Lowenstein Sandler

Client Alert

Global Trade & Policy

February 21, 2020

Finally, Case Law to Support Substantial Transformation Test Resulting in U.S. Country of Origin for API

By Doreen M. Edelman and Tamar Satterwhite

What You Need To Know:

- **A pharmaceutical product with API from multiple countries may now qualify as a U.S.-made end product for government procurement purposes.**
- **Pharmaceutical companies that import products with foreign API can participate in the U.S. government procurement bid process and ultimately win a contract with the U.S. government.**
- **There is potential for similar interpretation of country of origin rules for non-government procurement products with multiple API sources.**

On Monday, February 10, the U.S. Court of Appeals for the Federal Circuit in *Acetris Health, LLC v. United States*, held that a pharmaceutical product with an active pharmaceutical ingredient (API) made outside of the United States (in this case in India) could be considered as U.S.-made for government procurement purposes under the Federal Acquisition Regulation (FAR). Certain U.S. laws, including the FAR, prohibit government agencies from purchasing products from certain foreign countries and allow U.S.-made products to compete for government procurement.

The new circuit court ruling clarifies that the source of a product's API does not determine its country of origin; instead, the court held that a product could be either "manufactured" in the United States or "substantially transformed" in the United States to qualify as a U.S.-made end product for government procurement purposes. "The ruling has major commercial significance for the pharmaceutical industry and, in fact, for industry generally," stated Steven S. Rogers, Lowenstein Partner and former General Counsel of Aceto Corporation, of which Acetris is a wholly owned subsidiary. He led the legal team in a bid protest action before the U.S. Court of Federal Claims which challenged the interpretation by the Department of Veterans Affairs (VA) of the Trade Agreements Act of 1979 and the FAR that they barred the VA from purchasing "products of" certain foreign countries. The ruling allows more companies that import pharmaceuticals with API made outside of the United States to bid on U.S. government contracts. Participation in the government procurement bid process increases pharmaceutical companies' competitive opportunities to secure a potentially long-term and lucrative contract with the U.S. government.

In determining country of origin for products that incorporate materials or processing from multiple countries and that are not for government procurement purposes, U.S. Customs and Border Protection considers where the product's "substantial transformation" occurred but not where it was also wholly "manufactured." Lowenstein Sandler has successfully used the analysis in the new circuit court ruling, where either the product's place of "manufacturing" or its "substantial transformation" could be used to determine its country of origin, to advocate for companies with European and Asian API by persuading the U.S. government to accept such pharmaceutical products as U.S.-made products.

Contacts

Please contact the listed attorneys for further information on the matters discussed herein.

DOREEN M. EDELMAN
Partner
Chair, Global Trade & Policy
T: 202.753.3808
dedelman@lowenstein.com

MICHAEL J. LERNER
Partner
Chair, Life Sciences
T: 973.597.6394
mlerner@lowenstein.com