


FTC, State AGs Say Humira Judge Botched Actavis Reading

By **Bryan Koenig**

Law360 (October 14, 2020, 4:39 PM EDT) -- The Federal Trade Commission and a group of state attorneys general are urging the Seventh Circuit to address mistakes they say a district court made in tossing a lawsuit claiming AbbVie built an anti-competitive "patent thicket" around its blockbuster immunosuppressant Humira to keep cheaper biosimilars from the market.

In separate amicus briefs on Tuesday, the FTC and the enforcers from 20 states took aim at U.S. District Judge Manish Shah's application of the U.S. Supreme Court's landmark decision in [FTC v. Actavis Inc.](#) , which said so-called pay-for-delay or reverse payment settlements staving off generic competition could be anti-competitive in some circumstances.

In this case, Humira buyers are **trying to flip** a June ruling **tossing the groundbreaking suit** over a treatment that generated about \$19.2 billion globally last year.

The buyers contend that AbbVie not only aggressively asserted more than 130 patents related to Humira, many without merit, in order to fend off potential competitors, it also negotiated anti-competitive pay-for-delay settlements with those that challenged its intellectual property in deals that permitted European market entry in 2018 while maintaining the U.S. monopoly until 2023.

In their amicus briefs, the state attorneys general directly backed the buyer's bid to revive their suit, while the FTC avoided the merits of the argument even as it offered important backing to arguments that Judge Shah wrongly applied the Actavis ruling. Namely, the federal enforcer argued that Judge Shah wrongly gave AbbVie credit for making deals that allowed "early" biosimilars entry before Humira's patent protection ran out.

Market entry before patent expiration does not automatically enshrine a settlement as pro-competitive, the FTC said, and finding otherwise goes against the high court decision in Actavis to overrule so-called scope-of-the-patent tests, which can mask the fact that a successful challenge could have gotten a competitor on the market even sooner.

"Actavis held that, when the complaint plausibly alleges a large and unjustified reverse payment, settlements may violate the antitrust laws even if they allow 'early' competition before the patents expire," the FTC said.

"The court recognized that settling with an 'early' entry date is unproblematic only when it comes 'without the patentee paying the challenger to stay out prior to that point,'" the agency continued. "But when the patentee offers 'a share of its monopoly profits that would otherwise be lost in the competitive market,' even an 'early' entry settlement 'has the 'potential for genuine adverse effects on competition.'"

The FTC also assailed the lower court for protecting the settlements in the name of encouraging patent litigants to reach worldwide patent dispute deals.

"When the settlement is accompanied by a large and unjustified payment, Actavis directly rejected that concern as a basis for dismissal," the FTC said.

Judge Shah tossed the suit after finding AbbVie's patent litigation was not objectively baseless and was largely protected by the Noerr-Pennington doctrine, which shields certain activity intended to influence the government. Judge Shah also rejected accusations that AbbVie's settlements with potential biosimilar competitors, including Amgen Inc. and Sandoz Inc., were unlawful because they allowed immediate entry in Europe in exchange for staying out of the U.S.

Consumer advocates, academics and a drug store industry group have also assailed those findings in amicus briefs **submitted last week**.

As for the state attorneys general of California, Connecticut, Idaho, Maine, Michigan, Nebraska, North Carolina, Washington state and elsewhere, they argued on Tuesday that in addition to upending the lower court's Actavis interpretation, the Seventh Circuit should also adopt a "more flexible, holistic analysis" to considering "serial sham petitioning cases like this one."

Namely, the state attorneys general want the Seventh Circuit to adopt the U.S. Supreme Court's 1972 ruling in [California Motor Transport Co. v. Trucking Unlimited](#) to serial sham petitioning.

The alternative to California Motor Transport, according to the brief, is an exemption from Noerr-Pennington immunity only when particular patent petitions are found to be "objectively baseless." Serial petitions should be considered collectively, the attorneys general said, arguing that "incumbent monopolists" have many chances "to cheaply impose burdensome proceedings on their rivals" in the pharmaceutical space in particular.

"As this case demonstrates, the growth of the biologics market will exacerbate this problem because of the staggering number of patent filings claiming some of these drugs," the enforcers said. "The adverse consequences of immunizing such repeated petitioning activity and enforcement actions short of adjudicative decisions on the merits are already known and will only exponentially increase."

Counsel for the plaintiffs and AbbVie declined to comment on Wednesday.

The plaintiffs are co-led in the suit by Hagens Berman Sobol Shapiro LLP, Labaton Sucharow LLP and Girard Sharp LLP.

AbbVie is represented by Kirkland & Ellis LLP.

Amgen is represented by Sidley Austin LLP.

Samsung Bioepis is represented by O'Melveny & Myers LLP and Riley Safer Holmes & Cancila LLP.

Sandoz is represented by Baker Botts LLP and Benesch Friedlander Coplan & Aronoff.

The FTC is represented in-house by Bradley Grossman, Alden F. Abbott, Joel Marcus, Ian R. Conner, Gail Levine, Markus H. Meier, Bradley S. Albert, Kara L. Monahan and Timothy Kamal-Grayson.

The states are represented by their respective attorneys general offices.

The Open Markets Institute is represented by Adam J. Levitt and John E. Tangren of Dicello Levitt Gutzler LLC and in-house by Sandeep Vaheesan.

Consumer Action and U.S. PIRG are represented by James B. Zouras of Stephan Zouras LLP, Andrew Barlow of Doyle Barlow & Mazard PLLC and David Balto.

The National Association of Chain Drug Stores is represented by Scott E. Perwin, Lauren C. Ravkind and Anna T. Neill of Kenny Nachwalter PA, Barry L. Refsin and Monica L. Kiley of Hangley Aronchick Segal Pudlin & Schiller and in-house by Mary Ellen Kleiman.

The academics are represented by Michael A. Carrier of Rutgers Law School.

The appeal is UFCW Local 1500 Welfare Fund et al. v. AbbVie Inc. et al., case number 20-2402, in the U.S. Court of Appeals for the Seventh Circuit.

--Additional reporting by Matthew Perlman, Lauraann Wood and Jeff Overley. Editing by Nicole Bleier.

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