Canadian International Trade Tribunal
Tribunal canadien du commerce extérieur

CANADIAN INTERNATIONAL TRADE TRIBUNAL

Dumping and Subsidizing

FINDING AND REASONS

Inquiry No. NQ-2018-005

Nitisinone Capsules

Finding issued
Thursday, April 18, 2019

Reasons issued
Friday, May 3, 2019

Canada

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IN THE MATTER OF an inquiry, pursuant to section 42 of the *Special Import Measures Act*, respecting:

NITISINONE CAPSULES

FINDING

The Canadian International Trade Tribunal, pursuant to the provisions of section 42 of the *Special Import Measures Act*, has conducted an inquiry to determine whether the dumping of 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, has caused injury or is threatening to cause injury to the domestic industry.

Further to the Canadian International Trade Tribunal's inquiry, and following the issuance by the President of the Canada Border Services Agency of a final determination dated March 20, 2019, that the above-mentioned goods have been dumped, the Canadian International Trade Tribunal hereby finds, pursuant to subsection 43(1) of the *Special Import Measures Act*, that the dumping of the above-mentioned goods has not caused injury and is not threatening to cause injury to the domestic industry.

Jean Bédard

Jean Bédard
Presiding Member

Serge Fréchette

Serge Fréchette
Member

Georges Bujold

Georges Bujold
Member

The statement of reasons will be issued within 15 days.

Place of Hearing:	Ottawa, Ontario
Dates of Hearing:	March 19, 20 and 21, 2019
Tribunal Panel:	Jean Bédard, Presiding Member Serge Fréchette, Member Georges Bujold, Member
Support Staff:	Alain Xatruch, Counsel Gayatri Shankarraman, Lead Analys Josée St-Amand, Analyst Mylène Lanthier, Analyst

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CHU Sainte-Justine	
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President/Medical Director	President

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STATEMENT OF REASONS

INTRODUCTION

[1] The mandate of the Canadian International Trade Tribunal (the Tribunal) in this inquiry[1] is to determine whether the dumping of certain nitisinone capsules originating in or exported from the Kingdom of Sweden (Sweden) (the subject goods) has caused injury or is threatening to cause injury to the domestic industry.

[2] The Tribunal has determined, for the reasons that follow, that the dumping of the subject goods has not caused injury and is not threatening to cause injury to the domestic industry.

BACKGROUND

[3] This inquiry stems from a complaint filed with the Canada Border Services Agency (CBSA) on August 2, 2018, by Laboratoires KABS Inc. (KABS) and its affiliate MendeliKABS Inc. (MDK) (collectively, KABS-MDK), both of Longueuil, Quebec, and the subsequent decision by the President of the CBSA on September 21, 2018, to initiate an investigation into the alleged dumping of the subject goods.

[4] On September 24, 2018, as a result of the CBSA's decision to initiate the investigation, the Tribunal initiated a preliminary injury inquiry pursuant to subsection 34(2) of *SIMA*. On November 20, 2018, the Tribunal determined that there was evidence that disclosed a reasonable indication that the dumping of the subject goods had caused injury or was threatening to cause injury to the domestic industry.[2]

[5] On December 20, 2018, the CBSA made a preliminary determination of dumping, resulting in the imposition of provisional duties on the subject goods and the commencement of this injury inquiry. On December 21, 2018, the Tribunal issued a notice of commencement of inquiry.[3]

[6] The Tribunal's period of inquiry (POI) was from January 1, 2015, to September 30, 2018, and included two interim periods: January 1, 2017, to September 30, 2017 (interim 2017), and January 1, 2018, to September 30, 2018 (interim 2018).

[7] As part of its inquiry, the Tribunal sent questionnaires to KABS and MDK, as well as to importers, purchasers and a foreign producer of nitisinone capsules. Using the questionnaire replies, staff of the Secretariat to the Tribunal prepared public and protected investigation reports, which were issued on February 11, 2019.[4] The public investigation report was distributed, along with the remainder of the public record, to parties who had filed notices of participation in the inquiry. The protected investigation report containing information designated as confidential was distributed, along with the remainder of the protected record, to counsel who had signed the required declaration and undertaking.

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1. The inquiry is conducted pursuant to section 42 of the *Special Import Measures Act*, R.S.C., 1985, c. S-15 [*SIMA*].
2. *Nitisinone Capsules* (20 November 2018), PI-2018-006 (CITT) [*Nitisinone PI*].
3. The notice was published on the Tribunal's Web site and in the *Canada Gazette* (see C. Gaz. 2019.I.22).
4. A corrigendum to the public and protected versions of the investigation report was issued on February 14, 2019. A revision was also issued on February 26, 2019.

[8] The inquiry schedule appended to the notice of commencement of inquiry indicated that requests for product exclusions were to be filed by February 18, 2019. The Tribunal did not receive any such requests.

[9] On February 18, 2019, KABS-MDK, and Swedish Orphan Biovitrum AB (publ) (Sobi AB) and Swedish Orphan Biovitrum (SOBI) Canada, Inc. (Sobi Canada) (collectively, Sobi), filed with the Tribunal various requests for information (RFIs) directed at each other, at SigmaSanté and at one importer, Cycle Pharmaceuticals Ltd. (Cycle), who did not participate in the inquiry as a party. On February 20, 2019, SigmaSanté objected to one RFI. On February 25, 2019, the Tribunal issued directions to the parties, indicating which RFIs required responses. It also issued its own RFI directed to the aforementioned importer. The responses were received on March 4, 2019, and placed on the record. On March 7, 2019, Sobi requested that a supplemental RFI be issued to SigmaSanté. On March 8, 2019, the Tribunal directed that SigmaSanté respond to the RFI, which it did on March 13, 2019.

[10] On February 19, 2019, KABS-MDK filed a case brief, witness statements and other evidence in support of a finding of injury or threat of injury in respect of the subject goods.

[11] On February 22, 2019, the Delegation of the European Union to Canada (the EU Delegation) filed submissions mainly aimed at ensuring that the Tribunal's inquiry complied with the relevant World Trade Organization's (WTO) requirements.

[12] On February 26, 2019, Sobi filed a case brief, witness statements and other evidence opposing a finding of injury or threat of injury in respect of the subject goods. SigmaSanté also filed a case brief on the same date, but its submissions were primarily aimed at explaining the rules governing the tendering process for medications in the province of Quebec and identifying public interest considerations.

[13] On March 5, 2019, KABS-MDK filed a reply brief, a reply witness statement and additional evidence.

[14] Although the Centre hospitalier universitaire Sainte-Justine (CHU Sainte-Justine), BIOTECanada and the Canadian Organization for Rare Disorders filed notices of participation, they did not file any evidence or arguments, take a position, or otherwise participate in the inquiry.

[15] As is the case in most injury inquiries, the Tribunal accorded parties the opportunity to notify it of matters arising by March 14, 2019, just prior to the public hearing. KABS-MDK made three requests to the Tribunal, one of which was the subject of an objection by Sobi. The Tribunal issued directions to parties in relation to these requests on March 15, 2019.

[16] The Tribunal held a hearing in Ottawa, Ontario, on March 19, 20 and 21, 2019. It included public and *in camera* sessions. KABS-MDK and Sobi presented witnesses. The Tribunal called Mr. Yves Charbonneau of SigmaSanté and Mr. Matthew Kellison of the Patented Medicine Prices Review Board (PMPRB) as Tribunal witnesses.[5]

[17] The Tribunal issued its finding on April 18, 2019.

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5. These individuals were summoned by subpoena to appear as Tribunal witnesses.

RESULTS OF THE CBSA'S INVESTIGATION

[18] On March 20, 2019, the CBSA made a final determination of dumping in respect of the subject goods. The CBSA's period of investigation was from January 1, 2018, to June 30, 2018.

[19] The CBSA determined that 100 percent of the subject goods imported into Canada during this period had been dumped.[6] It also determined that the weighted average margin of dumping of the subject goods, when expressed as a percentage of the export price, was 1,594 percent for Sobi AB—the sole exporter of subject goods to Canada.[7]

PRODUCT

Product Definition

[20] The CBSA defined the subject goods as follows:[8]

> 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.

Product Information

[21] The CBSA provided the following additional product information:[9]

> [22] 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 $C_{14}H_{10}F_3NO_5$.
>
> [23] 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.
>
> [24] 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.
>
> [25] 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.

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6. Exhibit NQ-2018-005-04, Vol. 1 at 17.
7. Exhibit NQ-2018-005-04, Vol. 1 at 10, 17.
8. Exhibit NQ-2018-005-01, Vol. 1 at 10.
9. Exhibit NQ-2018-005-01A, Vol. 1 at 22; CBSA Preliminary Determination – Statement of Reasons (4 January 2019), online at: https://www.cbsa-asfc.gc.ca/sima-lmsi/i-e/nit2018/nit2018-pd-eng.html.

> [26] 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.
>
> [27] The product definition does not include nitisinone in liquid suspension.

Production Process

[22] The CBSA provided the following information regarding the production process for nitisinone capsules:[10]

> [28] 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.
>
> [29] 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.

PRELIMINARY ISSUE

[23] In its submissions, the EU Delegation noted that a lot of information in the Tribunal's public investigation report had been redacted and that, by failing to provide either non-confidential summaries of this information or statements as to why such summarizations were not possible, the Tribunal failed to comply with the requirements of Article 6.5.1 of the WTO *Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994*.[11] It added that the same applied to several exhibits in the Tribunal's list of exhibits and noted that, in certain cases, exhibits were entirely protected to the extent that even their titles were not disclosed. The EU Delegation therefore requested that non-confidential information be disclosed in a manner which complies with Article 6.5.1 in order to allow it to exercise its right of defence and protect its interests.

[24] The WTO Appellate Body has held that Article 6.5.1 of the WTO *Anti-dumping Agreement* serves to balance the goals of protecting confidentiality while ensuring the transparency of the investigation process.[12] As a result, any non-confidential summaries must protect the confidential information at issue, while at the same time contain sufficient detail to permit other parties a

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10. *Ibid.* at 22-23.
11. https://www.wto.org/english/docs_e/legal_e/19-adp.pdf [WTO *Anti-dumping Agreement*]. Article 6.5.1 provides as follows: "The authorities shall require interested parties providing confidential information to furnish non-confidential summaries thereof. These summaries shall be in sufficient detail to permit a reasonable understanding of the substance of the information submitted in confidence. In exceptional circumstances, such parties may indicate that such information is not susceptible of summary. In such exceptional circumstances, a statement of reasons why summarization is not possible must be provided."
12. WTO Appellate Body Report, *European Communities – Definitive Anti-Dumping Measures on Certain Iron or Steel Fasteners from China*, WT/DS397/AB/R [*EC – Fasteners*] at para. 542; see also WTO Panel Report, *Mexico – Anti-Dumping Duties on Steel Pipes and Tubes from Guatemala*, WT/DS331/R at para. 7.380.

reasonable understanding of the substance of the information, so that they may respond and defend their interests.[13]

[25] Other than simply stating that a lot of information in the Tribunal's public investigation report has been redacted, the EU Delegation has not called attention to any specific parts of the report or explained how the redactions prevented it from gaining a reasonable understanding of the substance of the information and from exercising its right of defence. That being said, the Tribunal acknowledges that the particulars of the current inquiry are such that more information has been redacted than is normally the case. The data presented in the investigation report is based on confidential information provided by respondents to the Tribunal's questionnaires. In this case, the domestic industry is comprised of two affiliated entities and there is only one exporter of the subject goods to Canada, who is also the only importer of record of those goods into Canada. Consequently, it is not possible to reveal aggregated data. Despite these limitations, the Tribunal believes that it has met its transparency obligations by placing as much information as possible in the public version of its investigation report. In this regard, the Tribunal notes that, while absolute figures are, for the most part, confidential, many tables in the report include percent change figures in order to allow parties to gain a reasonable understanding of the substance of the information.

[26] Moreover, when parties provide confidential information to the Tribunal, they must comply with the requirements of subsection 46(1) of the *Canadian International Trade Tribunal Act*,[14] which are very similar to those of Article 6.5.1 of the WTO *Anti-Dumping Agreement*. On March 4, 2019, the Tribunal informed KABS-MDK and Sobi that the non-confidential versions of their case briefs, witness statements and supporting materials did not fully comply with these requirements as, in some instances, they failed to provide sufficient detail or context to convey a reasonable understanding of the substance of the information designated as confidential. The Tribunal therefore requested that they file revised confidential and non-confidential versions of these documents that complied with subsection 46(1) of the *CITT Act*, which they did prior to the hearing.

[27] As for the exhibits which the EU Delegation alleged were entirely protected to the extent that even their titles were not disclosed, these were simply exhibit numbers that had been reserved by the Tribunal for future use. The Tribunal uses a standard numbering convention for exhibits in all of its inquiries and certain numbers are always reserved for specific documents.[15] At the time the EU Delegation was provided with the list of exhibits, some of the exhibit numbers listed did not yet have any actual documents associated with them. The words "reserved" or "not used" are usually written beside these exhibit numbers.

[28] Finally, the Tribunal notes that, pursuant to subsection 45(3) of the *CITT Act* and subrule 16(1) of the *Canadian International Trade Tribunal Rules*,[16] information that has been designated as confidential may be disclosed to counsel who have provided the required declaration and undertaking. Thus, it was open to the EU Delegation to obtain access to confidential information through counsel. As the Tribunal has previously stated, "[p]roviding access to confidential

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13. *EC – Fasteners* at para. 542; see, also, WTO Panel Report, *Argentina – Definitive Anti-Dumping Measures on Imports of Ceramic Floor Tiles from Italy*, WT/DS189/R at para. 6.38.
14. R.S.C. 1985, c. 47 (4th Supp.) [*CITT Act*].
15. For example, specific exhibit numbers are always reserved for the public and protected versions of the CBSA's final determination.
16. S.O.R./91-499.

information in this way allows the Tribunal to obtain maximum voluntary participation from interested parties, ensure transparency and, at the same time, protect confidential information."[17]

LEGAL FRAMEWORK

[29] The Tribunal is required, pursuant to subsection 42(1) of *SIMA*, to inquire as to whether the dumping of the subject goods has caused injury or retardation[18] or is threatening to cause injury, with "injury" being defined, in subsection 2(1), as "material injury to a domestic industry". In this regard, "domestic industry" is defined in subsection 2(1) by reference to the domestic production of "like goods".

[30] Accordingly, the Tribunal must first determine what constitutes "like goods". Once that determination has been made, the Tribunal must determine what constitutes the "domestic industry" for purposes of its injury analysis.

[31] The Tribunal can then assess whether the dumping of the subject goods has caused material injury to the domestic industry. Should the Tribunal arrive at a finding of no material injury, it will determine whether there exists a threat of material injury to the domestic industry.[19]

[32] In conducting its analysis, the Tribunal will also examine other factors that might have had an impact on the domestic industry to ensure that any injury or threat of injury caused by such factors is not attributed to the effects of the dumping.

LIKE GOODS AND CLASSES OF GOODS

[33] In order for the Tribunal to determine whether the dumping of the subject goods has caused injury or is threatening to cause injury to the domestic producer(s) of like goods, it must determine which domestically produced goods, if any, constitute like goods in relation to the subject goods. The Tribunal must also assess whether there is, within the subject goods and the like goods, more than one class of goods.[20]

[34] Subsection 2(1) of *SIMA* defines "like goods", in relation to any other goods, as follows:

> (a) goods that are identical in all respects to the other goods, or
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> (b) in the absence of any goods described in paragraph (a), goods the uses and other characteristics of which closely resemble those of the other goods.

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17. *Certain Fabricated Industrial Steel Components* (25 May 2017), NQ-2016-004 (CITT) at para. 25.
18. Subsection 2(1) of *SIMA* defines "retardation" as "material retardation of the establishment of a domestic industry." As a domestic industry is already established, the Tribunal will not need to consider the question of retardation.
19. Injury and threat of injury are distinct findings; the Tribunal is not required to make a finding relating to threat of injury pursuant to subsection 43(1) of *SIMA* unless it first makes a finding of no injury.
20. Should the Tribunal determine that there is more than one class of goods in this inquiry, it must conduct a separate injury analysis and make a decision for each class that it identifies. See *Noury Chemical Corporation and Minerals & Chemicals Ltd. v. Pennwalt of Canada Ltd. and Anti-dumping Tribunal*, [1982] 2 F.C. 283 (F.C.).

[35] In deciding the issue of like goods when goods are not identical in all respects to the other goods, the Tribunal typically considers a number of factors, including the physical characteristics of the goods (such as composition and appearance) and their market characteristics (such as substitutability, pricing, distribution channels, end uses and whether the goods fulfill the same customer needs).[21] In addressing the issue of classes of goods, the Tribunal typically examines whether goods potentially included in separate classes of goods constitute "like goods" in relation to each other. If those goods are "like goods" in relation to each other, they will be regarded as comprising a single class of goods.[22]

[36] In its preliminary injury inquiry, the Tribunal found, on the basis of available evidence, that domestically produced nitisinone capsules of the same description as the subject goods constituted "like goods" in relation to the subject goods and that there was a single class of goods.[23] As none of the parties have challenged these preliminary findings, and in the absence of any contradictory evidence, the Tribunal sees no reason to depart from them.

[37] The Tribunal therefore finds that domestically produced nitisinone capsules constitute "like goods" in relation to the subject goods and that there is a single class of goods.

DOMESTIC INDUSTRY

[38] Subsection 2(1) of *SIMA* defines "domestic industry" as follows:

> the domestic producers as a whole of the like goods or those domestic producers whose collective production of the like goods constitutes a major proportion of the total domestic production of the like goods except that, where a domestic producer is related to an exporter or importer of dumped or subsidized goods, or is an importer of such goods, "domestic industry" may be interpreted as meaning the rest of those domestic producers.

[39] The Tribunal must therefore determine whether there has been injury, or whether there is a threat of injury, to the domestic producers as a whole or those domestic producers whose production represents a major proportion of the total production of like goods.[24]

[40] In its preliminary injury inquiry, the Tribunal considered that the group composed of KABS and MDK constituted the domestic industry.[25] The Tribunal also referred to a previous case where it stated that the domestic industry can "be comprised of related entities respectively responsible for the

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21. See, for example, *Copper Pipe Fittings* (19 February 2007), NQ-2006-002 (CITT) at para. 48.
22. *Aluminum Extrusions* (17 March 2009), NQ-2008-003 (CITT) at para. 115; see also *Thermal Insulation Board* (11 April 1997), NQ-96-003 (CITT) at 10.
23. *Nitisinone PI* at paras. 27-28.
24. The term "major proportion" means an important, serious or significant proportion of total domestic production of like goods and not necessarily a majority: *Japan Electrical Manufacturers Assn. v. Canada (Anti-Dumping Tribunal)*, [1986] F.C.J. No. 652 (F.C.A); *McCulloch of Canada Limited and McCulloch Corporation v. Anti-Dumping Tribunal*, [1978] 1 F.C. 222 (F.C.A.); *China – Anti-dumping and countervailing duties on certain automobiles (US)*, (23 May 2014), WTO Docs. WT/DS440/R, Report of the Panel, at para. 7.207; *European Community – Definitive anti-dumping measures on certain iron or steel fasteners (China)*, (15 July 2011), WTO Docs. WT/DS397/AB/R, Report of the Appellate Body, at paras. 411, 412, 419; *Argentina – Definitive Anti-dumping duties on poultry (Brazil)*, (22 April 2003), WTO Docs. WT/DS241/R, Report of the Panel, at para. 7.341.
25. *Nitisinone PI* at para. 30.

production of like goods and their arm's-length sale at the first level of distribution in the marketplace."[26] The evidence gathered in the present inquiry indicates that this is precisely the situation. KABS, which owns 50 percent of MDK, produces nitisinone capsules exclusively for MDK who then markets and distributes them in Canada.[27]

[41] As KABS-MDK accounts for all domestic production and sales of like goods over the POI, and in the absence of any submissions to the contrary, the Tribunal finds that it constitutes the domestic industry for the purposes of the injury analysis.

INJURY ANALYSIS

[42] Subsection 37.1(1) of the *Special Import Measures Regulations*[28] prescribes that, in determining whether the dumping has caused material injury to the domestic industry, the Tribunal is to consider the volume of the dumped goods, their effect on the price of like goods in the domestic market, and their resulting impact on the state of the domestic industry. Subsection 37.1(3) also directs the Tribunal to consider whether a causal relationship exists between the dumping of the goods and the injury on the basis of the factors listed in subsection 37.1(1), and whether any factors other than the dumping of the goods have caused injury.

[43] However, before proceeding with its injury analysis, the Tribunal will describe the characteristics of the market for nitisinone capsules and the history of the supply of that drug in Canada. Understanding the particularities of that market is of paramount importance in this inquiry. Although the Tribunal already described the general characteristics of the market in its preliminary injury inquiry, additional information, including information gathered during the final injury inquiry stage, helps to provide further context for the Tribunal's injury analysis, particularly in regard to causation, which, as it turns out, is the pivotal issue in this inquiry.

Overview of the Nitisinone Capsules Market in Canada

[44] Nitisinone is the only drug approved in Canada for the treatment of hepatorenal tyrosinemia type 1 (HT-1),[29] which is a rare genetic disease that results in the liver of persons with the disease being unable to metabolize the amino acid tyrosine properly.[30] Nitisinone is used in combination with a dietary restriction of tyrosine and phenylalanine.[31] The disease manifests most commonly in infants and, if left untreated, is associated with high mortality and morbidity.[32] Due to its extremely low worldwide incidence,[33] HT-1 is considered an "orphan disease" and nitisinone, an "orphan drug".

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26. *Nitisinone PI* at para. 30, citing *Silicon Metal* (2 November 2017), NQ-2017-001 (CITT) at para. 47.
27. Exhibit NQ-2018-005-11.01C, Vol. 3 at 4; Exhibit NQ-2018-005-11.02C, Vol. 3 at 5. MDK is a joint venture between KABS, which is a company that specializes in drug development and contract manufacturing, and Mendelia Pharmaceutique.
28. SOR/84-927 [*Regulations*].
29. It is also sometimes referred to as hereditary tyrosinemia type 1.
30. Exhibit NQ-2018-005-C-03A, Vol. 13 at 2; Exhibit NQ-2018-005-C-07, Vol. 13 at 30.
31. Exhibit NQ-2018-005-C-07, Vol. 13 at 30.
32. Exhibit NQ-2018-005-C-07, Vol. 13 at 30.
33. Exhibit NQ-2018-005-C-03A, Vol. 13 at 3; Exhibit NQ-2018-005-C-07, Vol. 13 at 30.

[45] Worldwide, it is estimated that approximately 1,000 people are affected by HT-1.[34] In Canada, the estimates range from 110 to 117 people, with approximately 100 of those located in the province of Quebec.[35] The higher prevalence in Quebec, and particularly in the Saguenay region, is due to a "founder effect".[36] Therefore, according to these estimates, the Quebec market should represent between 85 and 90 percent of the entire Canadian market for nitisinone capsules. The Tribunal's data on the regional distribution of sales from MDK and importers confirms that this is indeed the case.[37] Thus, the Quebec market is unquestionably critical to the success of the domestic industry.

[46] Sobi AB of Sweden held the patent for nitisinone as a treatment for HT-1, which it sold under the brand name Orfadin™, during a 20-year period ending in September 2012.[38] During this period, and until September 2016, Orfadin™ was the only nitisinone product available in Canada, through Health Canada's "Special Access Programme" (SAP), which provides access to non-marketed drugs for practitioners treating patients with serious or life-threatening conditions when conventional therapies have failed, are unsuitable, or unavailable.[39]

[47] MDK, which was founded in 2013, conducted research and development related to the production of nitisinone before filing a New Drug Submission with Health Canada.[40] On September 20, 2016, MDK's nitisinone product—MDK-Nitisinone™—was the first such product to receive a Notice of Compliance (NOC) from Health Canada, which authorized its marketing or distribution in Canada.[41] As a result, the supply of Orfadin™ through Health Canada's SAP became prohibited and MDK-Nitisinone™ became the only authorized nitisinone product in Canada.[42] This allowed MDK to supply the entire Canadian market starting at that time. According to Dr. Bruno Maranda, MDK's President and Medical Director, its first sale was negotiated directly with the CHU Sainte-Justine in Montréal, Quebec, at prices the hospital previously paid for Sobi's Orfadin™, minus 10 percent.[43]

[48] On November 4, 2016, Cycle, a company located in the United Kingdom, received a NOC from Health Canada for its nitisinone tablets, which are manufactured in Switzerland, and from where they are imported into Canada.[44] Shortly thereafter, on December 13, 2016, Sobi AB received

34. Exhibit PI-2018-006-02.01, Vol. 1 at 16. It is estimated that approximately 400 patients are treated with nitisinone in Europe and 100 patients in the United States. See *Transcript of Public Hearing* at 47, 78.
35. *Transcript of Public Hearing* at 78, 166-167; Exhibit PI-2018-006-08.02, Vol. 3 at 6.
36. Exhibit NQ-2018-005-C-03A, Vol. 13 at 3. This effect refers to the loss of genetic variation that occurs when a new population is established by a small number of individuals from a larger population.
37. Exhibit NQ-2018-005-07 (protected), Tables 39, 40, Vol. 2.1.
38. Exhibit NQ-2018-005-C-03A, Vol. 13 at 5.
39. Exhibit NQ-2018-005-C-03A, Vol. 13 at 5.
40. Exhibit NQ-2018-005-11.02C, Vol. 3 at 5; *Transcript of Public Hearing* at 28.
41. Exhibit NQ-2018-005-11.02C, Vol. 3 at 5, 8; Exhibit NQ-2018-005-C-03A, Vol. 13 at 5. The NOC was for nitisinone capsules with a dosage of 2 mg, 5 mg and 10 mg. The NOC for the 20 mg dosage was obtained by MDK on November 30, 2017.
42. Exhibit NQ-2018-005-11.02C, Vol. 3 at 5; Exhibit NQ-2018-005-C-03A, Vol. 13 at 5.
43. Exhibit NQ-2018-005-A-03A, Vol. 11 at 2-3; *Transcript of Public Hearing* at 33-34.
44. Exhibit NQ-2018-005-14.12B, Vol. 5 at 4, 11-12.

a NOC for Orfadin™.[45] At this point, all three nitisinone products, which are considered bioequivalent by Health Canada, were able to compete on the Canadian market on equal footing.[46]

Quebec Market

[49] In Quebec, all patients with HT-1, regardless of age, are followed through the CHU Sainte-Justine as part of a structured clinical program.[47] As such, the CHU Sainte-Justine is the only health care institution in the province of Quebec that purchases nitisinone and, inescapably, is by far the largest purchaser of nitisinone in Canada.

[50] From the moment there is more than one potential supplier for a product and the estimated acquisition cost exceeds $100,000, health care institutions in Quebec are legally required to proceed by way of a public call for tenders.[48] For health care institutions located in the regions of Montréal and Laval, these calls for tenders are conducted by SigmaSanté, a joint procurement group recognized by the government of Quebec.[49] At the hearing, Mr. Yves Charbonneau, Director of Operations for SigmaSanté, explained that, for medications, calls for tenders are typically conducted on a three-year cycle and cover approximately 3800 different drugs.[50] Mr. Charbonneau also confirmed that contracts are awarded to suppliers that submit the lowest-priced compliant tender for each product.[51]

– **First call for tenders covering nitisinone**

[51] On January 11, 2017, following MDK, Sobi AB and Cycle's receipt of NOCs from Health Canada for their respective nitisinone product, SigmaSanté issued, for the first time, a call for tenders for capsules or tablets of nitisinone with a dosage of 2 mg, 5 mg and 10 mg (solicitation No. 2015-777-00-10, hereinafter referred to as the first call for tenders). The tender closing date was January 26, 2017.

[52] MDK, Sobi and Cycle tendered prices for all three dosages. Having tendered the lowest price for each dosage, MDK was awarded a contract for the supply of all three dosages of its nitisinone capsules to the CHU Sainte-Justine for a period of one year, from April 1, 2017, to March 31, 2018 (the first contract). This one-year contract was intended to cover the remaining period in SigmaSanté's 2015-2018 procurement cycle.[52] Therefore, during this time, MDK was the sole supplier of nitisinone capsules for the entire Quebec market.

45. Exhibit NQ-2018-005-C-03A, Vol. 13 at 6.
46. Exhibit NQ-2018-005-C-03A, Vol. 13 at 6.
47. Exhibit NQ-2018-005-27, Vol. 1 at 4; Exhibit PI-2018-006-02.01, Vol. 1 at 33.
48. Exhibit NQ-2018-005-D-01, Vol. 13 at 2; *Transcript of Public Hearing* at 207, 209. In some situations, a decision may be made to proceed by way of a public call for tenders even if only one product is available (see *Transcript of Public Hearing* at 208).
49. Exhibit NQ-2018-005-D-01, Vol. 13 at 2; *Transcript of Public Hearing* at 241.
50. *Transcript of Public Hearing* at 209.
51. *Transcript of Public Hearing* at 219-223. See also Exhibit NQ-2018-005-D-01, Vol. 13 at 2; Exhibit NQ-2018-005-27, Vol. 1 at 5.
52. *Transcript of Public Hearing* at 212.

– Second call for tenders covering nitisinone

[53] On September 27, 2017, SigmaSanté issued a second call for tenders for capsules or tablets of nitisinone with a dosage of 2 mg, 5 mg and 10 mg (solicitation No. 2018-4777-00-01, hereinafter referred to as the second call for tenders). The tender closing date was November 1, 2017.

[54] Once again, MDK, Sobi and Cycle tendered prices for all three dosages. However, this time, Sobi tendered the lowest price for each dosage and, as a result, was awarded a contract for the supply of all three dosages of its nitisinone capsules to the CHU Sainte-Justine for a period of three years, from April 1, 2018, to March 31, 2021 (the second contract). As a result, Sobi will be the sole supplier of nitisinone capsules for the entire Quebec market until March 31, 2021.

[55] The loss of this single contract by MDK deprives the domestic industry of access to between 85 and 90 percent of the entire Canadian market until April 2021.

Market for the Rest of Canada

[56] Based on the numbers presented earlier, there are, at most, 17 people affected by HT-1 that reside outside of Quebec. Information on the record indicates that they are located primarily in Ontario, with the remainder located in Alberta, British Columbia and the Atlantic Provinces.[53]

[57] There is no evidence that purchases of nitisinone outside of Quebec were, at any time, made via a competitive tendering process as has been the case in Quebec. According to Dr. Maranda, prior to MDK receiving a NOC from Health Canada, it made contact with the provinces of Alberta, British Columbia and Ontario, who all agreed to list and reimburse its nitisinone capsules.[54] As for Sobi, the evidence is that, apart from supplying Orfadin™ to a number of patients outside of Quebec on a compassionate-use basis, it did not make any sales outside of Quebec in 2017 and in 2018.[55]

[58] Contrary to the situation in Quebec, where nitisinone is covered by the government for all people affected by HT-1, coverage outside of Quebec is dependent on whether nitisinone is insured by public (i.e. federal, provincial or territorial) or private (i.e. paid by individuals or cost-shared with employers, unions or associations) drug plans.[56] To be considered for reimbursement under public drug plans (except Quebec), pharmaceutical companies must submit a health technology assessment application to the Canadian Agency for Drugs and Technologies in Health (CADTH), which evaluates the cost-effectiveness of a drug via the Common Drug Review (CDR) process and

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53. Exhibit NQ-2018-005-07 (protected), Tables 39, 40, Vol. 2.1; Exhibit NQ-2018-005-C-06A (protected), Vol. 14 at 12; *Transcript of Public Hearing* at 43-44, 92-93.
54. *Transcript of Public Hearing* at 43-44. According to Dr. Maranda, prices were never discussed or questioned—the provinces simply agreed to reimburse MDK. However, in the case of Ontario, the agreement was that MDK's nitisinone capsules would be reimbursed for existing patients on the condition that the drug be provided free of charge for all newly diagnosed patients (see *Transcript of Public Hearing* at 43).
55. Exhibit NQ-2018-005-C-05A, Vol. 13 at 12; *Transcript of Public Hearing* at 175. The supply of Orfadin™ on a compassionate-use basis occurs in situations where there is no public payer willing to cover the costs for this drug.
56. Exhibit NQ-2018-005-C-07, Vol. 13 at 163. It is important to note that government plans are mainly designed to provide insurance to special groups, such as children, seniors and cancer patients. Thus, even if nitisinone is insured under a provincial plan, it does not mean that all people affected with HT-1 will automatically be covered.

ultimately issues a recommendation as to whether it should be publicly funded.[57] The CADTH made such recommendations with respect to Sobi, MDK and Cycle's nitisinone products in February 2018, April 2018 and August 2018, respectively.[58] In the case of Sobi, the recommendation was conditional upon a price reduction of at least 74 percent from the list prices submitted, whereas for MDK and Cycle, it was conditional upon the total cost of treatment with nitisinone not exceeding the drug plan cost of other nitisinone products (i.e. Sobi's Orfadin™).[59]

[59] Once reimbursement recommendations are made by the CADTH, the pan-Canadian Pharmaceutical Alliance (pCPA) may conduct joint federal/provincial/territorial negotiations with the pharmaceutical companies to determine the cost and criteria under which governments will pay for a drug, concluding with a Letter of Intent (LOI) to fund the drug.[60] The LOI, which sets out agreed-upon prices, is then used by companies to negotiate Product Listing Agreements (PLAs) with each interested federal, provincial and territorial government.[61] Sobi, MDK and Cycle negotiated with the pCPA and each signed an LOI near the end of 2018.[62] All three must have also concluded PLAs with Alberta as the province has listed their nitisinone products on its formulary as of February 1, 2019.[63] The Tribunal also heard testimony to the effect that the prices set out in the LOIs, which are carried over into PLAs, are fixed prices (i.e. they are not ceiling prices) and are the same for Sobi, MDK and Cycle.[64]

[60] Therefore, it appears that, going forward, competition between Sobi, MDK and Cycle in provinces with whom they have concluded PLAs will be based on factors other than price.[65] It is assumed that MDK, and possibly Sobi and Cycle, would continue to supply the other provinces based on previous arrangements while awaiting the conclusion of PLAs. There is no evidence to suggest that price is a factor in these arrangements.[66]

[61] It is within this context that the Tribunal will now undertake its injury analysis.

Import Volume of Dumped Goods

[62] Paragraph 37.1(1)(a) of the *Regulations* directs the Tribunal to consider the volume of the dumped goods and, in particular, whether there has been a significant increase in the volume, either in absolute terms or relative to the production or consumption of the like goods.

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57. Exhibit NQ-2018-005-C-07, Vol. 13 at 161, 163. While private drug plans take note of these reimbursement recommendations, information about how decisions are made and which drugs are reimbursed by private insurance is not made publicly available (see Exhibit NQ-2018-005-C-07, Vol. 13 at 164).
58. Exhibit NQ-2018-005-C-07, Vol. 13 at 28-35; Exhibit PI-2018-006-02.01, Vol. 1 at 1189-1196. The information on the record pertaining to Cycle was obtained prior to the issuance of the final recommendation, which can now be accessed here: https://www.cadth.ca/sites/default/files/cdr/complete/SR0554_Nitisinone_Aug_23_18.pdf.
59. *Ibid.*
60. Exhibit NQ-2018-005-C-07, Vol. 13 at 161, 164; Exhibit NQ-2018-005-C-05A, Vol. 13 at 4-5.
61. Exhibit NQ-2018-005-C-07, Vol. 13 at 56, 164; Exhibit NQ-2018-005-C-05A, Vol. 13 at 6.
62. Exhibit NQ-2018-005-C-08 (protected), Vol. 14 at 16-21; Exhibit NQ-2018-005-12.02 (protected), Vol. 4 at 32-36; Exhibit NQ-2018-005-RI-09, Vol. 9 at 1-6; Exhibit NQ-2018-005-RI-09A (protected), Vol. 10 at 1-6. According to Dr. Maranda, the pCPA actually presented MDK with prices and gave it the opportunity to either accept them or refuse them (see *Transcript of Public Hearing* at 44-45; Exhibit NQ-2018-005-11.02C, Vol. 3 at 8).
63. Exhibit NQ-2018-005-C-05A, Vol. 13 at 13.
64. *Transcript of Public Hearing* at 44-45, 69, 126-127, 173-174; *Transcript of In Camera Hearing* at 135.
65. *Transcript of Public Hearing* at 69, 174.
66. *Transcript of Public Hearing* at 43-44.

[63] Absolute volumes of subject goods decreased over most of the POI as a result of MDK first receiving a NOC from Health Canada (thereby prohibiting the supply of Orfadin™ through Health Canada's SAP) and then being awarded the first contract. Volumes then increased significantly in interim 2018 following the award of the second contract to Sobi. Imports of subject goods accounted for nearly all imports of nitisinone over the POI.[67]

[64] In concrete terms, the volume of imports of subject goods decreased by 25 percent in 2016 and a further 46 percent in 2017 before increasing by 117 percent in interim 2018 as compared to interim 2017.[68] The Tribunal notes that, although Sobi imported subject goods in 2017, it made no sales in the Canadian market during that year.[69] Thus, if the volume of subject goods imported in 2017 were removed from the Tribunal's data, the decrease seen in 2017, and the subsequent increase in interim 2018, would be even more dramatic.

[65] A similar trend is also apparent in relative imports of subject goods. Relative to domestic production, the volume of subject goods decreased by 191 percentage points in 2017 over 2016 and then increased by 67 percentage points in interim 2018, as compared to interim 2017.[70] Relative to domestic sales from domestic production, the volume of subject goods decreased by 236 percentage points in 2017 over 2016 and then increased by 268 percentage points in interim 2018, as compared to interim 2017.[71]

[66] Therefore, the Tribunal finds that there has been a significant increase, both in absolute and relative terms, in the volume of imports of the subject goods in interim 2018, as compared to interim 2017.

Price Effects of Dumped Goods

[67] Paragraph 37.1(1)(b) of the *Regulations* directs the Tribunal to consider the effects of the dumped goods on the price of like goods and, in particular, whether the dumped goods have significantly undercut or depressed the price of like goods, or suppressed the price of like goods by preventing the price increases for those like goods that would otherwise likely have occurred. In this regard, the Tribunal distinguishes the price effects of the dumped goods from any price effects that have resulted from other factors affecting prices.

[68] As noted above, Sobi made no sales in the Canadian market in 2017 and made no sales outside of Quebec in 2018. It also did not make any sales in the Canadian market in the fourth quarter of 2016 as MDK's receipt of a NOC from Health Canada in September 2016 put an end to the supply of Orfadin™ through Health Canada's SAP, and Sobi AB only received its NOC three months later in December 2016.[72] Therefore, during the POI, the subject goods and the like goods directly competed with each other only in the Quebec market and on only two occasions, i.e. in the first and second calls for tenders issued by SigmaSanté in 2017.

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67. Exhibit NQ-2018-005-07 (protected), Table 13, Vol. 2.1.
68. Exhibit NQ-2018-005-06, Table 12, Vol. 1.1.
69. Exhibit NQ-2018-005-06, Tables 12, 16, Vol. 1.1. The reason why Sobi imported subject goods in 2017 was provided during the hearing (see *Transcript of In Camera Hearing* at 127-128).
70. Exhibit NQ-2018-005-06, Table 14, Vol. 1.1.
71. Exhibit NQ-2018-005-06, Table 14, Vol. 1.1.
72. This is confirmed by the data in the Tribunal's Investigation Report. See Exhibit NQ-2018-005-07 (protected), Schedules 1, 2, 3 and 5, Vol. 2.1. See also NQ-2018-005-C-01A, Vol. 13 at 5.

[69] It is with this information in mind that the Tribunal will now assess whether the subject goods significantly undercut, depressed or suppressed the price of the like goods.

Price Undercutting

[70] As detailed earlier, in the first call for tenders, MDK, Sobi and Cycle tendered prices for all three dosages of nitisinone capsules. Having tendered the lowest price for each dosage, MDK was awarded the first contract. The information on the record indicates that the prices tendered by MDK were substantially lower than those tendered by Sobi and Cycle.[73] As such, in this instance, it was the like goods that undercut the prices of the subject goods.

[71] In the second call for tenders, MDK, Sobi and Cycle once again tendered prices for all three dosages of nitisinone capsules. However, this time, it was Sobi that tendered the lowest price for each dosage. Consequently, it was awarded the second contract. The prices tendered by Sobi were as follows (per package of 60 capsules): $465.75 for the 2 mg dosage, $457.60 for the 5 mg and $426.00 for the 10 mg.[74] These prices were substantially lower than those tendered by MDK, which had increased from those it tendered in the first call for tenders.[75] According to Dr. Maranda, he had never witnessed a situation where prices decrease as the dosage increases.[76] At the hearing, Ms. Andrea Souchen of Sobi provided a logical explanation for this unusual inverse correlation.[77]

[72] Sobi submitted that the prices it tendered in the second call for tenders were consistent with the benchmark established by MDK in the first call for tenders and that, by driving down prices the way it did, MDK is responsible for the loss of the second contract. In this regard, Ms. Souchen testified that competitive bidding for pharmaceuticals usually results in continued price declines and that, accordingly, she expected all bidders to offer prices in the second call for tenders that were lower than in the first.[78]

[73] While the Tribunal does not dispute that the low prices tendered by MDK in the first call for tenders established a new benchmark and may have caused injury to MDK (i.e. self-inflicted injury—see discussion regarding price depression below), this does not give Sobi the *right* to undercut the prices of the like goods through the action of dumping. In other words, the reason or justification for the dumping is not a relevant consideration under *SIMA*. As the Tribunal has previously stated, "it is irrelevant who initiated the 'price war'. [T]he domestic industry has the right to reduce its prices to try to increase its market presence . . . and the importers have the same right. . . . However, once the imported product is offered at dumped prices which cause injury to the domestic industry, the line is crossed."[79] In any event, the Tribunal notes that the prices tendered by

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73. Exhibit NQ-2018-005-07 (protected), Table 4, Vol. 2.1.
74. Exhibit NQ-2018-005-C-03A, Vol. 13 at 4; *Transcript of Public Hearing* at 185. See also Exhibit NQ-2018-005-07 (protected), Table 4, Vol. 2.1.
75. Exhibit NQ-2018-005-07 (protected), Table 4, Vol. 2.1. Dr. Maranda explained that MDK tendered retention prices (*prix de préservation*) in the first call for tenders, but then raised prices in the second call for tenders in order to make them more economically viable (see *Transcript of Public Hearing* at 36, 41-42, 48).
76. *Transcript of Public Hearing* at 50.
77. *Transcript of In Camera Hearing* at 95-97.
78. Exhibit NQ-2018-005-C-05A, Vol. 13 at 11; *Transcript of Public Hearing* at 177, 195-196.
79. *Iodinated Contrast Media* (1 May 2000), NQ-99-003 (CITT) at 16; *Polyisocyanurate Thermal Insulation Board* (11 April 1997), NQ-96-003 (CITT) at 22-23.

Sobi in the second call for tenders were substantially lower than even those tendered by MDK in the *first* call for tenders, which had established a new benchmark.[80]

[74] Therefore, in light of the foregoing, the Tribunal finds that, while the subject goods have not undercut the price of the like goods in the first call for tenders, they have significantly undercut them in the second call for tenders.

Price Depression

[75] The average unit selling values of like goods decreased by 81 percent from 2016 to 2017 and subsequently increased by 51 percent in interim 2018, as compared to interim 2017.[81] These variations reflect initially high selling prices in 2016 when MDK's first sale was negotiated directly with the CHU Sainte-Justine,[82] lower selling prices under the first contract, which took effect on April 1, 2017, and higher selling prices in interim 2018 as the first contract came to an end and the only remaining sales were those made at higher selling prices outside Quebec, which, understandably, resulted in higher average unit selling values in interim 2018.

[76] Dr. Maranda explained that, in the first call for tenders, MDK tendered prices that were significantly lower than those previously paid for Sobi's Orfadin™ under Health Canada's SAP as it anticipated that Sobi would substantially lower its prices to maintain the Quebec market.[83] This anticipation or apprehension was, according to Dr. Maranda, primarily based on Sobi AB's filing of an application for judicial review of Health Canada's decision to issue a NOC to MDK, which he described as highly aggressive behaviour.[84] Other factors which pushed MDK to tender low prices were that it had built up inventory of its nitisinone capsules, that the CHU Sainte-Justine's decision to proceed by way of call for tenders changed its approach to market entry and finally, its desire to be present in its home market.[85]

[77] Although the Tribunal does not deny the existence of the factors which drove MDK to submit low prices in the first call for tenders, these factors alone are insufficient to find that the subject goods depressed the price of the like goods in 2017. Looking at the evidence objectively, the Tribunal fails to see the connection between Sobi AB's filing of an application for judicial review of a Health Canada decision and MDK's pricing strategy in the Quebec market. Further, as it has been stated above, Sobi made no sales in the Canadian market in 2017. There is also no evidence on the record of any offers by Sobi to sell at these low prices before the first call for tenders was issued in early 2017. In the absence of such evidence, MDK's apprehension does not form a sufficient basis upon which to find price depression.

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80. Exhibit NQ-2018-005-07 (protected), Table 4, Vol. 2.1.
81. Exhibit NQ-2018-005-06, Table 21, Vol. 1.1.
82. The prices were those the hospital previously paid for Sobi's Orfadin™, minus 10 percent. See Exhibit NQ-2018-005-A-03A, Vol. 11 at 2-3; *Transcript of Public Hearing* at 33-34.
83. Exhibit NQ-2018-005-A-03A, Vol. 11 at 3. KABS-MDK referred to this as an apprehension of dumping (*le dumping appréhendé*) (see Exhibit NQ-2018-005-A-01A, Vol. 11 at 36).
84. *Transcript of Public Hearing* at 37-39, 100-104, 131-132. The application for judicial review was discontinued by Sobi AB on January 13, 2017 (see PI-2018-006-02.01, Vol. 1 at 956-957).
85. *Transcript of Public Hearing* at 36-37, 40-41.

[78] Moreover, the prices tendered by MDK in the first call for tenders were substantially lower than those tendered by both Sobi and Cycle.[86] Ms. Souchen explained that the approach she took to determine the prices that would be tendered by Sobi in that first call for tenders was guided by the fact that there were three bioequivalent products on the market.[87] Despite Sobi already tendering discounted prices, Ms. Souchen was "quite shocked" at the "very high" level of discount provided by MDK.[88] Therefore, the Tribunal finds that, in fact, it is MDK that adopted an aggressive pricing strategy in the first call for tenders.

[79] In light of the foregoing, the Tribunal can only conclude that the prices tendered by MDK in the first call for tenders were unnecessarily low and that the ensuing depression in the average unit selling values of like goods observed in 2017 was solely attributable to MDK's actions.

[80] Therefore, the Tribunal finds that the subject goods have not depressed the price of the like goods in 2017 or interim 2018.

Price Suppression

[81] KABS-MDK did not argue that the subject goods suppressed the price of the like goods. Although the average unit cost of goods sold increased at a faster rate than the average unit selling values in interim 2018,[89] this was not attributable to the subject goods as these did not directly compete with the like goods in the market during this period. Therefore, the Tribunal finds that the subject goods have not suppressed the price of the like goods.

Resultant Impact on the Domestic Industry

[82] Paragraph 37.1(1)(c) of the *Regulations* requires the Tribunal to consider the resulting impact of the dumped goods on the state of the domestic industry and, in particular, all relevant economic factors and indices that have a bearing on the state of the domestic industry.[90] These impacts are to be distinguished from the impact of other factors also having a bearing on the domestic industry.[91] Paragraph 37.1(3)(a) of the *Regulations* requires the Tribunal to consider whether a causal relationship exists between the dumping of the goods and the injury, retardation or threat of injury,

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86. Exhibit NQ-2018-005-07 (protected), Table 4, Vol. 2.1.
87. Exhibit NQ-2018-005-C-05A, Vol. 13 at 9-10; *Transcript of In Camera Hearing* at 134-135.
88. *Transcript of Public Hearing* at 176.
89. Exhibit NQ-2018-005-07 (protected), Table 32, Vol. 2.1.
90. Such factors and indices include (i) any actual or potential decline in output, sales, market share, profits, productivity, return on investments or the utilization of industrial capacity, (ii) any actual or potential negative effects on cash flow, inventories, employment, wages, growth or the ability to raise capital, (ii.1) the magnitude of the margin of dumping or amount of subsidy in respect of the dumped or subsidized goods, and (iii) in the case of agricultural goods, including any goods that are agricultural goods or commodities by virtue of an Act of Parliament or of the legislature of a province, that are subsidized, any increased burden on a government support programme.
91. Paragraph 37.1(3)(b) of the *Regulations* directs the Tribunal to consider whether any factors other than dumping or subsidizing of the subject goods have caused injury. The factors which are prescribed in this regard are (i) the volumes and prices of imports of like goods that are not dumped or subsidized, (ii) a contraction in demand for the goods or like goods, (iii) any change in the pattern of consumption of the goods or like goods, (iv) trade-restrictive practices of, and competition between, foreign and domestic producers, (v) developments in technology, (vi) the export performance and productivity of the domestic industry in respect of like goods, and (vii) any other factors that are relevant in the circumstances.

on the basis of the volume, the price effect, and the impact on the domestic industry of the dumped goods.

[83] Given the Tribunal's above finding that the subject goods only significantly undercut the price of the like goods in the second call for tenders and that there has only been a significant increase in the volume of subject goods in interim 2018, its examination of the relevant economic factors and indices having a bearing on the state of the domestic industry will be focused on the interim 2018 period, i.e. the period during which the impact of the loss of the second contract started to be felt. The Tribunal has previously found that injury suffered by the domestic industry can, in certain circumstances, be considered material even if the duration of the injury represents only a portion of the POI.[92]

[84] After the Tribunal has examined whether the domestic industry suffered injury in interim 2018, it will consider whether a causal relationship exists between the dumping of the subject goods and any such injury. The question as to whether such a relationship exists is one of the key considerations in this inquiry. Sobi contends that, even if it had tendered higher prices than MDK in the second call for tenders, MDK still would not have been awarded the second contract. KABS-MDK takes the view that MDK would have been awarded the second contract in those circumstances.

[85] As the Tribunal ultimately finds that no causal relationship exists between the dumping of the subject goods by Sobi and the loss of the second contract by MDK, it will limit its examination of the relevant economic factors and indices having a bearing on the state of the domestic industry to the issues that it considers most significant taking into account the unique characteristics of the market for nitisinone capsules in Canada.

[86] Finally, before proceeding, the Tribunal recalls that MDK stopped supplying the CHU Sainte-Justine on March 31, 2018, when the first contract came to an end. Therefore, when considering various performance indicators for the interim 2018 period (i.e. the first three quarters of 2018), it must be borne in mind that MDK was making significant sales in the Quebec market in the first quarter of 2018. Therefore, these indicators do not show the full extent of the injury suffered due to the loss of the second contract.

Sales and Market Share

[87] The volume of MDK's domestic sales from domestic production increased by 320 percent from 2016 to 2017, due to the fact that, in 2016, it only had sales in the fourth quarter.[93] Predictably, the loss of the second contract resulted in the volume of domestic sales from domestic production decreasing by 65 percent in interim 2018, as compared with interim 2017.[94]

[88] As the Quebec market represents between 85 and 90 percent of the entire Canadian market, the market share lost by MDK in interim 2018 was dramatic and was mirrored perfectly by the market share gained by Sobi during this period.[95] The total apparent market grew slightly in 2016 with an increase of 3 percent, followed by a 16 percent increase in 2017 and practically no change in

92. See, for example, *Cold-rolled Steel* (21 December 2018), NQ-2018-002 (CITT) at para. 99.
93. Exhibit NQ-2018-005-06, Table 16, Vol. 1.1.
94. Exhibit NQ-2018-005-06, Table 16, Vol. 1.1.
95. Exhibit NQ-2018-005-07 (protected), Table 17, Vol. 2.1.

interim 2018 as compared with interim 2017.[96] Since the dosage for nitisinone is dependent on a patient's weight, demand generally increases as newborns are diagnosed and as patients get older.[97]

Production and Capacity Utilization

[89] KABS's total production volume increased by 333 percent from 2016 to 2017, but then decreased by 25 percent in interim 2018 as compared to interim 2017.[98] As MDK began making an important number of export sales in interim 2018, the decrease in KABS's production volume for domestic sales during this period was significantly greater than the decrease in total production stated above and more in line with the decrease in the volume of domestic sales.[99]

[90] The capacity utilization rate for total production increased by 117 percent from 2016 to 2017, but then decreased by 25 percent in interim 2018 as compared to interim 2017.[100] When considered in relation to production for domestic sales only, the capacity utilization rate decreased more significantly in interim 2018 as compared to interim 2017.[101] The Tribunal notes that capacity utilization levels were relatively low throughout the POI, which reflects KABS's high production capacity in relation to the overall size of the Canadian market.

Employment, Hours Worked and Wages

[91] Although KABS-MDK's direct employment number of employees remained the same throughout the POI, the number of direct employment hours worked increased by 55 percent from 2016 to 2017 and decreased 28 percent in interim 2018 as compared to interim 2017.[102] Direct employment wages followed a similar pattern with an increase of 28 percent in 2017 and a decrease of 25 percent in interim 2018.[103]

[92] Sobi submitted that the decline in direct employment hours worked in interim 2018 represents a reduction of a very small number of full-time equivalent employees and that such a small loss of employment does not support the materiality of any injury suffered by KABS-MDK.

[93] While, in absolute terms, the decline in direct employment hours worked can appear unimportant in light of the relatively small size of the domestic industry, the Tribunal is of the view that the decline, when expressed as a percentage of total hours worked, provides a better indication of the impact that the loss of the second contract had on the domestic industry.

Return on Investments

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96. Exhibit NQ-2018-005-06, Table 16, Vol. 1.1. As market volumes are measured by the number of packages of 60 capsules (all dosages combined), some of the variation in the total apparent market may be due to changes in the pattern of consumption of different dosages (see *Transcript of Public Hearing* at 109-110).
97. *Transcript of Public Hearing* at 70, 110; *Transcript of In Camera Hearing* at 79-80.
98. Exhibit NQ-2018-005-06, Table 36, Vol. 1.1.
99. Exhibit NQ-2018-005-07 (protected), Tables 35, 36, Vol. 2.1.
100. Exhibit NQ-2018-005-06, Table 36, Vol. 1.1.
101. Exhibit NQ-2018-005-07 (protected), Table 35, Vol. 2.1.
102. Exhibit NQ-2018-005-07 (protected), Table 35, Vol. 2.1; Exhibit NQ-2018-005-06, Table 36, Vol. 1.1.
103. Exhibit NQ-2018-005-06, Table 36, Vol. 1.1.

[94] KABS-MDK submitted that it had intended to start production of its nitisinone capsules, both for the domestic and export markets, in a new, much larger plant in Asbestos, Quebec, if it had obtained the second contract. It submitted that the increased production capacity at the plant is required in order to ensure there are no stock shortages. It further submitted that the development of the plant represents an investment of nearly $4.4 million and would have led to the creation of up to 50 jobs, both of which are now at risk.[104]

[95] Sobi submitted that KABS's failure to start production at the Asbestos, Quebec, plant is not relevant to the present injury inquiry as KABS's existing plant in Longueuil, Quebec, is capable of supplying the entire Canadian market three times over. It further submitted that the additional capacity at the Asbestos, Quebec, plant was meant to increase KABS's production capacity for international markets and for other pharmaceutical products.

[96] The evidence on the record indicates that production capacity at KABS's plant in Longueuil, Quebec, is significantly greater than the entire Canadian market, even when accounting for a maximum capacity utilization rate of 60 percent, which Dr. Jean-Simon Blais, President of KABS, claims is required to give him a sense of comfort.[105] That being said, Dr. Blais did testify that, in order to prevent shortages that could be caused by disasters, it is desirable to have large amounts of the active molecule of nitisinone stored and ready to be produced at each plant.[106] While the Tribunal will not second-guess KABS's strategy to achieve this production redundancy, it cannot consider the totality of the investment in the Asbestos, Quebec, plant as being related to the production of nitisinone. The Tribunal considers that, given the evidence that the Asbestos, Quebec, plant was intended to increase capacity for international markets and for other pharmaceutical products in addition to nitisinone,[107] it would be appropriate to consider, at most, a very small proportion of the investment in the plant as being impacted by the loss of the second contract.

Profitability

[97] The Tribunal considered the domestic industry's financial performance as it relates to domestic sales only. The domestic industry's gross margins decreased in 2017 as a result of MDK's low selling prices under the first contract and further decreased in interim 2018 when sales under that contract came to an end.[108] Although the domestic industry's net income declined as well in 2017, it improved in interim 2018.[109] Looking on a per-unit basis, gross margins and net income both declined in 2017, but then both improved in interim 2018.[110] The Tribunal also looked at the potential impact of costs related to the Asbestos, Quebec, plant. It notes that, if expenses related to the Asbestos, Quebec, plant are removed from the income statement, net income improves slightly but the trends observed above remain unchanged.

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104. Exhibit NQ-2018-005-A-01A, Vol. 11 at 28-29; *Transcript of Public Hearing* at 62.
105. Exhibit NQ-2018-005-07 (protected), Tables 15, 35, Vol. 2.1; *Transcript of Public Hearing* at 81-83, 114-115, 118.
106. *Transcript of Public Hearing* at 142-143.
107. Exhibit NQ-2018-005-A-08 (protected), Vol. 12 at 31-32; *Transcript of Public Hearing* at 65; *Transcript of In Camera Hearing* at 54-57.
108. Exhibit NQ-2018-005-07 (protected), Table 32, Vol. 2.1.
109. Exhibit NQ-2018-005-07 (protected), Table 32, Vol. 2.1.
110. Exhibit NQ-2018-005-07 (protected), Table 32, Vol. 2.1.

[98] Sobi submitted that the above is evidence that the domestic industry was more profitable in interim 2018 when not having to supply nitisinone at low selling prices under the first contract.

[99] The Tribunal observes that net income improved in interim 2018, when compared to interim 2017, as a result of a decrease in general, selling and administrative expenses that was even greater than the decrease in gross margins.[111] Additionally, the improvement seen in gross margins and net income, on a per-unit basis, in interim 2018 is illusory. While all MDK's sales in the second and third quarters of 2018 were made outside Quebec at higher prices, the volume of such sales was much lower owing to the fact that there are, at most, 17 people affected by HT-1 that reside outside of Quebec. Had MDK been awarded the second contract at the prices it tendered, its financial results for interim 2018 would, in all likelihood, have been significantly better.

Magnitude of the Margin of Dumping

[100] As noted above, the CBSA determined that the weighted average margin of dumping of the subject goods, when expressed as a percentage of the export price, was 1,594 percent for Sobi AB. This is one of the highest, if not the highest, margin of dumping determined by the CBSA. However, in the context of this case, the magnitude of the margin of dumping does not add much to the Tribunal's above analysis of injury. Even if the prices tendered by Sobi in the second call for tenders had been at the same level as those tendered by MDK, the margin of dumping would still have been very large.[112]

[101] Orphan drugs, in this case nitisinone, are not commodity products and the orphan drug industry is not one with a production imperative.[113] Given generally high costs of research and development and sales to a very small number of patients,[114] it is understandable that pharmaceutical companies that sell orphan drugs will seek to maximize returns within regulatory frameworks and pricing mechanisms in place in each country in which they sell. This can lead to situations where there are important differences in prices between a company's home and export markets, which, in turn, can lead to significant margins of dumping. Therefore, while the margin of dumping is exceptionally high in the present case, it should by no means be compared with margins normally found by the CBSA on commodity products or considered as having been a decisive factor in the Tribunal's injury analysis.

Causality

[102] As stated earlier, paragraph 37.1(3)(a) of the *Regulations* requires the Tribunal to consider whether a causal relationship exists between the dumping of the goods and the injury, retardation or threat of injury, on the basis of the volume, the price effect, and the impact on the domestic industry of the dumped goods. Thus, the Tribunal will consider whether a causal relationship exists between the dumping of the subject goods by Sobi and any injury suffered by KABS-MDK.

[103] This injury inquiry is somewhat unique in that it presents a situation where the volume, the price effect and the impact on the domestic industry of the dumped goods all relate to a single transaction, i.e. the second call for tenders and the subsequent award of a contract. This largely

111. Exhibit NQ-2018-005-07 (protected), Table 32, Vol. 2.1.
112. Exhibit NQ-2018-005-C-05A, Vol. 13 at 7-8; Exhibit NQ-2018-005-07 (protected), Table 4, Vol. 2.1.
113. Exhibit NQ-2018-005-C-03A, Vol. 13 at 3.
114. Exhibit NQ-2018-005-C-03A, Vol. 13 at 3.

facilitates the Tribunal's consideration of whether there is a causal link between the dumping and the injury.

[104] The Tribunal is of the view that, in these specific circumstances, it is appropriate to apply the "but for" test in order to determine whether such a causal link exists.[115] Thus, the Tribunal needs to ask whether KABS-MDK would have been injured, *but for* the dumping of the subject goods by Sobi. In other words, had the subject goods not undercut the price of the like goods in the second call for tenders, would MDK still have lost the second contract? If the answer to this question is affirmative, then the requisite causal relationship will not have been established.

[105] As mentioned previously, Sobi submitted that, even if it had tendered higher prices than MDK in the second call for tenders (i.e. if the subject goods had not been dumped), or even if it had not participated in the second call for tenders, the evidence obtained during the hearing clearly demonstrates that MDK still would not have been awarded the second contract. It submitted that this effectively breaks the causal link between the dumping of the subject goods and the loss of the second contract.

[106] For its part, KABS-MDK submitted that, but for the dumping of subject goods by Sobi, MDK would have been awarded the second contract. It submitted that the information provided by SigmaSanté as part of the Tribunal's RFI process confirms that MDK would have been awarded the second contract as Cycle's tender was determined to be non-compliant.

[107] It is clear from the positions of the parties that they disagree on what would have been the outcome of the second call for tenders if Sobi had tendered higher prices, or not participated at all. As the result of the application of a *but for* test is established on the basis of balance of probabilities, the Tribunal will need to determine which of the two outcomes would likely have occurred.

[108] In the second call for tenders, MDK, Sobi and Cycle tendered prices for all three dosages. Having tendered the lowest price for each dosage, Sobi was awarded the second contract.[116] The evidence on the record pertaining to the prices tendered by Cycle indicates that its prices were lower

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115. The Tribunal has previously performed a *but for* causation analysis in the context of an injury inquiry to determine whether the dumping or subsidizing of goods caused the domestic industry to lose a series of contracts that were awarded using competitive bidding processes. See *Unitized Wall Modules* (12 November 2013), NQ-2013-002 (CITT) at para. 105. KABS-MDK submitted that, contrary to the situation that prevailed in *Unitized Wall Modules*, where there were more than 20 contracts, the current situation pertains to a single contract that covers nearly all of the Canadian market. It submitted that, in these circumstances, performing this type of causation analysis would be unreasonable. KABS-MDK appears to be suggesting that the Tribunal should take a different approach, or simply ignore the question entirely, simply because the outcome of the *but for* causation analysis may not be favourable to the domestic industry. However, the Tribunal is required to address causation in its analysis and the refusal to do so in the face of clear facts would, in its view, constitute a reviewable error. The Tribunal is also not persuaded that KABS-MDK's submissions provide a sufficient or valid basis to distinguish the situation in this inquiry from that in *Unitized Wall Modules* or use a different approach to address the issue of causation.
116. The solicitation documents confirm that the contract was to be awarded to the supplier that submitted the lowest-priced compliant tender. See Exhibit NQ-2018-005-RI-04A, Vol. 9 at 33; Exhibit NQ-2018-005-27, Vol. 1 at 1-2.

than those of MDK for each dosage.[117] The Tribunal recalls that Cycle's nitisinone tablets, which are manufactured in Switzerland, are not subject goods.

[109] As part of the Tribunal's RFI process, Sobi requested that SigmaSanté state which entity would have been awarded the second contract had Sobi's prices been higher than MDK's prices. SigmaSanté responded by stating that MDK would have had the lowest-priced compliant tender as Cycle's tender was determined to be non-compliant.[118] The Tribunal notes that SigmaSanté did not state in its response that MDK would have been awarded the contract.

[110] At the request of Sobi, the Tribunal directed SigmaSanté to provide additional information regarding Cycle's tender and the reasons for its determination that it was non-compliant. The information provided by SigmaSanté indicates that Cycle's tender was determined to be non-compliant as it contained abnormally low prices.[119] It appears that these prices were the result of Cycle entering "case of 10" [translation] in the "format provided" [translation] field of the electronic bidding system, which had the effect of lowering its tendered price for each dosage by a factor of 10.[120] In its response to the Tribunal's questionnaire issued in the current inquiry, Cycle provided the prices it believed it had tendered (i.e. prices that were not divided by 10).[121] These are the prices that appear in the Tribunal's investigation report.[122]

[111] Notwithstanding SigmaSanté's determination that Cycle's tender was non-compliant, the Tribunal is of the view that the evidence on the record, which it will address below, suggests that it is more likely than not that Cycle would have been awarded the second contract had Sobi tendered higher prices or not participated at all.

[112] First, when Cycle was notified by SigmaSanté of its abnormally low prices, it was given an opportunity, in accordance with the terms of the solicitation and the applicable legislation, to provide reasons justifying these low prices.[123] Cycle responded by stating that its submitted prices should have been multiplied by 10 (i.e. that its tendered prices were for single packages of 60 nitisinone tablets and not for a case of 10 packages).[124] It is clear that, through this process, Cycle was not attempting to justify its low prices by demonstrating that it could execute the contract at those prices. Ultimately, Cycle's error was one of form rather than substance.[125] There is no evidence to suggest that Cycle failed to meet any other requirement of the solicitation or that it could not have executed the contract at the prices it believed it tendered.

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117. Exhibit NQ-2018-005-15.12B (protected), Vol. 6 at 43; Exhibit NQ-2018-005-07 (protected), Table 4, Vol. 2.1. The Tribunal notes that this information was not on the record at the time it made its preliminary determination of injury.
118. Exhibit NQ-2018-005-RI-04, Vol. 9 at 1.
119. Exhibit NQ-2018-005-RI-04A, Vol. 9 at 1, 4.
120. Exhibit NQ-2018-005-RI-04B (protected), Vol. 10 at 123, 266; Exhibit NQ-2018-005-27, Vol. 1 at 4.
121. Exhibit NQ-2018-005-15.12B (protected), Vol. 6 at 43.
122. Exhibit NQ-2018-005-07 (protected), Table 4, Vol. 2.1.
123. Exhibit NQ-2018-005-27, Vol. 1 at 2-4; Exhibit NQ-2018-005-RI-04B (protected), Vol. 10 at 266; *Transcript of Public Hearing* at 243.
124. Exhibit NQ-2018-005-27, Vol. 1 at 4; Exhibit NQ-2018-005-RI-04B (protected), Vol. 10 at 263, 267, 270, 273-274. The Tribunal notes that, while tenders in the first call for tenders were submitted in paper format, tenders in the second call for tenders were submitted using an electronic bidding system (see *Transcript of Public Hearing* at 223-224).
125. *Transcript of In Camera Hearing* at 140-141.

[113] Second, a final letter was sent to Cycle informing it that a committee had considered the reasons Cycle provided to justify its abnormally low prices and recommended that it should not be awarded the second contract.[126] However, this recommendation did not imply that the committee considered Cycle's tender as non-compliant or that it would have refused Cycle's explanation or correction if the corrected prices were lower than the prices tendered by Sobi. As Cycle was clearly not willing to supply its nitisinone tablets at 10 percent of its tendered prices, and as the corrected prices were in any case higher than the prices tendered by Sobi, the only possible outcome for the committee was a recommendation to not award the contract to Cycle. Moreover, the letter, which was sent to a number of suppliers who had tendered abnormally low prices (for other medications covered by the second call for tenders), clearly indicates that, in some cases, the committee recommended that a contract be awarded to these suppliers.[127]

[114] Finally, it is clear from the evidence on the record that once Cycle clarified that the prices it tendered were for single packages as opposed to boxes of 10, SigmaSanté did not see the need to pursue the matter any further given that those prices were now higher than the prices tendered by Sobi.[128] Crucially, at the hearing, the Tribunal heard testimony which leads it to believe that, had Cycle's corrected prices been the lowest of all prices tendered from the three companies, the correction would have been permitted and Cycle would have been awarded the second contract.[129] This outcome appears to be consistent with the *raison d'être* of Quebec's public procurement system, which is to maximize competition and obtain the best possible price while meeting the stated requirements.[130]

[115] In its written submissions, KABS-MDK argued that, for a number of reasons, the prices tendered by Cycle were suspect and should essentially be disregarded by the Tribunal when looking at the issue of causation.[131] As the large majority of KABS-MDK's submissions in this regard are confidential, the Tribunal's ability to address them meaningfully in these reasons is limited. Nevertheless, the Tribunal notes that it does not find any of the arguments put forth to be persuasive. In particular, it does note that Cycle's nitisinone tablets are not subject goods and are not currently the subject of a dumping investigation by the CBSA. As such, the Tribunal cannot presume that they are dumped. There is also nothing to suggest that Cycle is not a viable supplier for the Canadian market as it received a NOC from Health Canada and has made sales into the market.[132]

[116] Therefore, the Tribunal finds that a causal relationship does not exist between the dumping of the subject goods by Sobi and the injury suffered by KABS-MDK. MDK would not have been awarded the second contract, even if Sobi had offered prices that were not dumped, as the prices MDK tendered were higher than those of Cycle. On balance, the evidence indicates that it is the latter supplier who would have been awarded the contract in the absence of dumping.

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126. Exhibit NQ-2018-005-27, Vol. 1 at 4; Exhibit NQ-2018-005-RI-04B (protected), Vol. 10 at 275-276.
127. Exhibit NQ-2018-005-RI-04B (protected), Vol. 10 at 276.
128. Exhibit NQ-2018-005-27, Vol. 1 at 4; *Transcript of In Camera Hearing* at 141.
129. *Transcript of In Camera Hearing* at 144-145.
130. *Transcript of Public Hearing* at 229-230.
131. See Exhibit NQ-2018-005-A-02A (protected) at paras. 37-40, 93-94, 122-125, Vol. 12.
132. Exhibit NQ-2018-005-14.12, Vol. 5 at 4; Exhibit NQ-2018-005-07 (protected), Table 15, Vol. 2.1.

Conclusion

[117] In light of the foregoing, the Tribunal finds that the dumping of the subject goods has not caused injury to the domestic industry. Given this finding, the Tribunal need not examine the other factors raised by Sobi or whether the injury suffered by the domestic industry in interim 2018 is "material".

THREAT OF INJURY ANALYSIS

[118] Having found that the dumping of the subject goods has not caused injury to the domestic industry, the Tribunal must now consider whether the dumping is threatening to cause material injury.

[119] The Tribunal is guided in its consideration of this question by subsection 37.1(2) of the *Regulations*, which prescribes factors to be taken into account for the purposes of its threat of injury analysis.[133] Also of relevance is subsection 2(1.5) of *SIMA*, which indicates that a threat of injury finding cannot be made unless the circumstances in which the dumping of the goods would cause injury are clearly foreseen and imminent.

[120] The Tribunal is also mindful of Article 3.7 of the WTO *Anti-dumping Agreement*, which sets out the framework of obligations implemented in subsection 2(1.5) of *SIMA*:

> A determination of threat of injury shall be *based on facts and not merely on allegation, conjecture or remote possibility*. The *change in circumstances* which would create a situation in which the dumping would cause injury *must be clearly foreseen and imminent*.
>
> [Emphasis added]

[121] As the Tribunal has previously indicated,[134] the fundamental requirement that threat of injury findings must be based on facts and not on "allegation, conjecture or remote possibility" aims to mitigate the risk that such findings may be grounded in speculation about possible future events, rather than objective facts directing such a conclusion. The WTO Appellate Body recognized the

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133. Subsection 37.1(2) of the *Regulations* reads as follows: "For the purposes of determining whether the dumping or subsidizing of any goods is threatening to cause injury, the following factors are prescribed: (a) the nature of the subsidy in question and the effects it is likely to have on trade; (b) whether there has been a significant rate of increase of dumped or subsidized goods imported into Canada, which rate of increase indicates a likelihood of substantially increased imports into Canada of the dumped or subsidized goods; (c) whether there is sufficient freely disposable capacity, or an imminent, substantial increase in the capacity of an exporter, that indicates a likelihood of a substantial increase of dumped or subsidized goods, taking into account the availability of other export markets to absorb any increase; (d) the potential for product shifting where production facilities that can be used to produce the goods are currently being used to produce other goods; (e) whether the goods are entering the domestic market at prices that are likely to have a significant depressing or suppressing effect on the price of like goods and are likely to increase demand for further imports of the goods; (f) inventories of the goods; (g) the actual and potential negative effects on existing development and production efforts, including efforts to produce a derivative or more advanced version of like goods; (g.1) the magnitude of the margin of dumping or amount of subsidy in respect of the dumped or subsidized goods; (g.2) evidence of the imposition of anti-dumping or countervailing measures by the authorities of a country other than Canada in respect of goods of the same description or in respect of similar goods; and (h) any other factors that are relevant in the circumstances."

134. *Polyethylene Terephthalate Resin* (16 March 2018), NQ-2017-003 (CITT) [*PET Resin*] at para. 167.

inherent difficulty in a threat of injury finding of having to predict future events; it is nevertheless required by WTO law that "a 'proper establishment' of facts in a determination of threat of material injury must be based on events that, although they have not yet occurred, must be 'clearly foreseen and imminent' . . . ."[135] Therefore, for the Tribunal to find that the subject goods threaten to cause injury to the domestic industry, there must be positive evidence that bears out this substantive standard.

[122] Further, subsection 37.1(3) of the *Regulations* directs the Tribunal to consider whether a causal relationship exists between the dumping of the goods and the threat of injury on the basis of the factors listed in subsection 37.1(2), and whether any factors other than the dumping are threatening to cause injury.

[123] In light of the above, the Tribunal is of the view that a finding of threat of injury requires the same rigorous analysis with respect to causality and these factors, supported by cogent and convincing evidence, as does a finding of injury. There must also be a high probability of a change, compared to the circumstances that existed during the POI, to a situation in which the subject goods threaten to cause material injury in the very near future, in the absence of measures.[136]

[124] In the context of this case, the Tribunal found that, due to the presence of Cycle, the loss of the second contract by MDK would have occurred even if the subject goods had not undercut the price of the like goods. Accordingly, there was no causal relationship between the dumping of the subject goods by Sobi and the injury suffered by KABS-MDK during the POI. In terms of the situation outside of Quebec, given that Sobi made no sales in 2017 and 2018, no price effects or injury was observed during the POI. Therefore, in order for the Tribunal to determine that there is a *threat* of injury, it would need to establish that a change in the above circumstances, which would create a situation in which the dumping of the subject goods would cause injury, is clearly foreseen and imminent. As will be discussed below, the Tribunal finds that there is no such change in circumstances.

Time Frame for the Threat Analysis

[125] In assessing threat of injury, the Tribunal typically considers a time frame of 12 to 18 months, and no more than 24 months, beyond the date of its finding, depending on the unique circumstances of each case.

[126] KABS-MDK submitted that a time frame of 24 months is appropriate in this instance as the next call for tenders is likely to be issued by SigmaSanté in September 2020 and the resulting contract, which will cover nearly all of the Canadian market for a period of three years, will once again likely be awarded to the supplier that submits the lowest-priced tender.

[127] Sobi submitted that attempting to predict events in the Quebec market 24 months into the future would require significant speculation and conjecture. It submitted that a time frame of 12 to 18 months is more appropriate as lead times for delivery of nitisinone are very short and the Tribunal is able to predict with significant certainty what will happen in the Quebec market over this period.

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135. *Mexico – Anti-Dumping Investigation of High-Fructose Corn Syrup (HFCS) from the United States (Article 21.5 – US)* (22 October 2001), WT/DS132/AB/RW (Appellate Body) at para. 85.
136. *PET Resin* at paras. 170-172.

[128] The Tribunal is of the view that, in the circumstances of this case, a time frame of 24 months is appropriate. Although the second contract will come to an end on March 31, 2021, which is just shy of 24 months from now, a solicitation process aimed at putting a new contract in place for April 1, 2021, will begin before then.[137] SigmaSanté's second call for tenders had a closing date of November 1, 2017. It is therefore reasonable to assume that a new call for tenders would have a similar closing date in 2020, as call for tenders are typically conducted on a three year cycle.[138] Therefore, competition on the basis of price will occur in the Quebec market in 18 to 19 months from now and the eventual loss of a new contract by MDK would likely have some immediate consequences (e.g. it may impact business and investment decisions).

[129] Given that the Quebec market represents such a large proportion of the Canadian market, the award of the next contract is of foremost importance for the domestic industry. As for Sobi's argument regarding delivery lead times, the Tribunal is of the view that this is not a relevant consideration in the present context.

[130] As such, the Tribunal will look at the next 18 to 24 months in its analysis of threat of injury.

Tribunal's Analysis

[131] As the markets in Quebec and the rest of Canada display significantly different characteristics and each require a different analytical approach, the Tribunal will conduct a separate assessment of threat of injury for each one of them.

Threat of Injury in the Quebec Market

[132] Given the Tribunal's finding that the loss of the second contract by MDK was not caused by Sobi's dumping of the subject goods, any continuing injury suffered by KABS-MDK in relation to the loss of that contract cannot be considered within the context of the Tribunal's threat analysis. Its analysis will solely be focused on whether the dumping of the subject goods is threatening to cause injury in the context of the next call for tenders issued by SigmaSanté, on behalf of the CHU Sainte-Justine, for the purchase of nitisinone for all patients with HT-1 in Quebec.

[133] The first step in the Tribunal's analysis is to determine whether the next call for tenders issued by SigmaSanté, sometime in the fall of 2020, will have terms and conditions that are similar to those of the first and second call for tenders.

[134] Relying on Mr. Charbonneau's testimony, Sobi suggests that there is significant uncertainty as to the form of the next call for tenders as SigmaSanté has not closed the door to a multiple supplier tender, there is no evidence confirming the need for a single supplier for nitisinone due to automated dispensation requirements and there exist other potential channels for dispensing nitisinone to patients outside of hospital pharmacies that would not involve SigmaSanté.

[135] Having reviewed Mr. Charbonneau's testimony, the Tribunal is of the view that it does not raise any significant doubts as to the form of the next call for tenders. With respect to the use of a multiple supplier tender, although Mr. Charbonneau acknowledged that this was possible under Quebec law, he did state that, as a general rule, this approach was not used for medications and that,

137. *Transcript of Public Hearing* at 214.
138. *Transcript of Public Hearing* at 209.

to date, there was nothing suggesting that they would change their approach.[139] Mr. Charbonneau did state that some medications need to have a single supplier because machines will be calibrated to deal with that particular medication, but did not know whether this applied to nitisinone.[140] As for other potentials channels for dispensing nitisinone to patients outside of hospital pharmacies, while he acknowledged that these channels exists and that SigmaSanté has no involvement in them, he did not, in any way, suggest that there was a possibility for nitisinone to be dispensed through one of these channels.[141]

[136] To the contrary, Mr. Charbonneau was quite clear in stating that planning for the next call for tenders would begin in 12 months' time and that, unless otherwise directed, it would follow exactly the same process as the previous ones.[142] Therefore, the Tribunal is satisfied that the next call for tenders to be issued by SigmaSanté in the fall of 2020 will likely have the same modalities as the first and second calls for tenders. To conclude otherwise would be the result of speculation.

[137] Turning to the likely price effects and volumes of dumped goods and the likely performance of the domestic industry, the Tribunal is of the view that the evidence is fairly clear on these and that they need not be addressed at length.

[138] When the next call for tenders is issued, the subject goods will likely undercut the price of the like goods. There is no reason to believe that Sobi would not tender low prices again, especially considering Ms. Souchen's statement that competitive bidding for pharmaceuticals usually results in continued price declines and her own personal experience of never having seen a price for a drug increase once multiple bioequivalent products are available on the market.[143] Moreover, given Sobi's claimed low costs of production, tendering prices similar to those tendered in the second call for tenders are clearly feasible as they would still generate a profit.[144]

[139] If Sobi is awarded the next contract, the volume of dumped goods will continue at current elevated levels given the size of the Quebec market relative to the Canadian market. If MDK is not awarded the contract, all of the relevant performance indicators for the domestic industry will be impacted to the same degree as they were following the loss of the second contract.

[140] In short, the factual situation in 2020 will be exactly the same as it was for the second call for tenders, i.e. the volume, the price effect and the impact on the domestic industry of the dumped goods will all relate to a single transaction. This means that, in order to make a finding of threat of injury, a causal relationship will also need to be established between the dumping of the subject goods by Sobi and the threat of injury to KABS-MDK in the Quebec market. However, just as Cycle's presence in the second call for tenders severed the requisite causal link, the Tribunal cannot rule out this scenario repeating itself.

[141] There is no evidence on the record that suggests that Cycle will not participate in the next call for tenders, that it is not interested in the Canadian market or that it could not tender prices similar to those it previously tendered. It could even perhaps be awarded the next contract. As the Tribunal

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139. *Transcript of Public Hearing* at 215, 228, 234-235.
140. *Transcript of Public Hearing* at 215-216, 242.
141. *Transcript of Public Hearing* at 243-244.
142. *Transcript of Public Hearing* at 214, 228.
143. Exhibit NQ-2018-005-C-05A, Vol. 13 at 11.
144. Exhibit NQ-2018-005-C-03A, Vol. 13 at 4; Exhibit NQ-2018-005-C-05A, Vol. 13 at 11.

stated earlier, there is nothing to suggest that Cycle is not a viable supplier for the Canadian market as it received a NOC from Health Canada and has made sales into the market.

[142] In addition, there is evidence on the record indicating that there could potentially be other manufacturers interested in selling nitisinone in Canada. Witnesses for Sobi stated that the company is aware of such other manufacturers, although it does not have any knowledge of these manufacturers having sought authorization from Health Canada to sell nitisinone products in Canada.[145] At the hearing, Dr. Maranda spoke about there being a producer in Switzerland, one in Argentina and another one in Turkey.[146] However, to his knowledge, none of these producers have expressed an interest in selling to Canada and none have taken steps to obtain authorization from Health Canada.[147] Hence, while it is not clear whether any of these producers are seriously intent on selling to Canada, the Tribunal can nonetheless conclude that the potential exists. As such, to conclude that the circumstances in which the dumping of the subject goods would cause injury are clearly foreseen and imminent given the uncertainties surrounding the bidding dynamics and the likely conditions of competition in the Quebec market in the next 18 to 24 months would be the result of speculation.[148]

[143] In light of the foregoing, the Tribunal can only conclude that there is not a high probability of a change, compared to the circumstances that existed during the POI, to a situation in which the dumping of the subject goods would cause injury. In other words, it is not clearly foreseeable that Cycle, and potentially others, will not participate in the next call for tenders. Moreover, on the basis of the known facts, it is not clearly foreseeable that Sobi, and therefore the subject goods, will be the price leader in the market when the next call for tenders is launched. As such, the Tribunal cannot establish a causal relationship between the dumping of the subject goods by Sobi and the threat of material injury to KABS-MDK in the Quebec market.

Threat of Injury in the Rest of the Canadian Market

[144] For the rest of the Canadian market, the potential for the dumping of the subject goods to cause injury to the domestic industry is minimal. This is primarily due to the fact that price effects from the dumping of the subject goods are unlikely given that, as mentioned earlier, Sobi, MDK and Cycle have each signed LOIs with the pCPA and these LOIs set out the same fixed prices for all three. As a result, any PLAs concluded by Sobi, MDK and Cycle with interested federal, provincial and territorial governments will see them compete based on factors other than price.[149]

[145] Even if the Tribunal considers the fact that Sobi would still be dumping by selling nitisinone at prices set out in its LOI,[150] Dr. Maranda has stated that he considers these prices as being fair.[151]

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145. Exhibit NQ-2018-005-C-05A, Vol. 13 at 13; *Transcript of Public Hearing* at 188-189.
146. *Transcript of Public Hearing* at 128-129.
147. *Transcript of Public Hearing* at 128-129.
148. Of course, the Tribunal cannot rule out the possibility that a situation in which the dumping of the subject goods would cause injury might exist when the next contract for the supply of nitisinone in the Quebec market is awarded. However, a threat of injury finding requires more than a demonstration that future injury caused by dumping is possible. There must be evidence indicating that such injury and causal link are *clearly* foreseen and imminent.
149. *Transcript of Public Hearing* at 69, 174.
150. Exhibit NQ-2018-005-C-05A, Vol. 13 at 7-8.
151. *Transcript of Public Hearing* at 153-154.

At any rate, even if the Tribunal considers that the dumping is what allows Sobi to participate in the market outside of Quebec and therefore potentially reduce MDK's sales, that reduction, when put in context of the size of that market relative to the entire market, would not amount to injury that the Tribunal considers material.

[146] Therefore, the Tribunal concludes that there are no clearly foreseen changes in circumstances that would create a situation in which the dumping of the subject goods would threaten to cause material injury to KABS-MDK in the rest of the Canadian market.

Conclusion

[147] On the basis of the foregoing, the Tribunal finds that the dumping of the subject goods is not threatening to cause injury to the domestic industry within the next 24 months.

CONCLUSION

[148] The Tribunal finds, pursuant to subsection 43(1) of *SIMA*, that the dumping of the subject goods has not caused injury and is not threatening to cause injury to the domestic industry.

Jean Bédard

Jean Bédard
Presiding Member

Serge Fréchette

Serge Fréchette
Member

Georges Bujold

Georges Bujold
Member