

## Teva Exits Cancer Drug IP Row With 2031 Generic License

By Jasmin Boyce

*Law360 (July 25, 2023, 5:29 PM EDT)* -- The maker of blockbuster cancer treatment Cabometyx has dropped patent litigation against Teva Pharmaceuticals over a planned generic, instead striking a licensing deal that permits an off-brand version of the drug to be released in 2031.

Exelixis Inc. said in a Sunday announcement that it has agreed to settle claims that Teva Pharmaceuticals USA Inc. was illegally moving to create a generic version of Cabometyx — Exelixis' treatment for kidney, liver and thyroid cancer that generated more than \$1 billion in revenue in 2021, according to the company's annual report. The announcement comes shortly after a Delaware federal judge refused to invalidate a related patent on the brand-name drug in separate infringement litigation against generic maker MSN Laboratories.

According to the announcement, the agreement puts an end to all Delaware federal litigation between Exelixis and Teva over Cabometyx that had been lodged under the Hatch-Waxman Act — which regulates generic drugs and exclusivities related to new drug applications.

"Pursuant to the terms of the agreement, Exelixis will grant Teva a license to market its generic version of Cabometyx in the United States beginning on January 1, 2031, if approved by the U.S. Food and Drug Administration and subject to conditions and exceptions common to agreements of this type," the patent owner said.

The dispute dates to June 2021, when Exelixis filed infringement litigation in the District of Delaware, asserting a trio of patents issued by the U.S. Patent and Trademark Office from August 2017 to July 2018.

The patent owner argued at the time that Teva was illegally moving to create a Cabometyx generic before the asserted systems expired in as late as July 2033.

According to the complaint, Exelixis sought a court order that would delay the effective date of Teva's abbreviated new drug application if it was approved by the FDA.

Teva fired back in an answer to the complaint that was filed the following August, asserting a noninfringement defense and a host of counterclaims. According to the generic maker, all three asserted patents were invalid.

Exelixis had previously hit generic-drug maker MSN with related infringement litigation in October 2019,

alleging its planned generic would infringe multiple patents on Cabometyx.

Last month, U.S. District Judge Richard Andrews rejected MSN's validity challenge to a patent on Cabometyx — during a bench trial between the patent owner and MSN — potentially keeping MSN's planned generic version off the market until 2026, while clearing the company of infringing a second patent at issue in their dispute.

The patents-in-suit are U.S. Patent Nos. 9,724,342; 10,039,757 and 10,034,873.

Teva and its counsel did not immediately respond to requests for comment on Tuesday. Exelixis declined to comment beyond the announcement.

Exelixis is represented by Jack B. Blumenfeld and Anthony David Raucci of Morris Nichols Arsht & Tunnell LLP and Emily R. Whelan, Katherine P. Kieckhafer, Kevin S. Prussia, Lisa J. Pirozzolo and Timothy A. Cook of Wilmer Hale.

Teva is represented by Chandrika Vira, Grace Tuyiringire and J.C. Rozendaal of Sterne Kessler Goldstein & Fox PLLC and Nathan Roger Hoeschen of Shaw Keller LLP.

The suit is Exelixis, Inc. v. Teva Pharmaceutical Industries Limited et al., case number 1:21-cv-00871, in the U.S. District Court for the District of Delaware.

--Additional reporting by Ryan Davis. Editing by Kelly Duncan.