



## FEDERAL TRADE COMMISSION PROTECTING AMERICA'S CONSUMERS

# FTC Sues Pharmaceutical Companies for Illegally Blocking Consumer Access to Lower-Cost Versions of the Blockbuster Drug AndroGel

## Commission Alleges That AbbVie Inc. and Besins Healthcare Inc. Filed Sham Lawsuits; AbbVie and Teva Pharmaceuticals USA, Inc. Entered Anticompetitive Agreement to Delay Generic Entry

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FOR RELEASE

September 8, 2014

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*Note: A conference call for media with FTC Chairwoman Edith Ramirez will occur as follows:*

*Date: Sept. 8, 2014*

*Time: 1:00 p.m. ET*

*Call-in lines, which are for **media only**, will open 15 minutes prior to the start of the call. Chairwoman Ramirez and FTC staff will be available to take questions from the media about the case.*

In its latest action to ensure competition in the nation's healthcare markets, the Federal Trade Commission has filed a complaint in federal district court charging several major pharmaceutical companies with illegally blocking American consumers' access to lower-cost versions of the blockbuster drug AndroGel.

The FTC's complaint alleges that AbbVie Inc. and its partner Besins Healthcare Inc. filed baseless patent infringement lawsuits against potential generic competitors to delay the introduction of lower-priced versions of the testosterone replacement drug AndroGel. While the lawsuits were pending, AbbVie then entered into an anticompetitive pay-for-delay settlement agreement with Teva Pharmaceuticals USA, Inc. to further delay generic drug competition.

"The FTC is acting today to stop anticompetitive conduct by AbbVie, Besins Healthcare and Teva which has forced consumers to overpay hundreds of millions for the drug AndroGel," said FTC Chairwoman Edith Ramirez. "This action also reinforces the Commission's longstanding commitment to protect American consumers from collusive arrangements between branded and generic pharmaceutical companies that inflate the prices of prescription drugs and harm competition."

Today's complaint follows a long line of cases the FTC has brought to stop anticompetitive conduct in the pharmaceutical industry.

The FTC is seeking a court judgment declaring that the defendants' conduct violates the FTC Act, ordering the companies to disgorge their ill-gotten gains, and permanently barring them from engaging in similar anticompetitive behavior in the future.

AndroGel is a topical pharmaceutical gel product approved for testosterone replacement therapy in men with low testosterone. It has annual U.S. sales of more than \$1 billion.

The FTC's lawsuit centers on two main allegations of anticompetitive conduct:

AbbVie and Besins filed baseless patent infringement lawsuits against generic drug marketers Teva and Perrigo Company to delay FDA approval of a generic version of AndroGel and extend the monopoly profits for the branded version. The complaint charges AbbVie and Besins with monopolization.

After countersuing AbbVie and Besins and alleging that the infringement suit was baseless, Teva subsequently accepted illegal payments from AbbVie to drop its patent challenge and refrain from bringing its competing testosterone gel product to market. The complaint charges AbbVie and Teva with illegally restraining trade.

At issue in the alleged sham patent infringement suit is an ingredient in branded AndroGel, called isopropyl myristate or IPM. IPM is known as a “penetration enhancer” because it speeds the delivery of the drug’s active ingredient, testosterone, through the skin and into the bloodstream. The patent on branded AndroGel covers only a formulation using IPM as the penetration enhancer, according to the FTC complaint.

Although Teva and Perrigo developed testosterone gel products that did not contain IPM and used different penetration enhancers than AndroGel, AbbVie and Besins sued Teva and Perrigo for patent infringement. Under federal law, these lawsuits triggered an automatic 30-month stay of the FDA’s authority to approve Teva’s and Perrigo’s applications to market their testosterone gel products, regardless of the merits of the infringement claims.

The FTC alleges that AbbVie and Besins had no reasonable basis to contend that Teva’s and Perrigo’s penetration enhancers were equivalent to IPM and therefore covered by the narrow AndroGel formulation patent. AbbVie and Besins had in fact surrendered any claim to those penetration enhancers in gaining patent approval for AndroGel from the Patent and Trademark Office.

Thus, as alleged in the FTC complaint, the actual motivation for filing the infringement suits was to extend the large profits AbbVie and Besins were making from AndroGel sales in the U.S. market, at the expense of consumers and competition.

And, as further noted in the FTC complaint, AbbVie’s predecessor company publicly declined to bring the same suit against Perrigo just two years earlier, when Perrigo first sought FDA approval of its generic AndroGel product.

When AbbVie and Besins sued Teva, Teva asserted an antitrust counterclaim that the infringement suit constituted sham litigation. But, according to the FTC’s complaint, Teva subsequently recognized that it would be more profitable to reach an agreement with AbbVie to share the monopoly profits from AndroGel than to compete.

Under the agreement, Teva abandoned its countersuit and agreed to refrain from launching its lower-cost AndroGel alternative until a specified date, according to the complaint. In exchange, AbbVie paid its potential rival in the form of an authorized generic deal for an unrelated product – a cholesterol drug called Tricor, with annual U.S. sales of more than \$1 billion in 2011– that was highly profitable for Teva, but made no independent business sense for AbbVie.

Overall, this anticompetitive conduct blocked competition from both Teva’s and Perrigo’s lower-cost substitutes for brand-name AndroGel and preserved AbbVie’s and Besins’s AndroGel monopoly for a substantial period of time.

The complaint also names AbbVie’s predecessor company, Abbott Laboratories, and its wholly owned subsidiary, Unimed Pharmaceuticals, LLC, as defendants in the case.

The Commission vote to file the complaint was 3-2, with Commissioners Maureen K. Ohlhausen and Joshua D. Wright dissenting. It was filed under seal in the U.S. District Court for the Eastern District of Pennsylvania on September 8, 2014. A redacted version was made public.

**NOTE:** The Commission files a complaint when it has “reason to believe” that the law has been or is being violated and it appears to the Commission that a proceeding is in the public interest. The case will be decided by the court.

The FTC’s Bureau of Competition works with the Bureau of Economics to investigate alleged anticompetitive business practices and, when appropriate, recommends that the Commission take law enforcement action. To inform the Bureau about particular business practices, call 202-326-3300, send an e-mail to [antitrust@ftc.gov](mailto:antitrust@ftc.gov), or write to the Office of Policy and Coordination, Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Ave., NW, Room CC-5422, Washington, DC 20580. To learn more about the Bureau of Competition, read [Competition Counts](#). Like the FTC on [Facebook](#), follow us on [Twitter](#), and [subscribe to press releases](#) for the latest FTC news and resources.

#### **PRESS RELEASE REFERENCE:**

[Statement of FTC Chairman Joe Simons Regarding Federal Court Ruling in FTC v. AbbVie](#)

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