Canadian International Trade Tribunal
Tribunal canadien du commerce extérieur

CANADIAN INTERNATIONAL TRADE TRIBUNAL

Dumping and Subsidizing

DETERMINATION AND REASONS

Preliminary Injury Inquiry
No. PI-2018-006

Nitisinone Capsules

Determination issued
Tuesday, November 20, 2018

Reasons issued
Wednesday, December 5, 2018

Canada

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IN THE MATTER OF a preliminary injury inquiry, pursuant to subsection 34(2) of the *Special Import Measures Act*, respecting:

NITISINONE CAPSULES

PRELIMINARY DETERMINATION OF INJURY

The Canadian International Trade Tribunal, pursuant to the provisions of subsection 34(2) of the *Special Import Measures Act*, has conducted a preliminary injury inquiry into whether the evidence discloses a reasonable indication that 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 retardation or is threatening to cause injury to the domestic industry.

This preliminary injury inquiry follows the notification, on September 21, 2018, that the President of the Canada Border Services Agency had initiated an investigation into the alleged injurious dumping of the aforementioned goods.

Pursuant to subsection 37.1(1) of the *Special Import Measures Act*, the Canadian International Trade Tribunal hereby determines that the evidence discloses a reasonable indication that the dumping of the aforementioned goods has caused injury or is threatening to cause injury to the domestic industry.

Georges Bujold

Georges Bujold
Presiding Member

Serge Fréchette

Serge Fréchette
Member

Randolph W. Heggart

Randolph W. Heggart

Member

The statement of reasons will be issued within 15 days.

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STATEMENT OF REASONS

INTRODUCTION

[1] On August 2, 2018, Laboratoires KABS Inc. and its affiliate MendeliKABS Inc. (collectively, KABS-MDK) filed a complaint with the Canada Border Services Agency (CBSA) alleging that the dumping of certain nitisinone capsules originating in or exported from the Kingdom of Sweden (the subject goods) has caused injury or is threatening to cause injury to the domestic industry.

[2] On September 21, 2018, the CBSA initiated an investigation into the dumping of the subject goods, pursuant to subsection 31(1) of *Special Import Measures Act*.[1] In its statement of reasons regarding the initiation of the investigation, the CBSA estimated that, for the period of January 1, 2018, to June 30, 2018, the subject goods were dumped by a 592.8 percent margin of dumping, expressed as a percentage of the export price.

[3] Following the CBSA's decision to initiate an inquiry, the Canadian International Trade Tribunal (the Tribunal) began, on September 24, 2018, its preliminary injury inquiry, pursuant to subsection 34(2) of *SIMA*, into whether the evidence discloses a reasonable indication that the dumping of the subject goods has caused injury or is threatening to cause injury to the domestic industry.

[4] Swedish Orphan Biovitrum AB and Swedish Orphan Biovitrum Canada (collectively, Sobi) filed submissions opposing the complaint. The Delegation of the European Union to Canada (the EU Delegation) filed submissions mainly with respect to the World Trade Organization's (WTO) requirements for injury inquiries. Two other parties to the inquiry, SigmaSanté and the Centre hospitalier universitaire Sainte-Justine (CHU Sainte-Justine), did not file submissions opposing the complaint.

[5] On November 20, 2018, the Tribunal determined that there was evidence disclosing a reasonable indication that the subject goods have caused injury or are threatening to cause injury to the domestic industry, for the reasons that follow.

PRODUCT DEFINITION

[6] The CBSA defined the subject goods as follows:[2]

> 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.

1. R.S.C., 1985, c. S-15 [*SIMA*].
2. Exhibit PI-2018-006-05, Vol. 1 at 25. The CBSA's statement of reasons also contains additional information regarding the description of the subject goods.

PRELIMINARY ISSUES

Treatment of Confidential Information

[7] The EU Delegation notes that a non-confidential summary of the redacted information in Part VIII of the public complaint was not provided, nor was an explanation for its absence, contrary to 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* (the *Anti-Dumping Agreement*). The EU Delegation submits that, having failed to ensure that the public record meets these requirements, the Tribunal has limited its ability to make its case.

[8] KABS-MDK submits that it was as transparent as possible with regard to the information in the complaint, to the extent that it could do so without harming its commercial interests, and that certain information was redacted at the request of Sobi.

[9] The Tribunal recently explained, concerning similar allegations, that they refer to information on the CBSA's administrative record, which is transmitted to the Tribunal for the purposes of its preliminary injury inquiry. As such, this is an issue having to do with the CBSA's handling of confidential information provided by the parties to the inquiry. The Tribunal's preliminary injury inquiry is not the proper forum for addressing those concerns.[3]

[10] In the event that a final injury inquiry is initiated, the Tribunal will place as much information on the public record as possible. The Tribunal also requires that parties provide summaries of confidential information that meet the requirements of Article 6.5.1 of the *Anti-Dumping Agreement*.

Period of Injury Inquiry

[11] The EU Delegation also claims that the period of the injury inquiry in this case is not clear, that it should, as a general rule, be at least three years, and that a period of six months cannot be considered sufficient.

[12] As indicated in greater detail below, at the preliminary inquiry stage, the Tribunal's mandate is to examine all information on the record to determine if there is enough evidence to reasonably indicate the existence of material injury or a threat of material injury. This evaluation includes a temporal aspect, which necessarily varies based on the specific facts of the case.

[13] However, the information on the record of a preliminary inquiry does not always allow for an examination of whether there is a reasonable indication of injury over a period of three years. In fact, at this preliminary stage, the Tribunal is faced with the fact that the information on the record is considerably less detailed and comprehensive than in a final injury inquiry. The information available is typically limited to what is provided by the complainants and the CBSA.

[14] In this case, the Tribunal has information related primarily to the period of January to December 2017 and, to some degree, the period of January to June 2018. The Tribunal also has

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3. *Concrete Reinforcing Bar* (19 October 2016), PI-2016-002 (CITT) at para. 12 [*Reinforcing Bar*]; *Carbon Steel Welded Pipe* (18 September 2018), PI-2018-004 (CITT) at para. 18.

projections provided by the complainants based on data available for 2017 to describe the injury anticipated beyond that period.

[15] Based on that information, necessarily incomplete at this stage, the Tribunal will determine whether there is enough evidence to disclose a reasonable indication of injury or threat of injury. If the case moves on to the final injury inquiry stage, the Tribunal will then determine the appropriate period of inquiry in accordance with Canada's obligations under the WTO agreements.

Arguments Regarding the Impact of the Eventual Application of Anti-Dumping Duties

[16] Certain arguments raised by Sobi are related to the effect that the application of anti-dumping duties could have on Canadian price control mechanisms for prescription drugs and the supply of prescription drugs for Canadian patients.[4]

[17] The Tribunal's mandate in an inquiry pursuant to subsection 34(2) of *SIMA* is limited to examining the parties' submissions and the evidence regarding the existence of a reasonable indication that the dumping of the subject goods has caused, or is threatening to cause, injury to the domestic industry. Consequently, the Tribunal will not address Sobi's arguments regarding the potential impact that anti-dumping duties might have on Canadian price control mechanisms for prescription drugs or on end users. Such considerations can only be addressed in the context of a public interest inquiry conducted pursuant to section 45 of *SIMA*, which may only take place should the Tribunal make a finding of injury or threat of injury following a final injury inquiry under section 42 of *SIMA*.

LEGISLATIVE FRAMEWORK

Reasonable Indication

[18] The Tribunal's mandate in a preliminary injury inquiry is set out in subsection 34(2) of *SIMA*, which requires the Tribunal to determine ". . . whether the evidence discloses a reasonable indication that the dumping or subsidizing of the [subject] goods has caused injury or retardation or is threatening to cause injury."

[19] The term "reasonable indication" is not defined in *SIMA*, but is understood to mean that the evidence need not be ". . . conclusive, or probative on a balance of probabilities . . . ."[5]

[20] The reasonable indication standard is lower than the standard that applies in a final injury inquiry under section 42 of *SIMA*.[6]

[21] The evidence at the preliminary phase of proceedings will be significantly less detailed and comprehensive than the evidence in a final injury inquiry. Not all the evidence is available at the preliminary phase, and there is no oral hearing to fully probe what is available. As a result, the evidence cannot be tested to the same extent as it would be during a final injury inquiry.

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4. Exhibit PI-2018-006-08.02, Vol. 3 at paras. 3, 19.
5. *Ronald A. Chisholm Ltd. v. Deputy M.N.R.C.E.* (1986), 11 CER 309 (FCTD).
6. *Grain Corn* (10 October 2000), PI-2000-001 (CITT) at 7.

[22] The standard of evidence at this stage of the inquiry is lower than at the final stage and complaints will be read generously. The Tribunal gives the complainants the benefit of the doubt.[7]

[23] However, the outcome of preliminary inquiries must not be taken for granted.[8] Simple assertions are not sufficient.[9] Complaints, as well as the cases of parties opposed, must be supported by positive evidence that is both relevant and sufficient, in that it addresses the necessary requirements in *SIMA* and the relevant factors of the *Special Import Measures Regulations*[10] and does so in a manner that is sufficiently convincing at this stage of the inquiry.

[24] Before examining the allegations of injury or threat of injury, the Tribunal must address a number of framework issues. Specifically, the Tribunal must first identify the domestically produced goods that are "like goods" in relation to the subject goods, as well as the domestic industry that produces those like goods. This analysis is required because subsection 2(1) of *SIMA* defines "injury" as "material injury to a domestic industry" and "domestic industry" as "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 . . . ." Subsection 2(1) of *SIMA* further defines "like goods", in relation to any other goods, as "(a) goods that are identical in all respects to the other goods, or (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."

LIKE GOODS AND CLASSES OF GOODS

[25] KABS-MDK submits that the subject goods (Orfadin) and the nitisinone capsules manufactured by the domestic industry (MDK-Nitisinone) are like goods. It alleges that the two products are bioequivalent, as they contain an identical drug and, after comparison in an appropriate bioavailability study, meet specified standards for rate and extent of absorption.[11]

[26] Sobi also notes that the drugs are considered bioequivalent by Health Canada and that they compete in the Canadian market on an equal footing.[12]

[27] In fact, the evidence indicates that the two drugs are of substantially the same chemical composition, have the same properties and characteristics and have an identical end use, and that they are considered to be interchangeable in the Canadian market.

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7. *Sucker Rods* (17 July 2018), PI-2018-001 (CITT) at para. 13; *Certain Fabricated Industrial Steel Components* (10 November 2016), PI-2016-003 (CITT) at para. 13.
8. *Reinforcing Bar* at paras. 18-19.
9. Article 5 of the *Anti-Dumping Agreement* and Article 11 of the WTO *Agreement on Subsidies and Countervailing Measures* [the *SCM Agreement*] require an investigating authority to examine the accuracy and adequacy of the evidence provided in a dumping and subsidizing complaint to determine whether there is sufficient evidence to justify the initiation of an investigation, and to reject a complaint or to terminate an investigation as soon as an investigating authority is satisfied that there is not sufficient evidence of dumping and subsidizing or injury. Article 5 of the *Anti-Dumping Agreement* and Article 11 of the *SCM Agreement* also specify that simple assertions that are not substantiated with relevant evidence cannot be considered sufficient to meet the requirements of the articles.
10. S.O.R./84-927 [*Regulations*].
11. Exhibit PI-2018-006-02.01, Vol. 1 at pp. 20-22; Exhibit PI-2018-006-03.01 (protected), Vol. 2 at tab 16.
12. Exhibit PI-2018-006-08.02, Vol. 3 at paras. 25-26.

[28] In light of the foregoing, and of the factors relevant to the issues of like goods and classes of goods,[13] the Tribunal finds that the domestically produced nitisinone capsules of the same description as the subject goods are "like goods" in relation to the subject goods and that there is a single class of goods.

DOMESTIC INDUSTRY

[29] KABS (the producer of the entire domestic production of nitisinone) and MDK (holder of the MDK-Nitisinone commercialization rights) submit that they constitute a single entity for the purposes of this complaint.[14] The other parties do not appear to dispute the complainants' position.

[30] Therefore, for the purposes of this preliminary injury inquiry, the Tribunal considers that the group composed of KABS and MDK constitutes the domestic industry. The Tribunal previously took a similar approach, noting that the domestic industry "can, in principle, and within the meaning ascribed to that term under subsection 2(1) of *SIMA*, be comprised of related entities respectively responsible for the production of like goods and their arm's-length sale at the first level of distribution in the marketplace".[15]

INJURY ANALYSIS

[31] Before analyzing the allegations put forward by the complainants, the Tribunal will describe the unusual characteristics of the market for nitisinone capsules and the history of the supply of that drug in Canada. In fact, the backdrop for the allegations of injury and threat of injury in this case is a singular commercial context that must be considered when determining whether the evidence discloses a reasonable indication that the dumping of the subject goods has caused injury or is threatening to cause injury to the domestic industry.

[32] Nitisinone capsules are used for the treatment of hepatorenal tyrosinemia type I. Approximately 100 people suffer from this disease in Quebec, with a total of about 117 people in Canada.[16] Worldwide, it appears that approximately 1,000 people are affected by this disease.[17]

[33] Nitisinone treatment must be administered daily and the dosage varies according to the patient's weight. Demand in Canada is therefore relatively stable over the short and medium terms and represents a notable proportion of worldwide demand for this drug.

[34] Until September 2016, the subject goods were the only nitisinone product available in Canada, through Health Canada's "Special Access Programme".[18]

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13. In deciding the issues of like goods and classes of goods, the Tribunal considers 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). *Copper Pipe Fittings* (19 February 2007), NQ-2006-002 (CITT) at para. 48.
14. Exhibit PI-2018-006-02.01, Vol. 1 at 8.
15. For example, *Silicon metal* (2 November 2017), NQ-2017-001 (CITT) at para. 47.
16. Exhibit PI-2018-006-08.02, Vol. 3 at para. 17. The concentration of patients in Quebec is due to reasons related to the genetic history of the populations.
17. *Ibid.* at 6; Exhibit PI-2018-006-02.01, Vol. 1 at 16.

[35] On September 20, 2016, MDK-Nitisinone obtained a first Notice of Compliance from Health Canada,[19] authorizing its marketing in Canada. As such, supply through the "Special Access Programme" became prohibited and MDK-Nitisinone became the only authorized drug, a situation that allowed KABS-MDK to supply the entire Canadian market starting in September 2016.[20] Sobi and Cycle Pharmaceuticals Ltd. (which manufactures a third competing product in Switzerland) obtained notices of compliance for their respective products between November and December 2016.[21]

[36] For the first time in Quebec, the emergence of a competitive market led to the supply of nitisinone through open tendering. As indicated above, given its size, the Quebec market is of paramount importance for nitisinone suppliers in the country.

[37] In this regard, the pharmacy at CHU Sainte-Justine serves all Quebec patients suffering from tyrosinemia. It is therefore by far the leading purchaser of nitisinone in Canada, through SigmaSanté, an organization mandated by several health care institutions to conduct calls for tenders. Moreover, the evidence indicates that the SigmaSanté calls for tender typically cover the entire purchasing volume for a period of three years, and have, in the case of nitisinone, resulted in a contract awarded to a single supplier for the Quebec market, thereby precluding other suppliers from accessing that market during this period. The evidence also indicates that the contracts are generally awarded based on the lowest price.[22]

[38] In this case, SigmaSanté issued a first call for tenders in January 2017 (new call for tenders No. 2015-777-00-10) for the procurement of nitisinone. KABS-MDK won the contract, which covered the period of April 1, 2017, to March 31, 2018,[23] during which time KABS-MDK supplied nitisinone for patients in Quebec.

[39] In September 2017, SigmaSanté issued a second call for tenders (call for tenders No. 2018-4777-00-01), this time won by Sobi. The second contract covered the entire three-year procurement cycle, from April 1, 2018, to March 31, 2021.

[40] Given the unique characteristics of the Quebec market and the relative stability of demand in Canada, the loss of this contract deprives the domestic industry of access to the vast majority of sales in Canada until April 2021, irrespective of what happens by the end of 2018 regarding procurement in the other provinces.[24]

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18. *Ibid.* at pp. 15, 17, 28, 36, 56. This program allows Health Canada to evaluate, on a case-by-case basis, requests for access to prescription drugs not marketed in the country by practitioners treating patients with serious diseases.
19. For the 2.0 mg, 5.0 mg and 10.0 mg formulations. On November 30, 2017, MDK also obtained a Notice of Compliance for the 20 mg dosage.
20. Exhibit PI-2018-006-02.01, Vol. 1 at 30.
21. *Ibid.* at pp. 55, 647, 927-928.
22. Exhibit PI-2018-006-06.02, Vol. 1 at 3; Exhibit PI-2018-006-06.01, Vol. 1 at 2.
23. This was a one-year contract covering the remaining period in the 2015–2018 procurement cycle, hence the "retour en appel d'offres" (*new call for tenders*) reference in the relevant documentation. Exhibit PI-2018-006-08.02, Vol. 3 at 15.
24. The evidence indicates that KABS-MDK continues to supply the other provinces while awaiting the end of an evaluation and negotiation process.

[41] In short, this complaint takes place in a context in which the loss of a single contract can have severe and long-lasting injurious effects on the domestic industry. Moreover, given the time lag between the call for tenders, the awarding of the contract and its effective date, it is plausible that the injury indicators will not all manifest themselves at the same time. For example, it is plausible that the effects of the alleged dumping on prices and the subsequent impact on the domestic industry could materialize *before* any significant increase in the volume of imports of the subject goods. Similarly, it is conceivable that some effects of the alleged dumping on the performance of the domestic industry may not be experienced until later.

[42] The Tribunal has indicated the following regarding the unique challenges presented by similar situations in its injury or threat of injury analysis, specifically in the preliminary inquiry:

> ABB and CG [the domestic producers] submitted that, because of this time lag, some of the injurious effects stemming from dumping and lost sales during the POI may not be experienced until afterwards and that, therefore, it would be appropriate to take their financial projections into account for the purposes of determining whether the dumping has caused injury. *A determination that dumping "has caused" material injury must, by definition, be based on injurious effects that crystalized (i.e. became manifest) during the POI. Arguably, any foreseeably imminent injury to ABB and CG attributable to the dumping of the subject goods would support a determination that the dumping is threatening to cause material injury. However, the Tribunal does not need to expound more fully on this issue at this phase of the proceedings, as it is sufficient that the evidence discloses a reasonable indication that the alleged dumping is causing or threatening to cause material injury*.[25]
>
> [Emphasis added]

[43] Although this situation typically occurs in the case of capital goods,[26] which the subject and like goods in this case are not, given the market characteristics described above, the Tribunal will follow the same approach in this case.

[44] Consequently, the Tribunal will determine whether the evidence is sufficient to disclose a reasonable indication of injury or threat of injury caused by the dumping of the subject goods, without ruling definitively, at this stage, on the issue of whether the alleged injurious effects represent injury that has already occurred or are instead indicative of a threat of injury.

Import Volume of Subject Goods

[45] The complaint does not provide data on import volumes. However, KABS-MDK estimates that, in 2017, it held approximately 99 percent of the Canadian market, but that "the volume of dumped goods completely replaced the domestic industry's sales volume in the Quebec market as of

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25. *Liquid Dielectric Transformers* (22 June 2012), PI-2012-001 (CITT) at para. 32.
26. See, for example, *Unitized Wall Modules* (3 May 2013), PI-2012-006 (CITT) at para. 78. Generally, in the case of capital goods, sales in the national market depend on a certain number of relatively long procurement contracts and there is a time lag between the awarding of the contracts and their effective date. In this case, the evidence shows that the vast majority of sales in the Canadian market are made by a single supplier to a single procuring entity under a long-term contract awarded a few months before its effective date, hence the similarity with capital goods.

the spring of 2018" [translation].[27] The CBSA's estimates, based on its own import data and information provided in the complaint, by and large support the complainants' allegations.[28]

[46] The Tribunal finds that the evidence discloses a reasonable indication that the import volume of the subject goods increased significantly during the period of January 1, 2018, to June 30, 2018, and that it will continue to increase, as the contract awarded by SigmaSanté to Sobi took effect in April 2018 and guarantees approximately 88 percent[29] of the sales volume in Canada to Sobi until April 2021.

Effect on Prices of Like Goods

[47] The complaint provides the bid prices in the two calls for tender issued by SigmaSanté, as well as Sobi's price (as estimated by KABS-MDK) under the Special Access Programme.[30]

[48] KABS-MDK's bid prices in the first call for tenders were substantially lower than those of Sobi. However, in the second call for tenders, Sobi's prices were significantly lower compared to those of KABS-MDK. The evidence thus indicates significant price undercutting by Sobi to obtain the largest contract in the Canadian market.

[49] The complainants also allege that the simple fact that Orfadin was approved in Canada depressed KABS-MDK's price in the first call for tenders by SigmaSanté.[31] However, the complaint cites, at the most, the "risk" [translation] of Sobi significantly reducing prices in January 2017; the allegation is not supported by concrete evidence such as sales or sale offers at low prices by Sobi.[32]

[50] The Tribunal cannot find that the evidence discloses a reasonable indication that the subject goods have thus far depressed the prices of the like goods. In the second call for tenders, the price bid by KABS-MDK increased compared to its January 2017 prices, and the SigmaSanté procurement method did not provide the domestic industry an opportunity to lower its prices when faced with the lower competing offer presented by Sobi. Such a situation reflects the loss of sales caused by price undercutting rather than price depression.

[51] Besides, in light of the evidence regarding the dumped prices bid by Sobi in the second call for tenders by SigmaSanté and its interest in the Canadian market, it is plausible that the domestic industry may have to lower its prices in the near future if it wishes to compete with the offers from Sobi for future procurement contracts and retain sales in the rest of Canada (procuring entities in the other provinces do not seem to use SigmaSanté's "all-or-nothing" model).

[52] Finally, although the complaint uses the word "suppression" [translation] in a few places, it does not seem to be alleging price suppression within the meaning of subparagraph 37.1(1)(b)(iii) of

27. Exhibit PI-2018-006-02.01, Vol. 1 at 48.
28. Exhibit PI-2018-006-05, Vol. 1 at 8; Exhibit PI-2018-006-03.02 (protected), Vol. 2 at 10.
29. According to the estimated market size, in sales volume, provided by KABS-MDK; Exhibit PI-2018-006-03.01 (protected), Vol. 2 at para. 247.
30. Exhibit PI-2018-006-03.01 (protected), Vol. 2 at para. 199.
31. Exhibit PI-2018-006-02.01, Vol. 1 at pp. 46, 48-49; Exhibit PI-2018-006-11.01 (protected), Vol. 4 at paras. 60-62.
32. Exhibit PI-2018-006-02.01, Vol. 1 at 49.

the *Regulations*. In any event, the Tribunal finds that there is insufficient evidence to support such an allegation.

Resultant Impact on the Domestic Industry

Declining Sales and Market Share

[53] KABS-MDK submits that it failed to win the call for tenders issued by SigmaSanté in September 2017 due to the low-priced subject goods. It submits that the loss of that contract represents the loss of all sales in Quebec beginning in April 2018.

[54] Based on KABS-MDK's sales volumes for 2017,[33] and given that demand is relatively stable, the loss of the contract awarded by SigmaSanté represents, on an annual basis, a loss of approximately 88 percent of the domestic industry's sales volume in Canada as of April 2018. The domestic industry will, in time, suffer an equivalent loss of its domestic market share to the subject goods. This is the only possible conclusion in light of the evidence on the record, even though the complaint does not provide data regarding actual sales in the Canadian market by KABS-MDK since the beginning of 2018.

[55] It goes without saying that injury of this magnitude in terms of lost sales and market share can be qualified as material injury within the meaning of *SIMA*, if it materializes or becomes manifest during the period of inquiry. Considering that, based on the evidence, the anticipated decline in sales and market share appears to be imminent and clearly foreseen and results from a significant change of circumstances, i.e. an extended absence of any sales in Quebec by KABS-MDK as a result of the commencement of the contract won by Sobi, it also supports, at this stage, a finding of reasonable indication of a threat of material injury.

[56] Based on the evidence on the record, the Tribunal finds that there is a reasonable indication that the decline in the domestic industry's sales and market share since April 2018 is significant, even though it cannot be quantified precisely. Moreover, the evidence indicates that the injurious effects will intensify over the coming months, as the domestic industry can no longer make sales in Quebec. The only remaining issue is whether there is a reasonable indication that the dumping of the subject goods has, in and of itself, caused this injury or threat of injury.[34]

[57] In this regard, according to the contract award rules set out in the documents for call for tender No. 2018-4777-00-01, it would seem that the contract was indeed awarded based on the lowest price.[35] In other words, the price offered seems to have been the deciding factor in SigmaSanté's contract award decision in the case at hand. Since Sobi won that call for tenders by offering dumped prices, it can be asserted, at least on a preliminary basis, that it was the dumping of the subject goods that likely caused the domestic industry's decline in sales and market share. In this context, the complainants' position that the loss of the contract is directly attributable to Sobi's price undercutting is supported by more than mere assertions.

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33. Net sales volume for the period of January 1 to December 31, 2017, was provided. Exhibit PI-2018-006-03.01 (protected), Vol. 2 at para. 128.
34. *Gypsum Board* (5 August 2016), PI-2016-001 (CITT) at para. 44; *Copper Rod* (30 October 2006), PI-2006-002 (CITT) at paras. 40, 43; *Galvanized Steel Wire* (22 March 2013), PI-2012-005 (CITT) at para. 75; *Circular Copper Tubes* (22 July 2013), PI-2013-002 (CITT) at para. 82.
35. Exhibit PI-2018-006-03.01 (protected), Vol. 2 at article 1.15.02.

[58] It is worth recalling that, at this stage, the evidence does not need to be conclusive or probative on a balance of probabilities and that the complainants are entitled to the benefit of the doubt. Thus, bearing in mind the lower evidentiary threshold applicable at the preliminary inquiry stage, the evidence suggests the existence of a causal link between the dumping of the subject goods and the decline in the domestic industry's sales and market share. This issue will be discussed more fully in the examination of factors other than dumping cited by Sobi to explain the alleged injury to the domestic industry.

[59] The evidence also discloses a reasonable indication that the sales lost following the second call for tenders by SigmaSanté and the domestic industry's declining market share starting in April 2018 have begun, and will continue, to negatively impact its performance regarding the prescribed factors addressed in the following paragraphs.

Decreasing Revenues and Profitability

[60] The complaint provides the financial statements of KABS and MDK, respectively, for the fiscal years ending June 30, 2016 and 2017.[36] No data is provided for the period of June 2017 to June 2018. Given the significant value of the lost contract, the information on the record, albeit incomplete, is sufficient at the preliminary inquiry stage for the Tribunal to find that the inability to generate sales in the Quebec market until 2021 has started to undermine the performance of the domestic industry and will have serious consequences on its revenues and profitability.

[61] In this regard, the projections filed by the complainants as evidence are not without merit and their allegations represent more than mere assertions. The information on the record indicates that KABS-MDK's financial situation in 2017 improved compared 2016, which captured a first full year of nitisinone sales following the approval of MDK-nitisinone in September 2016. In light of the specific circumstances of the market for nitisinone capsules, described above, the financial data for 2017 also provide a plausible basis for the decline in sales (a drop of approximately 80 percent) and profitability that the complainants anticipate for the period of April 2018 to April 2019 as a result of the loss of the contract awarded by SigmaSanté following the September 2017 call for tenders.[37] According to the complainants, the anticipated negative impact on their profitability is such that it could lead to them ceasing production of nitisinone.[38]

Other Economic Indicators of the Domestic Industry's Situation

[62] Even though the record contains no specific data regarding production volumes, the complainants allege that, without sales in Quebec from April 2018 to April 2021, there are no remaining markets large enough to make their nitisinone production profitable, and that their production will therefore cease. The evidence previously mentioned generally supports this assertion.

[63] Moreover, given the significance of the lost contract, and taking into account the lower evidentiary threshold that applies in a preliminary inquiry, the Tribunal finds that there is enough evidence to assert that the inability to sell in the Quebec market appears to have had the following additional negative effects on the domestic industry:

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36. *Ibid.* at tab 84.
37. Exhibit PI-2018-006-02.01, Vol. 1 at 61; Exhibit PI-2018-006-03.01 (protected), Vol. 2 at paras. 253-254.
38. Exhibit PI-2018-006-02.01, Vol. 1 at pp. 61-62.

- A plant dedicated to the manufacture of nitisinone capsules, built in Asbestos, Quebec, following a large investment, remained inoperative as of the summer of 2018.[39]

- KABS and MDK had to lay off or reassign employees whose jobs were related to nitisinone, not to mention that the jobs anticipated at the Asbestos plant have not materialized.[40]

- Investments in the development of other prescription drugs targeting rare diseases will not be undertaken.[41]

Threat of Injury

[64] The complainants essentially argue that, in the next 12 to 18 months, the injury already caused to the domestic industry and discussed above will continue or worsen. KABS-MDK also notes that Sobi could undercut its prices for sales outside Quebec and completely squeeze it out of the Canadian market, and that Sobi has the production capacity to supply all of that market.

[65] These assertions are not challenged by Sobi and are supported by the evidence on the characteristics of the market for nitisinone capsules. In the specific context of that market, the complainants' allegations that they will experience further lost sales and revenue over the coming months are supported by sufficient evidence at this preliminary stage. This is a rare situation in which the loss of a single contract is enough to find severe and long-lasting injurious effects for the domestic industry.

[66] In short, the evidence discloses a reasonable indication that the injurious effects of the loss of the contract awarded following the second call for tenders by SigmaSanté and the availability of the subject goods at dumped prices will continue to be felt, and will even worsen, in the near and foreseeable future.

Causal Link and Possible Impact of Factors Other Than the Dumping of the Subject Goods

[67] As indicated in the analysis above, the evidence discloses a reasonable indication of the extent of the past adverse impact and of the injurious effect that is reasonably foreseeable from the loss of the contract awarded by SigmaSanté following the call for tenders issued in September 2017. The materiality of that injury, already manifest and anticipated, is clear from the evidence.

[68] Sobi is not challenging the existence of significant injurious effects already impacting KABS-MDK, their material nature or the fact that they will continue to be felt until 2021. Given that Sobi chose not to file rebuttal evidence on these issues, it appears to be implicitly admitting that there is a reasonable indication that the domestic industry has suffered or is threatened to suffer injury.

[69] Rather, Sobi submits that any injury suffered by the domestic industry from the loss of this contract is attributable to factors other than the dumping of the subject goods, in particular, the Canadian regulatory environment, which limits drug prices, the "all-or-nothing" nature of the September 2017 SigmaSanté call for tenders, and the complainants' own business decisions. Sobi also argues that the complainants are responsible for the injury that they allege because they set a

39. Exhibit PI-2018-006-10.01B, Vol. 3 at 3.
40. Exhibit PI-2018-006-10.01A, Vol. 1 at 2; Exhibit PI-2018-006-10.01B, Vol. 3 at 2.
41. Exhibit PI-2018-006-02.01, Vol. 1 at 62; Exhibit PI-2018-006-11.01A (protected), Vol. 4 at 2.

very low benchmark price in the previous SigmaSanté January 2017 call for tenders. In this regard, Sobi submits that it won the September 2017 contract because it followed the common industry practice of bidding prices below the incumbent supplier's bid price from the previous call for tenders (i.e. the benchmark price set in January 2017 by KABS-MDK), whereas KABS-MDK instead decided, of its own volition, to raise its prices.[42]

[70] The Tribunal took these factors into consideration and is of the view that they may have had an impact on the domestic industry. However, given the incomplete and often contradictory nature of the evidence on the record, it is difficult at this preliminary stage to evaluate the real impact that such other factors may have had on the domestic industry, as distinct from the impact of the dumping of the subject goods.

[71] As for the argument regarding the regulatory framework governing the pricing of prescription drugs in Canada, the evidence on the record indicates that the said framework is complex, but does not clearly establish the impact of its various components on the prices bid by Sobi and KABS-MDK. For example, Sobi refers to the role of the Common Drug Review (CDR) of the Canadian Agency for Drugs and Technologies in Health (CADTH) and that of the pan-Canadian Pharmaceutical Alliance, the evaluation and negotiation agencies to which prescription drug suppliers are subject in order to gain approval for coverage by public drug plans in provinces *other* than Quebec.[43] In this regard, Sobi explained that, in the case of Orfadin, the CDR led to a recommendation to reduce its list price by 74 percent (the list price being the price at which Orfadin was sold through the Special Access Programme). Sobi also argues that the pan-Canadian Pharmaceutical Alliance developed a generic pricing framework that illustrates the anticipated reductions in prices after generic drugs enter the market. According to Sobi, this framework guides expected nitisinone prices in the market, given that there are three bioequivalent products.

[72] In concrete terms, Sobi essentially argues that these agencies' recommendations, although not applicable to the SigmaSanté procurement process, guide purchaser expectations and supplier prices. According to Sobi, these expectations, in addition to buyers' expectation that bid prices in subsequent procurements decline over time,[44] would explain the bid prices in the second SigmaSanté call for tenders.

[73] For its part, KABS-MDK argues that the recommendations of the CDR were not made public until February 2018 and therefore could not influence the price bid by Sobi in the fall of 2017.[45] KABS-MDK also argues that SigmaSanté did not establish any price ceiling or refer to previous calls for tenders or recommendations of an external organization.[46] Finally, the Tribunal notes that the prices bid by both Sobi and KABS-MDK in the second SigmaSanté call for tenders do not seem to perfectly reflect the recommendations and guidelines referred to by Sobi. It is therefore not possible

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42. Exhibit PI-2018-006-08.02, Vol. 3 at pp. 20-21; Exhibit PI-2018-006-08.02A, Vol. 3 at paras. 9-10.
43. Exhibit PI-2018-006-08.02, Vol. 3 at paras. 34-49. Sobi also referred to the Patented Medicine Prices Review Board, which usually reviews the prices of patented medicine to ensure that they are not excessive. The evidence is not clear regarding the impact of such reviews on the prices of Orfadin while it was patented. Sobi also referred to the *Institut national d'excellence en santé et services sociaux*, a Quebec organization, but the evidence does not explain the role of that organization in relation to the facts of the complaint.
44. Exhibit PI-2018-006-08.02A, Vol. 3 at paras. 9-10.
45. Exhibit PI-2018-006-02.01, Vol. 1 at 66, 1181.
46. Exhibit PI-2018-006-10.01A, Vol. 1 at 4.

to determine, based on the information on the record, the impact that these could have had on the bid prices in this call for tenders.

[74] In light of this contradictory evidence, and given that the Tribunal generally gives the benefit of the doubt to the complainants at this preliminary stage, the Tribunal is of the view that there is not enough positive evidence to find that the injury to the domestic industry is due to the limits set by the Canadian regulatory environment on prescription drug prices.

[75] If the case proceeds to the final injury inquiry stage, the Tribunal intends to carefully examine the pricing mechanisms in this market, including by potentially obtaining the testimony of officials from the relevant regulatory agencies in question, to determine whether price ceilings are in fact set by regulation or by buyer expectations and whether those factors could have had a negative impact on the domestic industry distinct from the effects of the dumping of the subject goods. Industry pricing practices also warrant further examination.

[76] Regarding the argument that KABS-MDK itself caused the injury by setting a very low benchmark price in the January 2017 call for tenders, the Tribunal has previously stated that "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."[47]

[77] Moreover, on this issue, the Tribunal notes that, even if the prices offered by the domestic industry in the first call for tenders (January 2017) are used as a benchmark, the prices bid by Sobi in September were substantially lower than those bid by KABS-MDK in January 2017.

[78] With respect to Sobi's allegation that the complainants' business model is high-risk because the success of their business seems to essentially depend on a single client, it is supported by a lack of data regarding the domestic industry's export sales. However, there is not enough evidence at this preliminary stage to attribute the injury or threat of injury to the complainants' business decisions.

[79] In conclusion, the evidence on the record regarding the impact that these other factors may have had on the domestic industry is incomplete and inconclusive. In any event, in the context of a potential inquiry under section 42 of *SIMA*, the Tribunal intends to fully probe these factors, as well as other potentially relevant factors, and their relative importance.

[80] At this stage, the Tribunal finds that, considered as a whole, the evidence discloses a reasonable indication that the dumping of the subject goods has caused injury or is threatening to cause injury.

CONCLUSION

[81] The Tribunal determines that the evidence discloses a reasonable indication that the dumping of the subject goods has caused injury or is threatening to cause injury to the domestic industry.

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47. *Iodinated Contrast Media* (May 1 2000), NQ-99-003 (CITT) at 18; *Polyisocyanurate Thermal Insulation Board* (11 April 1997), NQ-96-003 (CITT) at pp. 24-25.

Georges Bujold

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Presiding Member

Serge Fréchette

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Member

Randolph W. Heggart

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