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What does it mean to manufacture? Federal circuit's Acetris decision fundamentally alters trade agreements act compliance

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MAY 4, 2020

On February 10, 2020, the U.S. Court of Appeals for the Federal Circuit issued its long-awaited decision in *Acetris Health LLC v. United States, No. 2018-2399 (Feb. 10, 2020)*.[1]

In *Acetris*, the Federal Circuit was asked to interpret the country of origin requirements under the Trade Agreements Act of 1979 ("TAA") and related regulations. For contractors with manufacturing facilities in the United States, the Federal Circuit did not disappoint.

While the decision in *Acetris* is most immediately critical to the pharmaceutical industry (as discussed here[2] and here[3]), the Federal Circuit's decision has widespread consequences for all government contractors required to demonstrate TAA compliance.

THE *ACETRIS* CASE, IN BRIEF

Acetris Health, LLC ("Acetris") is a distributor of generic pharmaceuticals.

In April 2017, the U.S. Department of Veteran Affairs ("VA") requested Acetris prove its products comply with the TAA by obtaining a country of origin determination from U.S. Customs and Border Protection ("CBP"), which commonly makes authoritative country of origin determinations.

At the time, Acetris supplied the VA with 10 pharmaceutical pills sourced from a manufacturer in Ohio, which manufactured the pills using an active pharmaceutical ingredient from India.

In February 2018, the CBP determined these pills were products of India, and therefore not compliant with the TAA, because the active ingredients were products of India, and the manufacturing process in the U.S. did not constitute a "substantial transformation" of the active ingredient — merely a packaging of the pills. *See* 83 Fed. Reg. 5130-33 (Feb. 5, 2018).

In March 2018, the VA issued a new solicitation, for which Acetris sought award. Acetris submitted a proposal, but Acetris also sued, alleging the VA misinterpreted the requirements of the TAA under the terms of the solicitation.

A NEW STANDARD FOR DEMONSTRATING TAA COMPLIANCE?

As a matter of law and federal policy, the U.S. Government prefers to buy U.S.-origin products, but that preference is often subject to numerous international trade agreements.

The TAA offers an exception to certain "Buy American" requirements, allowing the Government to purchase "foreign end products" only if those products are from certain designated countries with which the U.S. has a free trade agreement. 19 U.S.C. §§ 2501-2582.

> This decision is a victory for contractors with manufacturing facilities in the U.S., and particularly for pharmaceutical companies selling to the U.S. Government who perform compounding work in the U.S.

The TAA incorporates a country-of-origin test, defining "a product of a country" as:

An article is a product of a country or instrumentality only if (i) it is *wholly the growth, product, or manufacture of that country* or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it *has been substantially transformed 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 U.S.C. §2518(4)(B) (emphasis added).

The Federal Acquisition Regulation ("FAR") implements this statutory definition for foreign-made products; but with regard to U.S.-made end products, the FAR definition is slightly different. Specifically, FAR 52.225-5(b) defines a "U.S.-made end product" as:

an article that is mined, produced, or manufactured in the United States or 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.

FAR 52.225-5(a). Do you see the difference? Did you see the missing word? The FAR 52.225-5(b) definition of "U.S.-made end product" omits the term "wholly" — meaning that, in order to satisfy the TAA, a U.S.-made end product can be *partially* — not "wholly" — manufactured in the U.S.

For years, contractors argued this omission created a third avenue to demonstrate TAA compliance — "manufactured," but not wholly manufactured, in the United States. And, to be clear (and as discussed in greater detail below), "manufactured" is the standard that has been applied to the Buy American Act ("BAA"), 41 U.S.C. §§ 8301-8305, since 1933.

Despite this regulatory distinction — *wholly* manufactured for foreign-made end products vs. *not wholly* manufactured for U.S.-made end products — the Government argued that the lesser "manufactured" standard listed in FAR 52.225-5(b) was more akin to "substantial transformation" under the TAA, and therefore the regulations did not create a unique, *lesser* standard for TAA compliance.

The U.S. Court of Federal Claims rejected this argument. And now the Federal Circuit has too.

The Federal Circuit decision sides with contractors, confirming there are three ways for contractors to demonstrate TAA compliance under the FAR, i.e. demonstrating the end product being delivered to the Government is:

(1) substantially transformed in the U.S. or a designated country;

(2) wholly manufactured in a designated, free trade agreement country; or

(3) mined, produced, or manufactured in the U.S. (but not necessarily *wholly* manufactured). Given this formulation, unless and until the FAR is revised to more closely align with the statutory language of the TAA, contractors who manufacture products in the U.S. may have an easier path to compliance.[4]

WHAT DOES IT MEAN TO 'MANUFACTURE' IN THE UNITED STATES?

While the Federal Circuit seems to confirm this third avenue to TAA compliance, the Federal Circuit's decision fails to include any clear guidance on how to determine under the TAA whether a product is "manufactured" in the U.S.

The original decision of the lower court suggested borrowing the "manufacturing" definition from the BAA. Under the BAA, a product is deemed to be "manufactured" in the U.S. if the "cost of its components . . . manufactured in the United States exceeds 50 percent of the cost of all its components." FAR 52.225-1.

The Federal Circuit, however, declined to adopt the BAA standard, stating a product can be TAA compliant if manufactured in the U.S. from foreign-made components, not necessarily needing to meet the 50 percent component requirement of the BAA.

Therefore, not only does the *Acetris* decision confirm this third category, it appears to establish a comparatively low threshold for contractors to certify TAA compliance for products manufactured in the U.S. But it also seems to indicate that "manufactured" under the TAA may not necessarily mean the same thing as "manufactured" under the BAA; in this respect, there is confusion about what, specifically, is required to "manufacture" a product in the U.S. under the TAA moving forward.

Still, this revised framework did, in fact, make it easier for Acetris to prove TAA compliance with its pharmaceuticals.

The Federal Circuit rejected the Government's argument that Acetris' end products were products of India because the active ingredient originated in India, reasoning that the pills were not "wholly manufactured" in India, and therefore could not possibly be considered "products of India."

The Federal Circuit further explained that, because the foreign-sourced ingredients were measured, weighted, mixed, and compounded in the U.S. , the final end products (*i.e.*, the pills) were manufactured in the U.S. — thereby satisfying the definition of FAR 52.225-5.

In so holding, the Federal Circuit explicitly rejected the Government's argument that manufacturing a "U.S.-made end product" requires that end product be "substantially transformed" in the U.S. in order to be TAA compliant.

In sum, this decision is a victory for contractors with manufacturing facilities in the U.S., and particularly for pharmaceutical companies selling to the U.S. Government who perform compounding work in the U.S. Under the current FAR 52.225-5 definition of a "U.S.-made end product," products will be deemed to be TAA compliant if manufactured in the U.S., regardless of where the individual components or ingredients originated, regardless of whether the products are "wholly manufactured" in the U.S., and regardless of whether the products are "substantially transformed" in the U.S. But, as already noted above, the lingering question, is just how much "manufacturing" contractors must do in the U.S. ... That's the $64,000 question here, it would seem.

WHAT IS THE ROLE OF THE CBP GOING FORWARD?

For years, Contracting Officers have outsourced country of origin determinations to CBP, requiring contractors to spend time and money obtaining a CBP decision to prove TAA compliance.

Contracting Officers have taken the position these CBP country of origin decisions are binding, leaving the

Contracting Officer no discretion to dispute CBP's country of origin conclusion.

The Federal Circuit flatly rejected this argument, noting the procuring agency is "responsible for determining whether an offered product qualifies as a U.S.-made end product," not the CBP.

Despite this strong language, it seems unlikely this decision will curtail the practice of Contracting Officers requiring contractors to obtain CBP determinations to prove TAA compliance, if even as "advisory" decisions that are given great weight.

Upon receiving the CBP's decision, the Contracting Officer likely will use it to inform his or her "independent" country of origin determination.

While this decision does give contractors some ammunition to fight incurring the expense at CBP, ultimately, it seems as though this decision may change only how Contracting Officers document the file.

Still, it will be interesting to monitor CBP decisions moving forward to see how the *Acetris* decision impacts their country of origin analyses (if at all).[5]

In *Acetris*, the Federal Circuit flat out rejected any argument that the country-of-origin for the company's end product could be determined by a single component (*i.e.*, the active ingredient).

Yet frequently, CBP relies on the country of origin of the component that gives the final end product its "essential character," in making determinations, especially where an end product is made up of components from multiple countries and is not substantially transformed in any one location. (For a more detailed review of recent CBP decisions, see our blog here).[6]

The Federal Circuit did not address these subsidiary factors, but rather held that the origin of component parts is irrelevant in a manufacturing determination under the TAA.

While the Federal Circuit's decision relates only to whether a product qualifies as a U.S.-made end product, its rejection of the importance of a single component, as well as its differentiation between manufacturing and substantial transformation, could significantly impact CBP decisions moving forward.

ONE LAST NOTE ON JURISDICTION

The Government argued this case was moot because Acetris could not secure any award even if its interpretation of the TAA was correct, because Acetris' price was not competitive. As such, the Government argued, Acetris did not have standing.

The Federal Circuit agreed the case was moot with regard to a particular solicitation. However, in an unexpected twist, the Federal Circuit further ruled the case was *not* moot with regard to *future* procurements.

That is, with respect to government contracts that a bidder is "very likely" to bid on in the "relatively near future," where they are virtually certain to occur, protestors may have standing.

The Federal Circuit recognized Acetris was challenging a systemic issue that likely would impact any future VA procurements — the interpretation and application of TAA requirements.

This decision, therefore, should be beneficial to contractors looking to challenge agency decisions that have lasting implications, even if the contractor was not the most competitive offeror on a single procurement.

Notes

[1] https://bit.ly/2xMPXsO

[2] https://bit.ly/2QlCnCT

[3] https://bit.ly/38UOnBT

[4] On this subject, it is possible industry might see a new FAR case in the near-future, amending FAR 52.225-5 to align with the country-of-origin test in the statutory TAA language. In fact, the Federal Circuit even suggested the Government could take such a route in its decision. However, where the purpose of the TAA is to provide an *exception* to certain "Buy American" requirements, it would seem to make sense that the TAA regulations would impose lesser burdens on U.S.-based manufacturing, allowing U.S. manufacturers greater flexibility — not imposing *more* manufacturing requirements on U.S. manufacturers. After all, not even the Buy American Act (41 U.S.C. § 8302(a)) requires that products be *wholly* manufactured in the U.S. to qualify.

[5] While the Federal Circuit may not, per se, set binding precedent over the CBP (only the Court of International Trade has that authority), this decision clearly could alter the way CBP handles its analyses, particularly where the U.S. Court of Appeals for the Federal Circuit is the court that reviews decisions from the Court of International Trade. *See* 28 U.S.C. § 2645.

[6] https://bit.ly/39Yfmhr

This article first appeared in the May 4, 2020, edition of Westlaw Journal Government Contract.

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This article was first published Feb. 27, 2020, on the firm's Government Contracts & Investigations blog. Republished with permission.