

Judge Advises Freeing Amgen, Teva From Suits Over Sensipar

By **Julia Arciga**

Law360 (July 24, 2020, 10:02 PM EDT) -- A Delaware federal judge has recommended the dismissal of two antitrust class actions against pharmaceutical giants Amgen and Teva Pharmaceuticals over their agreement to pull a generic version of a calcium control drug off the market, saying the lawsuits failed to properly allege the agreement included an unlawful "pay for delay" deal.

U.S. Magistrate Judge Jennifer L. Hall said in an opinion on Thursday that the direct and indirect purchasers of Sensipar, also known as cinacalcet, had failed to prove that Amgen Inc. and Teva Pharmaceuticals USA Inc.'s 2018 agreement included "large and unjustified" reverse payments, which is required in order to state a federal antitrust claim.

Judge Hall pointed to Teva's relatively small \$40 million payment to Amgen as part of the agreement, which paled in comparison to the \$400 million in revenue Teva raked in before its generic version of Sensipar was pulled off the market.

She also rejected arguments that a clause in the agreement, which allows Teva to enter the market again if another Sensipar generic is released, counted as a form of reverse payment.

The judge considered claims that the agreement may have resulted in higher prices for customers, but said Amgen had a patent for cinacalcet formulations, which created an "exception" to general rules against monopolies and trade restraints.

She recommended that the Judicial Panel on Multidistrict Litigation, which transferred the cases to Delaware last year, grant Amgen and Teva's requests to dismiss the federal antitrust claims of the direct and indirect purchasers.

Judge Hall also recommended the panel dismiss the state antitrust claims of the indirect purchasers, who based their claims on the same facts as the federal claims. The complaints were dismissed without prejudice.

The class actions against the Amgen-Teva agreement were filed in February 2019. The lawsuits took issue with the agreement that took a Sensipar generic off the market and would push Teva's re-release of the generic to June 30, 2021 — five years before Amgen's patent over cinacalcet formulations was set to expire.

The direct and indirect purchasers said the agreement would prevent Teva from competing with Amgen, delay entry of generic versions of Sensipar by companies other than Teva, and raise and maintain the prices of the drug.

Amgen and Teva each asked the court to toss the cases, and Judge Hall heard the arguments for the motions in April.

The class actions were a part of a multidistrict litigation that hinges on an underlying patent infringement fight Amgen waged against more than a dozen companies to shield Sensipar from competition. The companies had filed abbreviated new drug applications with the U.S. Food and Drug Administration in the hopes of marketing their generic versions of Sensipar. The FDA initially approved Sensipar in 2004.

Counsel for the indirect purchasers, Ian Connor Bifferato of The Bifferato Firm PA, declined to comment on Friday.

Counsel for the direct purchasers, Teva and Amgen did not immediately respond to requests for comment.

The direct purchasers are represented by Robert J. Kriner Jr., Scott M. Tucker and Tiffany J. Cramer of Chimicles Schwartz Kriner & Donaldson-Smith LLP, Linda P. Nussbaum, Bart D. Cohen and Peter Moran of Nussbaum Law Group PC and Thomas M. Sobol, Hannah Schwarzschild and Bradley J. Vettrai of Hagens Berman Sobol Shapiro LLP.

The indirect purchasers are represented by Ian Connor Bifferato of The Bifferato Firm PA, Gregory S. Ascioffa, Jay L. Himes, Karin E. Garvey, Robin A. van der Meulen, Matthew J. Perez and Domenico Minerva of Labaton Sucharow LLP, Irving Scher, Melinda Coolidge, Scott A. Martin and Brent Landau of Hausfeld LLP, Brian P. Murray, Lee Albert and Gregory B. Linkh of Glancy Prongay & Murray LLP and Paul Costa, Roberta D. Liebenberg, Adam J. Pessin and Jeffrey S. Istvan of Fine Kaplan & Black RPC.

Amgen is represented by Jack B. Blumenfeld and Brian P. Egan of Morris Nichols Arsht & Tunnell LLP and Eric J. Stock, Mark Mixon and Ashley E. Johnson of Gibson Dunn & Crutcher LLP.

Teva is represented by John W. Shaw, Karen E. Keller and David M. Fry of Shaw Keller LLP and Richard A. Spehr, Henninger S. Bullock and Niketa Patel of Mayer Brown LLP.

The case is In re: Sensipar (Cinacalcet Hydrochloride Tablets) Antitrust Litigation, case number 1:19-md-02895, in the U.S. District Court for the District of Delaware.

--Additional reporting by Khorri Atkinson. Editing by Nicole Bleier.