Competition Tribunal | Tribunal de la concurrence

PUBLIC VERSION

Citation: *JAMP Pharma Corporation v Janssen Inc.*, 2024 Comp Trib 8
File No.: CT-2024-006
Registry Document No.: 83

IN THE MATTER OF the *Competition Act*, RSC 1985, c C-34, as amended;

AND IN THE MATTER OF an application by JAMP Pharma Corporation for an order pursuant to section 103.1 granting leave to make an application under section 79 of the *Competition Act*.

BETWEEN:

JAMP Pharma Corporation
(applicant)

and

Janssen Inc.
(respondent)

Decided on the basis of the written record.
Before: Mr. Justice Andrew D. Little (Chairperson)
Date of order: November 20, 2024

REASONS FOR ORDER AND ORDER DISMISSING AN APPLICATION FOR LEAVE UNDER SECTION 103.1

[1] The applicant, JAMP Pharma Corporation ("JAMP"), seeks leave under section 103.1 of the *Competition Act* to commence an application against Janssen Inc. ("Janssen") under the abuse of dominance provisions of the Act.

[2] For the following reasons, the application is dismissed.

I. THE APPLICATION FOR LEAVE

[3] By application filed on July 26, 2024, JAMP applied under section 103.1 for leave to commence an application against Janssen under section 79.

[4] In brief, JAMP characterizes Janssen as the dominant (and previously the only) supplier in Canada of biologic drugs that contain ustekinumab as an active ingredient, used to treat certain inflammatory autoimmune diseases. Janssen's initial biologic is known by the brand name STELARA® ("STELARA"). JAMP claims that Janssen has engaged in, and continues to engage in, a practice of anti-competitive acts that are intended to prevent or delay entry and expansion in the market for the supply of ustekinumab biologics by JAMP and other potential competitors that supply "biosimilars", which are highly similar versions of brand name biologics. According to JAMP, by engaging in this conduct, Janssen has also lessened, and continues to lessen, competition substantially in the market for the supply of ustekinumab in Canada. JAMP's proposed notice of application sets out extensive remedies it intends to seek if leave is granted, including broad prohibition orders and a large administrative monetary penalty.

[5] JAMP filed four affidavits on this application: the affidavit of Amélie Faubert, JAMP's Vice-President in charge of its BioJAMP Division; the affidavit of Sukhad Juneja, JAMP's Senior Vice-President, Global Portfolio & Scientific Affairs; the affidavit of Genia Radeva, JAMP's Vice-President, Market Access; and the affidavit of Emily Seaby, legal assistant at Goodmans LLP, counsel to JAMP. It also filed detailed written representations and a proposed notice of application under section 79.

[6] Janssen opposed JAMP's request for leave. By order dated August 22, 2024, the Tribunal granted Janssen permission to file limited responding affidavit evidence: *JAMP Pharma Corporation v Janssen Inc.*, 2024 Comp Trib 4. On September 6, 2024, Janssen filed an affidavit from Andy Williams, Janssen's Vice President, Sales & Marketing, and detailed written representations.

[7] The Commissioner of Competition filed written representations dated September 6, 2024.

[8] JAMP filed a reply memorandum dated September 9, 2024.

[9] By letter dated September 20, 2024, Janssen requested permission to file a sur-reply memorandum and provided the Tribunal with a draft of it, arguing that JAMP raised new allegations in its reply that were neither pleaded nor argued in its notice of application or

memorandum of fact and law, and which needed to be addressed. The *Competition Tribunal Rules* do not contemplate sur-reply representations on applications for leave. Janssen's request to file sur-reply representations will be dismissed, with the exception of paragraph 15 of its proposed representations which the Tribunal found useful. Janssen does not need to file representations containing only paragraph 15.

[10] By letter dated September 23, 2024, JAMP responded to Janssen's letter dated September 20, 2024. While it left it to the Tribunal to determine if Janssen's sur-reply was legally permissible and justifiable, it provided limited observations on two points raised in the sur-reply. As the sur-reply is not permitted for filing, neither is this sur-sur-reply.

II. THE TEST FOR LEAVE UNDER SUBSECTION 103.1(7)

[11] Subsections 103.1(7) and (7.1) provide:

General	Dispositions générales
…	…
Granting leave	**Octroi de la demande**
103.1 (7) The Tribunal may grant leave to make an application under section 75, 77 or 79 if it has reason to believe that the applicant is directly and substantially affected in the applicant's business by any practice referred to in one of those sections that could be subject to an order under that section.	**103.1 (7)** Le Tribunal peut faire droit à une demande de permission de présenter une demande en vertu des articles 75, 77 ou 79 s'il a des raisons de croire que l'auteur de la demande est directement et sensiblement gêné dans son entreprise en raison de l'existence de l'une ou l'autre des pratiques qui pourraient faire l'objet d'une ordonnance en vertu de ces articles.
Granting leave to make application under section 76	**Octroi de la demande**
103.1 (7.1) The Tribunal may grant leave to make an application under section 76 if it has reason to believe that the applicant is directly affected by any conduct referred to in that section that could be subject to an order under that section.	**103.1 (7.1)** Le Tribunal peut faire droit à une demande de permission de présenter une demande en vertu de l'article 76 s'il a des raisons de croire que l'auteur de la demande est directement gêné en raison d'un comportement qui pourrait faire

l'objet d'une ordonnance en vertu du même article.

[12] Subsection 103.1(7) applies to the present request for leave. The Tribunal's task is to determine whether it has "reason to believe" that the applicant is "directly and substantially affected in the applicant's business by any practice referred to in [section 79] that could be subject to an order under that section".

[13] The Tribunal must determine whether the application for leave is supported by evidence that gives rise to a *bona fide* belief that the applicant may have been directly and substantially affected in its business by the impugned practice, and that the practice "could" be subject to an order under section 79: *Symbol Technologies Canada ULC v Barcode Systems Inc,* 2004 FCA 339, [2005] 2 FCR 254 ("*Symbol Technologies FCA*"), at paras 17-19; *CarGurus, Inc v Trader Corporation,* 2017 FCA 181 ("*CarGurus FCA*"), at para 9; *Audatex Canada, ULC v CarProof Corporation,* 2015 Comp Trib 13 ("*Audatex CT – I*"), at paras 9, 17; *CarGurus, Inc v Trader Corporation,* 2016 Comp Trib 12 ("*CarGurus CT – I*"), at para 9.

[14] In a leave application under section 103.1, the Tribunal proceeds summarily and expeditiously to carry out a screening function based on the sufficiency of credible, cogent and objective evidence advanced: *Symbol Technologies FCA,* at para 24; *CarGurus FCA,* at paras 9, 21-23, 25-28; *Audatex CT – I,* at paras 11, 16-17, 19; *CarGurus CT – I,* at paras 9, 32.

[15] The overall legal threshold for an applicant to obtain leave is not difficult to meet, in that it is lower than proof on a balance of probabilities: *Symbol Technologies FCA,* at para 17; *Bank of Nova Scotia v B-Filer Inc.,* 2006 FCA 232 ("*B-Filer FCA*"), at para 1. The phrase "reason to believe" has been considered in some cases to mean reasonable grounds to believe: *Symbol Technologies FCA,* at paras 16, 25, 29 (adopting the approach in *National Capital News Canada v Milliken*, 2002 Comp Trib 41, at paras 9-10); *CarGurus, Inc v Trader Corporation,* 2016 Comp Trib 15 ("*CarGurus CT – II"*), at paras 64, 102; *Audatex Canada, ULC v CarProof Corporation,* 2015 Comp Trib 28 ("*Audatex CT – II*"), at paras 43, 55, 73; but see *Empire Company Limited v Canada (Attorney General),* 2024 FC 810, at paras 71-73.

[16] Although the legal threshold of "reason to believe" is lower than a balance of probabilities, it is not sufficient to adduce evidence that shows a mere possibility that the applicant is directly and substantially affected in applicant's business by the practice in question. The Federal Court of Appeal and the Tribunal have confirmed that the applicant must adduce sufficient credible, cogent and objective evidence to meet the statutory requirements: *CarGurus FCA,* at paras 21-23, 26-27, aff'g *CarGurus CT – II,* at paras 60, 64, 83, 87, 102; *Audatex CT – II,* at paras 43, 77, 83; S. McGrath and E. Keough, "Private Actions Before the Tribunal", in Nikiforos Iatrou, ed, *Litigating Competition Law in Canada,* 2nd ed (Toronto: LexisNexis Canada Inc, 2023) ch 7, esp. at pp. 233-234.

[17] The Tribunal has also held that "one should not have to wait until harm actually occurs before bringing an application under subsection 103.1(1)": *Audatex CT – II,* at para 83; *Nadeau Poultry Farm Limited v Groupe Westco Inc et al,* 2008 Comp Trib 7, at para 25.

[18] In *Audatex CT – II,* an application seeking leave to commence a section 75 proceeding, the Tribunal discussed the "direct" and "substantial" components in subsection 103.1(7):

> [45] With respect to the first part of the test under subsection 103.1(7) (being "directly and substantially affected by a refusal to deal"), the terms "directly" and "substantially" should be given their ordinary meaning. For the "substantial" component, terms such as "important" are acceptable synonyms to considering whether there has been a "substantial" impact, which is ultimately assessed by reviewing the circumstances at issue (*Canada (Director of Investigation and Research) v Chrysler Canada Ltd* (1989), 27 CPR (3d) 1 (Comp. Trib.), aff'd 38 CPR (3d) 25 (FCA) at para 64). In the *Nadeau* decision on the merits, Mr. Justice Blanchard specified that "the Applicant need not demonstrate that it is affected by the refusal to the point of it being unable to carry on its business. Rather, it is required to establish on a balance of probabilities that it is affected in an important or significant way" (*Nadeau Poultry Farm Limited v Groupe Westco Inc et al,* 2009 Comp. Trib. 6 […] at para 131, aff'd 2011 FCA 188). The "direct" component has not been interpreted, but its ordinary meaning calls for a close nexus between the refused supply and the impact on an applicant's business.

[19] In determining whether the alleged reviewable practice "could" be subject to an order, the Tribunal must consider all the elements of the reviewable practice: *Symbol Technologies FCA,* at paras 19-20, 22-23. The question is whether there is sufficient credible, cogent evidence of each of the elements of the alleged reviewable practice to support a *bona fide* belief that the alleged practice could be subject to an order under the relevant reviewable practice provision(s): *B-Filer FCA,* at paras 1-3, affirming *B-Filer Inc. v The Bank of Nova Scotia,* 2005 Comp Trib 38, at paras 52-53, 60; *Symbol Technologies FCA,* at paras 17-20; *Luigi Coretti v Bureau de la Sécurité Privée and Garda World Security Corporation,* 2019 Comp Trib 4, at paras 8-14; *Audatex CT – II,* at para 49.

[20] A decision on an application for leave under section 103.1 is not meant to be a final determination made on the basis of a full evidentiary record: *Audatex CT – I,* at paras 10, 12, 16; *CarGurus CT – I,* at para 15.

[21] Finally, on an application for leave, the Tribunal's analysis does not make any conclusions – one way or the other – as to whether a respondent has engaged in the reviewable practice that the applicant seeks to allege in a proposed notice of application. It is also not the Tribunal's role, when deciding an application for leave under section 103.1, to identify the most promising evidence in the record and craft its own allegations of a potential reviewable practice.

[22] Accordingly, these Reasons only assess the evidence and submissions filed on this application and whether the evidence is sufficient to meet the statutory test in subsection 103.1(7) that permits a private party to commence a proceeding under section 79 with leave of the Tribunal.

III. ANALYSIS

A. The meaning of "substantially affected in the applicant's business by any practice" in subsection 103.1(7) for section 79 proceedings

[23] The present application is the first to seek leave to commence a proceeding under section 79. JAMP has raised an interpretation issue under subsection 103.1(7).

[24] In its decisions on applications for leave to commence proceedings under sections 75 and 77, the Tribunal has analyzed whether the applicant has been "directly and substantially affected" in the applicant's business as a whole, rather than analyzing the impact of the impugned practice on a line or segment of the applicant's business: *Audatex CT – II,* at para 54; *Sears Canada Inc v Parfums Christian Dior Canada Inc and Parfums Givenchy Canada Ltd,* 2007 Comp Trib 6 ("*Sears Canada*"), at para 21.

[25] JAMP noted that in 2022, Parliament amended subsection 103.1(7) to enable private applications to the Tribunal under section 79, so this is the first opportunity for the Tribunal to interpret and apply the amended subsection 103.1(7) in conjunction with section 79. JAMP submitted that the Tribunal should take a different approach for leave applications that concern an alleged practice under section 79, as opposed to those under section 75 or 77 – that is, that an application for leave concerning an alleged practice under section 79 need not show a substantial impact on an applicant's entire business.

[26] JAMP made two arguments to support its position. First, JAMP contended that the Tribunal should interpret and apply subsection 103.1(7) in a manner that is harmonious with the words and structure of section 79. JAMP submitted that section 79 refers to control of a "class or species of business", a phrase that has been interpreted to be synonymous with a relevant product market (citing *The Director of Investigation and Research v The NutraSweet Company*, CT-1989-002 ("*NutraSweet*"), at pp. 53-56; *Canada (Commissioner of Competition) v Canada Pipe Co,* 2006 FCA 236, [2007] 2 FCR 57, ("*Canada Pipe FCA – II*") at paras 9-16; *The Commissioner of Competition v The Toronto Real Estate Board,* 2016 Comp Trib 7 (aff'd 2017 FCA 236) ("*TREB CT*"), at paras 162-165). According to JAMP, the phrase "applicant's business" is synonymous with the applicant's participation in the product market in which the respondent is alleged to have control under section 79. Thus, the Tribunal's analysis should focus on the effect of the impugned practice on the applicant's business in the product market at issue under section 79 – and not necessarily its entire business. JAMP contended that the analysis of the applicant's entire business should be understood in the context of applications to commence proceedings under paragraph 75(1)(*a*) (citing *Audatex CT – II,* at para 54 and *CarGurus CT – II,* at para 65). JAMP referred to the Tribunal's decision in *Sears Canada,* arguing that the Tribunal did not account for certain additional aspects of the reasoning under section 75 in *Canada (Director of Investigation and Research) v Chrysler Canada Ltd* (1989), 27 CPR (3d) 1 (Comp Trib) (aff'd (1991) 38 CPR (3d) 25 (FCA)) ("*Chrysler CT*").

[27] Second and alternatively, JAMP argued that the identification of the "applicant's business": (i) is a question of fact that must be determined from the evidence; and (ii) is not determined merely by reference to the holdings of the corporate entity making the application.

According to JAMP, to make a determination as to the scope of an applicant's business, the Tribunal should inquire about the applicant's actual business activities and the connections (if any) between those activities. In turn, this would allow the Tribunal to determine whether the applicant has the ability to continue to compete in the market to be defined under section 79 and whether the failure to grant leave might result in the loss of a competitor. JAMP argued that the Tribunal has previously disregarded certain sales that were unrelated to the impact of the practice (citing *Chrysler CT*) and the business of an American parent corporation (citing *Sears Canada*) and American business (citing *Audatex CT – II*). JAMP raised points about other provisions and case law under the *Competition Act,* and referred to concerns about a *de facto* rule that only single-line firms are able to obtain leave if an "entire" business approach is perpetuated: see Paul Erik Veel, "Private Party Access to the Competition Tribunal: A Critical Evaluation of the Section 103.1 Experiment", (2009) 18 *Dal J Leg Stud* 1.

[28] Janssen's position was that the Tribunal has consistently held that: (i) a "substantial effect" on a business must be measured in the context of the entire business – not a subset of an applicant's business or a product line affected by the alleged practice; and (ii) the effect must be attributable to the alleged practice. Janssen observed that Parliament did not amend the language "directly and substantially affected in the applicant's business" when it amended subsection 103.1(7) in 2022. According to Janssen, there is no reason to interpret the same words of subsection 103.7(1) differently in an application for leave to bring an application under section 79, as opposed to under sections 75 and 77. Janssen noted that in any event, since the 2022 amendments, Parliament has already amended subsection 103.1(7) to read "… directly or substantially affected in whole or part …" [emphasis added] (see S.C. 2024, c. 15, section 244); however, Parliament has also decided not to make that change come into force until June 20, 2025.

[29] The Commissioner's representations submitted that the Tribunal should take a liberal interpretation of the language "reason to believe that the applicant is directly and substantially affected in the applicant's business". According to the Commissioner, that approach would avoid a threshold under the current test that would bar meritorious claims of applicants who cannot demonstrate substantial effects on their entire businesses, particularly if the impugned practices have consequences for the Canadian economy. The Commissioner argued that "substantially affected in the applicant's business" in subsection 103.1(7) need not be interpreted the same as the phrase "substantially affected in his business" in paragraph 75(1)(*a*), because the two provisions have different purposes: the former limits standing, while the latter is a substantive element of a reviewable practice. The Commissioner noted that "substantially affected" is not an element of the reviewable conduct in section 79.

[30] In my view, the analysis must focus on the proper statutory interpretation of subsection 103.1(7) and whether the Tribunal's existing case law under subsection 103.1(7), decided before section 79 was added to the provision in 2022, requires the Tribunal to assess the impact of an impugned section 79 practice on the applicant's entire business.

[31] For the reasons below, I find that in applications for leave to commence a proceeding under section 79, an application is not required under subsection 103.1(7) to show that the applicant is directly and substantially affected in its entire business by the practice.

(1) Previous Tribunal decisions on leave to commence proceedings under sections 75 and 77

[32] It is convenient first to consider the Tribunal's previous decisions under subsection 103.1(7) and the approach used to interpret "directly and substantially affected in the applicant's business by any practice" in the context of applications for leave to commence proceedings under sections 75 and 77.

[33] The application of an "entire" business test is consistent in the decisions seeking leave to commence proceedings under section 75: see *Sears Canada,* at para 21; *Audatex CT – II,* at para 54; *CarGurus CT – II,* at para 65.

[34] The pivotal case is *Sears Canada*. The matter concerned the supply of prestige fragrances to Sears, a large department store. The suppliers had decided not to continue to do business with Sears and therefore stopped supplying it with their products. However, they continued to supply other large retailers in Canada. Sears's revenues from the sale of the suppliers' fragrances were an insignificant percentage of Sears's overall sales, and represented only a modest percentage of its total cosmetics business: *Sears Canada,* at para 10.

[35] The first question for the Tribunal was to define Sears's business for the purposes of the leave application. Sears took the position that its business was the sale of the two fragrances, whereas the respondent fragrance suppliers submitted that Sears's business was operating department stores.

[36] The Tribunal considered the case law at the time, including two categories of cases:

(a) the Tribunal's decision in *Chrysler CT* on the merits of an application under paragraph 75(1)(*a*); and

(b) four leave decisions under subsection 103.1(7): *1177057 Ontario Inc. (c.o.b. as Broadview Pharmacy) v Wyeth Canada Inc,* 2004 Comp Trib 22, *Paradise Pharmacy Inc v Novartis Pharmaceuticals Canada Inc,* 2004 Comp Trib 21; *Broadview Pharmacy v Pfizer Canada Inc,* 2004 Comp Trib 23; *Construx Engineering Corporation v General Motors of Canada,* 2005 Comp Trib 21.

[37] Based on that review, the Tribunal (*per* Simpson J) concluded that "the Tribunal has consistently taken the position that a substantial effect on a business is measured in the context of the entire business": *Sears Canada,* at para 21; see also paras 18-20.

[38] The Tribunal also considered the language in the statute, finding that "if Parliament had intended the substantial effect in subsection 103.1(7) and paragraph 75(1)(*a*) of the Act to be on a business in a class of articles such as the Dior and Givenchy Products, it would have said so": at para 26.

[39] The Tribunal concluded that "both the Tribunal's earlier decisions and the plain language used in the subsection lead to the conclusion that Sears' entire business as a department store retailer is the business under consideration for the purposes of subsection 103.1(7) of the Act": at para 27. The Tribunal applied that approach to whether Sears was

"directly and substantially affected" in its "business", concluding that it was not: at paras 33-34, 39.

[40] This approach to "business" has been applied since *Sears Canada* to matters involving leave to commence a proceeding under section 75. That is, for an application for leave to commence a proceeding under section 75, the Tribunal has effectively read "substantially affected in the applicant's business" as requiring that the impugned practice have a significant impact on the applicant's entire business. In *Audatex CT – II,* the Tribunal (*per* Gascon J) stated, at para 54:

> It is well-established that the business to be considered on a leave application pursuant to section 75 of the Act is the entire business of the applicant, not simply the product line affected by the refusal to supply (*Sears Canada Inc v Parfums Christian Dior Canada Inc,* 2007 Comp Trib 6 at para 21). The substantiality of the effect must therefore be measured against that whole business. In addition, the case law developed by the Tribunal in applications for leave requires that the effect to be looked at and considered is the impact attributable or linked to those entities whose supply is being refused. Indeed, subsection 103.1(7) refers to the applicant being directly and substantially affected "by the practice".
>
> [Emphasis added.]

See also S. McGrath and E. Keough, "Private Actions Before the Tribunal", cited above, esp. at pp. 231-232.

[41] Only a few Tribunal cases concerned leave to commence a proceeding under section 77.

[42] In the *CarGurus* matter, the applicant sought leave to commence a proceeding under sections 75 and 77. The applicant was a new entrant seeking data to support its intermediary services (websites) that provided listings of new and used vehicles for sale. The respondent refused to provide its data, which the applicant characterized as a practice of refusing to deal. The Tribunal's statement of the law repeated the passage above from *Audatex CT – II.* In its discussion of the law, the Tribunal did not separately address the meaning of "business" for the purposes of leave to start a proceeding under section 77.

[43] In the result, CarGurus's application to commence proceedings under both sections failed, owing to the absence of evidence to support the requirement that the applicant was directly and substantially affected in its business by the impugned practice. For present purposes, however, the Tribunal applied the same approach to "substantially affected in the applicant's business" for both sections 75 and 77: *CarGurus – CT II,* at paras 64-65, 102-104. On appeal, the Federal Court of Appeal did not distinguish the test for leave as between the two provisions (although the appellant's real challenge to the Tribunal's decision was not the test, but its application to the evidence: *CarGurus FCA,* at para 20). It appears that the applicant in the *CarGurus* matter did not raise any argument about a distinction as between sections 75 and 77.

[44] In *Stargrove Entertainment Inc v Universal Music Publishing Group Canada*, 2015 Comp Trib 26, the applicant sought leave under both sections 75 and 77, as well as section 76. In denying leave for sections 75 and 77, the Tribunal (*per* Barnes J) held that the approach in leave applications for section 75, set out in *Symbol Technologies FCA* at paragraphs 17-20, informed the granting of leave under section 77: *Stargrove,* at para 21. The Tribunal also commented:

> [28] The second fundamental deficiency in Stargrove's application for leave under sections 75 and 77 arises from its evidence concerning the impact of the alleged conduct on its business. Subsection 103.1(7) requires evidence of a direct and substantial affect. The evidence presented by Stargrove is manifestly insufficient to meet the burden it carries to show a "substantial" affect. Despite Mr. Perusini's acknowledgement that Stargrove's business model includes the sale of musical works it controls or which are now fully within the public domain, he has provided no evidence about the size of that part of its overall business relative to the market for the disputed musical works.

[45] The Tribunal's decision was that the evidence did not support a direct and substantial effect to permit a proceeding under either sections 75 or 77. Although the Tribunal referred in the quoted passage to "the size of [the] part of the applicant's overall business", it was to say that there was no evidence of how that part compared to the market for the disputed musical works. The Tribunal made no express comment about the word "business".

[46] This review of the cases suggests that:

(a) The Tribunal's decisions on applications for leave to commence proceedings under section 75 are consistent in requiring that an applicant show a direct and substantial impact on the applicant's entire business.

(b) The pivotal case, *Sears Canada,* based its approach to the word "business" in subsection 103.1(7) (as it read in 2007) on prior Tribunal decisions concerning the merits of an application under paragraph 75(1)(*a*) (*Chrysler CT*) and on prior leave decisions seeking to commence proceedings under section 75.

(c) Tribunal decisions have applied the same approach to the word "business" in applications for leave to commence proceedings under sections 75 and 77 – at least within a single application for leave. It has considered the practice at issue and how it impacts the applicant's business as a whole under section 75 and in a small number of cases, within the same analysis, under section 77.

(d) Importantly, it appears that the Tribunal has not been invited by any party to apply a different approach to the word "business" for the purposes of the "directly and substantially affected in the applicant's business" under section 77 or, until this application, section 79.

(2) The language of subsection 103.1(7): text, context and purpose

[47] I turn to the interpretation of subsection 103.1(7), applying the modern principle of statutory interpretation established by the Supreme Court: see *Canada (Minister of Citizenship and Immigration) v Vavilov,* 2019 SCC 65, [2019] 4 SCR 653, at paras 117-118. The words in the provision must be read in their entire context and in their grammatical and ordinary sense, harmoniously with the scheme and the object of the legislation, and the intention of Parliament. It is common to analyze the text, context and purpose of the provision: see *Secure Energy Services Inc v Canada (Commissioner of Competition),* 2023 FCA 172, at paras 16-42; *Canada (Commissioner of Competition) v Secure Energy Services Inc,* 2022 FCA 25, [2022] 2 FCR 430, at paras 49-68.

[48] The key issue is whether this provision requires a direct and substantial impact on the applicant's entire business, in an application for leave to commence a proceeding under section 79.

[49] We start with its **text**. The express language of the provision permits the Tribunal to grant leave to commence a proceeding under sections 75, 77 or 79 by applying a statutory test. Looking at the provision as a whole, there is a single test for all three provisions, a point reinforced by the phrase "in one of those sections" ("*en vertu de ces articles*"). That test is whether the Tribunal has reason to believe that an applicant is "directly and substantially affected in the applicant's business by any practice referred to in one of those sections that could be subject to an order under that section".

[50] Two points should be made. First, the provision does not expressly refer to the applicant's "entire" or "whole" business. That is a gloss added by the Tribunal case law based on an understanding of the word "business" ("*entreprise*"), reading subsection 103.1(7) with section 75 and case law under the latter provision (*Chrysler CT*).

[51] Second, the observation that there is a single statutory test for leave should be understood as referring to the whole test in the subsection, not one word or a single phrase. The express language in subsection 103.1(7) provides that there must be reason to believe that an applicant is directly and substantially affected in its business "by any practice" in sections 75, 77 or 79.

[52] Thus, for interpretation purposes, the very language of subsection 103.1(7) directs the Tribunal to consider the context of the practices in the provisions for which leave may be granted in sections 75, 77 and 79 (as appropriate for the leave application). It requires the Tribunal to assess the impact of a practice that could be subject to an order under any of sections 75, 77 or 79 on the applicant's business.

[53] In this light, the language of subsection 103.1(7) does not preclude the possibility that a single word ("business") or a single phrase ("directly and substantially affected in the applicant's business") may be understood and applied differently for practices that may fall under each of sections 75, 77 and 79. That is because the provision itself requires the Tribunal to read and apply the language of subsection 103.1(7) in conjunction with each of the three other stated provisions in the statute.

[54] Put another way, as the Tribunal did in *Sears Canada* by considering *Chrysler CT* and section 75, one must appreciate the nature of the reviewable practice in section 79 as defined by Parliament when interpreting subsection 103.1(7). Then when applying the provision, the Tribunal must consider the evidence concerning the nature of the impugned practice under section 79 and its impact on the applicant's business, just as it has done in all prior leave cases for sections 75 and 77 before the 2022 amendments.

[55] I acknowledge that, viewed in isolation, both "business" and "*entreprise*" may be understood as referring to a business as a whole. Those words also are capable of bearing both meanings – the whole business, and part of it. But the real point is that the meaning of the words found in subsection 103.1(7) is a matter of interpretation within the entire language of the subsection, not a single word or phrase in isolation or in the abstract.

[56] How should subsection 103.1(7) be considered for leave to commence a proceeding under section 79? Section 79 establishes the reviewable practice. Section 78 describes, non-exhaustively, anti-competitive acts for the purposes of subsection 79(1). Parliament has recently amended both provisions: see S.C. 2022, c. 10, sections 261-262; S.C. 2023, c. 31, sections 7.1-7.2; S.C. 2024, c. 15, section 247. Section 78 and subsection 79(1) are found in Appendix "A" to these Reasons.

[57] For present purposes, it may be readily noted that sections 78 and 79 do not include any "substantially affected" language as exists in paragraph 75(1)(*a*).

[58] Under section 78, "anti-competitive acts" are acts that are "…intended to have a predatory, exclusionary or disciplinary negative effect on a competitor, or to have an adverse effect on competition…" Only paragraph 78(1)(*e*) expressly mentions a business: "pre-emption of scarce facilities or resources required by a competitor for the operation of a business, with the object of withholding the facilities or resources from a market". Importantly for present purposes, there is no requirement arising from the description of "anti-competitive acts" in section 78 that would require an impact on the entirety of a competitor's business in order to be successful under section 79. In addition, the examples in section 78 include at least one that concerns conduct against a person not yet competing or that may be a small or nascent competitor in a market: paragraph 78(1)(*j*) expressly contemplates acts that prevent or impede entry into a market, or expansion in it, when it refers to "a selective or discriminatory response to an actual or potential competitor for the purpose of impeding or preventing the competitor's entry into, or expansion in, a market or eliminating the competitor from a market".

[59] The preamble or "chapeau" language in subsection 79(1) refers to substantial or complete "control" of a "class or species of business". The Tribunal and appeal courts have consistently interpreted such "control" of a "class or species of business" to mean significant market power in a defined product market: *NutraSweet,* at pp 53-56; *Canada Pipe FCA – II,* at paras 10-11; *TREB CT,* at paras 162-165; *The Commissioner of Competition v Vancouver Airport Authority*, 2019 Comp Trib 6 ("*VAA CT*"), at para 423.

[60] The operative language of subsection 79(1) concerns the alleged controlling respondent engaging in either a "practice of anti-competitive acts" in paragraph 79(1)(*a*), or "conduct … that had, is having or is likely to have the effect of preventing or lessening competition

substantially in a market …" (i.e., conduct that causes a substantial lessening or prevention of competition ("SLC/SPC")) in paragraph 79(1)(*b*). Neither one expressly requires proof that an affected competitor or potential competitor in the product market over which a respondent has such control be affected in the entirety of that competitor's business. To impose such a requirement would have a palpable narrowing impact on the scope of cases under paragraph 79(1)(*a*) (e.g., in cases involving new entrants or nascent competitors seeking to expand) and on "prevent" cases under paragraph 79(1)(*b*) (e.g., an established competitor in one market that is prevented from entering into a neighbouring geographic market by a dominant participant in the neighbour market).

[61] I note that the language of sections 78 and 79 contrasts with the language found in section 75 as it read in 2007. Tracing back to the reasoning in *Sears Canada*, section 79 contains the kind of language ("class or species of business") not found in section 75: *Sears Canada,* at para 26. (Parliament also amended section 75 in 2024 and it now refers to a person "substantially affected in the whole or part of their business": see S.C. 2024, c. 15, section 244; as previously noted, however, this amendment in not yet in force.)

[62] The text of subsection 103.1(7), read with sections 78-79, does not imply that an applicant must be directly and substantially affected in its entire business.

[63] Looking next at the **statutory context** of subsection 103.1(7), it is clear that an applicant under that provision must be both "directly" and "substantially" affected in its business, including when an applicant seeks to commence a proceeding under section 79. If Parliament had intended leave to be granted without a "substantial" impact on the applicant's business, Parliament could have inserted section 79 into subsection 103.1(7.1), alongside the reference to section 76.

[64] Other contextual factors arising in the statute in relation to sections 75, 77 and 79 have already been discussed owing to the express language in the provision. I add that sections 78-79 are focussed on behaviour, and competition more generally, within one or more markets. Section 79 requires that the respondent control or substantially control a market and contemplates effects on competition in a market. Section 78 refers to a market in its chapeau language and expressly in several of its paragraphs. In that context, there is no requirement that the alleged reviewable practice have a direct and substantial impact on the applicant's entire business; it is more consistent with sections 78-79 to enable the potential direct and substantial impact to be assessed on the applicant's business as it concerns the market(s) at issue, rather than to require its entire business to be directly and substantially affected.

[65] The **purpose** of subsection 103.1(7) is to permit a private party to commence proceedings under sections 75, 77 and 79 if it meets certain criteria established by Parliament. Otherwise, the *Competition Act* only permits the Commissioner to commence a proceeding under those provisions.

[66] Tribunal decisions have concluded that meeting the statutory criteria gives standing to an applicant that is itself affected by the particular practice at issue: *Symbol Technologies FCA,* at para 22; *Canadian Standard Travel Agency Registry v International Air Transport Association*, 2008 Comp Trib 14, at paras 9, 12.

[67] The Tribunal's screening or gatekeeping role serves various other objectives that are important to the just determination of proceedings before the Tribunal. I will mention two that are particularly related to section 79 proceedings. If an applicant is "directly" and "substantially" affected in its business by a reviewable practice, the applicant will presumably be able to provide the Tribunal – both at the leave stage and on any later section 79 application – with first-hand evidence about competition in the market(s) and industry at issue, including the nature and scope of the effects of the impugned practice on rivalrous behaviour. (In matters investigated and commenced by the Commissioner, including under section 79, the Commissioner has the ability to gather such information by seeking one or more orders under section 11 of the *Competition Act* against the target(s) of an inquiry or third party participants in the market that are likely to have relevant information, and through other means.)

[68] In addition, as *Symbol Technologies FCA* instructs, the Tribunal also ensures that there is sufficient cogent evidence going to each of the elements of the practice such that the Tribunal "could" issue an order (albeit on the lower legal standard expected for leave under subsection 103.1(7), discussed above at paragraphs 15-16, 19). A positive screening outcome implies that it is worthwhile for the parties and the Tribunal to spend resources on the proposed proceeding because the applicant's supporting evidence related to the elements of the reviewable practice discloses enough substantive merit to warrant a proceeding.

[69] Interpreting the words of subsection 103.1(7) in light of these purposes does not lead to a requirement that an applicant seeking to commence a proceeding under section 79 must show a direct and substantial impact on its entire business. An applicant may be directly and substantially affected in something less than its entire business and still be able to provide sufficient evidence about the nature of competition in the relevant market(s) and also be sufficiently impacted by the impugned practice to warrant a proceeding.

(3) Conclusion on this issue

[70] This analysis suggests that the text, context and purpose of subsection 103.1(7) as it currently reads requires the Tribunal to approach an application for leave to commence a proceeding under section 79 with a view to the impact of the practice on the applicant's business and apply the test set out in the subsection using all of its language. In my view, none of the text, context or purpose of the provision requires the Tribunal to consider the impact of an impugned practice under section 79 only if the impact is on the applicant's entire business.

[71] There are two final points to address.

[72] First, in 2024, Parliament amended subsection 103.1(7) to read:

Granting leave – sections 75, 77, 79 or 90.1	**Octroi de la demande : articles 75, 77, 79 ou 90.1**
103.1 (7) The Tribunal may grant leave to make an application under section 75, 77, 79 or 90.1 if it has reason to	**103.1 (7)** Le Tribunal peut faire droit à une demande de permission de présenter une demande en vertu des articles

believe that the applicant is directly and substantially affected in the whole or part of the applicant's business by any conduct referred to in one of those sections that could be subject to an order under that section or if it is satisfied that it is in the public interest to do so.	75, 77, 79 ou 90.1 s'il a des raisons de croire que l'auteur de la demande est directement et sensiblement gêné dans tout ou partie de son entreprise en raison de l'existence de l'un ou l'autre des comportements qui pourraient faire l'objet d'une ordonnance en vertu de l'un de ces articles ou s'il est convaincu que cela servirait l'intérêt public.

[Emphasis added.]

[73] The first underlined change would seem to resolve the legal issue presented in this case, but the provision does not come into force until June 2025.

[74] Janssen's position was that Parliament has already spoken by amending the provision. According to the respondent, Parliament decided both to amend the provision and to delay the impact of its amendment until June 2025, so JAMP should not be able to benefit from the amendment on this application. In response, JAMP points to the *Interpretation Act,* RSC, 1985, c I-21, subsection 45(3), which provides in relevant part that the "amendment of an enactment in whole or in part shall not be deemed to be or to involve any declaration as to the previous state of the law".

[75] Parliament's amendments do not necessarily imply the state of the previous law, or a change in it at the time of enactment: *Interpretation Act,* subsections 45(2) and (3); *Canada (Commissioner of Competition) v Premier Career Management Group Corp,* 2009 FCA 295, [2010] 4 FCR 413, at para 57. As such, Parliament's amendments in 2024 to add "the whole or part of" do not imply a declaration of the state of the prior law or a change in the law. It must be open to the Tribunal to interpret the provision from first principles and to conduct the interpretive analysis above for the added section 79. The fact that the new "the whole or part of" language was added to the provision in 2024 does not imply that a proper interpretation of the provision as it currently reads would not yield a similar result.

[76] The last point to note is that these Reasons do not question the Tribunal's decisions or legal analysis in prior cases involving applications for leave to commence proceedings under section 75 or 77. Instead, in 2022, Parliament amended subsection 103.1(7) to add the prospect of obtaining leave to commence proceedings under section 79. The present analysis concerns how the leave test in subsection 103.1(7) interacts with an alleged reviewable practice under section 79 in the amended provision. As the analysis shows, there are good reasons to conclude that this decision does not go against the Tribunal's prior decisions as they were concerned with sections 75 and 77, and is consistent with the interpretative approach taken in *Sears Canada*.

[77] In any event, the Tribunal must interpret and apply subsection 103.1(7) in light of section 79, and indeed section 75, as they currently read. The interpretation of subsection

103.1(7) in these Reasons will not create dissonance with the interpretation of subsection 103.1(7) in light of paragraph 75(1)(*a*), because the latter provision has also been amended recently to refer to a person "substantially affected in the whole or part of their business": see S.C. 2024, c. 15, section 244.

IV. SHOULD JAMP BE GRANTED LEAVE?

[78] JAMP alleges that Janssen has engaged in conduct that constitutes a reviewable practice under section 79 that has directly and substantially affected its business. It alleges that JAMP is directly and substantially affected in its business by a "practice" of anti-competitive acts under paragraph 79(1)(*a*) that is made up of multiple different acts by Janssen, occurring over the period from August 2021 to at least July 2024 when JAMP filed this application, and that they are "anti-competitive acts" under section 78. The same behaviour is alleged to be "conduct" that has had the effect of a SLC/SPC in a market under paragraph 79(1)(*b*).

[79] I have carefully read the parties' respective affidavit evidence and submissions. They disagreed on many issues, large and small – down to interpreting the same phrase in a document (as evidence of anti-competitive intent or as competitively innocuous). As this is a screening decision on an application for leave that should be resolved summarily, I have not addressed each and every point on which the parties disagreed nor attempted to resolve those differences. After sorting through the very zealous and sometimes blustery advocacy, I have attempted to weed out the parties' respective assertions and arguments from the objective evidence and to crystallize the essence of their positions.

[80] I will consider first the alleged reviewable practice and then whether JAMP is directly and substantially affected in its business by that practice.

A. Overview of the alleged reviewable practice

[81] For the alleged reviewable practice under section 79, JAMP maintains that Janssen has substantial or complete control over a class or species of business, namely the market for the supply of ustekinumab, and that Janssen engaged in conduct intended to maintain or extend Janssen's monopoly in the supply of ustekinumab in Canada, while also preserving STELARA's high prices (i.e., Janssen's biologic drug that contain ustekinumab as an active ingredient). JAMP relies on paragraph 79(1)(*a*), alleging that Janssen has engaged in anti-competitive acts intended to have an exclusionary negative effect on competitors and an adverse effect on competition, as contemplated by the chapeau language of section 78. JAMP also relies on paragraph 79(1)(*b*), alleging that Janssen's conduct caused a SLC/SPC in a market.

[82] JAMP launched its ustekinumab biosimilar, Jamteki, on March 1, 2024. JAMP claims that Janssen's actions before that date disincentivized JAMP from launching Jamteki for more than 2.5 years after the expiry of the last of Janssen's patents listed on STELARA. JAMP alleges that, from August 2021 until March 1, 2024, Janssen "gamed" the pharmaceutical regulatory system and used "sham" litigation to disincentivize JAMP and other potential rivals from launching their own ustekinumab drug. JAMP claims that this conduct delayed its entry

into the market and that it was highly beneficial to Janssen to do so, as Janssen continued to make high profits by selling STELARA at its monopoly-level high prices, without facing any competition.

[83] After JAMP and one other entrant launched their own biosmilars to ustekinumab in March 2024, JAMP alleges that Janssen engaged in a series of inter-connected anti-competitive acts including:

(a) the development of a fighting brand, namely FINLIUS® ("FINLIUS"), to create confusion and uncertainty in the market and delay switching (see paragraph 78(1)(*d*)). FINLIUS was approved by Health Canada in April 2023 but was not launched until July 2024;

(b) the misuse of Janssen's patient support program, BioAdvance® ("BioAdvance");

(c) the dissemination of deceptive communications to prescribing physicians and health care professionals, patients and insurers;

(d) predatory pricing of FINLIUS and providing STELARA [redacted] (see paragraph 78(1)(*i*)); and

(e) selective and discriminatory responses to a competitor for the purpose of impeding its expansion and eliminating it from a market (see paragraph 78(1)(*j*)).

[84] JAMP claims that some of these acts come from a "playbook" that Janssen developed when defending and maintaining its monopoly for another biologic drug, known as Remicade. JAMP claims that these anti-competitive acts delayed the growth of its sales, particularly by preventing switching away from STELARA (or FINLIUS) to Jamteki or another biosimilar of STELARA. JAMP alleges that the anti-competitive acts have or will cause JAMP to lose its "first mover" advantage in the sale of ustekinumab drugs.

[85] By way of remedies in the proposed proceeding under section 79, JAMP's notice of application intends to seek the following:

(a) Broad prohibition orders against Janssen, including that Janssen be prohibited:

i. for a period of 10 years, from (a) marketing, selling or otherwise taking any other action in respect of FINLIUS and (b) seeking approval from the Minister of Health, marketing, selling or otherwise taking any other action for any other "relabelled biologic" drug;

ii. for a period of 10 years, from licensing to any third party the rights to seek approval for, market, sell or otherwise taking any other action in respect of any "relabelled biologic" drug;

iii. for a period of 5 years, from offering a drug that is biosimilar to STELARA through or in connection with the Janssen BioAdvance patient services program;

iv. except as it concerns STELARA, for a period of 5 years, from communicating to third parties that a biosimilar drug, interchangeable drug or bioequivalent drug will be offered through or in connection with BioAdvance unless such drug is identified by its manufacturer and brand in the same communication(s);

v. for a period of 5 years, from charging any individual third party fees to obtain services provided under BioAdvance that are in excess of 110% of Janssen's actual costs of administering BioAdvance for the incremental benefit of that individual third party;

(b) an order requiring Janssen to make certain communications to all health care professionals whose patients were enrolled in BioAdvance for STELARA between January 1, 2021 and the date of the Tribunal's order;

(c) an order requiring Janssen to pay, in any manner that the Tribunal specifies, an administrative monetary penalty in an amount of three times the value of the benefit derived from Janssen's alleged anti-competitive practices, which is at least $1,000,000,000, or such other amount as JAMP may request and the Tribunal deems just; and

(d) an Order expediting the hearing of the application.

[86] To situate the analysis below, it is useful to set out a timeline of events:

- **2008 to 2020:** STELARA was approved by Health Canada to be marketed with indications for plaque psoriasis ("PSO") on December 12, 2008, psoriatic arthritis ("PSA") on January 21, 2014, Crohn's disease on December 12, 2016, and ulcerative colitis on January 23, 2020 (the latter two are forms of inflammatory bowel disease ("IBD")). Health Canada also approved marketing of STELARA for pediatric use (in patients aged 6 to 17) for PSO.

- **August 2021:** Expiry of the last patent listed on the Patent Register against STELARA.

- **Early 2022:** JAMP created its BioJAMP division.

- **July 25, 2022:** Janssen attempted to list a patent dubbed the "837 Patent" on the patent register against STELARA.

- **November 15, 2022:** On behalf of the federal Minister of Health, the Office of Submissions and Intellectual Property ("OSIP") provided Janssen with a final, negative decision on whether the 837 Patent was eligible to be added to the patent register against STELARA.

- **December 14, 2022:** Janssen filed an application for judicial review concerning OSIP's decision.

- **April 18, 2023:** Janssen received a Notice of Compliance ("NOC") from Health Canada approving FINLIUS. It is an alternative brand of STELARA. It is produced identically to STELARA (other than branding and packaging) and is indicated to treat the same conditions as STELARA. FINLIUS is not a biosimilar drug.

- **April 26, 2023:** Janssen filed a notice of application for judicial review of OSIP's decision to decline Janssen's attempt to list the 837 Patent on the patent register against FINLIUS.

- **May 24, 2023:** The Federal Court ordered a stay of Janssen's second judicial review proceeding with respect to FINLIUS, as agreed by the parties, pending the outcome of the judicial review proceedings related to OSIP's decision on the STELARA listing.

- **June 21, 2023:** A Federal Court decision dismissed the judicial review application of the OSIP decision dated November 15, 2022 regarding STELARA. In July 2023, the public version of the decision is released: *Janssen Inc. v Canada (Health)*, 2023 FC 870.

- [redacted] Settlement and License Agreement between Janssen Biotech Inc and Johnson & Johnson, and Alvotech hf ("Alvotech") and JAMP.

- [redacted]

- **November 8, 2023:** JAMP received NOC from Health Canada for its ustekinumab biosimilar, Jamteki, which is authorized for PSO and PSA indications but not for Crohn's disease or ulcerative colitis (that is, to treat IBD). Jamteki is not authorized for pediatric psoriasis indications.

- **November 21, 2023:** The Federal Court of Appeal dismissed the appeal from Federal Court's decision dated June 21, 2023: *Janssen Inc. v Canada (Health)*, 2023 FCA 229.

- **December 27, 2023:** Amgen Canada Inc. received an NOC for its own ustekinumab biosimilar, known as Wezlana.

- **February 28, 2024:** Janssen discontinued the judicial review application commenced in April 2023 in respect of its attempt to list the 837 Patent on the patent register against FINLIUS (following a status update request from the Federal Court).

- **March 1, 2024:** JAMP launched Jamteki, a ustekinumab biosimilar to compete with STELARA.

- **March 1, 2024:** Amgen launched its ustekinumab biosimilar, Wezlana.

- [redacted]**:** Term sheet between Janssen and Celltrion to include Celltrion's ustekinumab biosimilar, Steqeyma, in Janssen's BioAdvance program.

- **July 2, 2024:** FINLIUS, Janssen's second branded ustekinumab drug, is introduced to market.

- **July 26, 2024:** JAMP commenced the present application for leave under subsection 103.1(7).

- **July 30, 2024:** Celltrion received an NOC for its ustekinumab biosimilar, Steqeyma.

B. Could the impugned practice of anti-competitive acts be the subject of a Tribunal order under section 79?

(1) Control over a "class of species of business"

[87] I am satisfied that, for the purposes of this application only, there is sufficient cogent and credible evidence to give rise to a *bona fide* belief that that Janssen was, or is, in substantial control of a class or species of business. That is, there is sufficient evidence that Janssen had or has substantial market power in a potential product market for the supply of ustekinumab drugs in Canada, given the evidence in the record of the existence of a single supplier of ustekinumab until March 1, 2024 and Janssen's continued market share after August 2021 (99.8% in May 2024 according to one affidavit), the regulatory and commercial barriers to entry into the market and the continued pricing of STELARA into 2024. In the analysis below, I will use this possible product market for the purposes of this leave application and for ease of reference, will refer to it as a market.

(2) Effect of an agreement containing [redacted]

[88] In [redacted], Janssen Biotech Inc and Johnson & Johnson (defined in that agreement as "Janssen") and Alvotech and JAMP entered into a Settlement and License Agreement. [redacted]

[89] In addition, in the Settlement and License Agreement:

(a) [redacted]

(b) [redacted]

[redacted]

[redacted]

[Emphasis added.]

(c) [redacted]

[90] In this application, the parties exchanged submissions that disagreed over the scope and effect of [redacted]. The parties also disagreed concerning whether the Tribunal has jurisdiction to interpret and apply the terms of the Settlement and Licence Agreement, both as an agreement between two private parties and as a result of [redacted]

[91] Neither party suggested on this application that the Settlement and License Agreement was, for some reason, not enforceable.

[92] With respect to choice of jurisdiction, both parties have attorned and agreed by their conduct to the Tribunal considering and applying the Settlement and License Agreement on this leave application. JAMP did so by filing the application and relying on that agreement to explain why it delayed launching Jamteki until March 1, 2024 [Juneja affidavit, para 54; JAMP's submissions, para 33]. Janssen did so by relying on [redacted] terms in its responding evidence and submissions [Williams affidavit, paras 47-50 and Exhibit 62; Janssen's submissions, paras 25-26, 58, 93, 96, 100].

[93] Given my findings below, it is unnecessary to apply the terms of [redacted] on this application. I will nonetheless make two observations related to [redacted] provision. First, on a practical level, the Tribunal should be able to determine whether [redacted] bars a proposed

application that is the subject of an application for leave under section 103.1. To ignore the possible effect of such [redacted] would deprive the Tribunal of its screening role on a section 103.1 application and could lead to a waste of time and money by the parties, and a waste of Tribunal resources.

[94] Second, for the purposes of leave under subsection 103.1(7), the scope of [redacted] in this case only affects [redacted] Thus, to have an impact on this proceeding, the claim under paragraph 79(1)(*a*) or the claim under paragraph 79(1)(*b*) must have accrued [redacted]. The acts and conduct on which JAMP relies in its proposed section 79 application occurred [redacted] Neither party engaged with when a claim for abuse of dominance accrues under section 79, nor with the effect of [redacted]

(3) Alleged practice of anti-competitive acts for paragraph 79(1)(*a*)

[95] The question under paragraph 79(1)(*a*) is whether Janssen engaged in a "practice of anti-competitive acts". A "practice" under paragraph 79(1)(*a*) concerns more than one isolated anti-competitive act and may be comprised of different anti-competitive acts taken together: *NutraSweet*, at p. 35; *TREB CT*, at para 273; *Canada (Commissioner of Competition) v Canada Pipe Co*, 2006 FCA 233, [2007] 2 FCR 3 ("*Canada Pipe FCA – I*"), at para 60.

[96] Anti-competitive acts are described in section 78 and some are listed as illustrative examples in paragraphs 78(1)(*a*) to (*j*). In 2022, Parliament amended the chapeau language in subsection 78(1), which now provides that "anti-competitive act" in section 79 means "any act intended to have a predatory, exclusionary or disciplinary negative effect on a competitor, or to have an adverse effect on competition, and includes any of the following acts …": see S.C. 2022, c. 10, subsection 261(1).

[97] Referring to the chapeau language of subsection 78(1), JAMP alleges that Janssen's acts had an intended negative exclusionary or disciplinary effect on JAMP as a competitor, or were intended to have an adverse effect on competition. JAMP argued that some acts fall under specific paragraphs under subsection 78(1), namely (*d*), (*i*) and (*j*).

[98] According to JAMP, Janssen's acts can be characterized as anti-competitive because their subjective and objective purpose is "to negatively affect and exclude JAMP and other suppliers of biosimilars" that compete with STELARA and because their subjective and objective purpose is to have an adverse effect on competition by permitting Janssen to maintain its high pricing for STELARA and maintain its high market share (citing *Canada Pipe FCA – I*, at para 66).

[99] JAMP referred to the results of two Competition Bureau investigations: a position statement dated February 20, 2019, entitled "Inquiry into alleged anti-competitive conduct by

Janssen"[1] and a position statement dated June 27, 2022, entitled "Completion of Preliminary Investigation into Relabelled Biologic drugs".[2]

[100] The question for the Tribunal is whether there is sufficient cogent evidence to give rise to a *bona fide* belief that Janssen's alleged practice of anti-competitive acts could be subject to an order under paragraph 79(1)(*a*).

[101] I begin by recognizing that JAMP's proposed application concerns alleged anti-competitive acts by an allegedly dominant respondent that had a monopoly under the legislated patent regime until August 2021. JAMP seeks to commence a lawsuit, broadly speaking, against a respondent that it alleges is a dominant entity seeking to protect its dominant position, maintain its significant market power and continue to supply its products at high prices, in the face of new entrants including JAMP seeking to expand and take away market share.

[102] I also recognize that competition in the relevant market is affected not only by the suppliers that provide the biologic and the biosimilars, but by the patients, their prescribing physicians, applicable public and private insurance coverage and the available indications for each drug option as approved by Health Canada.

[103] Some ustekinumab patients are covered by public health care insurance plans in each Canadian province and territory. Some patients have private insurance plans, for example through their employment, that reimburse a portion of the cost. Others receive the drug for free (for example, on compassionate grounds).

[104] Competition in the market for the supply of ustekinumab concerns physicians writing prescriptions for both new and existing patients – the latter at the important point when the existing STELARA patients may have to switch to another drug because STELARA is not longer listed on (i.e. is removed from) a public formulary in their province or is no longer covered by the patient's private insurance and is replaced by a biosimilar that is listed or covered. That is, to continue treatment with reimbursement, the patient must switch to a biosimilar. In 2024, provincial public formularies have announced different dates when they have listed biosimilars for coverage, and different dates for when STELARA would no longer be covered. The evidence on changes to private insurance companies' coverage affecting STELARA, Jamteki, FINLIUS and others is not clear in the record (although some plans may mirror public coverage).

[105] Further and as previously indicated, not all ustekinumab drugs have the same indications (i.e., Health Canada has not provided a NOC for all possible treatment uses). JAMP's Jamteki is not indicated for IBD – but STELARA and FINLIUS are. Considering the number of patients, rather than the number of units of ustekinumab supplied, IBD patients appear to represent more [redacted] Put another way,

[1] https://competition-bureau.canada.ca/how-we-foster-competition/education-and-outreach/position-statements/inquiry-alleged-anti-competitive-conduct-janssen

[2] https://competition-bureau.canada.ca/how-we-foster-competition/education-and-outreach/position-statements/completion-preliminary-investigation-relabelled-biologic-drugs

Jamteki does not currently compete in the entire market for the supply of ustekinumab in Canada.

(a) Alleged "gaming" of the regulatory system and "sham" litigation

[106] The Tribunal discussed threatened or actual "sham" litigation as anti-competitive acts in two prior decisions: *Canada (Director of Investigation & Research) v Laidlaw Waste Systems Ltd* (1992), 40 CPR (3d) 289 (Comp Trib) ("*Laidlaw*"), at pp. 343-344 (and see pp. 309-314); *Canada (Commissioner of Competition) v Tele-Direct Publications Inc* (1997), 73 CPR (3d) 1 (Comp Trib), at pp. 205-206. The Tribunal remarked in *Tele-Direct,* at page 205:

> "Sham" litigation, or litigation which the plaintiff knows is without foundation but uses to stifle or impair competition, can be a technique of predation. In the words of Robert Bork: "As a technique for predation, sham litigation is theoretically one of the most promising."

[107] On the nature of "sham" litigation, see also *Harris v GlaxoSmithKline Inc,* 2010 ONSC 2326, esp. at para 128 (aff'd 2010 ONCA 872, at para 55).

[108] Here, JAMP's position is that Janssen "gamed" the regulatory process by attempting to list an additional patent (the "837 Patent") on the patent register against STELARA, knowing that it would disincentivize a biosimilar manufacturer from launching a new competing drug, owing to either the delay from the automatic 24-month preclusion of an NOC under the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (if the patent were listed), or the possible liability for damages for patent infringement if the new competing drug were launched "at risk". STELARA's "extraordinary revenues" would put the biosimilar manufacturer in this case at risk of "catastrophic damages".

[109] JAMP alleges that (i) Janssen knew that the Minister of Health was "very unlikely" to accept the 837 Patent for listing as it was out of time; and (ii) after Janssen received an unfavourable decision, it unsuccessfully sought judicial review in the Federal Court and then unsuccessfully appealed to the Federal Court of Appeal, knowing that both were very unlikely to succeed. JAMP characterized these proceedings as litigation efforts that resulted in "predictable and total failure", but argued that Janssen succeeded in its actual competitive objective – to signal to biosimilar manufacturers not to attempt entry while the litigation was ongoing.

[110] Janssen denied these allegations but did not engage in much argument on this application to justify its regulatory filing or its litigation. Instead, it argued that JAMP's position was blocked by the terms of [redacted] and that as a factual matter, JAMP's argument had no merit because JAMP could not enter the market for the supply of ustekinumab drugs until it obtained an NOC and, as a result of events within its own control, JAMP did not obtain the NOC for Jamteki until November 8, 2023.

[111] I am not persuaded that JAMP's has adduced sufficient cogent evidence in this area for the purposes of a *bona fide* belief that the alleged anti-competitive acts could be part of a practice that could be subject to an order under paragraph 79(1)(*a*).

[112] First, JAMP's submissions on this application did not engage with the merits of either the patent list filing or the merits of Janssen's judicial review proceedings (including the Federal Court's 70-page reasons), to attempt to show that they were without foundation (or "doomed to fail" as JAMP claimed) and had no substantive merit on an objective basis: see the discussions in *Laidlaw, Tele-Direct* and *Harris,* above. JAMP's affidavit evidence characterized the OSIP decision as straightforward and the court decisions as deciding that Janssen's filing was out of time, but the courts' decisions were not as simple as that. JAMP made no submissions and adduced no evidence to support an argument that Janssen's filings or litigation raised JAMP's costs.

[113] Second, to lead the Tribunal to find that an order could be made under section 79, JAMP must also adduce sufficient evidence leading to a *bona fide* belief that the alleged "sham" litigation or misuse of the regulatory process had a negative exclusionary effect by delaying JAMP's entry into the market, or an adverse effect on competition in the same manner. Otherwise the allegedly anti-competitive act would not fall under section 78.

[114] However, there is no evidence of such delayed entry by JAMP. There are several important points to be made here. For one, as Janssen pointed out in its submissions, JAMP could not have entered the market for the supply of ustekinumab drugs until it received the NOC for Jamteki on November 8, 2023. JAMP's evidence confirmed that a biologic drug cannot not be marketed or sold in Canada without an NOC (among other things). There is also no suggestion in the evidence or JAMP's submissions that Janssen's regulatory filings or judicial review proceedings affected the timing of the issuance of the NOC for Jamteki, or that they delayed the timing of JAMP's filings that led to it. By the time the NOC was issued on November 8, 2023, the Federal Court had already issued its judicial review decision. The Federal Court of Appeal dismissed the appeal on November 21, 2023. Lastly, JAMP launched Jamteki on March 1, 2024, [redacted] in the Settlement and License Agreement – an agreement whose enforceability JAMP has not challenged.

[115] In this context, JAMP has not shown that any uncertainty or liability risk that may have existed arising from the alleged "sham" litigation or gaming of the regulatory system – whether or not a possible claim was barred by [redacted] in the Settlement and License Agreement – had any negative exclusionary effect, or any adverse effect on competition, due to JAMP's delayed entry into the market for the supply of ustekinumab drugs.

[116] For completeness on this second point, I am aware the Tribunal in *Laidlaw,* at p. 344, quoted a longer passage from American antitrust Professor Bork in *The Antitrust Paradox* (1978). The quotation includes the following:

> The predator need not expect to defeat entry altogether. He may hope only to delay it. Sham litigation then becomes a useful tactic against any size firm, regardless of relative reserves, for it may be worth the price of litigation to purchase a delay of a year or several years in a rival's entry into a lucrative market. In such cases, successful predation does not require that the predator be able to impose larger costs on the victim, that the predator have greater reserves than the victim, or that the predator have better access to capital than the victim. No other technique of predation is able to escape

> all of these requirements, and that fact indicates both the danger and the probability of predation by misuse of governmental processes.

[117] While JAMP did not refer to it, the passage does not assist JAMP to succeed on this application for the reasons stated immediately above. Of course, since Professor Bork's book in 1978, quoted in *Laidlaw* in 1992, there have also been plenty of developments in US antitrust law in this area: see e.g. D. Carson and S. Russell, "Circuits Reinforce Split over When Noerr-Pennington Shields Serial Litigants", *The Antitrust Source* (February 2021), 1-14.

[118] Accordingly, I am unable to conclude that JAMP has provided sufficient cogent evidence of anti-competitive acts in this area for the purposes of a *bona fide* belief that an order could be made under paragraph 79(1)(*a*) of the *Competition Act*.

(b) Alleged practice of anti-competitive acts for conduct related to FINLIUS

[119] JAMP also maintained that it should be granted leave to commence an application under section 79 owing to Janssen's acts or conduct related to FINLIUS. JAMP says that Janssen implemented the "playbook" developed for Remicade, with strategies to slow the diversion of patients away from STELARA to lower-priced biosimilars by creating uncertainty in the marketplace. First, it sought and obtained Health Canada approval for FINLIUS as a second labelled brand of ustekinumab. According to JAMP, Janssen did so deliberately after years of selling STELARA and used FINLIUS as a "fighting brand", by obtaining a NOC for FINLIUS just at the point when its competitors were seeking to introduce their biosimilars to patients, prescribers and public and private insurers, for the purpose of delaying the biosimilars' entry or impeding their expansion and eliminating them from the market. JAMP also proposes to allege in its section 79 application that:

(a) Janssen engaged in more "sham" litigation in the Federal Court, after attempting to list the 837 Patent on the patent register against FINLIUS, which Health Canada declined to permit.

(b) Janssen supplied FINLIUS at prices designed to be harmful to biosimilars attempting to attract new patients, which was either predatory pricing or rendered competitors unable to recoup their costs.

(c) Janssen provided STELARA [redacted] to existing patients so they would not switch to a biosimilar before FINLIUS (or Celltrion's Steqeyma) became available.

(d) Janssen made misleading communications to patients, prescribers and public and private insurers in ways that created uncertainty, leading to less switching and fewer new prescriptions.

[120] Alleged "sham" litigation related to FINLIUS: With respect to the second alleged "sham" litigation in the Federal Court, JAMP's position was that after attempting to list the 837 Patent on the patent register against FINLIUS, which the OSIP declined to permit, Janssen again sought judicial review of that decision by notice of application filed on April 26, 2023. In that proceeding, the parties agreed to a stay pending the outcome of the judicial review

application concerning STELARA, described above. The stay was implemented by order dated May 24, 2023. Janssen discontinued the proceeding on February 28, 2024.

[121] As with the other judicial review proceedings in the Federal Courts, JAMP has not explained why Janssen's judicial review application was "without foundation" or had no objective merit. In addition, there is no cogent, credible evidence of a negative exclusionary effect of this litigation or any uncertainty created by it, or of any adverse effect on competition. Janssen discontinued the judicial review on February 28, 2024, just before the March 1, 2024, launch date of Jamteki [redacted].

[122] **FINLIUS as a "fighting brand":** The anti-competitive act described in paragraph 78(1)(*d*) refers to the "use of fighting brands introduced selectively on a temporary basis to discipline or eliminate a competitor". Fighting brands have not been the subject of Tribunal decisions under sections 78-79. In competition circles, they are typically understood as described in the statute, with fighting brands introduced at low prices and marketed aggressively to drive one or more competitors out of a market, so that the main brand can continue selling at high prices. Any losses on the sales of the fighting brand are, over time, made up by later sales of the high-priced brand after the competitors are gone or their potency is hobbled and the fighting brand has been withdrawn.

[123] Most of JAMP's allegations about FINLIUS could not fall within paragraph 78(1)(*d*), as FINLIUS was not introduced into the market until July 2, 2024. JAMP does not suggest that it has been forced out of the market by FINLIUS after July 2, 2024 and does not detail FINLIUS's negative exclusionary impact in the three weeks before JAMP filed the present application in late July. There is insufficient cogent evidence on this application to support a *bona fide* belief that FINLIUS could be a "fighting brand" under paragraph 78(1)(*d*).

[124] **Predatory pricing allegations:** The anti-competitive act described in paragraph 78(1)(*i*) refers to selling articles at a price lower than the acquisition cost for the purpose of disciplining or eliminating a competitor. The Tribunal discussed pricing below acquisition cost in *NutraSweet*, at pp. 43-44. The Tribunal described predatory pricing in *Tele-Direct*, at p. 199:

> The essence of an allegation of predatory pricing is that the firm foregoes short-run revenues by cutting prices, driving out rivals and thus providing itself with the opportunity to recoup more than its short-term losses through higher profits earned in the longer term in the absence of competition. A predatory pricing allegation is difficult because, at least in the short-run, consumers apparently benefit from lower prices. In addition, predation can only succeed if the predator has greater staying power than its rivals and a reasonable prospect of recouping its losses.

[125] JAMP referred to Janssen's pricing of Remicade, but offered no direct evidence of Janssen selling FINLIUS at predatory prices. It relied on Janssen providing STELARA [redacted].

[126] There is insufficient credible and cogent evidence to ground a *bona fide* belief in a finding of predatory pricing of FINLIUS. FINLIUS was only launched for about three weeks

before JAMP filed this application for leave. It also appears not to have been priced [redacted] during that time. [see Faubert Affidavit, para 35; Williams affidavit, paras 15-16, 18 and Exhibits 12-14.]

[127] JAMP relied on Janssen supplying patients with [redacted] STELARA, albeit with little evidence in its initial filing. Mr Williams's responding affidavit advised that "[u]ntil Steqeyma becomes available in Canada, [Janssen] supplies STELARA free of charge to new patients prescribed STELARA without private insurance coverage or with public insurance that no longer covers STELARA." In its reply, JAMP pointed to Janssen's evidence that [redacted] of STELARA patients received it [redacted]. JAMP submitted that Janssen used its BioAdvance system as an opportunity to predate [redacted] of patients. Janssen submitted in its sur-reply, at paragraph 15, that JAMP's position was "speculative" and that supplying patients with [redacted] STELARA was not anti-competitive but was "pro-social".

[128] Some patients have received STELARA [redacted] on a compassionate basis through BioAdvance. We do not know when Janssen began providing STELARA [redacted] to some patients, and whether the numbers (or proportion) changed over time. A document produced in Janssen's responding evidence, relied upon by JAMP in reply, shows a snapshot of supply of STELARA [redacted] to IBD patients and other patients, as of June 21, 2024. At that time, about [redacted] of IBD patients, and (as JAMP identified) [redacted] of patients overall, received STELARA [redacted]. [See Williams affidavit, Exhibit 8.] However, it is hard to see how doing so <u>to IDB patients</u> could have had a negative exclusionary effect on JAMP because Jamteki <u>was not indicated for IBD</u>. [redacted]. A training deck dated February 2024 (four months earlier) shows that nearly the same proportion ([redacted] by the Tribunal's math) of IDB patients received STELARA [redacted] as of that time. [See Williams affidavit, Exhibit 11.] While there is very limited, "snapshot" evidence on this point (by patient, not by unit; and no evidence from before the launch of biosimilar products), the evidence does not show that Janssen was providing STELARA to IBD patients [redacted] in greater or increasing proportions in the period following the introduction of biosimilar competition in March 2024. While the evidence in this record does not exclude entirely the possibility that Janssen is providing [redacted] STELARA to some non-IBD patients temporarily until they can be prescribed FINLIUS, the evidence suggests that some (unknown) proportion of patients is receiving STELARA [redacted] on a compassionate basis. JAMP also did not identify evidence showing, for example, that Janssen's supply of free STELARA to non-IBD patients changed with the introduction of biosimilars. I note that Janssen's internal training decks and its communications to physicians advised that [redacted]. [For example, see Williams affidavit, Exhibits 11, 25.]

[129] I conclude that the evidence of Janssen's supply of STELARA to patients for [redacted] is not sufficient and cogent in this record to support a *bona fide* belief that these anti-competitive acts could be part of a practice that could be subject to an order under section 78 and paragraph 79(1)(*a*).

[130] Communications with physicians, insurers, patients: JAMP's position is that Janssen caused uncertainty and delayed competition by misusing its patient support system (BioAdvance), by (i) sending communications to prescribing physicians that were

"intentionally vague" about the existence of a ustekinumab "option" and whether FINLIUS was a new biosimilar that might be substituted for STELARA and covered by some public insurers (rather than a new relabelled brand of Janssen's ustekinumab/STELARA); (ii) telling "half-truths" to prescribing physicians and omitting information in communications to physicians: JAMP pointed to Janssen statements that there was no need to take any steps to move patients off STELARA to a biosimilar, as Janssen sought to keep patients enrolled in its BioAdvance patient care program until it launched FINLIUS or had a biosimilar to offer patient enrolled in BioAdvance; and (iii) using BioAdvance to make "insurance discovery" of new patients to steer them and their physicians towards a Janssen product. Although Janssen provided responding evidence of its presentation decks to train employees, JAMP also maintained that Janssen deliberately marketed its products verbally to avoid the creation of written records.

[131] Janssen firmly denied that it misled physicians about FINLIUS being a biosimilar and noted the absence of any direct evidence from any prescribing physician or any insurer to support JAMP's position. Janssen's position was in essence that the communications were competitively innocuous. To explain its statements about an ustekinumab "option", Janssen also referred to its then-confidential negotiations with Celltrion [redacted] to produce a biosimilar (which eventually became Steqeyma).

[132] JAMP's evidence included written communications from Janssen dated May 1 and May 7, 2024, to health care professionals in Ontario. Janssen's responding record included communications to or intended for prescribing physicians (including the same letters dated May 1 and May 7, 2024, and training materials for communications with prescribers) in the period of March to July 2024. Those communications refer to [redacted]. Some [redacted]: see e.g. [redacted] and Janssen letters to Ontario and Alberta health care professionals dated May 7, 2024 and to Quebec health care professionals dated May 28, 2024. [See Williams affidavit, Exhibits 10, 47, 48, 49, 50; Faubert affidavit, Exhibits F12, F13.] JAMP relied on this evidence in the aggregate to support its position on Janssen's anti-competitive purpose, showing that Janssen misled physicians and created uncertainty to delay switching.

[133] Despite filing vigorous submissions to advance its theory on anti-competitive acts, the evidence to support JAMP's position on these issues was very thin. It was mostly based on alleged omissions and vague statements that JAMP claims led to uncertainty in the minds of physicians or to no action by them to switch patients to Jamteki.

[134] There is no evidence on this application from any prescribing physicians advising that they were misled by the contents of Janssen's communications, or by any omission in them. An affidavit of one of JAMP's employees stated that she was advised by prescribers who received Janssen's communications dated May 1 and May 7, 2024, that Janssen representatives called physicians and advised verbally that the unnamed biosimilar or ustekinumab option would be FINLIUS. This statement was made in the affidavit on information and belief from an unknown number of physicians who are responsible for an unknown number of patients and their prescriptions. I agree with Janssen that this is not cogent evidence that physicians were

misled by Janssen, or that Janssen's purpose in the communications was anti-competitive (exclusionary).

[135] JAMP referred to some evidence that physicians declined to meet with its representatives, which it characterized as "unusual". This is not sufficient and cogent evidence of an anti-competitive act.

[136] JAMP raised arguments about Janssen's marketing to insurers. There was an example of an insurer publication (from Alberta Blue Cross in March 2024) that erroneously characterized FINLIUS as a biosimilar; but there is no direct evidence as to why that error occurred and whether the error can be tied back to something Janssen did, let alone did in a manner that would qualify as an anti-competitive act under section 78.

[137] JAMP referred to a form from another insurer that mentions FINLIUS and had a "date" of March 2024 in its bottom corner of the page, before Janssen began to market FINLIUS. Little can be made of this.

[138] JAMP argued in reply that one of Janssen's documents explained "out loud" its goal of monopolizing relationships with prescribers and patients, so that it can execute upon its exclusionary strategies. JAMP relied on Janssen's slogan ("ONE point of contact") and its objective of keeping patients within its BioAdvance program. I do not find this evidence to be the exclusionary "smoking gun" that JAMP characterizes it to be.

[139] JAMP contended that Janssen targeted FINLIUS to private insurers only, in an effort to reduce the scope of the contestable market. JAMP did not identify specific activities having an alleged negative exclusionary effect on it, or explain how any alleged anti-competitive acts would cause such a result. In any event, the evidence in this record is not sufficient to support that Janssen's decision to get FINLIUS on private insurer formularies, or its efforts to do so, constitute an anti-competitive act under section 78 (particularly when the contestable market in which Jamteki participates is already a subset of market for the supply of ustekinumab, because as mentioned previously, Jamteki is not indicated to treat the IBD conditions in a majority of patients that take ustekinumab).

[140] JAMP relied on an email from a physician about a communication to a patient. This evidence relates to a single patient's circumstances and does not show a pattern of communications to many patients.

[141] I appreciate that JAMP, both in this area and overall, is seeking to connect numerous points of evidence into a coherent picture. However, the evidence in the record, including of a negative exclusionary effect on JAMP, is insufficient to give rise to a *bona fide* belief that Janssen's behaviour could be anti-competitive acts under section 78 giving rise to a practice that could be subject to an order, for the purposes of subsection 103.1(7).

[142] The anti-competitive act in paragraph 78(1)(*j*): In 2022, Parliament added paragraph 78(1)(*j*) as an example of an anti-competitive act. It refers to "a selective or discriminatory response to an actual or potential competitor for the purpose of impeding or preventing the competitor's entry into, or expansion in, a market or eliminating the competitor from a market": see S.C. 2022, c. 10, subsection 261(2).

[143] JAMP did not explain in its submissions how or why the evidence supports a finding of "a selective or discriminatory response" by Janssen under paragraph 78(1)(*j*). Its initial submissions summarily referred to Janssen supplying FINLIUS at a selective and discriminatory price, and to the timing of its launch and pricing level relative to Jamteki and Wezlana's entry and pricing. JAMP's reply position referred to the timing of FINLIUS's approval and later launch at prices that [redacted] after the launch of biosimilars, to impede their expansion. JAMP referred to the absence of "transparent" prices and argued that there were inconsistencies in Janssen's responding evidence. I am unable to find that the evidence is sufficient to support JAMP's position under paragraph 78(1)(*j*).

[144] Conclusion on paragraph 79(1)(*a*): The analysis above leads to the conclusion that there is not sufficient, cogent evidence in this record to support a *bona fide* belief that Janssen's use of FINLIUS as a relabelled brand (in and of itself or in combination with the evidence of other alleged acts associated with FINLIUS) could be anti-competitive acts under section 78. The evidence does not sufficiently and cogently support a negative exclusionary effect on JAMP, or an adverse effect on competition, from Janssen's activities for the purposes of section 78 including paragraphs 78(1)(*d*), (*i*) and (*j*).

[145] Overall, for all the reasons above, I conclude that JAMP has not adduced sufficient cogent and credible evidence on this application for leave to support a *bona fide* belief that the alleged practice of anti-competitive acts could be subject to an order under paragraph 79(1)(*a*).

(4) Alleged conduct having the effect of an SLC/SPC for paragraph 79(1)(*b*)

[146] JAMP seeks to file an application under paragraph 79(1)(*b*) alleging that Janssen engaged in "conduct" that had, is having or is likely to have the effect of an SLC/SPC in a market and that the effect is not the result of superior competitive performance. Again, *B-Filer FCA, Symbol Technologies FCA* and the related Tribunal case law instruct that the question on this application for leave is whether there is sufficient credible and cogent evidence to support a *bona fide* belief that an order may be made under paragraph 79(1)(*b*).

[147] JAMP summarily argued that it had adduced sufficient evidence of an SLC/SPC. On substantial prevention of competition, JAMP submitted that but for Janssen's anti-competitive conduct, rival manufacturers would have launched biosimilars to STELARA earlier than March 2024, and a substantial portion of Janssen's $2.1 billion in sales of STELARA would have been lost (either in revenue diverted to biosimilar manufacturers, or as a result of price competition, or both). According to JAMP's submissions, this substantial portion of sales that would have been lost is an approximate quantification of the amount by which competition was prevented between August 9, 2021 and March 1, 2024, and was very substantial.

[148] JAMP also contended that Janssen's ongoing anti-competitive conduct has been lessening competition substantially since the launch of Jamteki. Its position was as follows. JAMP's demand forecast for Jamteki was based on biosimilar penetration rates in the drug adalimumab, which Janssen itself (through a speech by one of its senior officers) believes is the best proxy for the expected biosimilar penetration rate for STELARA. JAMP's actual revenues from the sale of Jamteki are far lower than forecast, and JAMP believes that Amgen's sales are similarly depressed. JAMP argued that Janssen caused these drastically lower

revenues and that they occurred despite the pricing of Jamteki and Amgen's Wezlana at a very significant discount to STELARA. JAMP claims that but for Janssen's anti-competitive conduct, JAMP and Amgen would have generated substantially greater sales than they have realized between March 1, 2024 and present, and a substantial portion of Janssen's sales in that period of time would have been lost (either in revenue diverted to JAMP or Amgen, or as a result of price competition, or both). Again, the loss of sales approximately quantified the lessening of competition beginning on March 1, 2024.

[149] The question for the Tribunal in assessing an SLC/SPC on this application is whether the applicant has adduced evidence to support a *bona fide* belief that but for Janssen's conduct, there would be substantially more competition in the relevant market (comparing, on a relative basis, the level of competition in the present world with the impugned practice against the level of competition in a hypothetical world in which the conduct did not occur). That is, one asks whether, on the evidence, the market would be substantially more competitive were it not for the impugned practice: *Toronto Real Estate Board v Canada (Commissioner of Competition)*, 2017 FCA 236, [2018] 3 FCR 563, at paras 82-92; *Tervita Corp v Canada (Commissioner of Competition),* 2015 SCC 3, [2015] 1 SCR 161, at paras 50-51. The analysis is typically done in two stages: a "but for" analysis, and a substantiality analysis: *VAA CT*, at paras 632-634. The focus on market power in an SPC case is on whether the impugned practice has preserved, is preserving or is likely to preserve any existing market power enjoyed by the dominant competitor, by preventing or impeding new competition that otherwise likely would have materialized in the absence of the impugned practice. In an SLC case, the focus is on whether the impugned practice has facilitated, is facilitating or is likely to facilitate the exercise of new or increased market power by the dominant competitor: *VAA CT*, at paras 635-638.

[150] There is insufficient cogent evidence before the Tribunal to raise a *bona fide* belief that Janssen's conduct could have had the effect of a SLC/SPC in the market for the supply of ustekinumab drugs.

[151] First, JAMP did not do much more than describe the alleged SPC in its submissions. It adduced no evidence to quantify any substantial effects in the market (or a material part of it) and made no submissions to address market power issues: *Tervita*, at para 64. (I am aware that an applicant under section 79 may adduce evidence of qualitative effects and is not required in law to quantify all effects that may be quantified: see *TREB FCA*, at paras 94-96, 99-101.)

[152] Second, while it is true that no biosimilar entered the market to compete with STELARA from August 2021 to until March 2024, it is also true that no biosimilar could enter the market for the supply of ustekinumab drugs before receiving an NOC from Health Canada. JAMP received a NOC for Jamteki on November 8, 2023. Amgen received a NOC for Wezlana on December 27, 2023. JAMP also entered the Settlement and License Agreement, that contemplated [redacted] and JAMP did not challenge the enforceability of that agreement. Both biosimilars launched that day.

[153] There is insufficient cogent evidence to support a *bona fide* belief that the alleged conduct had the effect of an SPC before March 1, 2024.

[154] I turn to the period after March 1, 2024.

[155] JAMP's evidence was that in 2023, Canadian sales for STELARA were about $912.8 million. It appears that STELARA was about $4,000 per dose and that after initial doses, patients receive four doses per year. JAMP adduced some evidence about mandatory switching for existing patients in the provinces' public plans, made in announcements during 2024. Required switching for existing patients varied from province to province, with phase-in periods. There was little in the record about mandatory switching requirements for patients covered by private insurance plans, which appears to be a larger proportion of the patients overall. The affidavit evidence did not include an estimate of the number of new patients to be treated with ustekinumab drug each month or each year. Each province also made announcements about the start of coverage for biosimilars to treat new patients.

[156] Evidence of possible effects of Janssen's conduct on JAMP as a competitor (new entrant) is not the same as evidence of the effect of the conduct on the relative competitiveness of the market for the supply of ustekinumab in Canada. The "but for" analysis for an SLC/SPC concerns a counterfactual involving the level of competitiveness in the market, or at least a material part of it – not the impact on one competitor. JAMP's evidence on this application focused on the alleged effects of Janssen's conduct since March 1, 2024, on its sales and ability to compete, rather than the effects on the market.

[157] Even on that narrower basis, any effects only concerned part of the overall market because JAMP's Jamteki is not indicated for IBD, which represents a majority of patients and a larger majority of delivered doses of ustekinumab in Canada. That is, Jamteki only competes for part of the overall market for the supply of ustekinumab. So any evidence of an effect that could go to an SLC/SPC would only concern a subset of the broader market.

[158] In addition, the quantified effect on JAMP in its evidence concerned sales that were [redacted] less than forecast and only related to three months in 2024.

[159] Further, there was no evidence from Amgen, the maker of Wezlana, on this application related to any alleged effects of Janssen's conduct that may have prevented it from achieving higher sales or inhibited or lessened its ability to compete. I appreciate that on JAMP's theory of anti-competitive conduct, Janssen's conduct would affect both new entrants the same way. However, its thesis is not evidence that the alleged conduct in fact affected Amgen's relative ability to compete in the same way it affected JAMP's, or at all.

[160] As noted, the effect of an SLC/SPC can be assessed and be substantial if it extends throughout a material part of the market: *VAA CT,* at para 640. However, JAMP made no submissions to that effect.

[161] I have noted the small quantified effect on a single competitor over three months in 2024. Any measurement of the substantiality of the effects of Janssen's conduct on the market would be affected by other significant factors that may affect substantiality, including the policies of public and private insurers such as the staggered starts or dates of mandatory switching away from STELARA to biosimilars in each province, and whether and when each biosimilar became listed on a provincial formulary or began to be covered by a private insurer. These factors were not the subject of any evidence to support a substantial effect. There was

also evidence that competition for existing patients is affected by different factors than competition for patients that are new to ustekinumab. [See Faubert affidavit, paragraph 8(b).]

[162] JAMP's position on conduct having the effect of an SLC/SPC affecting the market after March 1, 2024, is not sufficiently supported by the evidence in this record.

[163] For these reasons, I find that JAMP has not adduced sufficient cogent and credible evidence to support a *bona fide* belief that the conduct at issue could be subject to an order under paragraph 79(1)(*b*).

C. Was JAMP directly and substantially affected in its business by the impugned practice?

[164] For the purposes of subsection 103.1(7), JAMP submitted that all of Janssen's conduct has and continues to directly and substantially affect JAMP's ustekinumab and biosimilars business.

[165] JAMP's first position on direct and substantial effect was that its affected "business" is only its ustekinumab business. To JAMP, "business" in subsection 103.1(7) should be interpreted to equate to the language in section 79, which refers to a "class or species of business". According to JAMP, this approach would yield a more meaningful competition analysis in the determination of standing to commence a section 79 application. In the alternative, JAMP submitted that it has been directly and substantially affected in its biosimilars business, which would necessitate a factual inquiry under subsection 103.1(7) into whether and how Janssen's conduct affected JAMP's biosimilars business. JAMP did not advance a position that it was directly and substantially affected by the practice in its entire business.

[166] Subsection 103.1(7) requires an applicant to show both a direct and a substantial impact on the "applicant's business" by the reviewable practice. The provision does not refer to a "class or species of business", i.e., a particular product market, or to an impact on the applicant's participation or attempted participation in a specific product market, but instead to a direct and substantial impact on "the applicant's business". "[B]usiness" and "class or species of business" are not linguistically synonymous, nor is it required in this case to determine whether they are necessarily equivalent in this statutory context. In addition, there is already scope for a competition analysis on this application: subsection 103.1(7) includes both a requirement of the applicant being directly and substantially affected in its business by the reviewable practice at issue and also an assessment of whether an order could be made under section 79. Finally, the interpretation earlier in these Reasons of the "applicant's business" only found that for proposed section 79 proceedings, "business" does not necessarily mean "entire business". It does not follow from that analysis that the test for standing imports an understanding of "business" that only means "class or species of business".

[167] For present purposes, it is unnecessary to define the term "the applicant's business" or otherwise to refine the language of subsection 103.1(7). The Tribunal must ask: is the applicant directly and substantially affected in its business by a practice in section 79?

[168] For greater certainty, for the purposes of the analysis in this case, it is not necessary to decide whether the relevant "business" is JAMP's operating division, BioJAMP, or whether it would be sufficient to show that JAMP's participation in a product market was directly and substantially affected by the alleged reviewable practice.

[169] JAMP sought to quantify the allegedly substantial impact of the section 79 practice on its business. JAMP advised that it makes decisions whether to launch and market a new prescription drug on a drug-by-drug basis. For each drug it evaluates and then ultimately launches, JAMP prepares and maintains a separate demand forecast and profit and loss statement. It did so when it evaluated whether or not to launch an ustekinumab drug. JAMP's affidavit evidence explained and attached these two forecasts as evidence of how Janssen's conduct substantially affected its Jamteki business or, alternatively, the business in its BioJAMP division. [See Faubert affidavit, esp. paragraphs 21, 22, 36-40; Exhibits F6, F8.]

[170] JAMP's position was as follows:

(a) Jamteki did not meet the expected revenues in its demand forecast in the first quarter after launch (April to June 2024, ignoring the month of launch). Its revenues of less than [redacted] from actual prescriptions by physicians were far lower than the forecast of approximately [redacted], an underperformance of [redacted] JAMP contrasts this performance with the initial sales of its other biosimilar, Simlandi, over a similar time period. BioJAMP only sells two biosimilar products: Simlandi and Jamteki.

(b) JAMP forecast that once Jamteki penetrated the market for ustekinumab, capitalizing on its first mover advantage, it would generate approximately [redacted].

(c) JAMP forecast in its profit and loss statement that it would [redacted] after launch and make [redacted] in subsequent years.

(d) JAMP is concerned that should additional competitors enter the market for the sale of ustekinumab, it will adversely affect BioJAMP's capacity to win market share, its first mover advantage will be lost [redacted].

(e) if Janssen's conduct continues and Jamteki's actual performance remains on its current trajectory,

   i. the sales of Jamteki will [redacted] and BioJAMP will re-evaluate whether it is [redacted];

   ii. [redacted].

[171] Some of these positions arguing that JAMP's business was "substantially affected" can be addressed summarily. The claims in (c), (d) and (e) are too speculative to ground a finding of a direct and substantial impact on JAMP's business. Similarly, for the position in (b) immediately above, the impact of the section 79 practice on JAMP's "first mover" advantage is vague and supported by little evidence related to competition apart from the obvious fact that JAMP's product launched on March 1, 2024. JAMP was actually one of two entrants to the market for the supply of ustekinumab on March 1, 2024. JAMP also did not describe what it considers the point at which Jamteki had penetrated the market. I appreciate that early entry and expansion in a market may well yield positive outcomes for the entrant but on the evidence, JAMP's position in (b) does not lend anything solid to its substantial impact position.

[172] JAMP did not provide financial information about its BioJAMP division that could enable the Tribunal to find that this loss of expected sales was a substantial impact in the context of BioJAMP's quarterly or annual business.

[173] In its submissions, Janssen identified a material and salient concern about causation – whether the applicant has been directly and substantially affected in its business by the reviewable practice.

[174] Causation has been an issue in prior applications for leave under subsection 103.7(1): see, e.g., *CarGurus CT – II,* at paras 118 and following. Some cases have also identified the "but for" or relative analysis of direct and substantial impact: *CarGurus FCA,* at paras 31-35.

[175] In this case, JAMP identified a number of different but inter-connected alleged anti-competitive acts, over a long period of time, which together were said to constitute a "practice" of anti-competitive acts under paragraph 79(1)(*a*) and "conduct" under paragraph 79(1)(*b*). The question is whether that practice or conduct caused the alleged direct and substantial impact on JAMP's business – particularly the failure to meet the forecasted sales of Jamteki in April to June 2024.

[176] At a more granular level, the question is whether the practice alleged – the "sham" litigation, the "gaming" of the regulatory system, the use of FINLIUS as an alleged "fighting brand" and its supply at predatory prices, and the communications with prescribing physicians, public and private sector insurers and patients – caused the alleged substantial impact on JAMP's business through lower sales of Jamteki than JAMP forecasted for April to June 2024 because, owing to Janssen's behaviour, physicians did not switch their existing patients from STELARA to Jamteki, or did not prescribe Jamteki to new patients.

[177] As a result of the assessment in these Reasons, particularly in Parts IV.B. and IV.C. above, the alleged practice of anti-competitive acts and the conduct that has the alleged effect of an SLC/SPC are not sufficiently supported by the evidence for the Tribunal to be able to form a *bona fide* belief that the alleged practice could be subject to an order under section 79. JAMP has not met the requirement that it is directly and substantially affected in its business (however that business may be defined) by a practice that could be subject to an order under section 79.

[178] In addition, it is apparent that JAMP's business could not have been substantially affected by some of the alleged behaviour as claimed, because that behaviour occurred later in time than the alleged impact. FINLIUS was only launched in the market in early July 2024 – after the first quarter of sales results for Jamteki. Prescriptions for FINLIUS after July 2, 2024 for new patients or for existing STELARA patients could not have affected JAMP's prescription results for April to June. Nor could its pricing in July 2024 cause the identified effects in previous months.

[179] For these reasons, I find that JAMP's evidence does not give rise to a *bona fide* belief that it was directly and substantially affected in its business by the reviewable practice under section 79.

V. CONCLUSION

[180] The applicant has not met the test under subsection 103.1(7). The application for leave must be dismissed.

[181] Apart from requesting their costs if successful on this application for leave, the parties did not address costs in their submissions. The Tribunal is inclined to fix costs, if any, in an all-inclusive lump sum. The parties will have ten (10) days from the release of this Order and Reasons to make simultaneous submissions on both entitlement to and quantum of costs, by letters not to exceed three (3) pages in length.

FOR THESE REASONS, THE TRIBUNAL ORDERS THAT:

[182] The application for leave under subsection 103.1 to commence a proceeding under section 79 is dismissed.

[183] An order as to costs will be made following receipt of the parties' submissions.

[184] Janssen's request to file sur-reply representations is dismissed, with the exception of paragraph 15 of its proposed representations. Janssen does not need to file representations containing only paragraph 15. JAMP's sur-sur-reply is not accepted for filing.

DATED at Ottawa, this 20th day of November, 2024

SIGNED on behalf of the Tribunal by the Chairperson.

(s) Andrew D. Little

COUNSEL OF RECORD:

For the applicant:

JAMP Pharma Corporation

Andrew Brodkin
David Rosner
Jordan Scopa
Jonathan Wall
Arash Rouhi

For the respondent:

Janssen Inc.

Robert Kwinter
Nicole Henderson
Cathy Beagan Flood
Jonathan Bitran
Brian Facey
Joe McGrade

APPENDIX A

Competition Act, RSC 1985, c C-34

Abuse of Dominant Position	Abus de position dominante
Definition of *anti-competitive act*	**Définition de *agissement anti-concurrentiel***
78 (1) For the purposes of section 79, ***anti-competitive act*** means any act intended to have a predatory, exclusionary or disciplinary negative effect on a competitor, or to have an adverse effect on competition, and includes any of the following acts:	**78 (1)** Pour l'application de l'article 79, ***agissement anti-concurrentiel*** s'entend de tout agissement destiné à avoir un effet négatif visant l'exclusion, l'éviction ou la mise au pas d'un concurrent, ou à nuire à la concurrence, notamment les agissements suivants :
(a) squeezing, by a vertically integrated supplier, of the margin available to an unintegrated customer who competes with the supplier, for the purpose of impeding or preventing the customer's entry into, or expansion in, a market;	**a)** la compression, par un fournisseur intégré verticalement, de la marge bénéficiaire accessible à un client non intégré qui est en concurrence avec ce fournisseur, dans les cas où cette compression a pour but d'empêcher l'entrée ou la participation accrue du client dans un marché ou encore de faire obstacle à cette entrée ou à cette participation accrue;
(b) acquisition by a supplier of a customer who would otherwise be available to a competitor of the supplier, or acquisition by a customer of a supplier who would otherwise be available to a competitor of the customer, for the purpose of impeding or preventing the competitor's entry into, or eliminating the competitor from, a market;	**b**) l'acquisition par un fournisseur d'un client qui serait par ailleurs accessible à un concurrent du fournisseur, ou l'acquisition par un client d'un fournisseur qui serait par ailleurs accessible à un concurrent du client, dans le but d'empêcher ce concurrent d'entrer dans un marché, dans le but de faire obstacle à cette

entrée ou encore dans le but de l'éliminer d'un marché;

(c) freight equalization on the plant of a competitor for the purpose of impeding or preventing the competitor's entry into, or eliminating the competitor from, a market;

c) la péréquation du fret en utilisant comme base l'établissement d'un concurrent dans le but d'empêcher son entrée dans un marché ou d'y faire obstacle ou encore de l'éliminer d'un marché;

(d) use of fighting brands introduced selectively on a temporary basis to discipline or eliminate a competitor;

d) l'utilisation sélective et temporaire de marques de combat destinées à mettre au pas ou à éliminer un concurrent;

(e) pre-emption of scarce facilities or resources required by a competitor for the operation of a business, with the object of withholding the facilities or resources from a market;

e) la préemption d'installations ou de ressources rares nécessaires à un concurrent pour l'exploitation d'une entreprise, dans le but de retenir ces installations ou ces ressources hors d'un marché;

(f) buying up of products to prevent the erosion of existing price levels;

f) l'achat de produits dans le but d'empêcher l'érosion des structures de prix existantes;

(g) adoption of product specifications that are incompatible with products produced by any other person and are designed to prevent his entry into, or to eliminate him from, a market;

g) l'adoption, pour des produits, de normes incompatibles avec les produits fabriqués par une autre personne et destinées à empêcher l'entrée de cette dernière dans un marché ou à l'éliminer d'un marché;

(h) requiring or inducing a supplier to sell only or primarily to certain customers, or to refrain from selling to a competitor, with the object of preventing a competitor's entry into, or expansion in, a market;

h) le fait d'inciter un fournisseur à ne vendre uniquement ou principalement qu'à certains clients, ou à ne pas vendre à un concurrent ou encore le fait d'exiger l'une ou l'autre de ces attitudes de la part de ce fournisseur, afin d'empêcher l'entrée ou la

participation accrue d'un concurrent dans un marché;

(i) selling articles at a price lower than the acquisition cost for the purpose of disciplining or eliminating a competitor;

i) le fait de vendre des articles à un prix inférieur au coût d'acquisition de ces articles dans le but de discipliner ou d'éliminer un concurrent;

(j) a selective or discriminatory response to an actual or potential competitor for the purpose of impeding or preventing the competitor's entry into, or expansion in, a market or eliminating the competitor from a market; and

j) la réponse sélective ou discriminatoire à un concurrent actuel ou potentiel, visant à entraver ou à empêcher l'entrée ou l'expansion d'un concurrent sur un marché ou à l'éliminer du marché;

(k) directly or indirectly imposing excessive and unfair selling prices.

k) l'imposition directe ou indirecte de prix de vente excessifs et injustes.

Prohibition if abuse of dominant position

79 (1) On application by the Commissioner or a person granted leave under section 103.1, if the Tribunal finds that one or more persons substantially or completely control a class or species of business throughout Canada or any area of Canada, it may make an order prohibiting the person or persons from engaging in a practice or conduct if it finds that the person or persons have engaged in or are engaging in

Ordonnance d'interdiction : abus de position dominante

79 (1) Lorsque, à la suite d'une demande du commissaire ou d'une personne autorisée en vertu de l'article 103.1, il conclut qu'une ou plusieurs personnes contrôlent sensiblement ou complètement une catégorie ou espèce d'entreprises à la grandeur du Canada ou d'une de ses régions et adoptent ou ont adopté une pratique ou un comportement ci-après, le Tribunal peut rendre une ordonnance leur interdisant d'adopter la pratique ou le comportement :

(a) a practice of anti-competitive acts; or

a) une pratique d'agissements anti-concurrentiels;

(b) conduct

b) un comportement qui a, a eu ou aura vraisemblablement

(i) that had, is having or is likely to have the effect of preventing or lessening competition substantially in a market in which the person or persons have a plausible competitive interest, and	pour effet d’empêcher ou de diminuer sensiblement la concurrence dans un marché dans lequel la personne ou les personnes ont un intérêt concurrentiel valable, cet effet ne résultant pas d’un rendement concurrentiel supérieur.
(ii) the effect is not a result of superior competitive performance.	
[…]	[…]