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Teva sues US FDA over bid to block approval of generic Copaxone

BLOOMBERG
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Teva Pharmaceutical Industries Ltd sued US regulators, seeking to block approval of a generic version of its multiple-sclerosis drug Copaxone, a product that accounts for more than half the company's revenue and is set to go off patent on May 24.

Israel-based Teva contends in the complaint that US Food and Drug Administration officials improperly dismissed the drugmaker's calls to subject competitors' generic versions of Copaxone to extensive testing before they go on the US market.

The suit, filed in federal court in Washington, is the company's latest move in its campaign to block generic rivals such as Mylan Inc and Novartis AG's Sandoz unit from putting out a less-expensive version of Copaxone. Last month, a US Supreme Court justice rejected Teva's bid for an injunction to prevent the sale of generic competitors' products.

"Unless this court acts now, the FDA's gamesmanship will preclude Teva from obtaining meaningful judicial review before the FDA allows these putative generic products to overwhelm the market," the company said in the complaint.

Copaxone brings in $3.2 billion in annual US sales and accounts for more than half of Teva's profit. A delay would give Teva time to switch patients from the 20-milligram dose that is slated to come off patent protection to a 40-milligram dose it says is covered by other patents until 2015.

Sandy Walsh, an FDA spokeswoman, didn't immediately return a call for comment on Teva's Copaxone suit. Teva is appealing a judge's 2013 dismissal of its suits against Mylan and Sandoz for infringing patents covering Copaxone. The case is pending before the US Supreme Court.

Sandoz, based in Basel, Switzerland, and Pennsylvania-based Mylan originally were sued by Teva after they asked the FDA for approval of generic drugs to compete with Copaxone, prescribed to reduce the frequency of relapses in MS patients.

In the latest suit, Teva officials said they filed a petition to require generic versions of Copaxone to undergo clinical-trial studies before being approved for sale. The FDA rejected that petition May 2 without addressing the merits of Tevas request, according to the complaint.

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