## IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA Alexandria Division

COMBAT MEDICAL, LLC, Plaintiff, v.	)	) )	
	)	Civil Action No. 1:19-cv-1609	
MARK T. ESPER, et al.,	)		
Defendants.	)		

## **MEMORANDUM OPINION**

This dispute arises out of a conflict between plaintiff Combat Medical, LLC and the U.S. Army Medical Material Agency ("USAMMA") over plaintiff's ability to sell its medical tourniquet to the U.S. Department of Defense. The complaint alleges that as a result of decisions made by the USAMMA, plaintiff has been effectively prevented from selling its medical products to any agency within the U.S. Department of Defense and further alleges that the USAMMA violated certain regulations in making the decisions that have adversely impacted plaintiff. At issue are (i) defendants' motion to dismiss for lack of jurisdiction, (ii) defendants' motion to dismiss for failure to state a claim, and (iii) plaintiff's motion for a preliminary injunction.

This matter has been fully briefed and is thus now ripe for disposition. Oral argument is dispensed with as the facts and legal contentions are adequately set forth in the existing record and oral argument would not aid in the decisional process. For the reasons that follow, defendants' motion to dismiss for lack of subject matter jurisdiction is granted, plaintiff's motion for a preliminary injunction is denied as moot, and this action is transferred to the Court of Federal Claims pursuant to 28 U.S.C. § 1631.

<sup>&</sup>lt;sup>1</sup> Rule 78, Fed. R. Civ. P., provides that a court may determine motions on the briefs without oral hearings. The hearing on these motions scheduled for June 12, 2020 is therefore cancelled.

I.

The standards that govern a motion to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1), Fed. R. Civ. P., and a motion to dismiss for failure to state a claim under Rule 12(b)(6), Fed. R. Civ. P., are well-settled and thus require only brief elaboration.

Pursuant to Rule 12(b)(6), a complaint must be dismissed when the plaintiff fails to state a claim upon which relief can be granted. The district court must examine the face of the complaint and, taking all allegations of fact as true and construing them in the light most favorable to plaintiff, decide whether the complaint contains "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

A party may also seek dismissal of the complaint pursuant to Rule 12(b)(1) on the ground that the court lacks subject matter jurisdiction to decide the claims alleged in the complaint. A defendant may challenge subject matter jurisdiction in one of two ways: facially or factually. *See Beck v. McDonald*, 848 F.3d 262, 270 (4th Cir. 2017); *Kerns v. United States*, 585 F.3d 187, 192 (4th Cir. 2009). In a facial challenge to subject matter jurisdiction, the defendant contends that a complaint "fails to allege facts upon which subject matter jurisdiction can be based." *Kerns*, 585 F.3d at 192 (quoting *Adams v. Bain*, 697 F.2d 1213, 1219 (4th Cir. 1982)). Thus, when considering a facial challenge to subject matter jurisdiction pursuant to Rule 12(b)(1), the plaintiff is "afforded the same procedural protection" as a plaintiff would be afforded in a Rule 12(b)(6) motion, namely the facts alleged in the complaint are taken as true. *Id.* Accordingly, the defendant's challenge "must be denied if the complaint alleges sufficient facts to invoke subject matter jurisdiction." *Id.* Here, defendants raise a facial challenge to subject matter jurisdiction.<sup>2</sup>

<sup>&</sup>lt;sup>2</sup> The Fourth Circuit has also recognized that a party may attack subject matter jurisdiction pursuant to Rule 12(b)(1)

II.

The following facts are derived from the well-pleaded allegations in the complaint, the exhibits attached to the complaint, and the documents incorporated by reference into the complaint,<sup>3</sup> which are taken as true for the purposes of a motion to dismiss. *See Papasan v. Allain*, 478 U.S. 265, 283 (1986).

- Plaintiff, Combat Medical, LLC ("Combat Medical"), is a North Carolina limited liability company that sells tactical medical supplies to the United States military, law enforcement, first responders, and other customers.
- Defendant Mark T. Esper is the Secretary of Defense, and defendant Ryan D. McCarthy is the Secretary of the Army. Esper and McCarthy have been sued in their official capacities. The U.S. Department of Defense is also a named defendant in this matter.
- The Tactical Mechanical Tourniquet ("TMT") is one of Combat Medical's distributed medical products.
- Combat Medical has sold approximately 170,000 TMTs, primarily to the Department of Defense ("DoD"), but also to law enforcement agencies.
- In 2004, the U.S. Army determined that it had a need for a purpose-built tourniquet to issue to soldiers serving in Iraq and Afghanistan.
- In March 2005, the Army Surgeon General selected the third-generation Combat Application Tourniquet ("CAT") sold by North American Rescue ("NAR")<sup>4</sup> as the approved primary tourniquet to be issued to soldiers as part of the Individual First Aid Kit ("IFAK").
- In 2010, after the Army had become aware of performance issues with the third-generation CAT, the DoD established a Tourniquet Working Group to develop standards for the

via a factual challenge, namely by showing that the jurisdictional allegations in the complaint are not true. *See Adams*, 697 F.2d at 1219. The court may then go beyond the allegations of the complaint and in an evidentiary hearing determine if there are facts to support the jurisdictional allegations. *Id.* This alternative approach to challenging subject matter jurisdiction is not in issue in this case.

<sup>&</sup>lt;sup>3</sup> Exhibits attached to the complaint are considered part of the complaint. *See* Fed. R. Civ. P. 10(c) (a "copy of a written instrument that is an exhibit to a pleading is a part of the pleading for all purposes"). Documents that are incorporated into a complaint by reference may also be considered on a motion to dismiss. *See Sec'y of State for Defence v. Trimble Navigation Ltd.*, 484 F.3d 700, 705 (4th Cir. 2007); *Phillips v. LCI Int'l Inc.*, 190 F.3d 609, 618 (4th Cir. 1999) (stating that "a court may consider [a document outside the complaint] in determining whether to dismiss the complaint" where the document "was integral to and explicitly relied on in the complaint" and there was no authenticity challenge).

<sup>&</sup>lt;sup>4</sup> NAR is one of Combat Medical's competitors.

safety, efficacy, and physical requirements of extremity tourniquets and evaluated tourniquets based on those requirements through a series of tests called the Joint Operational Evaluation of Field Tourniquets ("JOEFT").

- The JOEFT testing began with 13 different tourniquets and was conducted in four phases. The worst performing tourniquets were eliminated after each phase. By the final phase in 2017, three tourniquets remained in the JOEFT: (i) Combat Medical's TMT, (ii) NAR's seventh-generation CAT, and (iii) the Ratcheting Medical Tourniquet ("RMT").
- On September 3, 2017, the final JOEFT test report was issued. The report did not conclude which tourniquet was the superior performer, but stated that (i) the CAT achieved the highest combined success rate across arm and leg applications, (ii) the CAT had the shortest application times, and (iii) the CAT was ranked as the most preferred tourniquet design by the test subjects.<sup>5</sup>
- On September 19, 2018, the USAMMA, an agency within the U.S. Army Medical Research and Material Command, issued Medical Material Quality Control Message ("MMQC") 18-2324. MMQC 18-2324 "inform[s] all Army units that the Combat Application Tourniquet (CAT) is the chosen tourniquet for the U.S. Army in order to ensure our soldiers receive the best possible medical care." MMQC 18-2324 further states that: "The U.S. Army has completed extensive testing based on defined requirements to determine the extremity tourniquet which best meets the needs of the warfighter. The combat application tourniquet (cat) has met or exceeded all defined requirements, was the superior performer, and was reaffirmed as the chosen extremity tourniquet."
- MMQC 18-2324 provides that "[a]ny resupply kit previously procured that does not have the [CAT] must be canceled and the appropriate resupply kit procured, due to the inherent safety risk of an unauthorized tourniquet."<sup>7</sup>
- MMQC 18-2324 further directs Army units to work with the USAMMA and the Defense Logistics Agency to stop the procurement of two specific first aid kits identified by their National Stock Numbers ("NSN"). Both first aid kits identified in MMQC 18-2324 are

<sup>&</sup>lt;sup>5</sup> The final JOEFT test report is not attached to the complaint, but (i) the complaint references the final JOEFT test report four times, (ii) plaintiff has attached the final JOEFT test report to its motion for a preliminary injunction, and (iii) neither party disputes the report's authenticity. Accordingly, the final JOEFT test report may be considered in adjudicating defendants' motion to dismiss. *See Phillips v. LCI Int'l Inc.*, 190 F.3d 609, 618 (4th Cir. 1999) (stating that "a court may consider [a document outside the complaint] in determining whether to dismiss the complaint" where the document "was integral to and explicitly relied on in the complaint" and there was no authenticity challenge).

<sup>&</sup>lt;sup>6</sup> MMQC 18-2324, Dkt. 1-3, at 2.

<sup>&</sup>lt;sup>7</sup> *Id*.

- manufactured by Combat Medical and contain the TMT. The MMQC 18-2324 states that these kits "have a tourniquet in them that is not approved for Army use or procurement."
- The complaint alleges that no Army-issued regulation or procedure<sup>9</sup> authorizes the USAMMA to use an MMQC to instruct units to suspend or eliminate their supplies of a medical device for any reason other than (i) the receipt of a Product Quality Deficiency Report; (ii) a recall from the device's manufacturer, distributor, or the FDA; or (iii) the expiration of that device's shelf-life where applicable.
- The MMQC 18-2324 did not refer to any recall announced by the FDA, the manufacturer, or the distributor of the TMT, and it also did not refer to any Product Quality Deficiency Report concerning the TMT from any end users.
- The complaint alleges that the MMQC 18-2324 caused the cancellation of orders for the TMT and effectively barred Combat Medical from selling tourniquets to the Army.
- As a result of MMQ 18-2324, TMT's NSN was canceled, allegedly by an employee of the USAMMA. In order to sell to the Army or other departments within the DoD, a product must have an NSN.
- The complaint alleges that without an active NSN, Combat Medical was effectively barred from selling the TMT to any DoD purchaser, even though MMQC 18-2324 and the authorities on which it purported to rely applied solely to the Army.
- According to the complaint, the cancellation of TMT's NSN was not done in accordance with the Federal Logistics Information System Technical Procedures.
- Between February and November 2019, Army representatives from the USAMMA have allegedly interfered with four procurement processes that Combat Medical was involved with: (i) a Request for Information ("RFI") for a Vehicle Medical Kit for the Army in February 2019; (ii) discussions to sell Combat Medical's IFAK kits to the Army's 44th Medical Brigade in June and July 2019; (iii) discussions with the Army's 1st Corps to provide a solution to the 1st Corps' IFAK shortfalls in November 2019; and (iv) discussions with the 82nd Airborne Division to supply Combat Medical's IFAKs overnight so that the 82nd Airborne Division would have the IFAKs for their immediate deployment in November 2019. The complaint also alleges that Combat Medical did not receive these procurements because of the improper interference of USAMMA representatives.

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<sup>&</sup>lt;sup>8</sup> *Id.* at 3.

<sup>&</sup>lt;sup>9</sup> The MMQC 18-2324 refers to Chapter 4 of Army Regulation (AR) 40-61 and the Department of the Army Supply Bulletin (SB 8-75-11) for applicable policies and procedures. Chapter 4 of AR 40-61 states that medical material complaint procedures are contained in SB 8-75-11. SB 8-75-11 sets forth a process for submitting a "Product Quality Deficiency Report" to the USAMMA and the Defense Logistics Agency by the end-user of the device in question.

- As a result of these actions, Combat Medical alleges that it has lost several million dollars in sales and continues to be barred from selling the TMT and other products to DoD purchasers.
- The complaint alleges that MMQC 18-2324 and the cancellation of TMT's NSN both constitute final agency actions because both represent the end of the Army's decision-making process with respect to the TMT and because both directly affect Combat Medical.
- According to the complaint, defendants' actions, namely the issuance of MMQC 18-2324 and the cancellation of TMT's NSN, have placed NAR and its CAT into an indefinite sole source position for military procurements without going through the proper process under the Federal Acquisition Regulations ("FAR").
- According to the complaint, defendants' actions have resulted in Combat Medical's *de facto* debarment from providing Combat Medical's first aid kits to the U.S. military.
- According to the complaint, defendants' decision to ban the TMT without following agency procedure was arbitrary and capricious, and the decision has directly and adversely affected Combat Medical.
- The complaint alleges two specific claims: (1) defendants, in violation 5 U.S.C. § 702 of the Administrative Procedure Act, violated Army regulations via the issuance of MMQC 18-2324 and (2) defendants, in violation 5 U.S.C. § 702 of the Administrative Procedure Act, violated Army regulations via the cancellation of the NSN for Combat Medical's TMT.

## Ш.

Analysis properly begins with a recitation of first principles of federal court jurisdiction. Federal district courts are courts of limited jurisdiction with specific jurisdictional requirements and limitations. *See Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 552 (2005) (citing *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994)); *Strawn v. AT&T Mobility LLC*, 530 F.3d 293, 296 (4th Cir. 2008) (citation omitted). Accordingly, federal district courts can hear cases only to the extent authorized by the Constitution and by statute. *See Kokkonen*, 511 U.S. at 377. In the event a federal district court determines that it does not have jurisdiction over a

matter, it may not rule on the merits of a claim.<sup>10</sup> Thus, the merits of plaintiff's motion for a preliminary injunction cannot be considered until jurisdiction has been established.<sup>11</sup>

As the party claiming that there is subject matter jurisdiction here, plaintiff bears the burden of establishing that subject matter jurisdiction exists. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992); *Strawn*, 530 F.3d at 296. It is presumed that a case lies outside the limited jurisdiction of federal district courts until the party asserting jurisdiction establishes otherwise. *See Kokkonen*, 511 U.S. at 377. In this respect, plaintiff bases its claim of jurisdiction on the argument that this action does not fall within the Administrative Dispute Resolution Act ("ADRA"), 28 U.S.C. § 1491(b)(1), but instead is brought pursuant to the general provision of the Administrative Procedure Act ("APA"), 5 U.S.C. § 702. And plaintiff contends that it has standing to sue under the APA because it is "[a] person suffering legal wrong because of agency action" and no other statute "expressly or impliedly forbids the relief which is sought." 5 U.S.C. § 702.

The history of judicial review of government procurement decisions is both long and complicated.<sup>12</sup> In 1996, Congress passed the ADRA in part to reorganize the jurisdiction of the federal courts over challenges to government procurement decisions. Prior to the ADRA, the Court

<sup>&</sup>lt;sup>10</sup> See Catawba Indian Tribe v. South Carolina, 865 F.2d 1444, 1460 (4th Cir. 1989) (noting that a federal court has a "fundamental responsibility to insure that we decide only those cases that fall within our lawful authority as a court of limited jurisdiction"); Goldsmith v. Baltimore, 845 F.2d 61, 63–64 (4th Cir. 1988) ("A federal court must satisfy itself that it has jurisdictional power to rule on the merits of a case.").

<sup>&</sup>lt;sup>11</sup> *Di Biase v. SPX Corp.*, 872 F.3d 224, 232 (4th Cir. 2017) (finding that a district court cannot assume subject matter jurisdiction in order to decide a plaintiff's motion for a preliminary injunction).

<sup>&</sup>lt;sup>12</sup> For a summary of this history, see Emery Worldwide Airlines, Inc. v. United States, 264 F.3d 1071, 1078–80 (Fed. Cir. 2001); Impresa Construzioni Geom. Domenico Garufi v. United States, 238 F.3d 1324, 1330–33 (Fed. Cir. 2001).

of Federal Claims<sup>13</sup> and the federal district courts exercised overlapping jurisdiction to hear challenges to government procurement decisions in certain circumstances.<sup>14</sup>

The ADRA sought to streamline this complicated jurisdictional framework. Specifically, the ADRA created a transitional period during which the federal district courts and the Court of Federal Claims would enjoy concurrent jurisdiction over government procurement cases. *See* 28 U.S.C. Section 1491(b)(1). Specifically, the ADRA states that:

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

28 U.S.C. § 1491(b)(1). In addition, Congress enacted a sunset provision as part of the ADRA that terminated federal district court jurisdiction over these government procurement claims on January 1, 2001. Specifically, the sunset provision provides that:

The jurisdiction of the district courts of the United States over the actions described in section 1491(b)(1) of title 28, United States Code (as amended by subsection (a) of this section) shall terminate on January 1, 2001 unless extended by Congress.

28 U.S.C. § 1491 note; ADRA, Pub. L. No. 104–320, § 12(d), 110 Stat. 3870, at 3875 (1996). Congress has not extended the federal district courts' jurisdiction over § 1491(b)(1) claims.

<sup>&</sup>lt;sup>13</sup> This is the current name of the court. Prior to 1992, this court was known first as the United States Court of Claims and then as the United States Claims Court.

<sup>&</sup>lt;sup>14</sup> See, e.g., United States v. Grimberg Co., 702 F.2d 1362, 1372 (Fed. Cir. 1983) (en banc) (holding that the Court of Federal Claims was authorized to issue equitable relief in a contract claim against the United States only when the complaint was filed before the award of the contract); Scanwell Labs., Inc. v. Shaffer, 424 F.2d 859, 861–73 (D.C. Cir. 1970) (holding that federal district courts had jurisdiction under the APA to hear claims challenging the award of government contracts).

<sup>&</sup>lt;sup>15</sup> Senator Cohen, the sponsor of the sunset provision, explained that it was designed "to increase the efficiency of our procurement system by consolidating jurisdiction over bid protest claims in the Court of Federal Claims.... Consolidation of jurisdiction in the Court of Federal Claims is necessary to develop a uniform national law on bid

Accordingly, the Court of Federal Claims now has exclusive jurisdiction over claims brought pursuant to § 1491(b)(1).<sup>16</sup>

Plaintiff contends that the sunset provision of § 1491(b)(1) does not apply to the instant dispute because although plaintiff's claims potentially fall within § 1491(b)(1)'s "in connection with a procurement or a proposed procurement" provision, plaintiff's claims have not been brought by an "interested party", as required by § 1491(b)(1). In essence, plaintiff argues that it has standing to bring an APA claim, but not to bring a § 1491(b)(1) claim. Specifically, plaintiff contends that it is a "person suffering legal wrong because of agency action" pursuant to 5 U.S.C. § 702 of the APA, but that it is not an "interested party" pursuant to § 1491(b)(1) of the ADRA. As a result, plaintiff argues that its claims fall within a category of cases that relate to government procurement disputes that can still be heard in federal district courts under the APA.

For the reasons that follow, plaintiff's argument fails. Accordingly, defendant's motion to dismiss for lack of jurisdiction must be granted, and this action must be transferred to the Court of Federal Claims pursuant to 28 U.S.C. § 1631.<sup>17</sup>

A.

The central question is whether plaintiff's allegations fall within the types of claims covered by § 1491(b)(1) of the ADRA and thus are within the exclusive jurisdiction of the Court

protest issues and end the wasteful practice of shopping for the most hospitable forum." 142 Cong. Rec. S6156 (daily ed. June 12, 1996) (statement of Sen. Cohen).

<sup>&</sup>lt;sup>16</sup> See Baltimore Gas & Elec. Co. v. United States, 290 F.3d 734, 737 (4th Cir. 2002) ("Congress has not acted to extend district court jurisdiction, and thus federal bid solicitation disputes [pursuant to § 1491(b)(1)] may now be filed only in the Court of Federal Claims."); Emery Worldwide Airlines, Inc. v. United States, 264 F.3d 1071, 1079 (Fed. Cir. 2001) ("[I]t is clear that Congress's intent in enacting the ADRA with the sunset provision was to vest a single judicial tribunal with exclusive jurisdiction to review government contract protest actions.").

<sup>&</sup>lt;sup>17</sup> Title 28 U.S.C. § 1631 provides that if a court "finds that there is a want of jurisdiction, the court shall, if it is in the interests of justice, transfer such action or appeal to any other such court...in which the action or appeal could have been brought at the time it was filed or noticed..." Plaintiff has requested such relief in the alternative to its opposition to defendants' motion to dismiss. *See* Plaintiff's Brief in Opposition, Dkt. 30, at 24.

of Federal Claims. Because it is undisputed that plaintiff's claims have been brought "in connection with a procurement or proposed procurement," plaintiff's claims are the type of claims that fall within § 1491(b)(1) of the ADRA. 28 U.S.C. § 1491(b)(1).

With respect § 1491(b)(1) claims that "allege[] [a] violation of statute or regulation in connection with a procurement or a proposed procurement," the Federal Circuit has made clear that "[t]he operative phrase 'in connection with' is very sweeping in scope." *Acetris Health, LLC v. United States*, 949 F.3d 719, 728 (Fed. Cir. 2020) (quoting *RAMCOR Servs. Grp., Inc. v. United States*, 185 F.3d 1286, 1289 (Fed. Cir. 1999). 18 Thus, § 1491(b)(1) does not require that the dispute pertain to a particular procurement, but rather "as long as a statute [or regulation] has a connection to a procurement proposal, an alleged violation suffices to supply jurisdiction." *RAMCOR*, 185 F.3d at 1289. Although the ADRA does not expressly define "procurement" or "proposed procurement," the Federal Circuit has sensibly adopted the definition of procurement which Congress provided in 41 U.S.C. § 111. See Distributed Solutions, Inc. v. United States, 539 F.3d 1340, 1345 (Fed. Cir. 2008). Specifically, § 111 states that "procurement' includes all stages of the process of acquiring property or services, beginning with the process for determining a need for property or services and ending with contract completion and closeout." 41 U.S.C. § 111 (emphasis added). Accordingly, the phrase "in connection with a procurement or proposed

<sup>&</sup>lt;sup>18</sup> See also Palladian Partners, Inc. v. United States, 783 F.3d 1243, 1254 (Fed. Cir. 2015); Dist. Sols., Inc. v. United States, 539 F.3d 1340, 1345 (Fed. Cir. 2008).

<sup>&</sup>lt;sup>19</sup> The Fourth Circuit has sensibly held that the views of the Federal Circuit on the proper interpretation of Section 1491(b)(1) are especially of interest because the Federal Circuit has exclusive appellate jurisdiction over all ADRA cases filed on or after January 1, 2001. *See Baltimore Gas & Elec. Co. v. United States*, 290 F.3d 734, 737 (4th Cir. 2002).

<sup>&</sup>lt;sup>20</sup> Title 41 U.S.C. § 111 is within a subsection of statutory provisions related to the establishment of the Office of Federal Procurement Policy in the Office of Management and Budget. Title 41 U.S.C. § 111 was codified as 41 U.S.C. § 403(2) prior to January 3, 2011.

procurement" in § 1491(b)(1) is broad in scope and only requires a connection with any stage of the federal contracting process, including "the process for determining a need for property or services." *Distributed Solutions*, 539 F.3d at 1346.

Here, it is clear that plaintiff's complaint alleges a "violation of statute or regulation in connection with a procurement or proposed procurement" because "everywhere plaintiff turns, there is a procurement in this case." Labat-Anderson, Inc. v. United States, 346 F. Supp. 2d 145, 154 (D.D.C. 2004). The conduct that plaintiff is challenging is the USAMMA's distribution of MMQC 18-2324 and the USAMMA's cancellation of the TMT's NSN. MMQC 18-2324 specifically states that the Army must immediately stop any procurements of two first aid kits allegedly sold by plaintiff. The complaint alleges that MMQC 18-2324 improperly made the CAT the Army's chosen extremity tourniquet and thereby placed NAR in an indefinite sole source position for military procurements, which has adversely impacted plaintiff's ability to compete for future procurements. Moreover, the complaint alleges that the cancellation of the TMT's NSN prevents plaintiff from selling its TMT to any DoD agency and that prior to this cancellation plaintiff had sold a substantial number of TMTs to the DoD. The complaint further alleges four specific procurement processes that plaintiff did not win between February and November 2019, allegedly because of MMQC 18-2324 and the cancellation of TMT's NSN. These allegations make unmistakably clear that the complaint alleges a "violation of statute or regulation in connection with a procurement or proposed procurement" pursuant to § 1491(b)(1). In fact, plaintiff does not even dispute defendant's contention that the complaint's allegations fall within that clause of Section 1491(b)(1); instead plaintiff concedes that its claims "potentially fall[] within the broad sweep of the phrase 'in connection with a procurement or proposed procurement." As the

<sup>&</sup>lt;sup>21</sup> Plaintiff's Brief in Opposition, Dkt. 30, at 9.

complaint itself reflects, the USAMMA decisions challenged here "clearly affect the award and performance" of government contracts and thus fall within § 1491(b)(1). *RAMCOR Servs. Grp.*, *Inc. v. United States*, 185 F.3d 1286, 1289 (Fed. Cir. 1999) (holding that the broad scope of Section 1491(b)(1) includes allegations of a violation of any statute or regulation that has a connection to a procurement proposal).

Although neither party has cited a case concerning the issuance of MMQCs or the cancellation of NSNs, courts in various analogous contexts have held that where, as here, a plaintiff is allegedly prevented from providing a product or service, those claims may only be considered by the Court of Federal Claims pursuant to § 1491(b)(1). For example, agency decisions to provide services in-house, and therefore not use an external service provider, have been held to be within the exclusive jurisdiction of the Court of Federal Claims because the decision to provide services in-house involves determining a need for property or services otherwise offered by external service providers and meets the definition of "procurement" pursuant to § 1491(b)(1).<sup>22</sup> Similarly, the MMQC at issue here allegedly determined that the CAT was the exclusive tourniquet to be used by the Army, which necessarily indicates a need for the services of the CAT as opposed to other tourniquets, including plaintiff's TMT. In addition, agency decisions that determine whether a company is eligible for or precluded from a procurement have been held to be within the exclusive jurisdiction of the Court of Federal Claims in the context of small business determinations.<sup>23</sup>

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<sup>&</sup>lt;sup>22</sup> See, e.g., Fisher-Cal Indus., Inc. v. United States, 747 F.3d 899, 902-03 (D.C. Cir. 2014) (affirming dismissal of complaint for lack of subject matter jurisdiction where agency decided to in-source service rather than renew plaintiff's contract); Labat-Anderson, Inc. v. United States, 346 F. Supp. 2d 145, 154 (D.D.C. 2004) (transferring case to Court of Federal Claims after finding that the dispute over DoD's in-sourcing decision "arises out of, is a challenge to, seeks as a remedy concerning, and in every relevant respect has a 'connection' with a procurement or proposed procurement"); Rothe Dev., Inc. v. U.S. Dep't of Def., 666 F.3d 336, 338-339 (5th Cir. 2011) (affirming dismissal of complaint challenging in-sourcing decision for lack of jurisdiction); Vero Tech. Support, Inc. v. U.S. Dep't of Def., 437 F. App'x 766, 770 (11th Cir. 2011) (same).

<sup>&</sup>lt;sup>23</sup> See, e.g., PMTech, Inc. v. U.S. Small Bus. Admin., 2008 WL 11512197, at \*1-2 (E.D. Va. July 25, 2008)

Similarly, the MMQC at issue here allegedly precludes plaintiff from participating in various Army procurements of medical supplies, including the four specific procurement processes alleged in the complaint.

The recent Federal Circuit decision *Acetris Health, LLC v. United States*, 949 F.3d 719 (Fed. Cir. 2020), is particularly instructive in determining whether plaintiff's challenge here is "in connection with a procurement or a proposed procurement," as required by § 1491(b)(1). In *Acetris Health*, the plaintiff challenged the Department of Veterans Affairs' allegedly flawed interpretation of the Trade Agreements Act ("TAA") and the Federal Acquisition Regulations ("FAR") in connection with both existing and proposed procurements. *See* id. at 727. Despite the absence of any ongoing procurement process in *Acetris Health*, <sup>24</sup> the Federal Circuit held that plaintiff's challenge fell within § 1491(b)(1) because "the government has taken a definitive position as to the interpretation of the TAA and the FAR that would exclude [the plaintiff] from future procurements for other products on which it is a likely bidder." *Id.* Further, the Federal Circuit in *Acetris Health* also concluded that the plaintiff's "history of performance" on government procurements in that case combined with the fact that "future procurements are likely to occur" clearly established a connection to a proposed procurement sufficient to supply jurisdiction pursuant to § 1491(b)(1).

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<sup>(</sup>dismissing challenge to agency's designation of a competitor as a small business for lack of jurisdiction); *Adv. Sys. Tech., Inc. v. Barrito*, 2005 WL 3211394, at \*5-6 (D.D.C. Nov. 1, 2005) (same). Significantly, the Federal Circuit also has made clear recently that Small Business Administration determinations of who is eligible to bid on a government contract fall within the jurisdictional scope of § 1491(b)(1). *See Palladian Partners, Inc. v. United States*, 783 F.3d 1243, 1254 (Fed. Cir. 2015).

<sup>&</sup>lt;sup>24</sup> In *Acetris Health*, plaintiff's challenge to a specific procurement process had been rendered moot by the time of the Federal Circuit decision because plaintiff had not been the lowest bidder in that process subsequent to the filing of its complaint. But the Federal Circuit determined that although plaintiff's challenge to that specific procurement had been rendered moot, plaintiff's cause of action had not been rendered moot because of the continued impact of the agency's decision on future procurement processes. *See id.* at 726-28.

The facts alleged here are essentially similar to the facts in *Acetris Health* in several important respects. First, the complaint alleges that plaintiff has sold a significant number of TMTs to the DoD in the past, thereby alleging a history of performance on government procurements. Second, the challenged MMQC and the cancellation of the TMT's NSN are alleged to be definitive government positions that exclude plaintiff from future procurements on which plaintiff would be a likely bidder. Moreover, as noted *supra*, the complaint identifies four circumstances since the government decisions challenged here where precisely this has occurred.<sup>25</sup> And it is likely that the DoD will continue to require new supplies of first aid kits for the armed services in the future. As in *Acetris Health*, plaintiff's allegations fall within the jurisdiction of § 1491(b)(1) because of their connection with a procurement or a proposed procurement. Thus, *Acetris Health* and the cases listed *supra* in notes 22 and 23 point persuasively to the conclusion that plaintiff's claims in this case fall within the exclusive jurisdiction of the Court of Federal Claims pursuant to § 1491(b)(1).

Seeking to avoid this conclusion, plaintiff argues that there is general APA jurisdiction to rule on these claims. In support of this argument, plaintiff relies on a prior decision of this Court, *SourceAmerica v. U.S. Dep't of Education*, 368 F. Supp. 3d 974 (E.D. Va. 2019). But plaintiff's reliance on *SourceAmerica* is misplaced as that case is clearly distinguishable from the claims asserted in the instant case. In *SourceAmerica*, the defendants conceded that the plaintiffs' claims likely could not be brought in the Court of Federal Claims pursuant to § 1491(b)(1). Instead, the defendants in *SourceAmerica* stated that although plaintiffs' claims were not then eligible to be brought in the Court of Federal Claims, those claims might be brought in the Court of Federal

<sup>&</sup>lt;sup>25</sup> Although plaintiff's complaint alleges that representatives from the USAMMA interfered with plaintiff's participation in four specific Army procurement processes between February and November 2019, plaintiff has not alleged any separate claim based on these particular allegations. Instead, plaintiff's complaint alleges two specific claims, namely (i) defendants violated Army regulations via the issuance of MMQC 18-2324 and (ii) defendants violated Army regulations via the cancellation of the NSN for plaintiff's TMT.

Claims in the future *if* the defendants were to move forward with a procurement that harmed plaintiffs' interests. *See id.* at 990. Because the parties stated in *SourceAmerica* that § 1491(b)(1) would only apply if some future procurement action occurred and because plaintiffs had already suffered harm in that case, judicial review pursuant to the APA was not precluded by § 1491(b)(1).

In contrast to *SourceAmerica*, plaintiff's complaint here alleges that defendants have already conducted procurements, and continue to conduct procurements, that have harmed plaintiff's interests, including the loss of several million dollars in sales. Accordingly, the factual allegations and claims here are categorically different from the allegations and claims asserted in *SourceAmerica*. And importantly, the parties here, in sharp contrast to the parties in *SourceAmerica*, agree that the complaint alleges claims "in connection with a procurement or a proposed procurement" as required by § 1491(b)(1).<sup>26</sup>

In sum, it is unmistakably clear that plaintiff's complaint alleges a "violation of statute or regulation in connection with a procurement or proposed procurement" and thus falls within the coverage of § 1491(b)(1) and within the exclusive jurisdiction of the Court of Federal Claims. Accordingly, defendant's motion to dismiss for lack of jurisdiction must be granted, and this action must be transferred to the Court of Federal Claims.

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<sup>&</sup>lt;sup>26</sup> In addition to the factual differences between this case and *SourceAmerica*, *SourceAmerica* involved a challenge to a Randolph-Shepard Act (RSA) arbitration panel decision. And a number of courts, including the Court of Federal Claims, have held that review of RSA arbitration panel decisions is available under the APA and not under the ADRA. *See Kansas v. SourceAmerica*, 874 F.3d 1226, 1243 (10th Cir. 2017) ("[T]he Court of Federal Claims lacks Tucker Act jurisdiction whenever a plaintiff alleges that a federal agency violated the RSA or its attendant regulations and the plaintiff has yet to arbitrate those claims. This is so even if the plaintiff's allegations technically fall within the scope of 28 U.S.C. § 1491(b)(1)."); *Colorado Dept. of Human Services v. United States*, 74 Fed. Cl. 339, 347 (Fed. Cl. 2006); *SourceAmerica v. U.S. Dep't of Educ.*, 2018 WL 1453242, at \*5 (Mar. 23, 2018). Thus, the jurisdictional question posed in *SourceAmerica* was categorically different from the jurisdictional question presented here in several important respects.

В.

Perhaps recognizing that the ADRA's broad sweep would reach the claims in this case, plaintiff attempts to sidestep this by arguing that plaintiff is not an "interested party" and thus does not have standing to bring an action under the ADRA. This argument fails because the "interested party" requirement is not jurisdictional and thus need not be decided here before deciding whether plaintiff's claims fall within ADRA. Moreover, as the following analysis also shows, the "interested party" issue is appropriately decided by the Court of Federal Claims, not by federal district courts.

The Federal Circuit has defined the term "interested party" in § 1491(b)(1) as an "actual or prospective bidder or offeror whose direct economic interest would be affected by the award of the contract or by failure to award the contract." *Banknote Corp. of Am. v. United States*, 365 F.3d 1345, 1352 (Fed. Cir. 2004) (quoting *American Fed'n of Gov't Employees, AFL–CIO v. United States*, 258 F.3d 1294, 1299 (Fed. Cir. 2001) (hereinafter, *AFGE*).<sup>27</sup> The term "interested party" does not, however, define the types of claims that are covered by the ADRA, but rather establishes who is within the "zone of interests" of the ADRA for standing purposes. *See AFGE*, 258 F.3d at 1302. Accordingly, where, as here, the alleged claims fall within the types of claims covered by Section 1491(b)(1) and thus within the exclusive jurisdiction of the Court of Federal Claims, other federal district courts have declined to determine whether a plaintiff is an "interested party" that has standing to sue under § 1491(b)(1).<sup>28</sup> Those federal district courts have dismissed the cases

<sup>&</sup>lt;sup>27</sup> Section 1491(b)(1) does not provide a definition of the term "interested party." As a result, the Federal Circuit has adopted the definition of "interested party" provided in another statute that applies to government contract disputes, the Competition in Contracting Act (CICA), 31 U.S.C. § 3551(2). See Banknote Corp. of Am. v. United States, 365 F.3d 1345, 1351 (Fed. Cir. 2004). In this respect, the Federal Circuit's determination of the meaning of "interested party" is sensible, and the Federal Circuit's interpretation of the term "interested party" in § 1491(b)(1) of the ADRA is adopted here because the Federal Circuit has exclusive appellate jurisdiction over all ADRA cases.

<sup>&</sup>lt;sup>28</sup> See Fisher-Cal Indus., Inc. v. United States, 839 F. Supp. 2d 218, 225 (D.D.C. 2012), aff'd, 747 F.3d 899 (D.C.

without reaching the "interested party" issue and have properly left the standing question for the Court of Federal Claims to decide.

Plaintiff here essentially requests a determination of whether Combat Medical falls within the class of plaintiffs whom Congress has authorized to sue under § 1491(b)(1). But the Supreme Court has recently made clear that such "statutory standing" inquiries are not jurisdictional, despite prior decisions occasionally treating such inquiries as effectively jurisdictional. *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 128 n.4 (2014). As such, the Supreme Court reiterated that "the absence of a valid (as opposed to arguable) cause of action does not implicate subject-matter jurisdiction, *i.e.*, the court's statutory or constitutional *power* to adjudicate the case." *Id.* (quoting *Verizon Md. Inc. v. Public Serv. Comm'n of Md.*, 535 U.S. 635, 642–643 (2002)). Accordingly, whether plaintiff has standing to challenge the USAMMA's decisions as an "interested party" pursuant to § 1491(b)(1) is for the Court of Federal Claims to consider.<sup>29</sup> The

Cir. 2014) ("[W]hether the plaintiff is an 'interested party'...is more appropriately addressed by the Court of Federal Claims, which has exclusive jurisdiction to adjudicate the merits of the plaintiff's claims and whether the plaintiff has the ability to pursue them at all."); Colorado Bldg. & Const. Trades Council v. U.S. Dep't of Def., No. 12-CV-632-AP, 2012 WL 3609824, at \*3 (D. Colo. Aug. 22, 2012), appeal dismissed, No. 12-1418 (10th Cir. 2013) ("The question of whether [p]laintiffs ...have standing as 'interested parties' to challenge the insourcing decision is...for the Court of [Federal] Claims to consider.").

<sup>&</sup>lt;sup>29</sup> Moreover, even assuming, *arguendo*, that determining whether a plaintiff is an "interested party" is jurisdictional in the context of § 1491(b)(1), plaintiff is an "interested party" here because the complaint alleges four specific procurement processes which plaintiff was precluded from winning, purportedly due to the agency decisions challenged in the complaint. See Acetris Health, LLC v. United States, 949 F.3d 719, 727 (Fed. Cir. 2020) (referring to the question of whether a plaintiff is an "interested party" as jurisdictional). The cases that have concluded that a particular plaintiff was not an "interested party" involved plaintiffs who were not in any way involved in the procurement process. See City of Albuquerque v. United States Dep't of Interior, 379 F.3d 901, 910-11 (10th Cir. 2004) (holding that a city that desired to have an agency select office space in its central business area, as opposed to other areas in the city, was not an "interested party" under the ADRA where the city had no prior, existing, or prospective procurement relationship with the agency); AFGE, 258 F.3d 1294, 1298–1302 (Fed. Cir. 2001) (holding that federal employees and their union did not have standing under the ADRA to challenge agency decision to contract out work formerly performed by employees where they were not actual or prospective bidders and thus not "interested parties" under Section 1491(b)(1)); Forest Serv. Employees for Envt'l Ethics v. United States Forest Serv., 338 F. Supp. 2d 1135, 1142–43 (D. Mont. 2004) (holding that federal employees and their union were outside the ambit of the ADRA, and thus claims were within district court's APA jurisdiction, but dismissing the case for lack of a concrete injury). Thus, in this respect, Combat Medical is categorically different from the plaintiffs in those cases because Combat Medical has allegedly been negotiating medical supply procurements with the Army on an ongoing basis. See, e.g., Pub. Warehousing Co. K.S.C. v. Def. Supply Ctr. Philadelphia, 489 F. Supp. 2d 30, 42-43 (D.D.C. 2007) (dismissing case for lack of subject matter jurisdiction pursuant to the ADRA but also determining

operative jurisdictional question at issue here is whether the ADRA applies to the *action*, and here, as discussed in Part III.A., the complaint alleges an action "in connection with a procurement or a proposed procurement," which clearly falls within § 1491(b)(1) and the exclusive jurisdiction of the Court of Federal Claims.

\* \* \*

In sum, plaintiff may not circumvent the § 1491(b)(1) statutory scheme by simply citing to the APA because "Congress effectively subsumed APA jurisdiction of the district courts into the more specific jurisdictional language of the ADRA." *Emery Worldwide Airlines, Inc. v. United States*, 264 F.3d 1071, 1080 (Fed. Cir. 2001) (quoting *Novell, Inc. v. United States*, 109 F. Supp. 2d 22, 24–25 (D.D.C. 2000)).<sup>30</sup> Accordingly, the APA cannot provide the requisite waiver of sovereign immunity over this dispute because § 1491(b)(1) provides the Court of Federal Claims with jurisdiction.

For the reasons set forth above, defendants' motion to dismiss for lack of subject matter jurisdiction is granted, plaintiff's motion for a preliminary injunction is denied as moot, and this action is transferred to the Court of Federal Claims.<sup>31</sup>

that plaintiff is an "interested party" within § 1491(b)(1) where plaintiff was a government contractor who was seeking past performance information in the furtherance of the award of future contracts); *Acetris Health, LLC v. United States*, 949 F.3d 719, 727 (Fed. Cir. 2020) (holding that plaintiff was an "interested party" where the challenged government decisions would exclude plaintiff from future procurements for other products on which plaintiff would be a likely bidder); *Distributed Sols., Inc. v. United States*, 539 F.3d 1340, 1344–45 (Fed. Cir. 2008) (holding that a party "deprived of the opportunity to compete" was an "interested party" under § 1491(b)(1)).

<sup>&</sup>lt;sup>30</sup> See also Rothe Dev., Inc. v. U.S. Dep't of Def., 666 F.3d 336, 339 (5th Cir. 2011) (holding that the Court of Federal Claims has exclusive jurisdiction over plaintiff's claims and thus the APA does not waive sovereign immunity as to those claims); Vero Tech. Support, Inc. v. U.S. Dep't of Def., 437 F. App'x 766, 768 (11th Cir. 2011) (holding that because § 1491(b)(1) vests exclusive jurisdiction in the Court of Federal Claims, the APA cannot provide the requisite waiver of sovereign immunity); Goodwill Indus. Servs. Corp. v. Comm. for People Who Are Blind or Severely Disabled, 378 F. Supp. 2d 1290, 1294-95 (D. Colo. 2005) (same); Hi-Tech Bed. Sys. Corp. v. U.S. Gen. Servs. Admin., 2012 WL 12871622, at \*8 (D. Wyo. Mar. 8, 2012) (same); USA Jet Airlines, Inc. v. U.S. Dep't of Energy, 2011 WL 13284452, at \*3 (D.N.M. Sept. 27, 2011) (same).

<sup>&</sup>lt;sup>31</sup> Given the result reached here it is not necessary to reach or decide defendants' motion to dismiss for failure to state a claim.

An appropriate order will issue separately.

The Clerk is directed to provide a copy of this Opinion to all counsel of record.

Alexandria, Virginia May 4, 2020

T. S. Ellis, III
United States District Judge