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Acetris Wins Buy American Dispute With VA, but Not Drug Contract

Pharmaceutical distributor Acetris Health LLC successfully showed that the Department of Veterans Affairs' flawed interpretation of a Buy American rule hurt the company's ability to win a medication contract initially valued at $21 million, the U.S. Court of Federal Claims ruled.

As a result, the VA is now enjoined from relying on its improper Trade Agreements clause interpretation in future procurements, and from relying on Customs and Border Protection determinations for deciding whether a contractor is offering a product manufactured in the U.S. or a foreign country, Judge Margaret M. Sweeney said.

The VA, however, doesn't have to issue a new contract solicitation or reconsider Acetris's bid to provide Entecavir tablets, which treats chronic hepatitis B, because Acetris failed to offer the lowest price, the court said.

The Trade Agreements clause in the Federal Acquisition Regulation implements rules in the Buy American Act and Trade Agreements Act when incorporated into contract solicitations, as the VA did here.

Under the Buy American Act, federal agencies may purchase only articles produced in the U.S. The Trade Agreements Act provides exceptions to the Buy American Act by allowing the president to identify designated countries that can provide goods sold to agencies.

Golden State Medical Supply Inc. won the contract with a $6.5 million offer after the VA rejected Acetris's Entecavir tablets for having an ingredient from India.

More Eligible Products The court's ruling ''is very significant for this plaintiff and other contractors because the court has expanded compliance eligibility under the Trade Agreements clause, which means more products will likely by eligible for offering to the government,'' said Kristi Morgan Aronica of Weitz Morgan PLLC, Austin, Texas.

It is also significant because, rather than relying on Customs and Border Protection, ''the court concluded that procuring agencies and officials must 'independently ascertain' whether an offered product is manufactured in the U.S.,'' said Jon Williams of PilieroMazza PLLC, Washington.

''The injunctions apply only to future VA procurements, so it will be interesting to see whether other federal agencies change their approach to CBP's determinations about foreign made products,'' he told Bloomberg Government.

Customs and Border Protection is ''better-positioned'' than other agencies to perform this analysis, he added.

Future Contracts The VA improperly excluded ''domestic end products'' from the Trade Agreements clause's definition of eligible U.S-made end products in its medication solicitation, an error that was prejudicial to Acetris's ability to compete, the court said.

An item is a domestic end product if the cost of components produced or manufactured in the U.S. exceeds 50 percent of the cost of all components, the court said.

To side with the VA's clause interpretation ''would be to prevent the federal government from procuring a class of products–domestic end products–that it has always had the ability to purchase when the Trade Agreements Act applied to the procurement,'' the court said.

Without the injunctive relief granted, Acetris's ability to compete for other national VA contracts in the future would be severely diminished, the court said.

Before this ruling, Acetris's medication would likely have been ineligible for failing to comply with the Trade Agreements clause, but the court has enabled Acetris, and others who will rely on this precedent, to sell products that are neither ''wholly'' manufactured in the U.S., nor would have been considered substantially transformed in the U.S., which was the previous test for Trade Agreements Act compliance, Aronica said.

The court ''has expanded the ability of products to be eligible for sale under the Trade Agreements clause,'' and has given contractors more flexibility for compliance, she said.

Potential for Inefficiency Customs and Border Protection determined that the country of origin for Acetris's medication was India before the Acetris's protest filing in this case.

The VA acted improperly by relying on this determination instead of doing its own independent assessment as to whether Acetris's medication qualified as a U.S.-made end product, the court stated.

''It will also be interesting to see if VA appeals or if there is any Congressional or regulatory response to amend the applicable statutes and rules,'' Williams said.

''This ruling could create inefficiency in requiring federal agencies to do their own analysis to determine if a product is ''U.S.-made'' and potentially contradict a similar analysis done by CBP, which is better-positioned to do that analysis,'' he added.

Morgan, Lewis & Bockus LLP represented Acetris Health LLC.

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The case is *Acetris Health LLC v. United States*, Fed. Cl., No. 18-433C, 7/16/18.

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