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Medical Device Manufacturer Settles Trade Agreements Act Suit

A whistleblower alleged that the manufacturer knowingly violated the Trade Agreements Act's country of origin requirement.

Government contractors must agree that the products they sell to the U.S. government under contracts valued in excess of $204,000 comply with the Trade Agreements Act (TAA), 19 U.S.C. §§ 2501, et seq., unless the TAA requirement is waived. This requirement has provided grounds for whistleblower actions under the False Claims Act, particularly against companies that sell commercial items under Federal Supply Schedule (FSS) contracts, which require compliance with the TAA. Recently, medical device manufacturer Smith & Nephew, Inc. settled what may be the first such case involving allegations that a company knowingly sold medical devices manufactured in a country not compliant with the TAA to the company's government customers.[1]

Background

The TAA is intended to remove barriers to government procurement of foreign-sourced items and to incentivize countries to become signatories to the World Trade Organization Government Procurement Agreement (WTO GPA) and other international trade agreements. When applicable, the TAA prohibits the U.S. government from acquiring end items, including medical devices and supplies, other than those made in the United States or countries that have signed the WTO GPA (referred to as "designated country end products"), unless the agency determines that offers of eligible items are unavailable or insufficient to fill the agency's needs.[2]

The test for determining country of origin under the TAA is the "substantial transformation" test applied by U.S. Customs and Border Protection when assessing import duties. Determining where a product has been substantially transformed into the end item acquired by the government often requires a fact-intensive analysis. However, as recently affirmed by the U.S. Court of Appeals for the D.C. Circuit, resellers may reasonably rely on their suppliers' country of origin representations and, in such situations, need not conduct independent evaluations before they provide their own certifications.[3] This is an important decision for wholesalers and distributors that contract directly with agencies like the Department of Defense (DoD) and the Department of Veterans Affairs (VA) to supply medical devices that they purchase from the device manufacturers.

The TAA is implemented through mandatory contract clauses in government contracts over the threshold amount and country of origin representations and certifications made by companies responding to a federal contract solicitation as prescribed by the Federal Acquisition Regulation (FAR) Part 25.4 and FAR 52.225-3 through 52.225-6. A product's country of origin must be disclosed when it is manufactured in a nondesignated country, such as India or China. The contracting agency, in its discretion, may make a nonavailability determination or may request a categorical waiver of the TAA from the Office of the U.S. Trade Representative.

1. *United States ex rel. Cox v. Smith & Nephew, Inc.*, No. 2:08-cv-02832 (W.D. Tenn., order of dismissal, Sept. 4, 2014).

2. Part 25 of the Federal Acquisition Regulation sets forth the list of countries that qualify as designated countries. Products may also be eligible for government purchase under other free-trade agreements, such as the Caribbean Basin Initiative. 48 C.F.R. 25.403(c).

3. *United States ex rel. Folliard v. Gov't Acquisitions, Inc.*, No. 13-7049 (D.C. Cir. Aug. 29, 2014).

Once a company represents that an item is a U.S. or designated country end product and it is placed on the company's FSS contract, the company must ensure that units manufactured in nondesignated countries are not delivered to government customers ordering under the FSS. If a manufacturer of medical supplies sources a product in a nondesignated country for sale to commercial customers, it must have a second U.S. or designated country source before it sells the product to the federal government under its FSS contracts and must have inventory controls designed to ensure that shipments to government customers conform to the representations and certification of TAA compliance.[4]

Smith & Nephew

In the *Smith & Nephew* case, the company allegedly repackaged items imported from Malaysia, a nondesignated country, and failed to segregate them from products sourced in designated countries that could be sold to the government. Thus, the company could not ascertain whether units shipped to customers that ordered under its medical/surgical FSS contract or the GSA Advantage website were TAA compliant. Although the company voluntarily disclosed to the DoD Office of Inspector General and the VA National Acquisition Center that it may have violated procurement law and the terms of its contracts, the court did not bar a former employee from subsequently filing a whistleblower action against the company for knowingly violating the TAA. This case highlights the vulnerability of device manufacturers that source products from nondesignated countries to potential False Claims Act liability and the need not only for diligence in ascertaining country of origin, but also for controls to prevent products manufactured in nondesignated countries from being supplied to the government when such sales are not permitted.

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4. *See* Dear Manufacturer Letter (Sept. 25, 2012), *available at* http://www.va.gov/oal/business/fss/publicLaw.asp#three.