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Oral argument in Acetris TAA case

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Earlier this week, the U.S. Court of Appeals for the Federal Circuit (the Federal Circuit) heard oral argument in Acetris Health LLC v. U.S. 18-2399 (Fed. Cir, argued 1 Oct. 2019), an appeal of a decision that focuses on whether products manufactured in the United States with an active pharmaceutical ingredient (API) from Trade Agreements Act (TAA) "nondesignated countries" (such as India or China) can be considered of U.S. origin for federal procurement even if the manufacture is found not to effect a "substantial transformation" per the TAA.

The U.S. Court of Federal Claims (CoFC) had ruled in favor of Acetris, concluding that the U.S. manufacture of the Acetris Entecavir tablets was sufficient to confer U.S. origin per the governing Federal Acquisition Regulation (FAR) clause, accepting Acetris' argument that the clause required application of the less-stringent Buy American Act (BAA) "manufacture" standard for assessing origin, rather than the TAA's substantial transformation test.

Background

Acetris filed the CoFC case as one of two companion cases. The other action, which was filed in the U.S. Court of International Trade (CIT) (No. 1:18-cv-00040-RWG) (the CIT case) and predated the CoFC case, involves an appeal of administrative rulings on TAA country of origin (COO) by U.S. Customs and Border Protection (CBP), the agency authorized to interpret COO in both the customs and procurement contexts. In those rulings, CBP found that the COO of various Acetris drugs, including Entecavir, was the country where the API was made, having concluded that the final manufacturing process did not give rise to a substantial transformation. The rulings were in line with established CBP precedent. The CIT case was stayed, pending the resolution of the CoFC action.

Key issues discussed at oral argument

- API and origin. Rather than focusing on the issue of whether the BAA manufacture standard should be applied in the federal procurement origin analysis – the key issue in the appeal – the Federal Circuit examined at length the matter raised in the CIT case: whether final drug processing in the United States is sufficient to meet the substantial transformation test. The court questioned CBP's longstanding view regarding single-API drugs: that final manufacture does not generally effect a substantial transformation, and thus, that the origin of the API is determinative of the drug's country of origin.

- Procedural Matters/Jurisdiction. The court also had jurisdictional concerns that could present bases for vacating the lower court/CoFC decision.
    - The court questioned whether Acetris had established standing in the CoFC case, given that Acetris would not have been eligible to obtain an award under the contract at issue because its bid was not the lowest priced bid, and also because it had not met a deadline imposed by the agency. If it were found that the CoFC lacked jurisdiction, its decision would be vacated.
    - The court was also concerned with the similarity of the underlying facts between the CoFC and the CIT cases. Given that the CIT action predated the CoFC case, a finding that two actions contain substantially the same operative facts would mean dismissal of the CoFC claim per 28 U.S.C § 1500.

Next steps

Decisions typically are issued within six months of oral argument. The decision in this appeal might be issued as early as late October.

We will continue to notify of significant developments in the *Acetris* litigation. As always, do not hesitate to reach out to our Hogan Lovells team with any questions.

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