In the United States Court of Federal Claims

No. 18-433C
(Filed Under Seal: July 10, 2018)
(Reissued for Publication: July 16, 2018)[*]

**********		Preaward Bid Protest; Motion to Dismiss;
ACETRIS HEALTH, LLC,	*	Standing; Motion to Supplement the
	*	Administrative Record; Cross-Motions for
Plaintiff,	*	Judgment on the Administrative Record;
	*	Declaratory and Injunctive Relief; Buy
v.	*	American Statute; Trade Agreements Act of
	*	1979; Proper Construction of Solicitation's
THE UNITED STATES,	*	Trade Agreements Clause; Conflicting
	*	Solicitation Provisions; Reliance on
Defendant.	*	Customs and Border Protection's Country-
**********		of-Origin Determination

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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") construction and application 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 construction of the clause, the VA would not accept the Entecavir Tablets that plaintiff had been supplying to the VA under the incumbent contract. Presently before the court are defendant's renewed motion to dismiss on standing grounds, plaintiff's motion to supplement the administrative record, and the parties' cross-motions for judgment on the administrative record. As explained in more detail below, the court concludes that plaintiff has standing to protest, that supplementation of the administrative record is not necessary for the court to effectively review plaintiff's claims, and that plaintiff is entitled to some of the declaratory and injunctive relief it requests.

[*] This reissued Opinion and Order incorporates the agreed-to redactions proposed by the parties on July 13, 2018, and two other redactions in conformance with the parties' proposed redactions. The redactions are indicated with bracketed ellipses ("[. . .]").

I. BACKGROUND

A. Statutory and Regulatory Context

This bid protest concerns the construction and application of the Trade Agreements Act of 1979 ("Trade Agreements Act"), 19 U.S.C. §§ 2501-2582 (2012), its implementing regulations, and its associated contract clauses.[1]

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) (2018) ("The Buy American statute restricts the purchase of supplies that are not domestic end products."[2]). The Trade Agreements Act allows the federal government to waive the Buy American restriction "with respect to eligible products of any foreign country or instrumentality designated under [the Act], and suppliers of such products,"[3] such that those products and suppliers would be treated as favorably as "United States products and suppliers." 19 U.S.C. § 2511(a); accord FAR 25.402(a)(1) (indicating that "[t]he Trade Agreements Act . . . provides the authority for the President to waive the Buy American statute and other discriminatory provisions for eligible products from [designated] countries," such that those "eligible products receive equal consideration with domestic offers").

As reflected in FAR part 25 ("Foreign Acquisition"), the federal government has exercised its Trade Agreements Act authority and waived the Buy American restriction 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 restriction for products from WTO GPA countries only applies if the "value of the acquisition" is $180,000 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. FAR 25.003; see also id. (reflecting, as relevant here, that the United States and India are not included in any of the four groups and that [. . .] and [. . .] are WTO GPA countries). 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,

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[1] The court derives the information in the background section from the administrative record ("AR"), relevant statutes and regulations, and publicly available court filings.

[2] 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.

[3] 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."

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. 51,642, 51,642 (Sept. 28, 1998) (indicating that "[t]he Trade Agreements Act does not specifically address the treatment of U.S. made end products that do not qualify as domestic end products" and that the FAR was being amended–in accordance with an administrative 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"[4]). A domestic offer is "an offer of a domestic end product," and a domestic end product 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 [commercially available off-the-shelf ("COTS")] item."[5] FAR 25.003. It follows that a U.S.-made, nondomestic offer is an offer of a product that is substantially transformed in the United States. See also Int'l Bus. Machines, GSBCA No. 10532-P, 90-2 BCA ¶ 22,824 (holding that the then-existing Trade Agreements clause, which only allowed contractors to supply "domestic end products" or "foreign end products," impermissibly prevented the federal government from procuring "United States products"–in other words, products substantially transformed in the United States).

B. Plaintiff and Its Entecavir Tablets

Plaintiff, a domestic corporation with its principal place of business in Allendale, New Jersey, is a generic pharmaceutical distributor that specializes in providing pharmaceuticals to the federal government. Notice of Issuance of Final Determinations Concerning Certain Pharmaceutical Products, 83 Fed. Reg. 5118, 5132 (Feb. 5, 2018). Plaintiff obtains the pharmaceuticals it distributes from Aurolife Pharma LLC ("Aurolife"), a manufacturer of generic pharmaceuticals. See generally id. at 5118-39. Aurolife manufactures the pharmaceuticals it

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[4] In its cross-motion for judgment on the administrative record, defendant misconstrues a phrase in this Federal Register notice–"when a U.S. made end product that is not a domestic end product," 63 Fed. Reg. at 51,642–to mean that "not every domestic end product is a U.S.-made end product," Cross-Mot. 22. To the contrary, the phrase–and the remainder of the Federal Register notice–reflects that all domestic end products qualify as U.S.-made end products, and that there is a subset of U.S.-made end products that do not qualify as domestic end products.

[5] 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. Plaintiff alleges that Entecavir Tablets are COTS items, Am. Compl. ¶¶ 2, 32, and the solicitation at issue reflects the VA's intent to acquire a commercial item, see generally AR 52-123. However, the administrative record does not indicate whether plaintiff's Entecavir Tablets were sold commercially in "substantial quantities." The court need not decide whether plaintiff's Entecavir Tablets are COTS items.

supplies to plaintiff in a facility located in Dayton, New Jersey. See generally id.; AR 145-47, 573, 849.

To make Entecavir Tablets, Aurolife combines a number of active and inactive ingredients in a process that "converts the[] ingredients into finished, medically effective dosage tablets . . . ." 83 Fed. Reg. at 5132. Aurolife obtains the ingredients for its Entecavir Tablets from domestic and foreign suppliers; the active pharmaceutical ingredient ("API")–entecavir–is sourced from India and the remaining ingredients are sourced from five other countries, including the United States. Id.

Plaintiff supplied the VA with Entecavir Tablets under a national contract set to expire on April 12, 2018. AR 33, 125, 847; see also id. at 847 (indicating that the contract was terminated on April 5, 2018[6]). The VA could also obtain Entecavir Tablets using Federal Supply Schedule contracts or on the open market. Id. at 33-35, 847; see also id. at 841-42 (reflecting that the VA could obtain a lower price on the open market than it could using a Federal Supply Schedule contract).

C. Customs and Border Protection's Country-of-Origin Determination

On July 7, 2017, plaintiff requested final determinations from Customs and Border Protection ("CBP") regarding the country of origin of eleven of the pharmaceuticals it distributes, including its Entecavir Tablets.[7] See generally 83 Fed. Reg. at 5118-39. CBP issued its final determinations on January 30, 2018.[8] Id.; accord AR 941-68 (containing CBP's final determinations). In its final determination pertaining to plaintiff's Entecavir Tablets, CBP described the relevant facts and then set forth the legal standard under which it would make its determination. 83 Fed. Reg. 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 the Entecavir Tablets were products of a foreign country under the rule of origin. Id. The rule of origin provides:

> 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

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[6] A contract modification submitted by defendant with its cross-motion for judgment on the administrative record reflects that plaintiff and the VA agreed to a no-cost termination of the contract. Cross-Mot. App. 4-5.

[7] Although the administrative record does not reflect the reason why plaintiff made such a request, plaintiff alleges that it was advised by the VA that CBP was "'the sole federal entity with authority to make county of origin determinations for [Trade Agreements Act] purposes.'" Am. Compl. ¶ 49 (quoting a VA cure notice); accord Acetris Health, LLC v. United States, No. 18-433C, 2018 WL 2123461, at *3-4 (Fed. Cl. May 8, 2018).

[8] The final determinations were subsequently published in the Federal Register on February 5, 2018. 83 Fed. Reg. at 5118-39.

> 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) (2017).

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 the term "U.S.-made end product," CBP defined the term "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. 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 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. Plaintiff appealed this determination, as well as CBP's final determinations on the other ten pharmaceuticals, at the United States Court of International Trade ("CIT").[9] See Acetris Health, LLC v. United States, No. 1:18-cv-00040-RWG (Ct. Int'l Trade Apr. 10, 2018) (consent motion for test case designation and suspension); Acetris Health, LLC v. United States, No. 1:18-cv-00047-RWG (Ct. Int'l Trade Mar. 7, 2018) (complaint regarding CBP's Entecavir Tablets country-of-origin determination).

D. The Current Procurement

1. Solicitation

On March 14, 2018, the VA 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.[10] AR 52-53, 57. The VA provided in the solicitation that the resulting contract would be subject to the Trade Agreements Act. See id. at 81.

To implement the Trade Agreements Act's requirements, the solicitation incorporated by reference the Trade Agreements clause found at FAR 52.225-5, id., and included a Trade Agreements Certificate (as part of the FAR contract clause that sets forth the representations and certifications that each offeror must make), id. at 112. 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 the awardee would be 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 the terms "U.S.-made end product" and "designated country end product" mirror those set forth in FAR part 25). The Trade Agreements Certificate required offerors to certify that "each end product . . . is a U.S.-made or designated country end product, as defined in the" Trade Agreements clause.[11] AR 112.

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[9] 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. See Acetris Health, LLC v. United States, No. 1:18-cv-00040-RWG (Ct. Int'l Trade Apr. 25, 2018) (order granting motion for test case designation and suspension).

[10] 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. AR 57-58.

[11] Offerors were also required, "[f]or statistical purposes only," to "indicate whether the place of manufacture" of their Entecavir Tablets was "predominantly . . . [i]n the United States . . . or . . . "[o]utside the United States." AR 114; see also id. at 105 (defining "place of manufacture" 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").

The VA advised offerors that it intended to award a single firm-fixed-price requirements contract, id. at 121-22, for one base year and four option years, "to the responsible offeror that submit[ted] an offer meeting the solicitation requirements, and [was] the lowest price technically acceptable offer," id. at 122. It further advised offerors, in the Trade Agreements Certificate and elsewhere in the solicitation, that:

> 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 112; accord id. at 56, 123. To aid its FAR part 25 evaluation, the VA directed offerors to include in their proposals an additional certification not required by the FAR, as well as certain country-of-origin information:

> 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.
>
> 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.

Id. at 102. The VA set a March 28, 2018 deadline for submitting proposals. Id. at 52.

2. Questions and Answers

Before the proposal submission deadline, plaintiff sent the VA five questions concerning the solicitation. Id. at 126-27. The VA responded on March 21, 2018. Id. at 124-25. 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?

[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.

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?

[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 [plaintiff's then-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?

[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. (footnote added). Notwithstanding the VA's responses to its questions, plaintiff submitted a proposal in response to the solicitation on March 28, 2018. Id. at 129-202. Two other companies also submitted proposals: [. . .] and Golden State Medical Supply, Inc. ("Golden State"). Id. at 276-348, 422-95.

3. Discussions

The VA initiated written discussions with all three offerors on April 6, 2018, requesting that the offerors submit final proposal revisions addressing specific issues. Id. at 749-54. The VA raised the following issues with all three offerors:

- "Per the solicitation's Scope of Contract . . . , 'The contract effective date shall be no later than 60 days but no earlier than 04/13/2018.' The current contract expires 04/12/2018. If awarded a contract, state when [you] will be able to meet the contract effective date."

- "The Government requests that [you] certify whether the offer[ed] end product meets one of the definitions in FAR 52.225-5 of either 'U.S.-made end product' or 'Designated country end product.'"

- "The Government is requesting price consideration on line items 1 and 2. Your best and final offer should be stated in the Final Proposal Revision."

[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).

Id. at 749-53. In addition, the VA asked plaintiff to address "whether there has been any change to [CBP's] final ruling dated January 30, 2018," id. at 749, and suggested that [. . .] submit a letter of commitment that "state[d] whether or not the end product is [Trade Agreements Act] compliant and disclose[d] the country of origin of the API and the final country of the end product," id. at 751.

In its response to the VA's inquiries, plaintiff (1) asserted that it would be able provide certain quantities of Entecavir Tablets immediately upon award and full contract quantities within [. . .] days of award; (2) stated that the API of its Entecavir Tablets is manufactured in India; (3) certified that its Entecavir Tablets "meet[] the definition of 'U.S.-made end product' set forth in FAR 52.225, notwithstanding the determination by CBP, now on appeal, that the country of origin under its rules is India"; and (4) confirmed that there had been no change to CBP's final determination regarding the Entecavir Tablets. Id. at 757. [. . .], in turn, responded to the VA's inquiries by (1) indicating that it could provide its Entecavir Tablets [. . .] days after award, (2) providing a letter of commitment that did not include the requested country-of-origin information, and (3) certifying that its Entecavir Tablets were Trade Agreements Act compliant. Id. at 762-63. And, Golden State responded to the VA's inquiries by (1) providing an updated letter of commitment that indicated that for its Entecavir Tablets, the API's country of origin is [. . .] and the end product's country of origin is [. . .]; and (2) indicating that it could provide its Entecavir Tablets within sixty days of award. Id. at 768. None of the three offerors changed its proposed prices. Id. at 851-53; see also id. at 132 (indicating that plaintiff offered a price of $[. . .] per bottle for [. . .] Entecavir Tablets), 277 (indicating that [. . .] offered prices of $[. . .] per bottle of the 0.5 mg Entecavir Tablets and $[. . .] per bottle of the 1.0 mg Entecavir Tablets), 425 (indicating that Golden State offered prices of $50.60 per bottle of the 0.5 mg Entecavir Tablets and $53.70 per bottle of the 1.0 mg Entecavir Tablets).

4. Proposal Evaluation and Contract Award

On April 12, 2018, the VA informed plaintiff that it had rejected plaintiff's proposal "because the manufacturing location" of plaintiff's Entecavir Tablets–India–"is not a Trade Agreements Act designated country." Id. at 770. Thereafter, the VA prepared a Price Negotiation Memorandum that contained its source selection decision. Id. at 847-57. In that document, the VA noted that it had received three proposals, all of which it found to be technically acceptable. Id. at 848-49. In describing plaintiff's proposal, the VA noted that the API of plaintiff's Entecavir Tablets was from India, and that "CBP's ruling dated January 30, 2018 stated that [plaintiff's] offered product (also the product on their recently terminated contract) was not considered to be substantially transformed in a [Trade Agreements Act] designated country." Id. at 849. The VA then summarized its discussions with the three offerors. With respect to its discussions with plaintiff, the VA remarked:

> The [. . .] days of products availability is an exception to the solicitation terms, thereby rendering the proposal unacceptable. . . . The CBP decision has been appealed, and the appeal before the [CIT] is pending. The CBP decision is valid, and as a result [plaintiff's] offer will not receive further consideration. Although [plaintiff] was found to be technically acceptable, [its] products are not [Trade

> Agreements Act] compliant. A letter of rejection was sent to [plaintiff] on 04/12/2018. Two other companies submitted technically acceptable offers for [Trade Agreements Act]-compliant products.

Id. at 851. The VA proceeded to evaluate the two remaining proposals. Id. at 853. It noted that [. . .] proposed a total price (base year plus four option years) of $[. . .], and Golden State proposed a total price (base year plus four option years) of $6,465,583.50. Id.; see also id. at 838 (indicating that plaintiff proposed a total price (base year plus four option years) of $[. . .]). It then commented:

> Although [[. . .]'s letter of commitment] did not state the country of origin[of the] API and the final country of the end product as requested in the Final Proposal Revision, the Contract Specialist made the determination to not re-open discussions. This determination was made after comparing the prices of both technically acceptable offers. Re-opening discussions with both offerors in order to obtain this clarification from [. . .] would constitute an undu[e] delay in the procurement, as [. . .] offer was approximately $[. . .] higher than that of the next best offeror's prices.

Id.; see also id. at 847 (noting that the VA's estimated price for the contract was $20,659,900, which was based on the prices in its contract with plaintiff), 853 (noting that Golden State's proposed price of $6,465,583 would result in cost savings of $32,422,899 over the prices it would obtain on the open market). In short, because Golden State submitted the lowest-priced, technically acceptable proposal, the VA, upon concluding that Golden State was a responsible offeror, recommended that Golden State be awarded the contract. Id. at 856. Indeed, on May 9, 2018, the VA notified Golden State that it had been awarded the contract. Id. at 860; see also id. at 859 (indicating that [. . .] was notified that it was an unsuccessful offeror on May 9, 2018), 861-932 (containing the executed contract). The effective date of the contract was July 8, 2018. Id. at 860-61.

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 improperly construed the Trade Agreements clause as (1) prohibiting the purchase of plaintiff's Entecavir Tablets unless the VA determined 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 relied 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 [the] 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 amended its complaint only to clarify its allegation of standing, Am. Compl. ¶ 15; it has not sought to supplement its complaint with allegations pertaining to the VA's rejection of its proposal for the Entecavir Tablets contract or the VA's award of the Entecavir Tablets contract to Golden State, both of 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 bid protest pursuant to Rules 12(b)(1) and 12(b)(6) of the Rules of the United States Court of Federal Claims ("RCFC"). The court denied plaintiff's motion in a March 28, 2018 Opinion and Order and then denied defendant's motion in a May 8, 2018 Opinion and Order. Thereafter, the court adopted a schedule proposed by the parties for the final resolution of the bid protest. Defendant moved to dismiss plaintiff's bid protest for lack of standing, plaintiff moved to supplement the administrative record, and both parties moved for judgment on the administrative record. Briefing concluded on June 29, 2018, and the court heard argument on July 9, 2018. The court is now prepared to rule.

III. DEFENDANT'S MOTION TO DISMISS FOR LACK OF STANDING

A. Legal Standard

As a threshold matter, defendant moves to dismiss plaintiff's bid protest for lack of standing. "[T]he question of standing is whether the litigant is entitled to have the court decide the merits of the dispute or of particular issues." Warth v. Seldin, 422 U.S. 490, 498 (1975). In bid protests, standing "is framed by 28 U.S.C. § 1491(b)(1), which . . . imposes more stringent standing requirements than Article III." Weeks Marine, Inc. v. United States, 575 F.3d 1352, 1359 (Fed. Cir. 2009). Under §1491(b)(1), bid protests may only be brought by "interested parties." Interested parties are those "actual or prospective bidders or offerors whose direct economic interest would be affected by the award of the contract or by failure to award the contract." Am. Fed'n of Gov't Emps. v. United States, 258 F.3d 1294, 1302 (Fed. Cir. 2001) (citing 31 U.S.C. § 3551(2)(A) (2000)). Therefore, to have standing, a protestor must establish that it (1) is an actual or prospective offeror and (2) possesses a direct economic interest in the award of (or failure to award) the contract. CGI Fed. Inc. v. United States, 779 F.3d 1346, 1348 (Fed. Cir. 2015); see also Lujan v. Defenders of Wildlife, 504 U.S. 555, 561 (1992) (noting that the burden of establishing standing is on "[t]he party invoking federal jurisdiction"). In other words, a protestor must show that it is prejudiced by the procuring agency's conduct.[13] See Diaz v. United States, 853 F.3d 1355, 1358 (Fed. Cir. 2017) (explaining that to demonstrate a "direct economic interest," a protestor must "'show that it was prejudiced by a significant error in the procurement process.'" (quoting Labatt Food Serv., Inc. v. United States, 577 F.3d 1375, 1378

[13] A protestor must also demonstrate prejudice to succeed on the merits of its protest. See Data Gen. Corp. v. Johnson, 78 F.3d 1556, 1562 (Fed. Cir. 1996) ("[T]o prevail in a protest the protester must show not only a significant error in the procurement process, but also that the error prejudiced it.").

(Fed. Cir. 2009))); Info. Tech. & Applications Corp. v. United States, 316 F.3d 1312, 1319 (Fed. Cir. 2003) ("[B]ecause the question of prejudice goes directly to the question of standing, the prejudice issue must be reached before addressing the merits."); 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.").

B. Plaintiff Has Standing to Pursue Its Preaward Protest Claims

There is no question that plaintiff qualifies as an actual or prospective offeror with respect to the Entecavir Tablets procurement–plaintiff was a prospective offeror when the VA issued the solicitation and then became an actual offeror when it submitted its proposal. Rather, the parties' dispute focuses on whether plaintiff has a direct economic interest in the procurement. "Generally, to prove the existence of a direct economic interest, a [protestor] must show that it had a 'substantial chance' of winning the contract." Orion Tech., Inc. v. United States, 704 F.3d 1344, 1348 (Fed. Cir. 2013) (quoting Rex Serv. Corp. v. United States, 448 F.3d 1305, 1307 (Fed. Cir. 2006)). "An exception to that standard is when a prospective bidder challenges the terms of the solicitation itself, prior to actually submitting a bid. In that circumstance, the protestor can establish standing by demonstrating that it suffered a 'non-trivial competitive injury which can be redressed by judicial relief.'" Id. (quoting Weeks Marine, Inc., 575 F.3d at 1361).

In its motion to dismiss, defendant argues that plaintiff cannot demonstrate that it was prejudiced by the VA's conduct because plaintiff did not submit the lowest-priced proposal,[14]

[14] Defendant also advances an argument that appears contrary to the evidence in the administrative record. Specifically, defendant contends that the VA would have found plaintiff to be a nonresponsible offeror because plaintiff "represented in its final proposal revision that it was unable to comply with the solicitation's stated delivery schedule." Cross-Mot. 9. The solicitation provision upon which defendant relies– "1.4 Contract Effective Date" –provides:

> The contract effective date shall be 60 days but no earlier than 04/13/2018. Before the contract effective date, the [Pharmaceutical Prime Vendors] will begin placing orders with the contractor for delivery . . . . The contractor shall ensure that sufficient inventory of contract items awarded under this solicitation is available . . . to permit the [Pharmaceutical Prime Vendors] to begin timely distribution of Government orders by the contract effective date. Payment terms, time and place of delivery to [Pharmaceutical Prime Vendor] distribution centers and other business-to-business agreement terms shall be agreed upon between the [Pharmaceutical Prime Vendor] contractors and the contractor awarded a contract from this solicitation.

AR 57; accord id. at 74 ("Delivery order requirements such as product quantities, time and place of delivery, and method of delivery for product(s) awarded on resultant contract(s) will be determined between the awarded contractor(s) and Government Prime Vendor contractors."), 121 (indicating that the VA "contemplate[d] an award of a Firm Fixed Price, Requirements contract," which, pursuant to FAR 16.501-2(a), is a type of indefinite-delivery contract that "may be used to acquire supplies and/or services when the exact times and/or exact quantities of future

and therefore had no chance to be awarded the contract. In response, plaintiff contends that defendant incorrectly applies the "substantial chance" standard to its preaward allegations, and that under the proper standard, it has suffered a nontrivial competitive injury from the VA's conduct that can be redressed by the court. In its reply, defendant expands on the position it advanced in its motion, arguing that plaintiff has never had standing to pursue its claims in this court, even before it submitted a proposal. The court finds no merit in either of defendant's arguments.

With respect to defendant's first argument, the court notes, as a preliminary matter, that it is obliged to assess standing based on the allegations in the complaint. See Gwaltney of Smithfield, Ltd. v. Chesapeake Bay Found., Inc., 484 U.S. 49, 65 (1987) ("[A]llegations of injury are sufficient to invoke the jurisdiction of a court. . . . [A] suit will not be dismissed for lack of standing if there are sufficient 'allegations of fact'–not proof–in the complaint or supporting affidavits." (quoting Warth, 422 U.S. at 501)); Warth, 422 U.S. at 501 ("For purposes of ruling on a motion to dismiss for want of standing, both the trial and reviewing courts must accept as true all material allegations of the complaint, and must construe the complaint in favor of the complaining party."); Tech Sys., Inc. v. United States, 98 Fed. Cl. 228, 244 (2011) ("[Prejudice] is . . . assessed based on the cumulative impact of the well-pled allegations of agency error (which are assumed true at this juncture of proceedings)."); see also Distributed Sols., Inc. v. United States, 539 F.3d 1340, 1343 (Fed. Cir. 2008) (explaining that the allegations in the complaint confirmed that the protestors were challenging the procuring agency's decision to outsource the award of subcontracts, and not the award of the subcontracts by the outside entity); cf. CGI Fed. Inc., 779 F.3d at 1350 (rejecting the government's contention that the protestor's "prospective bidder status dissolved on the day bidding ended in the middle of its [Government Accountability Office] protest"). The complaint in this bid protest contains no allegations concerning plaintiff's submission of a proposal, the VA's evaluation of proposals, or the VA's award of the contract to Golden State (nor could it have, given that those events occurred after plaintiff filed its complaint).

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deliveries are not known at the time of contract award"). This provision does not set a delivery schedule or require that offerors be able to supply full contract quantities by the contract effective date. See also id. at 35 (noting, in the VA's acquisition plan, that "[t]here are no specific scheduling constraints for this procurement; this will be an indefinite delivery type contract and just-in-time delivery will be provided through the . . . Pharmaceutical Prime Vendor contractors"). Rather, it only (1) advises offerors when they should be prepared to begin supplying Entecavir Tablets under the contract and (2) requires offerors to ensure that they can meet demand as of that date. In its final proposal revision, plaintiff indicated that it would be able to supply [. . .] bottles of the 0.5 mg Entecavir Tablets and [. . .] bottles of the 1.0 mg Entecavir Tablets immediately upon award, and "full contract quantities [. . .] days after award notification." Id. at 757; see also id. at 53 (reflecting that offerors were directed, for the base year of the contract, to propose prices for 19,308 bottles of the 0.5 mg Entecavir Tablets and 5887 bottles of the 1.0 mg Entecavir Tablets–these quantities were classified elsewhere in the solicitation as "estimated quantities"). Plaintiff did not represent that it could not satisfy orders for Entecavir Tablets by the contract effective date.

Based on the allegations set forth in plaintiff's complaint, this protest falls squarely within the factual scenario presented in Weeks Marine, Inc. In that case, the United States Court of Appeals for the Federal Circuit ("Federal Circuit") observed:

> [I]n a case such as this, where a prospective bidder/offeror is challenging a solicitation in the pre-award context . . . , it is difficult for a prospective bidder/offeror to make the showing of prejudice that we have required in post-award bid protest cases. The reason of course is that, in a case such as this, there have been neither bids/offers, nor a contract award. Hence, there is no factual foundation for a "but for" prejudice analysis.

575 F.3d at 1361 (citation omitted). Several years later, in Orion Technology, Inc., the Federal Circuit reiterated that the "substantial chance" test does not apply "when a prospective bidder challenges the terms of the solicitation itself, prior to actually submitting a bid." 448 F.3d at 1307. Certainly, as defendant notes, there are cases in which the "substantial chance" test has been applied in preaward bid protests. See, e.g., CS-360, LLC v. United States, 94 Fed. Cl. 488, 495 (2010); DMS All-Star Joint Venture v. United States, 90 Fed. Cl. 653, 661 (2010); Med. Dev. Int'l, Inc. v. United States, 89 Fed. Cl. 691, 701 (2009). However, in all of those cases, the protestors challenged either the evaluation of bids/proposals or the award of the contract to another bidder/offeror, and the protests were filed after the submission of bids/proposals but before the procuring agency awarded the contract. See CS-360, LLC, 94 Fed. Cl. at 493-94 (bid submitted June 17, 2010, bid protest challenging rejection of bid filed July 13, 2010, contract award postponed until September 7, 2010); DMS All-Star Joint Venture, 90 Fed. Cl. at 659-60 (final revised proposals due February 3, 2009, bid protest challenging price realism analysis and proposed award filed October 28, 2009); Med. Dev. Int'l, Inc., 89 Fed. Cl. at 701 ("[The protestor] lodged its protest before the contract was awarded, but after the competitive range had been determined. . . . The factual record in this case is fully developed regarding the disputed issue: the competitive range determination."); see also Magnum Opus Techs., Inc. v. United States, 94 Fed. Cl. 512, 530 n.13 (2010) ("Occasionally pre-award cases arise in which proposals have been submitted and evaluated such that the competition can be assessed using a more stringent prejudice standard."); cf. Golden Mfg. Co. v. United States, 107 Fed. Cl. 264, 273 (2012) (holding, where the procuring agency amended the solicitation after it had eliminated the protestor's proposal from the competition, that the protestor's standing to contend that the amendment rendered the entire evaluation process invalid and that a new solicitation was necessary should be assessed under the "nontrivial competitive injury" test). In contrast, plaintiff lodged its protest before it submitted a proposal, and is not challenging the evaluation of proposals or the award of the contract to Golden State. Accordingly, the appropriate test to determine whether plaintiff has standing to pursue its claims is the "nontrivial competitive injury" test.

Defendant's second argument—that plaintiff never had standing to pursue its claims in this court—is equally unconvincing. Specifically, defendant contends that "[a]t the time [plaintiff] filed its original complaint, it could not have suffered any injury, having neither submitted a proposal nor had such a proposal rejected," and that "[t]hroughout the pendency of this protest, [plaintiff] has never been able to demonstrate that the errors it alleges were the cause of any injury it claims to have suffered." Reply 2-3. As an initial matter, it is well settled that a

protestor need not submit a proposal or have a proposal rejected to challenge an aspect of a procurement. See 28 U.S.C. § 1491(b)(1) (2012) (providing that the United States Court of Federal Claims has "jurisdiction to render judgment on an action by an interested party objecting to a solicitation . . . or any alleged violation of a statute or regulation in connection with a procurement or proposed procurement"); CGI Fed. Inc., 779 F.3d at 1348-52 (reflecting that a company that did not submit a bid in response to a solicitation had standing to protest because it was a prospective bidder and had a direct economic interest affected by the award of the contract); Weeks Marine, Inc., 575 F.3d at 1362-63 ("[I]n some cases the injury stemming from a facially illegal solicitation may in and of itself be enough to establish standing; in such a case a bidder should not have to wait until the solicitation is applied unfavorably to establish injury."); Distributed Sols., Inc., 539 F.3d at 1344-45 (reflecting that the contractors that responded to a Request for Information and alleged that they were prepared to submit bids in response to the anticipated solicitation had standing to protest because they were prospective bidders with a direct economic interest in the award of the contract). Indeed, the first prong of the bid protest standing inquiry adopted by the Federal Circuit expressly contemplates the filing of bid protests by prospective bidders and offerors.

Moreover, the allegations set forth in plaintiff's complaint are more than sufficient to establish that it had a direct economic interest in the award of a contract flowing from the Entecavir Tablets solicitation. Plaintiff generally alleges that the VA improperly (1) construed and applied the solicitation's Trade Agreements clause, (2) included a provision in the solicitation that was contrary to the Trade Agreements clause, and (3) relied on CBP's country-of-origin determination rather than independently construing and applying the solicitation's Trade Agreements clause. Plaintiff further alleges that as a result of this conduct, its ability to be awarded the Entecavir Tablets contract was greatly diminished because the VA would not consider its Entecavir Tablets to be U.S.-made end products in accordance with the Trade Agreements clause (it could only be awarded the contract if the VA received no proposals for U.S.-made or eligible Entecavir Tablets). Such an injury is nontrivial and competitive since plaintiff "has a definite economic stake in the solicitation being carried out in accordance with applicable laws and regulations." Weeks Marine, Inc., 575 F.3d at 1362; accord CGI Fed. Inc., 779 F.3d at 1351; see also Distributed Sols., Inc., 539 F.3d at 1344-45 (indicating that the protestors were prospective bidders that had "a direct economic interest in the government action at issue in that they were both deprived of the opportunity to compete" and "lost significant business opportunities amounting to approximately ten million dollars"). Further, such an injury can be redressed by the court through the award of declaratory and injunctive relief. Accordingly, plaintiff has standing to pursue its claims.

IV. PLAINTIFF'S MOTION TO SUPPLEMENT THE ADMINISTRATIVE RECORD

Before addressing the merits of plaintiff's claims, the court must resolve plaintiff's motion to supplement the administrative record. Generally, "the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court." Camp v. Pitts, 411 U.S. 138, 142 (1973). An administrative record typically contains the materials developed and considered by an agency in making a decision subject to judicial review. See id. at 142-43 (remarking that an agency's finding must be "sustainable on the administrative record made" by the agency at the time of its decision); Cubic

Applications, Inc. v. United States, 37 Fed. Cl. 345, 349-50 (1997) ("[T]he primary focus of the court's review should be the materials that were before the agency when it made its final decision."). The administrative record "should be supplemented only if the existing record is insufficient to permit meaningful review consistent with the" applicable standard. Axiom Res. Mgmt., Inc. v. United States, 564 F.3d 1374, 1381 (Fed. Cir. 2009); accord id. at 1380 ("[S]upplementation of the record should be limited to cases in which the 'omission of extra-record evidence precludes effective judicial review.'" (quoting Murakami v. United States, 46 Fed. Cl. 731, 735 (2000), aff'd, 398 F.3d 1342 (Fed. Cir. 2005))).

As set forth in its motion, plaintiff seeks to supplement the administrative record with six documents: (1) search results for Entecavir Tablets from the VA's online Pharmaceutical Catalog; (2) four documents related to, and generated during the pendency of, plaintiff's now-terminated contract to supply Entecavir Tablets to the VA (two cure notices, a cure notice extension letter, and a Contract Disputes Act claim letter); and (3) a declaration memorializing a telephone conversation regarding plaintiff's now-terminated contract. Alternatively, plaintiff requests that the court admit these six documents into the court's record.

With respect to all but the first document, plaintiff contends that the material at issue is relevant to the merits of its claims and that the court would not be able to effectively review its claims without including those documents in the administrative record. The court disagrees. As noted above, plaintiff asserts three claims: that the VA improperly (1) construed and applied the solicitation's Trade Agreements clause, (2) included a provision in the solicitation that was contrary to the Trade Agreements clause, and (3) relied on CBP's country-of-origin determination rather than independently construing and applying the solicitation's Trade Agreements clause. The administrative record, as currently constituted, contains evidence indicating (1) how the VA construed and applied the solicitation's Trade Agreements clause, (2) that the solicitation contained the provision challenged by plaintiff, and (3) that the VA relied upon CBP's country-of-origin determination. These facts are the same as those contained within the documents that plaintiff seeks to add to the administrative record. Thus, there is no need to supplement the administrative record with the documents identified by plaintiff.

With respect to the first document–the VA Pharmaceutical Catalog search results–plaintiff contends that the search results are relevant to assessing the harm it suffered from the VA's conduct. The court is permitted to consider extrarecord evidence in assessing the harm that a party to a bid protest–whether it be the protestor, the procuring agency, or the successful offeror–would suffer from the imposition of, or failure to impose, an injunction:

> Standing apart from evidence supplementing the administrative record . . . are evidentiary submissions that go to the prospective relief sought in this court. The latter relate to an issue wholly within the court's purview. Accordingly, "[i]t is the responsibility of this [c]ourt, not the administrative agency, to provide for factual proceedings directed toward, and to find facts relevant to, irreparability of harms or prejudice to any party or to the public interest through grant or denial of injunctive relief." PGBA, LLC v. United States, 60 Fed. Cl. 567, 568 n.1 (2004). . . . Evidence respecting relief . . . "necessarily would not be before an agency decision-maker effecting a procurement decision such as a source selection

> award, . . . but would necessarily post date and flow from such agency decision." AshBritt, Inc. v. United States, 87 Fed. Cl. 344, 367 (2009). Accordingly, such evidence is admitted, not as a supplement to the administrative record, but as part of this court's record.

PlanetSpace, Inc. v. United States, 90 Fed. Cl. 1, 5 (2009) (alterations in original) (citation omitted); accord CBY Design Builders v. United States, 105 Fed. Cl. 303, 328 n.19 (2012) (remarking that "the issue of prejudice . . . often cannot rest on matters in an administrative record"); E.W., Inc. v. United States, 100 Fed. Cl. 53, 57 (2011) ("[A] bid protester's entitlement to relief may often turn on considerations of injury that spring from the challenged actions, and to that extent could not be reflected in the agency record underlying those actions."). Accordingly, the court will consider the VA Pharmaceutical Catalog search results, to the extent necessary, when considering plaintiff's allegations of prejudice and harm.

In sum, the court denies plaintiff's motion to the extent that plaintiff seeks to supplement the administrative record with documents related to its now-terminated contract to supply the VA with Entecavir Tablets, and grants plaintiff's motion to the extent that plaintiff requests that the court entertain extrarecord evidence of the harm it would suffer from the VA's conduct.

V. THE PARTIES' CROSS-MOTIONS FOR JUDGMENT ON THE ADMINISTRATIVE RECORD

Finally, the court turns to the parties' cross-motions for judgment on the administrative record. In ruling on such motions, "the court asks whether, given all the disputed and undisputed facts, a party has met its burden of proof based on the evidence in the record." A & D Fire Prot., Inc. v. United States, 72 Fed. Cl. 126, 131 (2006) (citing Bannum, Inc. v. United States, 404 F.3d 1346, 1356 (Fed. Cir. 2005)). Because the court makes "factual findings . . . from the record evidence," judgment on the administrative record "is properly understood as intending to provide for an expedited trial on the administrative record." Bannum, 404 F.3d at 1356.

A. Legal Standard

The court reviews challenged agency conduct pursuant to the standards set forth in 5 U.S.C. § 706. 28 U.S.C. § 1491(b)(4). Specifically, "the proper standard to be applied in bid protest cases is provided by 5 U.S.C. § 706(2)(A): a reviewing court shall set aside the agency action if it is 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" Banknote Corp. of Am. v. United States, 365 F.3d 1345, 1350 (Fed. Cir. 2004). Under this standard, the court

> may set aside a procurement action if "(1) the procurement official's decision lacked a rational basis; or (2) the procurement procedure involved a violation of regulation or procedure." A court reviews a challenge brought on the first ground "to determine whether the contracting agency provided a coherent and reasonable explanation of its exercise of discretion, and the disappointed bidder bears a heavy burden of showing that the award decision had no rational basis." "When a

> challenge is brought on the second ground, the disappointed bidder must show a clear and prejudicial violation of applicable statutes or regulations."

Centech Grp., Inc. v. United States, 554 F.3d 1029, 1037 (Fed. Cir. 2009) (citations omitted) (quoting Impresa Construzioni Geom. Domenico Garufi v. United States, 238 F.3d 1324, 1332-33 (Fed. Cir. 2001)); accord Advanced Data Concepts, Inc. v. United States, 216 F.3d 1054, 1058 (Fed. Cir. 2000) ("The arbitrary and capricious standard . . . requires a reviewing court to sustain an agency action evincing rational reasoning and consideration of relevant factors.").

In addition to showing "a significant error in the procurement process," a protestor must show "that the error prejudiced it." Data Gen. Corp., 78 F.3d at 1562; see also Bannum, 404 F.3d at 1351 (holding that if the procuring agency's decision lacked a rational basis or was made in violation of the applicable statutes, regulations, or procedures, the court must then "determine, as a factual matter, if the bid protester was prejudiced by that conduct"). In a preaward bid protest, a protestor with standing to protest satisfies the prejudice requirement:

> Given the nature of a protest brought prior to the award of a contract or issuance of a solicitation, there is no meaningful way to further assess the prejudice to the plaintiff after examination of the merits–if the failure to hold a competition was wrongful or there was a material error in the solicitation, then the plaintiff has been wrongfully deprived of the opportunity to fully and fairly compete, which suffices to establish prejudicial injury on the merits.

Magnum Opus Techs., Inc., 94 Fed. Cl. at 531; accord BINL, Inc. v. United States, 106 Fed. Cl. 26, 36 (2012); Distributed Sols., Inc. v. United States, 104 Fed. Cl. 368, 380 (2012).

B. Plaintiff Has Established Prejudicial Agency Error

In its motion for judgment on the administrative record, plaintiff reasserts the three claims set forth in its complaint: that the VA improperly (1) construed and applied the solicitation's Trade Agreements clause, (2) included a provision in the solicitation that was contrary to the Trade Agreements clause, and (3) relied on CBP's country-of-origin determination rather than independently construing and applying the solicitation's Trade Agreements clause. The court addresses each claim in turn.

1. The VA Misconstrued the Trade Agreements Clause as Preventing the Purchase of Domestic End Products

Plaintiff first contends that the VA misconstrues the Trade Agreements clause included in the solicitation as preventing the purchase of products that qualify as domestic end products. Specifically, plaintiff argues, the Trade Agreements clause allows the VA to purchase U.S.-made or designated country end products, and that all domestic end products qualify as U.S.-made end products. Defendant disagrees with plaintiff, asserting that both the text and regulatory history of the relevant FAR provisions (including the Trade Agreements clause) reflect that whether a product is a domestic end product has no bearing on whether the product is a U.S.-made end

product, and that the proper test for determining whether an offered product is a U.S.-made or designated country end product is the Trade Agreements Act's rule of origin.

To resolve the parties' dispute, the court must first determine the proper construction of the Trade Agreements clause. As reflected in Part I, supra, the court finds that plaintiff's construction is the correct one.

The Trade Agreements clause contains the VA's determination "that the WTO GPA and FTAs apply to" its acquisition of Entecavir Tablets, and indicated that the awardee would be required to supply "only U.S.-made or designated country end products" under the contract.[15] FAR 52.225-5(b). The term "U.S.-made end product" is defined as "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 52.225-5(a). In other words, a U.S.-made end product can either be (1) "mined, produced, or manufactured in the United States" or (2) "substantially transformed in the United States . . . ." Id. As reflected by other provisions of the FAR, the former type of product is a domestic end product and the latter type of product is a nondomestic end product. See FAR 25.003; FAR 25.502(b)(2); FAR 25.504-2.[16]

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[15] Defendant relies on Klinge Corp. v. United States, 82 Fed. Cl. 127 (2008), to support its contentions that whether a product is a domestic end product has no bearing on whether the product is a U.S.-made end product, and that the Trade Agreements Act's rule of origin is the proper test to be applied. The court in Klinge Corp. remarked:

> When an acquisition meets the [Trade Agreements Act] threshold, the article to be acquired must be either "wholly the growth, product, or manufacture of [a signatory or designated] country" or, in cases where the article "consists in whole or in part of materials from another country . . . , 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."

Id. at 135 (quoting 19 U.S.C. § 2518(4)(B) (2000)). However, the court made this statement without acknowledging that the solicitation at issue incorporated the United States Department of Defense's trade agreements clause that allowed for the procurement of U.S.-made end products, id. at 128, and that the definition of the term "U.S.-made end product" is broader than the rule of origin because it allows for the procurement of products that are "manufactured in the United States," rather than "wholly" manufactured in the United States.

[16] FAR 25.504-2 provides:

> If the agency gives the same consideration given eligible offers [in other words, offers from a WTO GPA country] to offers of U.S.-made end products that are not domestic offers, it is unnecessary to determine if U.S.-made end products are domestic (large or small business). No further analysis is necessary. Award on the low . . . offer [as between eligible offers and offers of U.S.-made end products].

This conclusion is reinforced by the stated rationale for adding a class of products designated as "U.S.-made end products" to the FAR: allowing the federal government to procure, when a trade agreement applies to a procurement, products that were substantially transformed in the United States in addition to domestic end products and foreign end products. See 63 Fed. Reg. at 51,642 (explaining that the then-current FAR prohibited a contractor from supplying "U.S. made end products that do not qualify as domestic end products"–in other words, products substantially transformed in the United States–when the Trade Agreements Act applied). Indeed, to accept defendant's construction of the FAR would be to prevent the federal government from procuring a class of products–domestic end products–that it has always had the ability to purchase when the Trade Agreements Act applied to the procurement. See FAR 25.402(a)(1) (indicating that the federal government can give eligible products of designated countries "equal consideration with domestic offers"); Int'l Bus. Machines, GSBCA No. 10532-P, 90-2 BCA ¶ 22,824 (explaining that the then-existing Trade Agreements clause allowed for the acquisition of domestic end products but not products substantially transformed in the United States); see also 19 U.S.C. § 2511(a) (allowing the federal government to give equal treatment to eligible products of designated foreign countries and "United States products"). The fact that a trade

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Accord FAR 25.502(b)(2). Defendant argues that this language indicates that the VA, which gives equal consideration to eligible offers and offers of U.S.-made end products, need not inquire into whether an offered product is a domestic end product. Defendant is only partially correct. This language indicates that the VA need not discriminate between types of U.S.-made end products when determining the lowest-priced proposal. However, it does not excuse the VA from allowing offers of both domestic and nondomestic end products in the first instance. Cf. 63 Fed. Reg. at 51,642 (explaining that some procuring agencies "provide an evaluation preference to domestic end products, when such products are competing with other U.S. made end products that do not qualify as domestic end products").

Defendant's reliance on FAR 25.001(c)–which provides that "[t]he test to determine the country of origin for an end product under the Buy American statute . . . is different from the test to determine the country of origin for an end product under the trade agreements" and that "[u]nder the trade agreements, the test to determine country of origin is 'substantial transformation'"–is similarly misplaced. As plaintiff notes, the trade agreements do not prohibit the United States from purchasing its own domestic end products, but instead "only require the United States to determine which foreign products should receive non-discriminatory treatment so as to receive equal consideration with domestic offers . . . ." Reply & Resp. 9. Indeed, FAR 25.001 was included in rewrite of FAR part 25 as "an overview to help readers understand the part," 63 Fed. Reg. at 51,643, and specifically refers to FAR subpart 25.4 for the policies and procedures relating to acquisitions covered by trade agreements, FAR 25.001(b). FAR subpart 25.4, in turn, provides that "[o]ffers of eligible products receive equal consideration with domestic offers," FAR 25.402(a)(1), and that "in acquisitions covered by the WTO GPA, [procuring agencies are to] acquire only U.S.-made or designated country end products," FAR 25.403. And, as noted previously, a U.S.-made end product can be either "manufactured in the United States" or "substantially transformed in the United States . . . ." FAR 52.225-5(a). Thus, defendant takes FAR 25.001(c) out of context.

agreement applies to a procurement does not prevent the federal government from procuring domestically sourced products.

Having determined that the term "U.S.-made end product," as used in the Trade Agreements clause, includes domestic end products, the court must next ascertain whether the VA construed the term in this manner. The primary evidence of the VA's construction of the Trade Agreements clause is in its March 21, 2018 responses to plaintiff's questions concerning the solicitation. Plaintiff asked the VA:

> 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?

AR 125. The VA responded: "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." Id. Moreover, in response to a different question, the VA stated that the Trade Agreements Act's rule of origin is used to determine whether a product qualifies as a U.S.-made end product under the Trade Agreements clause.[17] The VA's responses clearly indicate that the VA did not consider the term "U.S.-made end product" to include domestic end products. Consequently, the VA misconstrued the Trade Agreements clause. The VA's failure to properly construe the Trade Agreements clause was arbitrary, capricious, and contrary to law.

2. The VA Improperly Required Offerors to Certify Compliance With the Trade Agreements Act

Plaintiff next claims that the VA improperly included the following provision in the solicitation:

> 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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[17] This statement is curious, given that the definition of the term "U.S.-made end product" differs from the rule of origin in a significant respect: a U.S.-made end product can be "manufactured in the United States," FAR 25.003; FAR 52.225-5(a), while the rule of origin refers to products that are "wholly the . . . manufacture" of the United States, 19 U.S.C. § 2518(4)(B). The omission of the word "wholly" from the definition of "U.S.-made end product" must be intentional since other definitions in the Trade Agreements clause (of "Free Trade Agreement country end product," "Least developed country end product," and "WTO GPA country end product") all include the word "wholly." See FAR 52.225-5(a). Indeed, if the authors of the FAR wanted to use the rule of origin to determine what products qualify as U.S.-made end products (as defendant argues), they would have ensured that the two definitions were identical.

> 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.

Id. at 102. Plaintiff objects both to the requirement that offerors "certify whether or not the end product offered in response to this solicitation is [Trade Agreements Act] compliant" and the requirement that offerors identify the country of origin for the offered end product's API. Defendant contends that both requirements were proper.

Pursuant to the challenged certification requirement, by directing manufacturers to certify that the offered products were "[Trade Agreements Act] compliant," the VA was directing offerors to affirmatively represent that their Entecavir Tablets were "wholly" manufactured or substantially transformed in the United States or a designated country in accordance with the Trade Agreements Act's rule of origin. This requirement conflicts with other provisions included in the solicitation (and taken directly from the FAR): the Trade Agreements clause and the Trade Agreements Certificate. Specifically, the Trade Agreements Certificate required offerors to certify that "each end product . . . is a U.S.-made or designated country end product, as defined in the" Trade Agreements clause, id. at 112, and the Trade Agreements clause defined the term "U.S.-made end product" as a product "manufactured in the United States" or "substantially transformed in the United States," FAR 52.225-5(a). In other words, there was no requirement that the end product be "wholly" manufactured in the United States. Thus, it was arbitrary and capricious for the VA to require manufacturers to certify that the offered products were "[Trade Agreements Act] compliant."

In contrast, because it was the VA's responsibility to ensure that all of the offered Entecavir Tablets qualified as U.S.-made or designated country end products, see also infra Section V.B.3, the VA was entitled to direct offerors to identify the country of origin of their Entecavir Tablets' APIs. Such information is relevant (even if not sufficient) to determining whether the Entecavir Tablets qualified as U.S.-made end products of a domestic nature (manufactured in the United States), U.S.-made end products of a nondomestic nature (substantially transformed in the United States), or designated country end products. Thus, the VA's request of such information was not arbitrary, capricious, an abuse of discretion, or contrary to law.

3. The VA Was Responsible for Determining, in the First Instance, Whether Plaintiff's Entecavir Tablets Qualified as U.S.-Made End Products

In its third and final claim, plaintiff contends that the VA should have analyzed, for itself, whether plaintiff's Entecavir Tablets qualified as U.S.-made end products, rather than relying on CBP's country-of-origin determination. In response, defendant argues that the VA was entitled to rely on CBP's final determination because CBP had "relevant expertise." Cross-Mot. 26. The court agrees with plaintiff that the VA erred in not assessing whether plaintiff's Entecavir

Tablets qualified as U.S.-made end products under the Trade Agreements clause for three reasons.

First, there can be no question that procuring agencies generally, and contracting officers in particular, are responsible for ensuring compliance with all pertinent laws and regulations when procuring goods and services. See FAR 1.602-1(b) ("No contract shall be entered into unless the contracting officer ensures that all requirements of law, executive orders, regulations, and all other applicable procedures, including clearances and approvals, have been met."). These laws and regulations include the Trade Agreements Act and the FAR. See also Klinge Corp., 82 Fed. Cl. at 135 (explaining that when a procuring agency has reason to believe that an offeror's Trade Agreements Act certification is inaccurate, "the agency has a duty to make reasonable inquiry and satisfy itself that the product offered meets the terms of the [A]ct"). There is no evidence in the administrative record reflecting that the VA assessed whether plaintiff's Entecavir Tablets qualified as U.S.-made end products in accordance with the Trade Agreements clause and FAR part 25 as a whole. Accord Veterans Contracting Grp., Inc. v. United States, 135 Fed. Cl. 610, 618-19 (2017) (holding that the VA's failure to "look beyond the fact of a ruling by [the Small Business Administration] to determine whether it was based on grounds consistent with or contrary to VA's eligibility regulations" was arbitrary and capricious). Rather, as set forth in its March 21, 2018 responses to plaintiff's questions, the VA merely stated its intent to apply the Trade Agreements Act's rule of origin.

Second, the Trade Agreements Act lacks any provision specifying that CBP, and not procuring agencies, is responsible for determining whether an offered product qualifies as a U.S.-made end product under the Trade Agreements clause. The Trade Agreements Act contains a subchapter titled "Government Procurement." See 19 U.S.C. §§ 2511-2518. Section 2511(a) provides that "the President may waive, in whole or in part, with respect to eligible products of any foreign country or instrumentality designated under subsection (b) of this section, . . . the application of any law, regulation, procedure, or practice regarding Government procurement" such that those products are accorded the same treatment as "United States products . . . ." (Emphasis added). Pursuant to § 2515(b)(1), CBP is authorized to determine whether "an article is or would be a product of a foreign country or instrumentality designated pursuant to section 2511(b)," and in making such a determination, is required to apply the rule of origin set forth in § 2518(4)(B). (Emphasis added). And, the rule of origin provides that

> [a]n 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.

Id. § 2518(4)(B). Reading these provisions together, it is apparent that CBP is empowered to determine whether a product is "wholly" manufactured in a foreign country in accordance with the Trade Agreements Act's rule of origin, but is not empowered to determine the threshold question of whether an offered product is a U.S.-made end product (particularly, whether an

offered product is a domestic end product) pursuant to the Trade Agreements clause.[18] Rather, the procuring agency is responsible to make that determination.

Third, defendant has not identified, and the court has not located, any provision in the FAR that directs procuring agencies to refer Trade Agreements clause compliance issues to CBP. In fact, CBP regulations reflect that the only parties that may request a country-of-origin determination from CBP are:

> (a) A foreign manufacturer, producer, or exporter, or a United States importer of merchandise,
>
> (b) A manufacturer, producer, or wholesaler in the United States of a like product,
>
> (c) United States members of a labor organization or other association of workers whose members are employed in the manufacture, production, or wholesale in the United States of a like product, or
>
> (d) A trade or business association a majority of whose members manufacture, produce, or wholesale a like product in the United States.

19 C.F.R. § 177.23. In contrast, the FAR describes other circumstances in which referral to another executive agency is necessary. See, e.g., FAR 19.301-1(b) ("The contracting officer shall accept an offeror's representation in a specific bid or proposal that it is a small business unless (1) another offeror or interested party challenges the concern's small business representation or (2) the contracting officer has a reason to question the representation. Challenges of and questions concerning a specific representation shall be referred to the [Small Business Administration] . . . ."); FAR 22.404-3(c)(2) ("Agencies should promptly submit to the Department of Labor an offeror's request for a project wage determination for a secondary site of the work."); FAR 26.103(a)-(b) ("Contracting officers and prime contractors, acting in good faith, may rely on the representation of an Indian organization or Indian-owned economic enterprise as to its eligibility, unless an interested party challenges its status or the contracting officer has independent reason to question that status. In the event of a challenge . . . , the contracting officer shall refer the matter to the [United States Department of Interior, Bureau of Indian Affairs]."). Similarly, the decision upon which defendant relies to support its contention that the VA was entitled to rely on CBP's expertise–NCL Logistics Co. v. United States–reflects that the procuring agency's referral of an issue to another agency was mandated by regulation. See 109 Fed. Cl. 596, 608 (2013) (indicating that "[t]he Acquisition Instruction requires contracting officers to vet all non-U.S. vendors operating in Afghanistan as directed by [the]

[18] The court does not opine on whether CBP properly applied the rule of origin to plaintiff's Entecavir Tablets, as it has no authority to do so. See 28 U.S.C. § 1581(e) (providing the CIT with "exclusive jurisdiction" to review CBP's final country-of-origin determinations). Indeed, the court need not undertake such an analysis since this bid protest concerns only the VA's conduct. Cf. Klinge Corp., 82 Fed. Cl. at 135-38 (reviewing a procuring agency's application of the Trade Agreements Act's rule of origin).

Fragmented Order," and that "the contracting officer submits all non-U.S. vendors for vetting by" the Joint Contingency Contracting System); id. at 618 ("[T]he contracting officer not only was entitled to rely upon [the vendor vetting assessment] in her nonresponsibility evaluation, she was required to do so.").

In sum, 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.

4. Plaintiff Was Prejudiced by the VA's Errors

The court has concluded that the VA erred in (1) construing the term "U.S.-made end product," as used in the Trade Agreements clause, to not include "domestic end products," as that term is defined in the FAR; (2) requiring manufacturers to certify that the offered products were "[Trade Agreements Act] compliant"; and (3) failing to independently assess whether plaintiff's Entecavir Tablets qualified as U.S.-made end products under the Trade Agreements clause. Plaintiff was prejudiced by these errors because they severely diminished plaintiff's ability to be awarded the Entecavir Tablets contract. See Magnum Opus Techs., Inc., 94 Fed. Cl. at 531; see also Caddell Constr. Co. v. United States, 125 Fed. Cl. 30, 51 (2016) ("[P]rejudice is presumed when the Government acts irrationally. . . . The crux of the inquiry on whether violation of statute or regulation was prejudicial should be focused on the magnitude and materiality of error to the procurement at hand–not on the plaintiff's chances for securing award.").

C. Plaintiff Is Entitled to Declaratory and Injunctive Relief

In accordance with 28 U.S.C. § 1491(b)(2), "[t]o afford relief" in a bid protest, the United States Court of Federal Claims "may award any relief that [it] considers proper, including declaratory and injunctive relief except that any monetary relief shall be limited to bid preparation and proposal costs." Accord Turner Constr. Co. v. United States, 645 F.3d 1377, 1388 (Fed. Cir. 2011) (holding that "once jurisdiction attaches [under 28 U.S.C. § 1491(b)], the Court of Federal Claims has broad equitable powers to fashion an appropriate remedy"). Plaintiff requests both declaratory and injunctive relief. With respect to the latter, plaintiff seeks a permanent injunction prohibiting the VA from (1) construing the term "U.S.-made end product" in the Trade Agreements clause as excluding products manufactured in the United States (in other words, a domestic end product), (2) continuing the Entecavir Tablets procurement using a solicitation that results in the rejection of offers of U.S.-made end products manufactured in the United States because the offeror does not certify Trade Agreements Act compliance, and (3) relying on CBP rather than independently ascertaining whether an offered product is manufactured in the United States pursuant to the definition of the term "U.S.-made end product."

1. Declaratory Relief

As an initial matter, the court concludes that plaintiff is entitled to declaratory relief in accordance with the analysis set forth above. Specifically, the court declares:

- 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.

2. Injunctive Relief

Plaintiff is also entitled to some, but not all, of its requested injunctive relief. In determining whether to award a permanent injunction, the court must consider whether (1) the plaintiff has succeeded on the merits, (2) the plaintiff will suffer irreparable harm if the court withholds injunctive relief, (3) the balance of hardships favors the grant of injunctive relief, and (4) it is in the public interest to grant injunctive relief. PGBA, LLC v. United States, 389 F.3d 1219, 1228-29 (Fed. Cir. 2004). The protestor bears the burden of establishing the factors by a preponderance of the evidence. Lab. Corp. of Am. Holdings v. United States, 116 Fed. Cl. 643, 654 (2014); Textron, Inc. v. United States, 74 Fed. Cl. 277, 287 (2006). None of the four factors, taken individually, is dispositive, and a "weakness of the showing regarding one factor may be overborne by the strength of the others." FMC Corp. v. United States, 3 F.3d 424, 427 (Fed. Cir. 1993).[19] Conversely, "the absence of an adequate showing with regard to any one factor may be sufficient, given the weight or lack of it assigned the other factors, to justify the denial" of injunctive relief. Id. The award of injunctive relief is within the discretion of the court. See Turner Constr. Co., 645 F.3d at 1388 ("We give deference to the Court of Federal Claims' decision to grant or deny injunctive relief, only disturbing its decision if it abused its discretion.").

Because plaintiff has established the existence of significant, prejudicial procurement errors, it has succeeded on the merits of its protest. Thus, the court addresses the remaining factors.

[19] Although FMC Corp. concerns the award of a preliminary injunction, 3 F.3d at 427, "[t]he standard for a preliminary injunction is essentially the same as for a permanent injunction with the exception that the plaintiff must show a likelihood of success on the merits rather than actual success," Amoco Prod. Co. v. Vill. of Gambell, 480 U.S. 531, 546 n.12 (1987).

a. Irreparable Injury

With respect to the irreparable injury factor, "a lost opportunity to compete for a contract on a level playing field" can be sufficient, on its own, to constitute an irreparable injury. Hosp. Klean of Tex., Inc. v. United States, 65 Fed. Cl. 618, 624 (2005), cited in Sys. Application & Techs., Inc. v. United States, 691 F.3d 1374, 1383 (Fed. Cir. 2012). The court has found that plaintiff's ability to compete for the Entecavir Tablets contract was severely diminished by the VA's improper conduct. Nevertheless, with respect to the Entecavir Tablets procurement specifically, plaintiff has not been irreparably injured by the VA's misconduct. The administrative record reflects that plaintiff submitted a proposal in response to the Entecavir Tablets solicitation, but did not offer the lowest price.[20] Thus, even if the VA had properly construed the Trade Agreements clause to permit the purchase of domestic end products and then determined that plaintiff's Entecavir Tablets qualified as domestic end products, plaintiff could not have prevailed in the competition. In short, while the VA's improper conduct diminished plaintiff's ability to compete for the Entecavir Tablets contract, it ultimately would not have prevented the VA from awarding plaintiff the contract. Therefore, requiring the VA to issue a new solicitation and reevaluate proposals would have no benefit for plaintiff.

In contrast, the administrative record reflects that plaintiff's ability to compete for other national contracts that the VA might award would be severely diminished in the same manner it was diminished in the Entecavir Tablets procurement. See AR 941-68 (containing eleven CBP country-of-origin determinations for pharmaceuticals that plaintiff supplied to the VA under national contracts–manufactured by Aurolife in Dayton, New Jersey–in which CBP concluded,

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[20] During oral argument, plaintiff's counsel contended that plaintiff would have offered a lower price for its Entecavir Tablets had its product been considered among those deemed to be Trade Agreements Act compliant. However, plaintiff's complaint contains no such allegations and the administrative record lacks any evidence that plaintiff could or would offer a lower price in such circumstances. Indeed, the administrative record reflects that the price plaintiff actually offered was lower than the price set forth in its now-terminated contract, and that both of those prices are substantially higher than the price offered by Golden State. Compare AR 132 (indicating that plaintiff offered a price of $[. . .] per bottle in response to the solicitation), with id. at 10 (indicating that plaintiff provided the VA with Entecavir Tablets under its now-terminated contract at a price of $164.00 per bottle), and id. at 862 (indicating that Golden State will be providing the VA with Entecavir Tablets for either $50.60 or $53.70 per bottle). Attorney argument is insufficient to establish an irreparable injury. See, e.g., Intelligent Waves, LLC v. United States, 135 Fed. Cl. 299, 314 (2017) (noting that the protestors, rather than submitting evidence in support of their claims of irreparable injury, relied on the averments of counsel, and holding that neither protestor "provided the court with the evidence necessary to carry its burden"); Totolo/King v. United States, 87 Fed. Cl. 680, 693 (2009) ("Nor can a court evaluate the parties' factual showings regarding the three equitable findings for injunctive relief without accepting post-final-agency-action evidentiary submissions."), appeal dismissed and remanded sub nom. Totolo/King Joint Venture v. United States, 431 F. App'x 895 (Fed. Cir. 2011) (per curiam); Ashbritt, Inc. v. United States, 87 Fed. Cl. 344, 367 (2009) (holding that evidence "pertaining to . . . the factors governing injunctive relief . . . is crucial to assess whether relief is warranted").

pursuant to the Trade Agreements Act's rule of origin, that the country of origin of each pharmaceutical was India); see also KWR Constr., Inc. v. United States, 124 Fed. Cl. 345, 362 (2015) (agreeing that "the lost opportunity to compete on future task orders and other contracts [would] cause irreparable harm" to the protestor); Miles Constr., LLC v. United States, 108 Fed. Cl. 792, 806 (2013) ("The real harm suffered by [the protestor] is the denial of the opportunity to compete for the Solicitation award and for future [service-disabled, veteran-owned small business] set-aside contracts. Denial of the opportunity to compete for a contract can constitute irreparable harm."). Thus, with respect to plaintiff's request for a permanent injunction prohibiting the VA from (1) 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 (2) 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," the court finds that plaintiff has been irreparably injured.

b. Balance of Harms

In addition to considering whether a protestor would suffer an irreparable injury absent a permanent injunction, "the court must weigh the irreparable harm plaintiff would suffer without an injunction against the harm an injunction would inflict on defendant . . . ." Progressive Indus., Inc. v. United States, 129 Fed. Cl. 457, 485 (2016). Defendant offers no evidence regarding the harm that the VA would suffer if it were prohibited from (1) 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 (2) 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." Indeed, the VA will likely benefit from properly, and independently, construing the Trade Agreements clause in future procurements because it would be able to entertain more, and potentially lower-priced, offers (in other words, offers it would have rejected previously for not being "Trade Agreements Act compliant")–competition would be enhanced. Thus, the balance of harms tilts in plaintiff's favor.

c. Public Interest

Finally, when "employing the extraordinary remedy of injunction," a court "should pay particular regard for the public consequences" of doing so. Weinberger v. Romero-Barcelo, 456 U.S. 305, 312 (1982). There is no dispute that "[t]here is an overriding public interest in preserving the integrity of the procurement process by requiring the Government to follow its procurement regulations." Bona Fide Conglomerate, Inc. v. United States, 96 Fed. Cl. 233, 242 (2010). Although "there is a countervailing public interest in minimizing disruption" to the procuring agency, Heritage of Am., LLC v. United States, 77 Fed. Cl. 66, 80 (2007), defendant has not explained how the VA would be disrupted by properly, and independently, construing the Trade Agreements clause in future procurements. Thus, the public interest favors the award of a permanent injunction.

d. Summary

In addition to prevailing on the merits of its protest, plaintiff has established that it will suffer some irreparable harm if the court withholds injunctive relief, that the balance of harms tips in its favor, and that an award of injunctive relief is in the public interest. Thus, an award of a permanent injunction is warranted.

VI. CONCLUSION

For the reasons set forth above, the court **DENIES** defendant's motion to dismiss on standing grounds, **GRANTS IN PART** and **DENIES IN PART** plaintiff's motion to supplement the administrative record, and **GRANTS IN PART** and **DENIES IN PART** the parties' cross-motions for judgment on the administrative record.[21] Plaintiff is entitled to declaratory and injunctive relief. Specifically, the 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."

The clerk is directed to enter judgment accordingly.

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[21] Additionally, the court **GRANTS** defendant's May 18, 2018 motion for leave to file a declaration. Plaintiff did not file a response in opposition to defendant's motion and, in fact, relied on the declaration attached to motion in its motion for judgment on the administrative record.

The court has filed this ruling under seal. The parties shall confer to determine agreed-to proposed redactions. Then, by **no later than Wednesday, July 18, 2018**, the parties shall file a joint status report indicating their agreement with the proposed redactions, **attaching a copy of those pages of the court's ruling containing proposed redactions, with all proposed redactions clearly indicated**.

Further, the court reminds the parties of their obligation under paragraph 12 of the protective order filed on May 10, 2018, to file redacted versions of protected documents for the public record. If the parties have not already filed redacted versions of their motions and supporting briefs, they shall file a joint status report by **no later than Wednesday, August 1, 2018**, explaining the reason for the delay.

IT IS SO ORDERED.

s/ Margaret M. Sweeney
MARGARET M. SWEENEY
Judge