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NC Small Biz Challenges VA Bid Process For Prostate Drug

By Hayley Fowler

Law360 (August 15, 2024, 5:03 PM EDT) -- A service-disabled veteran-owned small business in North Carolina is challenging the U.S. Department of Veterans Affairs' bid process for prostate medication, saying the terms unfairly favor foreign manufacturers despite purporting to prioritize American-made products.

The DaVinci Co. LLC, based in Greensboro, North Carolina, accused the VA in a **complaint filed Tuesday** of tainting the procurement process for the drug Tamsulosin by using a workaround in the Buy American Act that allows the government to invoke a nonavailability waiver if there are no American manufacturers of a product. In doing so, The DaVinci Co. said, the VA effectively turned the deal into an "open-source procurement" process and all but guaranteed a manufacturer in China or India will be selected.

"It is a case where the VA has deliberately forced the BAA into a procurement knowing that it would not receive any quotes for a domestic product and that it would then seek a nonavailability waiver — not out of necessity, but by design," the company said.

The DaVinci Co. argued the VA's back-door approach "is at war with both the language and purposes of the BAA and will only benefit a 'foreign manufacturer' in either China or India."

The Greensboro company acts as a middleman sourcing suppliers for government contracts with a focus on medical device, pharmaceutical and defense manufacturers, according to its website. The DaVinci Co. was consequently interested in bidding on the VA's solicitation for Tamsulosin, which is a prescription drug used to treat enlarged prostates.

The DaVinci Co. said the deal was intended as an "SDVOSB set aside," meaning companies such as itself — service-disabled veteran-owned small business — should have had priority.

On its face, the solicitation did invoke the BAA, which the complaint alleges was "meant to put American products on better competitive footing with products from countries with less expensive labor and less protective manufacturing and environmental standards."

But the VA allegedly knew there were no American manufacturers of Tamsulosin, allowing it to instead invoke a BAA nonavailability waiver, according to The DaVinci Co., which characterized the government's strategy as "irrational, arbitrary, and capricious."

The company said the VA's actions were particularly egregious given that it could have designed the deal to allow for Trade Agreements Act-compliant products from countries such as Germany, Spain, Slovenia and Canada.

"Indeed, under such a TAA approach, a U.S.-based SDVOSB reseller of Tamsulosin will still derive some benefit from the set aside decision, and the VA will still obtain an adequate source of supply at a fair and reasonable price," The DaVinci Co. said.

The company also accused the VA of lying when it submitted a waiver request to the Made In America Office. According to The DaVinci Co., the VA certified there were no eligible "U.S.-made or designated country end products."

In reality, the company said, the VA's market research team had found at least eight TAA-compliant sources, including one provided by The DaVinci Co. in its bid.

"Individually and together, the VA's inaccurate representations to the MIAO defeat the purpose of the review process ... and reveal, even prior to award, that the VA has not followed the published terms of the solicitation," the company said.

It alleged it has been prejudiced by the process because it "supplies designated country end products that would have a substantial chance of being selected" if it weren't for the VA's allegedly underhanded solicitation tactics.

The company is consequently seeking declaratory judgment and a permanent injunction preventing the VA from awarding the contract under the current terms.

In a statement to Law360, The DaVinci Co. said it is "committed to selling only quality pharmaceuticals to the Veterans Administration and always strives to offer to the VA products made in the US."

"Unfortunately, the VA has constructed a procurement that puts products manufactured in TAAdesignated countries at a significant competitive disadvantage to products made in countries that have not been designated as trusted trading partners, a situation that is in conflict with longestablished US trade policy," the company said.

It said the VA's efforts to use the BAA, despite knowing there are no domestic sources of Tamsulosin, is "contrary to both the text and purpose of the governing statutes and regulations, and so (after trying to resolve the issue with the VA at the agency level), the company has brought this lawsuit to protect not only its own interests, but the interests of our veterans who will use the product and all small businesses who want to sell to the VA products made in the United States or in trusted TAA-designated countries."

Spokespeople for the VA and the U.S. Department of Justice declined to comment Thursday.

The DaVinci Co. is represented by Jason N. Workmaster, Alejandro L. Sarria, Scott N. Flesch, Ashley Powers, Alexandra S. Prime and Connor W. Farrell of Miller & Chevalier Chtd.

Counsel information for the defendant was not available Thursday.

The case is The Davinci Co. LLC v. USA, case number 1:24-cv-01238, in the U.S. Court of Federal Claims.

--Editing by Lakshna Mehta.

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