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Amgen Sues Hospira Over Biosimilar Info, Notice

By **Jeff Overley**

Law360, New York (September 21, 2015, 3:36 PM ET) -- Amgen Inc. on Friday sued Hospira Inc. in Delaware federal court for allegedly violating information-sharing and advance-notice provisions of the Biologics Price Competition and Innovation Act, adding to a flurry of litigation that will decide how quickly biosimilars get to market.

The complaint is at least the third that Amgen has launched alleging violations of the BPCIA, and it relates to Hospira's proposed biosimilar of anti-anemia blockbuster Epogen, or epoetin alfa. All the pending litigation is in a holding pattern as observers await the Federal Circuit's possible en banc review of a panel decision in Amgen v. Sandoz Inc. interpreting the BPCIA provisions for the first time.

Friday's complaint asserted that Hospira improperly flouted the BPCIA's so-called patent dance — an exchange of information about intellectual property — by sharing only its approval application and not additional information about manufacturing processes.

"Because Hospira's manufacturing process for the [biosimilar] is still secret … Amgen cannot conduct a full and complete evaluation of its patent portfolio as to Hospira's specific processes of manufacture," Friday's complaint said.

Although the panel decision from the Federal Circuit found that the patent dance is optional, Amgen noted that it is seeking en banc review of the allegedly "erroneous decision."

Regardless, Amgen's complaint raises an unanswered question — also at issue in a case involving Janssen Pharmaceuticals Inc. and Celltrion Inc. — over the amount of information that must be shared in order to achieve compliance with the patent dance.

Separately, Amgen says that Hospira is poised to violate the BPCIA's requirement for biosimilar makers to provide their brand-name rivals with 180-day advance notice of marketing. According to Amgen, Hospira in April provided notice that was legally ineffective under the panel ruling, which found that notice can only be supplied after a biosimilar is licensed by the U.S. Food and Drug Administration.

"Hospira has refused to acknowledge the import of the holding in Amgen v. Sandoz," according to Friday's complaint. "Instead … Hospira has taken the position that it is under no obligation to, and will not, provide any notice."

That dispute touches on another unanswered question after the panel decision. Although the panel said

that 180-day notice can only be supplied after FDA licensing, its decision at times suggested that notice is only required when biosimilar makers refuse to participate in the patent dance.

Hospira was recently acquired by Pfizer Inc. A Pfizer spokeswoman said in response to the lawsuit that "the company will review the filings and respond to them accordingly."

Friday's complaint also alleges infringement of two specific patents. It joins two earlier Amgen complaints involving the same BPCIA provisions — the complaint against Sandoz that's now at the Federal Circuit and a complaint against Apotex Inc. in Florida federal court.

In addition to Epogen, Hospira's biosimilar would copy Janssen's epoetin alfa biologic Procrit, which Amgen manufactures under a licensing agreement with Janssen.

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

Amgen is represented by Kevin M. Flowers, Matthew C. Nielsen, John R. Labbe and Amanda K. Antons of Marshall Gerstein & Borun LLP, Jack B. Blumenfeld and Maryellen Noreika of Morris Nichols Arsht & Tunnell LLP and in-house counsel Wendy A. Whiteford, Michael G. Penn and Thomas F. Lavery IV.

Counsel information for Hospira was not immediately available.

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 Patricia K. Cole.
