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ALERT

Federal Circuit Decision on Pharmaceutical Product Country of Origin

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WHAT: A recent decision by the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) rejected a longstanding test for determining the country of origin of pharmaceutical products, for the purposes of the Trade Agreements Act (TAA). Under the new test adopted by the Federal Circuit, pharmaceutical products are considered to be products of the country where the pharmaceutical is "manufactured" into final tablet form—a significant departure from the longstanding rule that a pharmaceutical product was considered to be a product of the country where the active pharmaceutical ingredient (API) was produced.

The TAA prohibits the U.S. government from procuring products of a country that is not a signatory to the Work Trade Organization Government Procurement Agreement (WTO GPA) or other Free Trade Agreements. 19 U.S.C. § 2512(a)(1). The TAA goes on to outline the following rule-of-origin test for determining when a product is a product of a country:

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).**

In a long line of administrative determinations regarding the country of origin of pharmaceutical products, U.S. Customs and Border Protection (CBP) consistently held that the process of combining

Authors

Kevin J. Maynard
Partner
202.719.3143
kmaynard@wiley.law

Cara L. Sizemore
Partner
202.719.4192
csizemore@wiley.law

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chemical ingredients to form a finished pill or tablet, without changing the chemical or medicinal properties of the tablet's API, did not constitute "substantial transformation" for purposes of the TAA. Thus, under the long-standing rule established by CBP's determinations, a pharmaceutical was traditionally considered to be a product of the country where the API was produced, even if the API was processed into a finished tablet in a different country.

The contractor in *Acetris Health, LLC, v. United States*, 2018-2399 (Fed. Cir. 2020) is a distributor of pharmaceutical products that are manufactured in tablet form in the United States, using APIs from India (which is not a TAA-Designated Country). Relying on CBP's long-standing rule, the U.S. Department of Veterans Affairs (VA) had determined that Acetris's pharmaceutical products were not "TAA-compliant," even though the products were processed into tablets in the United States, because the APIs were from India.

Acetris successfully challenged the VA's determination at the U.S. Court of Federal Claims (COFC or the Federal Court), and the VA subsequently appealed. On appeal, the Federal Circuit sided with Acetris (for reasons that differed from the COFC). In reaching its decision, the Federal Circuit rejected CBP's long-standing rule that a pharmaceutical product's country of origin should be determined based on the country in which the API is produced and established a new standard based on the location where the product is "manufactured" into a finished tablet.

The Federal Circuit first noted that the government was unable to identify any "Supreme Court or Circuit authority holding that a pharmaceutical product's country-of-origin is determined by the country in which its API was manufactured." Applying the TAA's rule-of-origin test to the finished tablet (the "product" being acquired by the VA), the Federal Circuit ultimately determined that the finished tablets could not appropriately be considered a product of India because (i) the tablets were not "wholly the . . . manufacture of India," and (ii) the tablets were not "substantially transformed" in India. Because the finished tablets were not products of India under either of these tests, and because the TAA only bars the procurement of products from countries that have not entered into a Free Trade Agreement (like India), the Federal Circuit held that purchase of the tablets was not prohibited by the TAA.

The Federal Circuit also held that the purchase of the tablets was not prohibited by the Federal Acquisition Regulation (FAR) provisions and clauses implementing the TAA. Looking to the regulatory history of the applicable FAR provisions, the Federal Circuit noted that "the source of the components (here, the API) is irrelevant in determining where a product is 'manufactured'" for purposes of the TAA. Instead, the Federal Circuit noted that a product that is "'manufactured' in the United States from "foreign-made components" may nevertheless be considered a "U.S.-made end product" for purposes of the TAA. The Federal Circuit also remarked that the term "manufactured," for purposes of the TAA, does not require that a product undergo "substantial transformation." Applying these standards, the Federal Court held that the pharmaceutical products sold by Acetris were "manufactured" in the United States, even though the APIs were from India, because the ingredients were "measured, weighed, mixed and compounded" to form the finished tablet in the United States. As a result, held that Acetris's products qualified as "U.S.-made end products" for purposes of the TAA.

WHEN: The Federal Circuit issued its decision on February 10, 2020.

WHAT DOES IT MEAN FOR THE INDUSTRY: This decision represents a seismic shift in the long-standing ground rules for determining the country of origin of pharmaceutical products. Under CBP's long line of cases, mechanically processing chemical ingredients into a tablet or pill, without changing the chemical or medicinal properties of the API, did not constitute substantial transformation. As a practical matter, CBP's case law established a bright line test for determining the country of origin of pharmaceutical products, based on the origin of the API.

The Federal Circuit's holding in *Acetris* effectively creates a new standard for determining the country of origin of pharmaceutical products, based on the location where the APIs are "manufactured" into finished tablets. Contractors that relied on the previous CBP rulings to determine the country of origin of pharmaceutical products sold to the U.S. government may therefore need to re-examine their supply chains and manufacturing processes to determine whether their products comply with this new standard.

The Federal Court's decision on *Acetris* could also have impacts on determining country of origin beyond pharmaceutical products. In that regard, CBP cases frequently look to the country of origin of a product's "essential components" to determine country of origin—particularly in cases where a product consists of components from a number of different countries and where the process of assembling those components into a finished product do not result in "substantial transformation." While the holding in *Acetris* was limited to pharmaceutical products, the Federal Court's rejection of CBP's reliance on the origin of a product's components (in this case APIs) to determine the country of origin of the ultimate end product could have widespread implications if it were extended to apply to other types of products where CBP has determined the country of origin based on the origin of an "essential component."

Importantly, though, the decision could be short-lived and lead to a regulatory change: the Federal Circuit noted that "[i]f the government is dissatisfied with how the FAR defines 'U.S.-made end product,' it must change the definition." We will continue to monitor this area for further developments.

The Federal Circuit's decision can be found here.