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Boehringer Waves White Flag In Humira Patent Battle

By **Jeff Overley**

Law360 (May 14, 2019, 4:33 PM EDT) -- Boehringer Ingelheim on Tuesday abandoned its long-shot assault on the patent fortress surrounding AbbVie Inc.'s immunosuppressant Humira, saying it would reluctantly join a long list of biosimilar makers that have agreed to delay competition until 2023.

The deal between Boehringer and AbbVie ends one of the pharmaceutical industry's most intriguing legal fights and eliminates the last near-term threat to Humira, which earned $20 billion globally last year — including almost $14 billion in the U.S. — and is the world's top-selling drug.

Tuesday's settlement means that Boehringer won't fulfill its vow to launch Cyltezo, its biosimilar version of Humira, in the U.S. more quickly than other biosimilar makers. The company declared in February that it was "committed to making [Cyltezo] available to U.S. patients as soon as possible and certainly before 2023."

But under the deal, Cyltezo won't enter American pharmacies until July 1, 2023, placing it third in line among nine biosimilars set to hit the market that year.

Susan Holz, a spokesperson for Boehringer, told Law360 on Tuesday that "the decision to enter into a settlement was not taken lightly and the bottom line is that there is a need ... to enter the U.S. market as soon as possible."

"We had hoped that litigation was going to make Cyltezo available sooner," Holz said. "However, with the inherent unpredictability of litigation, the substantial costs of what would have been a long and complicated legal process and ongoing distraction to our business, we have concluded that this settlement is the best solution."

After AbbVie sued Boehringer in 2017 for allegedly infringing Humira's patents, Boehringer tried to turn the tables by accusing AbbVie of improperly amassing duplicative and unoriginal patents to delay competition.

Humira's Delayed Competition

Boehringer Ingelheim on Tuesday became the ninth drugmaker to agree not to introduce a biosimilar version of AbbVie's Humira until 2023.

Competitor	Earliest Entry Date
Amgen	Jan. 31, 2023
Bioepis	June 30, 2023
Boehringer	July 1, 2023
Mylan	July 31, 2023
Sandoz	Sept. 30, 2023
Fresenius	Sept. 30, 2023
Pfizer	Nov. 20, 2023
Momenta	Nov. 20, 2023
Coherus	Dec. 15, 2023

That strategy gave AbbVie "unclean hands" and rendered Humira's patents unenforceable, Boehringer argued.

Humira, or adalimumab, treats rheumatoid arthritis, psoriatic arthritis, Crohn's disease, ulcerative colitis and plaque psoriasis, among other conditions. AbbVie last month won U.S. Food and Drug Administration approval for Skyrizi, or risankizumab, to treat plaque psoriasis, and it is studying the product in several other conditions that Humira treats. AbbVie derives about 60% of its revenue from Humira but has predicted that biosimilars will eat into Humira's sales, and Skyrizi will likely help it make up for lost income.

Although ultimately unsuccessful, Boehringer's defense has drawn attention to AbbVie's aggressive compilation of intellectual property. Congress is eyeing bipartisan legislation to target "patent thickets," and a wave of proposed class actions has emerged in response to Humira's patents.

Some of the proposed class actions have also argued that AbbVie and several rivals improperly agreed to allow biosimilar sales in Europe in exchange for delaying biosimilar sales in the U.S.

In a statement on Tuesday, AbbVie said that it "will make no payments of any form" to Boehringer under the settlement between the companies. AbbVie added that Boehringer will pay royalties to license Humira's patents and will recognize the legitimacy of those patents.

AbbVie derives about 60% of its revenue from Humira, the world's top-selling drug. (Getty)

Boehringer previously announced that it would no longer pursue sales of Cyltezo in Europe. Holz on Tuesday said that "at this point in time, our focus remains on providing patient access to our biosimilar Cyltezo in the United States."

The patents-in-suit are U.S. Patent Nos. 8,926,975; 9,018,361; 9,266,949; 9,272,041; 9,546,212; 9,090,867; 9,096,666; and 9,255,143.

AbbVie is represented by William F. Lee, William G. McElwain, Amy K. Wigmore, Amanda L. Major and Joshua L. Stern of WilmerHale, Michael A. Morin, David P. Frazier, Inge A. Osman, Herman H. Yue, Michael R. Seringhaus and Gabrielle LaHatte of Latham & Watkins LLP, William B. Raich, Jonathan R. Davies and Mindy L. Ehrenfried of Finnegan Henderson Farabow Garrett & Dunner LLP, Michael P. Kelly, Daniel M. Silver and Alexandra M. Joyce of McCarter & English LLP and Michael A. Schwartz of Pepper Hamilton LLP.

Boehringer Ingelheim is represented by Bruce Wexler, Eric Dittmann, Isaac Ashkenazi, Young Park, Chad Peterman, Ashley Mays-Williams, and Nicholas Tymoczko of Paul Hastings LLP and by Christopher R. Hall, Jennifer L. Beidel, Andrea P. Brockway, Rebecca J. Feuerhammer, James D. Taylor Jr. and Jessica M. Jones of Saul Ewing Arnstein & Lehr LLP.

The case is AbbVie Inc. et al. v. Boehringer Ingelheim International GmbH et al., case number 1:17-cv-01065, in the U.S. District Court for the District of Delaware.

--Editing by Nicole Bleier.