

One Sentence Ends Amgen Blockbuster's Reign, Judge Says

By **Jeff Overley**

Law360 (May 3, 2019, 10:04 PM EDT) -- A single sentence in a patent settlement prevents Amgen Inc. from halting sales of a generic version of its blockbuster calcium-control drug Sensipar, a Delaware federal judge ruled in an opinion released Friday.

The opinion from U.S. District Judge Leonard P. Stark declined to halt an at-risk launch of generic cinacalcet by India-based drugmaker Cipla Ltd. According to Judge Stark, the upshot is "price erosion and loss of market share [that] are likely to be quite steep" for Sensipar, which earned \$1.4 billion in the U.S. last year.

Judge Stark's refusal to issue a preliminary injunction stemmed from his interpretation of one sentence in an agreement between Amgen and Cipla to settle patent litigation. At issue was whether the sentence meant one or two conditions had to be satisfied in order to bar Amgen from winning an injunction, with Judge Stark concluding that only one condition had to be met.

"In the court's view, this sentence clearly and unambiguously sets out two separate conditions ... either of which, if satisfied, render applicable the restriction on Amgen" halting at-risk sales, the judge wrote.

Judge Stark's ruling is the latest chapter in Amgen's aggressive and wide-ranging effort to protect sales of Sensipar. Amgen has waged extensive patent litigation to shield Sensipar from competition, and it has been accused of antitrust violations in connection with a deal to get Teva Pharmaceuticals to pull its version of generic cinacalcet off the market.

Teva's sales are also what led to the dispute between Amgen and Cipla. In their patent settlement, the drugmakers agreed that Amgen could not stop Cipla's at-risk sales under certain circumstances, but they disagreed over whether one or two circumstances must occur to stop Cipla's sales.

Friday's ruling turned on whether the patent settlement's use of the word "or" meant that one or two conditions had to be satisfied.

"[The] sentence ... uses the word 'or' and so expresses two conditions, each of which is sufficient to bar Amgen from obtaining relief," Judge Stark concluded, adding that both conditions were nevertheless satisfied.

One of the conditions required a court ruling that a third party had not infringed a Sensipar patent.

Because Teva in separate litigation was found to have not infringed, that condition was satisfied, Judge Stark wrote.

The other condition required ongoing sales of generic cinacalcet by a third party. Because Teva previously sold generic cinacalcet that is still in the pipeline, it may still be engaged in "indirect sales," and so that condition is also satisfied, Judge Stark wrote.

Amgen has already appealed Judge Stark's ruling to the Third Circuit, and it has asked Judge Stark for an injunction pending appeal.

Representatives of the parties could not immediately be reached for comment on Friday.

Amgen is represented by Jack B. Blumenfeld and Brian P. Egan of Morris Nichols Arsht & Tunnell LLP, and M. Sean Royall, Ashley E. Johnson, Jeffrey T. Thomas, Eric J. Stock and Kate Dominguez of Gibson Dunn & Crutcher LLP.

Cipla is represented by Sue L. Robinson, Brian E. Farnan and Michael J. Farnan of Farnan LLP, and James W. Dabney, Patrice P. Jean, Dina Hoffer, Deanne K. Cevasco, David E. Lansky and Lynn M. Russo of Hughes Hubbard & Reed LLP.

The case is Cipla Ltd. et al. v. Amgen Inc., case number 1:19-cv-00044, in the U.S. District Court for the District of Delaware.

--Editing by Adam LoBelia.