Court: Can drug companies pay to delay generics?

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In a Jan. 7, 2008, file photo then-Attorney Donald Verrilli talks to media outside the Supreme Court. Now President Barack Obama's top Supreme Court lawyer, Solicitor General Verilli will argue before the Supreme Court this week whether it is legal for patent-holding pharmaceutical companies to pay rivals, who make generic drugs, to temporarily keep those cheaper versions of their brand-name drugs off the market. The Obama administration is taking the position that the agreements are illegal if they're based solely on keeping the generic drug out of consumer's hands. (AP Photo/Evan Vucci, File)

(AP)—Federal regulators are pressing the Supreme Court to stop big pharmaceutical corporations from paying generic drug competitors to delay releasing their cheaper versions of brand-name drugs. They argue these deals deny American consumers, usually for years, steep price declines that can top 90 percent.

The Obama administration, backed by consumer groups and the American Medical Association which represents doctors, says these so-called "pay for delay" deals profit the drug companies but harm consumers by adding $3.5 billion annually to their drug bills.

But the pharmaceutical companies counter that they need to preserve longer the billions of dollars in revenue from their patented products in order to recover the billions they spend developing new drugs. And both the large companies and the generic makers say the marketing of generics often is hastened by these deals.

The justices will hear the arguments on Monday. The case before the court involves a deal reached between Brussels, Belgium-based Solvay—now part of a new company called AbbVie Inc.—and generic drugmaker Watson Pharmaceuticals allowing it to launch a cheaper version of Solvay's male hormone drug AndroGel in August 2015.

Such pay-for-delay deals arise when generic companies file a challenge at the Food and Drug Administration to the patents that give brand-name drugs a 20-year monopoly. The generic drugmakers aim to prove the patent is flawed or otherwise invalid, so they can launch a generic version well before the patent ends.

Brand-name drugmakers then usually sue the generic companies, which sets up what could be years of expensive litigation. When the two sides aren't certain who will win, they often reach a compromise deal that allows the generic company to sell its cheaper copycat drug in a few

years—but years before the drug's patent would expire. Often, that settlement comes with a sizeable payment from the brand-name company to the generic drugmaker.

Numerous brand-name and generic drugmakers and their respective trade groups say the settlements protect their interests but also benefit consumers by bringing inexpensive copycat medicines to market years earlier than they would arrive in any case generic drugmakers took to trial and lost. But federal officials counter that such deals add billions to the drug bills of American patients and taxpayers, compared to what would happen if the generic companies won the lawsuits and could begin marketing right away.

A study by RBC Capital Markets Corp. of 371 cases during 2000-2009 found brand-name companies won 89 at trial compared to 82 won by generic drugmakers. Another 175 ended in settlement deals, and 25 were dropped.

Generic drugs account for about 80 percent of all American prescriptions for medicines and vaccines, but a far smaller percentage of the $325 billion spent by U.S. consumers on drugs each year. Generics saved American patients, taxpayers and the healthcare system an estimated $193 billion in 2011 alone, according to health data firm IMS Health.

But government officials believe the number of potentially anticompetitive patent settlements is increasing. Pay-for-delay deals increased from 28 to 40 in just the last two fiscal years and the deals in fiscal 2012 covered 31 brand-name pharmaceuticals, Federal Trade Commission officials said. Those had combined annual U.S. sales of more than $8.3 billion.

The Obama administration argues the agreements are illegal if they're

based solely on keeping the generic drug off the market. Solicitor General Donald Verrilli, speaking at Georgetown Law School recently, noted that once a generic drug gets on the market and competes with a brand-name drug, "the price drops 85 percent." That quickly decimates sales of the brand-name medicine.

"These agreements should actually be considered presumptively unlawful because of the potential effects on consumers," Verrilli said.

In the case before the court, Solvay agreed to pay Watson an estimated $19 million-$30 million annually, government officials said. The patent runs until August 2020. Watson agreed to also help sell the brand-name version, AndroGel.

AndroGel, which brought in $1.2 billion last year for AbbVie, is a gel applied to the skin daily to treat low testosterone in men. Low testosterone can affect sex drive, energy level, mood, muscle mass and bone strength.

The FTC called the deal anticompetitive and sued Watson, now called Actavis Inc.

The federal district and appellate courts both ruled against the government, and the FTC appealed to the Supreme Court.

AbbVie, which is based in North Chicago, Illinois, said, "We are confident that these decisions will be upheld by the Supreme Court."

The Generic Pharmaceutical Association's head, Ralph Neas, said the settlements are "pro-consumer, pro-competition and transparent." He said every patent settlement to date has brought a generic drug to market before the relevant patent ended, with two-thirds of the new generic drugs launched in 2010 and 2011 hitting the market early due to a

settlement.

"By doing what the FTC wants, you're going to hurt consumers rather than help them," said Paul Bisaro, CEO of Actavis of Parsippany, New Jersey.

Bisaro said consumers will save an estimated $50 billion just from patent settlements involving Lipitor, the cholesterol-lowering drug made by Pfizer Inc. of New York that reigned for nearly a decade as the world's top-selling drug.

Lipitor's patent ran until 2017, but multiple generic companies challenged it. Pfizer reached a settlement that enabled Actavis and a second company to sell slightly cheaper generic versions starting Nov. 30, 2011, and several other generic drugmakers to begin selling generic Lipitor six months later. The price then plummeted from Pfizer's $375 to $530 for a three-month supply, depending on dosage, to $20 to $40 for generic versions.

Because generic companies tend to challenge patents of every successful drug, the FTC's position would impose onerous legal costs on brand-name drugmakers and limit their ability to fund expensive research to create new drugs, said the Pharmaceutical Research and Manufacturers of America, which represents brand-name drugmakers.

According to the 2010 RBC Capital Markets study, when trial victories, settlements between drugmakers and dropped cases are combined, generic companies were able to bring their product to market before the brand-name drug's patent expired in 76 percent of the 371 drug patent suits decided from 2000 through 2009.

Consumer, doctor and drugstore groups have lined up to support the Obama administration in this case.

"AARP believes it is in the interest of those fifty and older, and indeed the public at large, to hasten the entry of generic prescription drugs to the marketplace," said Ken Zeller, senior attorney with the AARP Foundation Litigation. "Pay-for-delay agreements such as those at issue in this case frustrate that public interest." AARP is an advocacy group for older Americans.

The American Medical Association, the giant doctors' group, believes pay-for-delay agreements undermine the balance between spurring innovation through patents and fostering competition through generics. AMA President Dr. Jeremy A. Lazarus said, "Pay for delay must stop to ensure the most cost-effective treatment options are available to patients."

Drugstores also believe pay-for-delay deals "pose considerable harm to patients because they postpone the availability of generic drugs which limits patient access to generic medications," said Chrissy Kopple of the National Association of Chain Drug Stores.

Eight justices will decide this case later this year. Justice Samuel Alito did not take part in considering whether to take this case and is not expected to take part in arguments.

The case is Federal Trade Commission vs. Actavis, Inc., 12-416.