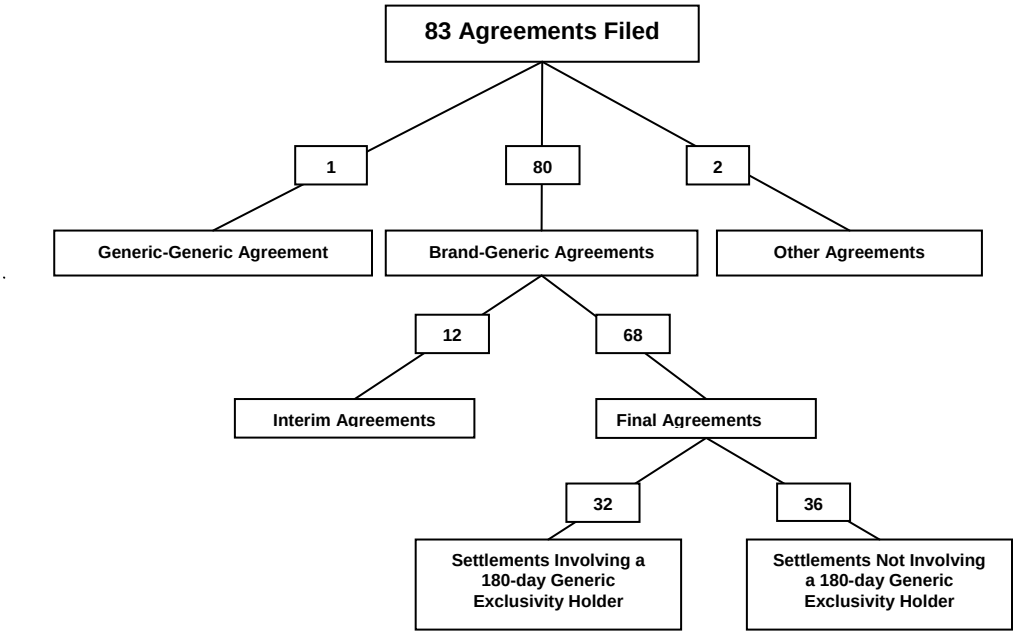
- Sixty-eight of the agreements were final resolutions of patent disputes between a brand company and a generic company.

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

- One was an agreement between generic companies.

- The remaining two agreements were brand-generic agreements that did 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.

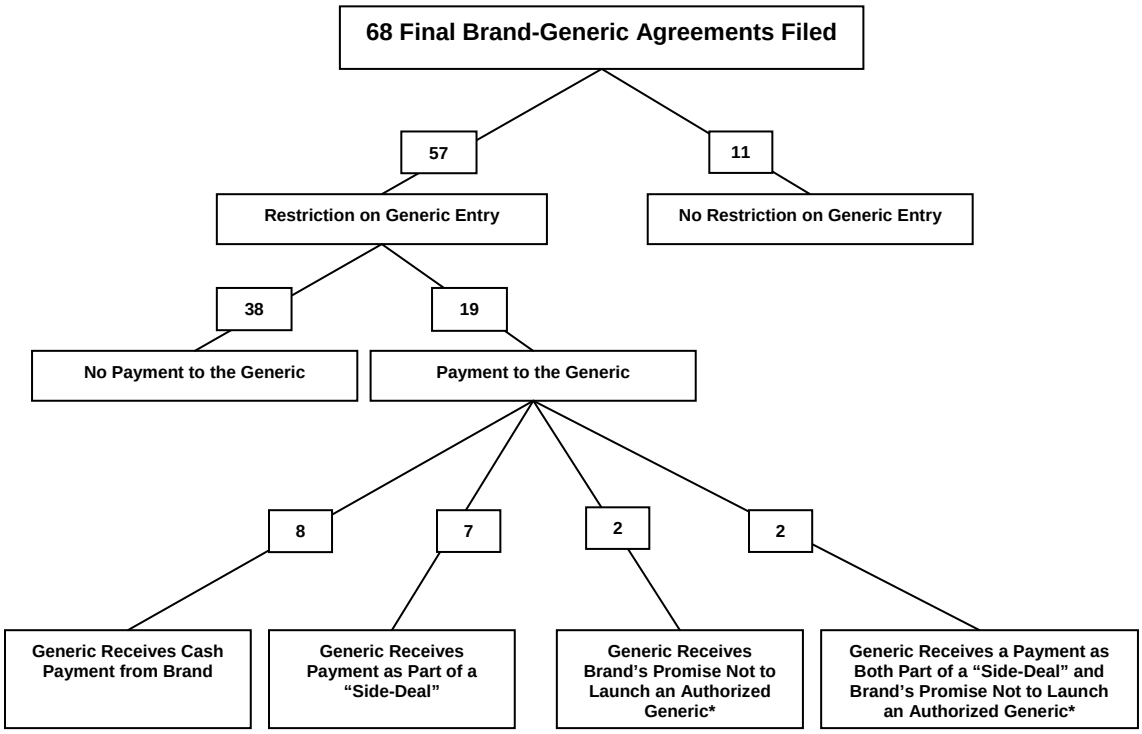
Figure I:
Overall Breakdown of Agreements Provided under the MMA in Fiscal Year 2009



I. Final Settlements

The analysis below categorizes the final settlements based on whether there is a restriction on the generic's ability to compete and what compensation, if any, flows between the parties. In FY 2009, 19 final settlements included both compensation to the generic company and a restriction on its ability to market its product, more than in any year since passage of the MMA in 2003. As in FY 2008 and FY 2007, a majority of these involved first filer-generic companies (13, or 68%). In FY 2009, the form of compensation to generics was split almost evenly between direct payments to the generic and side deals, which involve compensation to the generic that is not directly related to elements of the patent dispute. A handful of agreements also involved the brand's agreement not to compete with the generic through the launch of an authorized generic, for at least some period of time. Two agreements involved both side deals and an authorized generic restriction.

Figure II:
Breakdown of Final Settlements by Type of Payment



*** - The brand's promise not to launch an authorized generic took the form of either an agreement not to launch an authorized generic or to designate the generic first filer as the exclusive authorized generic.**

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

In FY 2009, 19 of the 68 final settlements that the Commission received (28%) included both provisions in which the generic manufacturer received some form of compensation from the manufacturer of the branded product and restrictions on the generic manufacturer's ability to enter with its product. The 19 agreements represent more final agreements with both compensation and restrictions on entry than in any prior year since passage of the MMA in 2003, and an increase in both number and percentage from FY 2008, in which 16 out of 66 (24%) final settlements included both compensation to the generic and a restriction on entry.

These 19 settlements resolved patent disputes on 14 different branded pharmaceutical products with combined annual U.S. sales of over $9.5 billion.[4]

In FY 2009, the compensation to the generics took different forms.

[4] By "branded pharmaceutical product," we mean pharmaceutical products sold under a particular New Drug Application ("NDA") number.

- In eight of the settlements, the brand made only a cash payment to the generic.

- In two of the settlements, the compensation principally took the form of an agreement by the branded company that effectively eliminated competition from an authorized generic product.

- In nine of the settlements involving compensation to the generic company and a restriction on its ability to market its product, the compensation flowed to the generic in the form of a side-deal. Two of these agreements involving side deals also included the brand's promise not to launch an authorized generic or to designate the generic first filer as the exclusive authorized generic.

In FY 2009, brand and generic companies entered into several different types of side deals.

- Four agreements included supply and distribution deals whereby the brand agreed to supply the generic with an unrelated drug to be sold by the generic**.** In three of these agreements, the generic would sell the drug under its own name. Of those three settlements, two also included a side co-promotion agreement under which the generic company agreed to promote a branded product unrelated to the underlying litigation. In the fourth of these settlements, the generic would sell an authorized generic version of two future dosage strengths of the drug that had not yet received FDA approval. This settlement also included a separate asset purchase agreement whereby the brand agreed to purchase unrelated assets from the generic.

- Two agreements involved supply agreements with the generic supplying the brand as a back-up supplier for the product at issue.

- Two agreements involved development agreements between the brand and the generic to develop products related to those at issue in the underlying litigation. Both development deals involved up-front payments from the brand to the generic.

- In one agreement, the brand agreed to purchase a license from the generic company to intellectual property related to the underlying drug, transferred eight products to the generic for the generic to sell, and made a cash payment characterized as attorneys fees.

The four agreements between the brand and generic in FY 2009 that effectively eliminated competition from an authorized generic product took two basic forms.

- In two agreements, the branded company promised that the generic company's product would not face competition from an authorized generic product for some period of time.

- In the two other agreements, the branded company designated the first-filer generic company as the exclusive distributor of an authorized generic product, effectively eliminating the possibility that the generic would face competition from an independent authorized generic product.

B. Thirty-eight settlements included a restriction on the generic's entry and no explicit compensation to the generic.

In FY 2009, 38 final settlements included a restriction on generic entry but no explicit compensation to the generic company.

- Of these 38 settlements filed in FY 2009, 15 involved generic companies eligible for 180-day exclusivity rights, while 23 involved generics without 180-day exclusivity rights.
    - Of the 15 final settlements that restricted 180-day exclusivity holders' generic entry but did not include explicit compensation to the generic:
        - Nine agreements involved products with multiple generic firms sharing potential 180-day exclusivity rights, including up to 10 first-filers in certain cases.
        - One occurred when the district court granted a preliminary injunction precluding the sale of the drug after the generic had already shipped certain quantities of the product into the distribution network but had not yet sold the generic to end users because of a "standstill agreement." After the court granted the preliminary injunction, rather than recall the previously shipped product, the final settlement permitted the generic to sell product that it had already shipped and pay the brand a royalty on those sales.
        - An additional two of these agreements included provisions that may have provided the generic with some implicit benefit. In one of these agreements, the generic agreed to pay the brand a royalty on generic sales, but the generic's royalty obligation is reduced or eliminated if the brand launches an authorized generic product. In the other agreement, the generic settled the day after launching "at risk," raising the possibility that the at-risk launch may have been designed to compensate the generic for subsequently staying out of the market by allowing it to sell its stock of the drug without competition from another generic. As part of the settlement, the brand agreed to release the generic from liability arising from its one-day sale of the drug.
- In FY 2009, 23 final settlements involving generics without 180-day exclusivity rights restricted generic entry but did not include explicit compensation.

- Of these 23 final settlements, 15 were entered either in conjunction with or after settlements with first filers on the same drug and provided for generic entry by the later filers at least 180 days after the first filer enters. An additional six settlements followed decisions in favor of the branded company in related patent litigation. Of those six, five agreements involved situations following a court decision favoring the brand in which the generic had launched at risk. In those agreements, the brand granted the generics a license to sell a limited quantity of the generic product over a specified period of time, but then the generic was required to withdraw from the market until patent expiration. The remaining two agreements with subsequently-filed generics were structured in a manner that could discourage first filers from launching at risk by granting subsequent filers a license to distribute an authorized generic product at the same time as the at-risk launch by the first filer.

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

Eleven of the 68 final settlements did not explicitly restrict generic entry. In three instances, generic products were already being marketed at the time of settlement. In two others, the brand dismissed the case without any restrictions on generic entry following an unfavorable interim court ruling. In one settlement, the agreement did not explicitly restrict an at-risk launch, but provided the generic with a disincentive to do so. In the remaining cases, the brand agreed to allow the generic to enter effective upon the generic receiving final FDA approval.

D. Final settlements between a brand and a first-filer generic company.

In 32 of the 68 final settlements discussed above, the generic manufacturer was eligible for 180-day exclusivity rights under the Hatch-Waxman Act. Thirty of those agreements contained an explicit restriction on generic entry, while two did not. Fifteen of those 30 agreements with a restriction on generic entry also included compensation to the generic manufacturer, while 15 did not include explicit compensation.

II. Interim Agreements

There were 12 interim agreements filed in FY 2009.

- Eight of these involved either (a) an agreement by the generic company to provide the branded manufacturer with advance notice of an at-risk generic launch so as to provide the brand the opportunity to seek a preliminary injunction; or (b) an agreement by the generic company not to introduce its generic product until the court ruled on a preliminary injunction motion. Two of these agreements required the brand to put up a bond pending the court's decision regarding the preliminary injunction. The third included possible compensation from the brand to the

generic in the form of the brand's commitment to not launch an AG if the generic prevailed in the patent litigation in exchange for the generic's agreement to not launch "at risk" for a period of five months.

- Four interim agreements included a covenant by the brand not to sue a generic for infringement of a specific patent. One of these agreements also provided that the parties would be bound by the results of related litigation.

III. Generic-Generic Agreements

In FY 2009, one agreement between generic manufacturers was filed pursuant to the MMA, compared to three in FY 2008. The single agreement related to an arrangement under which one generic manufacturer agreed to relinquish its 180-day exclusivity rights in exchange for profit-sharing on the other's generic product.

IV. Other Agreements

Two of the agreements filed in FY 2009 do not involve either a final settlement or an interim agreement arising out of patent litigation brought by the branded company. Both involve an agreement between a brand and a generic permitting the generic, which is currently selling an authorized generic on behalf of the brand, instead to begin selling a generic under its own ANDA.

Figure III: Breakdown of Final Settlements by Restriction and Compensation

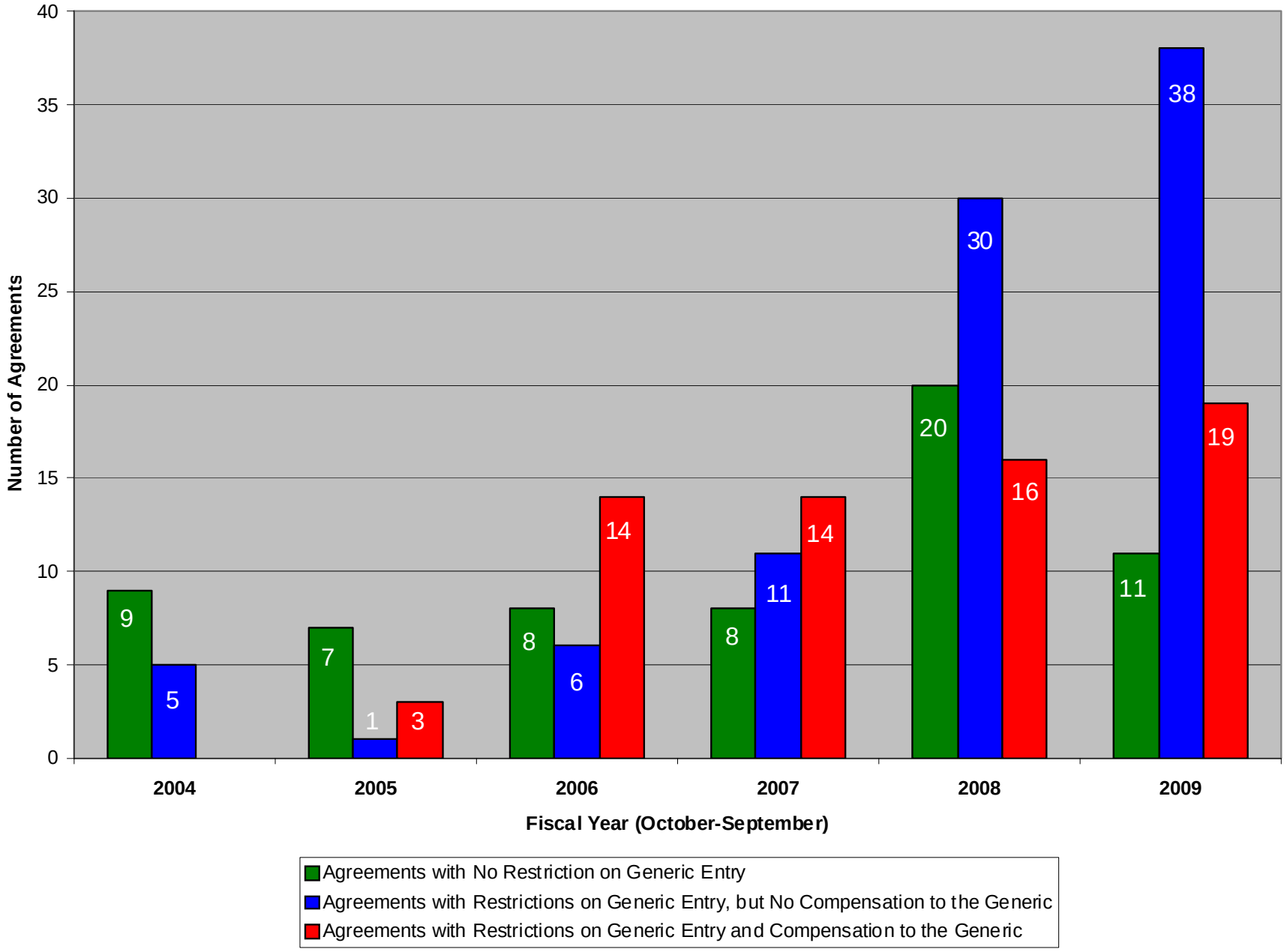


Figure IV: Breakdown of Final Settlements with First-Filers by Restriction and Compensation