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

Summary of Agreements Filed in FY 2004
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 with the Department of Justice within ten days of execution.[1] Below, the Bureau of Competition staff summarizes the number and types of agreements received during fiscal year 2004 (ending September 30, 2004) and compares this information with the data reported in 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 features include:

- whether the agreement was between brand-generic or generic-generic manufacturers;
- whether the agreement resolved 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]

I. The FTC received twenty-two agreements during FY 2004 (*See* Fig. 1).

A. Nineteen of the twenty-two agreements received during FY 2004 involved brand and generic manufacturers (*See* Fig. 1).

1. Fourteen of the nineteen brand-generic agreements resolved patent infringement litigation (*See* Figs. 1).

a. Nine of the fourteen did not restrict generic entry and had no or varying payment arrangements.

Nine of the fourteen settlements did not restrict generic entry either because (a) the

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

[2]"Generic Drug Entry Prior to Patent Expiration: An FTC Study," Federal Trade Commission, July 2002, at http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf.

[3]A subsequent generic filer means any generic filer that is not the first filer.

generic was already on the market and the settlement did not require the generic to withdraw its product (three agreements), (b) the agreement allowed the generic to market its product upon receiving FDA approval (five agreements), or (c) the brand agreed to supply the generic with product within three months of the agreement (one agreement) (*See* Fig 2). Of these nine agreements, three had no payments between the parties, two required a royalty from the generic to the brand, and four had payments from the brand to the generic (*See* Fig. 3).

b. Five of the fourteen placed some restriction on generic entry; most involved no payments.

The remaining five agreements placed some restriction on generic entry: three restricted generic entry until patent expiration, and two allowed entry prior to patent expiration (*See* Fig. 2). Four of these five settlements involved no payments at all, and, in the fifth settlement, the generic agreed to pay a royalty to the brand (*See* Fig. 3).

c. Eight of the fourteen brand-generic patent settlements involved a brand company and a first-filer generic company.

(1) Four of the eight brand-generic patent settlements with a first-filer did not restrict entry and had various payment provisions.

In one instance, the generic company was already marketing the product subject to the agreement. The other three allowed for generic entry immediately upon final FDA approval.

Two of the four agreements that did not restrict generic entry included no payments between the companies (*See* Fig. 3). A third agreement provided for payment of a royalty by the generic to the brand based on the generic company's sales. In the fourth agreement, the generic company won a decision of non-infringement, and the brand company subsequently settled the litigation with a payment by the brand to the generic.

(2) Four of the eight brand-generic patent settlements with a first-filer generic did restrict generic entry, but none included payments from the brand to the first-filer generic.

Of the four agreements that restricted generic entry, three provided for generic entry upon the expiration of the patent(s) at issue in the litigation and did not involve the exchange of any payments between the parties. The fourth agreement restricted generic entry for six months and provided for the payment of a royalty by the generic to the brand based on the generic company's sales.

d. The remaining six of the fourteen brand-generic patent settlements were with a subsequent generic filer (*See* Fig. 1); only one agreement placed any restriction on generic entry, and that agreement involved no payments.

In five of the six settlements involving subsequent filers, there was no restriction on generic entry. Of those five settlements, three included a payment from the brand to the generic.[4] In the fourth settlement, the brand company agreed to license and supply its product to the generic company in exchange for royalties and a share of the generic's profits from marketing the product.[5] The fifth settlement did not involve any payments among the parties.

Only one of the remaining six settlements placed any restriction on generic entry, and that settlement did not include any payments between the parties involved. The litigation involved multiple patents that were listed in the Orange Book. Under the settlement, the generic could enter approximately three years after the agreement, which was the expiration date for one of the patents at issue in the litigation and approximately eight years before the expiration of the other two patents.

2. Five of the nineteen brand-generic agreements did not settle patent litigation.

In one of those five agreements, the brand manufacturer purchased an exclusive license to the generic's product. In another, the brand company licensed its product to a generic company and agreed to supply that company with the product. In a third agreement, a brand company provided to the generic a license to intellectual property covering the brand company's product, and there was a short-term supply agreement in which the brand would sell its product to the generic. The remaining two brand-generic agreements were interim arrangements during the pendency of patent infringement litigation.

B. The remaining three agreements were generic-generic agreements and involved the transfer or sharing of the 180-day exclusivity period.

In all three generic-generic agreements, a first-filer (i.e., the first company to file an abbreviated new drug application with the FDA for a particular product) experienced a production impediment and partnered with another generic company to market the product during the exclusivity period. In all three agreements, the parties agreed to share the profits from the sale of the products involved. None of the three agreements restricted entry with a competing product by either party to the agreement.

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[4]Specifically, in two of the three settlements, the generic company was already marketing its generic product. In the third settlement, the brand made a payment to the generic company, but there was no restriction on the generic's ability to market its own generic product.

[5]The agreement required the brand to supply the generic within three months.

II. A Comparison of Settlements Collected in the Generic Drug Study and Settlements Filed Under the MMA in FY 2004.

Below is a comparison of the data collected on patent litigation settlement agreements for the Generic Drug Study with that collected during the first nine months (FY 2004) of the MMA.

A. The number of patent settlements involving brand-generic litigation appears to have increased.

Overall, the number of patent settlements involving brand-generic litigation has increased. In the seven years between 1992 and 1999, there were fourteen final settlements between the brand and the first-filer. Since 2000, there have been at least fourteen final settlements, with eight occurring since January 2004.[6] Similarly, there were six final settlements between the brand and a subsequent filer between 1992 and 1999, and there have been at least six final settlements between the brand and a subsequent filer since 2000.

B. Settlements after 1999 do not appear to include a payment from the brand to the generic in exchange for the generic's agreement not to market its product.

The structure of brand-generic settlements has changed over time in that settlements after 1999 do not appear to include a payment from the brand to the generic in exchange for the generic's agreement not to market its product. The Generic Drug Study showed 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. Since that time, the Commission is aware of no final settlements of patent litigation in the pharmaceutical industry in which the brand paid the generic to agree not to market its product. Neither the six settlements entered in 2000 and 2001 nor the fourteen settlements reported under the MMA contained payments in exchange for the generic's agreement not to market its product.

C. None of the settlements reported under the MMA placed a restriction on the generic's ability to develop or market a non-infringing product.

None of the settlements reported under the MMA placed a restriction on the generic's ability to develop or market a non-infringing product. This finding is consistent with the

[6] We lack complete data for the approximately three-year period between January 2001 and the beginning of the MMA reporting period. Specifically, we do not have any settlements of litigation that were entered after June 1, 2002 and before January 7, 2004. We also do not have settlements of litigation in which (1) the first paragraph IV certification was filed after January 1, 2001, and (2) the settlement was entered before June 1, 2002. It is quite likely that additional settlements occurred during this period for which we do not have information. For that reason, we qualify the number 14 with the words "at least."

agreements reported in the Generic Drug Study, i.e., that restrictions on the generic's ability to market non-infringing products occurred only in agreements in which the brand paid the generic not to market the allegedly infringing product.

Based on both the settlements collected in the Generic Drug Study and the settlements reported under the MMA, brand and generic companies have entered patent settlements that included a license to a product unrelated to the litigation in three of forty final settlements. The Generic Drug Study reported that two agreements included licenses for drug products other than the one subject to the ANDA litigation. In addition, there was one other situation in which the license to the unrelated product was memorialized in a separate agreement from the actual settlement of patent litigation, but the two agreements cross referenced each other. None of the agreements reported under the MMA included a license to an unrelated product or cross-referenced a separate agreement.

Figure I:
Overall Breakdown of Agreements Provided under the MMA in fiscal year 2004

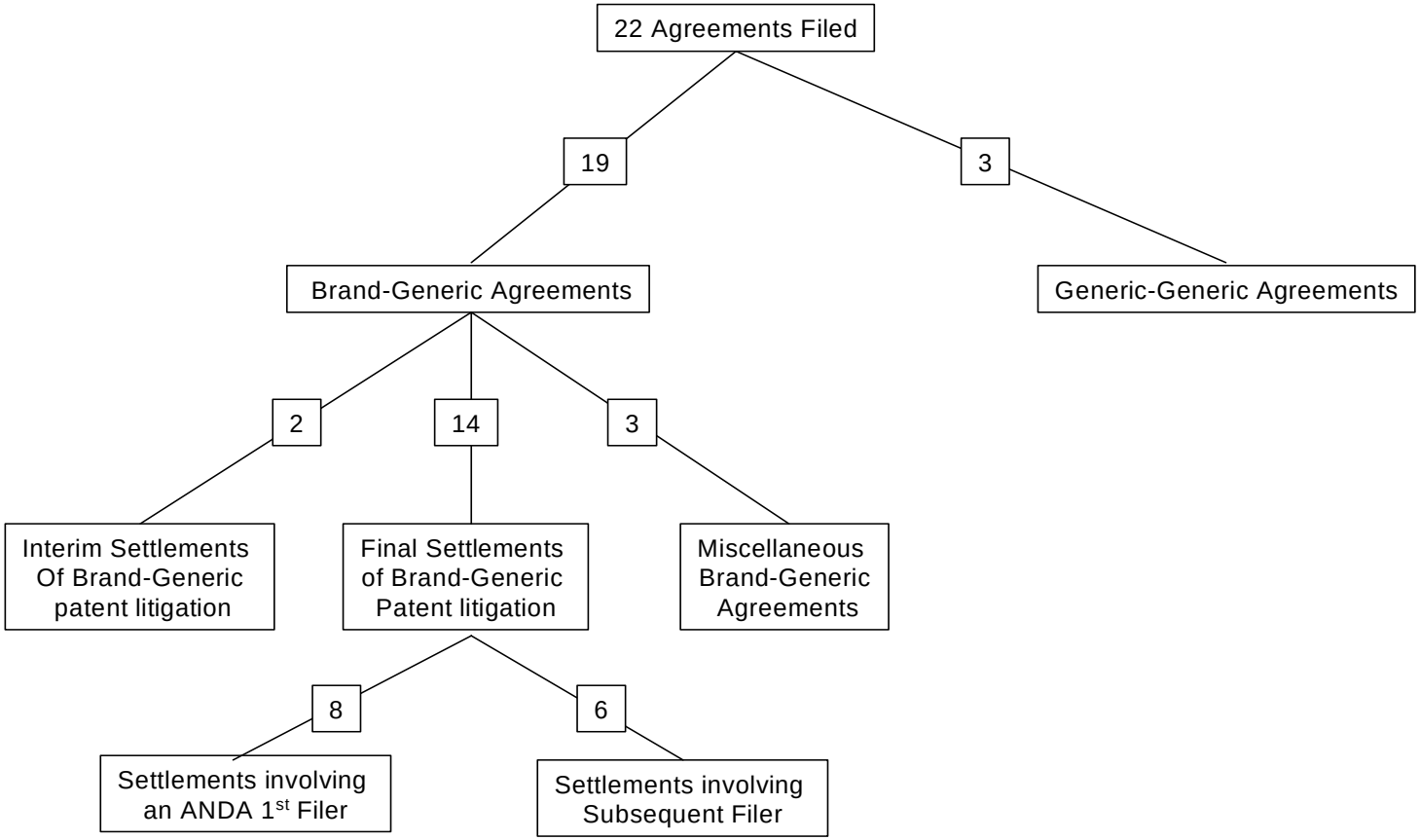

Figure II:
Breakdown of Final Settlements by Entry Restrictions

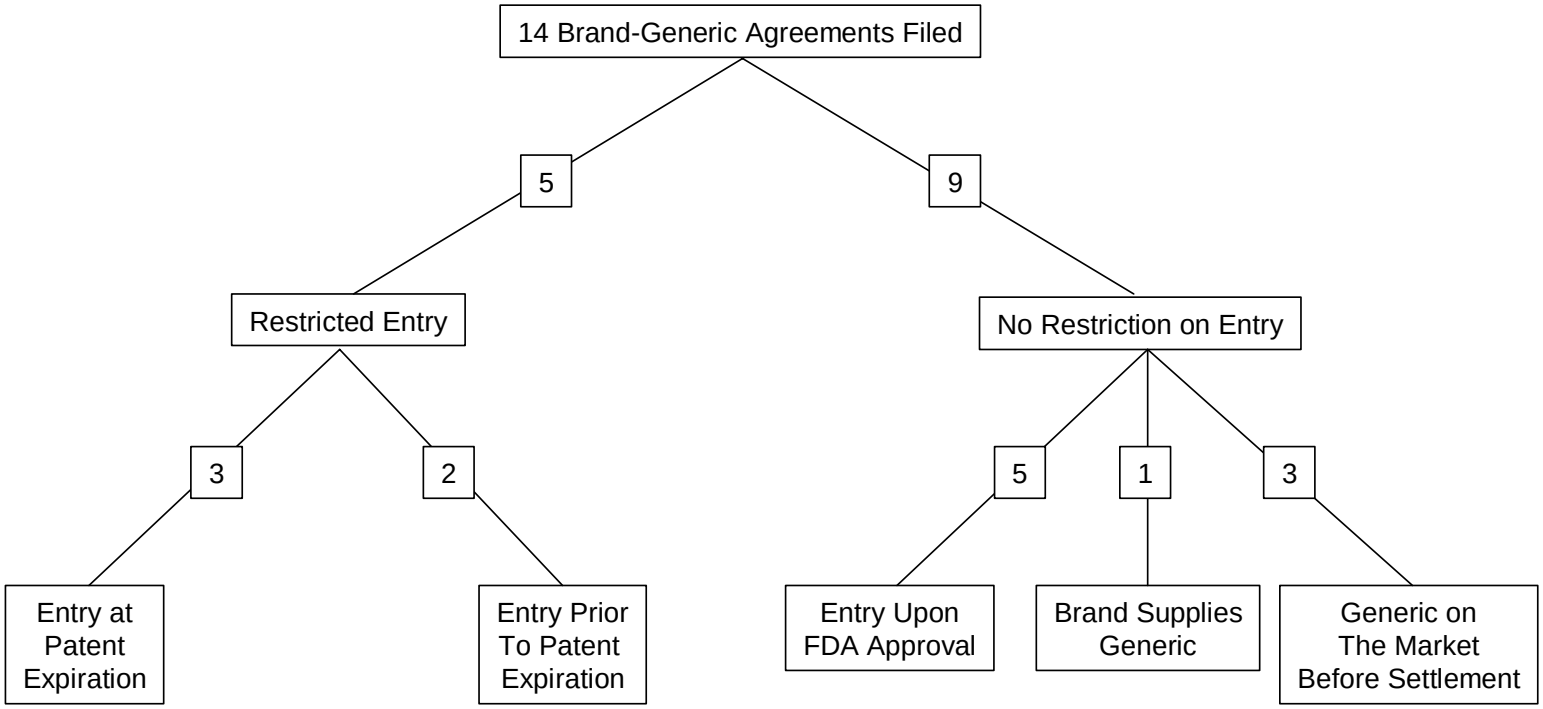

Figure III:
Breakdown of Final Settlements by Type of Payment