Updates
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Federal Circuit Decides Country of Origin Test for Drugs Under Trade Agreements Act

What *is* a thing? On February 10, 2020, the U.S. Court of Appeals for the Federal Circuit gave us a new answer to this old philosophical question. In the case of pharmaceuticals, the U.S. Department of Veterans Affairs (VA) had long held that the *thing* was synonymous with its active ingredient. But the Federal Circuit panel in *Acetris Health, LLC v. United States* disagreed. The court's opinion sets the stage for a big shake-up in how pharmaceuticals are treated under the Trade Agreements Act of 1979 (TAA) and, consequently, how federal agencies buy drugs.

Country of Origin Under the Trade Agreements Act

The TAA is designed to reconcile an apparent mismatch between two policies of the federal government. First, the Buy American Act of 1933 (BAA) requires federal agencies to purchase domestic, U.S.-made end products whenever feasible. At the same time, the government has entered into a variety of free trade agreements with allies and partners around the world. The TAA allows the government to waive the BAA's domestic preference requirements where it would conflict with a trade agreement. Effectively, the TAA allows federal agencies to treat products made in free-trade-signatory countries as if they were made in the United States.

But most products are made up of a variety of components, and those components themselves often come from different countries. In such circumstances, how do we identify the country in which the product is "made" under the TAA? The law provides two answers. First, if a product is wholly grown, produced, or manufactured in a certain country, it is a product of that country. Second, if a product is "substantially transformed" such that it has a different name, character, or use from the original or its components, it is a product of the country in which it was transformed.

The Acetris Health case directly confronted this question of where a pharmaceutical is "made." The government stated in its brief that "[r]ulings from U.S. Customs and Border Protection (CBP) had long held that the source of a pharmaceutical product's active ingredient generally dictates its country of origin." After the Federal Circuit's decision, such an interpretation of the TAA, as applied to pharmaceuticals, is no longer tenable.

At the Federal Circuit: The Pill Is the Product

As of 2017, Acetris had contracts to supply the VA with at least 13 pharmaceutical products. One such product was Entecavir, which is a tablet used to treat hepatitis B. The Entecavir tablets were manufactured in a plant in New Jersey. However, Entecavir's active ingredient was made in India. Since India is not a signatory to any trade agreements with the Unites States, products "made" there do not comply with the TAA.

Upon learning the country of origin for Entecavir's active ingredient, the VA demanded that Acetris request a country of origin determination from U.S. Customs and Border Protection (CBP). CBP determined that Entecavir was substantially transformed in India, the country where the drug's active ingredient was made.

The VA, relying on CBP's opinion, then rejected Acetris' tablets as non-TAA compliant. In the VA's view, even though the Entecavir tablets themselves were manufactured in New Jersey, their country of origin was India because that's where the active ingredient was produced. In response, Acetris challenged the VA's interpretation of the TAA at the U.S. Court of Federal Claims. That court held in Acetris' favor, and the VA appealed to the

Federal Circuit.

The Federal Circuit affirmed, basing its decision on the plain language of the TAA's country of origin test. Under the TAA, a "product" is "the final product that is procured—here, the pill itself—rather than the ingredients of the pill."

Additionally, an item is the product of a specific country "only if" one of the TAA's two country of origins prongs is fulfilled, i.e., the product is wholly the growth, product, or manufacture of that country, or the product has been "substantially transformed" in that country. Therefore, the Entecavir tablets could not possibly be a product of India because they were neither wholly manufactured in India, nor were they "substantially transformed" in India. On the contrary, the pills themselves were manufactured in New Jersey of ingredients that included, but did not consist entirely of, the active ingredient. Consequently, the court held they were TAA-compliant U.S.-made end products.

The court's holding confirms that it is not the active ingredient that is the product, as the VA originally assumed. Rather, for purposes of the TAA's substantial transformation analysis, "the pill is the product."

The Future for Pharmaceuticals

According to a recent article appearing in the *Los Angeles Times*, some experts estimate that up to 80% of drugs contain active ingredients sourced from non-TAA countries like China and India. After the Federal Circuit's decision, there is no longer any doubt that drug products whose active ingredient is made in India or China comply with the TAA, as long as such drug products are manufactured in the United States or a designated country. That means that more drugs and more suppliers will be able to enter the U.S. government market without concern about TAA compliance risk, and that government buyers must not reject a pharmaceutical product on TAA grounds if that product is manufactured in the United States—even if the active ingredient originates in China or India.

In the final part of its opinion, the court noted that "[i]f the government is dissatisfied with how the [law] defines 'U.S.-made end product,' it must change the definition, not argue for an untenable construction of the existing definition." No such changes have been proposed to date, but the possibility of such changes, in the form of proposed legislative and/or regulatory amendments, is something to watch closely in the coming months.

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