In the United States Court of Federal Claims

No. 18-433C
(Filed: March 28, 2018)

ACETRIS HEALTH, LLC,	*	Preaward Bid Protest; Motion for a Temporary Restraining Order and a Preliminary Injunction; Contract to Provide Entecavir Tablets; Procuring Agency Interpretation of Solicitation's Trade Agreements Clause; Country-of-Origin Determination; Exclusive Jurisdiction of the United States Court of International Trade
Plaintiff,	*	
v.	*	
THE UNITED STATES,	*	
Defendant.	*	

Stephen E. Ruscus, Washington, DC, for plaintiff.

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

OPINION AND ORDER

SWEENEY, Judge

In this preaward bid protest, filed on March 23, 2018, plaintiff Acetris Health, LLC challenges the United States Department of Veterans Affairs' ("VA") interpretation of the Trade Agreements clause–section 52.225-5 of the Federal Acquisition Regulation ("FAR")–included in the VA's solicitation to purchase Entecavir Tablets, one of the few medications approved by the United States Food and Drug Administration to treat chronic hepatitis B.[1] Plaintiff contends that under the VA's erroneous interpretation of the clause, the VA would not accept the Entecavir Tablets that plaintiff supplies to the VA under the incumbent contract.

Given the March 28, 2018 deadline for submitting proposals under the solicitation, plaintiff filed, along with its complaint, a motion for a temporary restraining order and a preliminary injunction. In that motion, plaintiff seeks to enjoin the VA from proceeding with the procurement using its current interpretation of the Trade Agreements clause.[2] Because defendant

[1] The contract resulting from the solicitation would provide a source of Entecavir for the VA, the United States Department of Defense, the Federal Bureau of Prisons, and the Indian Health Service.

[2] Specifically, plaintiff seeks to enjoin the VA from (1) "interpreting the [Trade Agreements] Clause of the Solicitation as prohibiting purchase of U.S.-made products

represented to the court that the VA would not agree to stay the proposal submission deadline or otherwise delay the procurement, it is necessary for the court to rule on plaintiff's motion. Defendant filed a combined motion to dismiss and response to plaintiff's motion on March 27, 2018, and the court heard argument on March 28, 2018.

I. LEGAL STANDARD

The United States Court of Federal Claims has the authority to award injunctive relief pursuant to 28 U.S.C. § 1491(b)(2), and is guided in making such an award by Rule 65 of the Rules of the United States Court of Federal Claims ("RCFC"). "[T]he factors considered in ruling on a temporary restraining order mirror those on motions for a preliminary injunction . . . ." 11A Charles A. Wright et al., Federal Practice and Procedure § 2951 (3d ed. 2013). In fact, when, as here, a party seeks both a temporary restraining order and a preliminary injunction, the opposing party has notice of the application for a temporary restraining order, and the court conducts an adversarial hearing, any temporary restraining order that issues pursuant to RCFC 65(b) is akin to a preliminary injunction. See id. Thus, in ruling on plaintiff's motion, the court will consider whether (1) plaintiff is likely to succeed on the merits; (2) 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. U.S. Ass'n of Imps. of Textiles & Apparel v. United States, 413 F.3d 1344, 1346 (Fed. Cir. 2005); PGBA, LLC v. United States, 389 F.3d 1219, 1228-29 (Fed. Cir. 2004); accord Winter v. Nat. Res. Def. Council, Inc., 555 U.S. 7, 20 (2008). 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). Conversely, "the absence of any one factor may be sufficient" to deny preliminary injunctive relief. Id.

Ultimately, preliminary injunctive relief is an extraordinary and drastic remedy. Id.; Mazurek v. Armstrong, 520 U.S. 968, 972 (1997) (per curiam). Nevertheless, the decision to award such relief is within the discretion of the court. FMC Corp., 3 F.3d at 427. "When injunctive relief is warranted, it will only be issued upon a showing by a preponderance of the admissible evidence." Textron, Inc. v. United States, 74 Fed. Cl. 277, 287 (2006).

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manufactured in the U.S., including [plaintiff's] Entecavir Tablets"; (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," and (3) "relying solely on [United States Customs and Border Protection ("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." Compl. 24-25.

II. DISCUSSION

A. Likelihood of Success on the Merits

To prevail on its motion for preliminary injunctive relief, plaintiff must establish that it is likely to succeed on the merits of its bid protest. Plaintiff asserts three claims in its complaint. Its first claim concerns the VA's interpretation of the Trade Agreements clause. The clause requires the contract awardee to "deliver . . . only U.S.-made or designated country end products," and defines a "U.S.-made end product" as "an article that is . . . manufactured in the United States or that is substantially transformed in the United States." FAR 52.225-5(b). According to plaintiff, the VA improperly interprets the Trade Agreements clause to prohibit the purchase of its Entecavir Tablets, which, plaintiff asserts, are manufactured in the United States. Plaintiff's second claim concerns the following solicitation provision: "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." Solicitation 51. Plaintiff contends that this provision improperly restricts offerors to proposing products from Trade Agreements Act countries, thereby precluding offerors from proposing products manufactured in the United States–a non-Trade Agreements Act country. In its third claim, plaintiff alleges that the VA is improperly deferring to CBP to interpret the Trade Agreements clause, and instead should make its own determination regarding whether a product is "manufactured in the United States" such that it qualifies as a "U.S.-made end product."

As an initial matter, the court notes that its bid protest jurisdiction is limited to resolving disputes "in connection with a procurement or a proposed procurement," 28 U.S.C. § 1491(b)(1) (2012), and does not extend to the resolution of disputes regarding the administration of existing or prior contracts, see, e.g., Coast Prof'l, Inc. v. United States, 828 F.3d 1349, 1355 (Fed. Cir. 2016); Gov't Tech. Servs. LLC v. United States, 90 Fed. Cl. 522, 527 (2009) ("The Federal Circuit has made it crystal clear that the [Contract Disputes Act of 1978] is the 'exclusive mechanism' for the resolution of disputes arising, as here, in contract management."). Here, the basis for a portion–if not the entirety–of plaintiff's first and third claims is the events that occurred during the VA's administration of the existing Entecavir Tablets contract. During its administration of that contract, which is ongoing,[3] the VA questioned whether the Entecavir Tablets supplied by plaintiff complied with the contract's requirements, requested that plaintiff seek a determination from CBP regarding the country of origin of its Entecavir Tablets, received CBP's determination that the country of origin of plaintiff's Entecavir Tablets was India, and relied on that country-of-origin determination in advising plaintiff that it would initiate default termination proceedings if plaintiff did not obtain another source of Entecavir Tablets. None of these actions can be challenged in this bid protest. Moreover, plaintiff has challenged CBP's country-of-origin determination at the United States Court of International Trade and, as defendant notes, that court possesses exclusive jurisdiction to entertain challenges to such

[3] The initial term of the contract expires on April 12, 2018.

determinations by CBP.[4] 28 U.S.C. § 1581(e) ("The Court of International Trade shall have exclusive jurisdiction of any civil action commenced to review any final determination . . . under section 305(b)(1) of the Trade Agreements Act of 1979[, which is codified at 19 U.S.C. § 2515(b)(1)]."). Plaintiff may not use this bid protest as a back door to challenge CBP's conclusion–adopted by the VA–that plaintiff's Entecavir Tablets were not manufactured in the United States.[5] In short, the court finds it likely that it lacks jurisdiction under 28 U.S.C. § 1491(b)(1) to consider plaintiff's first and third claims.

In contrast, plaintiff's second claim–that a provision in the solicitation improperly restricts offerors to proposing products from Trade Agreements Act countries and precludes offerors from proposing products manufactured in the United States–may be viable. In essence, plaintiff is arguing that the provision at issue conflicts with the solicitation's Trade Agreements clause and Trade Agreements Certificate, both of which allow for the provision of "U.S.-made end products." Alleged patent ambiguities within a solicitation are properly raised in a preaward bid protest. See Per Aarsleff A/S v. United States, 829 F.3d 1303, 1315 (Fed. Cir. 2016) ("A patent defect triggers the obligation to challenge the solicitation language and failure to do so generally constitutes waiver."); Blue & Gold Fleet, L.P. v. United States, 492 F.3d 1308, 1313 (Fed. Cir. 2007) ("[A] party who has the opportunity to object to the terms of a government solicitation containing a patent error and fails to do so prior to the close of the bidding process

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[4] During oral argument, the court asked the parties whether 28 U.S.C. § 1500 would preclude it from entertaining plaintiff's claims. Plaintiff responded that its claims before the United States Court of International Trade were different from its claims in this court. Defendant responded that 28 U.S.C. § 1500 might be implicated in this case, but that it could not be certain without further research. The parties shall address the applicability of 28 U.S.C. § 1500 in subsequent briefing.

[5] In its country-of-origin determination, CBP provided:

> In addition, you asked 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 [FAR 25.003], and implemented in [FAR] 52.225-5. As stated in 19 C.F.R. § 177.21, subpart B [of 19 C.F.R. part 177] 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 (see above) 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.

Notice of Issuance of Final Determinations Concerning Certain Pharmaceutical Products, 83 Fed. Reg. 5118, 5133 (Feb. 5, 2018).

waives its ability to raise the same objection in a bid protest action in the Court of Federal Claims.").

The provision challenged by plaintiff as inconsistent with the solicitations Trade Agreements clause and Trade Agreements Certificate requires an offeror to certify that its proposed "end product" is "[Trade Agreements Act] compliant." Solicitation 51. Presumably, to determine Trade Agreements Act compliance, one must look at the provisions of the Trade Agreements Act, 19 U.S.C. ch. 13 (2012), and its implementing regulations. Particularly relevant here are the regulations set forth in FAR subpart 25.4. FAR 25.402, which applies to the procurement at issue in this bid protest,[6] indicates that the President, through his or her authorized representative, has waived "the Buy American statute and other discriminatory provisions for eligible products from countries that have signed an international trade agreement with the United States, or that meet certain other criteria," meaning that "[o]ffers of eligible products receive equal consideration with domestic offers." FAR 25.402(a)(1); see also FAR 25.003 (explaining that an "eligible product" is "a foreign end product," and that a "foreign end product" is "an end product other than a domestic end product"). The regulation that concerns the specific international trade agreements referenced in the solicitation at issue, FAR 25.403, contains a provision indicating that 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). In other words, the description of the products deemed acceptable in the regulations implementing the Trade Agreements Act mirrors the description of the products deemed acceptable in the solicitation's Trade Agreements clause and Trade Agreements Certificate. Thus, Trade Agreements Act compliance–as required by the provision challenged by plaintiff–does not appear to constitute a requirement that conflicts with the Trade Agreements clause or the Trade Agreements Certificate. Because there is no apparent ambiguity in the solicitation, plaintiff is unlikely to succeed on the merits of its second claim.

In sum, plaintiff is unlikely to succeed on the merits of any of its claims.

B. Irreparable Injury

Next, with respect to the irreparable injury factor, a protestor "must show that without a preliminary injunction it will suffer irreparable harm before a decision can be rendered on the merits." Akal Sec., Inc. v. United States, 87 Fed. Cl. 311, 319 (2009); accord IBM Corp. v. United States, 118 Fed. Cl. 677, 683-84 (2014). Plaintiff argues that in the absence of an award of preliminary injunctive relief, it will either be foreclosed from offering its "U.S.-made end product" in response to the solicitation, or be subject to competition from offerors proposing noncompliant products, resulting in the loss of an opportunity to fairly compete for the contract. This court has recognized that a lost opportunity to compete for a contract–and the attendant inability to obtain the profits expected from the contract–can constitute irreparable injury. See,

[6] See FAR 25.400(a); FAR 25.402(b); FAR 52.225-5(b).

e.g., Akal Sec., 87 Fed. Cl. at 319; Heritage of Am., LLC v. United States, 77 Fed. Cl. 66, 78 (2007); Overstreet Elec. Co. v. United States, 47 Fed. Cl. 728, 743 (2000). Thus, plaintiff has established this factor.[7]

C. Balance of Harms

In addition to considering whether a protestor would suffer an irreparable injury absent an award of preliminary injunctive relief, "[t]he court must balance the harm plaintiff would suffer without preliminary relief against the harm that preliminary relief would inflict on defendant . . . . Generally, if the balance tips in favor of defendant, a preliminary injunction is not appropriate." Akal Sec., Inc., 87 Fed. Cl. at 320 (citation omitted); accord Reilly's Wholesale Produce v. United States, 73 Fed. Cl. 705, 715 (2006). Defendant, relying on the declaration of a contracting official involved in the Entecavir Tablets procurement, contends that an award of preliminary injunctive relief would harm the government because it would likely create a gap in the acquisition of Entecavir Tablets under a national contract, and a national contract is advantageous because it would allow for the acquisition of a consistent product at low prices. See also Moreno Decl. ¶¶ 6-10 (describing the significant cost savings provided by a national contract and the likely adverse consequences to patient health that would arise from the VA being unable to provide patients with a consistent, standardized medication). The harms described by defendant, especially the adverse effects to patient health that might result from dispensing a new Entecavir Tablet, outweigh the harm described by plaintiff. Thus, plaintiff has not established this factor.

D. 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 "the public interest in honest, open, and fair competition in the procurement process is compromised whenever an agency abuses its discretion in evaluating a contractor's bid." Overstreet Elec., 47 Fed. Cl. at 744; accord Bona Fide Conglomerate, Inc. v. United States, 96 Fed. Cl. 233, 242 (2010) (noting the "overriding public interest in preserving the integrity of the procurement process"). "However 'there is a countervailing public interest in minimizing disruption [to the agency].'" Akal Sec., Inc., 87 Fed. Cl. at 321 (quoting Heritage of Am., LLC, 77 Fed. Cl. at 78); accord Aero Corp., S.A. v. United States, 38 Fed. Cl. 237, 242 (1997) ("[A] procuring agency should be able to conduct procurements without excessive judicial infringement upon the agency's discretion."). It does not appear that the solicitation contains a patent ambiguity that, left unaddressed, would compromise the procurement. Further, as described above, an award of preliminary injunctive

[7] The court recognizes that plaintiff may suffer additional harm because the issues raised in this protest are also implicated in some of its other pharmaceutical contracts with the VA. However, the court must limit its analysis to only those injuries that plaintiff would incur from the failure to obtain preliminary injunctive relief in this bid protest.

relief would cause a harmful disruption at the VA and for the patients who obtain Entecavir Tablets through the VA's national contract. Thus, plaintiff has not established that the public interest would best be served by such relief.

III. CONCLUSION

Plaintiff has failed to establish that it is likely to succeed on the merits of its claims, that the balance of harms tips in its favor, or that an award of preliminary injunctive relief is in the public interest. Accordingly, the court **DENIES** plaintiff's motion for a temporary restraining order and a preliminary injunction. By **no later than Friday, April 6, 2018**, the parties shall file a joint status report suggesting a schedule for further proceedings.

IT IS SO ORDERED.

s/ Margaret M. Sweeney
MARGARET M. SWEENEY
Judge