



Decision

Matter of: Ortho-Clinical Diagnostics, Inc.

File: B-418324

Date: February 27, 2020

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Department of Justice, for the agency.
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participated in the preparation of the decision.

DIGEST

Protest that an agency misevaluated quotations is denied where, even though the agency assessed the protester's quotation as unacceptable for failing to meet a solicitation requirement, and allegedly waived part of the requirement in selecting the successful vendor's quotation, the protester was not prejudiced by the agency's actions as its quotation failed to meet another requirement that was not waived.

DECISION

Ortho-Clinical Diagnostics, Inc., of Raritan, New Jersey, protests the issuance of a Federal Supply Schedule (FSS) blanket purchase agreement (BPA) to Roche Diagnostics Corporation, of Indianapolis, Indiana, under request for quotations (RFQ) No. RFQ1380363, issued by the Department of Justice, Bureau of Prisons (BOP), for the lease of two integrated chemistry/immunochemistry analyzers for the United States Medical Center for Federal Prisoners in Springfield, Missouri. Ortho-Clinical argues that the RFQ contained defective specifications and that the BOP misevaluated quotations, treated vendors unequally, and improperly issued the BPA to Roche.

We dismiss the protest in part and deny it in part.

BACKGROUND

The RFQ, posted on the General Services Administration e-Buy system on August 22, 2019, sought quotations from vendors holding FSS contracts under Schedule No. 66 III (the clinical analyzers, laboratory, cost-per-test schedule), to lease two analyzers and supply the necessary supplies for 60 months. The RFQ provided that a

single BPA would be issued to the vendor whose quotation provided the best value under three factors: price, technical, and past performance history. Agency Report (AR), Tab 4, RFQ, at 17.

The requirement was for two integrated analyzers with the capability to perform clinically validated testing for a list of analyses, including “Bilirubin Conjugated, Bilirubin Total, Bilirubin Unconjugated” and “Syphilis (Automated).” RFQ at 4. The requirement was described as being for the installation and lease of the analyzers for 60 months, and the RFQ requested pricing on the basis of a price schedule per each individual sample that would be tested. To obtain pricing, the RFQ provided a table listing 70 tests on a separate for each, the annual estimated quantity for each test, and blank cells for the vendor to enter two prices on each line. The tests included “Bilirubin, Unconjugated” (line 11); “MHATP [microhemagglutination assay for *Treponema pallidum*¹] (TPPA [Treponema pallidum particle agglutination])” (line 45); “RPR [rapid plasma reagin]” (line 57); and “RPR Titer” (line 58). Price was to be evaluated using the “total aggregated pricing offered” for all performance periods. *Id.* at 17.

The BOP received quotations from four vendors, including Ortho-Clinical and Roche, which submitted the two lowest-priced quotations. Ortho-Clinical proposed to supply two of its analyzers but explained that, in order to meet the requirement to provide MHATP TPPA testing (which was not available on those two analyzers), it would provide a third analyzer (as well as installation, service, and support) to perform TPPA testing, until the TPPA assay was available on the two primary analyzers.² AR Tab 14, Ortho-Clinical Quotation, Section 2 (Response to Statement of Work), at 3.

The BOP concluded that Ortho-Clinical’s quotation failed to provide pricing for lines in the pricing table that were numbered 11, 57, and 58. AR Tab 8, Evaluation of Quotes Memorandum, at 1. Since the agency requested pricing for all lines in the RFQ’s pricing table, the quotations from Ortho-Clinical and another vendor were not considered for award. *Id.* The contracting officer contacted Ortho-Clinical to explain that its quotation would not be considered unless it provided pricing for all items. For line 11, the firm responded that it had quoted an approach where the bilirubin unconjugated assay were already part of the bilirubin conjugated test, so the unconjugated assay had not been separately priced. For lines 57 and 58, the firm responded that it did not provide pricing for the RPR or RPR Titer tests because its approach was for the agency to continue to perform those tests using the current methodology (that is, manually), but at a significantly lower volume due to its automation of the TPPA assay, which would serve as

¹ Treponema pallidum is the spirochete that causes syphilis in humans.

² In the pricing schedule, Ortho-Clinical’s quotation also noted that certain tests were not available on its FSS contract, including MHATP TPPA, RPR, and RPR Titer. AR Tab 14, Ortho-Clinical Quotation at 3.

an initial screen. Protest at 42 (Email from Ortho-Clinical Contract Manager to Contracting Officer (Oct. 31, 2019)).³

With respect to Roche's quotation, the contracting officer concluded that the quotation offered an evaluated price of \$4.8 million, and that no unacceptable information had resulted from the past performance and technical reviews.⁴ Contracting Officer's Statement at 1-2. The contracting officer assessed Roche's quotation as technically acceptable and determined that it provided the best value of the two acceptable quotations. Id. at 2. On November 18, the contracting officer established a BPA with Roche. Id. The agency provided notice of the award on November 20, Ortho-Clinical received a debriefing on December 2, and immediately filed this protest.

DISCUSSION

Ortho-Clinical argues that the RFQ contained defective specifications and that the BOP misevaluated the quotations, evaluated the vendors unequally, and improperly issued the BPA to Roche. As explained below, the protester's challenge to the terms of the RFQ is untimely, and our review of the record shows that the evaluation of its quotation as unacceptable was reasonable and that Ortho-Clinical was not prejudiced with respect to its alleged unequal evaluation treatment.

Challenge to Terms of RFQ

Ortho-Clinical's protest alleged that the RFQ unjustifiably restricted competition by specifying that all 70 tests had to be provided in a single analyzer unit, including MHATP (TPPA), RPR, and RPR Titers. Protest at 3. We agree with the BOP that the protester's argument challenges the express terms of the RFQ and so, to be timely, it had to be filed before the closing date for submission of quotations. 4 C.F.R. § 21.2(a). Again, the protest was filed after the BOP announced the selection of Roche--and thus, well after the RFQ closing date--so the protester's challenge to the terms of the RFQ is untimely. We informed the parties that the BOP need not address this issue in the agency report, and we now dismiss that ground of protest.

Evaluation Challenges

Ortho-Clinical argues that the BOP's evaluation of quotations was unreasonable because its own quotation was evaluated as unacceptable because it lacked syphilis tests while the BOP allegedly disregarded the lack of the same tests in the awardee's analyzer. The

³ The attachments to the protest were not separately numbered or otherwise indexed, so we use the PDF page numbering to identify them.

⁴ Ortho-Clinical was not represented by counsel that could seek admission under a protective order to certain documents, including Roche's quotation and the evaluation of that quotation. Our description of these documents is consequently limited.

firm argues that its quotation provided automated TPPA testing through a separate analyzer, and that Roche also either had to supply one or more additional analyzers, or had to propose that the BOP continue to perform those analyses directly, without automation. Thus the protester argues that the vendors were treated unequally. Protest at 3-4. Additionally, Ortho-Clinical argues the BOP's contention that Roche's quotation offered the full menu of tests is incorrect because Roche could not have represented that its analyzer would perform all three syphilis tests: TPPA, RPR, and RPR Titer testing. Protester's Comments at 1. Ortho-Clinical infers from the BOP's position that Roche must have materially misrepresented its product because regulatory approvals and public statements indicated that Roche's analyzers had only been approved for TPPA testing.⁵ Id. Additionally, Ortho-Clinical asserts that an automated TPPA test, by itself, is not an automated syphilis test because, under Centers for Disease Control (CDC) standards, the lab elements of a syphilis diagnosis also include an RPR or RPR Titer test.⁶ Id. at 4.

The BOP contends that Roche's quotation was acceptable because the only RFQ requirement was for the analyzer to provide "Syphilis (Automated)" testing. The BOP acknowledges that RPR and RPR Titer are listed in the RFQ pricing schedule, but the agency asserts that those pricing lines were simply "provided for the vendors to provide adequate information." AR Tab 9, Memorandum from Technical Evaluator to BOP Counsel (Dec. 19, 2019), at 2. The technical evaluation team explains that the pricing table "provided the BOP's current usage rate for the RPR/RPR titer tests and MHATP (TPPA) test as a reference point" and did not require that the analyzer perform those specific tests; the RFQ only required that the analyzer perform "an automated syphilis test." Supp. Declaration of Technical Evaluator, at 1. When read as a whole, according to the BOP's argument, the RFQ "did not require analyzers that could perform automated RPR/RPR Titer testing," and therefore Ortho-Clinical's protest is based on a misreading of the RFQ. Supp. Memorandum of Law (MOL) at 2.

Ortho-Clinical counters that the BOP's explanation is an attempt to rewrite the RFQ requirements because nothing in the RFQ indicated that the RPR and RPR Titer tests were listed in the price table only as background information for the vendors. Protester's Supp. Comments at 3. Read as a whole, according to Ortho-Clinical, the RFQ generally identified a requirement for automated testing for syphilis, and then in the pricing table

⁵ BOP argues that Ortho-Clinical failed to challenge the acceptability of Roche's analyzer's in its initial protest, and that the argument in its comments is thus untimely. Agency Response to Protester's Comments (Jan. 17, 2020) at 1. We disagree. Ortho-Clinical's initial protest directly asserted Roche's analyzer did not provide "those particular tests," in reference to TPPA, RPR, and RPR Titer (the specific tests that had been discussed just paragraphs earlier). Protest at 3. As such, we do not regard the inclusion of that argument in the protester's comments as raising an untimely new ground of protest.

⁶ Ortho-Clinical notes that patient history and clinical presentation are also elements of a diagnosis. Declaration of Ortho-Clinical's Medical Safety Officer, at 2.

listed the three specific syphilis tests (TPPA, RPR, and RPR Titer), which correspond to the tests used when making a syphilis diagnosis consistent with CDC guidance. Id.

Where an agency issues a solicitation to vendors holding FSS contracts, and conducts a competition among FSS vendors, we will review the record to ensure that the agency's evaluation is reasonable and consistent with the terms of the solicitation. Spectrum Comm, Inc., B-412395.2, Mar. 4, 2016, 2016 CPD ¶ 82 at 8. When the procurement is conducted pursuant to Federal Acquisition Regulation (FAR) subpart 8.4 and requires vendors to respond to a statement of work, the record must document the evaluation and selection as provided in FAR § 8.405-2(f), including the rationale for any tradeoffs made in the selection. Id.

Based on our review of the record, we agree with Ortho-Clinical that the RFQ required vendors to provide an analyzer that would perform all three syphilis tests. Further, for purposes of this decision, we assume as accurate Ortho-Clinical's assertion that Roche's analyzer does not perform RPR or RPR Titer tests. In effect, then, in selecting Roche's quotation for award, the BOP would have partially waived the automated syphilis testing requirement in the RFQ--specifically for automated RPR and RPR Titer testing. Yet, in citing the lack of automated RPR and RPR Titer tests when evaluating Ortho-Clinical's quotation, the BOP applied the waiver unequally.

Notwithstanding the conclusion above, our Office will not sustain a protest unless the protester demonstrates a reasonable possibility that it was competitively 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 chance of receiving the award. McDonald-Bradley, B-270126, Feb. 8, 1996, 96-1 CPD ¶ 54 at 3; see Statistica, Inc. v. Warren G. Christopher, 102 F.3d 1577, 1581 (Fed. Cir. 1996). Even in circumstances where the agency was unreasonable in accepting the awardee's proposal, a protester must still show that it was competitively prejudiced by a waiver of solicitation requirements in favor of the awardee. Orbital Scis. Corp., B-414603, B-414603.2, July 26, 2017, 2017 CPD ¶ 249 at 6. To demonstrate prejudice from the waiver or relaxation of solicitation requirements, a protester must show that it would have altered its proposal to its competitive advantage, or that the agency did not apply a similar waiver to the protester's proposal. Id.

Here, assuming that the BOP engaged in disparate evaluation treatment regarding the RPR and RPR Titer tests, Ortho-Clinical has not shown that it was competitively prejudiced. As Ortho-Clinical concedes, even though Roche has regulatory approval of an analyzer to perform TPPA testing, Ortho-Clinical's primary analyzer cannot perform that test at present. So, assuming that a waiver of the automated RPR and RPR Titer testing had been applied to both vendors' quotations, Ortho-Clinical's analyzer still fails to provide TPPA testing. Even though Ortho-Clinical quoted a separate analyzer to perform TPPA testing, as the BOP notes, that approach was inconsistent with the RFQ requirement for the analyzer to be integrated. Accordingly, the record shows that the BOP had a reasonable basis for evaluating Ortho-Clinical's quotation as unacceptable,

and that the firm was not competitively prejudiced by the award to Roche, even assuming that the BOP waived the requirement for automated RPR and RPR Titer testing.

The protest is dismissed in part and denied in part.

Thomas H. Armstrong
General Counsel