Canada Border Services Agency | Agence des services frontaliers du Canada

NIT 2018 IN

OTTAWA, April 4, 2019

STATEMENT OF REASONS

Concerning the final determination with respect to the dumping of

CERTAIN NITISINONE CAPSULES FROM SWEDEN

DECISION

On March 20, 2019, pursuant to paragraph 41(1)(b) of the *Special Import Measures Act*, the Canada Border Services Agency made a final determination respecting the dumping of certain nitisinone capsules from Sweden.

Cet *Énoncé des motifs* est également disponible en français.
This *Statement of Reasons* is also available in French.

Canada

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SUMMARY OF EVENTS

[1] On August 2, 2018, the Canada Border Services Agency (CBSA) received a written complaint from Laboratoires KABS Inc. and its associated company MendeliKABS Inc. of Saint-Hubert, Quebec, (hereinafter, "the complainant"), alleging that imports of certain nitisinone capsules (NIT) from Sweden are being dumped. The complainant alleged that the dumping has caused injury and is threatening to cause injury to the Canadian industry producing like goods.

[2] On August 23, 2018, pursuant to paragraph 32(1)(a) of the *Special Import Measures Act* (SIMA), the CBSA informed the complainant that the complaint was properly documented. The CBSA also notified the government of Sweden that a properly documented complaint had been received.

[3] The complainant provided evidence to support the allegation that NIT from Sweden has been dumped. The evidence also discloses a reasonable indication that the dumping has caused injury and is threatening to cause injury to the Canadian industry producing like goods.

[4] On September 21, 2018, pursuant to subsection 31(1) of SIMA, the CBSA initiated an investigation respecting the dumping of NIT originating in or exported from Sweden.

[5] Upon receiving notice of the initiation of the investigation, the Canadian International Trade Tribunal (CITT) commenced a preliminary injury inquiry, pursuant to subsection 34(2) of SIMA, into whether the evidence discloses a reasonable indication that the alleged dumping of NIT has caused injury or retardation or is threatening to cause injury to the domestic industry producing the like goods.

[6] On November 20, 2018, pursuant to subsection 37.1(1) of SIMA, the CITT made a preliminary determination that the evidence discloses a reasonable indication that the dumping of NIT from Sweden has caused injury or is threatening to cause injury to the domestic industry.

[7] On December 20, 2018, as a result of the CBSA's preliminary investigation and pursuant to subsection 38(1) of SIMA, the CBSA made a preliminary determination of dumping of NIT originating in or exported from Sweden. On the same date, pursuant to subsection 8(1) of SIMA, provisional duty was imposed on imports of dumped goods that are of the same description as any goods to which the preliminary determination applies, and that are released during the period commencing on the day the preliminary determination was made and ending on the earlier of the day on which the CBSA causes the investigation in respect of any goods to be terminated pursuant to subsection 41(1) of SIMA or the day the CITT makes an order or finding pursuant to subsection 43(1) of SIMA.

[8] On December 21, 2018, the CITT initiated an inquiry pursuant to section 42 of SIMA to determine whether the dumping of the above-mentioned goods has caused injury or retardation or is threatening to cause injury to the domestic industry.

[9] Based on the available evidence, the CBSA is satisfied that NIT originating in or exported from Sweden has been dumped. Therefore, on March 20, 2019, the CBSA made a final determination of dumping pursuant to paragraph 41(1)(b) of SIMA in respect of those goods.

[10] The CITT's inquiry into the question of injury to the domestic industry is continuing, and it will issue its decision by April 18, 2019. Provisional duty will continue to be imposed on the subject goods from Sweden until the CITT renders its decision.

PERIOD OF INVESTIGATION

[11] The Period of Investigation (POI) for this investigation is January 1, 2018, to June 30, 2018.

PROFITABILITY ANALYSIS PERIOD

[12] The Profitability Analysis Period (PAP) for this investigation is January 1, 2018, to June 30, 2018.

INTERESTED PARTIES

Complainant

[13] Founded in 1997, Laboratoires KABS Inc. is a company that specializes in drug development and contract manufacturing. The head office and production facilities of Laboratoires KABS Inc. are located in Longueuil, Quebec. MendeliKABS Inc. is an affiliated company that is the promoter of NIT produced by Laboratoires KABS Inc. and has been granted market authorization and accreditation by Health Canada. The complainant is the only producer of NIT in Canada.

[14] The contact information of the complainant is as follows:

Laboratoires KABS Inc.
4500, rue de Tonnancour
Saint-Hubert, Quebec
J3Y 9G2

MendeliKABS Inc.
4601, rue de Tonnancour
Saint-Hubert, Quebec
J3Y 9J3

Trade Unions

[15] The complainant has indicated that there are no trade unions that represent persons employed in the production of NIT in Canada.

Importers

[16] At the initiation of the investigation, the CBSA identified 5 potential importers of the subject goods from CBSA import documentation and from information submitted in the complaint. All of the potential importers were sent the CBSA's Importer Request for Information (RFI)[1] in respect of imports of NIT from Sweden.

[17] One company, Sobi Canada Inc. (Sobi Canada) provided a response to the Importer RFI.[2] The CBSA sent the company two supplemental RFIs (SRFIs) to clarify information provided in the response and request additional information. Sobi Canada provided its responses to the SRFIs[3] and CBSA officers subsequently conducted an on-site verification at the premises of Sobi Canada's parent company in Stockholm, Sweden.

[18] The other four contacted parties all indicated that they did not import subject goods during the POI. Two of them, Mapi Life Sciences Canada Inc. and MSD/GMD, performed certain roles and responsibilities within Sobi Canada's sales process relating to the quality control and distribution of the goods. The other two, the Sainte-Justine Hospital and SigmaSanté, are the unrelated subsequent purchaser of the subject goods and the entity responsible for the tender process for the supply of NIT in Québec, respectively.[4]

[19] Based on the information available on the record, the CBSA believes that Sobi Canada is the importer for SIMA purposes. As such, in this investigation, the CBSA specified Sobi Canada to be the importer of the subject goods imported during the POI.

Exporters

[20] At the initiation of the investigation, the CBSA identified one exporter, Swedish Orphan Biovitrum AB (Sobi AB), and one contract manufacturer, Apotek Produktion & Laboratorier, of the subject goods based on CBSA import documentation and information submitted in the complaint. Both companies were sent the CBSA's Dumping RFI[5].

[21] One company, Sobi AB provided a substantially complete response to the CBSA's Dumping RFI.[6] Sobi AB is the parent company of Sobi Canada. In its response, Sobi AB indicated that it considers itself to be the importer, exporter and manufacturer of the subject goods. The CBSA sent the company a SRFI to clarify information provided in the response and request additional information. Sobi AB provided its response to the SRFI[7] and CBSA officers subsequently conducted on-site verification at the premises of Sobi AB in Stockholm, Sweden.

[22] Based on the information available on the record, the CBSA determined that Sobi AB is the exporter of subject goods for SIMA purposes.

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[1] Exhibit 18 (NC) - Importer RFI
[2] Exhibit 24 (NC) - Response to Importer RFI from Sobi Canada Inc.
[3] Exhibits 29 (NC) and 39 (NC) - Responses to supplemental RFI #1 and 2 - Sobi Canada Inc.
[4] Exhibit 24 (NC) - Response to Importer RFI from Sobi Canada Inc. – Question A3
[5] Exhibit 17 (NC) - Exporter RFI
[6] Exhibit 33 (NC) - Response to Exporter RFI from Swedish Orphan Biovitrum AB
[7] Exhibit 44 (NC) - Response to supplemental RFI #1 - Sobi AB

[23] The other contacted party, Apotek Produktion & Laboratorier, indicated that it is neither the exporter nor producer of the subject goods.

PRODUCT INFORMATION

Definition[8]

[24] For the purpose of this investigation, subject goods are defined as:

> *Capsules and tablets of nitisinone with a dosage of 2 mg, 5 mg, 10 mg and 20 mg, whether or not they are packaged for retail, originating in or exported from the Kingdom of Sweden.*

Additional Product Information[9]

[25] The goods in question are commonly called nitisinone capsules (NIT). The chemical name and the active molecule of nitisinone is 2 (2 Nitro 4 Trifluoromethylbenzoyl) 1, 3 Cyclohexanedione ("NTBC") and its molecular formula is $C_{14}H_{10}F_3NO_5$

[26] Nitisinone is a drug approved for the treatment of hepatorenal tyrosinemia type 1 (HT-1). HT-1 is a rare metabolic disease affecting approximately 1,000 people worldwide. Prevalence of this disease is particularly high in Quebec, where approximately 100 people receive NIT as treatment for HT-1.

[27] NIT is an orally administered drug. The capsules contain a powder of nitisinone and a pharmacologically inert substance. These drugs are sold in hospital and community pharmacies by prescription.

[28] The product definition includes nitisinone that is packaged for retail consumption at the time it is imported, that is, packaged in plastic or glass containers with an exact unit count of the capsules. In general, these containers contain sixty (60) capsule units with the same dosage. Blister pack-type containers are also included, as well as containers containing more or less than 60 capsules.

[29] The product definition also includes nitisinone that is not packaged for retail consumption at the time it was imported, that is, in bulk containers intended for bottling or packaging in Canada.

[30] The product definition does not include nitisinone in liquid suspension.

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[8] Exhibit 2 (NC) - Complaint Nitisinone – Para 38 and amendment to the product definition received on August 21, 2018.

[9] Exhibit 2 (NC) - Complaint Nitisinone – Para 42-70.

Production Process[10]

[31] The NIT production process can be subdivided into two elements; the production of the medicinal ingredient nitisinone and the assembly of the ingredients into a capsule.

[32] First, the chemical compound nitisinone is synthesized under controlled laboratory conditions. It is then combined with an inert substance and encapsulated in the desired proportions. The non-medicinal ingredients used by the complainant include corn starch, titanium dioxide, gelatin, shellac and iron oxide. The non-medicinal ingredients used by the manufacturer of the subject goods differ slightly, however, this does not affect the substitutability of the products. The assembled capsules are then bottled in plastic containers, each containing 60 units of the specified dosage.

Classification of Imports

[33] The subject goods are normally classified under the following tariff classification numbers (tariff numbers):

3003.90.00.90
3004.90.00.79
3004.90.00.90

[34] The listing of tariff numbers is for convenience of reference only. The tariff numbers may include non-subject goods. Also, subject goods may fall under tariff numbers that are not listed. Refer to the product definition for authoritative details regarding the subject goods.

LIKE GOODS AND SINGLE CLASS OF GOODS

[35] Subsection 2(1) of SIMA defines "like goods" in relation to any other goods as goods that are identical in all respects to the other goods, or in the absence of any identical goods, goods the uses and other characteristics of which closely resemble those of the other goods.

[36] In considering the issue of like goods, the CITT typically looks at a number of factors, including the physical characteristics of the goods, their market characteristics and whether the domestic goods fulfill the same customer needs as the subject goods.

[37] After considering questions of use, physical characteristics and all other relevant factors, the CBSA initiated its investigation under the premise that domestically produced NIT are like goods to the subject goods. Further, the CBSA was of the opinion that the subject goods and like goods constitute only one class of goods.

[10] Exhibit 2 (NC) - Complaint Nitisinone – Paragraphs 42-55.

[38] In its preliminary injury inquiry for this investigation, the CITT reviewed the matter of like goods and classes of goods. On December 5, 2018, it issued its preliminary injury inquiry *Statement of Reasons* for this investigation, indicating that "domestically produced nitisinone capsules of the same description as the subject goods are 'like goods' in relation to the subject goods and that there is a single class of goods."[11]

THE CANADIAN INDUSTRY

[39] The complainant is the only producer of NIT in Canada and accounts for all of the domestic production of the like goods.[12]

IMPORTS INTO CANADA

[40] During the final phase of the investigation, the CBSA refined the volume and value of imports based on information from CBSA import entry documentation and other information received from Sobi AB and Sobi Canada.

[41] The following table presents the CBSA's analysis of imports of NIT for the purposes of the final determination:

Imports of NIT into Canada
(POI: January 1, 2018 to June 30, 2018)

Country of Origin/Export	% of Total Import Volume
Sweden	100.0%
All Other Countries	N/A
Total Imports	**100.0%**

INVESTIGATION PROCESS

[42] Information was requested from all known and potential exporters, producers, vendors and importers, concerning shipments of NIT released into Canada during the POI.

[43] The Dumping RFI notified the contacted parties that failure to submit all required information and documentation, including non-confidential versions, failure to comply with all instructions contained in the RFI, failure to permit verification of any information or failure to provide documentation requested during the verification visits may result in the margin of dumping and the assessment of anti-dumping duties on subject goods being based on facts available to the CBSA. Further, they were notified that a determination on the basis of facts available could be less favorable to them than if complete, verifiable information was made available.

[11] http://www.citt.gc.ca/en/node/8472
[12] Exhibit 2 (NC) - Complaint Nitisinone – Para 108.

[44] After reviewing the RFI responses, SRFIs were sent to Sobi Canada and Sobi AB to clarify information provided in the responses and request additional information considered necessary for the investigation.

[45] An on-site verification was conducted at the premises of Sobi AB in Stockholm, Sweden.

[46] Details pertaining to the information submitted by Sobi AB in response to the Dumping RFI as well as the results of the CBSA's dumping investigation are provided in the *Dumping Investigation* section of this document.

[47] As part of the final phase of the investigation, case briefs and reply submissions were provided by counsels representing the complainant and the importer/exporter. Details of all representations are provided in **Appendix 2.**

DUMPING INVESTIGATION

[48] The following presents the results of the investigation into the dumping of NIT originating in or exported from Sweden.

Normal value

[49] Normal values are generally based on the domestic selling prices of like goods in the country of export, in accordance with section 15 of SIMA, or on the aggregate of the cost of production of the goods, a reasonable amount for administrative, selling and all other costs, plus a reasonable amount for profits, in accordance with paragraph 19(b) of SIMA.

[50] Where, in the opinion of the CBSA, sufficient information has not been furnished or is not available, normal values are determined pursuant to a ministerial specification in accordance with subsection 29(1) of SIMA.

Export Price

[51] The export price of goods sold to importers in Canada is generally in accordance with the methodology of section 24 of SIMA based on the lesser of the adjusted exporter's sale price for the goods or the adjusted importer's purchase price. These prices are adjusted where necessary by deducting the costs, charges, expenses, duties and taxes resulting from the exportation of the goods as provided for in subparagraphs 24(a)(i) to 24(a)(iii) of SIMA.

[52] Where a compensatory arrangement exists, the export price may be based on the importer's resale price of the imported goods in Canada to unassociated parties, less deductions for all costs incurred in preparing, shipping and exporting the goods to Canada that are additional to those incurred on the sales of like goods for use in the country of export, all costs that are incurred in reselling the goods (including duties and taxes) or associated with the assembly of the goods in Canada and an amount representative of the average industry profit in Canada, pursuant to paragraphs 25(1)(c) and 25(1)(d) of SIMA. In any cases not provided for under paragraphs 25(1)(c) and 25(1)(d) of SIMA, the export price is determined in such a manner as the Minister specifies, pursuant to paragraph 25(1)(e).

[53] Where, in the opinion of the CBSA, sufficient information has not been furnished or is not available, export prices are determined pursuant to a ministerial specification under subsection 29(1) of SIMA.

Margin of Dumping

[54] The margin of dumping by exporter is equal to the amount by which the total normal value exceeds the total export price of the goods, expressed as a percentage of the total export price. All subject goods released into Canada during the POI are included in the calculation of the margin of dumping of the goods. Where the total normal value of the goods does not exceed the total export price of the goods, the margin of dumping is zero.

RESULTS OF THE DUMPING INVESTIGATION

Swedish Orphan Biovitrum AB (Sobi AB)

[55] Sobi AB is a producer and exporter of the subject goods located in Stockholm, Sweden. It is a public limited liability company listed on Nasdaq Stockholm. Sobi AB is an integrated biotechnology company with in-house capabilities that encompass the entire value chain, from research, preclinical and clinical development, biologics manufacturing and supply, to patient access and distribution.

[56] Sobi AB provided a response to the CBSA's Dumping RFI[13]. A SRFI was sent to Sobi AB to gather additional information and seek clarification[14]. Officers of the CBSA also performed an on-site verification at the premises of Sobi AB[15]. For the final determination, Sobi AB's submission was considered to be substantially complete and reliable.

[57] Sobi AB had domestic sales of like goods during the PAP. Normal values were either determined in accordance with section 15 of SIMA, based on domestic selling prices of like goods or in accordance with paragraph 19(b) of SIMA, based on the aggregate of cost of production, a reasonable amount for administrative, selling and all other costs, and a reasonable amount for profits.

[13] Exhibit 33 (NC) - Response to Exporter RFI from Swedish Orphan Biovitrum AB
[14] Exhibit 44 (NC) - Response to supplemental RFI from Swedish Orphan Biovitrum AB
[15] Exhibit 60 (NC) - Verification Exhibits - Swedish Orphan Biovitrum AB and Swedish Orphan Biovitrum Canada

[58] In this regard, the cost of production was in accordance with paragraph 11(1)(a) of the *Special Import Measures Regulations* (SIMR), based on Sobi AB's verified cost data associated with the subject goods shipped to Canada; the amount for administrative, selling and all other cost was in accordance with subparagraph 11(1)(c)(i) of the SIMR; and the amount for profits was in accordance with subparagraph 11(1)(b)(i) of the SIMR, based on Sobi AB's sales of like goods in their domestic market, during the PAP.

[59] For the subject goods shipped to Canada during the POI, the CBSA determined that the export price, as determined under section 24, is unreliable by reason of a compensatory arrangement pursuant to subparagraph 25(1)(b)(ii) of SIMA. As such, export prices were either determined pursuant to paragraph 25(1)(c) of SIMA or pursuant to paragraph 25(1)(e) of SIMA.

[60] For subject goods that were subsequently sold by the importer during the POI, export prices were determined pursuant to paragraph 25(1)(c) of SIMA, based on the importer's selling price to an unassociated party, adjusted by deducting the costs incurred on or after the importation of the goods and on or before their sale by the importer, an amount for profit by the importer and the costs, charges and expenses incurred in preparing the goods for shipment to Canada and resulting from the exportation and shipment of the goods. The amount for profit was determined pursuant to paragraph 22(c) of the SIMR based on the most recent profit data that was available to the CBSA. The amount for profit was determined to be 17.85%[16] based on a report produced by Industry Canada which represents profit from pharmaceutical and pharmacy supplies merchant wholesalers during the year 2016.

[61] For subject goods that were imported but not subsequently sold by the importer during the POI, export prices were determined pursuant to paragraph 25(1)(e) of SIMA by calculating the weighted average export price, as determined for each dosage sold by the importer during the POI using the methodology of paragraph 25(1)(c) of SIMA.

[62] For the final determination, the total normal value compared with the total export price results in a margin of dumping of 1,594% for Sobi AB, expressed as a percentage of the export price.

[16] Exhibit 40 (NC) - Industry Canada - Pharma Wholesale Supply Industry Statistics

Summary of Results

[63] A summary of the results of the dumping investigation respecting all subject goods released into Canada during the POI is available in Appendix 1 and as follows:

Summary of the Margin of Dumping
(POI: January 1, 2018 to June 30, 2018)

Country of origin or export	Margin of Dumping (as % of Export Price)	Volume of Subject Goods as a Percentage of Total Imports
Sweden		
Sobi AB	1,594%	100%
All Other Exporters	N/A	0%

[64] Under paragraph 41(1)(a) of SIMA, the CBSA is required to terminate an investigation in respect of the goods of an exporter if the CBSA is satisfied that the goods have not been dumped or the margin of dumping of the goods of that exporter is insignificant, meaning a margin of dumping that is less than 2% of the export price of the goods.

[65] As can be seen from the table above, the goods under investigation have been dumped and the margin of dumping on the goods is greater than the threshold of 2% and is therefore not considered insignificant. As a result, the legislative requirement is satisfied for making a final determination of dumping.

DECISION

[66] On March 20, 2019, pursuant to paragraph 41(1)(b) of SIMA, the CBSA made a final determination of dumping respecting NIT originating in or exported from Sweden.

FUTURE ACTION

[67] The provisional period began on December 20, 2018, and will end on the date the CITT issues its finding. The CITT is expected to issue its decision by April 18, 2019. Provisional anti-dumping duty will continue to apply until this date on imports of subject goods from Sweden. For further details on the application of provisional duty, refer to the *Statement of Reasons* for the preliminary determination, which is available through the CBSA's website at: www.cbsa-asfc.gc.ca/sima-lmsi/menu-eng.html.

[68] If the CITT finds that the dumped goods have not caused injury and do not threaten to cause injury, all proceedings will be terminated. In this situation, all provisional duties paid or security posted by importers will be returned.

[69] If the CITT finds that the dumped goods have caused injury, the anti-dumping duties payable on subject goods released by the CBSA during the provisional period will be finalized

pursuant to section 55 of SIMA. Imports released by the CBSA after the date of the CITT's finding will be subject to anti-dumping duty equal to the margin of dumping.

[70] The importer in Canada shall pay all applicable duties. If the importers of such goods do not indicate the required SIMA code or do not correctly describe the goods in the customs documents, an administrative monetary penalty could be imposed. The provisions of the *Customs Act* apply with respect to the payment, collection or refund of any duty collected under SIMA. As a result, failure to pay duty within the prescribed time will result in the application of interest.

RETROACTIVE DUTY ON MASSIVE IMPORTATIONS

[71] Under certain circumstances, anti-dumping duty can be imposed retroactively on subject goods imported into Canada. When the CITT conducts its inquiry on material injury to the Canadian industry, it may consider if dumped goods that were imported close to or after the initiation of the investigation constitute massive importations over a relatively short period of time and have caused injury to the Canadian industry. Should the CITT issue a finding that there were recent massive importations of dumped goods that caused injury, imports of subject goods released by the CBSA in the 90 days preceding the day of the preliminary determination could be subject to anti-dumping duty.

PUBLICATION

[72] A notice of this final determination of dumping will be published in the *Canada Gazette* pursuant to paragraph 41(3)(a) of SIMA.

INFORMATION

[73] This *Statement of Reasons* is posted on the CBSA's website at the address below. For further information, please contact the officers identified as follows:

Mail: SIMA Registry and Disclosure Unit
Trade and Anti-dumping Programs Directorate
Canada Border Services Agency
100 Metcalfe Street, 11th floor
Ottawa, Ontario K1A 0L8
Canada

Telephone: Hugo Dumas 613-954-7262
Jonathan Thiffault 613-948-7809

E-mail: simaregistry@cbsa-asfc.gc.ca

Website: www.cbsa-asfc.gc.ca/sima-lmsi

Doug Band
Director General
Trade and Anti-dumping Programs Directorate

ATTACHMENTS

Appendix 1: Summary of the Margin of Dumping
Appendix 2: Representations

APPENDIX 1 – SUMMARY OF THE MARGIN OF DUMPING

Country of Origin or Export	Margin of Dumping*
Sweden	
Swedish Orphan Biovitrum AB	1,594%
All Other Exporters	N/A

*As a percentage of export price.

Note: The margin of dumping reported in this table was determined by the Canada Border Services Agency (CBSA) for the purposes of the final determination. The margin of dumping may not reflect the amount of anti-dumping duty to be levied on future importations of dumped goods. In the event of an injury finding by the Canadian International Trade Tribunal, normal values for future shipments to Canada have been provided to the exporter who provided sufficient information in their response to the CBSA, as appropriate. These normal values would come into effect the day after an injury finding. Information regarding normal values of the subject goods should be obtained from the exporter. Imports from any other exporters will be subject to an anti-dumping duty rate, as applicable, in accordance with a ministerial specification and in an amount equal to the margin of dumping found for "all other exporters" at the final determination.

Please consult the SIMA Self-Assessment Guide for more detailed information explaining how to determine the amount of SIMA duties owing.

Normally, normal values will not be applied retroactively. However, normal values may be applied retroactively in cases where the parties have not advised the CBSA in a timely manner of substantial changes that affect values for SIMA purposes. Therefore, where substantial changes occur in prices, market conditions, costs associated with production and sales of the goods, the onus is on the concerned parties to advise the CBSA.

APPENDIX 2 - REPRESENTATIONS

On December 7, 2018, a representation containing case arguments was received on behalf of Swedish Orphan Biovitrum AB (Sobi AB) and Sobi Canada Inc. (Sobi Canada)[17] (collectively "Sobi").

Following the February 4, 2019 closing of the record, the Canada Border Services Agency (CBSA) received case briefs on behalf of Les Laboratoires KABS inc. and MendeliKABS inc. (the complainant)[18] and Sobi.[19]

Following the February 11, 2019 reply submission due date, the CBSA received reply submissions on behalf of all parties.[20][21]

Certain details provided in case briefs and reply submissions were designated as confidential information by the submitting counsel. This has restricted the ability of the CBSA to discuss all issues raised in these submissions.

The CBSA has provided responses below to representations that relate to the final determination of dumping. The CBSA will not address representations pertaining to future enforcement in this *Statement of Reasons*.

The material issues raised by the parties are summarized as follows:

REPRESENTATIONS

The producer of subject goods

CASE ARGUMENTS

In a submission received by the CBSA on December 7, 2018, counsel for Sobi stated that Sobi AB is the producer of the subject goods in Sweden because it causes the goods to be produced, it owns the intellectual property and the right to produce the nitisinone capsules and it owns the subject goods throughout the entire production process.[22] While Sobi AB uses service providers for the synthesis of the pharmaceutical ingredient, the encapsulation and the final packaging of the goods, counsel argues that the agreements with these service providers are, in fact, tolling agreements.[23] Counsel further states that the SIMA handbook recognizes that tollers cannot be considered exporters and by extension that they could not be the producers of the goods.

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[17] Exhibits 041 (PRO) and 042 (NC) – Comments and supporting documents provided by Sobi AB and Sobi Canada
[18] Exhibits 064 (PRO) and 065 (NC) – Case Briefs Filed on Behalf of MendeliKABS Inc.
[19] Exhibits 062 (PRO) and 063 (NC) – Case Briefs Filed on Behalf of Sobi AB and Sobi Canada
[20] Exhibits 068 (PRO) and 069 (NC) – Reply Submissions filed on behalf of MendeliKABS and Laboratoire KABS
[21] Exhibits 066 (PRO) and 067 (NC) – Reply Submissions filed on behalf of Sobi AB and Sobi Canada
[22] Exhibit 042 (NC) – Comments and supporting documents provided by Sobi AB and Sobi Canada, paragraph 3
[23] Ibid, paragraph 3-4

Reply Submissions

Counsel for the complainant claimed that the CBSA does not have all the necessary information to confirm whether Sobi AB retains the ownership of the goods at all times, as the subcontracted producers did not respond to the CBSA's Request for Information (RFI). As such, counsel claims that the information submitted to the CBSA by Sobi AB should be considered incomplete.[24]

Counsel for Sobi AB replied that Sobi has fully cooperated with the CBSA and that it has provided all the information requested from it. Counsel claims that Sobi's information on the record can be relied on by the CBSA.[25]

CBSA's Position

Based on the information available on the record, the CBSA has identified Sobi AB to be the producer of the goods.

Determination of normal values under Section 15 of SIMA

Case Arguments

Counsel for Sobi made a number of representations concerning the determination of normal values under section 15 of SIMA. Specifically, counsel for Sobi argued that government control, in the form of government-run prescription drug tender processes and government regulations preventing price increases, in addition to the reimbursement of NIT under the Swedish benefits scheme, mean that sales of NIT in Sweden do not meet the requirement of paragraph 15(c) of SIMA that sales be made under competitive conditions. In addition, counsel for Sobi argued that Sobi AB's sales in Sweden cannot be used to determine normal values as the requirement of paragraph 16(2)(a) with regards to domestic sales to multiple unrelated parties made at substantially the same time was not met.[26]

Reply Submissions

Counsel for the complainant made a representation concerning paragraph 15(c) of SIMA regarding domestic sales being under competitive conditions. Counsel claimed that the domestic market of the exporter, while regulated, remains competitive, as no evidence supporting a particular market situation, as defined in paragraph 16(2)(c) of SIMA was provided.[27] With regards to paragraph 16(2)(a) of SIMA, counsel for the complainant stated that there is no provision in SIMA to prescribe sixty-day periods when selecting comparable domestic sales and that the CBSA should select a relevant period based on information specific to the investigation.

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[24] Exhibit 065 (NC) – Case Briefs Filed on Behalf of MendeliKABS Inc, paragraph 9-13
[25] Exhibit 067 (NC) – Reply Submissions filed on behalf of Sobi AB and Sobi Canada, paragraph 4
[26] Exhibit 063 (NC) – Case Briefs Filed on Behalf of Sobi AB and Sobi Canada, paragraph 7-27
[27] Exhibit 065 (NC) – Case Briefs Filed on Behalf of MendeliKABS Inc, paragraph 21

Counsel for Sobi replied that the complainant did not address how the CBSA could rely on Swedish market pricing given the lack of sales to multiple unrelated customers at substantially the same time. Further, counsel argued that the complainant did not offer any evidence to refute the arguments submitted by the counsel for Sobi. Counsel for Sobi claimed that drug regulations in Sweden have a distorting effect on prices, particularly because suppliers are not permitted to raise them. Counsel claims that the inability to raise prices, and the resulting consequences of discouraging suppliers from making irrevocable price reductions, means that the Swedish market is not one where price results from the free interplay of supply and demand as required under paragraph 15(c) of SIMA and disqualifies the Swedish market as basis for determining normal values.[28]

CBSA's Position

Section 15 of SIMA provides a list of requirements that must be satisfied for purposes of determining normal values based on the price of like goods in the exporter's domestic market. Specifically, paragraph 15(c) of SIMA instructs the CBSA to consider only those sales that are made in the ordinary course of trade for use in the country of export under competitive conditions.

While the prescription drug industry sector in Sweden is regulated, the CBSA found that the domestic sales of Sobi AB were made in the ordinary course of trade, since they were made in accordance with the common business practices of that industry sector. In addition, given that suppliers compete on monthly tenders, the CBSA noted that the sales of NIT in Sweden were made under competitive conditions.

As a result, in determining normal values under section 15 of SIMA, the CBSA was satisfied that all legislative requirements had been met, including paragraph 15(c) and paragraph 16(2)(a) of SIMA.

The amendments to SIMA and the SIMR that came into force on April 26, 2018, include provisions to address particular market situations. Specifically, in determining normal values under section 15 of SIMA, paragraph 16(2)(c) of SIMA instructs the CBSA to exclude any sales of like goods in the country of export, if the CBSA is of the opinion that a particular market situation exists in the exporter's domestic market and as a result, a proper comparison cannot be made.

In this investigation, based on the information available on the record, the CBSA was of the opinion that there is not sufficient evidence to establish the presence of a particular market situation in Sweden, which does not permit a proper comparison between the sale of like goods in Sobi AB's domestic market in Sweden and the sale of the subject goods to the importer in Canada.

[28] Exhibit 067 (NC) – Reply Submissions filed on behalf of Sobi AB and Sobi Canada, paragraphs 5,6

Trade level adjustment

CASE ARGUMENTS

Counsel for Sobi made a representation concerning the application of a trade level adjustment pursuant to section 9 of SIMR. Specifically, counsel claimed that Sobi AB is responsible for marketing and selling nitisinone capsules in Sweden and that Sobi Canada is entirely responsible for those activities in Canada. Counsel claimed that Sobi Canada is a national distributor in Canada and that a trade level adjustment is warranted.[29]

CBSA'S POSITION

After considering the facts on the record, the CBSA determined that a trade level adjustment pursuant to section 9 of the SIMR was warranted. The CBSA applied a trade level adjustment to the domestic selling prices of the like goods relating to the amount of costs, charges and expenses incurred by Sobi AB in carrying out selling activities in relation to domestic sales that the exporter had not incurred on sales to Canada.

Determination of normal values under paragraph 19(a) of SIMA

CASE ARGUMENTS

Counsel for Sobi submitted a representation arguing that calculating normal values based on Sobi AB's selling prices in Norway under paragraph 19(a) would reflect more fairly the market value of the goods sold to Canada than the application of section 15 and paragraph 19(b) of SIMA.[30] Counsel argued that attempting to determine a reasonable amount for profit for the purpose of establishing normal value under paragraph 19(b) would be of questionable merit because paragraph 13(a) of the SIMR limits the extent to which sales that do not comply with the requirements of section 15 and subsection 16(2) can be used to determine a reasonable amount for profit.

On December 7, 2018, counsel for Sobi identified Denmark and Finland as alternative markets to use for determining normal values.[31] In the latest case brief submitted on February 4, 2019, counsel identified Norway as the only appropriate surrogate market, as it is the only market in which Sobi AB sells nitisinone capsules that are subject to generic competition, sold to unrelated importers and to multiple purchasers.[32]

[29] Exhibit 063 (NC) – Case Briefs Filed on Behalf of Sobi AB and Sobi Canada, paragraph 28 - 33
[30] Ibid, paragraph 33
[31] Exhibit 042 (NC) – Comments and supporting documents provided by Sobi AB and Sobi Canada, paragraph 25
[32] Exhibit 063 (NC) – Case Briefs Filed on Behalf of Sobi AB and Sobi Canada, paragraph 34-39

REPLY SUBMISSIONS

Counsel for the complainant also made a representation concerning the determination of normal values under paragraph 19(a), using Denmark and Finland as surrogate markets. Counsel made a representation claiming that the markets are not of comparable size as there are very few sales of the goods in these countries and that these sales do not constitute a comparable basis for SIMA purposes. Further, counsel argued that Sobi was the only bidder on the tender in Denmark, placing Sobi AB in a monopolistic situation.[33]

Counsel for the complainant proposed that sales made in the United States of America (USA) would serve as a better surrogate market, stating that this market is subject to generic competition, that the prices for nitisinone capsules are publicly known and the number of patients taking the drug is similar to that of Canada.[34]

Counsel for Sobi replied that the USA cannot be used as a surrogate country under paragraph 19(a). Counsel argues that there is a very significant difference between the USA and the other countries proposed as surrogates, stating that the USA has no public price control mechanism in place. Also, counsel states that all of Sobi AB's sales to the USA were to a related importer, therefore also precluding the use of the USA sales for normal values.[35] Further, counsel for Sobi stated that the CBSA did not request sales data for the USA and that the unverified prices relied on by the complainant cannot be used in the place of detailed and verified data. Moreover, counsel claims that the prices relied upon by the complainant are not prices offered by Sobi AB, and that these prices occur at a trade level much further downstream than the level at which Sobi AB sells to Canada, making them unreliable.[36]

Counsel for the complainant replied that while the Swedish market is regulated, it allows for a proper comparison for SIMA purposes as it is a market which takes into account the competitive situation of the producer and allows for negotiation between producers and distributors. Counsel stated that prescribing doctors and pharmacists have the right to choose a substitutable product on medical grounds and that patients have the right to request a substitute for the drug and pay the difference between the reimbursed product and the substituted product. Counsel argued that the fact that the goods are ultimately paid for by the government's healthcare program is of no interest for SIMA purposes.[37]

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[33] Exhibit 065 (NC) – Case Briefs Filed on Behalf of MendeliKABS Inc, paragraph 24, 25
[34] Ibid, paragraph 26, 27, 28
[35] Exhibit 067 (NC) – Reply Submissions filed on behalf of Sobi AB and Sobi Canada, paragraph 9, 10
[36] Ibid, paragraph 11, 12
[37] Exhibit 069 (NC) – Reply Submissions filed on behalf of MendeliKABS and Laboratoire KABS, paragraph 14-21

Finally, counsel for the complainant stated that the SIMA handbook outlines that when examining sales in a surrogate market, these prices should not be lower than those of similar goods on the domestic market of the exporter. Counsel stated that the SIMA handbook indicates that one of the principal difficulties inherent in using a surrogate market is the fact that if the exporter is dumping goods in Canada, it may also be dumping goods in other markets, thus making the usage of domestic sales in a surrogate country inapplicable for determining normal values. Counsel for the complainant supported this statement by providing a comparison table of selling prices of NIT in Norway and Sweden.[38]

CBSA's Position

In situations in which the exporter did not make such a number of sales of like goods in the domestic market that comply with all the terms and conditions referred to in section 15 of SIMA, the CBSA determined normal values pursuant to paragraph 19(b) of SIMA based on the cost of production of the goods, a reasonable amount for administrative, selling and all other costs and a reasonable amount for profit. The amount for profit was determined pursuant to subparagraph 11(1)(b)(i) of the SIMR.

Identify of the importer for SIMA purposes

Case Arguments

Counsel for Sobi AB made a number of representations concerning the identity of the importer for SIMA purposes. Specifically, counsel claimed that Sobi AB was the importer for SIMA purposes because the delivery terms of the sales are DDP (delivered, duty paid), that Sobi AB owns the goods when they enter Canada, and that it is responsible for the goods until final delivery to Sobi Canada's warehouse. In addition, counsel indicated that Sobi AB retains the Canadian Drug Establishment License, retains the custom broker and exercises control over the price of the goods sold by Sobi Canada.[39] Counsel also argued that the Supreme Court has defined the importer as "[…] the party who has title to the goods at the time the goods are transported into Canada.", and that "the CITT decisions have repeatedly relied on this statement.[40]

Reply Submissions

Counsel for the complainant also made representation concerning the identity of the importer for SIMA purposes. Specifically, counsel stated that, for the preliminary determination, the CSBA established that Sobi Canada is the importer for SIMA purposes, and that this decision cannot be changed for final determination.[41]

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[38] Ibid, paragraph 27, 31, Annex A
[39] Exhibit 063 (NC) – Case Briefs Filed on Behalf of Sobi AB and Sobi Canada, paragraph 40, 43
[40] Ibid, paragraph 41
[41] Ibid, paragraph 15

Counsel for the complainant also replied to Sobi's case brief, arguing that following subsection 2(1) of SIMA, the importer is the person that truly is the importer of the goods. Counsel states that this notion is very distinct of the question of the identity of the importer under the Customs Act. Counsel refers to case number MP-2003-001, dated March 11, 2004, in a request for a decision on the identity of the importer where the Tribunal interpreted that intent of the Parliament was for the parties to identify "the importer in Canada" rather that simply "the importer".[42]

Counsel for Sobi replied that the decision made by the CBSA for the preliminary determination is not binding. Counsel refers to paragraph 38(1)(c), stating that its statutory language confirms that the person identified as the importer at the time of the preliminary determination is an indication of the President's belief at the time, based on the limited information available to him. Further, counsel argues that there is now new additional information confirming that Sobi AB is the importer.[43]

CBSA's Position

Based on the information available on the record, the CBSA believes that Sobi Canada is the importer for SIMA purposes. As such, in this investigation, the CBSA specified Sobi Canada to be the importer of the subject goods imported during the POI.

Determination of export prices

Case Arguments

Counsel for Sobi AB made a number of representations concerning the determination of the export prices. Specifically, counsel stated that export price should be calculated under paragraph 25(1)(c) of SIMA, given that there is no true sale on importation.[44]

Reply Submissions

Counsel for the complainant also made a representation concerning the determination of the export price. Specifically, counsel stated that export price should be calculated under section 25 of SIMA.[45]

[42] Exhibit 069 (NC) – Reply Submissions filed on behalf of MendeliKABS and Laboratoire KABS, paragraph 37-39
[43] Exhibit 067 (NC) – Reply Submissions filed on behalf of Sobi AB and Sobi Canada, paragraph 13-16
[44] Exhibit 063 (NC) – Case Briefs Filed on Behalf of Sobi AB and Sobi Canada, paragraph 46
[45] Exhibit 065 (NC) – Case Briefs Filed on Behalf of MendeliKABS Inc, paragraph 19

CBSA's Position

Where information on the record was sufficient, the export price of the subject goods was determined pursuant to paragraph 25(1)(c) of SIMA, based on the importer's selling price to an unassociated party, adjusted by deducting the costs incurred on or after the importation of the goods and on or before their sale by the importer, an amount for profit by the importer and the costs, charges and expenses incurred in preparing the goods for shipment to Canada and resulting from the exportation and shipment of the goods.

Where the export price of the subject goods could not be determined under paragraph 25(1)(c), the export price was determined pursuant to paragraph 25(1)(e) of SIMA by calculating the weighted average export price, as determined for each dosage sold by the importer during the POI using the methodology of paragraph 25(1)(c) of SIMA.

Deductions to arrive at the section 25 export price

Case Arguments

Counsel for Sobi argued that a specific period of time should be selected in order to calculate Sobi Canada's selling expenses in determining the export price pursuant to section 25 of SIMA.[46] Counsel claims that the POI was a period of start up and adjustments for Sobi Canada, which led to exceptionally high operating costs and that the CBSA should deduct operating expenses that have occurred in the second half of 2018 in determining the export price under section 25.

Reply Submissions

Counsel for the complainant replied that the adjustment requested by Sobi is not reasonable.[47] Counsel argued that Sobi Canada was not in a period of start-up during the POI as Sobi Canada was incorporated in Canada on November 1, 2015. Further, counsel stated that while normal value adjustments concerning start-up costs are permitted pursuant to subsection 23(1) of SIMA and subsection 13.1(1) of the SIMR, there is no provisions in SIMA to make such adjustment to the export price.

CBSA's Position

When determining the export price of the goods pursuant to paragraph 25(1)(c) of SIMA, the CBSA deducted the costs incurred on or after the importation of the goods and on or before their sale by the importer, an amount for profit by the importer and the costs, charges and expenses incurred in preparing the goods for shipment to Canada and resulting from the exportation and shipment of the goods.

[46] Exhibit 063 (NC) – Case Briefs Filed on Behalf of Sobi AB and Sobi Canada, paragraph 46-48
[47] Exhibit 069 (NC) – Reply Submissions filed on behalf of MendeliKABS and Laboratoire KABS, paragraph 44-49

First sale to an unassociated party

Case Arguments

Counsel for the complainant argued that McKesson Canada is a distributor hired by the Centre Hospitalier Universitaire (CHU) Sainte-Justine and that it acts as a third party logistic provider, not as a principal in the transaction. As such, counsel for the complainant claims that following the provisions for paragraph 25(1)(c) of SIMA, the selling price to CHU Sainte-Justine should serve as the basis to determine export prices, adjusted to take into account the administrative fees of the distributor in Canada[48].

Reply Submissions

Counsel for Sobi replied that the sale to McKesson Canada is the first sale to an unassociated party in Canada. The counsel claimed that the tender agreement signed with SigmaSanté to supply Quebec hospitals with nitisinone requires Sobi to supply the product to the province's designated distributor. Further, counsel states that Sobi has provided purchase orders and invoices relating to these sales and that as such, the CBSA should use this information for its section 25 export price analysis.[49]

CBSA's Position

Based on the information available on the record, the CBSA determined that the first sale by Sobi Canada to an unassociated party was made to McKesson Canada.

The amount for profit pursuant to subparagraph 25(1)(c)(ii) of SIMA

Case Arguments

Counsel for Sobi claimed that the amount for profit to deduct from Sobi Canada's selling price pursuant to subparagraph 25(1)(c)(ii) of SIMA should be based on the transfer pricing study conducted by Deloitte and updated in December 2018.[50] Counsel argued that the suggested approach would satisfy the requirements of paragraphs 22(b) and (c) of the SIMR and that it is the best available profit information on the record.[51]

Reply submission

Counsel for the complainant replied that this proposed approach does not comply with paragraphs 22(a) to (c) of the SIMR, stating that the amount for profit arising from the sale of the goods for the purpose of the adjustment pursuant to subparagraph 25(1)(c)(ii) of SIMA must be from sales in Canada.[52]

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[48] Exhibit 065 (NC) – Case Briefs Filed on Behalf of MendeliKABS Inc, paragraph 17 - 19
[49] Exhibit 067 (NC) – Reply Submissions filed on behalf of Sobi AB and Sobi Canada, paragraph 18
[50] Exhibit 063 (NC) – Case Briefs Filed on Behalf of Sobi AB and Sobi Canada, paragraph 49, 50
[51] Ibid, paragraph 55
[52] Exhibit 069 (NC) – Reply Submissions filed on behalf of MendeliKABS and Laboratoire KABS, paragraph 50-52

CBSA's Position

The amount for profit was determined pursuant to paragraph 22(c) of the SIMR based on a report produced by Industry Canada which represents profit from pharmaceutical and pharmacy supply merchant wholesalers during the year 2016. This information represents the most recent profit data that was available to the CBSA.