

Xtampza Not Infringing 2 OxyContin Patents, Judge Says

By **Alison Noon**

Law360 (October 1, 2018, 9:17 PM EDT) -- An opioid painkiller designed to deter sniffing and injection does not infringe two of Purdue Pharma LP's OxyContin-related patents, a Massachusetts federal judge has ruled in a victory for Collegium Pharmaceutical Inc. and its two-year-old Xtampza XR.

U.S. District Judge F. Dennis Saylor granted summary judgment Friday in favor of Collegium on claims arising from two patents involving abuse-deterrent properties such as a hard tablet that resists crushing and a gelling agent to impede snorting and injecting. He allowed claims involving a third patent focused on OxyContin's formula to go forward, despite his "considerable misgivings" about some of them.

Collegium uses myristic acid to dissolve oxycodone base in wax. Purdue claimed Collegium was using an extra amount of the acid as an "irritant" or abuse-deterrent ingredient to cause a burning sensation when an Xtampza pill is snorted. Collegium said that all the myristic acid is necessary to solubilize oxycodone and drive salt formation, so any abuse-deterrent, overlapping effects are happy accidents.

Judge Saylor sided with Collegium, finding non-infringement on U.S. Patent Nos. 8,652,497 and 9,155,717.

"Collegium has put forth evidence that what appears to be 'excess myristic acid' is in fact an excipient and performs a necessary function," Judge Saylor wrote. "Purdue has not rebutted that evidence with anything other than speculation and argument."

He allowed claims to proceed involving U.S. Patent No. 9,073,933, which involves reducing toxicity in OxyContin's oxycodone hydrochloride compositions, though he said he foresaw Collegium prevailing based on issue preclusion.

In early 2014, Purdue lost a major OxyContin-related infringement case to Teva Pharmaceuticals USA Inc. in the Southern District of New York. Collegium's primary argument was that Purdue tried to relitigate those losses in Massachusetts federal court.

Collegium's question of issue preclusion invited Judge Saylor to lean on the factual findings that were litigated and essential to Teva rulings, he said, not just the outcomes of the previous case.

"Here, a variety of factual questions were actually litigated in the Teva case; indeed, the bench trial lasted 20 days," Judge Saylor wrote.

The presiding judge in the Teva case found that evidence “overwhelmingly proved” that an organic compound called 8α had no effect on the final product, indicating to Judge Saylor that a finding of obviousness could easily result and undermine Purdue’s claim that Collegium copied its 8α. But Judge Saylor said Purdue should get an opportunity to deny the significance of the substance in the Teva case’s end result, which he said could be hard to do after that judge spent “so much trial time” addressing that issue.

“Under the circumstances, this Court will not resolve those questions here,” Judge Saylor wrote. “It does appear, however, that the materiality of the 8α limitation in the product claims is very much in doubt, and therefore casts doubt on the validity of claims 1 and 16.”

Similarly, he declined to rule on whether Collegium’s products contained 95 percent oxycodone hydrochloride.

“There is substantial doubt as to whether the 95% limitation has any real significance, and if it does whether the limitation would have been obvious to a person of skill in the art,” Judge Saylor wrote. “Again, the resolution of those issues will await another day.”

Judge Saylor also indicated a jury may have to decide the alleged equivalency of oxycodone myristate and oxycodone hydrochloride.

Xtampza and OxyContin are among about a dozen abuse-deterrent opioid formulas officially labeled as such by the U.S. Food and Drug Administration. The FDA approved a label change to Xtampza in November 2017 to include comparative data indicating that Xtampza is more difficult to abuse than OxyContin.

Representatives for Purdue and Collegium did not return messages seeking comment Monday.

The patents in suit are U.S. Patent Nos. 9,073,933; 8,652,497 and 9,155,717.

Collegium is represented by Robins Kaplan LLP and Morgan Lewis & Bockius LLP.

Purdue is represented by Morris Nichols Arsht & Tunnell LLP, Ropes & Gray LLP, Jones Day and Sidley Austin LLP.

The case is Purdue Pharma LP et al. v. Collegium Pharmaceutical Inc., case number 1:15-cv-13099, in the U.S. District Court for the District of Massachusetts.

--Editing by Peter Rozovsky.