Canadian International Trade Tribunal
Tribunal canadien du commerce extérieur

CANADIAN INTERNATIONAL TRADE TRIBUNAL

Procurement

DECISION AND REASONS

File No. PR-2011-006

Sanofi Pasteur Limited

Decision made
Thursday, May 12, 2011

Decision and reasons issued
Thursday, May 26, 2011

Canada

IN THE MATTER OF a complaint filed pursuant to subsection 30.11(1) of the *Canadian International Trade Tribunal Act*, R.S.C. 1985 (4th Supp.), c. 47

BY

SANOFI PASTEUR LIMITED

AGAINST

THE DEPARTMENT OF PUBLIC WORKS AND GOVERNMENT SERVICES

DECISION

Pursuant to subsection 30.13(1) of the *Canadian International Trade Tribunal Act*, the Canadian International Trade Tribunal has decided not to conduct an inquiry into the complaint.

Jason W. Downey
Jason W. Downey
Presiding Member

Dominique Laporte
Dominique Laporte
Secretary

STATEMENT OF REASONS

1. Subsection 30.11(1) of the *Canadian International Trade Tribunal Act*[1] provides that, subject to the *Canadian International Trade Tribunal Procurement Inquiry Regulations*,[2] a potential supplier may file a complaint with the Canadian International Trade Tribunal (the Tribunal) concerning any aspect of the procurement process that relates to a designated contract and request the Tribunal to conduct an inquiry into the complaint. Subsection 30.13(1) of the *CITT Act* provides that, subject to the *Regulations*, after the Tribunal determines that a complaint complies with subsection 30.11(2) of the *CITT Act*, it shall decide whether to conduct an inquiry into the complaint.

2. The complaint relates to a procurement (Solicitation No. 6D034-100134/B) by the Department of Public Works and Government Services (PWGSC) for two influenza vaccines: a targeted vaccine for people over the age of 65 (item 001); and a trivalent influenza vaccine for the general population (item 002).

3. Sanofi Pasteur Limited (Sanofi) alleged that PWGSC failed to disqualify the proposal of one of its competitors, Novartis Pharmaceuticals Canada Inc. (Novartis). Specifically, Sanofi claimed that the products that Novartis proposed in response to the Request for Proposal (RFP) did not meet the mandatory criterion of the RFP that the products be "latex-free".

4. On August 5, 2010, PWGSC issued an RFP for Canada's annual influenza vaccine and backup pandemic supply. The due date for the receipt of bids was September 9, 2010. Bidders were required to bid on both item 001 and item 002. According to PWGSC, both Sanofi and Novartis submitted compliant bids. The RFP evaluation scheme provided that, depending on the number of compliant bids received, up to two contracts could be awarded and vaccines would be ordered, on an apportioned basis, based on the relative value of the first- and second-placed bidders.

5. The Tribunal notes that Sanofi was partially successful in competing for this requirement and entered into a contract with PWGSC on February 15, 2011.

6. According to Sanofi, on February 10, 2011, PWGSC informed it that PWGSC would order not less than 37 percent of the vaccines from Sanofi. Sanofi submitted that, on February 16, 2011, PWGSC informed it that the other 63 percent would be ordered from Novartis.

7. On February 22, 2011, PWGSC conducted a telephone debriefing with Sanofi during which Sanofi claimed to have learned that the two vaccines proposed by Novartis were those known as Agriflu and Fluad®.

8. On February 23, 2011, Sanofi objected to PWGSC, claiming that the products offered by Novartis were not latex-free, as had been required by the RFP.

9. Sanofi based this claim, in part, on information relating to a product insert used in the United States for Agriflu, which states the following: "The tip caps of the . . . prefilled syringes may contain natural rubber latex which may cause allergic reactions in latex sensitive individuals". As a remedy, Sanofi argued that PWGSC should cancel the contract with Novartis and award Sanofi 100 percent of the contract.

10. On April 21, 2011, PWGSC responded to Sanofi's objection.

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1. R.S.C. 1985 (4th Supp.), c. 47 [*CITT Act*].
2. S.O.R./93-602 [*Regulations*].

11. In its response, PWGSC stated that the latex-free requirement in the RFP was included to meet provincial and territorial requirements that the vaccines would be safe for use in latex-allergic or latex-sensitive individuals. In addition, this response indicated that the RFP required bidders to include, among other things, a statement in their bids that provided their specific acknowledgement that their proposed products would be latex-free and that the evaluators had reviewed Novartis' bid and determined that the proper certification had been provided.

12. PWGSC's letter further explained that, as a matter of contract administration and in response to the allegations raised by Sanofi, the Public Health Agency of Canada (PHAC), as technical authority for the requirement, had sought additional information from Novartis and had consulted with the Biologics and Genetic Therapies Directorate of the Department of Health.

13. According to PWGSC's letter, after consideration of the results of these inquiries, the PHAC concluded that Novartis had satisfactorily demonstrated that its products had been effectively treated to eliminate latex proteins and had confirmed, through testing, that its products did not have any detectable latex proteins associated with latex allergies.

14. On May 5, 2011, Sanofi filed a complaint with the Tribunal alleging that PWGSC violated the trade agreements by moving away from a rigorous approach in evaluating the goods as being "latex-free", according to the RFP, ". . . to a less stringent standard of being 'safe for use in latex allergic/sensitive individuals' or not containing 'detectable latex proteins associated with latex allergies'."

15. The filing of this complaint was timely according to subsections 6(1) and (2) of the *Regulations*.

Analysis

16. According to paragraph 7(1)(*c*) of the *Regulations*, to initiate an inquiry, the Tribunal must find that the complaint discloses a reasonable indication that the procurement has not been carried out in accordance with whichever of Chapter Ten of the *North American Free Trade Agreement*,[3] Chapter Five of the *Agreement on Internal Trade*,[4] the *Agreement on Government Procurement*,[5] Chapter K*bis* of the *Canada-Chile Free Trade Agreement*[6] or Chapter 14 of the *Canada-Peru Free Trade Agreement*[7] applies. In other words, the Tribunal must examine the complaint to determine if there is a reasonable indication that the procuring entity appears to have conducted the procurement in a manner that was in violation of one of the applicable trade agreements.

17. Article 506(6) of the *AIT* provides as follows:

> The tender documents shall clearly identify the requirements of the procurement, the criteria that will be used in the evaluation of bids and the methods of weighting and evaluating the criteria.

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3. *North American Free Trade Agreement between the Government of Canada, the Government of the United Mexican States and the Government of the United States of America*, 17 December 1992, 1994 Can. T.S. No. 2 (entered into force 1 January 1994) [*NAFTA*].
4. 18 July 1994, C. Gaz. 1995.I.1323, online: Internal Trade Secretariat <http://www.ait-aci.ca/index_en/ait.htm> [*AIT*].
5. 15 April 1994, online: World Trade Organization <http://www.wto.org/english/docs_e/legal_e/final_e.htm> [*AGP*].
6. *Free Trade Agreement between the Government of Canada and the Government of the Republic of Chile*, 1997 Can. T.S. No. 50 (entered into force 5 July 1997) [*CCFTA*]. Chapter K*bis*, entitled "Government Procurement", came into effect on September 5, 2008.
7. *Free Trade Agreement between Canada and the Republic of Peru*, online: Department of Foreign Affairs and International Trade <http://www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/peru-perou/chapter-chapitre-14.aspx> (entered into force 1 August 2009) [*CPFTA*].

18. Article 1015(4)(d) of *NAFTA*[8] provides as follows:

> [A]wards shall be made in accordance with the criteria and essential requirements specified in the tender documentation . . . .

19. The Tribunal notes that, according to Annex D - Section I of the RFP, "MANDATORY TECHNICAL CRITERIA - ANNUAL INFLUENZA VACCINE PROPOSAL", regarding "PRODUCT- LATEX", the RFP requires that the "[b]idder . . . acknowledge that all products will be latex-free".[9] In this regard, according to the PWGSC's letter of April 21, 2011, Novartis provided PWGSC with the necessary certification in its proposal.

20. After bid evaluation and contract award, Sanofi claims that the vaccines proposed by Novartis do not respect the "latex-free" requirement of the RFP.

21. PWGSC's April 21, 2011, letter reads as follows:

> Accordingly, in order to be compliant with this Mandatory requirement, bidders were required to include a statement that provided the specified acknowledgement. On that basis, the evaluators reviewed the Proposal submitted by Novartis in response to the Solicitation and determined that *the proper certification had been provided*, on this basis, the Proposal was compliant with the Mandatory requirement.
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> [Emphasis added]

22. The Tribunal is of the view that, at the time of evaluating the proposals and awarding the contract, PWGSC was entitled to rely on Novartis' certification. The Tribunal finds that the complaint (i.e. that the "latex-free" requirement of the RFP was not satisfied at the time of the evaluation of proposals) does not present any evidence that PWGSC's conclusion was not reasonable or was inconsistent with the requirements in the RFP.

23. In fact, the evidence submitted with the complaint indicates that PWGSC was in possession of Novartis's certification at the time of bid evaluation.[10] In fact, there is no indication that PWGSC had any reason to question Novartis' certification during the bid evaluation phase.

24. This approach is consistent with past Tribunal decisions on this matter, such as *Kinetic Solutions*[11] and *Airsolid Inc.*[12]

25. In *Kinetic Solutions*, a similar complaint was filed. In disposing of the complaint, the Tribunal stated the following:

> 18. When PWGSC evaluated Advantage Fitness's proposal and awarded the contract, it was entitled to rely on the certifications provided by Advantage Fitness. Furthermore, there is no evidence which indicates that, at that time, PWGSC was in possession of information which should have made it question the authenticity of these certifications. Therefore, the Tribunal is of the view that, at the time of contract award, PWGSC was correct in determining that Advantage Fitness's proposal met the minimum requirements set out in the RFP in respect of the recumbent bike. There is nothing in the complaint which indicates that PWGSC's decision to award the contract to Advantage Fitness was not made in accordance with the criteria and essential requirements specified in the tender documentation or that it contravened the aforementioned provisions of the trade agreements.

8. The *AGP*, the *CCFTA* and the *CPFTA* have similar provisions.
9. RFP at 44.
10. As indicated in PWGSC's letter dated April 21, 2011.
11. *Re Complaint Filed by 3202488 Canada Inc. o/a Kinetic Solutions* (18 February 2011), PR-2010-089 (CITT).
12. *Re Complaint Filed by Airsolid Inc.* (18 February 2010), PR-2009-089 (CITT).

26. More specifically, in *Airsolid Inc.*, the Tribunal adopted the following position when dealing with complaints such as this one:

> 11. At the time of evaluating the proposals and awarding the contract, PWGSC was entitled to rely on the document that was, in all likelihood, taken from Zodiac Marine's catalogue, and there was no evidence that would have made it question the information provided by the winning bidder concerning the dimensions of Zodiac Marine's SRMN 600 model. Furthermore, there was no evidence to indicate that PWGSC knew, prior to contract award, about the allegation that Zodiac Marine's SRMN 600 model could have been shorter than 6 metres, as alleged by Airsolid in its complaint.
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> 12. The Tribunal is of the view that the information in the complaint indicates that, at the time of contract award, PWGSC was correct in concluding that Zodiac Marine's SRMN 600 model met the mandatory requirements of the invitation to tender, since the document provided by the winning bidder clearly indicated that the model of boat at issue was 6 metres long. Consequently, the Tribunal is of the view that nothing in the documents provided by Airsolid indicates that the decision to award the contract to its competitor was not in accordance with the criteria and essential requirements specified in the tender documentation or contravened the provisions of the above-mentioned trade agreements, in particular, Article 506(6) of the *AIT* and Article 1015(4)(d) of *NAFTA*, as well as the similar provisions in the *CCFTA* and the *CPFTA*.

27. In considering its obligations under paragraph 7(1)(*c*) of the *Regulations*, the Tribunal had regard to a number of arguments provided by Sanofi in an attempt to demonstrate that PWGSC failed to apply the evaluation criterion of "latex-free" in a rigorous fashion.

28. Specifically, Sanofi, produced a U.S. product insert for Agriflu which indicated the following: "The tip caps of the . . . prefilled syringes may contain natural rubber latex which may cause allergic reactions in latex sensitive individuals."

29. Sanofi did not however indicate whether Canadian and U.S. health legislations were harmonious on the subject of labelling for the presence or absence of latex. Without a clear indication as to how the Tribunal must consider the U.S. labelling of a U.S. product in the context of a Canadian RFP for a Canadian product, the Tribunal cannot satisfactorily rely on this insert for direction.

30. Also, Sanofi did not indicate whether these U.S. goods are, in any way, the goods proposed by Novartis in response to the RFP at issue. The evidence does not show that the goods to which the U.S. product insert applies are in fact the goods that were proposed by Novartis in response to the RFP.

31. Finally, as for the tip caps, Sanofi did not demonstrate, other than through argument, that they are in fact used by Novartis in conjunction with the goods proposed in response to the RFP or that the proposed goods actually do contain latex. There was no demonstration either that PWGSC somehow would have known this at the time of bid evaluation and otherwise ignored it.

32. Sanofi also submitted Canadian product monographs[13] for Agriflu and FLUAD®, the other product that Novartis proposed, in an attempt to show that these monographs do not specifically state that these products are not latex-free. The Tribunal notes that nowhere in the respective product monographs does it mention that either Agriflu or FLUAD® and their packaging, vials, syringes or dispensers *do* contain latex.

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13. According to Sanofi, companies must have a product monograph approved by the Department of Health which contains, among other information, all representations to be made in respect of the promotion of new drugs, adequate directions for the use of the drug, information that should be provided to the consumer respecting the use of the product, etc.

33. Included in the complaint documents, Sanofi submitted a February 16, 2011, clarification request from the Department of Health relating to one of its own products, Fluzone influenza vaccine, in an attempt to demonstrate that a certain wording present in the Agriflu and FLUAD® product monographs could be held to mean that these vaccines are not latex-free. The Tribunal notes that this clarification request does not deal with either the Agriflu or the FLUAD® vaccines and finds it difficult to draw a parallel with a product that has nothing to do with the present RFP.

34. Finally, Sanofi submitted for consideration correspondence between Sanofi and Novartis dated December 8, 2010, in which Mr. John Dorsey, Vice-President and Head of Novartis, stated the following:

> You are correct in your observations that the current product monograph states that "the syringe plunger does not contain latex" and that promotional materials have made the claim that Agriflu* is latex free. The claim was submitted and approved by PAAB [Pharmaceutical Advertising Advisory Board]. *We do confirm that Agriflu* is latex free* and we are planning to update our monograph accordingly.
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> [Emphasis added]

35. According to its February 23, 2011, correspondence, it appears that Sanofi also supplied this letter to PWGSC.

36. Having considered all of these arguments, the Tribunal cannot come to the conclusion that these contentions or the documents that support them are indicative of the actual nature of the products that were proposed by Novartis in response to the current solicitation. The Tribunal finds that none of the arguments presented by Sanofi, individually or collectively, indicate that PWGSC failed to follow the trade agreements in evaluating the proposal submitted by Novartis.

37. Consequently, the Tribunal is of the view that nothing in the documents provided by Sanofi indicates that the decision to award the contract to its competitor was contrary to the criteria and essential requirements specified in the tender documentation or that it contravened the provisions of the above-mentioned trade agreements, in particular, Article 506(6) of the *AIT* and Article 1015(4)(d) of *NAFTA*, as well as the similar provisions in the *AGP*, the *CCFTA* and the *CPFTA*.

38. As such, the Tribunal concludes that the information on the record does not disclose a reasonable indication that the procurement has not been conducted in accordance with the relevant trade agreements.

39. In light of the foregoing, the Tribunal will not conduct an inquiry into the complaint and considers the matter closed.

DECISION

40. Pursuant to subsection 30.13(1) of the *CITT Act*, the Tribunal has decided not to conduct an inquiry into the complaint.

Jason W. Downey

Jason W. Downey
Presiding Member