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

Astellas Accused Of Delaying Generic Drug Approval

By **Dan Rivoli**

Law360, New York (September 14, 2011, 9:50 PM ET) -- Astellas Pharma US Inc. was hit with a putative class action by a union benefit fund Wednesday in Massachusetts federal court for allegedly keeping a generic version of its immune-suppressing drug off the market and jacking up indirect purchasers' costs.

The New Mexico United Food and Commercial Workers Union's and Employers' Health and Welfare Trust Fund said Astellas has abused the generic drug application system to keep a cheaper rival of its Prograf drug from getting approved. The fund cited Astellas' September 2007 citizen petition to the U.S. Food and Drug Administration and subsequent court cases filed to delay approval of a generic version of Prograf, called tacrolimus.

The petition, ultimately rejected by the FDA in 2009, never addressed the adequacy of the abbreviated new drug application, presented evidence disputing the generic's bioequivalence to Prograf, or raise concerns about public health — "the issues for which citizen petitions were primarily implemented," the suit said.

"Astellas' petition and court actions were a sham," the complaint said. "Any pharmaceutical industry stakeholder, including Astellas, was aware that Astellas' arguments would fail at the FDA."

Reports and studies contained in Astellas' petition were "cherry-picked" to include information in support of its arguments, the suit alleges. Accurately discussing the documents cited would have undercut Astellas' arguments for filing the petition, the complaint said.

The fund also criticized Astellas for making "baseless" requests, such as asking the FDA to require labeling changes to alert caregivers and patients about switching between generic and branded products.

"Astellas made its submissions to the FDA not to influence the FDA policy or procedure but instead to delay the FDA approval of generic Prograf and unlawfully extend the company's monopoly for Prograf products in the United States," the suit said.

Without a generic Prograf on the market, indirect purchasers like the fund were denied low-cost drugs. The fund is seeking to represent at least 10,000 class members comprising those who bought or were reimbursed for purchasing Prograf since Sept. 21, 2007 — the date Astellas filed its citizen petition to the FDA.

A representative for Astellas could not be reached for comment.

The fund is represented by Thomas M. Greene, Michael Tabb and Ilyas J. Rona of Greene LLP, James R. Dugan II, Douglas R. Plymale, David Franco and Kevin Oufnac of the Dugan Law Firm, Don Barrett, Brian Herrington and Charles Barrett of Barrett Law Group PA, and Shane Youtz of Youtz & Valdez PC.

Counsel information for Astellas was not immediately available.

The case is New Mexico United Food and Commercial Workers Union's and Employers' Health and Welfare Trust Fund v. Astellas Pharma US Inc., case number 1:11-cv-11621, in U.S. District Court for the District of Massachusetts.

--Editing by Kat Laskowski.

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