

Court ruling clears way for Novartis' low-cost biotech drug

July 21 2015

A federal appeals court has ruled that Novartis can begin selling its lower-cost copy of an Amgen Inc. drug in September, rejecting a bid to further delay the launch of the knock-off biotech medication.

Novartis received federal approval in March to sell its cheaper copy of Amgen's Neupogen, which is used to boost blood cells in cancer patients. It was the first time the Food and Drug Administration had approved a lower-cost copy of a biotech drug.

But the launch of Novartis' Zarxio has been delayed by litigation brought by Amgen Inc.

On Tuesday, the U.S. Court of Appeals for the Federal Circuit rejected Amgen's claims of unfair competition but also said Novartis would have to wait until Sept. 2 before selling its [drug](#).

The delayed launch stems from a provision of the law governing approval of biosimilars, the industry term for the quasi-generic biotech drugs. The court ruling handed down Tuesday states that companies marketing new biosimilars must give 180 days advance notice to the original drugmaker after receiving FDA approval. Novartis had argued that the 180 days' notice could be given prior to FDA approval.

The court ruling means biotech makers like Amgen Inc. can expect six additional months of exclusive marketing for their drugs even after a biosimilar is approved.

In Europe, Novartis has sold its version of Neupogen, called Zarzio there, since 2009. The drugmaker also markets two other biosimilar drugs in about 60 countries.

Other blockbuster biotech drugs expected to face biosimilar competition in the U.S. include anti-inflammatory drugs Remicade and Humira and cancer drugs Herceptin and Avastin.

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Citation: Court ruling clears way for Novartis' low-cost biotech drug (2015, July 21) retrieved 15 July 2023 from <https://medicalxpress.com/news/2015-07-court-novartis-low-cost-biotech-drug.html>

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