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The Paragraph Four Report® is dedicated to mining, tracking, and analyzing Paragraph Four activity as it affects pharmaceutical products, generic and branded companies, and the industry. The Report is a publication of Parry Ashford Inc., Miami, FL. More details, information, searchable databases and analysis can be found on-line at ParagraphFour.com.

Supreme Court on Settlements
Practical Problems Notwithstanding

Ever since I started ParagraphFour.com ten years ago, the US Federal Trade Commission has been trying to severely restrict settlements in Paragraph IV cases. Much of this activity has been chronicled in the *Quarterly Note* over the years which subscribers can access in the site's Archives.

The FTC took case after case, seeking to declare settlements of Paragraph IV cases in violation of antitrust law. Using terms such as "paying to keep the generic off the market" or "reverse payments," the FTC wanted everyone to believe that settlements of these cases were not only bad but cost consumers in the long run.

On June 17, 2013, the US Supreme Court issued its ruling in FTC v. Actavis concerning the settlement of the AndroGel case.[1] The case reached the Supreme Court from the 11th Circuit Court of Appeals which had dismissed the FTC's latest case, ruling that unless there is sham patent litigation or fraud at the US Patent and Trademark Office, the settlement is valid under antitrust law.

The FTC appealed, asking the Supreme Court to apply a stricter rule being that a PIV settlement is presumed to violate antitrust law and that a court need only take a "quick look" at it before declaring it anticompetitive and then require the settling parties to prove that it does not violate antitrust law. The Court rejected the FTC position.

However, the Court nonetheless reversed and remanded the case back to the original district court. In so doing, the majority of the Court concluded that PIV settlements can **sometimes** violate antitrust law and that the FTC needs to prove it through a "rule of reason" using several indicators such as "large and unjustified" payments, "risk of significant anticompetitive effects," and/or "market power derived from the patent."

So, the FTC needs to continue to prove a settlement is unlawful and do this for each case, one at a time. Without a simple rule to follow such as a "quick look" or presumption of anticompetiveness, it is entirely possible the FTC will never be able to have a court strike down any settlement. This ruling will also likely take a few more years to sort out.

In spite of the rejection, the FTC immediately issued a press release, declaring all-out victory and cheering "a significant victory for American consumers." It went further: "We look forward to moving ahead with the Actavis litigation and showing that the settlements violate antitrust law."

While the FTC release was a predictable justification for spending years of litigation and countless millions chasing a legal position the Supreme Court flat-out rejected, the FTC neglects to acknowledge the practical problem it presents -- How to prove it.[2]

When I practiced law, I emphasized the practical realities for my clients. Establishing facts, managing litigation as quickly as possible from Point A to B, and pursuing the practical value of cases (ie spending time and money versus possible reward) were constant, iterative considerations.

[1] FTC v Actavis, US Supreme Court #12-0416 (570 U.S. ____ (2013)).

[2] One could speculate that the FTC has already acknowledged the difficulty in proving these cases by asking courts to presume settlements as unlawful.

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Many Supreme Court opinions are written with an academic slant. When reading this Opinion, I could only wonder about the practicality sorely missing from its pages. Just exactly how will the FTC prove antitrust matters when given a set of general and vague considerations? One thing is certain. District courts are going to require a lot more than a legal position of "Judge, this settlement really stinks. Consumers lose on this one."

And it is not like proving these cases was easy to begin with -- over the past ten years, the FTC has lost just about every one. Now with vague considerations to work with, the FTC still needs to establish its position case-by-case, and FTC v. Actavis never defines how a settlement will **sometimes** violate antitrust law.

Surely Chief Justice Roberts would agree with my sentiments regarding the capability problem. In his dissenting opinion, he sarcastically wrote, "Good luck to the district courts that must, when faced with a patent settlement, weigh the 'likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations present in the circumstances.'" (page 15) Clearly, he agrees that these cases will not only be problematic to establish but also to administer as a practical matter.

The two industry trade groups representing the brands and generics also issued press releases. In spite of their inherent and competing differences, their feelings were shared. They both believe that this Opinion will only serve to add legal and administrative costs to the Paragraph IV process. On this point, I think most people would agree.

However, they also raised the possibility that FTC v. Actavis will deter settlements, and perhaps in turn, deter generic companies from filing ANDA's that challenge patents. While always a possibility, I am not too certain this will be a likely outcome for a few reasons.

First, if a generic company prepares an ANDA with a reasonable position vis-a-vis the patent(s) in question, this Opinion will have little deterrent effect on filing. Wasn't this the intent of the Hatch-Waxman Act to begin with?

Second, the discovery process will always find out strengths and weakness of PIV cases for both sides. Settling cases often makes practical sense and on terms that reflect the practical challenges each face. Wouldn't most judges -- often former litigators -- agree that reasonable settlements would pass antitrust muster like they have in the past?

Third, there are many things that both parties can trade off in a settlement reflecting practicalities and even benefit the consumer with early generic product introductions. Frankly, I expect that ANDA filers and the PIV market will continue to press on: settling a few cases, trying others.

I think the CEO of Actavis, when commenting on FTC v. Actavis, stated it best, "We believe this decision continues to provide for a lawful and legitimate pathway for resolving patent challenge litigation in a manner that is pro-competitive and beneficial to American consumers."

About the Editor

Gregory Glass is the Editor of The Paragraph Four Report.

Mr. Glass earned an MBA from the Fuqua School of Business at Duke University. For fifteen plus years, he has worked in the pharmaceutical industry in a variety of capacities including market research, legal, managed care sales, and product strategy and has authored many papers.

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