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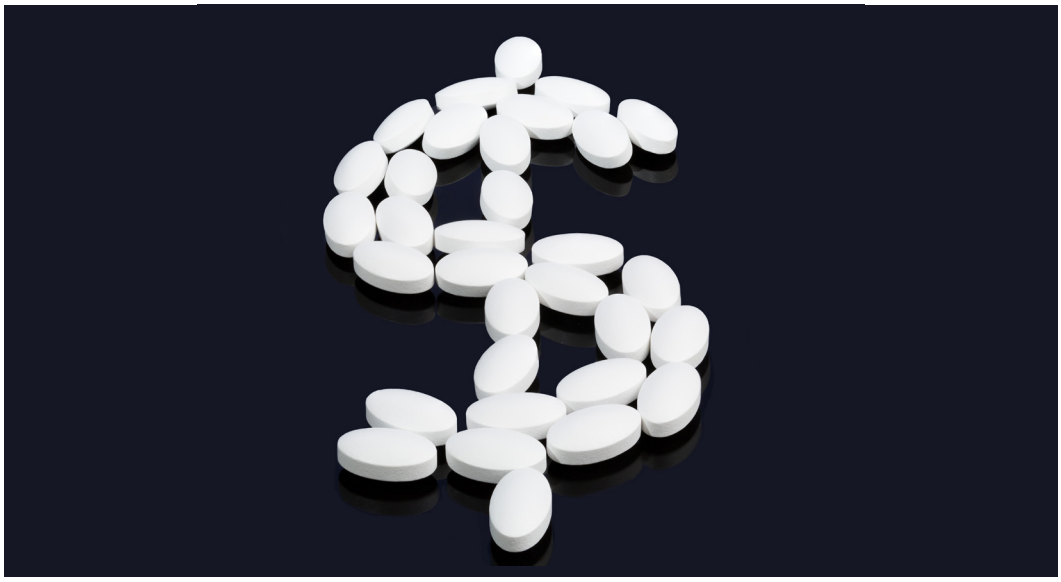
FTC Report Tallies Hatch-Waxman Settlement in First Full Year After *Actavis*



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On January 13, 2016, the Federal Trade Commission (FTC or the Commission) released an overview of the pharmaceutical patent settlements (available at https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/160113mmafy14rpt.pdf) filed with the Commission in Fiscal Year 2014 (October 1, 2013 – September 30, 2014). The FTC has published similar reports annually since the passage of the Medicare Modernization Act of 2003, which requires parties that settle patent infringement litigation brought pursuant to the Hatch-Waxman Act to file copies of their agreements with the FTC and the Department of Justice. The FTC's latest report reflects the second full year of agreements following the U.S. Court of Appeals for the Third Circuit's decision in *In re K-Dur Antitrust Litigation*, 686 F.3d 197 (3d Cir. 2012), and the first full year of agreements following the Supreme Court's decision in *FTC v. Actavis*, 133 S. Ct. 2233 (2013).

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Reports before FY 2013 predominantly reflected settlement practices under the "scope of the patent test," the once-prevailing standard for evaluating Hatch-Waxman settlements. Under the scope of the patent test, a settlement containing a "reverse payment" from the patent holder to the alleged infringer does not warrant antitrust scrutiny so long as the settlement's exclusionary scope is no greater than that created by the patent in dispute. In *K-Dur*, the Third Circuit broke with the other courts of appeal, rejecting the scope of the patent test and holding that any reverse payment accompanied by delayed generic entry should be treated as *prima facie* evidence of an unreasonable trade restraint and reviewed under a quick look test. Then, less than one year later, in *Actavis*, the Supreme Court rejected both the quick look test and the scope of the patent test, holding that where a plaintiff alleges a large and otherwise unjustified reverse payment, the settlement should be reviewed under the traditional rule of reason analysis.

According to the FTC report, Hatch-Waxman litigants filed 160 final settlements with the FTC in FY 2014. This number is a slight increase compared to the number of final settlements filed in fiscal years 2013 (145), 2012 (140) and 2011 (156). However, the Commission does not report whether the total number of Hatch-Waxman cases has changed over time, so it is unclear whether the percentage of patent infringement cases that ultimately settle has changed. Of the 160 reported settlements, the FTC reports that 21 "potentially involve pay for delay."[1] For another eight, the FTC said it was "not clear from the face of each settlement agreement whether certain provisions act as compensation to the generic patent challenger." The remaining 131 agreements, according to the Commission, involved no payment from the patent holder to the alleged infringer: 20 allowed immediate generic entry and 111 allowed generic entry at a later agreed-upon entry date, but involved no compensation to the generic.

Much like the FTC's report last year, the FY 2014 report sheds little light on the Commission's view regarding the scope of appropriate antitrust scrutiny for reverse payment settlements. The report makes it clear that the FTC believes at least some level of review should occur when the agreement involves a side business deal, precludes the brand from competing during the term of an early entry license (*e.g.*, a so-called "no authorized generic" agreement), or includes a cash payment. What is not clear is whether, in the Commission's opinion, all agreements involving cash payments or side business deals "potentially involve pay for delay," or whether (or when) it believes license terms other than exclusivity (*e.g.*, supply arrangements and royalty payments) merit antitrust review. For example, for the second straight year, the FTC classified an

agreement in which the generic's obligation to pay royalties was reduced or eliminated if the brand company launched an authorized generic as an agreement where it was "not clear" whether there was a reverse payment. The report does not elaborate on any other agreements the FTC deemed difficult to classify.

From the FTC's perspective, the number of "potential" reverse payment settlements has substantially declined. The 21 potential reverse payment agreements reported in FY 2014 is the lowest since FY 2009, and the percentage of final settlements that the FTC deemed potential reverse payment settlements is the lowest since FY 2005. Also, the number of "potential" reverse payment deals involving first filers, which in the Commission's view present special concern because of the potential to block other generic entry, was the lowest since FY 2007 and the lowest as a percentage of final settlements since FY 2005.

The FTC's report suggests that litigants not only have attempted to avoid potential reverse payments entirely, but also have shifted the *types* of consideration exchanged in Hatch-Waxman settlements. For example, nine of the FTC's 21 "potential pay-for-delay" settlements included compensation solely in the form of a cash payment of less than $5 million, purportedly to cover litigation fees. The prevalence of such payments accords with the *Actavis* Court's express endorsement of settlements reflecting avoided litigation costs. Similarly, the Supreme Court suggested that a fair value payment for services rendered would be deemed "justified," and six of the FTC's 21 "potential pay-for-delay" settlements involved compensation in the form of a side business deal.

The FTC reported fewer agreements — five in FY 2014 and four in FY 2013, compared to 19 and 11 in FY 2012 and FY 2011, respectively — in which the Hatch-Waxman litigants agreed to an exclusivity term that barred the brand manufacturer from marketing an authorized generic in competition with the generic manufacturer's product. Migration away from this license term is not surprising, given the FTC's well-publicized position that such exclusive licenses are a form of reverse payment. The Third Circuit's decision in June 2015 that such settlements are subject to rule of reason review[2] may push the number of agreements involving exclusive licenses even lower in the FTC's next report.

Followers of Hatch-Waxman litigation will eagerly await the FTC's FY 2015 report to see how ongoing litigation over the definition of "payment," and the several cases expected to be reviewed by circuit courts of appeal this year, will affect these trends.

Endnotes

1. The 21 agreements involve 20 different branded pharmaceutical products, with combined annual U.S. sales of about $6.2 billion.

2. *King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 288 (3d Cir. 2015).