

Settlements With Payments To Generics Increase: FTC

Wednesday, March 28, 2007 --- On January 17, 2007, the Federal Trade Commission (FTC) issued its third annual report detailing settlement activity between brand and generic firms resolving patent suits. (The report can be found at <http://www.ftc.gov/reports/mmact/MMAreport2006.pdf>.)

The report notes that the number of settlements between brands and generics filed with the FTC more than doubled in fiscal year 2006 (to 45 total), compared to the number of settlements filed with the FTC in each of the previous two years.

The report emphasizes that so-called reverse-payment or exclusion-payment settlements—in which the brand firm provides compensation to the generic firm and in which there also is some restriction on generic entry—increased substantially.

In fiscal year 2006, 14 of 28 (or 50%) of the final settlements filed with the FTC included such a reverse payment. In contrast, in fiscal year 2005, only 3 of 11 settlements contained reverse payments, and none of the 14 filed settlements in fiscal year 2004 contained reverse payments.

The FTC report attributes the increase to several recent appellate court decisions that have upheld settlements containing reverse payments.

Indeed, all of the agreements reported to the FTC in fiscal year 2006 occurred after the Eleventh Circuit reversed the FTC decision in *FTC v. Schering-Plough*, which had held that a reverse payment from Schering-Plough to generic firm Upsher-Smith in return for delayed generic entry violated the antitrust laws.

This data strongly suggests that the Eleventh Circuit decision had a palpable impact on settlement practices in the pharmaceutical industry.

* Details on the FTC Report *

Under the 2003 Medicare Modernization Amendments, certain settlements of patent litigation between brand and generic firms (and, in some instances, between generic firms themselves) must be filed with the FTC. (Details on the types of agreements that must be filed with the FTC are available at www.ftc.gov/os/2004/01/040106pharmrules.pdf.)

The filing requirements simply provide notice to the FTC of the settlement; the parties do not need to wait for FTC approval before finalizing their settlement, and FTC inaction does not prevent the agency from subsequently

investigating or challenging a particular settlement.

Since the enactment of these amendments, the FTC has issued annual reports providing details on the settlements filed during that fiscal year.

The FTC—as it stated in its Schering-Plough decision and still maintains in public statements by FTC officials despite the Eleventh Circuit reversal in that case—takes the position that compensation paid to a generic firm harms consumers when the generic firm also agrees to an entry date.

In the FTC's view, absent such compensation, the parties would have reached a compromise on the entry date based on their objective views of the merits of the patents in dispute. Consumers are harmed because the introduction of compensation into the equation moves the entry date back and delays access to lower-cost generic drugs.

In light of its view that reverse payments often harm consumers, the FTC notes in its report that the substantial increase in patent settlements containing such compensation is alarming.

The report makes several other noteworthy observations, including:

- Of the 28 final settlements between brand and generic firms, 11 involved abbreviated new drug application (ANDA) first-filers. Of these 11 first-filer settlements, 9 included a payment from the brand firm to the generic firm, and an accompanying restriction on generic firm entry—a much larger percentage than exists in those settlements not involving first-filers. Such settlements are “especially problematic” (as noted by Commissioner Jon Leibowitz in his oral remarks to the Senate Judiciary Committee, provided on the same day as the release of the FTC report), because first-filers receive 180 days of market exclusivity and thus “may create a bottleneck for other generics who want to enter.” (The official FTC testimony can be found at www.ftc.gov/speeches/leibowitz/070117anticompetitivepatentsettlements_ser Commissioner Leibowitz' oral statement can be found at www.ftc.gov/speeches/leibowitz/071701oralstatement.pdf.)
- In five of the reported settlement agreements (all of which included a payment from the brand firm to the generic firm), the generic firm agreed to restrictions on marketing products that were not the subject of the patent dispute. The FTC notes that this was the first time it has observed such settlements.
- In addition, there were 10 settlements filed with the FTC that contained side deals in which the brand firm provided some form of compensation to the generic firm for rights not directly related to the patent dispute, and the generic firm agreed to an entry date as part of the settlement. (These side deals are described in more detail below.) The FTC noted in its recent Senate Judiciary Committee testimony that such terms were observed in settlements that restrained generic entry, but “virtually never in settlements that did not.” (The report notes that there were only two reported side deals

in which there was no explicit restriction on the generic's ability to market its product.) This observation appears to reflect the agency's skepticism regarding agreements that involve in-kind compensation unrelated to the underlying patent suit.

- In one reported settlement, the only compensation provided by the brand firm to the generic firm was characterized by the parties to the settlement as "saved litigation expenses." (Other settlements contained saved litigation expenses, but also included other compensation.) The report does not state the amount paid, but the FTC generally has viewed certain de minimis payments that may reasonably reflect saved litigation costs to be acceptable. For example, the FTC's Schering-Plough decision and other prior pharmaceutical patent settlements' consent agreements provide such an exception for the lesser of payments equivalent to the brand firm's litigation costs, or \$2 million.

- In three reported final settlements, the compensation provided by the brand firm was either an agreement by the brand not to launch or sponsor an authorized generic during the 180-day exclusivity period granted to the settling generic firm, and/or some amount of compensation equivalent to saved-litigation expenses. The FTC's attention to this statistic—and, in particular, its reference to such an agreement on authorized generics as "compensation"—may reflect FTC concerns over such provisions.

* FTC Review of Side Deals in the Context of Settlement *

The report also provides a useful general discussion of agreements containing side deals—settlements in which the brand and generic firms enter into an agreement "involving elements not directly related to the resolution of the patent litigation."

Such side deals can, according to the report, act as a means to provide compensation to the generic firm if the side deal is not bona fide or could be characterized as conveying a value to the generic firm that exceeds the value of what the brand firm acquires.

In such instances, the FTC will examine the side deal to determine whether it provided net compensation to the generic firm. Thus, in the Schering-Plough case, the agency found that the brand firm's payment of \$60 million to the generic firm exceeded the value of the products that the brand licensed from the generic in a side deal.

The FTC continues to express skepticism about such side deals in the context of patent settlements. Its recent testimony before the Senate Judiciary Committee stated that this "pattern indicates that such 'side agreements' may be serving as a vehicle to compensate a generic challenger for its agreement to a later entry date than the generic firm would otherwise accept."

The report provides useful details regarding 10 reported final settlements that

contained side deals in which the generic firm received compensation from the brand firm in a variety of forms, including:

- Intellectual property licenses – In five reported agreements, the parties entered into a side deal in which the generic firm received licenses to intellectual property, which the FTC characterized as compensation. (In three instances the licenses related to the products in litigation, and in two they were unrelated.)
- Co-promotion arrangements – In four reported agreements, the parties entered into a side deal in which the generic firm agreed to co-promote certain of the brand firm's products (in two instances the co-promoted product related to the products in litigation, and in two others the products were unrelated), in exchange for monetary compensation from the brand firm.
- Supply agreements – In three reported agreements, the parties entered into a side deal in which the generic firm agreed to supply the brand firm with either raw materials or the finished drug product in exchange for monetary compensation. Two of the agreements provided a minimum purchase-price guarantee for the generic firm, and the other included a payment from the brand firm regardless of whether or not the generic firm actually supplied product to the brand.
- No authorized generic agreements – In one reported settlement, the brand firm agreed to refrain from marketing an authorized generic of the product at issue during the generic firm's 180-day exclusivity period. In a second settlement, the brand firm agreed to refrain from marketing an authorized generic of the product at issue, but also granted a license on an unrelated product (and agreed not to launch an authorized generic during the exclusivity period for that product).
- Development agreements – In two reported settlements, the parties entered into a side deal in which the brand firm provided compensation to the generic firm to develop products unrelated to the patent litigation that produced the settlement (including upfront payments, milestones, sales percentages, and/or development fees).

The FTC's detailed analysis of side deals reflects its continued concern that such deals may be used as a vehicle for brand and generic firms to agree on delayed generic entry in exchange for compensation flowing from the brand to the generic firm. The FTC's emphasis in the report on side deals unrelated to the underlying patent litigation could indicate that the agency may subject such deals to additional scrutiny in the future.

* Settlements without Compensation or Restrictions on Generic Entry *

The report also describes 14 final settlements that either did not include compensation from the brand firm to the generic firm, or did not restrict generic-firm entry.

These settlements included six instances without compensation in which the generic firm either settled and withdrew its patent challenge or withdrew from the market (following an “at-risk” launch) after an adverse appellate decision. In the remaining eight instances, the parties reached a settlement that did not include any explicit restriction on the generic firm’s ability to market its products.

* What’s Next: Enforcement or Legislation? *

The report demonstrates that the FTC remains concerned about the impact of reverse-payment patent settlements, and has taken note of the recent increase in the number of these settlements. The FTC’s Senate Judiciary Committee testimony stated that such “settlements restrict competition at the expense of consumers, whose access to lower-priced generic drugs is delayed, sometimes for many years.”

Thus, investigation of settlements is almost certain to continue, and potentially could result in the FTC bringing an enforcement action in court. Commission officials have stated that they are determining whether there is an appropriate settlement to bring to litigation.

However, the FTC’s recent Senate testimony suggests that a legislative solution may be needed:

Recent court decisions, however, have made it more difficult to bring antitrust cases to stop exclusion payment settlements, and the impact of those court rulings is becoming evident in the marketplace.... For that reason, the Commission supports legislation to prohibit these anticompetitive settlements and strongly supports the intent of the legislation introduced by Senators Kohl, Leahy, Grassley, and Schumer, including the objective to adopt a bright-line approach to addressing exclusion payments.

One month following that testimony, the Senate Judiciary Committee passed S. 316, a bill that bans brand firms from providing “anything of value” to generic firms in exchange for delaying its entry into the market. That bill still must pass the full Senate, and its fate remains quite uncertain, as it likely will face significant opposition from both the brand and generic pharmaceutical industries.

Thus, until the fate of this legislation is decided, the potential for FTC investigation of reverse-payment settlements should remain a significant concern for pharmaceutical firms seeking to resolve pending patent disputes, and firms must understand the risks associated with the settlement of such disputes.

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