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CLIENT ALERT

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On July 16, 2018, the Court of Federal Claims released a far-reaching decision in *Acetris Health, LLC v. United States*, concluding that a drug could qualify as a "U.S.-made end product" under the Trade Agreements clause, FAR 52.225-5, despite a Customs and Border Protection (CBP) ruling under the Trade Agreements Act (TAA), that the drug had not been "substantially transformed" in the United States, the usual test for whether a product from a designated country is eligible for sale to the United States under the TAA. The court concluded that a drug which met the definition of a "domestic end product" would also qualify as a "U.S.-made end product" and enjoined the Department of Veterans Affairs from relying on the CPB ruling in declaring the product ineligible. In doing so, the court has given effect to often overlooked language in the FAR 25.003 definition of "U.S.-made end product" that allows *either* an item manufactured in the United States *or* an item substantially transformed in the United States to be eligible for sale to the federal government. The decision opens the door for manufactured COTS items to be eligible under the TAA as long as final assembly occurs in the United States, without regard to the source of a COTS product's components. It might even have broader implications because the FAR has never included an express definition of "manufacture," and the definition of "U.S. made end product" does not expressly reference the definition of "domestic end product," under which, in the Buy American context, "manufacture" is just one of two elements for determining eligibility.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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