FEDERAL TRADE COMMISSION
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FTC Enters Global Settlement to Resolve Reverse-Payment Charges against Teva

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The Federal Trade Commission has reached a global settlement resolving pending claims in three separate federal court antitrust lawsuits involving subsidiaries of pharmaceutical manufacturer Teva Pharmaceuticals Industries Ltd. If approved by the various courts, the stipulated order will prohibit Teva from engaging in reverse-payment patent settlement agreements that impede consumer access to lower-priced generic drugs.

"This settlement represents another milestone in the Commission's unwavering commitment to put an end to harmful reverse-payment agreements," said Chairman Joe Simons. "This broad settlement prevents the world's largest manufacturer of generic drugs from entering into collusive agreements that prevent price competition by keeping generic drugs off the market."

Under the stipulated order for a permanent injunction, Teva is prohibited from entering into a patent infringement settlement agreement that includes a reverse payment transferring value from the brand to the generic. Although Teva is currently bound by a prior order in *FTC v. Cephalon*, the new order is broader, prohibiting Teva from entering into the two most pernicious and common forms of reverse payments: (1) a side deal, in which the generic company receives compensation in the form of a business transaction entered at the same time as the patent litigation settlement; and (2) a no-AG commitment, in which a brand company agrees not to compete with an authorized generic version of a drug for a period of time. The prior order had not prohibited no-AG commitments. The new revised order, which would last for 10 years from the date of entry, provides immediate relief to consumers, without the costs and risks of trial and appeal in three pending cases.

To effectuate the global settlement, the Commission authorized staff to file the necessary motions in three pending federal court cases:

FTC v. Actavis (No. 09-cv-955 N.D. Ga.): The Commission filed its complaint on January 27, 2009, alleging a reverse-payment agreement between Solvay (the brand, now AbbVie Products LLC) and Watson (the generic, now Actavis Holdco, a subsidiary of Teva) to delay the release of a generic version of AndroGel, a popular testosterone replacement drug. Following the district court's dismissal of the FTC's complaint, the Supreme Court, in June 2013 reversed that decision (570 U.S. 136), finding that reverse-payment agreements can violate the antitrust laws. The FTC's case was remanded, and trial is scheduled to begin on March 4, 2019.

Under the global settlement, the Commission will ask the court to dismiss Teva from the proceedings. The Commission's charges against Solvay will proceed to trial as scheduled.

FTC v. Allergan plc (No. 17-cv-321 N.D. Cal.): The Commission filed its complaint on January 23, 2017, alleging a reverse-payment agreement to block consumer's access to lower-cost versions of Lidoderm with compensation in the form of (1) a no-AG commitment between Endo Pharmaceuticals (the brand, partnered with Teikoku, the creator and manufacturer of Lidoderm) and the generics (Watson Laboratories, now part of Teva, and Watson Pharmaceuticals, now Allergan Finance, a subsidiary of Allergan plc) and (2) $96 million of branded Lidoderm product given to Watson at no cost. Lidoderm is a topical patch used to relieve pain associated with a complication of shingles known as post-herpetic neuralgia. Endo and Teikoku already settled the Commission's charges in stipulated orders that bar them from entering into similar agreements, including ones that contain a no-AG commitment, for 10 years.

Under the global settlement, the Commission will ask the court to dismiss the remaining claims against Teva, Allergan plc, and Allergan Finance, LLC, which effectively will end this litigation if approved by the court.

FTC v. AbbVie, Inc. (No. 14-cv-5151 E.D. Pa.): The Commission filed its complaint on September 8, 2014, alleging a reverse-payment agreement between AbbVie, Inc. (and its predecessor company, Abbott Laboratories, and subsidiary Unimed (the brand companies)) and Teva (the generic). The complaint also contains allegations that AbbVie and its partner Besins Healthcare Inc. filed baseless patent infringement lawsuits against potential generic competitors, including Teva, to delay the introduction of lower-priced versions of AndroGel. The court dismissed the FTC's reverse-payment claim in 2015. This ruling is on appeal to the Third Circuit Court of Appeals.

Under the global settlement, the Commission will resolve its claims against generic Teva. The FTC's appeal of the dismissal of the reverse-payment claim will continue against the brand companies, as will the appeal of the district court's ruling on the sham litigation claim.

The Commission vote to accept the settlement and file the necessary papers in the various cases was 4-0-1. Commissioner Christine S. Wilson did not participate.

NOTE: Stipulated final orders have the force of law when signed and entered by a District Court judge.

The Federal Trade Commission works to promote competition, and protect and educate consumers. You can learn more about how competition benefits consumers or file an antitrust complaint. Like the FTC on Facebook, follow us on Twitter, read our blogs, and subscribe to press releases for the latest FTC news and resources.

PRESS RELEASE REFERENCE:
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