The AIPLA Antitrust News

A Publication of the AIPLA Committee on Antitrust Law **May 2019**

Chair's Corner

This has been another productive year for the AIPLA Committee on Antitrust Law. On our March committee call, many of us had the privilege to enjoy a very informative presentation on "SEP Licensing in Europe After Huawei v. ZTE", by Dr. Spyros Makris. A number of members of the Committee worked on comments on a proposal for an amicus brief concerning the standard of antitrust review where settlements of IP disputes are concerned. And thanks again to all who provided input for the FTC's Hearings on Competition and Consumer Protection in the 21st Century. Our written comments addressed changes to the legal landscape over the last twelve years that have affected the enforcement of patents. AIPLA Vice President Barbara Fiacco spoke on one of the FTC's innovation-themed panels. Committee members also attended the hearings.

We look forward to seeing many of you at the AIPLA Spring Meeting in Philadelphia, PA this week. The meeting will take place at the Loews Philadelphia Hotel.

This year, we are excited to be holding a joint meeting with the Standards and Open Source Committee, featuring a discussion entitled "Preemptively Avoiding Patent and Antitrust Issues While Participating in Developing Standards – A Guide for Corporate Counsel". The program will take place on Thursday, May 16 from 3:30 to 5:30 p.m.

Looking ahead, at the AIPLA Annual Meeting in October we will present a CLE session, "Global Licensing – How to Avoid Antitrust Pitfalls". We hope to see you all there!

Our current newsletter includes an article by Stephanie Kato, William Lavery and Paul Ragusa regarding the FTC's opinion on *In the Matter of Impax Labs., Inc.*, Docket No. 9373 (FTC March 28, 2019), which closely examined a reverse payment settlement.

Our Committee publishes this newsletter three times each year. We welcome articles on any relevant topic. To contribute, please contact Stephen Larson at Stephen.Larson@knobbe.com.

AIPLA Antitrust Committee

Richard Stark, Chair
Cravath, Swaine & Moore LLP
RStark@cravath.com

Dina Kallay, Vice Chair
Head of Antitrust, Ericsson
Dina.Kallay@ericsson.com

Stephen Larson, Editor
Knobbe Martens Olson & Bear LLP
Stephen.Larson@knobbe.com

FTC Issues Decision in *Impax*, Scrutinizes Reverse Payments under *Actavis*

Stephanie Kato, William Lavery and Paul Ragusa[1]

On March 28, 2019, the Federal Trade Commission ("FTC" or "Commission") issued its opinion on *In the Matter of Impax Labs., Inc.*, Docket No. 9373 (FTC March 28, 2019) ("*Impax*") and closely examined a reverse payment settlement. The case involved a settlement between Endo Pharmaceuticals, Inc. ("Endo"), the maker of an extended-release formulation of oxymorphone branded as Opana ER, and Impax Laboratories, Inc. ("Impax"), the first generic manufacturer to file an Abbreviated New Drug Application (ANDA) and paragraph IV certification relating to certain dosage strengths of Opana ER. The Commission considered the question of whether a reverse payment settlement from Endo to Impax as part of a settlement where Impax dropped its patent challenge and delayed launch of its generic product, violated Section 5 of the FTC Act, 15 U.S.C. § 45. The Commission reversed the decision of FTC Administrative Law Judge D. Michael Chappell and concluded that Impax violated Section 5 of the FTC Act. *Id.* at *4.

In a unanimous opinion, the Commission agreed with the ALJ's finding that "Impax received a large and unjustified payment," but overturned his initial decision dismissing because "Impax did not sustain its burden of linking the procompetitive benefits to the challenged restraint." *Id.* at *32. The payment was not a simple cash payment from Endo to Impax, but instead took other forms, including an agreement by Endo to not market an authorized generic for the six months that Impax would have generic exclusivity after launch (a "No-AG Commitment"), a credit tied to a "product hop" in the event Endo's Opana ER sales fell by more than 50 percent prior to market entry by Impax - which ultimately resulted in a $102 million payment (the "Endo Credit"), and a separate development and co-promotion agreement ("DCA") providing for additional payments from Endo to Impax. A freedom to operate license was also granted but was not considered by the parties to be part of a reverse payment. *Id.* at *19-22.

---

[1] Stephanie Kato is an associate and Paul Ragusa is a partner in the New York office of Baker Botts LLP, where they both practice intellectual property law, including the litigation of cases involving Abbreviated New Drug Applications. William Lavery is a partner in the Washington DC office of Baker Botts LLP, where his practice focuses on antitrust and competition law, including in merger and other investigations before the Federal Trade Commission and the U.S. Department of Justice and in private and government antitrust litigation.

In making its determination, the Commission had its first opportunity in an action challenging an alleged reverse payment settlement to apply the Supreme Court's guidance in *FTC v. Actavis*, 570 U.S. 136 (2013).[2] In *Actavis*, the Supreme Court held that reverse payments between a branded and generic drug manufacturer could have "significant adverse effects on competition" and violate the antitrust laws, even where the agreements do not exceed the exclusionary scope of the patent. *Id.* at 148, 158-60. The Court held that reverse payment settlements should be assessed under the rule of reason and directed lower courts to structure the rule-of-reason analysis scrutinizing reverse payment settlements under antitrust laws. *Id*. at 160.

In the wake of *Actavis*, lower Federal Courts have attempted to develop such a rule-of-reason framework. The Commission applied a burden-shifting analysis examining whether the plaintiff proved that "the challenged restraint has a substantial anticompetitive effect that harms consumers in the relevant market," and if so, whether the defendant showed a procompetitive rationale for the restraint. *Impax* at *15 (citations omitted).

The Commission held that Complaint Counsel met its *prima facie* burden to demonstrate competitive harm arising from the reverse payment settlement. *Id.* at *42. The Commission found that Impax had received a "large and unjustified" payment and thus the "risk of earlier entry was real: there was a plausible threat that Impax could have entered the market prior to the agreed-upon entry date." *Id.* at *16. The Commission also held that there was significant record evidence demonstrating that Endo commanded market power. *Id.* at *31. The Commission considered all value flowing to Impax, including the "No-AG Commitment," which gave Impax six months of exclusivity in the market and obligated Endo not to market an authorized generic during those six months, as well as the "Endo Credit," a sum of money that Impax would receive if Endo moved the market away from the original formulation before Impax entered. *Id.* at *19-20.

After finding that Complaint Counsel had met its initial burden of showing that the

---

[2] In November 2018, in *In the Matter of 1-800 Contacts, Inc.*—a case involving trademark settlement agreements—the Commission rejected 1-800 Contacts' argument that the Supreme Court's *Actavis* decision stood for the proposition that there can be no antitrust challenge to a settlement agreement that is "commonplace" in form. Docket 9372 (FTC November 7, 2018), at *13. The Commission held that that Actavis "created no such shield from antitrust review," and instead merely characterized two specific types of settlements as commonplace. *Id.* The Commission further held that Actavis "made it clear that the form of the settlement alone is not what subjects an agreement to antitrust scrutiny." *Id.*

settlement was large and unjustified, the Commission held that Impax failed to show a procompetitive rationale for the restraint. The Commission found that Impax "did not sustain its burden of linking the procompetitive benefits with the challenged restraint," which was the use of a reverse payment settlement to eliminate the risk of Impax's entry into the market before the negotiated time. *Id.* at *32. The Commission held that even if Impax's justifications were valid, Complaint Counsel had identified a viable less restrictive alternative that could have been used: a no-payment settlement allowing an earlier generic entry date. *Id.* at *42.

Accordingly, the Commission reversed Judge Chappell's initial decision and held that Impax had engaged in an unreasonable restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, and an unfair method of competition in violation of Section 5 of the FTC Act, 15 U.S.C. § 45. *Id.* at *42. Impax can appeal the Commission's ruling within 60 days of the final order.