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FTC Publishes Annual MMA Report and Updated Filing Procedures

June 2019

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On May 23, 2019, the Federal Trade Commission (FTC) published its annual report on pharmaceutical patent settlements filed with the FTC under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), followed a week later by a retrospective analysis of the thirteen MMA reports published since 2004. On June 6, 2019, the FTC also announced updated filing procedures for certain settlements of pharmaceutical patent litigation.

Patent Settlements Are Up While "Reverse Payments" Are Down

The FTC's MMA reports largely focus on the number of pharmaceutical patent settlements executed each year and the type of provisions that the FTC considers to be part of such settlements. Relying on the latest available data from fiscal year 2016, the FTC concludes that:

- the number of pharmaceutical patent settlements have continued to increase, while the number of so-called "reverse payments" have declined;
- "of the 232 final settlements received in FY 2016, only one contained a no-AG [authorized generic] commitment or a side deal—the most commonly challenged forms of reverse payments"; and
- no "side deals" were executed contemporaneous with a patent settlement in either FYs 2015 or 2016.[1]

Despite this decline, there was a 70% increase in pharmaceutical patent settlements compared to FY 2015 in which "it is not clear from the face of the agreement whether certain provisions act as compensation from the brand to the generic company"—referred to by the FTC as "possible compensation."[2] The FTC warns that it "will be closely scrutinizing such agreements as filings with side deals and traditional no-AG commitments continue on a downward trend."[3]

The FTC Continues To Endorse A $7 Million Litigation Cost Threshold

The Supreme Court's seminal *FTC v. Actavis* decision recognized that "where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the

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1 Jamie Towey & Brad Albert, *Then, now, and down the road: Trends in pharmaceutical patent settlements after* FTC v. Actavis, FTC Bureau of Competition (May 28, 2019), https://www.ftc.gov/news-events/blogs/competition-matters/2019/05/then-now-down-road-trends-pharmaceutical-patent.

2 *Id.*

3 *Id.*

same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement."[4] Against this backdrop, the FTC's recent MMA report concludes that for FY 2016:

- 29 of the 30 settlements that restrict generic entry and include explicit compensation "contain payment in the form of litigation fees, with the brand manufacturer's payment to the generic manufacturer ranging from $250,000 to $7 million"; and
- the average payment was $2.85 million.[5]

This is not the first time that the FTC has endorsed this $7 million threshold. For example, the MMA report for FY 2015 states that "recent stipulated orders for permanent injunction entered by the Commission in reverse-payment cases have not prohibited settlements that restrict a generic's entry and include a cash payment of $7 million or less in litigation fees."[6]

Continued Review By The FTC And Updated Filing Procedures

The FTC's report and follow-on analysis emphasize that the FTC will continue to scrutinize pharmaceutical patent settlements, particularly where the terms may achieve the same effect as an explicit payment from the brand to the generic company. On June 6, 2019, the FTC also announced procedural updates for filing certain settlements of pharmaceutical patent litigation with the FTC and Department of Justice, including that starting on June 17, 2019 MMA filings should be submitted electronically. The FTC's announcement also emphasizes that Congress last year extended reporting requirements to certain biologic and biosimilar agreements.[7] Congress also "expanded the types of documents that must be submitted with any relevant agreement," such as "any agreements that the parties entered into within 30 days before or after a relevant agreement."[8]

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4 *FTC v. Actavis*, 570 US 136, 156 (2013).

5 Overview of Agreements Filed in FY 2016, A Report by the Bureau of Competition, https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/mma_report_fy2016.pdf.

6 Overview of Agreements Filed in FY 2015, A Report by the Bureau of Competition, https://www.ftc.gov/system/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-modernization/overview_of_fy_2015_mma_agreements_0.pdf.

7 FTC Press Release, Pharmaceutical Agreement Filing Procedures Updated (June 6, 2019), https://www.ftc.gov/news-events/press-releases/2019/06/pharmaceutical-agreement-filing-procedures-updated?utm_source=govdelivery.

8 *Id.*