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HIV Drug Buyers Urge $3.6B Verdict Against Gilead And Teva

By **Bonnie Eslinger**

Law360 (June 27, 2023, 10:11 PM EDT) -- Gilead and Teva "cut a pay-off deal" to keep prices for two HIV drugs as "expensive as possible for as long as possible" and should be ordered to return overcharges totaling $3.6 billion, a lawyer for drug purchasers said Tuesday at the conclusion of a California federal antitrust trial.

The closing arguments cap weeks of testimony and other evidence in the antitrust case brought by health plans and insurers that claim they paid inflated prices for Gilead-brand Truvada and Atripla, as well as for Teva's generic versions of the HIV drugs. A lawyer for the drug purchasers told the seven-member jury that Gilead Sciences Inc. and Teva Pharmaceutical Industries Ltd. "cut a pay off deal between them to keep these two pills, Truvada and Atripla, as expensive as possible for as long as possible," first by extending Gilead's monopoly and then by providing Teva with a 180-day exclusive head start on the market before other generics.

The arrangement came at the expense of the plaintiffs, which include hundreds of health and union funds, self-insured employers, and insurers, said the lawyer, Tom Sobol of Hagens Berman Sobol Shapiro LLP. The defense put on by Gilead and Teva during the trial featured "hypocrisy galore" and "cynicism," and "a complete disregard for what actually happened," said Sobol.

The claims stem from an underlying patent dispute Teva initiated in 2008, challenging Gilead's patents for Truvada and Atripla. Gilead responded by suing Teva, but the two companies reached an out-of-court agreement ending their claims in 2014.

In that underlying patent case in New York federal court, Teva told the judge in a 2013 pretrial memorandum that Gilead "will say whatever it takes to preserve their monopoly." Teva has now switched sides and is fighting the purchasers' claims alongside Gilead, Sobol said.

Now, "those two defendants come into the courtroom, pay someone to get on the stand — an expert — to say there's no patent monopoly," he said.

During the trial proceedings in the New York patent case, Teva learned it had missed a key deadline, so it would not qualify for a 180-day period of exclusivity provided under federal law for generic manufacturers that are the first to challenge brand patents, Sobol reminded jurors.

"It had blown exclusivity for those two drugs," he said. "Gilead wanted more time, and Teva wanted exclusivity: You match those two together, and you get pay for delay."

And the deal paid off, he said. When Gilead had the market to itself, the price of Truvada was $50 a pill. During the six months of market exclusivity it got under the settlement, Teva charged $44.23 for its version of the drug. It was only when other generics were able to get on the market that the price plummeted, to $1.74 per pill, according to Sobol.

"Teva made over $600 million during its exclusivity payoff time," he said. "It's been suggested that this isn't really a deal ... that's exactly the kind of cynicism and hypocrisy I'm telling you about."

Sobol called the profits Teva received during that six months "a large reverse payment," and claimed Gilead's willingness to pay off a generic suggested Gilead knew its patents weren't strong. The lawyer reminded jurors that Kenyon & Kenyon LLP, an intellectual property law firm Teva hired, concluded that the patents for a key ingredient in Truvada and Atripla could be invalidated as "obvious." Other evidence backs the assertion that Gilead's patents were weak, said Sobol.

According to an expert for the plaintiffs, a conclusion that Teva would have won the case in 2014 means Teva's version of the HIV drugs and other generic versions could have entered the market as early as February 2018. In an alternative scenario where Teva settles, the plaintiffs' expert said a May 2019 entry date would be likely.

Toward the end, Sobol took aim at Gilead's argument that it didn't have market power with Truvada and Atripla because there were other HIV drugs on the market. He told jurors they could infer that Gilead had market power because it consistently raised the prices for the two drugs, even with other drugs coming onto the market.

"You also know by the huge amounts of profits," the lawyer added.

During the time of the alleged overpayment, from 2018 to 2020, Gilead brought in $8.2 billion in revenues from Truvada and Atripla, Sobol said.

"What do we want back? $3.6 billion," he said.

Closing arguments were also made by counsel for plaintiffs United HealthCare Services Inc. and health plans that have brought individual claims, including Humana Inc. and Kaiser Foundation Health Plan Inc.

United Healthcare's lawyer, Hamish Hume of Boies Schiller Flexner LLP, reminded jurors of the testimony they received from a representative of the company saying Gilead had refused to offer United HealthCare any discounts or rebates on the two HIV drugs. The representative also noted that United HealthCare is the largest or second-largest health insurance company in the country.

"If you refuse to negotiate with your biggest buyer, the person that spends the most amount of money on the drugs you're selling, that's market power," Hume said.

The lawyer for the seven individual health plans, Jeffrey Poston of Crowell & Moring LLP, told jurors that the agreement Gilead and Teva reached, "subverted competition" and "kept prices high, so those two drug companies could divvy up the rigged profits."

Teva and Gilead's contention that the patents at issue were strong doesn't hold up to inspection, Poston added.

"If Gilead's patents were so strong and Teva's case so weak, why did Gilead give Teva six months contractual exclusivity royalty free?" the lawyer asked, later adding, "Giant for-profit drug companies don't just give stuff away for free."

Closing arguments for the defense will continue on Wednesday, but Christopher Holding of Goodwin Procter LLP, who represents Teva, got in a few words with jurors on Tuesday before the judge called it a day.

The evidence shows Gilead's patents were strong, and it was unlikely that any generic company would have been able to invalidate those patents in court, Teva's lawyer said.

"Back in 2013 and 2014, Teva knew it was in trouble on Gilead's patents," Holding said. "Teva was putting on the best defense it could for sure, but Teva thought it was unlikely to win."

So, in actuality, the settlement agreement between Teva and Gilead created early entry, Holding said, allowing Teva on the market in September 2020, a year before key patents expired.

"Gilead was not offering, and Teva could not have gotten an earlier licensed entry date," Holding said.

Teva's lawyers reminded the jury of an internal company email from Feb. 10, 2014, as the New York patent trial was reaching its end, in which a top lawyer for the company told her boss that the chances of invalidating Gilead's patents were low, and "it makes sense to try to get the best settlement we can now and move on."

On Tuesday, U.S. District Judge Edward Chen provided the jury with information about the relevant law at issue in the case, including the alleged Sherman Act violation.

"It is anti-competitive for a brand manufacturer and generic manufacturer to settle a patent infringement dispute by having the brand manufacturer pay, in any form, the generic manufacturer to delay entry into the market, thereby allowing the brand manufacturer to avoid the risk of generic competition," the judge said.

The trial kicked off on May 25 and just before opening arguments, it was announced that Gilead and Teva **had reached a settlement** with some plaintiffs, including major pharmacies, and Gilead settled with direct purchasers.

The trial continues on Wednesday with the remainder of the closing arguments.

The end-payor plaintiffs are represented by Hilliard Shadowen LLP and Hagens Berman Sobol Shapiro LLP.

United HealthCare Services Inc. is represented by Zelle LLP and Boies Schiller Flexner LLP.

Humana Inc., Blue Cross and Blue Shield of Florida Inc., Health Options Inc., Centene Corp., Triple-S Salud Inc., Blue Cross and Blue Shield of Kansas City and Kaiser Foundation Health Plan Inc. are represented by Crowell & Moring LLP and Berry Silberberg Stokes PC.

Gilead Sciences Inc., Gilead Holdings LLC, Gilead Sciences LLC and Gilead Sciences Ireland UC are

represented by Kirkland & Ellis LLP and Proskauer Rose LLP.

Teva is represented by Goodwin Procter LLP.

The case is In re: HIV Antitrust Litigation, case number 3:19-cv-02573, in the U.S. District Court for the Northern District of California.

--Additional reporting by Gina Kim, Dorothy Atkins and Bryan Koenig. Editing by Kristen Becker.
