United States Court of Appeals for the Federal Circuit

ACETRIS HEALTH, LLC,
Plaintiff-Appellee

v.

UNITED STATES,
Defendant-Appellant

2018-2399

Appeal from the United States Court of Federal Claims in No. 1:18-cv-00433-MMS, Chief Judge Margaret M. Sweeney.

Decided: February 10, 2020

STEPHEN E. RUSCUS, Morgan, Lewis & Bockius LLP, Washington, DC, argued for plaintiff-appellee. Also represented by JAMES D. NELSON, DAVID B. SALMONS, DONNA LEE YESNER.

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KYLE R. JEFCOAT, Latham & Watkins LLP, Washington, DC, for amicus curiae The Association for Accessible Medicines. Also represented by GENEVIEVE PATRICIA HOFFMAN; JEFFREY FRANCER, The Association for Accessible Medicines, Washington, DC.

Before DYK, PLAGER, and STOLL, *Circuit Judges.*

DYK, *Circuit Judge*.

This case concerns restrictions on the procurement of foreign-origin pharmaceutical products by the Department of Veterans Affairs ("VA"). The Trade Agreements Act of 1979 ("TAA") bars the VA from purchasing "products of" certain foreign countries, such as India. The Federal Acquisition Regulation ("FAR") directs agencies to purchase "U.S.-made end products" before end products from certain foreign countries.

The VA interpreted the statute and regulation to define the country of origin of a pharmaceutical product to be the country in which the product's active ingredient is manufactured, here India. Acetris Health, LLC ("Acetris") challenged the VA's interpretation of the TAA and the FAR in a bid protest action at the United States Court of Federal Claims ("Claims Court"). The Claims Court granted Acetris declaratory and injunctive relief, holding that the VA misinterpreted the TAA and the FAR and enjoined the VA, in future procurements, from utilizing an erroneous interpretation. *Acetris Health, LLC v. United States*, 138 Fed. Cl. 579, 606–07 (2018). The government appeals.

We hold that this suit is justiciable and agree with the Claims Court on the result, but find the Claims Court's remedy to be imprecise in certain respects. Accordingly, we affirm-in-part, vacate-in-part, and remand for the entry of a declaratory judgment and injunction consistent with this opinion.

BACKGROUND

I

Two statutes restrict the government's ability to procure foreign-origin products. The first of these statutes to be enacted, the Buy American Act of 1933 ("BAA"), provides in relevant part that:

> [O]nly manufactured articles, materials, and supplies that have been manufactured in the United States substantially all from articles, materials, or supplies mined, produced, or manufactured in the United States, shall be acquired for public use unless the head of the department . . . determines . . . their cost to be unreasonable.

41 U.S.C. § 8302(a)(1) (emphasis added). A 1954 Executive Order, now implemented in the FAR, specifies that the unreasonable cost exception to the BAA applies where the lowest domestic offer by a large business is over 6% higher than the lowest foreign offer, and the lowest domestic offer by a small business is over 12% higher than the lowest foreign offer. 48 C.F.R. ("FAR") § 25.105. Congress has also exempted commercial-off-the-shelf ("COTS") products from the "substantially all" requirement, 41 U.S.C. § 1907, so a COTS product "manufactured" in the United States is BAA-compliant even if it is manufactured from predominantly foreign components, FAR § 25.101(a)(2). Acetris contends that this exception applies to its products, and the government does not contend otherwise.

The second of these statutes is the TAA. The TAA was designed to encourage foreign countries to enter reciprocal government-procurement trade agreements. Those agreements prohibit foreign countries from discriminating against American-made products and prohibit the United States from discriminating against foreign-origin products. Under the statute, countries that have entered into such agreements, and that do not discriminate against

American-made products, are allowed to compete for U.S. government procurements on non-discriminatory terms. At the same time, products from countries that have not entered into such trade agreements are barred from government procurements. Countries that have entered into such agreements are described as parties to the World Trade Organization ("WTO") Agreement. Section 2512(a)(1) of the TAA provides that:

> [T]he President, in order to encourage additional countries to become parties to the [WTO] Agreement and to provide appropriate reciprocal competitive government procurement opportunities to United States products and suppliers of such products—
>
> > (A) shall, with respect to procurement covered by the Agreement, prohibit the procurement . . . of products—
> >
> > (i) which are products of a foreign country or instrumentality which is not designated pursuant to section 2511(b) of this title [i.e., have not entered into reciprocal trade agreements], and
> >
> > (ii) which would otherwise be eligible products [i.e., products covered by the Agreement or another reciprocal trade agreement][1]. . . .

19 U.S.C. § 2512(a)(1) (emphasis added). The TAA defines "a product of a country" as follows:

> 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

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[1] *See* 19 U.S.C. § 2518(4) (defining "eligible product").

> (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). Accordingly, for procurements "covered by the [WTO] Agreement," the TAA generally prohibits government procurement of "products of a foreign country" unless the country is a party to the "Agreement" referenced in section 2512(a)(1). India, notably, is not a party to the Agreement. Thus, the TAA bars procurement of "products of" India.[2]

As the government states, "[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." Appellant's Br. 6. The VA has adopted the CBP's interpretation. The central merits question is whether this interpretation is correct, i.e., whether the products involved here are "products of a foreign country," i.e., India, under the meaning of the TAA.

Also pertinent here are the provisions of the FAR. The FAR's Trade Agreements Clause ("TA Clause"), which harmonizes and implements the BAA and TAA in contracts

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[2] The President can "designate[]" (i.e., waive the requirements of the TAA for) a country that is *not* a party to the Agreement in certain circumstances, such as if the country is a "least developed country," or not a "major industrial country" and "will provide appropriate reciprocal competitive government procurement opportunities to United States products and suppliers of such products." *See* 19 U.S.C. § 2511(b). India has not been "designated" by the President under section 2511(b).

covered by the WTO Agreement, states in relevant part that the "Contractor shall deliver under this contract only U.S.-made or designated country end products." FAR § 52.225-5.

The FAR defines a "U.S.-made end product" as follows:

> U.S.–made end product means 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 § 25.003.

II

Plaintiff-Appellee Acetris is a generic pharmaceutical distributor that specializes in providing pharmaceuticals to the federal government. Acetris obtains many of its pharmaceutical products from Aurolife Pharma LLC ("Aurolife"), which makes them in a facility located in Dayton, New Jersey using an active pharmaceutical ingredient ("API") made in India. In 2017, Acetris had contracts to supply the VA with at least 13 pharmaceutical products, including Entecavir Tablets (used to treat hepatitis B).

On March 1, 2017, the VA sent a letter to Acetris requesting it to recertify its compliance with the TAA for each of 13 contracts Acetris then held with the VA. Acetris responded that its products were "TAA compliant." J.A. 558. On March 30, 2017, the VA sent an email to Acetris stating that Acetris' response was "insufficient" and "demanded" that Acetris provide a compliance letter "that followed the definition of substantial transformation under the TAA, as set forth in FAR 52.225-5," which directs agencies to acquire "U.S.-made end products." J.A. 558. In Acetris' response to this email, it stated that its products were "'U.S.-made end products' as defined in FAR 52.225-5, because

each is 'an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States.'" J.A. 559.

In response, on April 17, 2017, the VA "requested" that Acetris obtain a country-of-origin determination from the CBP for each of ten Acetris products. J.A. 558. The VA reiterated this request in a subsequent letter dated June 6, 2017, stating that it had "probable cause" to believe that ten of Acetris' products, including Acetris' Entecavir Tablets, were made using API made in India, and so were allegedly not TAA-compliant. J.A. 559.

Acetris sought such rulings from the CBP and, on January 30, 2018, the CBP issued its country-of-origin determinations, holding that the Acetris products were products of India because their APIs were made in India and no substantial transformation had occurred in the United States. *See, e.g.*, *Notice of Issuance of Final Determinations Concerning Certain Pharmaceutical Products*, 83 Fed. Reg. 5130–33 (Feb. 5, 2018). Acetris challenged the CBP's determinations in the Court of International Trade ("CIT"), contending that its products' country-of-origin is the United States. Acetris' CIT cases are stayed pending resolution of this appeal.

On March 8, 2018, the VA sent a letter to Acetris noting the CBP's determination and requesting that Acetris find another source for each of the Acetris products that CBP had determined to be products of India. The VA stated that it was "the VA's intention to no longer purchase the current Acetis [sic] products" after March 26, 2018. J.A. 2269. On April 5, 2018, to avoid termination for default, Acetris agreed to a no-cost cancellation of its Entecavir contract. The record does not indicate the disposition of Acetris' other contracts.

On March 14, 2018, the VA issued a new solicitation seeking proposals for Entecavir tablets. Acetris again sought an award of the Entecavir contract. Before the

submission deadline, Acetris sent the VA five questions concerning the solicitation. The VA's response indicated that it would continue to rely on the CBP's determination, stating: "[t]he substantial [transformation] determination is determined by [CBP]" and "[CBP's] determination is final and cannot be overturned. The API was manufactured in India and India is deemed Non-[TAA] compliant." J.A. 894. (fifth alteration added).

On March 23, 2018, Acetris filed suit in the Claims Court challenging the VA's interpretation of the TAA and the FAR to exclude Acetris' products. Acetris' core contention was that its products, though manufactured using foreign-made API, are not "products of" India (under the TAA) and are "U.S.-made end products" (under the FAR) because they are manufactured into tablets in the United States. The complaint recounted the VA's position—reflected in its March 30, 2017, April 17, 2017, June 6, 2017, February 22, 2018, and March 8, 2018 letters—that ten of Acetris' products were not TAA and FAR-compliant. The complaint further alleged that the VA "appl[ied] the VA's improper interpretation of the clause contrary to the FAR and indicat[ed] the VA's intent impermissibly to treat Acetris' products as non-compliant" with the TAA and the FAR. J.A. 110–11. Thus, Acetris contended that the VA acted unlawfully in excluding Acetris' products from consideration for VA contracts, and Acetris requested broad declaratory and injunctive relief. The complaint focused particularly on the VA's actions in connection with Acetris' Entecavir solicitation.

After filing the Claims Court suit, on March 28, 2018, Acetris submitted an offer in response to the Entecavir solicitation. Two other entities also submitted offers: Golden State Medical Supply, Inc. ("Golden State") and AvKare, Inc. Of the three bidders, Golden State offered the lowest per-bottle price and Acetris offered the highest. The VA awarded the contract to Golden State, consistent with the

VA's policy to award contracts to the lowest-price technically acceptable bid.

The government moved to dismiss the Claims Court suit on several grounds, two of which are relevant here. First, the government contended that Acetris lacked an injury sufficient to confer standing because Acetris, as the highest-price bidder, would not have won the Entecavir contract even if Acetris' position as to the interpretation of the FAR were meritorious. Second, the government contended that Acetris' earlier-filed CIT suits divested the Claims Court of jurisdiction due to 28 U.S.C. § 1500, which provides that the Claims Court of "shall not have jurisdiction of any claim for or in respect to which the plaintiff . . . has pending in any other court." The Claims Court denied the government's motions.

The Claims Court then ruled on the parties' cross-motions for judgment on the administrative record, rejecting the government's interpretation of the TAA and FAR on the merits and agreeing with Acetris' interpretation. The Claims Court found that Acetris' products were "manufacture[d] . . . in a facility located in Dayton, New Jersey." *Acetris*, 138 Fed. Cl. at 586. The Claims Court then held that the government's interpretation of the TAA and the FAR was incorrect and erroneously excluded Acetris' products. *Id.* at 600–01. The Claims Court granted Acetris both declaratory and injunctive relief. *Id.* at 606–07.

The government appeals. We have jurisdiction to review the Claims Court's judgment under 28 U.S.C. § 1295(a)(3).

DISCUSSION

We review the Claims Court decisions regarding justiciability and its interpretation of the TAA and the FAR de novo. *See Trusted Integration, Inc. v. United States*, 659 F.3d 1159, 1163 (Fed. Cir. 2011); *Bannum, Inc. v. United States*, 404 F.3d 1346, 1351 (Fed. Cir. 2005).

I

We first address the government's contention that the case is moot because, after the filing of the complaint, Acetris bid on the Entecavir solicitation. Acetris was not the lowest bidder for the Entecavir solicitation, so it could not have secured the award even if its interpretation of the TAA and FAR were correct. The Claims Court denied the government's motion to dismiss the case as moot, reasoning that standing was to be assessed solely on the allegations in the complaint, so later events were not properly considered in determining standing. *Acetris*, 138 Fed. Cl. at 595–96. That is not correct. The Supreme Court has "repeatedly held that an 'actual controversy' must exist not only 'at the time the complaint is filed,' but through 'all stages' of the litigation." *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 90–91 (2013). Because a lack of "controversy" is a jurisdictional defect, *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 559 (1992), the Claims Court should have considered the post-filing evidence. *See Int'l Elec. Tech. Corp. v. Hughes Aircraft Co.*, 476 F.3d 1329, 1330 (Fed. Cir. 2007) ("[A] court in the first instance must determine whether or not it has subject matter jurisdiction even *sua sponte*.").

This evidence demonstrates that the case is moot insofar as Acetris challenges the Entecavir procurement. The VA's Entecavir solicitation explicitly stated that the lowest-price technically acceptable offer would be awarded the contract. Yet Acetris submitted the highest-price offer of the three offers. Acetris therefore would not have been awarded the Entecavir contract even if it were correct on the merits of its challenge to the VA's interpretation of the TAA and the FAR. Because Acetris cannot show prejudice resulting from the VA's purportedly flawed interpretation of the TAA and the FAR as applied to the Entecavir solicitation, Acetris has no injury-in-fact with respect to that

solicitation.[3] *See Myers Investigative & Sec. Servs., Inc. v. United States*, 275 F.3d 1366, 1370 (Fed. Cir. 2002) ("[P]rejudice (or injury) is a necessary element of standing."). Thus, Acetris does not now have standing to challenge the Entecavir solicitation.

A

Nonetheless, we conclude that this case is not moot because Acetris' challenge is not limited to the Entecavir procurement. We first address constitutional standing. The government contests justiciability under Article III, arguing that Acetris' challenge as applied to future procurements is "entirely hypothetical, . . . rather than an injury that actually occurred." Appellant's Br. 34–35 (citing *Lujan*, 504 U.S. at 560). But, as the Supreme Court has explained, an Article III injury-in-fact may be, as it is here, "the inability to compete on an equal footing in the bidding process," rather than "the loss of a contract." *Ne. Fla. Chapter of Associated Gen. Contractors of Am. v. City of Jacksonville, Fla.*, 508 U.S. 656, 666 (1993). Indeed, the Court has found Article III standing where, as here, a prospective bidder alleges that it would be unlawfully disadvantaged in competing for a government contract that the bidder is "very likely" to bid on in the "relatively near future." *Adarand Constructors, Inc. v. Pena*, 515 U.S. 200, 211–12 (1995). These future procurements are virtually certain to occur, and, absent the alleged error by the VA, Acetris is "very likely" to bid on those procurements.

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[3] The parties disputed—both in the Claims Court and in this appeal—whether the "substantial chance" test or the "non-trivial competitive injury" test is appropriate here. With respect to Acetris' challenge to the Entecavir solicitation as well as the other solicitation discussed below, the result is the same regardless of the test used.

B

Acetris also has statutory standing. The statute conferring bid protest jurisdiction provides in relevant part that:

> [T]he Unite[d] States Court of Federal Claims . . . shall have jurisdiction to render judgment on an action by an interested party objecting to a solicitation by a Federal agency for bids or proposals for a proposed contract or to a proposed award or the award of a contract or any alleged violation of statute or regulation in connection with a procurement or a proposed procurement. [T]he United States Court of Federal Claims . . . shall have jurisdiction to entertain such an action without regard to whether suit is instituted before or after the contract is awarded.

28 U.S.C. § 1491(b)(1) (emphasis added).

As relevant here, two phrases define the boundaries of section 1491(b)(1) jurisdiction: (1) that the challenge be "in connection with a procurement or a proposed procurement"; and (2) that the challenger be an "interested party."

Acetris broadly challenges the VA's purportedly flawed interpretation of "U.S.-made end products" in connection with both existing and proposed procurements. Acetris has standing because the government has taken a definitive position as to the interpretation of the TAA and the FAR that would exclude Acetris from future procurements for other products on which it is a likely bidder. The CBP has consistently held drug products manufactured in the United States with API from a foreign country to be products of that foreign country. The government agreed at oral argument that, "as long as the CBP decision was in place," there was no "reason to believe that the VA would take a different position about the country of origin . . . in any future contract." Oral Argument at 18:30. Thus, there is

every indication that the VA will evaluate future bids using the interpretation of the TAA now challenged by Acetris. The CBP has held already at least ten of Acetris' products to be "products of" India, *see* 83 Fed. Reg. 5118, 5118–39 (Feb. 5, 2018), and, as noted in letters referenced in and attached to the complaint, the VA has indicated on the basis of these determinations that Acetris' products are not TAA- and FAR-compliant. It is equally clear that the government will likely prohibit these products in the near future. And, in view of Acetris' history of performance, there is every indication that Acetris would seek to supply and could supply these products if it were awarded contracts for them. *See CliniComp Int'l, Inc. v. United States*, 904 F.3d 1353, 1357 (Fed. Cir. 2018). Thus, Acetris has established both a substantial chance of securing those contracts and a "non-trivial competitive injury" as to its other products sufficient to make it an "interested party." *See Weeks Marine, Inc. v. United States*, 575 F.3d 1352, 1363 (Fed. Cir. 2009); *Distributed Sols., Inc. v. United States*, 539 F.3d 1340, 1344–45 (Fed. Cir. 2008) (holding that protester "deprived of the opportunity to compete" was an "interested party").

Acetris' challenge also fits easily within the procurement language of the statute. We have held that the word "procurement" in section 1491(b)(1) "includes all stages of the process of acquiring property." *See Res. Conservation Grp., LLC v. United States*, 597 F.3d 1238, 1244 (Fed. Cir. 2010) (emphasis omitted). The reference to "proposed procurements" likewise broadly encompasses all contemplated future procurements by the agency. This is not a situation where, as in *Geiler/Schrudde & Zimmerman v. United States*, 743 F. App'x 974 (Fed. Cir. 2018), the bid protester could not identify any future procurements on which the protester intended to bid. The future procurements are likely to occur. And "[t]he operative phrase 'in connection with' is very sweeping in scope." *RAMCOR Servs. Grp., Inc. v. United States*, 185 F.3d 1286, 1289 (Fed. Cir. 1999). "As long as a statute has a connection to a procurement

proposal, an alleged violation suffices to supply jurisdiction." *Id.* (emphasis added).

Here, since the VA's actions under the TAA and the FAR "so clearly affect the award and performance" of other VA procurements on which Acetris intends to bid in the relatively near future, the TAA and FAR have "a connection" with "a procurement or proposed procurement." *See id.*

Acetris' challenge to the VA's ruling is not moot because Acetris continues to have both constitutional and statutory standing.

C

The government contends that Acetris' previously filed pending suits in the CIT, in which Acetris challenged CBP's country-of-origin determinations for Acetris' products, divest the Claims Court of jurisdiction under 28 U.S.C. § 1500. Section 1500 provides that the Claims Court "shall not have jurisdiction of any claim for or in respect to which the plaintiff . . . has pending in any other court." In *United States v. Tohono O'Odham Nation*, 563 U.S. 307, 317 (2011), the Supreme Court interpreted section 1500 to preclude Claims Court jurisdiction where an earlier-filed suit is "based on substantially the same operative facts" as the Claims Court suit, "regardless of the relief sought in each suit."

We have explained that "[u]nder *Tohono*, the question is whether the second Claims Court . . . suit would have been barred by res judicata if it had been brought in district court" under "res judicata principles as of 1868, when the predecessor to § 1500 was first enacted." *Res. Invs., Inc. v. United States*, 785 F.3d 660, 666 (Fed. Cir. 2015) (footnote omitted). At that time, the two tests for res judicata were the "act or contract test" and the "evidence test." *Trusted Integration*, 659 F.3d at 1169.

Under the "act or contract test," "[t]he true distinction between demands or rights of action which are single and

entire, and those which are several and distinct, is, that the former immediately arise out of one and the same act or contract, and the latter out of different acts or contracts." *Tohono*, 563 U.S. at 316 (quoting J.C. Wells, Res Adjudicata and Stare Decisis § 241, p. 208 (1878)). Under the "evidence test," two suits involve the same claim if "the same evidence support[s] and establish[es] both the present and the former cause of action." *Id.* (quoting 2 H. Black, Law of Judgments § 726, p. 866 (1891)). If the suits are the "same" under either of these tests, the Claims Court suit will be barred by section 1500. *Res. Invs.*, 785 F.3d at 666.

Acetris' second CIT claim is that, contrary to the CBP's ruling, the Acetris product is "manufactured in the [United States]" under the FAR because the processing steps in the United States are sufficiently "complex, time consuming, and expensive." CIT Complaint ¶¶ 86–94. The CBP had no colorable authority to opine on the FAR (i.e., the second CIT claim), which is a matter solely of procurement law. The CBP's statutory authority to provide country-of-origin determinations comes from 19 U.S.C. § 2515(b)(1), which only authorizes "determinations . . . under section 2518(4)(B) of this title." Section 2518(4)(B) provides the TAA's statutory country-of-origin test, which is different from the FAR's test. The CIT thus lacks colorable jurisdiction to review the merits of a CBP decision on Acetris' FAR compliance (which the CBP did not have authority to make in the first instance). Accordingly, any decision by the CIT on this claim would not have res judicata effect, and any factual allegations in the CIT complaint pertaining only to this claim do not have preclusive effect under section 1500.[4]

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[4] *Tohono* held that, under section 1500, a claim filed at a first court can divest the Claims Court of a second, later-filed claim even where the first court would have

We next turn to the first CIT claim, which involves the TAA, at issue in both the CIT and the Claims Court cases. Neither the "act or contract" test nor the "evidence" test supports a section-1500 bar. As to the "act or contract" test, the CIT cases challenge the CBP's act of issuing a TAA determination. In contrast, the Claims Court case challenges the actions of a different government agency—the VA—in adopting an interpretation of the TAA (and the FAR) that excludes products manufactured in the United States with foreign-made API (including, but not limited to, Acetris' products) from government procurements. Thus, the CIT and Claims Court suits do not "immediately arise out of one and the same act." *See Tohono*, 563 U.S. at 316 (citation omitted).

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lacked subject-matter jurisdiction over the second claim. *Tohono*, 563 U.S. at 315–17. This represents a departure from the usual rule that res judicata cannot preclude a later-filed claim over which the first court lacked jurisdiction. *See Res. Invs.*, 785 F.3d at 666. But in *Tohono* the earlier-filed claims were properly filed in the district court; *Tohono* did not consider situations where, as here, the first court lacks jurisdiction over the earlier-filed claim. And we do not read *Tohono* to override the principle that a court cannot rule on the merits of—and thus res judicata effect cannot arise from—a claim over which the court has no colorable jurisdiction. Restatement (Second) of Judgments § 12 (1982) (no preclusion where "[t]he subject matter of the action was so plainly beyond the court's jurisdiction that its entertaining the action was a manifest abuse of authority"); *see also United States v. U. S. Fid. & Guar. Co.*, 309 U.S. 506, 512 (1940) (holding that res judicata did not apply where district court had no statutory authority to adjudicate a claim against the United States); *Christopher Vill., L.P. v. United States*, 360 F.3d 1319, 1326–33 (Fed. Cir. 2004).

As to the "evidence" test, Acetris' first CIT claim has some factual overlap with the Claims Court claim. But many of the VA actions challenged in Acetris' Claims Court complaint occurred after the CIT complaints were filed and are not challenged in the CIT claims. And, to the extent that there is overlap between those claims, it largely involves the "res gestae," not the "operative facts," of the claims. *See Trusted Integration*, 659 F.3d at 1170; *see, e.g.,* Complaint, *Acetris Health LLC v. United States*, No. 18-47 (Ct. Int'l Trade Mar. 7, 2018), ECF No. 4 [hereinafter "CIT Complaint"], ¶¶ 79–85.

The CIT and Claims Court claims are not the "same" under the evidence test. With respect to the first CIT claim, Acetris contends that its products are TAA-compliant because they are "products of the United States" having been "substantially transformed" in the United States under 19 U.S.C. 2518(4)(B). In contrast, at the Claims Court, Acetris contends that its products are TAA-compliant because they are not "products of India" since they are neither "wholly the . . . manufacture" of India nor "substantially transformed" in India. These claims are not based on the same evidence. The "products of the United States" question in the CIT turns on whether a substantial transformation occurred in the United States. The "product of India" question in the Claims Court turns on whether the product was "wholly the . . . manufacture" of or "substantially transformed" in India. Thus, an adverse decision on the factual assertion that forms the basis for Acetris' CIT claim—that the processing steps in New Jersey cause a "substantial transformation" of the product from its constituent API sufficient to result in a "product of the United States" under the TAA—cannot preclude Acetris' Claims Court claim asserting that the product is not a "product of India" because the product is neither "wholly the . . . manufacture" of India nor "substantially transformed" in India.

Because the evidence at issue in the CIT cases does not "support and establish" the Claims Court claims, the

evidence test does not bar jurisdiction here. *See Tohono*, 563 U.S. at 316 (emphasis added); *see also Trusted Integration*, 659 F.3d at 1170 (noting that "under the evidence test . . . the overlapping evidence need[s] to be both relevant to and legally operative to prove the prior claim before res judicata [acts] as a bar to the subsequent claim" (emphasis in original)).

Section 1500 does not preclude jurisdiction here.

II

A

Turning to the merits, the government contends that the CBP's country-of-origin determinations are "binding" on the VA and so left no discretion to the VA to conduct an "independent [country-of-origin] analysis." Appellant's Br. 48. We reject that argument. As the Claims Court noted, "the procuring agency"—here, the VA—is "responsible for determining whether an offered product qualifies as a U.S.-made end product." *Acetris*, 138 Fed. Cl. at 602–03. Indeed, as the government admitted at oral argument, there is "not a requirement" for the VA to defer to the CBP's determination.

B

We conclude that the VA's interpretation of the TAA and the FAR was erroneous, as the Claims Court held. The TAA provides in relevant part that "the President . . . shall, with respect to procurement covered by the [WTO Agreement], prohibit the procurement . . . of products . . . which are products of a foreign country or instrumentality which is not designated pursuant to section 2511(b) of this title." 19 U.S.C. § 2512(a)(1). The question here is whether Acetris' products, which are made into tablets in the United States using API made in India, are "products of" India for which procurement is prohibited by the TAA. The TAA's rule-of-origin test provides that:

> 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 government argues that Acetris' tablets are products of India because the tablets' API was made in India. But 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. To the contrary, it is clear from the TAA that the "product" is the final product that is procured—here, the pill itself—rather than the ingredients of the pill. Acetris' tablets do not meet prong (i) of the TAA's country-of-origin test for India because the tablets are not "wholly the . . . manufacture" of India. Acetris' tablets similarly do not meet prong (ii) because the tablets' components are not "substantially transformed" into tablets in India. Because an article is a product of a country "only if" prongs (i) or (ii) are met, Acetris' tablets are therefore not a "product of" India. Indeed, the government concedes that under the construction of "product" that we have adopted (i.e., that "the pill is the product"), "the pill is not the product of India." Oral Argument at 11:50–12:50.

Accordingly, since the TAA only excludes products from government procurement if they are "products of" a foreign country like India, the TAA does not bar the VA from procuring Acetris' products.

The FAR also does not bar Acetris' products. The FAR's Trade Agreements ("TA") Clause provides in

relevant part that "[t]he Contractor shall deliver under this contract only U.S.-made . . . end products." FAR § 52.225-5. The FAR does not adopt the TAA's country-of-origin test for determining what are "products of a foreign country or instrumentality." 19 U.S.C. § 2518(4)(B). Instead, the FAR defines "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." FAR § 25.003.

The regulatory history of the term "U.S.-made end product" makes clear that the source of the components (here, the API) is irrelevant in determining where a product is "manufactured." When the term was introduced to the FAR, the government explained it as follows: "[t]he proposed rule defines U.S. made end products as products that are manufactured or substantially transformed in the United States, regardless of the source of the components." *Federal Acquisition Regulation; Foreign Acquisition (Part 25 Rewrite)*, 63 Fed. Reg. 51642 (Sept. 28, 1998) (emphasis added). A product need not be wholly manufactured or substantially transformed in the United States to be a "U.S.-made end product." Instead, such products may be—as Acetris' products are—"manufactured" in the United States from foreign-made components. The solicitation here similarly provides that "the place of manufacture is the location 'where ingredients are measured, weighed, mixed and compounded.'" J.A. 100. The government does not dispute that Acetris' products are measured, weighed, mixed and compounded in—and so, under the VA's own definition, "manufactured" in—a facility in Dayton, New Jersey. *See Acetris*, 138 Fed. Cl. at 586; Oral Argument at 4:10 (government stating that the "pill form [of an Acetris product] is made in New Jersey"). Therefore, on the plain

meaning of the FAR, Acetris' products are "U .S.-made end products."[5]

The government cites the Supreme Court's decision in *Anheuser–Busch Brewing Ass'n v. United States*, 207 U.S. 556 (1908), for the proposition that the terms "'manufacture' and 'substantial transformation' share a common meaning" (i.e., that there cannot be a "manufacture" without a "substantial transformation"). Appellant's Reply Br. 14–16. To the government, Acetris' products are not "manufactured" in the United States because they are not substantially transformed in the United States. Even assuming (without deciding) that Acetris' products are not substantially transformed in the United States,[6] the government's argument fails. Under *Anheuser–Busch*, the "first sense" of the term "manufacture" is when "a new article is produced of which the imported material constitutes an ingredient or part." *Anheuser–Busch*, 207 U.S. at 562. That definition is clearly satisfied here; the India-made

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[5] The Claims Court concluded and Acetris argues extensively on appeal that the term "U.S.-made end products" necessarily includes "domestic end products" (i.e., BAA-compliant products). This is not the relevant inquiry. 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" (i.e., that they are COTS items or their components are at least 50% (by cost) American-made). *See* FAR § 25.003; J.A. 881 (VA solicitation stating that "the Government will evaluate offers of U.S.-made or designated country end products without regard to the restrictions of the Buy American statute").

[6] Acetris' products may very well be substantially transformed in the United States, but we need not decide this question here.

API "constitutes an ingredient or part" of the tablets produced in New Jersey.

To be sure, *Anheuser–Busch* construed the word "manufacture" to also require that "a new and different article must emerge, 'having a distinctive name, character, or use,'" 207 U.S. at 560 (quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)), a construction that has since been referred to as the "substantial transformation" test. But, under the FAR, a "U.S.-made end product" may either be (i) "manufactured in the United States"; or (ii) "substantially transformed in the United States." FAR § 25.003. The language of the FAR reflects an intent not to require "substantial transformation" for analysis under the FAR; "manufacture" does not require substantial transformation.

If the government is dissatisfied with how the FAR defines "U.S.-made end product," it must change the definition, not argue for an untenable construction of the existing definition.

III

Having concluded that Acetris is correct on the merits, we turn to the issue of remedy. The Claims Court granted Acetris the following relief:

> [T]he court DECLARES that:
>
> > The term "U.S.-made end product," as used in the Trade Agreements clause, includes "domestic end products," as that term is defined in the FAR.
> >
> > The VA's failure to construe the term "U.S.-made end product," as used in the Trade Agreements clause, to include "domestic end products," as that term is defined in the FAR, was arbitrary, capricious, and contrary to law.

> It was arbitrary and capricious for the VA to require manufacturers to certify that the offered products were "[Trade Agreements Act] compliant."
>
> The VA's failure to independently assess whether plaintiff's Entecavir Tablets qualified as U.S.-made end products under the Trade Agreements clause was arbitrary, capricious, and contrary to law.

In addition, the court ENJOINS the VA, in future procurements, from

> construing the term "U.S.-made end product" in the Trade Agreements clause as excluding products manufactured in the United States (in other words, domestic end products), and
>
> relying on CBP rather than independently ascertaining whether an offered product is manufactured in the United States (in other words, a domestic end product) pursuant to the definition of the term "U.S.-made end product."

J.A. 89 (second brackets in original).

We find that the Claims Court judgment is both imprecise and confusing. On remand, the Claims Court should declare that: (1) under the TAA, a pharmaceutical product using API made in India does not, because of that fact, thereby become the "product of" India; and (2) under the FAR, the term "U.S.-made end product" may include products manufactured in the United States using API made in another country. The Claims Court should also enjoin the VA from excluding Acetris' products manufactured in Aurolife's Dayton, New Jersey facility from future procurements.

CONCLUSION

We conclude that this case is justiciable, and that the VA erred in interpreting the TAA and the FAR to exclude pharmaceutical products that, like Acetris' products, are manufactured in the United States using API made in a foreign country. Such products are not, under the TAA, the "product of" the country in which their API was made, and are "U.S.-made end products" under the FAR. We remand the case for the Claims Court to enter judgment consistent with this opinion.

AFFIRMED-IN-PART, VACATED-IN-PART, AND REMANDED

COSTS

No costs.