[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 pa

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 principa

[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
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allowed the generic company to retain its 180-day exclusivity rights. Finally, one agreement
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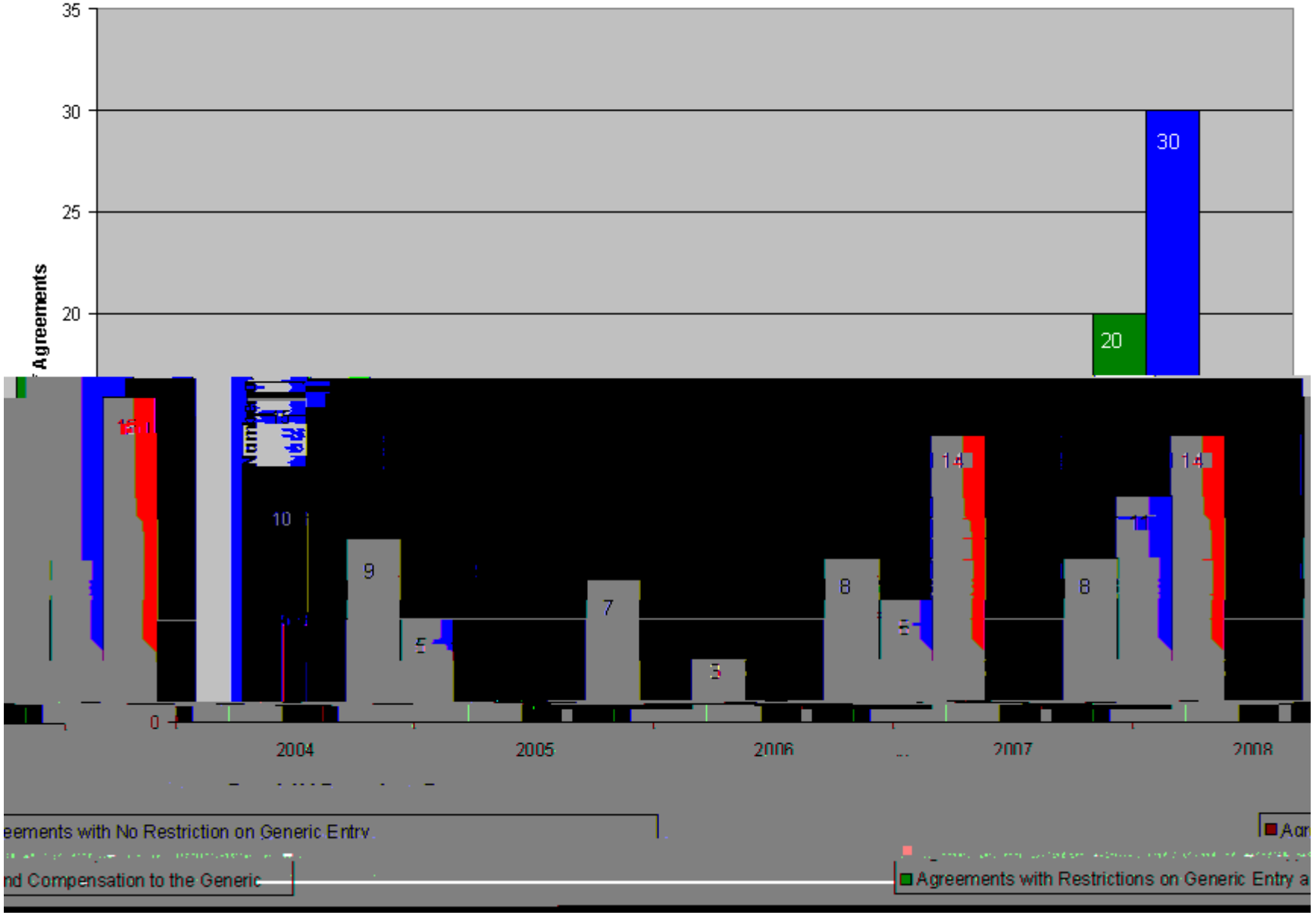
Figure III: Breakdown of Final Settlements by Restriction and Compensation



tlements with First-Filers by Restriction and Compensation

Figure IV: Breakdown of Final Set