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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Amgen Gets \$70M In Biosimilar Patent Suit Against Hospira

By **Vince Sullivan**

Law360, Wilmington (September 22, 2017, 10:21 PM EDT) -- A Delaware federal jury awarded Amgen Inc. \$70 million in damages late Friday after finding that Hospira Inc. infringed a patent for the anemia treatment Epogen, rejecting Hospira's argument that it was protected by a safe harbor meant for companies seeking federal approval for biosimilar products.



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After five hours of deliberation, the jury found that Hospira infringed Amgen's patent that covers the creation of specialized erythropoietin protein cells, or EPO, that stimulate the creation of red blood cells in anemia patients. The jury found that 14 of Hospira's 21 EPO batches were not covered by a safe harbor that allows for using patented processes while pursuing regulatory approval for biosimilar treatments.

"Amgen is very happy with the verdict," an Amgen representative said after the jury returned its verdict Friday night, which also found that Amgen's EPO creation patent is valid.

Hospira was found not to have infringed a second Amgen patent covering a process for selecting and collecting different forms of EPO molecules for better results.

Amgen, which markets its EPO treatment under the Epogen brand name, was asking for \$170 million in damages and alleging Hospira created 21 batches of its biosimilar in order to create a stockpile of the product ahead of its anticipated regulatory approval by the U.S. Food and Drug

Administration.

Hospira's defense focused on the creation of those batches of the biologic as a necessary action to pursue FDA approval, which the company has not yet received. These actions should be covered by the safe harbor created by the U.S. Biologics Price Competition and Innovation Act passed in 2009, which governs the development of biosimilar products.

"It manufactured 21 batches," Amgen attorney John R. Labbé of Marshall Gerstein & Borun LLP told the jury during closing arguments Friday afternoon. "It did so to create a stockpile of commercial product worth nearly a billion dollars."

Hospira created several batches of the product in 2009 and 2012, which Labbé did not contend were infringing actions. The problems arose from Hospira's continued production of those 21 batches beginning in 2013 and ending in 2015.

"The issue here is the reasonableness of Hospira's activities," Labbé said. "Was its manufacture of the batches ... reasonably related to obtaining FDA approval?"

Hospira attorney Thomas J. Meloro of Willkie Farr & Gallagher LLP said his client's actions were for the express purpose of creating enough product to verify its manufacturing processes and gaining regulatory approval for its biosimilar product.

"Hospira met the safe harbor requirements because its activities were reasonably related to developing and submitting information to the FDA in efforts to obtain FDA approval," Meloro said.

The jury agreed that seven of the 21 batches in question fell under the protection of the safe harbor because they were shown to have been used in testing for regulatory purposes. Amgen's patents expired in late 2015 and early 2016.

Representatives for Hospira declined to comment after the verdict.

The five-day trial was one of the first to test the rules for developing biosimilars, which are similar in nature to generic pharmaceuticals. Amgen's Epogen was one of the first biologic treatments approved for sale, and Hospira's product is one of the first biosimilars to pursue approval.

The patents-in-suit are U.S. Patent Numbers 5,756,349 and 5,856,298.

Amgen is represented by Robert J. Whetzel and Jason Rawnsley of Richards Layton & Finger PA; Kevin M. Flowers, Matthew C. Nielsen, Mark H. Izraelewicz, John R. Labbé, Julianne M. Hartzell, Benjamin Horton, Tiffany D. Gehrke, Douglas G. Bolesch and Yun Weis of Marshall Gerstein & Borun LLP; Nicholas Groombridge, Eric Alan Stone, Jennifer H. Wu, Ana J. Friedman and Stephen A. Maniscalco of Paul Weiss Rifkind Wharton & Garrison LLP; and in-house counsel Wendy A. Whiteford and Thomas F. Lavery IV.

Hospira is represented by Dominick T. Gattuso of Heyman Enerio Gattuso & Hirzel LLP, and Thomas J. Meloro, Michael W. Johnson, Heather M. Schneider, Tara Thieme and Philip F. DiSanto of Willkie Farr & Gallagher LLP.

The case is Amgen Inc. et al. v. Hospira Inc., case number 1:15-cv-00839, in the U.S. District Court for the District of Delaware.

--Editing by Breda Lund.

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