Skadden

Skadden, Arps, Slate, Meagher & Flom LLP & Affiliates

September 10, 2014

FTC Doubles Down in Challenge to Pharmaceutical Settlement

On September 8, 2014, the Federal Trade Commission (FTC) filed a federal antitrust complaint in the United States District Court for the Eastern District of Pennsylvania against defendants AbbVie, Abbott Laboratories, Unimed Pharmaceuticals, Besins Healthcare and Teva Pharmaceuticals alleging violations of Section 5 of the FTC Act, 15 U.S.C. § 45(a), for entering into an agreement to maintain a monopoly over and restrain generic competition to AndroGel, a testosterone replacement therapy product. The complaint claims that the defendants entered into an illegal "reverse-payment" settlement, but additionally — and in a departure from previous cases the FTC has filed — that AbbVie, Abbott, Unimed and Besins (the Abbott Defendants) filed sham patent infringement lawsuits against potential competitors Teva and Perrigo Company. This is the first FTC suit to challenge as anti-competitive the underlying patent infringement litigation that led to the allegedly illegal settlements.

The commissioners voted 3-2 in favor of bringing the complaint, with the Democratic appointees voting in favor and the Republican appointees dissenting. In all previous reverse-payment cases brought by the FTC, the vote of the commissioners had been unanimous. This will be the third reverse-payment case litigated by the FTC and the first since the landmark Supreme Court decision in *FTC v. Actavis*. The FTC's recent activity in this area also includes other investigations.

Sham litigation refers to the filing of "objectively baseless" litigation against a competitor for the purpose of utilizing the judicial or other governmental processes in order to directly interfere with the business relationships of that competitor. Litigation is objectively baseless if no reasonable litigant could realistically expect success on the merits of the claim. Reverse-payment settlements are the label given by the FTC and some commentators to a patent litigation settlement in which settlement consideration flows from the patent holder to the alleged infringer. In the pharmaceutical industry, the alleged infringer is typically a firm that proposes to enter the market with a generic version of a patented drug, and the patent holder is the originator (or a licensor) of a branded drug product. The pharmaceutical regulatory environment, specifically the Hatch-Waxman Act, incentivizes generic patent challenges while providing patent holders with an opportunity to seek legal redress in court against potential infringers before the generic product is commercialized.

Investigating and challenging reverse-payment settlements has been a hallmark of FTC healthcare enforcement, culminating (for the time being) in the United States Supreme Court's landmark decision in *FTC v. Actavis*. In that decision, which concerned other generic versions of AndroGel, the Court ruled that reverse-payment settlements are to be analyzed under the Rule of Reason, a mode of antitrust analysis requiring a detailed inquiry into the potential anti-competitive and pro-competitive effects of the transaction in question. While leaving most of the contours of this analysis to the discretion of lower federal courts, the Court enunciated a set of five "considerations" as reasons why such agreements should be subject to antitrust review. The key consideration is the presence of a "large and unjustified" payment on behalf of the patent holder to the alleged infringer. Notably, the Court explicitly rejected the FTC's proposed "quick look"

If you have any questions regarding the matters discussed in this memorandum, please contact the following attorneys or call your regular Skadden contact.

Steven C. Sunshine
Washington, D.C.
202.371.7860
steve.sunshine@skadden.com

Sharis A. Pozen
Washington, D.C.
202.371.7555
sharis.pozen@skadden.com

Karen Hoffman Lent
New York
212.735.3276
karen.lent@skadden.com

Paul M. Eckles
New York
212.735.2578
paul.eckles@skadden.com

* * *

1440 New York Avenue, NW,
Washington, D.C. 20005
Telephone: 202.371.7000

Four Times Square, New York, NY 10036
Telephone: 212.735.3000

WWW.SKADDEN.COM

standard, which would have held such agreements presumptively illegal unless the defendants could demonstrate overwhelming pro-competitive benefits. Additional reverse-payment suits such as *AbbVie* form the FTC's "second bite at the apple" in defining the law of antitrust and pharmaceutical patent settlements.

The FTC's complaint in *AbbVie* marks a key development because it is the first FTC reverse-payment case to be filed in the wake of the *Actavis* decision. It also represents a departure from the FTC's approach in these types of cases in that it alleges that the underlying patent infringement litigation was baseless and motivated by anti-competitive purposes (*i.e.*, a "sham"), which led to Teva's participation in that anti-competitive scheme by settling with the Abbott Defendants. In past investigations and suits over reverse-payment settlements, the FTC has not challenged the validity of the underlying patent infringement litigation. The FTC's argument lays out a detailed explication of the patent environment and history, focusing on an ingredient in branded AndroGel called isopropyl myristate (or IPM), which is known as a "penetration enhancer" because it speeds the delivery of the drug's active ingredient, testosterone, through the skin and into the bloodstream. Although Teva and Perrigo developed testosterone gel products that did not contain IPM and used different penetration enhancers than AndroGel, the Abbott Defendants sued Teva and Perrigo for patent infringement. The Abbott Defendants therefore allegedly used the statutory 30-month litigation stay merely as a tactic to delay introduction of generic AndroGel.

In the underlying patent litigation at issue, Teva had asserted an antitrust counterclaim that the infringement suit constituted sham litigation. But according to the FTC's complaint, "Teva subsequently recognized that it would be more profitable to reach an agreement with AbbVie to share the monopoly profits from AndroGel than to compete." Teva and the Abbott Defendants entered into an agreement whereby Teva would be authorized to market a generic version of TriCor, an anti-cholesterol drug that was still under patent protection. The FTC's complaint argues that this exchange is a "large and unexplained" payment under *FTC v. Actavis*, because the economic benefits to Teva to market a generic version of TriCor were substantially greater than the benefits of continuing to attempt to market generic Androgel, and there was no independent business justification on the part of the Abbott Defendants apart from delaying the introduction of generic AndroGel.

The split vote of the commission means that Maureen Ohlhausen and Joshua Wright, both Republican appointees, did not find there was sufficient reason to believe that the law had been violated or that a proceeding would be in the public interest. Neither commissioner has provided a reason for the dissent, and it remains to be seen whether this division among the commissioners signals a potential shift in direction or policy for the FTC. Given that the investigation that ultimately led to the FTC's filing in the *AbbVie* case had been open for some time, it is possible that the commission chose to delay taking action until Commissioner Terrell McSweeney was confirmed and able to provide the deciding vote. The FTC does not take action in the event of a 2-2 vote, which presumably would have been the status of the vote prior to Commissioner McSweeney's arrival. It also is possible that the dissenting commissioners were opposed to a particular aspect of the complaint as it was brought.

(Attorney contacts appear on the next page.)

Skadden

Additional Contacts in the Antitrust and Competition Group

Clifford H. Aronson	New York	212.735.2644	clifford.aronson@skadden.com
Simon Baxter	Brussels	32.2.639.0310	simon.baxter@skadden.com
Jess Biggio	New York	212.735.2060	jessica.biggio@skadden.com
Alec Y. Chang	New York	212.735.4142	alec.chang@skadden.com
C. Benjamin Crisman, Jr.	Washington, D.C.	202.371.7330	benjamin.crisman@skadden.com
Frederic Depoortere	Brussels	32.2.639.0334	frederic.depoortere@skadden.com
Shepard Goldfein	New York	212.735.3610	shepard.goldfein@skadden.com
Peter E. Greene	New York	212.735.3620	peter.greene@skadden.com
Matthew P. Hendrickson	New York	212.735.2066	matthew.hendrickson@skadden.com
Ian G. John	New York	212.735.3495	ian.john@skadden.com
James A. Keyte	New York	212.735.2583	james.keyte@skadden.com
John H. Lyons	Washington, D.C.	202.371.7333	john.h.lyons@skadden.com
Gary A. MacDonald	Washington, D.C.	202.371.7260	gary.macdonald@skadden.com
Jeffrey A. Mishkin	New York	212.735.3230	jeffrey.mishkin@skadden.com
John M. Nannes	Washington, D.C.	202.371.7500	john.nannes@skadden.com
Neal R. Stoll	New York	212.735.3660	neal.stoll@skadden.com
Ingrid Vandenborre	Brussels	32.2.639.0336	ingrid.vandenborre@skadden.com
James S. Venit	Brussels	32.2.639.0300	james.venit@skadden.com