THE GOVERNMENT CONTRACTOR®

THOMSON REUTERS

Information and Analysis on Legal Aspects of Procurement

Vol. 62, No. 9 **March 4, 2020**

Focus

¶ 55

FEATURE COMMENT: Where Is It From? Domestic Preference Law In Flux After *Acetris* Federal Circuit Decision

The U.S. Court of Appeals for the Federal Circuit struck down an element of the Government's long-standing definition of what qualifies as U.S.-made for purposes of procurement law. In *Acetris Health LLC v. U.S.*, 949 F.3d 719 (Fed. Cir. 2020); 62 GC ¶ 46, a three-judge panel found the Department of Veterans Affairs' definition of U.S.-made to be "untenable" and instead found that pharmaceuticals with an active ingredient from India that are manufactured into final form in the U.S. qualify as U.S.-made for purposes of procurement law. The decision, if not successfully challenged, will have broad-ranging impacts not only in the pharmaceutical industry but for many Government contractors with international supply chains. It also raises important questions about how federal agencies will implement the Court's guidance.

Background—As Government contractors are well aware, two different statutes incentivize Federal Government procurement of U.S.-origin products: the Buy American Act (BAA) and the Trade Agreements Act (TAA). In short, the BAA creates a price-evaluation preference in the evaluation process for "domestic end products" defined as an article manufactured in the U.S., for which (assuming the article is not a commercial off the shelf or COTS item) the cost of the U.S. domestic components exceeds 50 percent of the cost of all the components. For commercial off the shelf or COTS items, the U.S. manufactured article does not have to meet a domestic component content requirement. See 41 USCA § 8302; 41 USCA § 1907.

The TAA implements the U.S.' obligations under the World Trade Organization (WTO) Government Procurement Agreement (GPA). The TAA operates by waiving the BAA price evaluation preference in procurements above a particular price threshold (currently $182,000, 84 Fed. Reg. 70615 (Dec. 23, 2019)) for items from "designated countries," thus requiring Federal Government procuring agencies to treat items from designated countries the same as items from the U.S. Reports emerged recently indicating that the White House is considering withdrawing from the GPA. See, e.g., Bloomberg, "Trump Considers Withdrawing from WTO's $1.7 Trillion Purchasing Pact" (Feb. 4, 2020); Feature Comment, Anderson and Yukins, "Withdrawing The U.S. From The WTO GPA: Assessing Potential Damage To The U.S. And Its Contracting Community," 62 GC ¶ 35.

Importantly, the TAA also prohibits the procurement of products "which are products of a foreign country," meaning products of non-designated countries. Countries are "designated" if they are parties to the GPA or another free trade agreement with the U.S., or are otherwise designated by the president. In practical terms, most European countries, as well as a number of the U.S.' other significant trading partners are "designated countries"; notable non-designated countries include China, Russia, Thailand, Malaysia, Brazil, the Philippines and India.

The TAA uses a different definition than the BAA to determine the origin of non-U.S. products:

(1) It is "wholly the growth, product, or manufacture of that country," or

(2) It "has been substantially transformed [in that country] into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed."

19 USCA § 2518(4)(B).

Notably, while a COTS article may just be "manufactured in the U.S." to qualify as a "domestic end product" under the BAA, under the TAA, that same article must be "wholly the growth, product,

or manufacture" of a designated country to qualify as a "product of a [designated] country" under the TAA (or else be substantially transformed in a designated country).

The Federal Acquisition Regulation implements the requirements of the BAA and TAA for purposes of U.S. Government procurements. Importantly, the FAR's TAA clause states that contractors shall deliver "only U.S.-made or designated country end products," FAR 52.225-5, defining U.S. product origin as follows:

(1) an article that is mined, produced, or manufactured in the United States; or
(2) that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

See FAR 25.003.

The FAR goes on to define designated country end product origin differently:

(1) an article that is wholly the growth, product, or manufacture of the designated country; or
(2) in the case of an article that consists in whole or in part of materials from another country, has been substantially transformed in the designated country into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

See FAR 25.003.

The contracting officer is the official decision-maker on the country of origin for a particular procurement. But these CO determinations are unreported, and companies bidding on a particular procurement have no practical way to access the determinations made in previous procurements. Filling that gap, U.S. Customs and Border Protection (CBP) has generally been the source of "precedent" and guiding opinions on country of origin determinations, which are published in the *Federal Register*. 19 USCA § 2518(4)(B). Relevant here, CBP has generally held that, if a drug's active pharmaceutical ingredient (API) originates from a non-designated country (e.g., India or China), a company generally cannot "substantially transform" the API by combining it with other non-active pharmaceutical ingredients and packaging it into another form in another country. See. e.g., Customs Ruling HQ H289712 (Jan. 30, 2018) (underlying CBP determination regarding Entecavir, the drug at issue in *Acetris*). There are some exceptions to this general rule. For example, in Customs Ruling HQ 563301 (Aug. 26, 2005), CBP found that frozen bulk parathormone imported into Germany from third countries was substantially transformed in Germany in light of "extensive processing" that transformed "the raw parathormone from an unstable, non-sterile, frozen material unsuitable for human use into a pharmaceutical agent ready for human use." In addition, for drugs with multiple APIs, CBP has found that the process of combining multiple APIs into a combination product may constitute substantial transformation. See, e.g., Customs Ruling HQ 563207 (June 1, 2005).

According to CBP, to which the VA and other agencies have long deferred, except in rare cases, a drug that is processed from bulk API into finished dosage form in the U.S. with non-designated country API is merely "assembled" in the U.S., and does not qualify as "substantially transformed" in the U.S., so as to qualify as U.S.-made. Moreover, CBP interprets the phrase "manufactured in the United States" for purposes of the FAR's definition of "U.S.-made end product" to "correlate[]" to the TAA language requiring the products be "wholly manufactured" in a country. See, e.g., Customs Ruling HQ H289712 (Jan. 30, 2018). For the first time, the Federal Circuit considered this position in *Acetris*.

Acetris—Acetris is a generic pharmaceutical distributor that obtains many of its products from a facility located in New Jersey that uses API made in India. In connection with 13 contracts that Acetris held with the VA, the VA directed Acetris to obtain a CBP country of origin determination. CBP, in accordance with the line of cases mentioned above, held that because the API was from India, the country of origin of Acetris' products was India, because no substantial transformation occurred in the U.S. Notice of Issuance of Final Determinations Concerning Certain Pharmaceutical Products, 83 Fed. Reg. 5130–33 (Feb. 5, 2018). CBP rejected Acetris' argument that it was unnecessary to rely on the "substantial transformation" prong because the products were "manufactured in the United States," finding that this language in the FAR "correlates" to the TAA language requiring the products be "wholly manufactured" in a country. Opinion at 10. CBP concluded: "Since the production of [Acetris' product] partially occurs in India, we do not find that they are manufactured in the United States." Id. The VA

indicated it would rely on this CBP determination to find Acetris' products not TAA compliant in future procurements.

Acetris filed a pre-award protest in the Court of Federal Claims challenging the VA's exclusion of its products. Acetris repeated its assertion that its products are "U.S.-made end products" because they are manufactured into pills in the U.S. (using the foreign-made API), invoking the FAR's definition of "domestic end product," which does not require the item to be "wholly" manufactured in the U.S. The COFC agreed with Acetris' interpretation, finding "there was no requirement that the end product be 'wholly' manufactured in the United States" in order to be TAA compliant, and that as Acetris' products were "manufactured" in New Jersey, they satisfied the solicitation's requirements. *Acetris Health, LLC v. U.S.*, 138 Fed. Cl. 579 (2018).

The Federal Circuit—The Government appealed the COFC decision. In a three-judge panel opinion authored by Judge Dyk, the Federal Circuit affirmed the COFC's decision but remanded the case to clarify the remedy.

First, the Federal Circuit panel declared the "product" being procured was not the API, or the "ingredients of the pill," but rather was "the pill itself." *Acetris* at 731.

Second, the panel reasoned that the TAA does not exclude Acetris' products as the product of India, a non-designated country, under either prong of its country of origin test: (1) the products are not "wholly" manufactured in India, and (2) they are not substantially transformed in India "because the tablets' components are not 'substantially transformed' into tablets in India." Id. Accordingly, the TAA does not exclude Acetris' products as being the product of a non-designated country.

Third, the panel found that the FAR does not exclude Acetris' products either. The manufacturing prong of the FAR's country of origin test for U.S. operations lacks the "wholly" qualifier included for "designated countries" in the TAA clause. Thus, the panel reasoned that Acetris' products are manufactured into pills in the U.S., even if they are not "wholly" so manufactured. They accordingly qualify as a U.S. end product under the FAR. The panel concluded: "If the government is dissatisfied with how the FAR defines 'U.S.-made end product,' it must change the definition, not argue for an untenable construction of the existing definition." Id. at 732–733.

Because the panel found the COFC's order "imprecise and confusing," the panel remanded the case to the COFC, which it instructed to declare that:

> (1) under the TAA, a pharmaceutical product using API made in India does not, because of that fact, thereby become the "product of" India; and
>
> (2) under the FAR, the term "U.S.-made end product" may include products manufactured in the United States using API made in another country.

Id. at 733.

Implications—*Acetris* represents a potential sea change in the Government's application of the BAA/TAA provisions. Previously, the VA and other federal agencies deferred to CBP's country of origin determinations, which essentially meant where CBP had determined that drugs containing API from a non-designated country had a foreign country of origin, those drugs were then ineligible for federal procurements requiring a FAR TAA certification. In certain circumstances, the CO may make a "non-availability determination" and award procurements to non-TAA compliant offerors. See FAR 25.103(b)(2). With respect to Federal Supply Schedule 65 I B contracts for pharmaceutical products, the VA has made a blanket non-availability determination for all Special Item Number 42-2A covered drugs, and such drugs must be included on a manufacturer's FSS contract regardless of country of origin. See TAA—Non-Availability Determinations under 65 I B, *www.va.gov/opal/nac/fss/taa.asp* (last updated March 15, 2019). A Federal Circuit decision has now confirmed that such drugs satisfy domestic-preference compliance requirements so long as they are not deemed to be products of a non-designated country and are manufactured in the U.S. This holding could have substantial ramifications for companies with supply chains in non-designated countries such as India and China.

This decision leaves open several related questions:

First, the decision's reasoning only directly applies when the final products are manufactured in the U.S. The panel's holding rests on the FAR's definition of "U.S.-made end product," which expressly qualifies acceptability on the product being "manufactured in the U.S." What about products that are manufactured in designated countries using API from non-designated countries? Products manufactured in designated countries from non-designated country API would not seem to qualify under the decision's reasoning, since

they do not meet the requirement spelled out in both the TAA and the FAR that they be "wholly manufactured" in the designated country. However, such a result would fundamentally contradict the purpose of the GPA, which is to afford equal treatment to domestic and designated country products.

Second, the Federal Circuit declined to reach the second prong of the FAR test addressing "substantial transformation," as it found that the products in question met the first prong of being "manufactured" (although not wholly so) in the U.S. "Mere assembly" has not typically been considered to qualify as "substantial transformation" under the standards applied by CBP, yet some may argue that is what happened to the products in question here. (However, the panel stated in passing that the pills "may very well be substantially transformed in the United States".) If substantial transformation of a pharmaceutical product does not rest on the origin of the API, on what does it rest? What treatment will be afforded to products manufactured in non-designated countries from designated-country API? How will courts and agencies respond to arguments that non-pharmaceutical products containing foreign components are "substantially transformed" in the U.S., given this ruling?

Third, the decision shifts back to procuring agencies to determine country of origin for their procurements. While CBP still has jurisdiction to issue advisory opinions relating to the TAA, and of course still determines country of origin for customs and import purposes, the decision rejected the notion that CBP has authority relating to the FAR definitions as applied in procurements. The *Acetris* decision instead made it clear that COs have first authority to make country of origin decisions in pending procurements. Will agencies continue to defer to CBP (with more substantial justifications for doing so), or will CBP lose its expert status in this arena? Under this new regime, how valid or persuasive will previous CBP rulings be?

Fourth, it is worth underlining that the saga of *Acetris* is not over yet. While the Federal Circuit decision was fairly clear regarding what it expects in the COFC's remand decision, it's not over until it's over. The Government may request a rehearing en banc or Supreme Court review, and Congress or the administration may weigh in. How will congressional concerns regarding Chinese supply chain issues impact this issue? What impact will this decision have on the Trump administration's announcement that the U.S. may move to withdraw from the WTO GPA? Trump Considers Withdrawing From WTO's $1.7 Trillion Purchasing Pact (Feb. 4, 2020), Bloomberg.

Companies would be wise to watch this space carefully.

✦

This Feature Comment was written for THE GOVERNMENT CONTRACTOR by Arnold & Porter partner* Kristen Ittig *and associate* Amanda Sherwood.** ***Kristen and Amanda focus their practices on representing clients in Government contracts matters and are resident in the firm's Washington, D.C. office.