ABA SECTION OF ANTITRUST LAW
Promoting Competition Protecting Consumers

The Antitrust Counselor

Vol. 10.1 | September 2015

The Newsletter of the ABA Section of Antitrust Law's Corporate Counseling Committee

Welcome to the New Section Year

Greetings from the Corporate Counseling Committee leadership team! As we start the new Section year, we want to reintroduce our team and share our plans for the upcoming year.

Our Team:
We have a very diverse team this year, including three in-house attorneys and attorneys based in California, New York, Texas, New Jersey and Washington, D.C. Our co-chairs are Derek Ludwin and Jerry Swindell. They are joined by vice chairs Kathy Beasley, Joel Cohen, Rani Habash, Elai Katz, and Sara Walsh. Rounding out the team is our young lawyer representative, Melissa Whitehead.

Programs:
We hope that you will take full advantage of the programs and other resources that we have on tap for the year. We will, of course, continue our very popular Monthly Update program. If you have not been receiving the notices and materials for the Monthly Update, all notices and materials will be made via Connect.

As we did last year, we are planning to develop additional committee programs of interest to the membership. We are particularly interested in developing program ideas generated by our members that you can moderate. If you have an idea or even the germ of an idea, please contact any of us. We can help you develop the idea, select your speakers and generate the materials.

Publications:
We are planning to publish four issues of our newsletter, *The Antitrust Counselor*. If you have ideas for articles, we encourage you to reach out to Joel Cohen (jmcohen@dpw.com), Rani Habash (rani.habash@dechert.com) or any of the committee leadership. This is a great opportunity for young lawyers or in-house counsel to get involved with the Committee.

Pharmaceutical Litigation Update: Changing Landscape

Chahira Solh and Astor Heaven

A team of attorneys from Crowell & Moring LLP presented the June Monthly Update for In-House Counsel. The following article summarizes one of the recent developments discussed during the program.

Cases involving pharmaceuticals and related patent rights have been making their way through the courts, and with each decision, companies are getting further guidance on how best to proceed with their business decisions. During the monthly update in June, three cases were discussed, each having a significant impact on how companies may manage the lifecycle of drugs that are at the end of their patent lives. Each of the cases presents unique issues for companies to consider: How have courts narrowed (or broadened) the definition of what constitutes a reverse payment? Is there antitrust liability for decisions involving product design?

As discussed in the December 2014 edition of *The Antitrust Counselor*,[19] the Supreme Court's 2012 decision in *Federal Trade Commission v. Actavis Inc.*[20] was a landmark decision dealing with reverse payments. In *Actavis*, the Supreme Court held that reverse payment settlements are subject to antitrust scrutiny under the rule of reason where the payment by the patent holder to the potential infringer is "large and unjustified." Though *Actavis* was meant to provide clarity in the reverse-payment analysis, lower courts have struggled to interpret and apply the Supreme Court's ruling. For example, does the reverse payment need to be in cash or can there be other considerations?

Reverse payments can take many forms, and courts have been grappling with where to draw the line for what constitutes a reverse payment and how much to analyze a company's business decisions. In particular, two cases discussed during the June Monthly Update address how courts have tackled reverse-payment cases since *Actavis*.

In the Federal Trade Commission's case against AbbVie Inc.,[21] the district court addressed whether a reverse payment that did not involve a cash payment could be considered "large and unjustified" under *Actavis*. The district court rejected the Federal Trade Commission's theory that a separate supplier contract with extremely favorable terms could be considered a reverse payment. In doing so, the district court helped define the boundaries of what constitutes a reverse payment.

In the *Cipro I and Cipro II*[22] cases, the California Supreme Court confirmed that reverse payment cases can be brought under state antitrust laws, which can sometimes be easier to navigate than their federal counterparts. Although this holding broadened the scope of the *Actavis* decision, the California Supreme Court also provided helpful guidance by prescribing a structured rule of reason analysis to be applied in reverse payment cases.

The third case discussed during the June Monthly Update is a controversial decision by the Second Circuit related to product hopping.[23] The Second Circuit held that a decision by a drug company to stop making an older version of a drug losing patent protection in favor of a newer version of the drug with patent protection violates the antitrust laws. This decision is surprising and has broadened the interpretation of how the antitrust laws apply to what would normally be considered product design.

A more detailed discussion of these three cases follows.

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[19] *Intellectual Property Settlements: Actavis Developments Trend Toward Broader Interpretations, with Some Interesting Guidance*, Rick Juckniess, The Antitrust Counselor Vol. 9.2 (Dec. 2014).

[20] 133 S. Ct. 2223 (2012).

[21] *Federal Trade Commission v. AbbVie Inc., et al.* (Pending in the U.S. District Court for the Eastern District of Pennsylvania, Case No. 2:14-cv-05151).

[22] *In re Cipro Cases I and II* 61 Cal. 4th 116 (2015).

[23] *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015.

Federal Trade Commission v. AbbVie Inc., et al.[24]

In the first case brought by the Federal Trade Commission ("FTC") related to reverse payments since the *Actavis* decision, the FTC suffered a blow when the district court dismissed the FTC's pay-for-delay antitrust claims against AbbVie Inc. ("AbbVie") and Teva Pharmaceuticals USA Inc. ("Teva") over testosterone replacement treatment AndroGel.

According to the FTC, AbbVie and Besins filed baseless patent litigation against Teva seeking to delay entry of a generic version of AndroGel. Teva initially countersued, alleging the initial infringement claims were a sham—claims that are objectively baseless and intended only to interfere with a rival's business. Teva eventually entered into a settlement in which it agreed not to launch a generic version of AndroGel until a set date and, as part of a second agreement, became the seller of the authorized generic of another AbbVie drug, cholesterol medication TriCor.

In its complaint, the FTC alleged that this TriCor agreement, which was signed at the same time as the AndroGel Agreement, constituted a "large and unjustified payment" from AbbVie to Teva because Teva would pay AbbVie less than the market-rate to sell the authorized generic of TriCor.

The district court took issue with the FTC's description of the TriCor agreement as a "large and unjustified payment" under *Actavis*. In fact, the district court held that the TriCor settlement agreement did not fit the definition of a reverse payment because it was procompetitive. The district court reasoned that the agreement allowed generic entry earlier than would otherwise have been possible, and actually benefited consumers. The court chastised the FTC for ignoring the fact that the deal allowing Teva to sell an authorized generic version of TriCor benefited consumers.

The Court also rejected the FTC's sham litigation allegation against Teva. Although the FTC had alleged that the settlement was actually a sham, there had been no prior judicial determination that the settlement was in fact a sham.

From the beginning, the FTC's case was controversial. Prior to this case, the FTC's reverse-payment cases had unanimous support from the agency's five Commissioners. In the AbbVie case, however, Commissioner Ohlhausen and former Commissioner Wright voted against issuing a complaint. Their concerns appear to be centered on the FTC's sham litigation allegations.

The FTC requested that the district court reconsider this dismissal, but the district court denied the request. The FTC then requested a partial final judgment on the dismissal, which would have allowed the agency to take the dispute directly to the Third Circuit. The district court denied the FTC's request.

Cipro I and II

Although only interpreting state law, the California Supreme Court's seminal opinion in *In re Cipro Cases I and II*[25] will likely have significant impact nationally on antitrust law and on patent litigation. The case was brought under the Cartwright Act and California's Unfair Competition Law, and was the first state appeals court to consider reverse payments following *Actavis*. The opinion makes clear that reverse-payment claims can be brought under state antitrust laws in addition to the typical federal antitrust claims.

The *Cipro* case alleges that Bayer paid nearly $400 million to other generic drug makers to keep them from offering generics until after Cipro's patents expired. The California Supreme Court reversed summary judgment that had been granted in favor of the defendants.

In its opinion, the Court outlined a structured rule of reason test designed to facilitate the analysis required under *Actavis*, to show that a reverse payment was anticompetitive:

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[24] Pending in the U.S. District Court for the Eastern District of Pennsylvania, Case No. 2:14-cv-05151.

[25] *In re Cipro Cases I and II* 61 Cal. 4th 116 (2015).

- First, the plaintiff needs to show that the settlement delayed generic entry in exchange for payment or other financial consideration.

- The burden shifts to the defendant to produce evidence that the compensation was justified.

- Then, the plaintiff needs to demonstrate that the payment exceeds reasonable value of litigation costs or collateral products or services.

- Finally, the defendant can then provide any other "additional justifications" to demonstrate that the settlement agreement is procompetitive.

If a plaintiff clears these hurdles, a court will likely conclude that the payment must have been intended to delay a generic from entering the market. Although *Cipro* was decided by a state court, its clear and easily applied guidance on analyzing pay-for-delay cases could result in other courts employing a similar structured rule of reason test. This will likely pave the way for future cases in both federal and state courts.

New York v. Actavis PLC et al.[26]

The New York Attorney General brought a case against Actavis PLC (now known as Allergan) and Forrest Laboratories LLC involving product hopping, which resulted in a landmark ruling in favor of the government. This is the first time an appellate court has tackled product hopping.

"Product hopping" occurs when a drug maker is trying to move the market from an older version of a drug that is losing patent protection to a newer formulation with continuing exclusivity in an alleged effort to extend the life of its monopoly. There are two types of product hopping: hard switch and soft switch. A hard switch is where a drug maker withdraws a drug, or effectively takes an older version of its drug, off the market when it faces generic competition, pushing patients to a newer version that still enjoys patent protection. A soft switch is where a drug maker does not withdraw an old drug, but stops marketing it or limits production, and tries to encourage doctors to prescribe a newer version

Actavis, through its subsidiary Forrest Labs, makes Namenda in an immediate release form, which was losing patent protection. Actavis also makes an extended release version of Namenda, which it was hoping to market to patients as a replacement of the immediate release version. The Namenda case involves a hard switch. Actavis wanted to pull its immediate release Namenda from the market, in favor of its extended release version. The patent on the instant release version will expire at the end of 2015, and there were companies ready to manufacture generic versions.

The New York Attorney General brought a suit that alleged that drug makers violated federal antitrust law by trying to force patients to switch to the new formulation. Actavis argued that these marketing decisions were business and strategic decisions and, that under federal patent law, it had no obligation to keep making an older drug to help its competitors.

The Second Circuit found that defendants' hard switch tactic crossed the line from "persuasion" to "coercion," and was therefore anticompetitive. The court noted that it would have been competitive if the drug makers had sought to persuade patients and their doctors to switch from Namenda immediate release to the new Namenda extended release while both were on the market—a soft switch. And with generic immediate release drugs on the horizon, patients and doctors could evaluate the products and their generics on the merits and choose. This was not the case here, since Actavis wanted to pull the older version of the drug off the market.

Actavis argued that its decision to pull its Namenda immediate release product was simply a business decision, but that argument was rejected by the court. The Second Circuit rejected Actavis' claim that it had the right to try to fight off "freeriding" by generic drug makers using state laws that provide for the automatic substitution of generics for brand-name prescriptions under certain circumstances. The court noted that this type of generic substitution is authorized by law, and would not constitute freeriding. The court also rejected Actavis' argument that the plan to pull the drug was procompetitive. Pointing to comments from the companies' own executives

[26] *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638 (2d Cir. 2015).

describing their plan to block generic competition, the court ruled that the purported business justification was "pretextual."

The Second Circuit upheld a preliminary injunction barring Actavis from pulling the Namenda immediate release version. Although Actavis asked the Second Circuit for a rehearing, the panel refused to take another look at these issues.

Conclusion

The case law involving pharmaceutical patents and antitrust liability continues to evolve. Companies need to closely follow litigation and government enforcement to make sure that their practices do not result in antitrust liability. The two reverse payments cases discussed above show that the interpretation of the Supreme Court's *Actavis* decision is still playing out in the courts. Courts are carefully analyzing the various factors and considerations to determine if a particular arrangement violates the antitrust laws. Companies also need to carefully consider developing product hopping case law, including that in the *Namenda* case which expands the scope of potential antitrust liability for product design changes. All companies can expect increased litigation based on holdings in certain of these recent cases, and private litigants have already relied on them in pending pharmaceutical litigations.

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The Antitrust Counselor is published quarterly by the American Bar Association Section of Antitrust Law, Corporate Counseling Committee.