

What FTC Is Saying In 1st Post-Actavis Pay-For-Delay Case

Law360, New York (September 11, 2014, 12:13 PM ET) -- On Sept. 8, 2014, the Federal Trade Commission filed a federal antitrust complaint in the United States District Court for the Eastern District of Pennsylvania against defendants AbbVie Inc., Abbott Laboratories Inc., Unimed Pharmaceuticals LLC, Besins Healthcare Inc. and Teva Pharmaceuticals Industries Inc. 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.



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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 U.S. 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 health care enforcement, culminating (for the time being) in the 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" 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.

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