FTC accuses Endo, other drugmakers of antitrust violations

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This Jan. 28, 2015, file photo, shows the Federal Trade Commission building in Washington. The Federal Trade Commission is accusing several drugmakers of violating antitrust laws with agreements that delayed availability of cheaper generic versions of two pain treatments. The FTC alleges Endo Pharmaceuticals Inc., maker of Opana ER pain pills and the Lidoderm pain patch, paid Impax Laboratories and Watson Laboratories, respectively, to delay selling their approved generic versions of the products. Endo says the FTC complaint has no merit. Impax and Watson didn't immediately respond to requests for comment. (AP Photo/Alex Brandon, File)

The Federal Trade Commission has accused several drugmakers of violating antitrust laws, via agreements the commission said delayed the U.S. launches of cheaper generic versions of two popular pain treatments.

It's the first so-called "pay for delay" case brought by the commission in which a drug's original maker agreed not to sell its own "authorized generic" version until well after a generic drugmaker began selling its product. That guaranteed the generic drugmaker would have no competition, and so could keep prices high, for at least six months.

The FTC alleges Endo Pharmaceuticals Inc., maker of Opana ER pain pills and the Lidoderm pain patch, paid Impax Laboratories Inc. and Watson Laboratories Inc., respectively, to delay selling their approved generic versions. Watson is now part of Allergan PLC, which is nominally based in Ireland but has operational headquarters in Parsippany, New Jersey.

Endo, which is based in Dublin and has U.S. headquarters in Malvern, Pennsylvania, wrote in an email to The Associated Press that "the FTC complaint has no merit" because Endo's agreements allowed the generic versions to go on sale before expiration of the brand-name drugs' patents. Patents guarantee drugmakers the exclusive right to sell their drug for about 10 to 12 years after it is launched.

Neither Allergan nor Impax, which is based in Hayward, California, responded to Associated Press inquiries.

According to the FTC complaint, Endo and two partner companies made a reverse payment under a May 2012 agreement with Watson. That's because the deal barred them from selling an authorized generic version of the Lidoderm patch until months after Watson began selling its generic version.

FTC chairwoman Edith Ramirez said in a statement that such settlements barring authorized generic competition "harm consumers twice—first by delaying the entry of generic drugs and then by preventing additional generic competition in the market following generic entry."

The FTC complaint alleges that Endo paid Watson "hundreds of millions of dollars" to delay selling generic Lidoderm patches until September 2013, and Endo also agreed not to sell an authorized generic that would compete with Watson's version for 7 1/2 months.

The last patent covering Lidoderm expired in October 2015, according to Endo spokeswoman Heather Zoumas-Lubeski.

However, Watson had filed a lawsuit challenging the validity of Lidoderm's patent. Such lawsuits are part of the complex rules under which companies wanting to sell a generic version of a brand-name drug seek the right to be the first generic allowed on the market. If the generic company wins the lawsuit, it gets the exclusive right to sell its generic for 180 days, usually at a slightly lower price than the brand-name drug—unless it's competing with an authorized generic from the brand-name company.

Because such lawsuits are risky and expensive for both sides, the brand-name drugmaker and the generic challenger often reach a settlement allowing the generic company to sell its version at some point before the drug's key patent expires. Those agreements generally are legal—unless the brand-name drugmaker makes a payment in return to the generic company.

After the 180 days, other companies with approved generic versions can begin selling them. The increased competition then pushes down prices, eventually as much as 85 percent.

Meanwhile, Opana ER's key patent expired in September 2013. However, under a 2010 agreement with Endo, Impax began selling its generic version in January 2013.

According to the FTC, Endo paid Impax more than $112 million, then used the delay until January 2013 to try to switch patients to a new formulation of Opana ER with a longer patent life.

Lidoderm was a blockbuster, with U.S. sales alone approaching $1 billion in 2012, while OPEC ER had U.S. sales exceeding $250 million in 2010, the FTC said.

Both are pricey. A month's supply of brand-name Lidoderm patches costs about $300, while generic lidocaine patches sell for $160 to $245. A month's worth of 10-milligram Opana ER pills costs about $300, while generic oxymorphone pills cost about $225 to $250.