Pharma Ruling Broadens Gov't Drug Procurement Options

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A recent Federal Circuit court decision promises to significantly impact and broaden the scope of the types of foreign-produced pharmaceutical products companies can sell to the U.S. government.

In Acetris Health LLC v. U.S.,[1] the U.S. Court of Appeals for the Federal Circuit examined whether a pharmaceutical should be classified as a product of the country that produced the active pharmaceutical ingredient, or API, regardless of where the remainder of the manufacturing took place.

The Federal Circuit affirmed in part a ruling from the U.S. Court of Federal Claims and held that it was unreasonable for the U.S. Department of Veterans Affairs to classify a pharmaceutical manufactured in the U.S. as a product of India solely because the product's API was produced in India.

The court also held that a product need not be "substantially transformed" in the U.S. in order to meet the Federal Acquisition Regulation definition of a "U.S.-made end product," finding that U.S. manufacturing was sufficient to meet the definition.

The Federal Circuit's decision, if it stands, will open the door for sales to the U.S. government by companies that source APIs from certain countries, such as India and China, but who manufacture their final products in the U.S. or a permitted country.

U.S. Restrictions on Foreign Purchases

The U.S. government generally promotes use of domestic products through the Buy American Act. The BAA, as implemented in FAR Part 25, encourages agencies to purchase domestic products by applying a price preference to supplies manufactured in the U.S. from at least 50% U.S. component parts.

However, the U.S. is also a party to multiple trade agreements that provide for reciprocal, nondiscriminatory treatment of certain foreign-origin end products. The Trade Agreements Act waives application of the BAA restrictions for products from designated countries. To further encourage foreign countries to become parties to these trade agreements, the TAA also bars the acquisition of products from countries that have not entered into trade agreements with the U.S. including, notably, India and China.

The FAR implements the TAA requirements through its trade agreements clause.[2] This clause specifies that contractors shall only deliver designated country end products (products from countries that have signed free trade agreements) or U.S.-made end products (products manufactured or substantially transformed in the U.S.).[3]

Substantial Transformation Test and Its Application to Pharmaceuticals

The TAA's standard for determining a product's country of origin incorporates the so-called

substantial transformation test. Specifically, the TAA provides that an article originates in either: (1) the country in which the product is wholly grown or manufactured; or (2) in the case of an article that is made with materials from multiple countries, the country in which "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."[4]

The FAR similarly incorporates a substantial transformation standard by defining 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."

The FAR defines a designated country end product as "wholly the growth, product, or manufacture" of a designated country or "substantially transformed in [a 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."[5]

Historically, when applying the substantial transformation test to a specific set of facts, the VA and other federal agencies have deferred to U.S. Customs and Border Protection — not because they are required to do so, but because CBP has a long history of administering the substantial transformation standard in the context of rules governing the marking and declaration of imported products' country of origin.

Consistent with the language in the TAA, when a product comprises materials and labor from more than one country, CBP considers the product's origin to be the country where the materials have been substantially transformed into a new and different article of commerce distinct from that of the articles from which it was transformed.[6] In its rulings, CBP considers the totality of the circumstances, including the origin of the product's components, the extent of the processing that occurs within a given country, and whether such processing renders a product with a new name, character, and use.

Generally, CBP will find a substantial transformation to have taken place when the manufacturing process in one country changes the essential use of components made in other countries through a complex and meaningful process. By contrast, mere assembly usually does not amount to substantial transformation.

Applying these principles to pharmaceutical products, CBP has consistently focused on the source of and extent to which a drug's API is substantially transformed in the manufacturing process. Generally, the agency has ruled that an API is not substantially transformed through a manufacturing process that essentially processes bulk APIs into measured doses, regardless of whether such doses are ultimately in tablet, capsule, injectable or other forms.[7]

Even though such manufacturing is complex, requires advanced expertise, and may entail numerous operations, including measuring, mixing with excipients, testing, filtering, and packaging, in most cases CBP finds that the API is not substantially transformed because, after processing, the API retains its chemical and physical properties and because the essential use of the API does not change.

CBP has ruled that an API can be substantially transformed in limited circumstances (e.g., the combination of multiple APIs or where the efficacy of the API is chemically enhanced)[8]; however, in the vast majority of cases, CBP finds that the finished drug's country of origin is the origin of drug's API.

This approach has long been an obstacle for companies seeking to supply pharmaceutical products to the VA, particularly suppliers of generic drugs, because a large percentage of such drugs are manufactured with APIs originating in India or China — two nondesignated countries under the TAA.

The Federal Circuit's Acetris Decision

The Acetris decision addressed two issues: (1) whether the source of a pharmaceutical product's API (in this case, India) governs an end product's country of origin under the TAA's substantial transformation test, and (2) whether a product must be wholly manufactured or substantially transformed in the U.S. in order to qualify as an eligible U.S.-made end product under the FAR.

The Federal Circuit held that the TAA did not prohibit acquisition of the drug simply because the API was a product of India. The court found that Acetris' final product was the pill itself, rather than the ingredients of the pill. The court then found that the pill itself did not constitute a product of India, because "the tablets' components are not 'substantially transformed' into tablets in India."

The Federal Circuit rejected the government's argument that the source of the API governs the country of origin, noting that "the government cannot 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."

The court concluded that Acetris' drug was therefore neither wholly a product of India nor substantially transformed in India, and accordingly did not constitute a product of India under the TAA's definition. Because the drug was not a product of a nondesignated country, the TAA did not exclude the product from government procurement.

The Federal Circuit also held that, regardless of whether Acetris' product was substantially transformed in the U.S. — a question the court did not reach — the product nevertheless constituted a U.S.-made end product because a product can meet the requirement either by substantial transformation in the U.S. or manufacturing in the U.S.:
A product need not be wholly manufactured or substantially transformed in the United States to be a "U.S.-made end product."

In other words, the court concluded that a product may be eligible for U.S. purchase under the FAR trade agreements clause in any of three scenarios:

- Substantial transformation in a designated country;
- Substantial transformation in the U.S.; or
- Manufacturing in the U.S.

The Federal Circuit did not have to reach the question of whether Acetris' products are substantially transformed in the U.S. (although the court noted they "may very well be"), but concluded that Acetris' products fall into the third eligibility category as manufactured in the U.S., despite being manufactured from foreign components.[9]

The court noted that the regulatory history of the term "U.S.-made end product" was clear

that the source of a product's components — including the source of active ingredients — is irrelevant and, instead, "such products may be — as Acetris' products are — 'manufactured' in the United States from foreign-made components."

Implications for the Pharmaceutical Industry

The Acetris decision, if affirmed on appeal, could have significant implications for the pharmaceutical industry, especially for generic drug manufacturers.

The VA routinely grants a nonavailability determination exception to non-TAA compliant brand drugs (i.e., "covered drugs" under Special Item Number 42-2A). Non-TAA compliant generic drugs (SIN 42-2B drugs) have typically not been granted such an exception and therefore have been excluded from the government procurement process.

Because many generic drugs use APIs sourced from non-TAA designated countries, the VA's policy of using the country of API manufacturing as the country of origin has resulted in many generic drug manufacturers being excluded from the federal supply schedule. The Acetris decision reverses that policy and allows the TAA status of a pharmaceutical product to be based on the country where the final drug product is manufactured.

The court's analysis is also consistent with the U.S. Food and Drug Administration's interpretation of the word "manufacture." Under FDA regulations, only the finished drug product manufacturer may be identified as the manufacturer on a drug product label.[10]

Although the FDA's requirement to label a drug's manufacturer is distinct from the CBP requirement to mark the product's country of origin, the API-centric interpretation adopted by CBP and the VA has long been at odds with the FDA labeling requirements, resulting in drug labels that include conflicting manufacturer address and country of origin statements.

The reasoning set forth in Acetris — namely that the country of API manufacturing is not the country of origin for a drug product — if applied to country of origin marking, would resolve a longstanding disparity between the FDA and CBP concerning the site of drug manufacturing and significantly simplify drug labels.

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[1] Acetris Health LLC v. U.S., No. 18-2399 (Fed. Cir. 2020).

[2] FAR 52.225-5.

[3] FAR 52.225-5(a) (defining "designated country end product" and "U.S.-made end product"); FAR 52.225-5(b) ("The Contractor shall deliver under this contract only U.S.-made or designated country end products except to the extent that, in its offer, it specified delivery of other end products in the provision entitled 'Trade Agreements Certificate.'").

[4] See 19 U.S.C. § 2518(4)(B).

[5] FAR § 25.003.

[6] CBP applies different country of origin standards when free trade agreements, like NAFTA, apply because these agreements have special "rules of origin" for various classes of imported articles.

[7] See, e.g., Customs Rulings HQ 561975 (Apr. 3, 2002) and HQ 561544 (May 1, 2000).

[8] See, e.g., Customs Ruling HQ 563207 (Jun. 1, 2005).

[9] With regard to the third category, the Federal Circuit also noted that to qualify as a "U.S.-made end product," a product need not meet the definition of "domestic end product" from the FAR, which would require 50% domestic components unless the item qualified as "commercially available off-the-shelf." Here, the decision deviates from the holding of the lower court, which had concluded that the definition of "U.S.-made end products" necessarily includes domestic end products. The Federal Circuit stated that this was not the proper consideration: "Products that, like Acetris' products, are 'manufactured in the United States' and so are 'U.S.-made end products' whether or not they meet the other requirements of 'domestic end products.'"

[10] 21 C.F.R. § 201.1(b).