

J&J Unit Secures Duty-Free Treatment For HIV Drug

By Alex Lawson

Law360 (February 6, 2020, 7:06 PM EST) -- The U.S. Court of International Trade ruled Thursday that the HIV drug Prezista should enter the U.S. duty-free, handing victory to a Johnson & Johnson subsidiary that claims to have paid \$100 million in duties to import the medicine.

Janssen Ortho LLC, which brings Prezista into the U.S. from Ireland and Switzerland, convinced CIT Judge Jennifer Choe-Groves that the drug fits within the criteria of the pharmaceutical annex to the U.S. tariff code that allows roughly 7,000 drugs and components to enter the U.S. without duty payment.

U.S. Customs and Border Protection has classified imports of Prezista's active ingredient, darunavir ethanolate, as a type of drug compound known as sulfonamides, but declined to grant it duty-free treatment because the pharmaceutical annex lists only "darunavir" as being eligible and does not list the "ethanolate" suffix.

Judge Choe-Groves ruled that the two names are essentially interchangeable, citing testimony from U.S. Food and Drug Administration chemist Rao Kambhampati at trial and similar positions held by the World Health Organization and the National Institutes of Health.

The case stretches back to 2013, when Janssen filed suit trying to change CBP's classification of the drug from a sulfonamide to another part of the tariff code that covers "medicaments ... consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses."

Judge Choe-Groves rejected the alternative classification, but accepted Janssen's secondary argument that if the drug is indeed correctly classified, it should fall under the purview of the pharmaceutical annex and enter the U.S. duty free.

"The court concludes that darunavir ethanolate is a name by which darunavir is known, and is within the terms of Table 1 of the Pharmaceutical Appendix," she wrote."

The dispute over the drug's proper classification was settled with a CIT bench trial, and Judge Choe-Groves will now conduct a second trial to examine Janssen's claim that its due process rights were violated because CBP "lacked the neutrality and detachment required ... by virtue of their actual or institutional interest in the outcome of the proceeding."

Attorneys for Janssen and the government did not immediately respond to requests for comment Thursday.

Janssen is represented by Gregory L. Diskant, Amy N. Vegari, Andrew D. Cohen, Daniel M. Eisenberg, Emma EllmanGolan and Joshua A. Kipnees of Patterson Belknap Webb & Tyler LLP.

The government is represented by attorneys Monica P. Triana of the U.S. Department of Justice's International Trade Field Branch, by Guy R. Eddon and Jason M. Kenner of the DOJ's Commercial Litigation Branch and by Alexandra Khrebtukova of U.S. Customs and Border Protection.

The case is Janssen Ortho LLC v. United States, case number 13-cv-00296, in the U.S. Court of International Trade.

--Editing by John Campbell.