

Litigation and Enforcement Highlights – June 2018

Pharmaceutical litigation and enforcement actions took the spotlight in the news last month. In this edition, we highlight two high profile enforcement cases and continue to follow the Allergan patent saga. In enforcement, we saw developments in the FTC's antitrust enforcement against generic drugmaker Impax and the DOJ's anti-kickback enforcement against brand manufacturer Pfizer. These actions could set important precedents for similar cases and significantly impact price and competition in the pharmaceutical industry. Meanwhile, Allergan continues to defend against attacks of its tribal immunity maneuver in a seemingly losing battle.

FTC Appeals Dismissal of Pay-for-Delay Case Against Impax

In an unexpected loss for the Federal Trade Commission (FTC), an administrative law judge (ALJ) [dismissed](#) antitrust claims against generic drug manufacturer Impax for illegally delaying a generic drug from entering the market in a [“pay-for-delay”](#) attempt to restrict competition. The FTC filed an administrative [complaint](#) in 2017, alleging that Impax accepted more than \$112 million from brand manufacturer Endo Pharmaceuticals for agreeing not to market a generic version of Endo's opioid painkiller, Opana ER.[\[1\]](#) Endo had previously settled FTC's charges in another case.[\[2\]](#)

This case is the latest in a string of pay-for-delay deals in which brand-name drugmakers pay their generic competitors to delay cheaper alternatives from entering the market. In a 162-page decision, the ALJ in this case applied a full “rule of

reason” analysis to balance the possible benefits of the alleged anticompetitive agreement against the extent of the threat to competition. The decision concluded that the procompetitive benefits of the settlement outweighed the anticompetitive harm and dismissed all of FTC’s claims.

However, this case is far from over, as the FTC has already filed its notice to appeal the decision to the full commission. As the Trump administration recently nominated five new commissioners to the FTC, it will be interesting to see how these newly appointed commissioners will approach the case. Experts expect the FTC to reverse the ALJ decision based on the 2013 Supreme Court decision in *FTC v. Actavis Inc.*[\[3\]](#) In that case, the majority ruled in favor of the FTC, holding that a brand name manufacturer’s payment to a generic competitor to settle patent infringement claims violated antitrust laws. The outcome of the appeal, which will be heard in August, could have lasting impacts on competition in the pharmaceutical market, as the FTC hopes to kick off additional enforcement actions against drug companies for similar anticompetitive cases.

Pfizer Pays Settlement in DOJ’s Crackdown of Illegal Kickback Scheme

Pfizer Inc., the largest U.S. drug manufacturer, has agreed to pay \$23.8 million to [settle](#) the Department of Justice’s (DOJ) charges of illegal kickbacks to Medicare patients. DOJ’s claims allege that Pfizer raised the wholesale price of three of its drugs by more than 40 percent. To mask the effects of the price hike, from 2012 to 2016, Pfizer used an independent charity to cover Medicare patients’ out-of-pocket co-pay costs for those drugs, and then donated to the charity to cover those co-pay expenses. Under this scheme, Pfizer was able to generate more

revenue for itself through the increase in Medicare co-pay costs.

As a growing number of drugmakers use patient assistance charities to raise prices, federal enforcement agencies have increased their efforts to crack down on the phenomenon. The anti-kickback statute of the False Claims Act prohibits pharmaceutical companies from paying for Medicare patients' copayments to induce purchase of their drugs. In the past two years, federal authorities have investigated a number of drugmakers, including Gilead, Pfizer, Johnson & Johnson, and Sanofi, regarding this practice.[\[4\]](#) At least two other drugmakers have reached similar settlements in recent months, including United Therapeutics in a \$210 million settlement in December 2017, and Jazz Pharmaceuticals in a \$57 million settlement in May 2018.[\[5\]](#)

Allergan Under Fire as Its Patent Transfer Saga Continues

Last month, we [reviewed](#) how Allergan transferred its Restasis patent rights to a Native American tribe when the Supreme Court upheld the constitutionality of [inter partes review](#) (IPR), which had denied Allergan's claim of tribal immunity in the patent challenge of Restasis. The fallout continues this month, as Allergan faces a [new antitrust suit](#) filed by four drug retailers, including Walgreens and Albertsons, over the same ploy.[\[6\]](#) The retailers allege that "Allergan devised and carried out a multifaceted and anticompetitive scheme to maintain that monopoly and prevent would-be generic competitors from competing with Restasis."

The saga began when generic drugmakers Mylan, Teva, and Akorn challenged Allergan's Restasis patents under the IPR process, which is seen as a speedier and less-expensive way to invalidate

patents than lawsuits. In response, Allergan transferred its patent rights to the Saint Regis Mohawk Tribe in New York for nearly \$14 million, in an attempt to shield its best-selling drug from competitors' patent challenges. The IPR panel rejected this maneuver in February, holding that the tribe cannot invoke sovereign immunity to avoid IPR.

Allergan is currently appealing the IPR decision against the tribe's claim of sovereign immunity to the U.S. Court of Appeals for the Federal Circuit. During oral arguments on June 4, when the court questioned whether Allergan's actions were a blatant attempt to circumvent the patent review process established by Congress, Allergan's attorney admitted that "it is Congress's job to change it if they don't like the system." [\[7\]](#)

The outcome of Allergan's challenge could determine how other patent owners defend against the IPR process, which the Supreme Court has now endorsed. In the unlikely event that the Federal Circuit rules in favor of Allergan, many more brand manufacturers could follow suit and exploit the sovereign immunity loophole. Such tactics would effectively prevent generic drugs from entering the market and allow pharmaceutical companies to maintain their monopolies, thereby resulting in higher drug prices for the general population. The Source will continue to follow and analyze the effects of Allergan's legal challenges.

That's all for this month's Litigation and Enforcement Highlights. Stay tuned for the latest developments in these cases and check back next month for more litigation and enforcement actions on The Source [Blog](#). In the meantime, be sure to check out the [Enforcement page](#) of The Source for timeline and geographic trends of federal, state, and private enforcement

actions.

[1] In the Matter of Impax Laboratories, Inc. See FTC case page: <https://www.ftc.gov/enforcement/cases-proceedings/141-0004/impax-laboratories-inc>

[2] [FTC v. Allergan plc, and Watson Laboratories, Inc. et al.](#)

[3] FTC v. Actavis Inc., 133 S. Ct. 2223, 2013 BL 158126 (U.S. 2013).

[4] Ed Silverman, *Pfizer agrees to pay nearly \$24M for illegally using a charity to pay kickbacks to Medicare patients*, Stat News, May 24, 2018.

[5] Jonathan Stempel, *Pfizer to pay \$23.85 million to settle U.S. co-payment kickback probe*, Reuters, May 24, 2018.

[6] Walgreen Co. et al. v. Allergan, Inc., E.D.N.Y., No. 18-cv-2907.

[7] Susan Decker, *Allergan Use of Tribe's Sovereignty Called Risk to Patent System*, Bloomberg Law, Jun. 4, 2018.