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Amarin's Vascepa Patents Struck Down As Generics Ramp Up

By **Britain Eakin**

Law360 (March 31, 2020, 6:16 PM EDT) -- Amarin Pharma Inc. saw claims in six patents covering its blockbuster omega-3 heart drug Vascepa dashed by a Nevada federal court Monday, opening the door to generic competition and causing a 70% plunge in its stock.

Though the district court found that abbreviated new drug applications for generics from Hikma Pharmaceuticals USA Inc. and Dr. Reddy's Laboratories Inc. would induce infringement of the Vascepa patents, the judge held that the asserted claims were obvious in light of earlier printed publications.

"The court is persuaded that defendants presented clear and convincing evidence at trial that all asserted claims are invalid as obvious," the decision said.

The impact of the district court loss rippled immediately into Amarin's stock prices, which tumbled dramatically overnight from \$13.58 a share at closing Monday to \$4.19 per share Tuesday morning at opening.

Amarin Chief Executive Officer John Thero said in a statement that the company plans to appeal the decision.

"Amarin strongly disagrees with the ruling and will vigorously pursue all available remedies, including an appeal of the court's decision and a preliminary injunction pending appeal to, if an ANDA is approved by FDA, prevent launch of generic versions of Vascepa in the United States," he said.

The company said it would press ahead with educational and promotional efforts related to Vascepa, saying it would offer an update on those efforts once the outcome of its effort to block the generics is finalized.

Amarin said it does not believe that any of the companies are ready to immediately launch a generic version of Vascepa, which uses fish oil to lower the levels of certain fats in the bloodstream.

Hikma's president of generics Brian Hoffmann meanwhile welcomed the decision and said the company is looking at options to launch a generic product if it gets FDA approval, including an "at-risk" launch if Amarin appeals.

"We are very pleased with the district court's decision, which demonstrates our continued ability to successfully litigate to bring greater value to our customers and patients in the U.S.," Hoffmann said in a statement. "We look forward to providing patients and health care providers in the U.S. with a generic version of this important medicine."

Amarin Pharma and Amarin Pharmaceuticals Ireland Ltd. got approval for Vascepa from the U.S. Food and Drug Administration in 2012, and it sued the generic companies in October 2016 after they filed ANDAs for generic versions of Vascepa.

According to the district court's decision, Vascepa has yet to turn a profit, though Amarin said in a recent presentation for investors that its 2019 revenue increased 87% from the year before. The

decision also noted that Vascepa pulled in \$228 million in sales in 2018, and said the company has invested \$465 million in research and development between 2008 and 2018.

Counsel for the parties did not return a request for comment.

The patents-in-suit are U.S. Patent Nos. 8,293,728; 8,318,715; 8,357,677; 8,367,652; 8,431,560; and 8,518,929.

Amarin is represented by Chelsea Latino and Adam Hosmer-Henner of McDonald Carano LLP, Jeffrey B. Elikan, Megan P. Keane, Michael N. Kennedy, Christopher N. Sipes, Einar Stole, Eric R. Sonnenschein, Han Park, Daniel J. Farnoly, Jordan L. Moran and Alaina M. Whitt of Covington & Burling, and Jason D. Smith and Nicholas J. Santoro of Santoro Whitmire Ltd.

Hikma is represented by Charles B. Klein, Eimeric Reig-Plessis, George C. Lombardi, Claire A. Fundakowski and Alison M. Heydorn of Winston & Strawn LLP, and W. West Allen of Howard & Howard Attorneys PLLC.

Dr. Reddy's is represented by Constance S. Huttner, Frank D. Rodriguez, James Barabas, Caroline Sun and Beth Finkelstein of Windels Marx Lane & Mittendorf LLP, and Michael D. Rounds and Ryan J. Cudnik of Brownstein Hyatt Farber Schreck LLP.

The case is Amarin Pharma Inc. et al. v. Hikma Pharmaceuticals USA Inc. et al., case number 2:16-cv-02525, in the U.S. District Court for the District of Nevada.

--Editing by Adam LoBelia.