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VIA E-MAIL

Competition Tribunal
Thomas D'Arcy McGee Building
90 Sparks Street, Suite 600
Ottawa, ON K1P 5B4

Dear Registrar:

RE: *JAMP Pharma Corporation v. Janssen Inc.* – File No. CT-2024-006

We are counsel to Janssen Inc. in the above-captioned application by JAMP Pharma Corporation pursuant to section 103.1 of the *Competition Act* (the "**Act**")[1] seeking leave to bring an application against Janssen under section 79 of the Act (the "**Leave Application**").

This letter is intended to serve as an informal motion by Janssen, seeking an order from the Tribunal that Janssen be granted: i) leave to file affidavit evidence as part of Janssen's responding representations to the Leave Application; and ii) an extension of the deadline to deliver Janssen's responding materials, including the affidavit evidence, until September 20, 2024.

I. The Test for Leave to File Responding Evidence in an Application for Leave

Rule 119(3) of the *Competition Tribunal Rules* (the "**Rules**")[2] gives the Tribunal discretion to permit a respondent to file affidavit evidence as part of its representations opposing an application for leave.[3] The Tribunal has permitted such evidence where: i) the proposed evidence is relevant to the test for leave under section 103.1 of the Act; ii) it addresses discrete issues and is not part of an effort to adduce wide-ranging evidence; and iii) it is in the interests of justice to do so, having regard to the summary nature of leave applications.[4]

On the Leave Application, the Tribunal must decide whether JAMP has led sufficient credible evidence to give rise to a bona fide belief that it may have been directly and substantially affected in its business by a reviewable practice, and that the practice in question could be subject to an order.[5] While this is a

[1] R.S.C. 1985, c. C-34.
[2] SOR/2008-141
[3] Janssen sought JAMP's consent to the filing of affidavit evidence, which it refused.
[4] *Audatex Canada, ULC v CarProof Corporation*, 2015 CACT 13 at paras 16-19 ["*Audatex*"].
[5] *Symbol Technologies Canada ULC v. Barcode Systems Inc.*, 2004 FCA 339 at para 16 ["*Symbol Technologies*"].

lower standard than proof on a balance of probabilities, the Tribunal must still consider whether there is sufficient credible evidence regarding all elements of the alleged reviewable practice.[6]

As detailed below, Janssen's proposed evidence will contain specific facts that are relevant to whether the alleged conduct could be subject to an order under section 79 of the Act. In particular, it will address specific allegations made in JAMP's Leave Application based on speculation and/or hearsay, which Janssen's evidence will demonstrate are simply false or misleading. Many of the relevant facts are in the exclusive knowledge of Janssen and it is in the interests of justice that they be before the Tribunal as it exercises the screening function. While Janssen broadly denies the allegations and the economic and legal theories contained in the Leave Application, the proposed responding evidence focuses on facts that are material to the leave test, for which it is essential that the Tribunal have an accurate factual record before it.

II. Janssen's proposed evidence

Janssen's proposed evidence is directly relevant to whether: i) Janssen has engaged or is engaging in anticompetitive acts within the meaning of section 79 of the Act as alleged in the Leave Application; or ii) JAMP's business could have possibly been directly and substantially affected by those alleged acts (which are denied).

Janssen's evidence will also demonstrate that many of JAMP's claims cannot be subject to an order of the Tribunal, as such claims are barred [redacted].

a. Janssen has not engaged in any anticompetitive acts

Much of the conduct that JAMP alleges in the Leave Application simply has not occurred. JAMP's allegations are based on speculation, unreasonable inferences drawn from limited documentary evidence, and inaccurate hearsay. Janssen seeks leave to adduce evidence on the following points to demonstrate that JAMP's allegations cannot give rise to a *bona fide* belief that Janssen has engaged in reviewable practices.

- Finlius is not a "fighting brand" and was not introduced for reasons relating to patent litigation. Janssen will introduce evidence that Finlius was introduced as [redacted].

- Pricing of Stelara and Finlius is comparable to biosimilar alternatives. Confusingly, JAMP alleges both that Janssen has not lowered the price of Stelara in response to the introduction of biosimilars and that Janssen is engaging in predatory pricing with respect to Finlius. Both are simply untrue. Janssen's proposed evidence will explain that as a competitive response to the introduction of ustekinumab biosimilars, [redacted]

[6] *Symbol Technologies, supra* at para 18.

[redacted].[7]

- Janssen did not mislead anyone about Finlius or its BioAdvance patient support program. JAMP alleges, without any direct evidence, that Janssen misled physicians, private insurers, and patients in an effort to prevent or delay switching to biosimilars by stating that Finlius was a biosimilar to Stelara. This is untrue, and entirely inconsistent with Janssen's marketing and communications strategies concerning Finlius. Finlius is not, and Janssen has never represented it to be, the biosimilar option in the BioAdvance program. [redacted].

  The BioAdvance program will, in fact, support patients who are prescribed an ustekinumab biosimilar option, [redacted], and the communication scripts and training provided to its salesforce and BioAdvance coordinators regarding Finlius and the introduction of a third-party ustekinumab biosimilar to the BioAdvance patient support program. Moreover, this evidence relating to [redacted] is necessary in light of JAMP's request for orders prohibiting Janssen from offering a biosimilar through BioAdvance or communicating with third parties about a biosimilar being supported through BioAdvance —practices that could not be subject to an order as doing so would inhibit competition among biosimilars.

- NDA claims are false. JAMP alleges, without any evidence, that Janssen has non-disclosure agreements with prescribers that prohibit them from communicating with sales representatives of competitors. This is patently false, and Janssen will provide clear and unequivocal direct evidence to the contrary.

b. JAMP could not have been directly and substantially affected

JAMP's claims regarding the effects of Janssen's alleged conduct (which is denied) do not paint an accurate picture of the competition between Stelara, Finlius, and biosimilars, or the public and private insurance landscape. Janssen will provide evidence demonstrating that:

- Jamteki is not indicated for the majority of ustekinumab patients. JAMP speculates that Jamteki's performance has been affected by anticompetitive conduct by Janssen. Janssen will introduce evidence showing that in fact, Jamteki cannot be marketed for most ustekinumab patients because of its medical classification. Specifically, the evidence will describe the approved indications for

[7] This evidence will also demonstrate that private insurers have, for the most part, continued covering Stelara and/or started covering Finlius alongside biosimilar options [redacted]. This affords patients and physicians maximum choice of treatments at a comparable cost and indicates that JAMP's business is not directly and substantially affected by Janssen's alleged conduct.

ustekinumab products (Stelara, Finlius and their biosimilars) and the relative proportions of patients who use ustekinumab for each indication. Notably, Jamteki is not indicated for the treatment of Crohn's disease or ulcerative colitis, which represent the vast majority of ustekinumab sales in Canada. On the other hand, Stelara, Finlius, and Wezlana (Amgen's ustekinumab biosimilar) are indicated for these conditions.

- Stelara is being delisted from public formularies and Finlius is only available to private payors. Janssen will introduce evidence showing that any alleged conduct cannot substantially prevent or lessen competition with respect to public insurers, which represent a substantial proportion of the market for ustekinumab (with that proportion also being a subject of Janssen's evidence). Stelara has been or will shortly be delisted by every province's public formulary (the timing of which will also be a subject of Janssen's evidence), and every province has implemented or will shortly implement a non-medical switch policy that will shift existing patients away from Stelara. Finlius is not listed on any public formulary, [redacted]. Thus, Janssen will not be competing for public payors at all. Moreover, JAMP's allegations relating to its performance fail to take into account the effect of when the biologic is delisted and non-medical switching implemented by provincial authorities, rather than any conduct of Janssen.

- JAMP's comparison to Simlandi is misleading. JAMP claims that it has been harmed as compared to its experience with a different product, Simlandi (an adalimumab biosimilar to AbbVie's Humira). This is misleading, because JAMP's evidence does not acknowledge that Simlandi entered the market under very different circumstances—after the entry of multiple other biosimilars, and after public formulary delisting had been completed and non-medical switch policies had already been implemented. In other words, Simlandi entered the market only after innovator biologics had effectively exited the public insurer market. Janssen will provide discrete evidence regarding the chronology of regulatory approvals and delisting/non-medical switching for ustekinumab products (Stelara, Finlius, Jamteki and other biosimilars), as compared to adalimumab products (Humira, Simlandi and other biosimilars).

c. JAMP is barred from bringing many of its claims under the terms of [redacted]

Janssen will introduce into evidence the [redacted]. JAMP refers to the [redacted].

[redacted].

[redacted] bars JAMP from advancing a significant portion of the claims pleaded in the draft notice of application, [redacted]. JAMP is, therefore, barred from advancing such claims, [redacted]. As such, this

evidence is of vital importance to the Tribunal's gatekeeping function. The Tribunal should not be required to screen claims as part of a leave application that cannot be the subject of an order under the Act because they are already barred [redacted].

III. Deadline for Serving and Filing Janssen's Response

Janssen seeks an extension of the time provided under Rule 119(1) of the Rules to file its response to the Leave Application. Given the serious and highly technical nature of the allegations raised by JAMP, Janssen requires additional time to prepare its response, particularly the affidavit evidence referred to above (assuming leave to do so is granted). Aside from the inherent time requirements of preparing such affidavits, several key Janssen personnel (including its likely affiant) have been or will be unavailable for significant parts of August due to pre-planned summer holidays.

There is no urgency to JAMP's application. JAMP's counsel initially raised the issues in the Leave Application in a demand letter to Janssen dated May 31, 2024. JAMP then waited two months, until July 29, 2024, to advise that JAMP had filed the present Leave Application, which was served on August 1, 2024. Having waited at least two months to commence this proceeding, it does not now lie in JAMP's mouth to claim that this matter is one of such exigency that it would be derailed by a four-week extension for Janssen to properly prepare and file its evidence.

We thank the Tribunal for its consideration of the above and would be pleased to address any questions it may have in writing or at a case conference.

Yours respectfully,

Nicole Henderson

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c: Andrew Brodkin, Jordan Scopa, David Rosner, Jon Wall, Arash Rouhi, *Goodmans LLP*
Robert E. Kwinter, Cathy Beagan Flood, Jonathan Bitran, Joe McGrade, Brian A. Facey, *Blake Cassels & Graydon LLP*