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COMPETITION TRIBUNAL
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August 15, 2024

Via Email

OTTAWA, ONT.

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The Honourable Andrew D. Little
Chair, Competition Tribunal
Thomas D'Arcy McGee Building
90 Sparks Street, Suite 600
Ottawa, ON K1P 5B4

Dear Justice Little:

Re: Informal Motion re Responding Evidence and Extension of Time in *JAMP Pharma Corporation v Janssen Inc.* – CT-2024-006 (the “Proceeding”)

We are counsel to JAMP Pharma Corporation (“**JAMP**”) in the Proceeding and are submitting this letter in opposition to the motion of Janssen Inc. (“**J&J**”) for leave to submit responding affidavit evidence and for an extension of time to deliver J&J’s responding materials.

JAMP attempted to cooperate with J&J to facilitate the timely briefing of this motion (so that a decision could issue before the deadline for J&J’s responding materials) and to accommodate a reasonable extension of time for the delivery of J&J’s responding materials. JAMP proposed a schedule that would have permitted the motion to be fully briefed by Friday, August 16 and proposed to extend the deadline for J&J’s responding materials by seven days from the later of the existing deadline (August 21) or the date of this Tribunal’s decision on this motion.

J&J elected to ignore JAMP and go its own way by delaying the delivery of its motion and requesting an unprecedented extension of time that would provide it with 45 days to prepare its responding materials from the notice under s. 103.1(5) (and 52 days from the date of service). In any litigation in any forum, 52 days is a lifetime. Before this Tribunal and its expedited procedures, it is an eternity. J&J’s transparent strategy of delay serves its goal of continued uncertainty in the ustekinumab market and the maintenance of its dominant position.

Despite these delay tactics, given the great haste in JAMP’s delivery of this response, hope for a decision before the deadline for delivery of J&J’s responding materials remains. Further, if the Tribunal is mindful to grant an extension, JAMP continues to be agreeable to the aforementioned extension, which would result in a minimum of 29 days for J&J to prepare its response from the date of service. Any longer delay would clearly not be in the interests of justice.

I. The Law.

Section 103.1(6) of the *Competition Act* (the “**Act**”) provides that “a person served with an application for leave may, within 15 days after receiving notice under subsection (5), make representations to the Tribunal...” Rule 119 of the *Competition Tribunal Rules* (the “**Rules**”) also provides for a 15 day deadline and specifies that the responding “representations in writing shall not contain affidavit evidence, except with leave of the Tribunal.” Rule 5 provides that time limits in the Rules may only be extended by an order or direction of a judicial member.

The Tribunal has considered whether to permit responding or reply evidence in a section 103.1 proceeding under the Rules in three decisions.¹ In summary, the Tribunal held:

1. Respondents are only permitted to file written representations. The filing of affidavit evidence by a respondent is the exception, subject to the discretion of the Tribunal.²
2. It is the burden of the respondent to demonstrate the existence of specific facts and circumstances justifying the filing of affidavit evidence.³ Those facts and circumstances must focus on the actual issues to be determined by the Tribunal. While the Tribunal has explained that such issues include all elements of the test for leave under section 103.1(7), the Tribunal also provided more specific guidance to suggest that the responding evidence can only be submitted in relation to the elements of the reviewable trade practice at issue in the case (section 79, in this case).⁴ The Tribunal has never accepted responding evidence as to whether an applicant has been directly and substantially affected.
3. The motion should set out, in as much detail as possible, the discrete facts and specific evidence the respondent wishes to include in the proposed affidavit. In this regard, the Tribunal has observed that the filing of a draft affidavit would be helpful. The motion must also indicate how each discrete fact or specific evidence to be filed is necessary to the written representations and would be of assistance to the Tribunal in its screening function.⁵
4. In exercising its discretion, the Tribunal must bear in mind that a s. 103.1 application is a screening process meant to be decided expeditiously and not on the basis of a full evidentiary record.⁶ The filing of wide-ranging evidence aiming to provide a full

¹ *Audatex Canada, ULC v. CarProof Corporation*, [2015 Comp. Trib. 13](#) [*Audatex Affidavit Order*]; *Audatex Canada, ULC v. CarProof Corporation*, [2015 Comp. Trib. 28](#) [*Audatex Leave Decision*]; and *CarGurus, Inc v Trader Corporation*, [2016 Comp. Trib. 12](#) [*CarGurus Affidavit Order*].

² *Audatex Affidavit Order*, para. 13.

³ *Audatex Affidavit Order*, para. 16.

⁴ *Audatex Affidavit Order*, para. 17 and *CarGurus Affidavit Order*, paras. 13 and 14.

⁵ *Audatex Affidavit Order*, para. 17 and *Audatex Leave Decision*, para. 40.

⁶ *Audatex Affidavit Order*, para. 16.

evidentiary record would not be in the interests of justice and could be expected to lengthen the leave application process, to the detriment of the applicant.⁷

Separately, both the *Competition Tribunal Act* and the Federal Court of Appeal recognize that proceedings before the Tribunal, including s. 103.1 applications, are to be decided expeditiously.⁸

II. J&J's Application to File Responding Affidavit Evidence Should be Rejected.

J&J's application to file responding affidavit evidence should be rejected *in toto*. J&J seeks leave to introduce evidence about *eight* individual topics, which exceeds the number of topics sought to be introduced by a single respondent in any prior case.⁹ J&J's proposed evidence – which it says is needed to “paint an accurate picture of competition” – is in the nature of the “wide-ranging evidence” that the Tribunal has previously indicated it will not permit. J&J's application should therefore be rejected. Moreover:

1. J&J has failed to discharge its burden to explain how the four individual topics in Sections II.b and II.c of its motion are related to the individual elements in section 79. As noted, the Tribunal has never permitted responding evidence as to whether an applicant has been directly and substantially affected (and the topic in Section II.c does not even relate to that).
2. J&J has failed to discharge its burden to explain how the eight individual topics are either necessary to the written representations it intends to make, or would be of assistance to the Tribunal in its screening function. J&J merely asserts that “it is in the interests of justice that [J&J's eight topics] be before the Tribunal as it exercises the screening function.” This bare effort cannot be enough to discharge a burden or engage the Tribunal's discretion.
3. J&J has provided little detail about the scope of the facts it seeks to adduce in evidence. Notably, J&J has not provided the Tribunal with a draft affidavit(s), which will make it challenging for the Tribunal to draft a narrow and specific order regarding which evidence might be permitted. This dynamic sets the stage for further arguments among the parties on whether evidence is properly permitted, and may cause further delay.

The Tribunal should not be put to the burden of closely examining each of J&J's eight requests individually – doing so would improperly relieve J&J of its burden. However, if the Tribunal is inclined to review the topics individually, then JAMP's submissions as to why J&J should not be permitted to file affidavit evidence about each topic are contained in the Appendix.

⁷ *Audatex Affidavit Order*, para. 19.

⁸ *Competition Tribunal Act*, [R.S.C., 1985, c. 19](#) at s. 9(2) [*Tribunal Act*] and *Symbol Technologies Canada ULC v. Barcode Systems Inc.*, [2004 FCA 339](#) at para. 19 [*Symbol Technologies*].

⁹ *Audatex Affidavit Order*, at paras. 20 and 21 (six topics for CarProof and two for MarketPlaats); *Audatex Leave Decision*, at paras. 37 and 39 (permitting reply evidence for only the topics that the respondents provided evidence in respect of, but not another topic); and *CarGurus Affidavit Order*, at paras. 17 to 22 (five topics).

III. J&J's Application for an Extension of Time Should Be Rejected.

J&J seeks an extension of time under Rule 119 to file its response. The Tribunal ought to reject J&J's request for the following reasons:

1. J&J argues that it requires additional time because "several key personnel" are not available due to pre-planned summer holidays. There is no "time of year" exception to the Federal Court of Appeal's requirement that applications be decided expeditiously or the Act's timing requirements.¹⁰ In addition, J&J does not identify the personnel (or its affiant), explain why those individuals are necessary to preparing its response, or provide any details of their holidays. J&J makes a bare assertion only. That a handful of unnamed vacationing personnel (and no one else) would be capable of addressing the specific topics noted in J&J's letter defies belief, especially for a company of J&J's size. J&J's argument about its vacationing personnel makes no attempt to account for the interests of justice (which is required by *Audatex Affidavit Order* and *CarGurus Affidavit Order*).
2. J&J argues that this application is not urgent. However, all applications, whether "urgent" or not, are to be decided expeditiously according to the Act's mandatory schedule.¹¹
3. J&J's characterization of events between JAMP and J&J between the end of May and late July only underscores the urgency of this application. As JAMP's application shows, J&J goes to great lengths to obfuscate its conduct and create confusion in the marketplace. JAMP worked quickly to marshal evidence of J&J's conduct and prepare an application.
4. J&J's argument that JAMP's July filing means that this matter is not urgent is a misunderstanding of how s. 103.1(7) operates. Most of the effects that JAMP experienced to date (which are necessary to demonstrate that JAMP has been substantially affected under s. 103.1(7)) occurred in June and July. The Act requires that an applicant wait until it has been substantially affected before commencing an application. The urgency of JAMP's application increases over time as JAMP suffers detriment from further delay.
5. As noted at the outset, J&J's request for an extension until September 20, whether it wins or loses this motion, is unprecedented and unjustifiable. Such an extension would afford J&J 45 days from the notice under s. 103.1(5) of the Act, which is three times longer than the Act permits. We can find no record of the Tribunal permitting an extension of this length in similar circumstances.¹² Moreover, J&J waited to bring this motion until the

¹⁰ *Symbol Technologies* at para. 19 and [Competition Act](#) at s. 103.1(6).

¹¹ *Symbol Technologies* at para. 19 and [Competition Act](#) at s. 103.1(6).

¹² For example, in *Audatex Affidavit Order*, the Tribunal did not make a specific order on timing, but the [publicly accessible record](#) shows that the respondents filed their responses 23 days after the notice under section 103.1(5) and seven days after the order permitting the filing of responding evidence. The timing for filing a response in *CarGurus Affidavit Order* was longer, but that timing was agreed by the parties (it was not ordered by the Tribunal).

evening of August 13, which, absent JAMP's great haste in providing this response, would have rendered it impossible for the Tribunal to issue an order well in advance of the Act's mandated August 21 deadline.¹³ Such delay is particularly troubling given that J&J was served with the application on July 30 (14 days before the bringing of this motion)¹⁴ and did not submit a draft affidavit with its motion (which would have helped the Tribunal to rule more efficiently and permitted J&J to finalize its response promptly after the Tribunal's decision). In the circumstances, no matter what the Tribunal's decision is on this motion, J&J should not be able to benefit from its own delay in bringing this motion. If the Tribunal is nevertheless mindful to grant any extension, it ought to be no longer than the seven day extension previously offered by JAMP.

Costs of This Motion Should be Awarded to JAMP in All Circumstances.

Given that: (i) J&J's motion seeks leave to introduce wide-ranging evidence (which is not permissible), and (ii) J&J delayed bringing this motion, which, absent JAMP's great haste in responding, would have made it impossible for the Tribunal to issue an order well in advance of the Act's mandated August 21 deadline, JAMP respectfully submits that, no matter the outcome of this motion, JAMP should be awarded its costs.

* * *

We are available to address any questions you may have about the foregoing.

Yours truly,

Goodmans LLP

David Rosner

cc: Andrew Brodtkin, Jordan Scopa, Jon Wall and Arash Rouhi – *Goodmans LLP*
Robert Kwinter, Cathy Beagan Flood, Nicole Henderson, Jonathan Bitran and Brian Facey
– *Blake, Cassels & Graydon LLP*

¹³ In correspondence among counsel, JAMP encouraged J&J to bring this motion promptly and indicated a willingness to agree to a seven-day extension for the filing of J&J's response if J&J did so. JAMP's goal was that this motion be fully briefed by Friday, August 16. J&J rejected this offer. A copy of that correspondence is enclosed.

¹⁴ Section III of J&J's motion states that J&J was not served until August 1, which is incorrect. See the Affidavit of Service of Jon Wall dated July 30, 2024 (filed with the Tribunal that same day).



Appendix: JAMP's Responses to J&J's Eight Individual Topics for Responding Affidavit Evidence

J&J's Individual Topics	JAMP's Responses
1. Finlius is not a "fighting brand" and was not introduced for reasons relating to patent litigation.	<ul style="list-style-type: none"> • Whether Finlius is a "fighting brand" (and thus an anti-competitive practice) is at the heart of the dispute. This is not an issue that can be determined at the section 103.1 leave application stage, which instead merely assesses whether there is sufficient credible evidence to give rise to a <i>bona fide</i> belief that the applicant may have been directly and substantially affected in its business by the practice, and the practice in question could be subject to an order. • J&J does not explain why information on this topic is necessary to J&J's written representations, or how this information will assist the Tribunal.
2. Pricing of Stelara and Finlius is comparable to biosimilar alternatives.	<ul style="list-style-type: none"> • JAMP has alleged that J&J's pricing has been both predatory and selective and discriminatory, which are anti-competitive practices. Whether such pricing is contrary to the Act is at the heart of the dispute. Once again, this is not an issue that can be determined at the section 103.1 leave application stage (see Item 1, above). • J&J does not explain why information on this topic is necessary to J&J's written representations, or how this information will assist the Tribunal.
3. Janssen did not mislead anyone about Finlius or its BioAdvance patient support program.	<ul style="list-style-type: none"> • Whether J&J has misled health care professionals and patients (and whether misleading statements constitute an anti-competitive practice) is at the heart of the dispute. Once again, this is not an issue that can be determined at the section 103.1 leave application stage (see Item 1, above). • J&J asserts that evidence on this topic is necessary to respond to one of the requested orders in the s. 79 application, but that requested order is not at issue in a s. 103.1 leave application (it would only be at issue at the remedy stage of a s. 79 application). In a 103.1 leave application, the Tribunal's only ability is to grant leave to make an application under s. 79. • J&J does not explain why information on this topic is necessary to J&J's written representations on the test under s. 103.1, or how this information will assist the Tribunal.
4. NDA claims are false.	<ul style="list-style-type: none"> • J&J's characterization of JAMP's allegation is inaccurate. JAMP asserts that J&J has used a variety of means to pressure healthcare professionals not to accept or consider marketing from biosimilar manufacturers, one of which is to pressure healthcare professionals that participate in its advisory boards (who are commonly required to enter into NDAs). See paragraph 11 of the Faubert Affidavit and paragraphs 123 to 125 of the Memorandum of Fact and Law. As a result, whether or not J&J has NDAs with health care professionals will not refute JAMP's broader allegation. J&J makes no assertion that it will lead evidence about the contractual restrictions (and their enforcement) on health care professionals who participate on its ustekinumab advisory board. • J&J does not explain why information on this topic is necessary to J&J's written representations, or how this information will assist the Tribunal.
5. Jamteki is not indicated for the majority of ustekinumab patients.	<ul style="list-style-type: none"> • The facts J&J wishes to introduce are already in evidence. The indications for Stelara and Finlius are included in the product monographs, filed as Exhibits J9 and J26 to the Juneja Affidavit. The relative proportions of patients who use ustekinumab for each indication is included in the demand forecast filed as Exhibit F6 to the Faubert Affidavit (see, for example, tab "Forecast Usteki Year 1" at cells A55 to F68, describing the usage of ustekinumab in different formats and for different indications). That demand forecast also makes clear that Jamteki is indicated for only a subset of Stelara's indications.

J&J's Individual Topics	JAMP's Responses
	<ul style="list-style-type: none"> J&J does not explain how this information is relevant to any element of section 79, why information on this topic is necessary to J&J's written representations, or how this information will assist the Tribunal.
<p>6. Stelara is being delisted from public formularies and Finlius is only available to private payors</p>	<ul style="list-style-type: none"> Many of the facts that J&J wishes to introduce are already in evidence. The ustekinumab-specific policies of the different provincial and territorial drug formularies are described at paragraphs 18 – 26 of the Radeva Affidavit, and the underlying documents are found in Exhibits R5 to R19 of the Radeva Affidavit. J&J's assertions about Stelara and Finlius are at the heart of the dispute. Once again, this is not an issue that can be determined at the section 103.1 leave application stage (see Item 1, above). J&J does not explain how this information is relevant to any element of section 79, why information on this topic is necessary to J&J's written representations, or how this information will assist the Tribunal.
<p>7. JAMP's comparison to Simlandi is misleading.</p>	<ul style="list-style-type: none"> Whether biosimilar penetration rates for Humira (for which Simlandi is a biosimilar) are a good comparator to Stelara is not something that the Tribunal is to determine at the section 103.1 leave application stage. Once again, the Tribunal's duty at the section 103.1 leave application stage is simply to assess whether there is sufficient credible evidence to give rise to a <i>bona fide</i> belief that the applicant may have been directly and substantially affected in its business by the practice, and the practice in question could be subject to an order. J&J's own CFO has pointed to Humira as the best comparator for Stelara (see para. 35 of JAMP's Memorandum of Fact and Law) – this is clearly credible evidence that the comparison is appropriate. J&J does not explain how this information is relevant to any element of section 79, why information on this topic is necessary to J&J's written representations, or how this information will assist the Tribunal.
<p>8. Janssen will introduce into evidence [REDACTED] and argue that JAMP is barred from making certain allegations.</p>	<ul style="list-style-type: none"> J&J does not explain how this information is relevant to any element of the test under section 103.1(7), why information on this topic is necessary to J&J's written representations regarding section 103.1(7), or how this information will assist the Tribunal in its screening function under section 103.1(7). J&J's contention that JAMP is barred from bringing "many of its claims" is denied by JAMP. [REDACTED] he Tribunal's jurisdiction is limited to those matters that are prescribed in s. 8 of the <i>Competition Tribunal Act</i>. Somewhat similar wide-ranging evidence from other litigation was specifically rejected in <i>CarGurus Affidavit Order</i> at para. 17 to 21.