In the United States Court of Federal Claims

BID PROTEST
No. 15-1015C
(Filed Under Seal: February 25, 2016 | Reissued: March 1, 2016)[*]

AvKARE, INC., Plaintiff, v. THE UNITED STATES OF AMERICA, Defendant.	Keywords: Motion to Stay Judgment Pending Appeal; RCFC 62(c); Injunction

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OPINION AND ORDER

KAPLAN, Judge.

Plaintiff AvKARE, Inc. (AvKARE) filed this pre-award bid protest in September 2015. Compl., ECF No. 1. On February 12, 2016, the Court granted judgment on the administrative record in favor of the government and dismissed AvKARE's complaint. ECF No. 47. AvKARE then filed a notice of appeal and a motion to stay the Court's judgment pending the outcome of the appeal. ECF Nos. 49–50. In its motion, AvKARE requested that the Court order the government to extend AvKARE's current contract through the pendency of its appeal. For the reasons set forth below, AvKARE's motion to stay the judgment is **DENIED**.

[*] This Opinion was originally issued under seal, and the parties were given the opportunity to request redactions. Neither party requested redactions, and the opinion is now being reissued in full.

I. Background[1]

A. AvKARE's Contract Renewal Offer and Contract Extensions

AvKARE holds a Federal Supply Schedule (FSS) contract with the United States Department of Veterans Affairs (VA) to supply generic pharmaceuticals to VA and other government purchasers. See Compl. ¶ 43. AvKARE has held this contract since 2010. Id. ¶ 49.

AvKARE's contract was originally set to expire on March 31, 2015. Compl. ¶ 44. In response to the VA's perpetually open solicitation, AvKARE submitted an offer to renew the contract on October 31, 2014. Id. The VA evaluated AvKARE's offer and found it deficient in several respects. See Admin. R. (AR) Tabs 341–48. Of most relevance here, the VA concluded that AvKARE was not the "manufacturer" of the generic pharmaceuticals, but rather was a "dealer/reseller." AR Tab 344 at 21608. Further, the VA determined that AvKARE lacked significant commercial sales of the drugs it wished to offer on the FSS contract. Id. at 21606. For these reasons, the VA informed AvKARE that it needed to provide certain commercial sales practice (CSP) information about its suppliers as required by the solicitation's CSP clause, which was mandated by 48 C.F.R. § 515.408(b). See id.

AvKARE disagreed. It informed the VA that it, in its view, it was not required to include its suppliers' CSP information with its renewal offer because it was the manufacturer of the items it wished to sell, not a dealer/reseller. See AR Tab 360 at 21679; see also Compl. ¶¶ 28–29. Moreover, AvKARE claimed that its commercial sales were, in fact, significant. AR Tab 360 at 21677–78. When the parties could not resolve these disputes, AvKARE filed a bid protest in this Court on March 3, 2015. See Compl., AvKARE, Inc. v. United States (AvKARE I), No. 15-cv-216, ECF No. 1. The government then agreed to extend AvKARE's contract through September 31, 2015, and AvKARE voluntarily dismissed that case. See Notice of Voluntary Dismissal, AvKARE I, ECF No. 17.

Between March 2015 and September 2015, the VA obtained and analyzed updated commercial sales information from AvKARE. See AR Tabs 191, 386–87. This information did not include AvKARE's suppliers' CSP information, as AvKARE still contended that it was not required to produce that information. See AR Tab 382 at 21740. On September 3, 2015, the VA informed AvKARE that its position regarding AvKARE's renewal offer had not changed: it still considered AvKARE a dealer/reseller, and it had again determined that AvKARE lacked significant commercial sales. AR Tab 417. AvKARE then filed this action; and the government again extended AvKARE's contract,

[1] A detailed recitation of the facts relevant to this case is set forth in the Court's Opinion and Order denying AvKARE's motion for judgment on the administrative record. See ECF No. 47 at 2–11.

this time through January 31, 2016. Finally, the government granted a third extension, which expires after February 29, 2016.

B. AvKARE's Requests for Modification

Between 2010 and 2014, the VA granted several requests for modification (RFM) submitted by AvKARE to add new generic drugs to its contract. Id. ¶ 50. Following an inspection of AvKARE's facilities in September 2014, however, the VA began to deny AvKARE's RFMs. Id. ¶¶ 63–64. The VA's rationale for denying these RFMs paralleled the reasoning behind its decision on AvKARE's renewal offer—i.e., that AvKARE was not the manufacturer of the drugs, lacked significant commercial sales of the drugs, and had not provided manufacturers' CSP information for the drugs. See AR Tab 173 at 20954–55.

C. Prior Proceedings in This Case

1. AvKARE's Complaint

In its complaint, AvKARE alleged both that the VA improperly refused to consider AvKARE's offer to renew its FSS contract and that it improperly refused to grant AvKARE's RFMs. Compl. ¶¶ 44–71. According to AvKARE, the VA routinely granted RFMs made by similar pharmaceutical repackagers holding VA FSS contracts issued under the same solicitation. Id. ¶¶ 72–79. AvKARE requested relief on several grounds, including (1) that the VA's refusals were the result of bad faith and bias against AvKARE, id. ¶¶ 80–86, 102–06; (2) that the VA's refusals constituted an unlawful de facto debarment, id. ¶¶ 87–92; (3) that the VA's refusals were arbitrary and capricious, id. ¶¶ 93–97; and (4) that the VA had breached the obligation of good faith and fair dealing, id. ¶¶ 98–101.

2. AvKARE's First Motion to Supplement the Administrative Record

The government compiled an extensive administrative record. See ECF Nos. 16–17. On October 20, 2015, AvKARE moved to supplement the record. Pl.'s Mot. to Suppl. the R., ECF No. 19. Among the documents it sought to include were documents purportedly showing that the VA treated AvKARE differently than another generic pharmaceutical repackager, whose requests for modification the VA allegedly granted as a matter of course. Pl.'s Mem. in Supp. of its Mot. to Suppl. the R. at 5–7, ECF No. 20. The Court denied AvKARE's motion, concluding that AvKARE failed to show that the existing record was insufficient to permit effective judicial review. See Opinion and Order (Op. Den. Mot. to Suppl.) at 4, ECF No. 32. Among other things, the Court explained that the documents proffered by AvKARE in support of its disparate treatment claim provided only "general background" about the other repackager, and thus failed to supply the Court with any "factual basis for assessing the VA's decision-making process with respect to [the other repackager], let alone inferring that [the VA] treated AvKARE differently based on bias or bad faith." Id.

3. AvKARE's Second Motion to Supplement the Administrative Record

On January 28, 2016, AvKARE filed a second motion to supplement the administrative record. ECF No. 43. This time, it sought to include deposition testimony from the General Services Administration's (GSA) current director of FSS programs, who (in a parallel proceeding before the Civilian Board of Contract Appeals) had testified about the GSA's policies and practices for obtaining CSP information and for assessing price reasonableness if CSP information was unobtainable. See Pl.'s Mem. in Supp. of its 2d Mot. to Suppl. the Admin. R. (Pl.'s 2d Mot. to Suppl.) at 2–4, ECF No. 44. The Court concluded, however, that this testimony was not necessary to permit effective judicial review, as the record already reflected the key takeaway from the testimony—that the VA understood that if relevant manufacturers' CSP information was demonstrably unobtainable, then the VA could properly rely on a different method of price analysis to evaluate AvKARE's proposal. See Opinion and Order (Op. Den. MJAR) at 21 n.13, ECF No. 47 (citing AR Tab 436 at 22534). Accordingly, the Court denied the motion. See id.

4. The Parties' Cross-Motions for Judgment on the Administrative Record

On February 12, 2016, the Court denied AvKARE's motion for judgment on the administrative record and granted the government's cross-motion for judgment on the administrative record. The Court explained that it lacked jurisdiction over AvKARE's RFM claims because those claims arose under the Contract Disputes Act and AvKARE had not first submitted claims to the contracting officer as required by that Act. See Op. Den. MJAR at 12–14. Next, the Court held that AvKARE was not a "manufacturer" under the plain meaning of the term. Id. at 14–16. The Court rejected AvKARE's argument that certain definitions of the term found in other statutory and regulatory regimes applicable to the pharmaceutical industry compelled a different conclusion. Id. at 16–18. To the contrary, the existence of these specialized definitions showed that "when legislators and regulators wish to subject entities like AvKARE that repackage and re-label pharmaceuticals to the same restrictions as entities that fall within the plain meaning of the term 'manufacturer' . . . they do so explicitly." Id. at 17.

The Court next concluded that the CO's determination that AvKARE lacked significant commercial sales was not arbitrary, capricious, or contrary to law. Turning to AvKARE's claim that the VA acted in bad faith, the Court held that the record offered no basis to rebut the presumption of regularity in the VA's decisionmaking, as "the VA communicated regularly with AvKARE about AvKARE's proposal [and] repeatedly explained to AvKARE why the proposal remained deficient." Id. at 20. In particular, the Court rejected AvKARE's argument that the VA exhibited bad faith by failing to analyze its proposed prices using a method that did not depend on manufacturers' CSP information. In doing so, the Court reasoned that AvKARE never attempted to substantiate to the VA its position that "relevant information about its suppliers' commercial sales practices cannot be obtained." Id. Instead, AvKARE "consistently took the position that it was not legally obligated to provide any such information at all, even if it did exist, because AVKARE is not a dealer/reseller and/or because its suppliers'

commercial sales practices could not possibly be relevant to a determination of whether AvKARE's prices were fair and reasonable." Id. at 20–21.

Finally, the Court held that AvKARE's de facto debarment claim failed "for largely the same reasons" as its bad faith treatment claim. Id. at 22. The Court noted that, far from demonstrating a "systematic intent to refuse to award AvKARE future contracts," the VA "consistently told AvKARE that it would move forward with reviewing AvKARE's proposal if AvKARE supplied the required manufacturers' CSP information." Id.

II. The Merits of AvKARE's Motion to Stay the Judgment Pending Appeal

In its motion to stay the Court's judgment, AvKARE requests that the Court "[enter] an injunction to require [the government] to extend and hold in abeyance the expiration of [its] existing Federal Supply Schedule 65IB Contract." Pl.'s Mot. for Stay Pending Appeal at 1, ECF No. 50. In determining whether to grant AvKARE's motion, the Court considers four factors: (1) whether AvKARE "has made a strong showing that [it] is likely to succeed on the merits;" (2) whether AvKARE "will be irreparably injured absent [an injunction];" (3) whether issuing an injunction "will substantially injure the other parties interested in the proceeding;" and (4) "where the public interest lies." See Standard Havens Prods., Inc. v. Gencor Indus., Inc. 897 F.2d 511, 512 (Fed. Cir. 1990) (quoting Hilton v. Braunskill, 481 U.S. 770, 776 (1987); see also E.I DuPont de Nemours & Co. v. Phillips Petroleum, 835 F.2d 277, 278 (Fed. Cir. 1987).

These factors "contemplate individualized judgments in each case" and "cannot be reduced to a set of rigid rules." Hilton, 481 U.S. at 777. Accordingly, the Court must "assess[] [the] movant's chances for success on appeal and weigh[] the equities as they affect the parties and the public." DuPont, 835 F.2d at 278; see also Caddell Const. Co. v. United States, No. 15-645C, 2016 WL 537314, at *19 (Fed. Cl. Feb. 10, 2016) (observing that "[n]o individual factor is dispositive" and that "the [c]ourt must weigh each factor against the magnitude of the injunctive relief requested"). As discussed below, the Court concludes that based on these four factors, AvKARE's motion should be denied.

A. Whether AvKARE is Likely to Succeed on the Merits

AvKARE is not likely to succeed on the merits. First, AvKARE's arguments that it is the manufacturer lack merit. As the Court explained in its Opinion, the fact that some specialized statutes and regulations define "manufacturer" to include repackagers indicates that repackagers "would not otherwise be considered 'manufacturers' of drug products in light of that term's ordinary meaning." Op. Den. MJAR at 17. And AvKARE is wrong to state that the definition found in a separate VA procurement statute, 38 U.S.C. § 8126(h), applies to "the item[s] of supply at issue here," see Pl.'s Mem. in Supp. of its Mot. for Stay Pending Appeal (Pl.'s Mem.) at 7, ECF No. 51, because (as the Court explained) that provision applies to single-source drugs, not generic drugs like those AvKARE sells. See Op. Den. MJAR at 17.

Moreover, the solicitation's reference to the FDA's current good manufacturing practices (CGMP) is not somehow dispositive, as the relevant CGMP regulations do not define the term "manufacture" standing alone; rather, they define the "[m]anufacture, processing, packing, or holding" of drug products to include repackaging. See 21 C.F.R. § 210.3(12). Thus, those regulations are of little aid in determining the meaning of the term "manufacturer" when it appears on its own, as it does in the GSA regulation that supplied the template for the solicitation's CSP provision. See 48 C.F.R. § 515.408(b).

AvKARE is equally unlikely to succeed on the merits of its remaining claims. In terms of its bad faith claim, AvKARE contends that by denying its first motion to supplement the administrative record, the Court hobbled its ability to show that the VA treated it disparately. See Pl.'s Mem. at 9–11. As the Court observed in that Opinion, a plaintiff wishing to supplement the administrative record with alleged evidence of bad faith must first make a "'strong showing of bad faith or improper behavior,'" Pitney Bowes Gov't Sols., Inc. v. United States, 93 Fed. Cl. 327, 332 (2010) (quoting Ala. Aircraft Indus., Inc. v. United States, 82 Fed. Cl. 757, 766 (2008)), and that showing must "rest on 'hard facts,' not merely innuendo or suspicion," Inforeliance Corp. v. United States, 118 Fed. Cl. 744, 747 (2014) (quoting Int'l Res. Recovery, Inc. v. United States, 61 Fed. Cl. 38, 43 (2004)).

The evidence AvKARE sought to introduce about the other offeror did no such thing, for (as the Court explained) it provided no "factual basis for assessing the VA's decision-making process with respect to [the other offeror], let alone inferring that [the VA] treated AvKARE differently based on bias or bad faith." Op. Den. Mot. to Suppl. at 4. In other words, the proposed documents shed no light on whether the offeror to which AvKARE sought to compare itself was similarly situated to AvKARE in any relevant way. And, to the contrary, documents in the existing record indicate that AvKARE's competitor in fact differed from AvKARE in relevant ways. See AR Tab 413 at 22489 (email to AvKARE stating that the VA "[is] not treating [other offerors] any differently than they are treating AvKARE;" that "AvKARE is the only repackager who asserts that they are the manufacturer;" that "[o]ther companies similarly situated to AvKARE acknowledge that they are a dealer/reseller;" and that "[d]epending on the other companies [sic] commercial sales VA may or may not require manufacturer's CSP data, that is a case by case determination"). Thus, AvKARE's invitation to infer bad faith based on the VA's treatment of the other offeror rested not on "hard facts" about the VA's decisionmaking, but on mere "innuendo or suspicion." See Inforeliance, 118 Fed. Cl. at 747.

AvKARE further argues that by denying its second motion to supplement the administrative record, the Court prevented it from showing that the VA violated certain GSA regulations and policies that govern the VA's administration of its FSS contracts. See Pl.'s Mem. at 8–9. But as the Court has explained, to the extent the deposition testimony AvKARE wished to include was relevant to the case, it was duplicative of information already in the record. See Op. Den. MJAR at 21 n.13. On the other hand, several portions of the testimony that AvKARE wished to include were not relevant to the case. For example, AvKARE wished to include testimony establishing that there are "other means of determining price" if the contractor "is the manufacturer" and lacks

commercial sales. See Pl.'s Mem. in Supp. of its 2d Mot. to Suppl. the R. at 6. This testimony is irrelevant to VA's decisions in this case because the VA determined (correctly) that AvKARE was not the manufacturer.

Similarly, AvKARE wished to include statements establishing what the VA could have done if manufacturers' CSP information was "not available or . . . just not there." Id. at 9. These statements are irrelevant because, as the Court explained, there is no evidence in the record showing that the information the VA seeks from AvKARE is not available; instead, AvKARE has consistently taken the position that "it is not legally obligated to provide the VA with manufacturers' CSP information, even if it does exist and is obtainable." Op. Den. MJAR at 20–21 & n.13. Accordingly, denying AvKARE's second motion to supplement the record did not somehow prevent AvKARE from showing that the VA violated applicable GSA regulations, as the non-duplicative information AvKARE wished to include related only to hypothetical situations, not the actual facts of the case.

In this regard, the Court is not persuaded by the claim AvKARE advances in its reply brief that it was only as a result of representations made in the government's brief that it understood that the VA would be willing to employ a different method of price analysis upon a demonstration by AvKARE that it could not obtain manufacturers' CSP information. See Pl.'s Reply in Sup. of its Mot. for Stay Pending Appeal at 2–4, ECF No. 54 (describing the government's acknowledgment of this possibility as a "'game changer' that establishes a wonton lack of good faith and fair dealing on the part of the VA in its treatment of AvKARE"). First of all, the administrative record itself reveals that the VA held this view. See AR Tab 436 at 22534 (email from the VA's FSS director stating that "[i]f CSP data is not received, AvKare must prove that CSP data is not available from their manufacturers," and that "[if] CO verified CSP data is not available from manufacturer, then proceed to reliance solely on price analysis"). Thus, AvKARE has been aware of this position since at least October 2015 when the government produced the administrative record. In addition, the Court also discussed this issue with the government at the oral argument on the parties' cross-motions for judgment on the administrative record. See Transcript of Hearing at 57:2–17 (Jan. 13, 2016).

More importantly, the VA's explicit acknowledgment during this litigation that it would consider alternative methods of price analysis if AvKARE proved that CSP information could not be obtained from its suppliers does not assist AvKARE's argument that the VA did not act in good faith. As the Court has noted, AvKARE has never walked back its position that it is the manufacturer and therefore that it is not required to provide its suppliers' CSP information. Nor does the record provide any indication that AvKARE made an effort to show that manufacturers' CSP information was not available; instead, the record shows that AvKARE consistently and categorically denied that it had an obligation to produce it. See AR Tab 360 at 21679 (asserting that AvKARE need not provide manufacturers' CSP information because "we are not a dealer or reseller" and "[the dealer/reseller] provision is not applicable to our offer"); AR Tab 382 at 21740 (asserting AvKARE's belief that manufacturers' CSP information "is neither required (as AvKARE is the manufacturer of its private label products and has significant commercial sales of those products) nor relevant"). In fact, AvKARE still clings to those arguments

before this Court. There was no occasion, therefore, for the VA to consider whether AvKARE had made a sufficient showing of unavailability to justify use of an alternative method of price analysis, nor any decision for this Court to review regarding the VA's supposed failure to do so.

Finally, AvKARE is unlikely to succeed on the merits of its de facto debarment claim. At the outset, AvKARE's contention that the Court improperly excluded evidence demonstrating its de facto debarment claim is belied by AvKARE's own memorandum in support of its first motion to supplement the record, in which it stated that "the record as filed contains ample evidence of the agency's de facto debarment of AvKARE." See Pl.'s Mem. in Supp. of it Mot. to Suppl. the R. at 2. Moreover, the Court did not "import" a bad faith standard into its analysis of AvKARE's de facto debarment, as AvKARE would have it. See Pl.'s Mem. at 9–10. That is, the Court did not deny AvKARE's de facto debarment claim because it denied AvKARE's bad faith treatment claim; rather, it denied AvKARE's de facto debarment claim for "largely the same reasons" it denied AvKARE's bad faith claim. See Op. Den. MJAR at 22. Specifically, the Court concluded that the VA's conduct did not amount to a "systematic effort" to deny contract awards to AvKARE because the VA's decision not to further evaluate AvKARE's renewal stemmed from the parties' dispute over a legal issue—i.e., whether AvKARE was the "manufacturer" or not. As the government itself has admitted, had the Court held that AvKARE was the manufacturer, the VA would have moved forward with its evaluation. See Def.'s Reply to Pl.'s Response to Def.'s Cross-Mot. for J. on the Admin. R. at 6–7, ECF No. 40. Thus, the VA has not demonstrated a systematic intent to deny AvKARE even the contract at issue in this case, let alone any other contract AvKARE might seek.

Accordingly, for all the reasons discussed above and set forth in its opinion granting judgment on the administrative record to the government, the Court concludes that AvKARE is not likely to succeed on the merits of its appeal.

B. Whether AvKARE Will Suffer Irreparable Harm Absent and Injunction

AvKARE argues that it will suffer irreparable harm if the Court does not issue an injunction because the loss of its FSS contract will decrease its annual revenues by more than $6 million and force it to terminate twelve employees. Pl.'s Mem. at 12. While significant, these are the types of harms that any incumbent contractor experiences upon the loss of a contract. See Akima Intra-Data, LLC v. United States, 120 Fed. Cl. 25, 28–29 (2015); CRAssociates, Inc. v. United States, 103 Fed. Cl. 23, 26–27 (2012) (noting that "[i]f plaintiff is right that these typical types of harm warrant a stay pending appeal here, then such would be true for every incumbent who fails to obtain a successor contract"); PGBA, LLC v. United States, 60 Fed. Cl. 196, 221 (2004). Notably, AvKARE has not alleged that the loss of this contract would pose an immediate threat to its entire business. See Akima Intra-Data, 120 Fed. Cl. at 28–29.

Further, the Court finds that to the extent that AvKARE does suffer harm as a result of the denial of a stay, such harm is to some extent of its own making. Thus, the only obstacle to AvKARE's ability to secure consideration of its offer is its refusal to either provide its suppliers' CSP information or demonstrate that it cannot obtain the

information the VA seeks. Moreover, the VA has agreed to multiple extensions of AvKARE's contract during the course of this litigation, notwithstanding that AvKARE has flatly refused to comply with the VA's request for its suppliers' CSP information. Thus, AvKARE has not shown that it will suffer irreparable harm absent an injunction.

C. Whether Issuing the Injunction Will Substantially Injure the Other Parties Interested in the Proceeding

Given the nature of the FSS contract at issue, issuing a stay to AvKARE will not "substantially injure any other parties interested in the proceeding" except as outlined below in the discussion of the public interest. Unlike a typical procurement, granting an injunction in favor of AvKARE would not prevent any other VA FSS schedule contractors from moving forward with their own contracts. This factor, accordingly, should be subsumed within factor four, which concerns where the public interest lies.

D. Where the Public Interest Lies

The parties dispute the extent to which the public interest, measured by dollars spent, favors AvKARE. AvKARE claims that the government would save more than $2 million each month if AvKARE's contract remains in effect, Pl.'s Mem. at 13, while the government contends that the figure is much lower, Def.'s Opp'n to Pl.'s Post-J. Mot. for a Prelim. Injunction at 8, ECF No. 53.

This debate over the extent to which AvKARE is or is not providing the government with a good deal, however, is not the measure of whether granting a stay would serve the public interest. As a general matter, the public has a strong interest in ensuring compliance with the laws governing procurement. See SAI Indus. Corp. v. United States, 60 Fed. Cl. 731, 747 (2004); Metcalf Const. Co., Inc. v. United States, 53 Fed. Cl. 617, 645 (2002); see also FAR 1.102(a) (stating that that purpose of the federal acquisition system as a whole is "to deliver on a timely basis the best value product or service to the customer, while maintaining the public's trust and fulfilling public policy objectives"). And that interest is particularly acute here, where the regulation in question provides the method for resolving the debate over whether AvKARE's prices are fair and reasonable, and thus for determining whether contracting with AvKARE serves the taxpayers' interests. See Info. Scis. Corp. v. United States, 80 Fed. Cl. 759, 799 (2008) (discussing the public's interest in "ensuring that the ultimate awardee offers the 'best value' to the Government, pursuant to the terms of the Solicitation and applicable procurement regulations").

In short, GSA has determined that in order to help the government avoid being overcharged for products that are also sold commercially, it is necessary to insist that dealer/resellers without significant commercial sales supply manufacturers' CSP data, at least absent a demonstration that such data is not obtainable. Accordingly, the public has a strong interest in seeing this regulatory requirement enforced as to AvKARE's offer. That interest would be frustrated, however, if AvKARE's contract were extended again, this time by court order rather than by the consent of the parties.

CONCLUSION

For the reasons set forth above, the Court concludes that AvKARE is unlikely to succeed on the merits of its appeal and that it has not made a persuasive case that it will necessarily suffer irreparable harm if the Court does not issue the injunction. Moreover, the public interest in compliance with a regulatory regime designed to ensure fair and reasonable pricing of items on the Federal Supply Schedule favors denial of AvKARE's stay request. Therefore, AvKARE's motion to stay the Court's judgment pending appeal is **DENIED**.

IT IS SO ORDERED.

/s/ Elaine D. Kaplan
ELAINE D. KAPLAN
Judge