United States Small Business Administration
Office of Hearings and Appeals

SIZE APPEAL OF: AcelRx Pharmaceuticals, Inc., Appellant, Appealed From Size Determination No. 6-2013-64	SBA No. SIZ-5501 Decided: September 24, 2013

APPEARANCES

Thomas O. Mason, Esq., Frances E. Purcell, Jr., Esq., Christopher J. Kimball, Esq., Cooley LLP, Washington, D.C., for Appellant

DECISION [1]

I. Introduction and Jurisdiction

This is an appeal from a size determination of AcelRx Pharmaceuticals, Inc. (Appellant). According to the size determination, Appellant is not eligible for a deferral and reduction of the fee owed to the Department of Health and Human Services, Food and Drug Administration (FDA) for reviewing a new drug application. For reasons discussed *infra*, the appeal is denied and the size determination is affirmed.

The Small Business Administration (SBA), Office of Hearings and Appeals (OHA) decides size determination appeals under the Small Business Act of 1958, 15 U.S.C. § 631 *et seq.*, and 13 C.F.R. parts 121 and 134.

II. Background

A. The Request for a Size Determination

On April 22, 2013, SBA's Office of Government Contracting, Area VI (Area Office)

[1] This decision was originally issued under a protective order. Pursuant to 13 C.F.R. § 134.205, I afforded Appellant an opportunity to propose redactions to the published decision. Appellant proposed redactions, which OHA considered in redacting the decision. OHA now publishes a redacted version of the decision for public release.

received from FDA a request for a size determination of Appellant, in accordance with 13 C.F.R. § 121.901. Appellant had requested a small business waiver of the Prescription Drug User Fee Act (PDUFA) fee it owes the FDA for reviewing a human drug application under the user fee provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 379g & 379h(d).

B. Size Determination

On August 16, 2013, the Area Office issued Size Determination No. 6-2013-64 concluding Appellant is not a small business concern under the 500-employee size standard established by the PDUFA. The Area Office determined Appellant's size as of April 22, 2013, the date it received the request for a size determination of Appellant.

The Area Office explained that the largest blocks of Appellant's diluted shares are owned by [Fund 1] with [xx]%; [Next Largest Shareholder] with [xx]%; [[xxxxxxx] with [xx]%; [Fund 2] with [xx]%; and [xxxxxxxx] with [xx]%. Smaller blocks of stock are owned by [Fund 3] with [xx]%, and [Fund 4] with [xx]%. Size Determination at 2.

The Area Office explained that [Funds 1-4] "are significantly owned by" three common owners: [Investor 1], [Investor 2], and [Investor 3].[2] Size Determination at 3. The Area Office determined these three investors share an identity of interest based on this common investment, and therefore aggregated their interests in these funds. 13 C.F.R. § 121.103(f). Taken together, the three investors own a majority interest of the funds. Accordingly, because the three investors have the collective ability to control the four venture capital funds based on their ownership, the funds are affiliated with each other. *Id.* §§ 121.103(a)(1) and (c)(1).

As a result of this affiliation, the Area Office aggregated the four funds' shares of Appellant's stock. Because their [xx]% aggregated share is more than twice that of [Next Largest Shareholder], Appellant's next largest shareholder, the Area Office found Appellant affiliated with [Funds 1-4] under the largest minority shareholder rule, 13 C.F.R. § 121.103(c)(1). *Size Appeal of Novalar Pharm., Inc.*, SBA No. SIZ-4977 (2008).

The Area Office then calculated Appellant's size. Although Appellant was itself an eligible small business, it exceeded the size standard when its employees were aggregated with those of its affiliates.[3] Size Determination at 5.

C. The Appeal

On August 30, 2013, Appellant filed the instant appeal with OHA. Appellant argues the size determination lacks evidentiary support, and requests that OHA remand this matter for a proper analysis as to whether Appellant and the venture capital funds are affiliated.

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[2] [Collectively, Investors 1-3 own a majority of each fund].

[3] [Funds 1 and 4] also have significant ownership interests in [Affiliate 1], [Affiliate 2], [Affiliate 3], [Affiliate 4], and [Affiliate 5]. Accordingly, the Area Office found the funds, and therefore Appellant, affiliated with these firms as well. 13 C.F.R. § 121.103(a) and (c).

Appellant specifically contends the Area Office determined, without factual support, that the four venture capital funds are affiliated based on their owners' identity of interest. Appellant argues such summary conclusions are impermissible. *Size Appeal of Tri-Ark Indus., Inc.*, SBA No. SIZ-4200 (1996) ("a size determination must state in writing the basis for its findings and conclusion. A size determination that consists of summary conclusions, and provides neither adequate notice to interested parties nor an appropriate basis for review by [OHA], will be remanded to the Area Office for corrective action."); *see also Size Appeal of DynaLantic Corp.*, SBA No. SIZ-5125 (2010) (remanding size determination based on lack of evidence in the record to support affiliation finding.)

Appellant argues this faulty determination occurred during the course of the size investigation and in the size determination itself. During the size investigation, Appellant argued the funds are not affiliated with Appellant or each other because the funds are separate entities with separate ownership interests in Appellant, and [Fund 1]'s ownership interest was not large relative to that of the next largest shareholder. Email from James Welch to Esmeralda Sanchez (May 17, 2013). The Area Office responded:

> [Funds 1-4] are considered affiliates of one another, even if they are considered "separate" entities. Our regulations dictate that when their combined holdings is considered significant relative to any other holding, the owner of that largest block can be deemed to have the power to control the firm in question.

Email from Esmeralda Sanchez to James Welch (May 20, 2013). Appellant argues the Area Office provided no explanation for the conclusion that the funds are affiliated, and requested no information regarding those funds before concluding they were affiliated. Appellant explains that once the Area Office determined the funds were affiliated with each other, the Area Office then requested SBA Form 355s for the funds.

Appellant argues the size determination itself also lacks factual findings to support the determination that the venture capital funds are affiliated. Although the size determination references the ownership of the four funds, the size determination contains no supportive analysis demonstrating how such ownership renders the funds affiliated with each other.

Next, Appellant asserts it lacked a meaningful opportunity to rebut the finding that [Investors 1-3] have an identity of interest. According to Appellant, the Area Office restricted its rebuttal to two issues: whether the three owners have ownership interests in entities other than the four funds; and whether the owners serve on boards other than those of the four funds. Moreover, the Area Office did not consider the responses it submitted to these questions. On remand, Appellant requests that OHA direct the Area Office to offer Appellant a fuller opportunity to rebut the presumption of identity of interest.

III. Discussion

A. Timeliness and Standard of Review

Appellant filed its appeal within fifteen days after its receipt of the size

determination.[4] Therefore, the appeal is timely. 13 C.F.R. § 134.304(a).

Appellant has the burden of proving, by a preponderance of the evidence, all elements of its appeal. Specifically, Appellant must prove the size determination is based upon a clear error of fact or law. 13 C.F.R. § 134.314. OHA will disturb the size determination only if, after reviewing the record, the administrative judge has a definite and firm conviction that the Area Office erred in making its key findings of fact or law. *Size Appeal of Taylor Consultants, Inc.*, SBA No. SIZ-4775, at 11 (2006).

B. Governing Law

The Small Business Act authorizes the SBA to determine the size status of concerns for the purposes of that statute. Small Business Act §§ 3(a)(2)-(3), 8(b)(6); 15 U.S.C. §§ 632(a)(2), 637(b)(6). The SBA has rulemaking authority for establishing the size standards and other rules and regulations necessary to carry out the Small Business Act. *See* §§ 3(a)(2)-(3), 5(b)(6); §§ 15 U.S.C. 632(a)(2)-(3), 634(b)(6). These other necessary rules issued by SBA include the affiliation rules and the other size regulations at 13 C.F.R. part 121.

The SBA's size regulations authorize SBA to provide a size determination on request from other agencies of the federal government. 13 C.F.R. § 121.901. This regulation contains no specific size standard to be used in the case of a request by the FDA under the PDUFA; however the PDUFA itself provides for a 500-employee size standard. 21 U.S.C. §§ 379g(11), 379h(d)(4)(A). The SBA's other size regulations, including those governing affiliation and OHA's precedential case law interpreting the size regulations, also apply to size determinations. *Size Appeal of Novalar Pharm., Inc.*, SBA No. SIZ-4977, at 10-12 (2008).

C. Merits of the Appeal

It is undisputed that Appellant does not exceed the size standard of 500 employees. Thus, the only question before me is whether the Area Office committed clear error of law in concluding that Appellant is affiliated with its four venture capital fund owners. I find no such error.

Appellant argues unpersuasively that the Area Office did not provide factual support for its determination that the four funds are affiliated. The applicable SBA regulation provides that "[i]ndividuals or firms that have identical or substantially identical business or economic interests (such as family members, individuals or firms with common investments, or firms that are economically dependent through contractual or other relationships) may be treated as one party with such interests aggregated." 13 C.F.R. § 121.103(f). The Area Office explained that the funds are affiliated because their common owners—[Investors 1-3]—have common investments in these funds. Size Determination at 3. This finding is supported by the SBA Form 355s for the funds.

[4] Appellant represents it received the size determination by email on August 19, 2013. Appeal at 1 n.1.

Appellant also complains that the size determination contains no supportive analysis demonstrating how such ownership renders the funds affiliated with each other. As Appellant points out, an area office must offer more than unsupported conclusions. *Size Appeal of Peerless Chain Co.*, SBA No. SIZ-4784, at 9 (2006) ("Rather than offer unsupported conclusions, an area office must be able to cite evidence that proves that concern "x" owns concern "y" or concern "z" owns a certain percentage of concern "k." Absent such evidence, it is clear error for the Area Office to maintain one concern can control another.) Specifically, the area office must "state in writing the basis for its findings and conclusions." 13 C.F.R. § 121.1009(e). The purpose behind this rule is to provide adequate notice to Appellant and an appropriate basis for review. *Tri-Ark Indus., Inc.*, SBA No. SIZ-4200, at 5 (1996). In this case, the Area Office explained that the funds' common owners have an identity of interest as a result of their common investment in the funds, and cited the relevant regulation and supporting evidence. Thus, the Area Office satisfied § 121.1009(e)

Contrary to Appellant's citations, *Size Appeal of Tri-Ark Industries* and *Size Appeal of DynaLantic Corporation* do not support the proposition that an area office must articulate its reasoning to the challenged firm during the size investigation. In those cases, OHA remanded the size determination because the area office did not articulate its reasoning in the size determination itself, not because the area office failed to explain the affiliation finding to the challenged firm during the size investigation. *Tri-Ark Indus.*, SBA No. SIZ-4200, at 5 (1996); *DynaLantic Corp.*, SBA No. SIZ-5125, at 11 (2010).

I also note that the Area Office did not need to find an identity of interest among [Investors 1-3] to request SBA Form 355s for the four funds. Appellant's SBA Form 355 required Appellant to list the name and address of those who own more than 10% of its stock. SBA Form 355, Question 4 and Instruction 8. Appellant, therefore, had to reveal that [Fund 1] owns [xx]% of Appellant. The Area Office was then free to ask for more information regarding the ownership of [Fund 1] and the other investments held by [Fund 1]'s owners. Accordingly, the Area Office would have inevitably discovered the common investments held by [Investors 1-3].

Finally, Appellant's argument that it did not receive a full opportunity to rebut the presumption of identity of interest is contradicted by the record. During the course of the size investigation, the Area Office informed Appellant:

> SBA allows you to rebut the determination that [Investors 1-3] are considered to have an identity of interest based on common investments
> 1. Do the three investors hold any ownership in any other entity external to that of the [xxxx] family of venture capital firms? If so, please indicate.
> 2. Do the three investors hold positions in any Board [o]f an entity external to that of the [xxxx] family of venture capital firms? If so, please indicate.

Email from Esmeralda Sanchez to [xxxxx] (June 26, 2013). Appellant argues that the Area Office restricted its opportunity to rebut the presumption of identity of interest to these two questions. According to this correspondence, though, the Area Office did not expressly limit Appellant's rebuttal. In addition to responding to the Area Office's questions, Appellant could have offered whatever evidence or argument it desired to rebut the presumption.

The record also undermines Appellant's claim that the Area Office ignored the responses regarding the investors' roles in other companies. The Area Office included these responses in the record, and although the Area Office did not discuss the responses in the size determination, it is not clear that a more thorough discussion would have resulted in a different outcome. Accordingly, any error in this regard is harmless. *Size Appeal of iGov Techs.*, SBA No. SIZ-5359, at 13-14 (2012).

In sum, I find the Area Office properly determined [Investors 1-3] have an identity of interest, and collectively have the power to control [Funds 1-4]. Because these funds' aggregated ownership interest in Appellant is more than twice that of the next largest shareholder, I cannot find clear error in the determination that Appellant is affiliated with [Funds 1-4] under the largest minority shareholder rule, 13 C.F.R. § 121.103(c)(1). *Size Appeal of Novalar Pharm., Inc.*, SBA No. SIZ-4977 (2008).

IV. Conclusion

For the above reasons, I DENY the instant appeal and AFFIRM the Area Office's Size Determination. This is the final decision of the Small Business Administration. 13 C.F.R. § 134.316(d).

CHRISTOPHER HOLLEMAN
Administrative Judge