In the United States Court of Federal Claims

No. 18-433C
(Filed: May 8, 2018)

**********		Preaward Bid Protest; Motion to Dismiss;
ACETRIS HEALTH, LLC,	*	Contract to Provide Entecavir Tablets;
	*	Procuring Agency Interpretation of
Plaintiff,	*	Solicitation's Trade Agreements Clause;
	*	Country-of-Origin Determination by
v.	*	Customs and Border Protection; Exclusive
	*	Jurisdiction of the United States Court of
THE UNITED STATES,	*	International Trade; 28 U.S.C. § 1500;
	*	Ripeness; Failure to State a Claim Upon
Defendant.	*	Which Relief Can Be Granted
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Stephen E. Ruscus, Washington, DC, for plaintiff.

Daniel B. Volk, United States Department of Justice, Washington, DC, for defendant.

OPINION AND ORDER

SWEENEY, Judge

In this preaward bid protest, plaintiff Acetris Health, LLC challenges the United States Department of Veterans Affairs' ("VA") interpretation of the Trade Agreements clause included in a solicitation to purchase Entecavir Tablets, one of the few medications approved by the United States Food and Drug Administration to treat chronic hepatitis B. Plaintiff contends that under the VA's erroneous interpretation of the clause, the VA would not accept the Entecavir Tablets that plaintiff supplies to the VA under the incumbent contract. Defendant moves to dismiss plaintiff's complaint pursuant to Rules 12(b)(1) and 12(b)(6) of the Rules of the United States Court of Federal Claims ("RCFC"). For the reasons set forth below, the court denies defendant's motion.

I. BACKGROUND

Plaintiff, a domestic corporation with its principal place of business in Saddle Brook, New Jersey, is a generic pharmaceutical distributor that specializes in providing pharmaceuticals to the federal government.[1] Compl. ¶ 10. At the time it lodged this protest, plaintiff had

[1] The court derives the facts from the complaint, the exhibits attached to the complaint, the exhibit attached to plaintiff's original response in opposition to defendant's motion to dismiss, and the docket of Acetris Health, LLC v. United States, No. 1:18-cv-00047-RWG (Ct. Int'l Trade filed Mar. 7, 2018).

contracts with the VA to provide the government with at least thirteen different pharmaceuticals, including Entecavir Tablets.[2] Compl. Exs. 4, 6, 8. Plaintiff obtained these pharmaceuticals from Aurolife Pharma LLC ("Aurolife"), Compl. Exs. 4, 6, a manufacturer of commercially available off-the-shelf ("COTS") generic pharmaceuticals, Compl. Ex. 2 ¶ 1. Aurolife manufactures all of the pharmaceuticals it supplies to plaintiff in a facility located in Dayton, New Jersey. Id. ¶¶ 1, 4.

Aurolife manufactures Entecavir Tablets by combining a number of active and inactive ingredients, id. ¶ 7, in a process that is designed to ensure the production of "a stable drug product that maintains desired physico-chemical properties and adequate content uniformity resulting in the desired pharmacological effect," id. ¶ 8; accord id. ¶ 6 ("The manufacturing of Entecavir Tablets employs processes that transform these ingredients into finished, medically safe and effective dosage tablets."). The multistep process, all stages of which occur in the United States, includes "testing of raw materials for potency; weighing the raw materials for discharge; sifting of intra-granular materials; dry mixing granulation; drying; sifting and milling; sifting of extra-granular materials; blending and lubrication; compression; coating dispersion preparation; coating; and packing and labeling." Id. ¶ 14. Aurolife obtains the raw materials for the Entecavir Tablets from domestic and foreign suppliers; the active pharmaceutical ingredient ("API")–entecavir–is sourced from India. Id. ¶ 7; see also Notice of Issuance of Final Determinations Concerning Certain Pharmaceutical Products, 83 Fed. Reg. 5118, 5132 (Feb. 5, 2018) (indicating that plaintiff obtains entecavir from India and the remaining ingredients from five other countries, including the United States).

On December 19, 2016, plaintiff executed a contract with the VA to supply Entecavir Tablets to the VA and the United States Department of Defense through their Pharmaceutical Prime Vendor Programs.[3] Compl. Ex. 3 at 1-2, 6. The contract was subject to the Trade Agreements Act of 1979 ("Trade Agreements Act"), 19 U.S.C. §§ 2501-2582 (2012). See Compl. Ex. 3 at 30.

In general, the Buy American statute restricts the goods that can be acquired by the federal government to "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 . . . ." 41 U.S.C. § 8302(a) (2012); accord Federal Acquisition Regulation ("FAR") 25.101(a) (2016) ("The Buy American statute restricts

[2] In addition to Entecavir Tablets, plaintiff supplied the government with Rosuvastatin Calcium Tablets, Carvedilol Tablets, Simvastatin Tablets, Gabapentin Capsules, Metoprolol Tartrate Tablets, Paroxetine Hydrochloride Tablets, Levetiracetam Tablets, Donepezil Hydrochloride Tablets, Levofloxacin Tablets, Montelukast Sodium Tablets, Zidovudine, and Venlafaxine. Compl. Exs. 4, 6, 8.

[3] Other agencies that procure pharmaceuticals through the Pharmaceutical Prime Vendor Programs include the Indian Health Service, the Federal Bureau of Prisons, the Federal Health Care Center, and certain State Veteran Homes. Compl. Ex. 1 at 6-7.

the purchase of supplies that are not domestic end products."[4]). The Trade Agreements Act allows the federal government to waive the Buy American statute "with respect to eligible products of any foreign country or instrumentality designated under [the Act], and suppliers of such products . . . ."[5] 19 U.S.C. § 2511(a); accord FAR 25.402(a)(1).

As reflected in FAR part 25, the federal government has exercised its Trade Agreements Act authority and waived the Buy American statute for acquisitions covered by the World Trade Organization Government Procurement Agreement ("WTO GPA") or a Free Trade Agreement ("FTA"). FAR 25.402(a)(1); see also FAR 25.402(b) (reflecting that the waiver of the Buy American statute for products from WTO GPA countries only applies if the "value of the acquisition" is $191,000 or greater). For "acquisitions covered by the WTO GPA," federal government purchases are restricted to "U.S.-made or designated country end products . . . , unless offers for such end products . . . are either not received or are insufficient to fulfill the requirements." FAR 25.403(c). A "designated country end product" is an end product from one of four groups of countries–WTO GPA countries, FTA countries, least developed countries, or Caribbean Basin countries–none of which includes the United States or India. FAR 25.003. A "U.S.-made end product" is "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." Id. Offers of a "U.S.-made end product" can be "domestic" offers or "not domestic" offers. FAR 25.502(b)(2); FAR 25.504-2; accord Federal Acquisition Regulation; Foreign Acquisition (Part 25 Rewrite), 63 Fed. Reg. 51642, 51642 (Sept. 28, 1998) (reflecting that the FAR was being amended–in accordance with a General Services Board of Contract Appeals decision holding "that the Trade Agreements Act does not prohibit the purchase of U.S. products"–"to permit the purchase of all U.S. made end products, whether or not they are domestic end products"). A domestic offer is "an offer of a domestic end product," which is "[a]n end product manufactured in the United States, if–(i) [t]he cost of its components mined, produced, or manufactured in the United States exceeds 50 percent of the cost of all its components . . . or (ii) [t]he end product is a COTS item."[6] FAR 25.003.

To implement the Trade Agreements Act's requirements, plaintiff's contract with the VA incorporated by reference the Trade Agreements clause found at FAR 52.225-5, Compl. Ex. 3 at

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[4] The term "domestic end product" does not appear in the Buy American statute, see 41 U.S.C. ch. 83, but, as described below, is defined in FAR 25.003.

[5] Pursuant to FAR 25.003, an "eligible product" is "a foreign end product," and a "foreign end product" is "an end product other than a domestic end product."

[6] As relevant here, a COTS item is a commercial item (an item "that is of a type customarily used by the general public or by non-governmental entities for purposes other than governmental purposes, and" is either sold or offered for sale "to the general public") that is "[s]old in substantial quantities in the commercial marketplace" and "[o]ffered to the Government, under a contract or subcontract at any tier, without modification, in the same form in which it is sold in the commercial marketplace." FAR 2.101. Entecavir Tablets are COTS items. Compl. ¶¶ 2, 32.

30, and included the standard Trade Agreements Certificate set forth in FAR 52.212-3(g)(5), id. at 75. The Trade Agreements clause contained the VA's determination "that the WTO GPA and FTAs appl[ied] to" its acquisition of Entecavir Tablets, and indicated that plaintiff was required to supply "only U.S.-made or designated country end products" under the contract. FAR 52.225-5(b); see also FAR 52.225-5(a) (reflecting that the Trade Agreements clause's definitions of "U.S.-made end product" and "designated country end product" mirrored those set forth in FAR part 25); Compl. Ex. 4 at 1 (indicating that plaintiff's contract exceeded the $191,000 threshold for applying the Trade Agreements Act). The Trade Agreements Certificate required plaintiff to certify that "each end product . . . is a U.S. made or designated country end product, as defined in the" Trade Agreements clause. Compl. Ex. 3 at 75; see also id. at 79 (reflecting that plaintiff certified that "the place of manufacture" of its Entecavir Tablets was "predominantly . . . [i]n the United States"[7]). The Trade Agreements Certificate also included language regarding the evaluation of proposals:

> The Government will evaluate offers in accordance with the policies and procedures of FAR Part 25. For line items covered by the WTO GPA, the Government will evaluate offers of U.S.-made or designated country end products without regard to the restrictions of the Buy American statute. The Government will consider for award only offers of U.S.-made or designated country end products unless the Contracting Officer determines that there are no offers for such products or that the offers for such products are insufficient to fulfill the requirements of the solicitation.

Id. at 76. The contract, which was awarded to plaintiff for one base year and four option years, bore an effective date of April 13, 2017. Id. at 1.

On March 1, 2017, the VA sent plaintiff a letter requesting that plaintiff recertify its compliance with the Trade Agreements Act with respect to thirteen of its pharmaceutical contracts, including the contract for Entecavir Tablets. Compl. Ex. 4 at 1. Plaintiff responded with a signed statement from Aurolife that provided: "The products . . . supplied by Aurolife to Acetris have API[s] and other key pharmaceutical ingredients from India and other countries respectively with the manufacturing and processing done in the United States and are [Trade Agreements Act] compliant." Id. The VA found this response to be "insufficient, and demanded that Acetris provide a compliance letter that followed the definition of substantial transformation under the [Trade Agreements Act], as set forth in FAR 52.225-5." Id. Plaintiff responded on April 6, 2017, that the pharmaceuticals at issue–including the Entecavir Tablets–"are '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.'" Id. Once again, the VA was dissatisfied with plaintiff's response; it explained:

[7] For purposes of this certification, the term "place of manufacture" was defined as "the place where an end product is assembled out of components, or otherwise made or processed from raw materials into the finished product that is to be provided to the Government." Compl. Ex. 3 at 64.

> [The Trade Agreements Act] . . . requires that end products (including pharmaceuticals) may only be acquired by the Government from either the United States or a designated country under the [Trade Agreements Act]. . . . Under [Trade Agreements Act] standards, the test that is utilized to determine an end product's country of origin is substantial transformation. [S]ubstantial transformation for [Trade Agreements Act] purposes depends on whether a given article has been given a different character or use as a result of the process it underwent in either the United States or designated country. FAR 52.225-5. Within the entire federal Government, the United States Custom[s] and Border Protection (CBP) is the sole federal entity with authority to make country of origin determinations for [Trade Agreements Act] purposes.
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> Accordingly, VA has probable cause to assume that the API and other key ingredients for the pharmaceutical products [at issue] are sourced from India via Aurolife . . . and the end products themselves may not be considered substantially transformed in either the United States or a designated country under the [Trade Agreements Act] by CBP.

Id. at 1-2; see also 19 U.S.C. § 2515(b)(1) (providing for the "prompt issuance of advisory rulings and final determinations on whether, under [the rule of origin set forth in] section 2518(4)(B) . . . , an article is or would be a product of a foreign country or instrumentality"); 19 C.F.R. pt. 177, subpt. B (2017) ("Government Procurement; Country-of-Origin Determinations").

Due to its concerns, the VA, on April 17, 2017, requested that plaintiff obtain an "advisory determination" from CBP regarding the country of origin of the pharmaceuticals at issue, including the Entecavir Tablets. Compl. Ex. 4 at 2. Then, on June 6, 2017, not having any evidence that plaintiff sought the requested determinations from CBP, the VA sent plaintiff a cure notice advising plaintiff that its failure to obtain the determinations was "endangering performance" of the contracts. Id. at 1-3. The VA indicated that it would consider terminating plaintiff's contracts for default if plaintiff did not, within thirty days, provide the VA with evidence that it had sought country-of-origin determinations from CBP. Id. at 2.

On July 7, 2017, plaintiff requested final determinations from CBP regarding the country of origin of eleven pharmaceuticals, including its Entecavir Tablets. See generally 83 Fed. Reg. at 5118-39. CBP issued its final determinations on January 30, 2018.[8] Id. In its final determination pertaining to the Entecavir Tablets, CBP described the relevant facts and then set forth the legal standard under which it would make its determination. Id. at 5132. With respect to the applicable legal standard, CBP noted that pursuant to 19 U.S.C. § 2515(b)(1), it was required to determine whether Entecavir Tablets were products of a foreign country under the rule of origin. Id. The rule of origin provides:

[8] The final determinations were subsequently published in the Federal Register on February 5, 2018. 83 Fed. Reg. at 5118.

> 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); accord 19 C.F.R. § 177.22(a).

CBP then noted that it was required to apply the rule of origin "consistent with" the FAR, 83 Fed. Reg. at 5132 (citing 19 C.F.R. § 177.21), and in that regard, it recognized that the FAR "restrict[s] the U.S. Government's purchase of products to U.S.-made or designated country end products for acquisitions subject to the [Trade Agreements Act]," id. at 5132-33 (citing FAR 25.403(c)(1)). After reciting the definition of "U.S.-made end product,"[9] CBP defined "substantial transformation" and explained how it applied that definition in prior cases:

> A substantial transformation occurs when an article emerges from a process with a new name, character or use different from that possessed by the article prior to processing. A substantial transformation will not result from a minor manufacturing or combining process that leaves the identity of the article intact.
>
> In determining whether a substantial transformation occurs in the manufacture of chemical products such as pharmaceuticals, CBP has consistently examined the complexity of the processing and whether the final article retains the essential identity and character of the raw material. To that end, in cases concerning pharmaceutical products, CBP has considered whether the API retained its chemical and physical properties as a result of the processing performed and whether the processing changed the medicinal use of the API.

Id. at 5133 (citations omitted). Focusing on whether a substantial transformation occurred in the manufacture of plaintiff's Entecavir Tablets, CBP analyzed the relevant facts and found that because "the API does not undergo a change in name, character or use[,] . . . no substantial transformation occurs in United States, and the Entecavir tablets would be considered a product of India, where the API was produced, for purposes of U.S. government procurement." Id. CBP then addressed plaintiff's question of "whether the Entecavir tablets are 'manufactured in the United States' within the meaning of the term 'U.S.-made end products', as set forth in" the FAR and the Trade Agreements clause. Id. CBP responded in the negative:

> As stated in 19 C.F.R. § 177.21, subpart B is intended to be applied consistent with the [FAR]. The definition of country of origin in subpart B, 19 C.F.R. § 177.22(a) has two rules . . . as does [FAR] 25.003. The term "manufactured in

[9] CBP cited FAR 25.003 for the definition of "U.S.-made end product." 83 Fed. Reg. at 5133. As noted above, this definition is identical to the one that appears in the Trade Agreements clause found at FAR 52.225-5.

> the United States" in [FAR] 25.003 correlates to the first rule of 19 C.F.R. § 177.22(a) which provides that an article is a product of a country or instrumentality if "it is wholly the growth, product, or manufacture of that country or instrumentality". Since the production of Entecavir tablets partially occurs in India, we do not find that they are manufactured in the United States.

Id. Based on these findings, CBP held that "[t]he country of origin of the Entecavir tablets for U.S. Government procurement purposes is India." Id.

On February 5, 2018, less than a week after CBP issued its final determinations regarding the country of origin of plaintiff's pharmaceuticals, plaintiff requested that the VA, pursuant to the Contract Disputes Act of 1978, 41 U.S.C. §§ 7101-7109, issue a final decision that all of the pharmaceuticals were "U.S.-made end products" as defined in the contracts' Trade Agreements clauses. Compl. Ex. 5. Plaintiff contended that it was the responsibility of the VA's contracting officer, and not CBP, to interpret the term "U.S.-made end product" used in the contracts' Trade Agreements clauses. Id. at 2.

On February 22, 2018, after receiving a copy of the Federal Register notice containing CBP's final determinations, the VA notified plaintiff that it could no longer use Aurolife to supply the subject pharmaceuticals under the relevant contracts, and instead must use a Trade Agreements Act compliant source. Compl. Ex. 6. The VA advised plaintiff that a failure to identify a new source and supply Trade Agreements Act compliant pharmaceuticals would result in the initiation of the termination-for-cause process. Id. at 2. The VA further advised that it intended to issue new solicitations for all of the pharmaceuticals addressed by CBP in its final determinations. Id.; accord Compl. Ex. 9 (reflecting that the VA issued a presolicitation notice for the acquisition of Entecavir Tablets on March 9, 2018).

Plaintiff and the VA held a telephone conference on March 6, 2018, to discuss the contents of the February 22, 2018 letter and plaintiff's contention that the pharmaceuticals it supplied to the VA were compliant with the terms of the contract. Compl. Ex. 7 ¶ 10. During the conference call, the VA "asserted that it did not intend to issue a formal contracting officer's decision on [plaintiff's] claim" and "reiterated its position that, absent a federal court decision to the contrary, its policy [was] to rely entirely on CBP's Final Determinations in determining whether it [could] acquire products under the Trade Agreements Clause." Id. ¶ 11. Subsequently, in a March 8, 2018 letter, the VA indicated that it would cease purchasing the eleven pharmaceuticals from plaintiff effective March 26, 2018, and memorialized plaintiff's representation that if it did not obtain a new source for the pharmaceuticals by March 26, 2018, it would "agree to cancel the[] contracts and withdraw[its] requests for final decisions." Compl. Ex. 8 at 1.

Also on March 8, 2018, plaintiff appealed CBP's final determinations at the United States Court of International Trade ("CIT").[10] In its complaint challenging the final determination

[10] Plaintiff separately appealed each final determination. As of the date of this decision, one of the eleven cases has been designated as a test case, with proceedings in the remaining ten cases suspended pending the outcome of the test case. Acetris Health, LLC v. United States, No.

regarding its Entecavir Tablets, plaintiff contends that the Entecavir Tablets are "U.S.-made end products" under the FAR because they are manufactured in the United States and/or substantially transformed in the United States. CIT Compl. 2; id. ¶¶ 80-82 (substantial transformation), 87-91 (manufacture). It therefore requests that the CIT determine, contra CBP,

> that Entecavir Tablets are manufactured in the United States and also are substantially transformed in the United States where the raw chemical active and inactive ingredients are utilized in the formulation and manufacture of usable Drug Product with a name, character and use different from each of the underlying active and inactive ingredients.

Id. at 4; accord id. at 27 (requesting that the CIT find that plaintiff's Entecavir Tablets "are substantially transformed in the United States" and are "U.S.-made end products within the meaning of [FAR] 52.225-5 because they are manufactured in the United States"). Alternatively, plaintiff asserts that CBP lacks the authority to issue final determinations regarding whether a product that is not wholly manufactured in another country "is properly characterized as manufactured in the U.S. under" the Trade Agreements clause found at FAR 52.225-5. Id. ¶ 98. Consequently, it requests that the CIT declare that CBP lacks such authority and remand the final determination "to CBP to strike the affected language." Id. ¶ 103; accord id. at 27.

As it had represented to plaintiff, the VA, on March 14, 2018, issued a solicitation for proposals to supply Entecavir Tablets to the VA and the United States Department of Defense through their Pharmaceutical Prime Vendor Programs. Compl. Ex. 1 at 1-2, 6. In the solicitation, the VA provides:

> Manufacturers must also certify whether or not the end product offered in response to this solicitation is [Trade Agreements Act] compliant. Offers that fail to meet this requirement before contract award shall be rejected and shall receive no further consideration.
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> In addition to identifying Country of Origin for the end product offered under this solicitation in accordance with contract clause 52.212-3 Offeror Representation and Certifications, the offeror shall also identify the Country of Origin for all [APIs]. Offerors shall certify whether or not the end product(s) offered in response to this solicitation are from the United States or a [Trade Agreements Act] qualifying or designated country.
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> The Government will evaluate offers in accordance with the policies and procedures of [FAR] Part 25. The Government will only consider offers of U.S.-made or designated country end products for award. If the Contracting Officer determines that there are no offers for such products sourced from countries that are Trade Agreement[s] Act . . . compliant, then the Contracting Officer may

1:18-cv-00047-RWG (Ct. Int'l Trade Apr. 25, 2018) (order granting motion for test case designation and suspension).

> determine to consider products not covered by the Trade Agreement[s] Act . . . pursuant to FAR Part 25.

Id. at 51; accord id. at 5, 72. In accordance with this provision, the solicitation, like the existing Entecavir Tablets contract, incorporates the Trade Agreements clause found at FAR 52.225-5,[11] id. at 30, and includes the standard Trade Agreements Certificate, id. at 61. The solicitation also includes the same requirement for the offeror to identify "the place of manufacture" of the Entecavir Tablets. Id. at 79. The VA set the deadline for submitting proposals as March 28, 2018. Id. at 1.

Before the proposal submission deadline, plaintiff sent the VA five questions concerning the solicitation. Compl. Ex. 10. The VA responded on March 21, 2018. Compl. Ex. 11 at 1-2. The questions and answers are as follows:

> 1. The solicitation states . . . that the Government will evaluate offers in accordance with the policies and procedures of FAR Part 25, and will only consider offers of "U.S.-made or designated country end products" for award. FAR 25.003 defines "U.S.-made end product" for purposes of FAR Part 25 as a product that is manufactured in the U.S. or is substantially transformed in the U.S. into a new article of commerce. Will the VA consider offers of [Entecavir Tablets] to be offers of "U.S.-made end products" under the first criterion if the Entecavir Tablets are manufactured in the U.S. from an active chemical ingredient manufactured in India?
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> [Answer:] Under the rule of origin set forth under 19 U.S.C. § 2518(4)(B): 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.
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> 2. The solicitation states . . . that offerors that are not manufacturers must submit a letter of commitment from the manufacturer, and that the manufacturer must also certify whether or not the product offered in response to the solicitation is "[Trade Agreements Act] compliant." By "[Trade Agreements Act] compliant" does the VA mean the product offered is either a U.S.-made or designated country end product as both terms are defined in FAR Part 25?

[11] The Trade Agreements clause incorporated into this solicitation is an updated version of the Trade Agreements clause included in plaintiff's Entecavir Tablets contract. Compare Compl. Ex. 1 at 30 (incorporating the October 2016 version of the clause), with Compl. Ex. 3 at 30 (incorporating the February 2016 version of the clause). The differences between the two versions are irrelevant in this protest.

[Answer:] The letter must disclose the country of origin of the API and the[n] confirm it is [Trade Agreements Act] compliant.

3. The solicitation states . . . that the offeror must not only identify country of origin of the offered end products in accordance with [the Trade Agreements Certificate], but also must identify country of origin of all [APIs] in the end products, and must "certify whether or not the end product(s) offered are from the United States or a Trade Agreement[s] Act . . . qualifying or designated country." Does the phrase "end product(s) offered are from the United States" mean that end products offers are "U.S.-made end products" as defined in FAR Part 2[5] and if a manufacturer identifies the country of origin of API as a non-designated country, will the VA still consider an offer of Entecavir Tablets compliant if the tablets are manufactured in the United States?

[Answer:] In [the Trade Agreements Certificate] there is a section to disclose the country of origin. Also, the interested company that is not the manufacture[r] must produce a Letter of Commitment prior to award.

4. The solicitation states . . . that the Government will evaluate offers in accordance with the policies and procedures of FAR Part 25. FAR subpart 25.5 governs evaluation of foreign offers in supply contracts, and FAR 25.504-2 "WTO GPA/Caribbean Basin Trade Initiative/FTAs" states there are two categories of offers of "US-made end products": those that offer domestic end products and those that offer products that are not domestic end products but otherwise meet the definition of U.S.-made end product, and both may be considered in an acquisition covered by the WTO-GPA. Will the VA consider offers of products manufactured in the U.S. that qualify as domestic end products as defined in FAR Part 25 to be "U.S.-made end products" for purposes of the solicitation, whether or not they qualify as U.S.-made end products under the substantial transformation criterion?

[Answer:] If the manufacture of the drug is not [Trade Agreements Act] compliant and there are no [Trade Agreements Act] offers received then the Government may take Non-[Trade Agreements Act] offers. The substantial [transformation] determination is determined by [CBP]. The Buy American Act is under $190,000 and the Trade Agreement[s] Act is $190,000 and above.[12]

5. Will the VA consider "Entecavir Tablets" currently offered under [the existing contract] that are manufactured in the U.S. to be US-made end products as defined in FAR Part 25, even if [CBP] has determined under its rules for determining if a product is a product of a designated country that the tablets are a product of India?

[12] Effective January 1, 2018, the threshold for applying the Trade Agreements Act to procurements covered by the WTO GPA is $180,000. Procurement Thresholds for Implementation of the Trade Agreements Act of 1979, 82 Fed. Reg. 58248 (Dec. 11, 2017).

> [Answer:] [CBP's] determination is final and cannot be overturned. The API was manufactured in India and India is deemed Non-[Trade Agreements Act] compliant.

Id. at 1-2 (footnote added). Notwithstanding the VA's responses to its questions, plaintiff submitted a proposal in response to the solicitation. Resp. Ex. In an April 12, 2018 letter, the VA informed plaintiff that it rejected plaintiff's proposal "because the manufacturing location"–India–"is not a Trade Agreements Act designated country." Id.

II. PROCEDURAL HISTORY

Five days before the March 28, 2018 proposal submission deadline, plaintiff filed a protest in this court challenging the solicitation on three grounds. In its first claim for relief, plaintiff contends that the VA is improperly interpreting the Trade Agreements clause as (1) prohibiting the purchase of plaintiff's Entecavir Tablets unless the VA determines that there are no Trade Agreements Act compliant products available to purchase, and (2) excluding the purchase of products that qualify as both "domestic end products" under the Buy American statute and "U.S.-made end products" under the Trade Agreements clause. Compl. ¶¶ 74-75. In its second claim for relief, plaintiff contends:

> The VA Solicitation requirement that "[m]anufacturers must also certify whether or not the end product offered in response to this solicitation is [Trade Agreements Act] compliant" and statement that "[o]ffers that fail to meet this requirement before contract award shall be rejected and shall receive no further consideration" unduly restrict[] offers to products of [Trade Agreements Act] countries, [and] excludes products manufactured in the U.S., which is not a [Trade Agreements Act] country . . . .

Id. ¶ 82 (first and third alterations in original). In its third claim for relief, plaintiff contends that the VA improperly relies on CBP to make a country-of-origin determination rather than independently determining whether plaintiff's Entecavir Tablets qualify as "U.S.-made end products" under the Trade Agreements clause incorporated into the solicitation. Id. ¶¶ 88-90. To remedy these purported errors, plaintiff seeks both declaratory and injunctive relief. Compl. Prayer for Relief ¶¶ 1-7. Specifically, it seeks declarations that

- "the [Trade Agreements] Clause permits purchase of U.S.-made end products that are manufactured in the U.S. even if CBP has stated that the [API] used, along with inactive ingredients, in the manufacture of the products, is from India and not 'substantially transformed' in the manufacturing process," id. ¶ 1;

- "the VA's Solicitation is defective, arbitrary and capricious and violates the FAR," id. ¶ 3;

- "the [Trade Agreements] Clause's standard for determining a U.S.-made end product based on the 'manufactured in the United States' criterion is separate and different from the standard in CBP's regulation, and permits the government to purchase U.S.-made end products manufactured in the U.S. from foreign components," id. ¶ 5; and

- "the VA's refusal to interpret and give full effect to the U.S.-made end product provision of the [Trade Agreements] Clause, in complete reliance on CBP, is an abdication of its responsibility to interpret the contract terms, arbitrary and capricious, an abuse of discretion and contrary to FAR," id. ¶ 6.

And, it seeks an injunction prohibiting the VA from

- "interpreting the [Trade Agreements] Clause of the Solicitation as prohibiting purchase of U.S.-made products manufactured in the U.S., including [its] Entecavir Tablets," id. ¶ 2;

- "proceeding with the contemplated procurement through a Solicitation that mandates rejection of any offer for which the manufacturer has not certified [Trade Agreements Act] compliance where the offered product is a U.S.-made product manufactured in the United States," id. ¶ 4; and

- "relying solely on CBP to interpret the [Trade Agreements] Clause and refusing to interpret and give full effect to the definition of U.S.-made end product in the [Trade Agreements] Clause and the first alternative criterion under that definition: the product is manufactured in the United States," id. ¶ 7.

Plaintiff has not sought to amend its complaint to add allegations concerning the VA's rejection of its proposal, which occurred after plaintiff lodged this preaward protest.

With its complaint, plaintiff filed a motion for a temporary restraining order and preliminary injunction. In its response to plaintiff's motion, filed four days later, defendant moved to dismiss the protest pursuant to RCFC 12(b)(1) and RCFC 12(b)(6). After the court denied plaintiff's motion in a March 28, 2018 decision, the parties suggested a schedule to complete briefing on defendant's motion to dismiss. The court adopted the proposed schedule, pursuant to which briefing concluded on May 1, 2018. The court heard argument on May 3, 2018, and the parties completed supplemental briefing on May 8, 2018. The court is now prepared to rule.

III. DISCUSSION

Defendant moves to dismiss plaintiff's protest on four grounds: (1) that plaintiff's real claim is a challenge to CBP's country-of-origin determination, which is a claim within the CIT's exclusive jurisdiction pursuant to 28 U.S.C. § 1581(e); (2) that plaintiff filed its protest while it had another suit pending–the CIT suit–based on the same operative facts in violation of 28

U.S.C. § 1500;[13] (3) that plaintiff's protest is not ripe for review because plaintiff is seeking a determination regarding its eligibility for a contract for which it had not submitted a proposal; and (4) that plaintiff has not stated a claim upon which the court can grant relief.

A. Standard of Review

In ruling on a motion to dismiss a complaint pursuant to RCFC 12(b)(1) and RCFC 12(b)(6), the court generally assumes that the allegations in the complaint are true and construes those allegations in the plaintiff's favor. Trusted Integration, Inc. v. United States, 659 F.3d 1159, 1163 (Fed. Cir. 2011). With respect to RCFC 12(b)(1), the plaintiff bears the burden of proving, by a preponderance of the evidence, that the court possesses subject matter jurisdiction. Id. The allegations in the complaint must include "the facts essential to show jurisdiction." McNutt v. Gen. Motors Acceptance Corp., 298 U.S. 178, 189 (1936). And, if such jurisdictional facts are challenged in a motion to dismiss, the plaintiff "must support them by competent proof." Id.; accord Land v. Dollar, 330 U.S. 731, 735 & n.4 (1947) ("[W]hen a question of the District Court's jurisdiction is raised, . . . the court may inquire by affidavits or otherwise, into the facts as they exist." (citations omitted)). If the court finds that it lacks subject matter jurisdiction, it must, pursuant to RCFC 12(h)(3), dismiss the complaint.

A claim that survives a jurisdictional challenge remains subject to dismissal under RCFC 12(b)(6) if it does not provide a basis for the court to grant relief. Lindsay v. United States, 295 F.3d 1252, 1257 (Fed. Cir. 2002) ("A motion to dismiss . . . for failure to state a claim upon which relief can be granted is appropriate when the facts asserted by the claimant do not entitle him to a legal remedy."). To survive a motion to dismiss under RCFC 12(b)(6), a plaintiff must include in the complaint "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). In other words, a plaintiff must "plead[] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (citing Bell Atl. Corp., 550 U.S. at 556). "[O]nce a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint."[14] Bell Atl. Corp., 550 U.S. at 563. Indeed, "[t]he issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." Scheuer v. Rhodes, 416 U.S. 232, 236 (1974), overruled on other grounds by Harlow v. Fitzgerald, 457 U.S. 800, 814-19 (1982).

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[13] Defendant did not seek the dismissal of plaintiff's protest under 28 U.S.C. § 1500 in its motion to dismiss. The court raised the possibility that § 1500 might be applicable to this protest during oral argument on plaintiff's motion for a temporary restraining order and preliminary injunction, and invited the parties to address the applicability of § 1500 in subsequent briefing. Plaintiff addressed the issue in its response in opposition to defendant's motion, defendant addressed the issue in its reply in support of its motion, and plaintiff addressed defendant's contentions in its surresponse.

[14] In so holding, the United States Supreme Court ("Supreme Court") determined that the "no set of facts" language set forth in Conley v. Gibson, 355 U.S. 41, 45 (1957), "has earned its retirement," Bell Atl. Corp., 550 U.S. at 563.

B. The CIT Does Not Possess Exclusive Jurisdiction to Entertain Plaintiff's Claims

Defendant first argues that the United States Court of Federal Claims ("Court of Federal Claims") lacks jurisdiction to entertain plaintiff's protest because plaintiff's claims are within the exclusive jurisdiction of the CIT. Whether the court has jurisdiction to decide the merits of a case is a threshold matter. Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 94-95 (1998). "Without jurisdiction the court cannot proceed at all in any cause. Jurisdiction is power to declare the law, and when it ceases to exist, the only function remaining to the court is that of announcing the fact and dismissing the cause." Ex parte McCardle, 74 U.S. (7 Wall.) 506, 514 (1868).

The ability of this court to hear and decide suits against the United States is limited. "The United States, as sovereign, is immune from suit save as it consents to be sued." United States v. Sherwood, 312 U.S. 584, 586 (1941). The waiver of immunity "cannot be implied but must be unequivocally expressed." United States v. King, 395 U.S. 1, 4 (1969). The Tucker Act, the principal statute governing the jurisdiction of the Court of Federal Claims, waives sovereign immunity for claims against the United States in bid protests. See 28 U.S.C. § 1491(b) (2012). Specifically, the 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 . . . without regard to whether suit is instituted before or after the contract is awarded.

Id. § 1491(b)(1). In contrast, the CIT possesses exclusive jurisdiction to entertain challenges to CBP's country-of-origin determinations. Id. § 1581(e) ("The Court of International Trade shall have exclusive jurisdiction of any civil action commenced to review any final determination . . . under section 305(b)(1) of the Trade Agreements Act of 1979[, which is codified at 19 U.S.C. § 2515(b)(1)]."); Xerox Corp. v. United States, 753 F. Supp. 2d 1355, 1357 (Ct. Int'l Trade 2011). See generally 28 U.S.C. §§ 1581-1584 (describing the CIT's subject matter jurisdiction, which does not include bid protests).

Defendant observes that plaintiff repeatedly asserts in its complaint that its Entecavir Tablets are manufactured in the United States, contrary to the conclusion reached by CBP and adopted by the VA. Consequently, defendant contends, plaintiff is attempting to reargue the case that it presented to CBP and in which CBP issued a final determination. However, defendant avers, the only tribunal with the authority to review CBP's final determination is the CIT.

Plaintiff responds that it is not requesting that this court overturn CBP's country-of-origin determination and that the issues before this court are not issues that are before the CIT. It contends that in this court, it is challenging the VA's (1) interpretation and application of FAR part 25, (2) reliance on CBP's final determination despite CBP's failure to address whether plaintiff's Entecavir Tablets qualified as "domestic end products," and (3) issuance of a defective solicitation that prevented plaintiff's Entecavir Tablets from being considered for award as

"domestic end products." In contrast, plaintiff asserts, the only issue before the CIT is whether CBP correctly applied the Trade Agreements Act's rule of origin to plaintiff's Entecavir Tablets.

Although plaintiff has framed its allegations in this court as a challenge to the solicitation, the court is mindful that "in determining the existence or not of jurisdiction," it must look beyond plaintiff's characterization of its claims and ascertain "the true nature" of plaintiff's suit. Katz v. Cisneros, 16 F.3d 1204, 1207 (Fed. Cir. 1994); accord Norby Lumber Co. v. United States, 46 Fed. Cl. 47, 51 (2000) (noting that the plaintiff's styling of claims as arising under the Contract Disputes Act of 1978, rather than the Administrative Procedure Act, was not determinative of the true nature of the claims). There can be no dispute that, broadly speaking, plaintiff's ultimate goal is to have its Entecavir Tablets deemed to be "U.S.-made end products" or "domestic end products." Plaintiff devotes a portion of its complaint to explaining why its Entecavir Tablets qualify as "U.S.-made end products" and "domestic end products." See Compl. ¶¶ 2, 16-32, 41, 74-75, 81; accord Compl. Ex. 3; Compl. Ex. 7 ¶¶ 6-8, 15. Further, plaintiff requests an injunction preventing the VA from interpreting the solicitation's Trade Agreements clause as prohibiting the purchase of "U.S.-made end products" that are manufactured in the United States, "including [its] Entecavir Tablets." Compl. Prayer for Relief ¶ 2.

Nevertheless, upon closer examination, it is apparent that the claims asserted by plaintiff in its complaint are not the type of claims that are within the CIT's exclusive jurisdiction. In its first claim for relief, plaintiff, relying on the answers it received from the VA to the questions it posed after the VA issued the solicitation, contends that the VA is misinterpreting the solicitation's Trade Agreements clause as prohibiting the purchase of products that qualify as both "U.S-made end products" and "domestic end products." In its second claim for relief, plaintiff contends that certain solicitation provisions effectively exclude products manufactured in the United States even though such products qualify as "U.S.-made end products." And, in its third claim for relief, plaintiff contends that the VA is responsible for interpreting the terms of the solicitation and should not abdicate that responsibility to CBP. In short, all of plaintiff's claims are aimed at the actions (or inaction) of the VA, and not at the country-of-origin determination rendered by CBP. Thus, they are properly the subject of a preaward bid protest, a type of suit that is within the jurisdiction of the Court of Federal Claims, and not within the jurisdiction of the CIT.

C. 28 U.S.C. § 1500 Does Not Bar Plaintiff's Claims

That this court has jurisdiction to entertain the subject matter of plaintiff's claims does not end the jurisdictional inquiry. In light of the pending CIT litigation, plaintiff's claims in this court may be barred by operation of 28 U.S.C. § 1500, which "divests the court of jurisdiction when a related action is pending in another court." Brandt v. United States, 710 F.3d 1369, 1373 (Fed. Cir. 2013); see also id. at 1379 (noting that § 1500 was enacted to both prevent claimants from obtaining relief for the same conduct in separate fora and protect the federal government from having to defend duplicative lawsuits). Specifically, the statute provides:

> The United States Court of Federal Claims shall not have jurisdiction of any claim for or in respect to which the plaintiff or his assignee has pending in

> any other court any suit or process against the United States or any person who, at the time when the cause of action alleged in such suit or process arose, was, in respect thereto, acting or professing to act, directly or indirectly under the authority of the United States.

28 U.S.C. § 1500; see United States v. Tohono O'odham Nation, 563 U.S. 307, 311 (2011) (explaining that § 1500 indicates that the Court of Federal Claims "has no jurisdiction over a claim if the plaintiff has another suit for or in respect to that claim pending against the United States or its agents"); Keene Corp. v. United States, 508 U.S. 200, 209 (1993) (reading § 1500 "to bar jurisdiction over the claim of a plaintiff who, upon filing, has an action pending in any other court 'for or in respect to' the same claim"). Consequently, the "court must make two inquiries: (1) whether there is an earlier-filed 'suit or process' pending in another court, and, if so, (2) whether the claims asserted in the earlier-filed case are 'for or in respect to' the same claim(s) asserted in the later-filed Court of Federal Claims action." Brandt, 710 F.3d at 1374. "If the answer to either of these questions is negative, then the Court of Federal Claims retains jurisdiction." Id.

There is no dispute that at the time plaintiff filed its bid protest in this court, its appeal of CBP's country-of-origin determination was pending at the CIT. Thus, the only issue to be resolved is whether the claims plaintiff asserts in its CIT complaint are "for or in respect to" the claims it asserts in its bid protest complaint. To make this determination, the court must examine the operative facts in each case: "Two suits are for or in respect to the same claim . . . if they are based on substantially the same operative facts, regardless of the relief sought," Tohono, 563 U.S. at 317, or the legal theories asserted, Keene, 508 U.S. at 212, in each suit. Such an inquiry is "consistent with the doctrine of claim preclusion, or res judicata, which bars 'repetitious suits involving the same cause of action' once 'a court of competent jurisdiction has entered a final judgment on the merits.'" Tohono, 563 U.S. at 315 (quoting Comm'r v. Sunnen, 333 U.S. 591, 597 (1948)); see also Trusted Integration, 659 F.3d at 1164 ("[B]ecause § 1500 embodies principles of res judicata, determining whether two suits arise from substantially the same operative facts for purposes of that provision can be informed by how claims are defined for res judicata purposes." (citing Tohono, 563 U.S. at 315-16)), 1170 n.5 ("We do not adopt these [res judicata] tests as the standard by which to measure whether two claims arise from substantially the same set of operative facts, nor do we believe Tohono directs us to do so. Rather, we test our conclusion that the claim in [the Court of Federal Claims complaint] is not barred by § 1500 by reference to these tests simply to confirm that our conclusion remains true to the principles encompassed in that statutory provision."). But see Resource Invs., Inc. v. United States, 785 F.3d 660, 665 (Fed. Cir. 2015) (determining whether the operative facts in two suits sufficiently overlap by "apply[ing] the res judicata test approved by Tohono"[15]). However, the court should

[15] When "there is direct, irreconcilable conflict between two panel decisions of the" United States Court of Appeals for the Federal Circuit ("Federal Circuit"), "the earlier decision is controlling precedent." Briseno v. United States, 83 Fed. Cl. 630, 633 n.5 (2008) (citing Newell Cos. v. Kenney Mfg. Co., 864 F.2d 757, 765 (Fed. Cir. 1988) ("This court has adopted the rule that prior decisions of a panel of the court are binding precedent on subsequent panels unless and until overturned in banc. Where there is direct conflict, the precedential decision is the first." (citation omitted))). Thus, the statement in Trusted Integration that res judicata is used "simply

not define the claims narrowly to avoid the application of § 1500. See Tohono, 563 U.S. at 312 ("The phrase 'in respect to' does not resolve all doubt as to the scope of the jurisdictional bar, but 'it does make it clear that Congress did not intend the statute to be rendered useless by a narrow concept of identity.' It suggests a broad prohibition, regardless of whether 'claim' carries a special or limited meaning." (citation omitted) (quoting Keene, 508 U.S. at 213)); see also Keene, 508 U.S. at 213 (noting that use of "a narrow concept of identity" would provide "a correspondingly liberal opportunity to maintain two suits arising from the same factual foundation").

"Determining whether two suits are based on substantially the same operative facts 'requires a comparison between the claims raised in the Court of Federal Claims and in the other lawsuit.'" Trusted Integration, 659 F.3d at 1164 (quoting Keene, 508 U.S. at 210). In comparing the claims, a court may not rest on "a side-by-side comparison of the two complaints to see how much verbiage is in common." Petro-Hunt, L.L.C. v. United States, 105 Fed. Cl. 37, 43 (2012), aff'd, 862 F.3d 1370 (Fed. Cir. 2017), petition for cert. filed, 86 U.S.L.W. 3396 (U.S. Feb. 1, 2018) (No. 17-1090). "[R]ather, the court must first isolate the facts in the complaint that are 'operative,' i.e., those that must be proven in order to recover on a given claim." Id.

Although neither the Supreme Court nor the Federal Circuit has definitively stated what constitutes an "operative fact" for § 1500 purposes, those courts have provided some guidance. For example, "[a] distinction must be drawn between background facts, which describe the context for the claims presented in each suit, and operative facts, which provide the essential elements of the government conduct at issue in the two suits." U.S. Home Corp. v. United States, 108 Fed. Cl. 191, 195 (2012) (citing Cent. Pines Land Co. v. United States, 697 F.3d 1360, 1365 (Fed. Cir. 2012); Trusted Integration, 659 F.3d at 1168)); see also Resource Invs., 785 F.3d at 665 (noting that certain allegations "were central to" the claim in each court, and were not "merely . . . background fact[s]"). Further, facts are operative if they "identify government conduct that gives rise to claims against the United States." U.S. Home, 108 Fed. Cl. at 195 (citing Tohono, 563 U.S. at 318; Keene, 508 U.S. at 203-05; Trusted Integration, 659 F.3d at 1162-63; Harbuck v. United States, 378 F.3d 1324, 1328-29 (Fed. Cir. 2004)); accord id. at 198 ("The correct test, derived from Keene and Trusted Integration, is whether the challenged government conduct is substantially the same in the two suits."); see also Wyandot Nation of Kan. v. United States, 115 Fed. Cl. 595, 598 (2014) ("[F]acts are operative if they are relevant to establishing a claim. That is, if a fact satisfies, or helps to satisfy, an element of a legal claim, it is an 'operative fact' within the meaning of Section 1500. Put another way, the meaning of the term 'operative' is very close [to] that of 'material,' in that both terms act to isolate that class of facts that impact the determination of legal claims from those which do not. In sum then, two actions would be based on 'substantially the same material facts' if the same facts would be relevant to some theory of liability in both cases." (citations omitted)).

Defendant argues that a comparison of the two complaints filed by plaintiff reveals "that they are based on the same operative facts." Reply 3. Defendant correctly observes that "[m]any

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to confirm" that a conclusion regarding the application of § 1500 "remains true to the principles encompassed in that statutory provision," 659 F.3d at 1170 n.5, appears to be controlling.

of the same paragraphs in the complaint in this Court also appear in the CIT complaint." Id. Specifically, the court notes the following general equivalencies:[16]

Subject of Allegation(s)	Court of Federal Claims Complaint	CIT Complaint
Ingredients and Manufacture of Entecavir Tablets	¶¶ 2, 17-31	¶¶ 16-17, 19, 21-22, 24-36
Entecavir Tablets Are COTS Items	¶ 32	¶ 7
Plaintiff's Contract With the VA	¶¶ 4, 36-39, 43, 45	¶¶ 6, 8-10, 12-14
CBP Final Determination	¶¶ 50-51	¶¶ 55, 59, 73, 77

Defendant further asserts that plaintiff's "CIT complaint demonstrates that eligibility under the FAR provisions implementing the Trade Agreements Act . . . is exactly what [plaintiff] asked CBP to determine and what it is now asking the CIT to review," id. at 4, and that plaintiff bases its complaint in this court on these same arguments. Defendant specifically identifies the following allegations from plaintiff's CIT complaint as contentions that plaintiff relies on here:

- "Specifically, Acetris requested a final determination [from CBP] regarding whether the Company's Entecavir Tablets products comply with [FAR] 52.225-5, which governs the Company's sale of Entecavir Tablets to the VA under its contract, considering, as the Clause requires, both whether the products are U.S.-made end products manufactured in the U.S. and, separately, whether the products are substantially transformed in the U.S." CIT Compl. ¶ 56.

- "With the submission of the July 7, 2017 ruling request and all subsequent submissions prior to Customs issuance of a Final Determination, Acetris provided all information necessary for CBP to issue a Final Determination regarding the U.S. manufacture and U.S. substantial transformation of Entecavir Tablets for purposes of government procurement." Id. ¶ 58.

- "There is no requirement that, to be considered manufactured in the U.S. within the meaning of the FAR, the components of a COTS item like Entecavir Tablets have to be substantially transformed in, or products of, the U.S." Id. ¶ 91.

- "The Final Decision improperly equates the manufacture test in FAR 52.225-5, applicable to U.S.-made end products, of which domestic end products under the [Buy American statute] are a subset, with the separate and different [Trade Agreements Act] 'wholly manufactured' test used to determine foreign products eligible for a [Trade Agreements Act] waiver of the [Buy American statute] procurement preferences when a product is not U.S. made." Id. ¶ 92.

[16] The paragraphs in the two complaints are not necessarily identical, but they contain substantially similar factual allegations.

- "The Final Decision therefore improperly concludes, from the fact that Entecavir Tablets are not wholly manufactured in the U.S., components included, that the [Entecavir Tablets are] not manufactured in the U.S." Id. ¶ 93.

- "Accordingly, the Court should reverse CBP's ruling and hold that Entecavir Tablets are manufactured in the U.S." Id. ¶ 94.

Finally, defendant contends that plaintiff requests duplicative relief in its complaints, comparing plaintiff's request in this court for an "injunction prohibiting the VA from interpreting the [Trade Agreements] Clause of the Solicitation as prohibiting purchase of U.S.-made products manufactured in the U.S., including [its] Entecavir Tablets," Compl. ¶ 2, with plaintiff's request that the CIT "find that Entecavir Tablets are U.S.-made end products within the meaning of [FAR] 52.225-5 because they are manufactured in the United States," CIT Compl. 27.

Plaintiff disagrees that the two complaints are based on the same operative facts. It argues that neither "the claim central to this bid protest–that the [VA] arbitrarily excluded domestic end products that must be considered when the [Trade Agreements] Clause applies," nor its other two claims–"that the Solicitation as interpreted by the VA is defective . . . and that the . . . VA's refusal to interpret and give full effect to the U.S.-made end product provision of the [Trade Agreements] Clause, in complete reliance on CBP, is an abdication of its responsibility to interpret the contract terms"–are not claims in its CIT complaint. Resp. 19-20. It further contends that the facts necessary for the CIT to opine on CBP's country-of-origin determination–i.e., facts "concerning the nature of the manufacturing process that occurred at its supplier's New Jersey facility"–are not necessary to resolve its protest. Id. at 20. In fact, plaintiff asserts that the "determinative facts" in this protest

> concern the [VA's] failure to determine whether Acetris' Entecavir product is a domestic end product, [the VA's] decision that Acetris' product is ineligible for award despite its qualification as a domestic end product when the [Trade Agreements Act] applies, and [the VA's] complete reliance on the CBP country of origin determination without any independent consideration of differences between the standards applied by CBP and the applicable procurement regulations.

Id. at 20-21; see also Surresp. 3 (suggesting that the operative facts in this protest concern "(a) whether the [VA] applied the [pertinent] standard to determine if Acetris' product was manufactured in the U.S. and thus a domestic end product [it] was required to consider for award, and (b) whether the [VA] performed an analysis of whether CBP's determination applied the [pertinent] standard and thus potentially could be relied upon for purposes of the [VA's] eligibility decision."). All of these facts, plaintiff asserts, "occurred after the CBP determination, are not recited by and form no part of the CBP determination, and are not at issue in the CIT case." Resp. 21.

There is no question that the two suits filed by plaintiff share many background facts. Indeed, the overlap in background facts is the direct consequence of (1) the VA's demand that plaintiff obtain a final determination from CBP after awarding a contract to plaintiff and (2) the VA's reliance on CBP's final determination in its subsequent procurement. Further, there can be no dispute that plaintiff's ultimate goal is to have Entecavir Tablets it obtains from Aurolife deemed to be "U.S.-made end products" or "domestic end products," such that it could be eligible for the VA's procurement of Entecavir Tablets. However, the precise nature of plaintiff's claims in this court differ significantly from the claims it has raised at the CIT.

Here, plaintiff's claims are narrowly focused on whether the VA (1) complied with the FAR in interpreting the Trade Agreements clause, (2) included terms in the solicitation that conflict with the Trade Agreements clause, and (3) erroneously relied on a CBP final determination without adjudging whether CBP's analysis was consistent with the inquiry required by the Trade Agreements clause. The operative facts necessary to prove these claims are the provisions included in the solicitation and the VA's failure to properly interpret and apply FAR part 25 and the Trade Agreements clause that it included in the solicitation. In contrast, plaintiff asserts in its CIT complaint that its Entecavir Tablets are, in fact, "U.S.-made products" and, alternatively, that CBP lacks jurisdiction to determine whether a product is a "U.S.-made end product" under the solicitation's Trade Agreements clause. The operative facts necessary to prove the claims at the CIT are (1) the sources of the ingredients in plaintiff's Entecavir Tablets, (2) how and where plaintiff's Entecavir Tablets are manufactured, and (3) CBP's application of the rule of origin set forth in the Trade Agreements Act–a statutory provision that sets forth an eligibility standard that is separate and distinct from the eligibility standard included in the solicitation's Trade Agreements clause.

In short, the operative facts underlying the two complaints are not substantially the same.[17] Thus, § 1500 does not preclude this court's exercise of jurisdiction over plaintiff's protest.

D. Plaintiff's Claims Are Ripe

Defendant next argues that plaintiff's claims are not ripe for review by this court. A claim is not ripe for judicial review when it is contingent upon future events that may or may not occur. Thomas v. Union Carbide Agric. Prods. Co., 473 U.S. 568, 580-81 (1985). The ripeness doctrine "prevent[s] the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." Abbott Labs. v. Gardner, 387 U.S. 136, 148-49 (1967), overruled on other grounds by Califano v. Sanders, 430 U.S. 99 (1977). It derives "from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction." Reno v. Catholic Soc. Servs., Inc., 509 U.S. 43, 57 n.18 (1993).

[17] Indeed, this court can hold that the VA was required to (1) make its own determination regarding whether plaintiff's Entecavir Tablets qualify as "U.S.-made end products" and (2) consider "domestic end products" as "U.S.-made end products" without holding that plaintiff's Entecavir Tablets actually qualify as "U.S.-made end products."

In determining whether a claim is ripe for judicial review, courts must "evaluate both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." Abbott Labs., 387 U.S. at 149. The first prong of the ripeness analysis is not satisfied unless "the challenged agency action is final." Tokyo Kikai Seisakusho, Ltd. v. United States, 529 F.3d 1352, 1362 (Fed. Cir. 2008); accord NSK, Ltd. v. United States, 510 F.3d 1375, 1384 (Fed. Cir. 2007) (citing Abbott Labs., 387 U.S. at 149). A final agency action displays two characteristics. "First, the action must mark the 'consummation' of the agency's decisionmaking process–it must not be of a merely tentative or interlocutory nature." Bennett v. Spear, 520 U.S. 154, 177-78 (1997) (citation omitted). "[S]econd, the action must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" Id. at 178 (citation omitted). The second prong of the ripeness analysis is satisfied when the challenged agency action has an "immediate and substantial impact" on the plaintiff. Gardner v. Toilet Goods Ass'n, 387 U.S. 167, 170 (1967); see also Sys. Application & Techs., Inc. v. United States, 691 F.3d 1374, 1385 (Fed. Cir. 2012) ("Unlike the standard for obtaining injunctive relief, which requires a showing of irreparable harm, the standard for ripeness requires a lesser showing of hardship.").

Defendant's ripeness argument is premised on its characterization of the allegations in plaintiff's complaint as plaintiff's attempt to have its ineligibility for a contract reviewed before it submits a proposal in response to the solicitation. Defendant argues that because the VA had not, at the time plaintiff lodged its protest, determined plaintiff's eligibility to be awarded the Entecavir Tablets contract (by rejecting plaintiff's proposal), there is no final decision for the court to review. In short, defendant asserts, preaward bid protests "are not appropriate mechanisms for a bidder to have its eligibility determined hypothetically, in advance of any concrete final decision for this Court to review." Mot. 7.

In response, plaintiff argues first that the VA's written responses to its questions regarding whether its Entecavir Tablets would be eligible for award under the solicitation–which "left no doubt that [its] offer would not be eligible for award"–constitute a final agency decision. Id. at 13. Plaintiff further argues that had it

> waited until after award to challenge disqualification of its bid, given the [VA's] responses to its questions concerning the Solicitation terms, and the patent discrepancy between the language of the regulation and the VA's interpretation, the Government would undoubtedly have asserted that it was too late for [it] to challenge the terms.

Id. at 15.

The court disagrees with plaintiff that the VA's responses to its questions indicate that plaintiff's offer of Entecavir Tablets "would not be eligible for award"; plaintiff could be awarded the Entecavir Tablets contract if (1) it offered Entecavir Tablets from a supplier whose product met the requirements imposed by the VA in the solicitation or (2) the VA did not receive any Trade Agreements Act compliant offers. However, the VA's responses to plaintiff's questions reflect that the VA would not consider the Entecavir Tablets that plaintiff obtained

from Aurolife to be "U.S.-made end products" in accordance with the solicitation's Trade Agreements clause. In other words, the VA indicated the manner in which it would be interpreting the Trade Agreements clause (and the other relevant solicitation provisions)–an interpretation that plaintiff contends is improper. The VA's position in this respect was not tentative or interlocutory, and had the effect of limiting the Entecavir Tablets that could be offered in response to the solicitation by any prospective offeror. Thus, the VA's responses to plaintiff's questions constitutes a final agency determination. Accord Sys. Application & Techs., 691 F.3d at 1384.

Moreover, the proper time to challenge an agency's interpretation of a solicitation provision–especially an interpretation made evident by the agency's responses to a prospective offeror's questions regarding the provision–is before the deadline for submitting proposals. Had plaintiff not pursued its claims before the proposal submission deadline, it likely would have been precluded from later challenging the pertinent solicitation provisions. See id. at 1384-85 ("If [the protestor's] claims were not ripe until after the contract award, then [the protestor] could never protest this proposed amendment to the terms of the solicitation."); Blue & Gold Fleet, L.P. v. United States, 492 F.3d 1308, 1313 (Fed. Cir. 2007) (holding that a prospective offeror is required to "object to the terms of a government solicitation . . . prior to the close of the bidding process" to avoid waiving "its ability to raise the same objection subsequently in a bid protest action in the Court of Federal Claims").

Because plaintiff's claims are based on a final agency decision that had an "immediate and substantial impact" on plaintiff, they are ripe for judicial review.

E. Plaintiff Has Stated Claims Upon Which the Court Can Grant Relief

Defendant's final argument is that plaintiff has not stated a claim upon which the court can grant relief. With respect to plaintiff's first claim for relief–that the VA is misinterpreting the Trade Agreements clause as excluding products that qualify as "domestic end products"–defendant argues that because both the Trade Agreements clause and the FAR provision implementing the Trade Agreements Act require the provision of "U.S.-made or designated country end products," and because the Trade Agreements Act "neither prohibits domestic products, nor is the VA interpreting it to do so," plaintiff's "complaint does not include a plausible allegation that the VA has misinterpreted the FAR to prohibit a domestic product." Mot. 8 (citation omitted). In response, plaintiff correctly asserts that its complaint contains allegations that the VA is required under the solicitation "to determine eligibility of products in accordance with FAR Part 25," Resp. 16 (citing Compl. ¶ 59), and that the VA's "decision to exclude products that qualify as domestic end products when the [Trade Agreements Act] applies violates the FAR," id. at 16 (citing Compl. ¶ 40). Indeed, plaintiff's complaint includes an allegation that the VA represented to plaintiff in writing that it did not consider "domestic end products" to satisfy the "U.S.-made end product" requirement. See Compl. ¶ 69. These allegations allow the court to reasonably infer that the VA's interpretation of the Trade Agreements clause was arbitrary, capricious, an abuse of discretion, or contrary to the FAR, a type of claim that is within the court's bid protest jurisdiction. Thus, plaintiff has stated a claim upon which the court can grant relief.

With respect to plaintiff's second claim for relief–that the provision of the solicitation requiring manufacturers to certify that their product is Trade Agreements Act compliant improperly excludes products that are manufactured in the United States–defendant argues that because "nothing in the [Trade Agreements Act] excludes U.S.-made products" and "the portion of the solicitation Acetris seems to complain about made clear that U.S.-made products were acceptable," plaintiff's complaint does not include a plausible allegation that "requiring certification of [Trade Agreements Act] compliance" is arbitrary or violates the FAR. Mot. 8. The court disagrees. Plaintiff's complaint includes an allegation that the certification requirement that the VA added to the solicitation reflects a misinterpretation of the Trade Agreements clause, Compl. ¶ 82, as well as an allegation that the VA represented to plaintiff in writing that a "U.S.-made or designated country end product" would not be Trade Agreements Act compliant, id. ¶ 68. These allegations allow the court to reasonably infer that the VA's inclusion of a provision in the solicitation that requires Trade Agreements Act compliance was arbitrary, capricious, an abuse of discretion, or contrary to the FAR, a type of claim that is within the court's bid protest jurisdiction. Thus, plaintiff has stated a claim upon which the court can grant relief.

With respect to plaintiff's third claim for relief–that the VA abdicated its responsibility to interpret the "U.S.-made end product" provision of the Trade Agreements clause by deferring to CBP–defendant argues that because "contracting officials are permitted to rely on the determinations rendered by other Government entities with relevant expertise," "[t]here is no plausible allegation in the complaint on which it might be appropriate for the Court to enjoin the VA from relying on CBP's country-of-origin determination . . . ." Mot. 9. Again, the court disagrees. Plaintiff's complaint includes allegations that only the VA has the authority to interpret the solicitation's provisions, and that the VA's deference to CBP's country-of-origin determination was improper. Compl. ¶¶ 87-89. These allegations allow the court to reasonably infer that the VA's decision to forgo making its own determination regarding whether an offered product qualifies as a "U.S.-made end product" and instead rely solely on CBP to determine the product's country of origin was arbitrary, capricious, an abuse of discretion, or contrary to the FAR, a type of claim that is within the court's bid protest jurisdiction. Thus, plaintiff has stated a claim upon which the court can grant relief.

In its reply, defendant revisits its contention that the allegations in plaintiff's complaint amount to nothing more than an improper attempt to have this court review and/or determine whether plaintiff's Entecavir Tablets qualify as "U.S.-made end products." It asserts that "there is neither any basis in statute or regulation for the Court to impose on the VA an independent obligation to rule on [Trade Agreements Act] compliance nor any room beside CBP's determination for the VA to do so in this case." Reply 8. It explains that "[u]nder both common sense and the plain language of the [Trade Agreements Act's] rule of origin, on which the statute authorizes CBP to opine," plaintiff's Entecavir Tablets "cannot both be a product of India that is ineligible for award under the [Trade Agreements Act] and also a U.S.-made product that is eligible." Id. at 8-9. Thus, defendant avers, "[w]hen CBP decided on the former, that decision left no room or reason for the VA to entertain Acetris's arguments as to latter, which had been comprehensively presented to CBP by Acetris." Id. at 9.

The court does not construe the allegations in plaintiff's complaint as an effort to have this court determine whether plaintiff's Entecavir Tablets qualify as "U.S.-made end products" or to have this court overrule CBP's country-of-origin determination. Indeed, the court has no intention of taking either action. Rather, the only issues before the court concern whether the VA improperly (1) interpreted the solicitation's Trade Agreements clause, (2) included a provision in the solicitation that was contrary to the Trade Agreements clause, and/or (3) relied on CBP's country-of-origin determination rather than independently interpreting the solicitation's Trade Agreements clause.

IV. CONCLUSION

As explained above, the court concludes that it possesses jurisdiction to entertain plaintiff's claims, that 28 U.S.C. § 1500 is not a jurisdictional bar to plaintiff's protest, that plaintiff's claims are ripe, and that plaintiff has stated claims upon which this court can grant relief. Accordingly, the court **DENIES** defendant's motion to dismiss. The court will conduct a telephonic status conference on **Thursday, May 10, 2018, at 11:00 a.m. (EDT)**, to discuss further proceedings.

IT IS SO ORDERED.

s/ Margaret M. Sweeney
MARGARET M. SWEENEY
Judge