

Scott Cunning in Financial Times: Biosimilars Set to Compete with Two of World's Biggest Drug Franchises

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The world's top grossing drug, Humira, generated \$14bn in global sales last year for AbbVie, the Chicago-based pharmaceuticals group that owns the medicine. The anti-inflammatory treatment, used for conditions from arthritis to Crohn's disease, has enjoyed 14 years of market exclusivity, unburdened by the kind of copycat medicines that tend to push drug-makers over the patent cliff.

Now AbbVie must contemplate the end of the party, after advisers to the US Food and Drug Administration recommended this week that the drug regulator approve a copycat version of the medicine...

The case hinges on the 180-day notice period that biosimilar makers such as Sandoz are required to give to branded makers such as Amgen before they launch the copycat product...

Six months might not sound like a lot of time when one considers that biologic drugs already enjoy 12 years of exclusivity. But Scott Cunning, an intellectual property partner in corporate law firm Haynes Boone, says it is more important than it might seem.

"When you're talking about franchises that are worth billions of dollars, six months can be lucrative," he says. "It also gives them the time to get their ducks in a row so that they have their patent challenges lined up."

Excerpted from *Financial Times*. To read the full article, please [click here](#) (subscription required).