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

Summary of Agreements Filed in FY 2008
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 2008 (October 1, 2007 to September 30, 2008).

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 between the parties;[2] and
- whether the agreement involved a generic company eligible for 180-day exclusivity rights.[3]

In FY 2008, the Commission received 82 agreements under the MMA. This compares to 45 agreements for each of FY 2007 and FY 2006.

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

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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 one drug company to another 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 could effectively compensate a generic company.

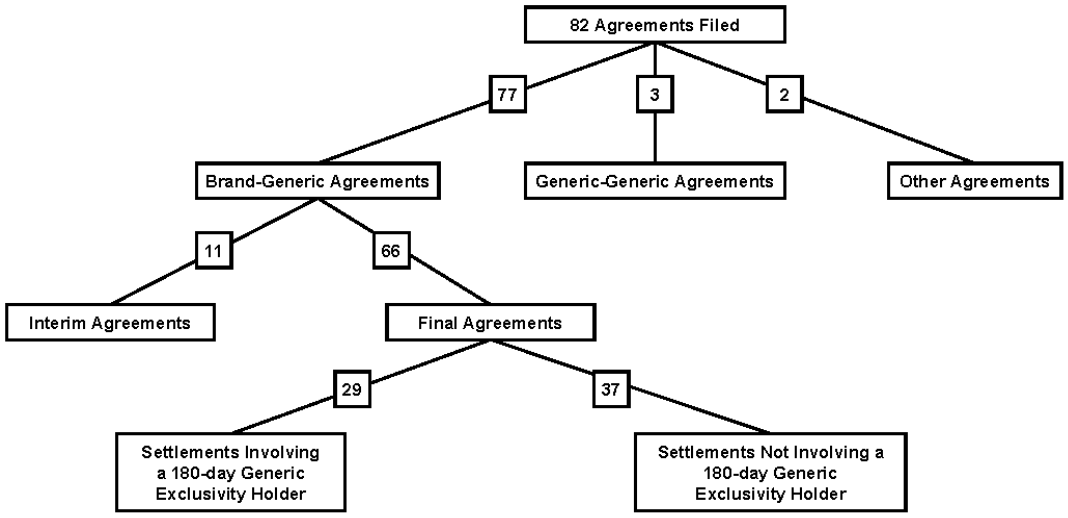
[3] Under the Hatch-Waxman Act, the first generic drug company to file an ANDA with a Paragraph IV certification is eligible for 180 days of generic marketing exclusivity. During that exclusivity, the FDA may not approve any additional generic filers. Generic companies holding potential 180-day exclusivity rights are often referred to as "first filers."

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

- 3 were agreements between generic companies.

- The remaining 2 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.

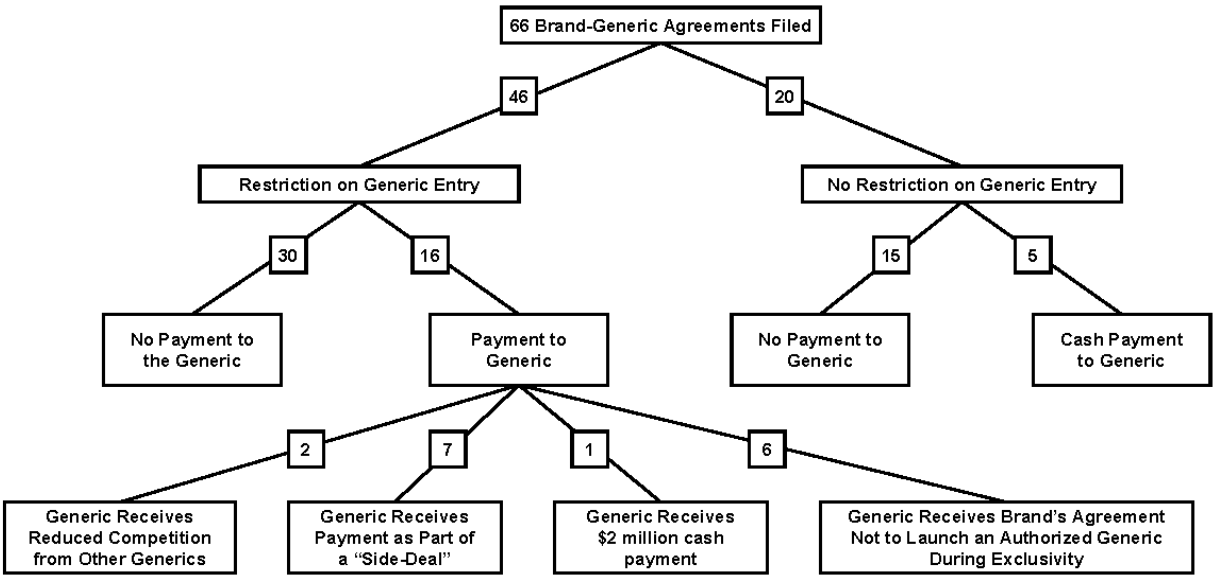
Figure I:
Overall Breakdown of Agreements Provided under the MMA in Fiscal Year 2008



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. In FY 2008, more settlements included both compensation to the generic company and a restriction on the generic's ability to market its product –16 – than in any year since passage of the MMA in 2003. As in FY 2007, most of these involved first filer generic companies (13, or 81%). Unlike in FY 2007, the form of compensation in these agreements was split roughly evenly between (i) side deals involving elements not directly related to the resolution of the patent dispute; and (ii) the brand's agreement not to compete with an authorized generic for some period of time.

Figure II:
Breakdown of Final Settlements by Type of Payment



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

In FY 2008, 16 of the 66 final settlements that the Commission received (24%) 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. This is more than in any prior year since passage of the MMA in 2003, though a decline in percentage terms from FY 2007, in which 14 out of 33 (42%) final settlements included both compensation to the generic and a restriction on entry.

The 16 agreements received in FY 2008 resolved patent disputes on 13 different branded pharmaceutical products with combined annual U.S. sales of over $10 billion.[4] The compensation to the generic took different forms.

- In seven of the final settlements containing compensation to the generic company and a restriction on the generic's ability to market its product, the compensation flowed to the generic principally in the form of a side-deal.

[4] 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.

- In six instances, the compensation took principally the form of an agreement by the branded company to effectively eliminate competition from an authorized generic product.

- In two instances, terms of the settlement agreement ensured that the generic company would face reduced competition from other generic companies following generic entry.

- In one settlement, the brand made a $2 million cash payment to the generic.

Branded and generic companies entered into several different types of side deals. Three settlements involved side co-promotion agreements under which the generic company agreed to promote a branded product to doctors. Two settlements involved side authorized generic deals under which the branded company licensed the generic company to sell authorized generic versions of products that were not the subject of litigation between the brand and the generic. One settlement involved a side supply deal under which the generic agreed to supply active pharmaceutical ingredient to the branded company. Finally, one settlement involved a side deal under which the branded company purchased significant unrelated assets from the generic company.

Agreements to effectively eliminate competition from an authorized generic product took two basic forms. In four 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 two agreements, the branded company appointed the 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 settlements included a restriction on the generic's entry and no explicit compensation to the generic.

In FY 2008, 30 final settlements included a restriction on generic entry but no explicit compensation to the generic company. Of these 30 settlements, 14 involved generic companies eligible for 180-day exclusivity rights, while 16 did not implicate 180-day exclusivity.

Of the 14 final settlements that restricted 180-day exclusivity holders' generic entry but did not include explicit compensation to the generic, five involved products as to which nine or more generic firms shared potential 180-day exclusivity rights. Four agreements did not provide for explicit payments, but included provisions that may provide the branded company with incentives not to launch an authorized generic product. For instance, in three 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. Agreements involving two products contained complex international provisions providing for immediate generic entry in some countries, but not in others, including the United States. One agreement settled a dispute over a patent that had been successfully asserted against a different generic company as to a related drug. One agreement settled a dispute over a compound patent and

allowed the generic company to retain its 180-day exclusivity rights. Finally, one agreement involved a generic company that shared potential 180-day exclusivity rights with other generic companies that had settled earlier.

Of the 16 final settlements not implicating 180-day exclusivity rights that restricted generic entry but did not include explicit compensation, 13 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. Of the remaining three settlements, one settlement followed a decision in favor of the branded company in a related patent litigation. One agreement provided that the generic company would switch back to a paragraph III certification on a compound patent, after it briefly converted its original paragraph III certification to a paragraph IV certification. The last settlement in this category followed a ruling in related patent litigation favorable to the branded company and provided that the generic could market its product in limited quantities for a limited period of time. Although the agreement does not provide for explicit compensation, the generic could benefit from reduced generic competition during the license period.

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

Twenty of the 66 final settlements did not explicitly restrict generic entry. In a number of instances, generic products were already being marketed by the time of settlement. Five settlements that did not restrict generic entry involved cash payments from the branded company to the generic company, with a median payment of $1.8 million.

D. Final settlements involving first-filer generic companies.

In 29 of the 66 final settlements discussed above, the generic manufacturer was eligible for 180-day exclusivity rights under the Hatch-Waxman Act. Twenty-seven of those agreements contained a restriction on generic entry, while two did not. In both of the two agreements that contained no restriction on generic entry, the branded company agreed to make cash payments to the generic company. Thirteen of the 27 agreements with a restriction on generic entry also included compensation to the generic manufacturer, while 14 did not include explicit compensation.

II. Interim Agreements

There were 11 interim agreements in FY 2008. Seven 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. One agreement followed an at-risk launch, and provided for a temporary "stand still" to facilitate settlement negotiations. Two agreements

provided that the parties would be bound by the results of related patent litigation. Finally, one agreement set forth stipulations as to various timing issues, including the date from which the 30-month stay triggered by the patent litigation would begin to run.

III. Generic-Generic Agreements

In FY 2008, three agreements between generic manufacturers were filed under the MMA. Two of these agreements related to arrangements under which one generic manufacturer agreed to relinquish its 180-day exclusivity rights in exchange for profit-sharing on the other's generic product. One of the agreements was related to simultaneous patent settlements that two generic companies sharing potential 180-day exclusivity rights entered with a branded company. The agreement between the generic companies provided that each would not interfere with the other's generic launch.

IV. Other Agreements

Two of the agreements filed in FY 2008 do not involve either a final settlement or an interim agreement arising out of patent litigation brought by the branded company. One agreement was between a branded company and one of several later-filing generic companies and provided that the generic company would market an authorized generic product upon the launch of the first filer's generic product. No patent litigation was pending at the time of the agreement. The other agreement was entered between a branded and generic company engaged in patent litigation, but did not settle the litigation. The agreement appointed the generic company as the brand's exclusive authorized generic and allowed the generic to enter before the conclusion of appeals in the patent litigation. The agreement thus effectively ensured that the generic company would not face competition from an independent authorized generic product.

Figure III: Breakdown of Final Settlements by Restriction and Compensation

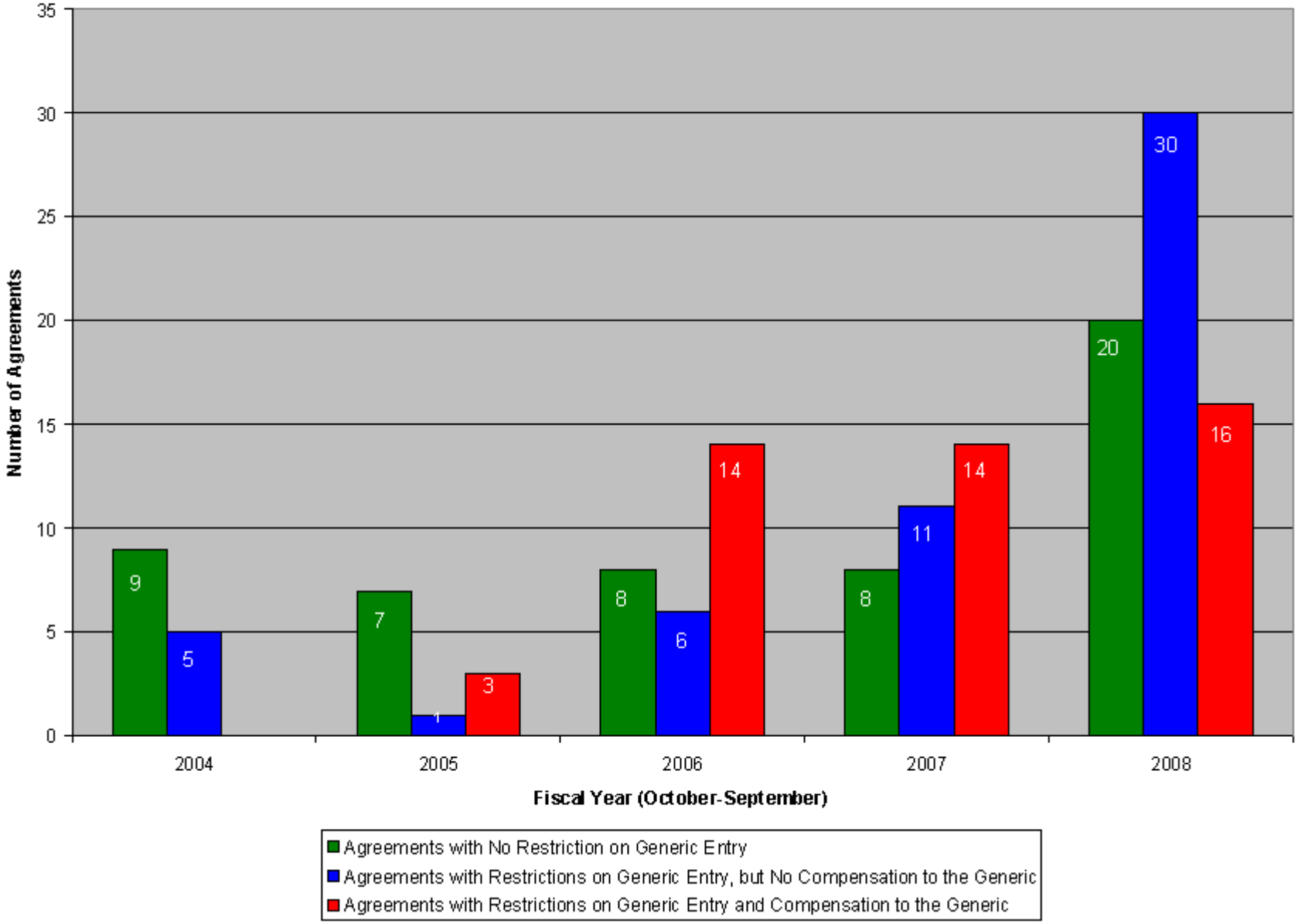


Figure IV: Breakdown of Final Settlements with First-Filers by Restriction and Compensation