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FTC Report Tallies Hatch-Waxman Settlements for FY2013

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On December 22, 2014, the Federal Trade Commission (FTC or the Commission) released an overview of pharmaceutical patent settlements (available at http://www.ftc.gov/system/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement/141222mmafy13rpt-1.pdf) filed with the Commission in Fiscal Year 2013 (October 1, 2012–September 30, 2013). The FTC has published similar reports annually since the passage of the Medicare Modernization Act of 2003, which requires parties that settle Hatch-Waxman litigation to file copies of their agreements with the FTC and the Department of Justice. This latest report reflects the first 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), which created a split among courts of appeals as to the standard that courts should apply in evaluating Hatch-Waxman settlements. Although the U.S. Supreme Court resolved the split a year later in *FTC v. Actavis*, 133 S. Ct. 2233 (2013), that decision came at the tail end of FY2013.

Prior reports 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 did not warrant antitrust scrutiny so long as the settlement's exclusionary scope was no greater than that created by the patent in dispute. In *K-Dur*, the Third Circuit broke with the other courts of appeal, holding that any reverse payment accompanied by delayed generic entry should be treated as *prima facie* evidence of an unreasonable trade restraint and should be 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. Thus, FY2013 was the first full year in which Hatch-Waxman litigants expected that some patent litigation settlements previously thought kosher could be subject to antitrust review.

The FTC reports that Hatch-Waxman litigants filed 145 final settlements in FY2013. This number is similar to the number of final settlements filed in fiscal years 2012 and 2011, although the FTC does not report whether the total number of Hatch-Waxman cases has changed over time. Of the 145 reported settlements, the FTC reports that 29 "potentially involve pay for delay."[1] For another 10, the FTC said it was "not immediately obvious . . . whether certain provisions act as compensation to the generic patent challenger." The remaining 106 agreements, according to the FTC, involved no payment for delay: 31 allowed immediate generic entry and 75 allowed the generic to enter at a later agreed-upon entry date.

The FTC's report, however, sheds little light on what kinds of agreements fall outside those the Commission believes merit antitrust scrutiny. The report makes it clear that the Commission would subject to review at least some agreements involving a cash payment to determine whether the payment approximated the generic's litigation fees, agreements involving side business deals and agreements where the vehicle for early entry is an exclusive license that precludes the brand from competing during the period of exclusivity. 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 the Commission believes valuable license terms other than exclusivity (e.g., supply arrangements and royalty payments) merit antitrust review. For example, 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 immediately obvious" whether there was a reverse payment. The report does not elaborate on any other agreements the FTC deemed difficult to classify.

Although *Actavis* was not decided until the end of the fiscal year, the numbers do suggest some overarching trends. At least from the FTC's perspective, the number of "potential" reverse payment settlements has held fairly steady, even though both *K-Dur* and *Actavis* increased the potential for antitrust review. While the 29 potential reverse payment agreements reported in FY2013 is lower than the record-breaking 40 reported in FY2012, the number is about the same as the 31 reported in FY2010 and the 28 reported in FY2011. If the 10 unclassified agreements are deemed reverse payment settlements, the FY2013 total is only one fewer than the FY2012 record. Surprisingly, the percentage of early-entry-only settlements without any reverse payment has declined over the last three years — from 64 percent in FY2011 to 57 percent in FY2012 to 51 percent in FY2013. However, the number of "potential pay-for-delay" deals involving first filers, which present special concern in the FTC's view because of the potential to block other generic entry, was the lowest since 2008.

One explanation for these results is that, while litigants have taken note of the shifting standard, many litigants still are not willing or able to settle with no consideration (other than the early entry date) flowing to the generic. Litigants instead have shifted the *types* of consideration exchanged in Hatch-Waxman settlements to give them a better chance of evading or withstanding antitrust scrutiny. For example, 14 of the FTC's 29 "potential pay-for-delay" settlements included compensation "solely in the form of a cash payment from the brand to the generic that purported to reimburse some or all of the generic's litigation fees." The prevalence of such payments accords with the *Actavis* Court's express endorsement of settlements reflecting avoided litigation costs.[2] Similarly, both the Third Circuit and the Supreme Court suggested that a fair value payment for services rendered would be deemed "justified," and 11 of the FTC's 29 "potential pay-for-delay" settlements involved compensation in the form of a side business deal.

By contrast, the FTC reported fewer agreements — only four — 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 exclusive licenses are a form of reverse payment subject to antitrust review.

Followers of Hatch-Waxman litigation will eagerly await the FTC's FY2014 report, which will be the first to reflect an entire year of settlements inked post-*Actavis,* to see how the Supreme Court's new rule and ongoing litigation over the definition of "payment" will affect these trends.

Endnotes

1. The 29 agreements involve 21 different branded pharmaceutical products, with combined annual U.S. sales of about $4.3 billion. This sales total is about half that at issue in recent years.
2. Similarly, in briefing before the Supreme Court, the FTC advocated that defendants in an antitrust lawsuit should be able to rebut a plaintiff's *prima facie* case by showing that any payments were "commensurate with the litigation costs that the brand-name manufacturer would otherwise have borne." Opening Brief at 17. It remains unclear whether the FTC distinguishes between past and expected litigation costs.