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Comptroller General
of the United States

United States General Accounting Office
Washington, DC 20548

Decision

Matter of: Novartis Pharmaceuticals Corporation

File: B-285038.4; B-285038.5

Date: February 1, 2002

Ronald K. Henry, Esq., Kaye, Scholer, Fierman, Hays & Handler, for the protester.
Donald A. Tobin, Esq., and Lori Ann Lange, Esq., Bastianelli, Brown & Kelley, for the intervenor.
Maura C. Brown, Esq., and Phillipa L. Anderson, Esq., Department of Veterans Affairs, for the agency.
John L. Formica, Esq., and James A. Spangenberg, Esq., Office of the General Counsel, GAO, participated in the preparation of the decision.

DIGEST

The protester was not prejudiced by the agency's alleged defective evaluation of the offerors' proposed implementation and small disadvantaged business plans submitted in response to a solicitation, where the record reflects that, even if the protester had been aware of the manner in which the agency evaluated proposals, it would not have submitted a different proposal that would have had a reasonable possibility for award, particularly given its significantly high price.

DECISION

Novartis Pharmaceuticals Corporation protests the award of a contract to Mylan Pharmaceuticals Inc. under request for proposals (RFP) No. 797-NC-00-0043, issued by the Department of Veterans Affairs (VA), for the drug clozapine.[1] Novartis argues that the agency's evaluation of proposals and selection of Mylan's proposal as representing the best value to the government was unreasonable and not in accordance with the evaluation factors set forth in the solicitation.

We deny the protest.

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[1] Clozapine, originally manufactured only by Novartis under their trademark Clozaril®, is used for the treatment of schizophrenia. Novartis currently supplies virtually all of the clozapine required by the VA for its patients. Agency Report (AR) (Nov. 19, 2001) at 2 n.1.

BACKGROUND

The RFP provided for the award of a fixed-price contract for a base period of 1 year with four 1-year options. The RFP, as amended, contemplated establishing a source to provide an estimated 20,040 bottles of clozapine tablets per year for purchase through VA's Pharmaceutical Prime Vendor (PPV) program.[2] RFP at 3; amend. 4 at 2. The solicitation stated that award would be made to the offeror submitting the proposal determined to be most advantageous to the agency. The RFP provided that price was the most important factor; less important were the past performance and implementation plan evaluation factors, which were equal in importance; and the small disadvantaged business (SDB) factor, which was significantly less important than the other factors; price was said to be more important than the combined weight of the other factors.[3] RFP at 32.

The solicitation requested that offerors submit technical proposals that included completed past performance forms and an implementation plan. RFP at 31. The RFP stated that the implementation plan was to detail how the offeror would satisfy the RFP's requirements regarding the operation and maintenance of a clozapine registry, such that each issue addressed would be complete and detailed enough to assure the agency of the offeror's understanding and capability to perform the cited requirements, and to "substantiate that the contract will be fully operational on the contract start date."[4] RFP at 4, 31. The RFP included a detailed six-page specification of the registry requirements, and stated that "by signing this solicitation and providing a proposal the offeror assures the VA that their registry meets the [listed registry] requirements." RFP at 5-10.

Proposals were received from five firms by March 31, 2000. The agency evaluated the proposals received, conducted discussions with the three offerors whose proposals were found in the competitive range (including Novartis and Mylan), and requested and evaluated final revised proposals.

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[2] Under the PPV Program the VA awards separate contracts for the product distribution and for the product itself. Once a supply source is obtained for a product, it is distributed for use nationwide. RFP at 3.

[3] Although not disclosed in the RFP, the record reflects that the evaluation factors, consistent with the source selection plan, were accorded the following weights in the source evaluation: price (60 percent); past performance (17 percent); implementation plan (17 percent); SDB (6 percent). AR (Nov. 19, 2001), Tab 17, Source Selection Plan, at 1.

[4] We denied Novartis's protest of an alleged ambiguity in the solicitation regarding the submission of the implementation plan. Novartis Pharm. Corp., B-285038, July 6, 2000, 2000 CPD ¶ 116.

Before an award selection was made, the agency became aware of various medical studies that caused it to review its requirements and obtain additional information from the offerors and the Food and Drug Administration. Based on the results of this review, VA amended the RFP on March 30, 2001 to provide that while "[a]ll new patient starts will be prescribed the awardee's product," the "VA has made the medical decision not to make it mandatory that physicians switch patients to the awarded drug due to the highly sensitive nature of this drug," and that "the decision to switch patients must be physician driven." This amendment changed the estimated quantity of clozapine to be purchased by the agency from 33,401 to 20,040 bottles per year, and provided revised price schedules to be completed by the offerors. Additionally, the amendment made a number of changes to the "registry requirements" section of the RFP by deleting or revising some provisions and adding new ones. Offerors were requested to acknowledge the amendment by April 20, 2001, in order to remain in the competition. RFP amend. 4.

After receiving the amendment, Novartis sent the agency a letter dated April 12, 2001, stating that Novartis was confused "with respect to the operation of the registry" as required by the amended RFP, and posing a number of questions. AR (Dec. 17, 2001), Tab 6, Novartis Letter to VA, at 1 (April 12, 2001). The agency responded by explaining with regard to the amendment's effect on the "registry requirements" that "[t]he amendment does not request any additional technical information from any offerors. However, if you want to submit additional data you may do so." AR (Dec. 17, 2001), Tab 7, Agency Letter to Novartis (April 17, 2001), at 2.

The three competitive range offerors submitted signed copies of amendment No. 4 with completed price schedules only. AR (Dec. 17, 2001), Tabs 8 and 10, Offerors' Responses to Amend. No. 4. None submitted a revised technical proposal addressing the amended registry requirements.

Subsequently, in response to further protests by Novartis, the agency issued amendment Nos. 5 and 6 to allow for the submission of revised technical proposals and prices. Mylan and the third offeror responded by submitting signed copies of the amendment with completed price schedules only. AR (Dec. 17, 2001), Tabs 8 and 10, Offerors' Responses to Amend. No. 6. Novartis responded by submitting, in addition to a signed copy of the amendment and a completed price schedule, a two-page cover letter providing certain "[n]ew information," such as Novartis's research on potential additional uses of Clozaril® and copies of certain testimony before Congress. AR (Nov. 19, 2001), Tabs 15 and 22, Novartis Response to Amend. No. 6.

The agency reconvened the TEP (which had previously completed its evaluation of the final revised technical proposals) to evaluate the information provided by Novartis in response to amendment No. 6. The TEP concluded that Novartis's response "provided no new insight," and accordingly, that the proposal's "previous

technical rating require[d] no changes." AR (Nov. 19, 2001), Tab 18, Memo for the Record (Sept. 20, 2001).

The proposals of all three offerors received ratings of "highly acceptable" under the past performance factor, "acceptable" under the implementation plan factor, and "acceptable" overall.[5] AR (Nov. 19, 2001), Tab 13, Memo for Record (Oct. 12, 2001), at 2-5. Novartis's proposed price based upon the estimated quantities set forth in the solicitation was [DELETED] per year, the third offeror's price was [DELETED], and Mylan's price was $1,090,365. AR (Nov. 19, 2001), Tab 14, Price Analysis. The agency determined that Mylan's proposal represented the best value to the government, and awarded a contract to that firm. AR (Nov. 19, 2001), Tab 13, Memo for Record (Oct. 12, 2001), at 6.

After requesting and receiving a debriefing, Novartis filed these protests. Novartis protests that the agency's evaluation of proposals under the past performance, implementation plan, and SDB factors was unreasonable.

PAST PERFORMANCE EVALUATION

With regard to the agency's evaluation of proposals under the past performance factor, Novartis generally complains that Mylan should not have received the same "highly acceptable" rating as Novartis because Mylan has "essentially no experience 'under procurements of a same or similar nature to the proposed procurement,'" which was one of the considerations in evaluating past performance under the RFP. Protester's Comments/Supplemental Protest at 15; see RFP at 32.

The evaluation of past performance is a matter within the discretion of the contracting agency. In reviewing an agency's evaluation of past performance, we will not reevaluate proposals, but instead will examine an agency's evaluation to ensure that it was reasonable and consistent with the solicitation and with applicable procurement statutes and regulations. Acepex Mgmt. Corp., B-283080 et al., Oct. 4, 1999, 99-2 CPD ¶ 77 at 3.

The solicitation provided that proposals would be evaluated under the past performance factor to "determine whether the offeror has consistently demonstrated adherence to contract terms and conditions and a commitment to customer service," and that "the offeror [would] be evaluated on the depth[,] breadth and relevance of its experience and performance under procurements of a same or similar nature to the proposed procurement." RFP at 32.

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[5] The possible ratings were outstanding, highly acceptable, acceptable, poor, and unsatisfactory. AR (Nov. 19, 2001), Tab 13, Memo for Record (Oct. 12, 2001), at 2.

The record reflects that Mylan has performed a number of contracts involving the supply of pharmaceuticals, including clozapine, with estimated values that exceed Mylan's proposed price for this solicitation by a significant amount. AR (Nov. 19, 2001), Tab 29, Mylan's Past Performance Questionnaires. The agency noted, in evaluating Mylan's proposal as "highly acceptable" under the past performance factor that that firm's references reported that it is "very customer orient[]ed" and is "willing to make changes [that its] customer required." The agency added that, according to the references, Mylan's products were "consistently in good condition, on time, [with] no recalls," and that Mylan was an "excellent company to do business with." AR (Nov. 19, 2001), Tab 13, Memo for Record (Oct. 12, 2001), at 5. Based upon the record here, which reflects that Mylan has performed contracts for the supply of pharmaceuticals with estimated values that exceed Mylan's proposed price here, and that the references' responses were quite favorable, the agency's evaluation of Mylan's proposal as "highly acceptable" under the past performance factor was reasonable.

IMPLEMENTATION PLAN EVALUATION

Protest Contentions and Agency Response

Novartis next objects to the agency's evaluation of proposals under the implementation plan factor. Specifically, the protester argues that the agency failed to evaluate proposals in accordance with the terms of the RFP because it did not evaluate whether the proposals met the mandatory clozapine registry requirements set forth in the solicitation as issued and modified by amendment No. 4. In support of this argument, Novartis provides an analysis detailing what, in its view, are each of the "mandatory minimum requirements" set forth in the six pages of registry specifications in the RFP with particular reference to those in amendment No. 4. The protester next provides a detailed review of Mylan's proposal, pointing out each instance where, in the protester's view, Mylan's proposal fails to specifically address, or takes exception to, what the protester has identified as a mandatory minimum requirement. Novartis also states that its proposal should have received a higher rating under this factor because of its superior ability to implement the mandatory minimum requirements, given that Novartis's registry is already in place. The protester concludes that it was prejudiced by the agency's failure to conduct a rational evaluation of the implementation plan because Mylan's proposal should have been rejected as unacceptable, and because in any case a rational technical evaluation would have demonstrated the superiority of Novartis's implementation plan over Mylan's, which would have led to an award to Novartis.

The agency responds that its evaluation of proposals under the implementation plan factor was reasonable and included an adequate assessment of whether the proposals met the agency's requirements for the registry as set forth in the solicitation. The agency asserts that it was not required to evaluate proposals to determine whether they affirmatively demonstrated compliance with each and every

term in the registry requirements section of the solicitation that could be construed as creating a requirement. In this regard, the agency points out that the section of the solicitation providing the registry requirements began by stating that "[b]y signing this solicitation and providing a proposal the offeror assures the VA that their registry meets the following requirements." See RFP at 5. The agency adds with regard to amendment No. 4 that "VA added these requirements fully intending them to be [contract] requirements," and that "[i]t was never VA's intent to evaluate and rate them." AR (Dec. 17, 2001) at 3. The agency argues that because Mylan signed both the original solicitation and amendment No. 4, it was obligated to provide a registry that meets the solicitation's requirements. AR (Dec. 17, 2001) at 6. The agency points out here that the offerors' understanding of amendment No. 4 was in apparent agreement with the agency's, given that none of the offerors, including Novartis, submitted a revised technical proposal addressing the amendment's additions and deletions to the registry requirements. Finally, the agency argues that, despite Novartis's claims to the contrary, Mylan's proposal did not take exception to any of the solicitation's requirements.

Implementation Plan Evaluation Record

In our view, with regard to the solicitation as issued, Novartis is correct in asserting that the agency did not perform the type of detailed evaluation of proposals under the implementation plan factor that would ensure that the proposals affirmatively demonstrated compliance with each and every term in the RFP that could be considered as creating a mandatory requirement. Rather, the record reflects that the TEP engaged in a more generalized review of proposals. Specifically, the evaluation summaries included in the record reflect that the TEP evaluated the proposals' implementation plans by reviewing them to determine how they approached the transfer of data, report transmission modes, report transmission requirements, and data security. AR (Nov. 19, 2001), Tabs 20, 25, 30, Revised TEP Scoring. We note that while Novartis's implementation plan was considered acceptable, Mylan's initial proposal was found technically unacceptable under the implementation plan factor, and that Mylan, in response to the discussion questions posed by the agency, submitted a lengthy and detailed revised proposal that was ultimately evaluated as acceptable. AR (Nov. 19, 2001), Tabs 25-28, Mylan's Initial Technical Proposal, TEP's Evaluation of Mylan's Initial Technical Proposal, Mylan's Revised Technical Proposal, TEP's Evaluation of Mylan's Revised Proposal. The record also evidences that Novartis is correct in contending that the agency did not perform any evaluation to determine whether the proposals met the registry requirements added by amendment No. 4; indeed, there effectively was nothing to evaluate, given that none of the offerors, including Novartis, submitted a revised technical proposal responding to the amendment.

Lack of Prejudice

We need not decide whether the agency was obligated to perform the type of detailed evaluation of proposals under the implementation factor as argued for by Novartis, or whether the agency was remiss in failing to evaluate proposals to determine whether they met the registry requirements added by amendment No. 4. Our Office will not sustain a protest unless the protester demonstrates a reasonable possibility that it was prejudiced by the agency's actions, that is, unless the protester demonstrates that, but for the agency's actions, it would have had a substantial prospect of receiving award. McDonald-Bradley, B-270126, Feb. 8, 1996, 96-1 CPD ¶ 54 at 3; see Statistica, Inc. v. Christopher, 102 F.3d 1577, 1581 (Fed. Cir. 1996). As explained below, and as argued by the agency, the record demonstrates that Novartis was not prejudiced by the manner in which the agency evaluated proposals under the implementation plan factor.

Alleged Exceptions by Mylan to Registry Requirements

First, from our review of the record and as illustrated by the following examples, we agree with the agency that while Mylan's proposal (and those of the other offerors, including Novartis) did not affirmatively demonstrate compliance with each and every term in the registry requirements section of the RFP that could be construed as creating a requirement, Mylan's proposal did not, despite the protester's view to the contrary, take exception to any of the RFP's terms.

For example, the protester asserts that Mylan's proposal is inconsistent with certain of the clozapine registry "data security" requirements contained in the initial RFP (and not modified by amendment No. 4). Specifically, the protester points out that Mylan's proposal included the statement that [DELETED], and argues that this statement effectively takes exception to the solicitation's provision that "[d]ata must be secured in a storage system which restricts access to direct clozapine registry employees and prevents unauthorized alterations, misuse, or transmissions." Protester's Comments/Supplemental Protest at 13-14; see RFP at 10; AR (Nov. 19, 2001), Tab 26, Mylan's Revised Technical Proposal, at 4 of 6. However, this section in Mylan's proposal begins with the statement that Mylan understands [DELETED], and continues with the explanation that [DELETED]. AR (Dec. 17, 2001) at 17; AR (Nov. 19, 2001), Tab 26, Mylan's Revised Technical Proposal, at 3 of 6. Accordingly, we agree with the agency here that Mylan's proposal can reasonably be read only as making the agency aware of an [DELETED], rather than as taking exception to the statement in the RFP providing for restricted access to the registry.

As another example, the protester asserts that Mylan's proposal is inconsistent with the clozapine registry "data security" provision which states that "[d]ata supplied to the clozapine registries . . . is subject to the Privacy Act of 1974." Protester's Comments/Supplemental Protest, at 11-12; see RFP at 9. The protester, while conceding that Mylan's proposal "described the capability of its system" with regard

to the provisions of the RFP relating to data security as well as Mylan's "understanding that disclosure is illegal," nevertheless argues that Mylan's proposal is unacceptable with regard to this aspect of the data security requirements solely because it "did not promise protection from disclosure." Protester's Comments/Supplemental Protest, at 11-12; Protester's Reply to Supplemental Agency Report (Dec. 21, 2001) at 16.

In evaluating Mylan's proposal, the agency found it "very detailed" with respect to these data security provisions. AR (Nov. 19, 2001), Tab 25, TEP's Evaluation of Mylan's Revised Proposal. Specifically, the agency points out that Mylan's proposal states with regard to data security that [DELETED]. AR (Nov. 19, 2001), Tab 26, Mylan's Revised Proposal, at 9 of 10. The agency also points out that Mylan's proposal "included an overview of the Privacy Act," and stated that it would provide appropriate National Clozapine Coordinating Center personnel, who are authorized to access the data, [DELETED]. Id.; AR (Nov. 19, 2001), Tab 25, TEP's Evaluation of Mylan's Revised Proposal at 4; AR (Dec. 17, 2001) at 14. Despite the protester's view to the contrary, we cannot find the agency's evaluation of Mylan's proposal as "acceptable" with regard to these data security provisions objectionable, given that, as reflected above, the agency reasonably determined that the proposal reflected an adequate understanding of, and approach to, accomplishing the agency's data security needs.

Mylan's Failure to Address Registry Requirements

Novartis also points to a number of separate registry provisions, contained in either amendment No. 4 or in the initial clozapine registry specifications unchanged by amendment No. 4, and asserts that Mylan's proposal should be considered unacceptable because it did not specifically address these provisions in its proposal. For example, Novartis claims that Mylan did not show in its proposal that it complies with registry provision in amendment No. 4 providing that "[t]he clozapine registry of the offeror . . . [m]ust be able to issue authorization numbers via telephone and facsimile at a minimum." The protester claims that "[n]one of the materials provided in the Agency Report indicate[] that . . . Mylan . . . has complied with this mandatory minimum requirement, or is willing and able to comply with this requirement in the future." Protester's Comments/Supplemental Protest at 5.

Although the RFP may have contemplated more detailed responses to the registry provisions, we cannot find unreasonable the agency's effective determination that Mylan's proposal would meet VA's clozapine registry needs as reflected in the RFP. As discussed previously, Mylan's proposal included a relatively detailed implementation plan that did not take exception to any of the terms of the solicitation. It also included a signed copy of the solicitation that, according to the RFP (at 5), assured that Mylan's registry met the solicitation's registry requirements. As such, the fact that Mylan's proposal did not specifically address each and every term in the registry requirements section of the solicitation that could be construed

as creating a requirement (just as Novartis's proposal did not address each and every one of these provisions) does not render unreasonable the agency's judgment that Mylan's proposal offers a registry that will satisfy the agency's needs.

Protester Not Prejudiced

There is nothing in the record that suggests that Novartis would have submitted a different offer that would have had a reasonable possibility of award, even if it had known that the agency would not perform the type of detailed evaluation of proposals under the implementation factor as argued for by Novartis, or perform any evaluation to determine whether the proposals met the registry requirements added by amendment No. 4. In this regard, none of the offerors, including Novartis, submitted a revised technical proposal that addressed the revised "registry requirements" set forth in amendment No. 4. See Hollingsead Int'l, B-227853, Oct. 19, 1987, 87-2 CPD ¶ 372 at 7 (protester was not prejudiced by the agency's failure to evaluate certain information required by the solicitation where each of the offerors, including the protester, submitted proposals that were deficient in this regard).

Moreover, Novartis did not submit the kind of detailed response to the registry requirements that it claims was required, but admits that there were "gaps" in its proposal. Specifically, Novartis concedes that it "would have been wise for Novartis to submit more technical information about its existing registry," instead of assuming the agency was fully aware of the registry's details, and that this lack of detail resulted in its proposal receiving only an "acceptable" rating for its implementation plan. Protester's Reply to Supplemental Agency Report (Dec. 21, 2001) at 10. Thus, it is not at all clear that Novartis's proposal should have been rated superior to Mylan's under the implementation plan factor, even if the detailed evaluation argued for by Novartis had been performed.

Additionally, the solicitation specified that price would be more important than all other factors combined in determining which proposal represented the best value to the agency. Indeed, as compared to the 60 percent weight attributed to price, the implementation plan was worth only 17 percent. Novartis's proposed price of [DELETED] for each year's estimated quantity was more than [DELETED] Mylan's proposed price of $1,090,365, and there is no indication in the record or reason to believe that Novartis would have priced its offer differently, had it been aware of how the agency would evaluate proposals under the implementation plan factor.[6] Moreover, as discussed above, the protester has not shown the two offerors' equal

[6] For example, we do not see how Novartis could credibly claim that its proposed price would have been less had it known that the agency would not evaluate proposals to ensure that they specifically complied with the registry requirements as amended by amendment No. 4, given that Novartis did not revise its technical proposal to address these amended requirements.

"highly acceptable" ratings for past performance (worth 17 percent) were unwarranted. Thus, given that the agency reasonably determined that Mylan's proposal did not take exception to the RFP's requirements and thus met its needs as reflected in the solicitation, the tremendous difference in the prices proposed by Novartis and Mylan, and the absence of any evidence of how Novartis could have improved its competitive posture if the implementation plan had been evaluated in the detail argued by Novartis, we fail to see any reasonable possibility that Novartis was prejudiced by the agency's actions here. See SOS Interpreting, Ltd., B-287477.2, May 16, 2001, 2001 CPD ¶ 84 at 4; Instrument Control Serv., Inc., B-285776, Sept. 6, 2000, 2000 CPD ¶ 186 at 4.

SDB FACTOR EVALUATION

The protester also contends that the record does not evidence any meaningful evaluation of proposals under the SDB factor. As mentioned previously, the RFP stated that the SDB factor was significantly less important than the past performance or implementation plan factors. RFP at 32. Consistent with this, the source selection plan provided that the SDB factor was to receive a weight of only 6 percent. AR (Nov. 19, 2001), Tab 17, Source Selection Plan, at 1. In evaluating proposals, the agency found that Novartis proposed to subcontract [DELETED] worth of work, or [DELETED] percent of the total contract value, to an SDB. AR (Nov. 19, 2001), Tab 13, Memo for Record (Oct. 12, 2001), at 3. With regard to Mylan's proposal, the agency noted that "Mylan indicated that they could not attribute any goals specific to the product Clozapine although their subcontract goals are 5% for SDB." Id. at 5. The record does not include an adjectival rating for any of the proposals under the SDB evaluation factor. Although the record indicates that the contracting officer, who served as the source selection authority for this acquisition, was aware of the offerors' SDB plans, it is unclear from the record how the competing approaches were considered in the source selection decision or whether they were considered at all. Id. at 3, 5-6.

Again, given the relatively low weight the SDB factor was accorded in the evaluation, the fact that Novartis's proposed SDB plan provided for a total of only [DELETED] worth of work to be subcontracted to an SDB concern, and the significant overall price difference between Mylan's and Novartis's proposal, we fail to see how Novartis was prejudiced by the apparent lack of attention to this factor paid by the agency in determining that Mylan's proposal represented the best value to the agency (even considering this problem in conjunction with the implementation plan evaluation).

The protest is denied.

Anthony H. Gamboa
General Counsel