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**Comptroller General
of the United States**

**United States Government Accountability Office
Washington, DC 20548**

Decision

Matter of: Celadon Laboratories, Inc.

File: B-298533

Date: November 1, 2006

Lawrence A. Kessner, Esq., for the protester.

Douglas Kornreich, Esq., Department of Health and Human Services, for the agency.

Katherine I. Riback, Esq., and James A. Spangenberg, Esq., Office of the General Counsel, GAO, participated in the preparation of the decision.

DIGEST

Agency failed to determine whether the evaluators of the protester's proposal under a Small Business Innovation Research program solicitation had a conflict of interest, where the evaluators were employed by firms that promote a type of technology that assertedly is directly challenged by the type of technology offered in the protester's proposal.

DECISION

Celadon Laboratories, Inc. protests the decision of the Department of Health and Human Services (HHS) not to fund its phase I proposal under the Small Business Innovation Research (SBIR) program solicitation No. PHS 2006-1. Celadon asserts that the agency failed to reasonably consider conflicts of interest that it contends likely impaired the objectivity of the four members of the Special Emphasis Panel (SEP), which evaluated its proposal.

We sustain the protest.

The SBIR program is conducted pursuant to the Small Business Innovation Development Act, 15 U.S.C. § 638 (2000), which requires certain federal agencies to reserve a portion of their research and development funds for awards to small businesses. Firms first apply for a 6-month phase I award to test the scientific, technical, and commercial merit and feasibility of a certain concept. If phase I is successful, the firm may be invited to apply for a phase II award to further develop the concept. After the completion of phase II, firms are expected to obtain funding from the private sector and/or non-SBIR government sources to develop the concept

into a product for sale in the private sector and/or military markets. See Small Business Administration's SBIR Website, <http://www.sba.gov/sbir/>.

To commence the program, the agency issues an SBIR solicitation that sets forth research and development topics and subtopics that emphasize the need for proposals with advanced concepts to meet specific agency requirements, which may be general or narrow in scope, depending on the needs of the agency. The object of this phase I procurement is to obtain and evaluate small business proposals under stated evaluation criteria to determine which small businesses should receive phase I contracts. During phase I, the agency will determine the scientific and technical merit and feasibility of the proposed effort and the quality of performance of the small business concern with a relatively small agency investment before consideration of further federal support in phase II. SBIR Program Policy Directive ¶ 4(a).

On August 4, 2005, HHS issued this solicitation which identified a number of research topics for the National Institutes of Health (NIH) and the Centers for Disease Control. One of the topics included in the solicitation was Topic 216, Development of Inhibitory Reagents for the Study of Protein Function, which was a research topic of interest requested by the National Cancer Institute (NCI), a division of NIH. The purpose of this topic was to solicit proposals from small business concerns to encourage the development and commercialization of new technology for the generation of small molecules and novel mechanisms to modulate protein function within a cancer cell. Solicitation at 33.

Proposals submitted in response to this solicitation were to be evaluated by an SEP. The SEP is an independent peer review panel, which evaluates the proposals, determines which small business concerns should receive phase I contracts and makes specific recommendations related to the scope, direction and/or conduct of the proposed research. Solicitation at 18.

In this instance, the SEP, assembled by the NCI, consisted of three members from private industry and one from academia. According to the agency, in preparation for their work on the SEP, prospective members were mailed a copy of NIH's rules, including those relating to conflicts of interest. Prior to their first meeting, the four members provided to HHS a signed NIH Pre-Review Certification Form, in which each member certified that he/she did not have a conflict of interest with the firms that had submitted proposals for review, including Celadon. Additionally, according to the agency, conflicts of interest were addressed in the SEP orientation conference and at the beginning of the first review meeting.

On April 8, 2006, the protester's chief executive officer expressed concern to the agency about the composition of the SEP, asserting that each of its members had a

real conflict of interest that would likely bias their review of Celadon's proposal.¹ Agency Report (AR), Tab 6, Letter from Celadon to NCI (April 8, 2006). In this letter, and in an April 19 letter, Celadon identified with specificity why each of the SEP members had what Celadon considered a real conflict of interest. *Id.*; AR, Tab 10, Letter from Celadon to NCI (April 19, 2006). Basically, Celadon asserted that all four of the SEP members work for, or are associated with, a segment of the industry, specifically vendors that rely on siRNA technology, a technology that Celadon, without rebuttal, asserts was directly competitive with the technology it offered in its proposal, specifically siLNA technology. Celadon provided supporting details for why it considered each of these evaluators to have a real conflict of interest because of their employers' commitment to, and reliance on, siRNA technology. AR, Tab 10, Letter from Celadon to NCI (April 19, 2006).

By April 25, the SEP had completed its evaluation of Celadon's proposal and found it to be technically unacceptable. In response to the concerns that had been expressed by Celadon, the agency took the following measures:

The Contracting Officer asked the Project Officer to review the proposal and the minutes of the SEP and provide a recommendation as to whether the minutes reflect an accurate assessment of the proposal. The Project Officer's response concurred with the assessment of the SEP and [he] felt the minutes accurately reflected both the strengths and weaknesses of the proposal. The Contracting Officer reviewed the conflict of interest certifications, the minutes of the SEP and the recommendation of the Project Officer and concluded that, in his opinion, there was no bias exhibited in the review of the Celadon proposal.

Contracting Officer's Statement at 2.

On July 13, the agency informed Celadon that its proposal would not be considered for award and on that same day, Celadon requested a formal debriefing. The agency provided a debriefing on July 14, and Celadon filed this protest on July 24.

The agency initially contends that Celadon's protest was untimely because it was aware of the composition of the SEP prior to the rejection of its proposal and it did not file a protest within 10 days of becoming aware of the composition of the SEP.

Our Bid Protest Regulations contain strict rules for the timely submission of protests. These timeliness rules reflect the dual requirements of giving parties a fair opportunity to present their cases and resolving protests expeditiously without

¹ During the course of this procurement, the protester had been informed by an NCI official of the identity of the SEP members.

disrupting or delaying the procurement process. Peacock, Myers & Adams, B-279327, Mar. 24, 1998, 98-1 CPD ¶ 94 at 3-4; Professional Rehab. Consultants, Inc., B-275871, Feb. 28, 1997, 97-1 CPD ¶ 94 at 2. Under these rules, a protest such as Celadon's, based on other than alleged improprieties in a solicitation, must be filed not later than 10 days after the protester knew or should have known of the basis for protest, whichever is earlier. 4 C.F.R. § 21.2(a)(2) (2006). An exception to this general rule is a protest that challenges "a procurement conducted on the basis of competitive proposals under which a debriefing is requested and, when requested, is required." Id. In such cases, with respect to any protest basis which is known or should have been known either before or as a result of the debriefing, the protest must be filed not later than 10 days after the date on which the debriefing is held. Id.

Here, the protest was filed within 10 days of the debriefing Celadon received, even though it knew its protest bases sometime earlier. The above-mentioned exception to our timeliness rules, however, applies only to procurements conducted on the basis of "competitive proposals," a term not defined by our Bid Protest Regulations, nor by statute or regulation.² See Systems Plus, Inc. v. United States, 68 Fed. Cl. 206 (2005). We have previously determined that the use of negotiated procedures in accordance with Federal Acquisition Regulation (FAR) Part 15 and as evidenced by the issuance of a request for proposals, constitutes a procurement conducted on the basis of competitive proposals. Professional Rehab. Consultants, Inc., supra, at 2. Here, while this SBIR procurement was not conducted under FAR Part 15 procedures, the solicitation requested "proposals" to be judged under specified evaluation criteria.³

We need not resolve whether this procurement was conducted on the basis of competitive proposals within the meaning of our timeliness rules because we find that this protest is appropriate for consideration under the significant issue exception to our timeliness rules. 4 C.F.R. § 21.2(c). What constitutes a significant issue is to be decided on a case-by-case basis. Pyxis Corp., B-282469, B-282469.2, July 15, 1999, 99-2 CPD ¶ 18 at 4. We generally regard a significant issue as one of widespread interest to the procurement community and that has not been previously decided. Satilla Rural Electric Membership Corp., B-238187, May 7, 1990, 90-1 CPD ¶ 456 at 3. The issue here--the application of conflict of interest regulations to peer review evaluators in SBIR procurements--is not one that we have previously decided and is one that can be expected to arise in future SBIR procurements. Accordingly, we consider the issue raised to be a significant one that should be treated on the merits.

² We note, however, that Federal Acquisition Regulation (FAR) § 6.401(b), "Competitive Proposals," begins with the reference, "See Part 15 for procedures."

³ We note that the agency cited FAR Part 15 in offering Celadon a debriefing. AR, Tab 14, Letter from NCI to Celadon (July 14, 2006).

Celadon protests that the agency failed to reasonably consider the real conflicts of interest of each of the members of the SEP that would impair the SEP's objectivity in evaluating its proposal. Celadon claims that all three of the SEP members work for companies "whose economic lifeblood" is the development and sale of proprietary siRNA technology, which would be directly competitive with the technology proposed in Celadon's proposal. Protest at 3. While the fourth panelist was an academic researcher, Celadon contends that his work is supported by one of these companies involved with siRNA technology.

Federal Acquisition Regulation (FAR) § 3.101-1 provides as follows:

Government business shall be conducted in a manner above reproach and, except as authorized by statute or regulation, with complete impartiality and with preferential treatment for none. Transactions relating to the expenditure of public funds require the highest degree of public trust and an impeccable standard of conduct. The general rule is to avoid strictly any conflict of interest or even the appearance of a conflict of interest in Government-contractor relationships.

NIH is required to have peer review evaluators of proposals for research and development contracts. 48 C.F.R. § 315.305(a)(3)(ii)(F) (2005). There are specific regulations governing scientific peer review of research grant applications and research and development contract projects, including "biomedical and behavioral research and development contract project concepts and proposals for contract projects administered by the National Institutes of Health," such as proposals in response to this SBIR program solicitation. 42 C.F.R. Part 52h. Among other things, this regulation defines apparent and real conflicts of interest for peer review evaluators and generally prohibits evaluators with such conflicts from evaluating proposals covered by 42 C.F.R. Part 52h.⁴ 42 C.F.R. §§ 52h.1, 52h.5. This regulation specifically contains the following definition of a "real conflict of interest":

Real conflict of interest means a reviewer or close relative or professional associate of the reviewer has a financial or other interest in an application or proposal that is known to the reviewer and is likely to bias the reviewer's evaluation of that application or proposal as

⁴ The regulation also provides that the Director may waive any requirements relating to a "real conflict of interest," if the Director determines that there are no other practical means for securing appropriate expert advice on the particular matter, and that the real conflict of interest is not so substantial as to be likely to affect the integrity of the advice to be provided by the reviewer. 42 C.F.R. § 52h.5(b)(4). There was no such waiver here.

determined by the government official managing the review (the Scientific Review Administrator, or equivalent), as acknowledged by the reviewer, or as prescribed by this part. A reviewer shall have a real conflict of interest if he/she or a close relative or professional associate of the reviewer:

(1) Has received or could receive a direct financial benefit of any amount deriving from an application or proposal under review;

(2) Apart from any direct financial benefit deriving from an application or proposal under review, has received or could receive a financial benefit from the applicant institution, offeror or principal investigator that in the aggregate exceeds \$10,000 per year; . . .

(3) Has any other interest in the application or proposal that is likely to bias the reviewer's evaluation of that application or proposal. Regardless of the level of financial involvement or other interest, if the reviewer feels unable to provide objective advice, he/she must recuse him/herself from the review of the application or proposal at issue. The peer review system relies on the professionalism of each reviewer to identify to the designated government official any real or apparent conflicts of interest that are likely to bias the reviewer's evaluation of an application or proposal.

42 C.F.R. § 52h.2(q).

Celadon contends that each of these evaluators had a "real conflict of interest" under paragraph (3) above in that they each had an "interest in the application or proposal that is likely to bias the reviewer's evaluation of that application or proposal," given that each of the evaluators was employed by a firm whose "economic lifeblood" was directly competitive with the technology proposed in Celadon's proposal.

42 C.F.R. § 52h.2(q)(3).

The record shows that the agency's investigation of Celadon's allegations consisted of verifying that each member of the SEP certified that he/she had no conflict of interest with regard to Celadon, and reviewing the evaluation record and finding no evidence of bias in the evaluation. While it is true that the NIH regulations contemplate a self-assessment by evaluators as to whether they think they have a real conflict of interest, the regulations do not contemplate that a self-certification by the evaluator is all that is ever needed to satisfy the requirement that he or she does not have a real conflict of interest, particularly where, as here, specific and colorable allegations of a real conflict of interest on the part of the evaluators were brought to the attention of cognizant agency officials. Under the circumstances present here, NIH was required to specifically determine whether these evaluators had real conflicts of interest under the applicable regulations. However, the record shows that NIH made no such determination.

While the agency contends that the conflicts identified by the protester are too remote to be considered real conflicts of interest, it has not explained why this is the case in light of the protester's specific documented allegations that each of the members of the SEP, by virtue of their employment or financial relationship with a firm that promoted siRNA technology, would not be able to objectively evaluate Celadon's proposal that offered siLNA technology.⁵ We have recognized that an actual or apparent conflict of interest may arise when an agency employee has both an official role in the procurement process and a personal stake in the outcome. For example, we sustained a protest because of a conflict of interest that invalidated the evaluation where, in the course of a competitive sourcing study conducted pursuant to the procedures of Office of Management and Budget Circular A-76, 14 of the 16 agency employees who were responsible for evaluating private-sector proposals also held positions that were subject to the study (and could be affected by the outcome of their evaluation). DZS/Baker LLC; Morrison Knudsen Corp., B-281224 et al., Jan. 12, 1999, 99-1 CPD ¶ 19 at 5. While we do not decide whether the evaluators here had real conflicts of interest, the record shows that the agency failed in its obligation to determine whether these individuals' employment caused them a real conflict of interest that could bias their evaluation of Celadon's proposal as contemplated under its applicable regulation.⁶

The agency's determination that there is no evidence of actual bias on the part of the evaluators in the evaluation of Celadon's proposal does not address the concerns arising from a conflict of interest. The strict limitations on both actual and apparent conflicts of interest reflect the reality that the potential harm flowing from such situations is, by its nature, frequently not susceptible to demonstrable proof of bias or prejudice. Department of the Navy--Recon., B-286194.7, May 29, 2002, 2002 CPD

⁵ In support of this proposition the agency cites Grassetti v. Weinberger, 408 F.Supp. 142 (N.D. Cal. 1976). The plaintiff in that case argued that the three members in the peer review panel had a conflict of interest in that these individuals, or the institutions with which they were associated, were recipients of NCI funded grants. The court found the alleged conflicts were too remote, and granted the defendant's motion for summary judgment on the grounds that the record failed to show any violation of law in the denial of the plaintiff's grant application.

⁶ We disagree with the agency's characterization of Celadon's protest as being limited to a complaint about the "balance" of the SEP and thus not for consideration by our Office. See University Research Corp., B-253725.4, Oct. 26, 1993, 93-2 CPD ¶ 259 at 7 (GAO will not generally review objections to the composition of a peer review panel absent a showing of possible abuse of discretion because of a conflict of interest or actual bias on the part of the evaluators). In fact, the focus of Celadon's protest is on the alleged conflicts on the part of all of the evaluators, a matter that the agency has not yet adequately investigated.

¶ 76 at 11. Thus, where the record establishes that a conflict of interest exists on the part of the evaluators, to maintain the integrity of the procurement process, we will presume that the protester was prejudiced, unless the record establishes the absence of prejudice. The Jones/Hill Joint Venture, B-286194.4 *et al.*, Dec. 5, 2001, 2001 CPD ¶ 194 at 14. Indeed, where the majority of the evaluators have conflicts, as is alleged to be the case here, we have consistently presumed prejudice in the evaluation. The Jones/Hill Joint Venture, *supra*; DZS/Baker LLC; Morrison Knudsen Corp., *supra*.

We would ordinarily recommend that the agency consider whether there is a conflict of interest on the part of the evaluators in accordance with 42 C.F.R. § 52h and take appropriate corrective action if a conflict of interest on the part of the evaluators was determined to exist. However, here the agency has stated that all the SBIR funds for the fiscal years have been allocated and it has no funds for additional awards under the SBIR solicitation.⁷ Under the circumstances, we recommend that it reimburse Celadon its proposal preparation costs. We also recommend that the agency reimburse Celadon for the costs of filing and pursuing its protest, including reasonable attorney's fees. Celadon's certified claim for costs, detailing the time spent and costs incurred, must be submitted to the agency within 60 days of receiving this decision. 4 C.F.R. § 21.8(f)(1).

The protest is sustained.

Gary L. Kepplinger
General Counsel

⁷ Moreover, it does not appear that it would be feasible to disturb the awards already made under this solicitation.