

Janssen Turns To High Court In Bid To Block Zytiga Generics

By **Matthew Bultman**

Law360 (November 21, 2018, 5:09 PM EST) -- Janssen Biotech Inc. said on Tuesday it was going to sprint to the U.S. Supreme Court after the Federal Circuit refused to block sales of generic versions of Zytiga while Janssen appeals a ruling that invalidated a patent on the blockbuster oncology medication.

The Federal Circuit on Tuesday afternoon denied Janssen's request for an injunction preventing the launch of generic Zytiga until the appeals court has a chance to review a New Jersey federal judge's decision finding the patent is invalid because it was obvious. The court said it wasn't convinced that an injunction was warranted.

Hours after the ruling, Janssen said it would file an emergency application on Wednesday with the Supreme Court for the injunction pending appeal. The company has said it will be "irreparably harmed" if generic competition hits the market.

Zytiga is used to treat prostate cancer and brought in \$5.7 billion in sales between April 2011 and the end of 2017. The patent, which Janssen exclusively licenses from BTG International Ltd., covers the use of chemotherapy medication abiraterone with a steroid to reduce side effects.

Following a bench trial, U.S. District Judge Kevin McNulty ruled late last month that the invention would have been obvious. The judge said the combination of the two drugs was "less like serendipity and more like inevitability."

According to court documents, Mylan NV, Teva Pharmaceuticals Inc. and Hikma Pharmaceuticals LLC have already received regulatory approval for a generic version of Zytiga and are in position to launch their products. Several other companies also have plans to introduce generic competition.

Urging the Federal Circuit to prevent the sale of generics until its appeal is resolved, Janssen argued earlier this month that generic competition would "drastically change the market" in ways that can't be "reversed or rectified."

"Given these imminent threats, temporary injunctive relief is the only way to avoid irreparable harm to Janssen," it said.

Following the Federal Circuit's ruling Tuesday, Janssen asked the court for a temporary injunction "to preserve the status quo at least until the Supreme Court" can rule on its emergency application. The appeals court denied that request in a short order Wednesday morning.

The Federal Circuit has expedited the briefing schedule and is set to hear oral arguments in the case on Jan. 24.

The patent at issue is U.S. Patent No. 8,822,438.

Janssen is represented by Sidley Austin LLP. BTG is represented by Finnegan Henderson Farabow Garrett & Dunner LLP.

The generic drug companies are represented by Perkins Coie LLP, Winston & Strawn LLP, Sterne Kessler Goldstein & Fox PLLC and McNeely Hare & War LLP.

The cases are BTG International Ltd. et al. v. Amneal Pharmaceuticals LLC et al., case numbers 19-1147 and 19-1148, in the U.S. Court of Appeals for the Federal Circuit.

--Editing by Jack Karp.