PUBLIC

CT-2024-006

THE COMPETITION TRIBUNAL

IN THE MATTER OF the *Competition Act*, R.S.C. 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 of the *Competition Act* seeking leave to bring an application under section 79 of the *Competition Act*;

AND IN THE MATTER OF an Application by the JAMP Pharma Corporation for an order pursuant to section 79 of the *Competition Act*;

BETWEEN

JAMP PHARMA CORPORATION

Applicant

- and -

JANSSEN INC.

Respondent

Sur-Reply of the Respondent, Janssen Inc.
(To Application for Leave Pursuant to Section 103.1 of the* Competition Act*)

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PART I: OVERVIEW

1. With great rhetorical flourish, JAMP's reply attempts to pivot its case from its initially-pleaded allegations of anticompetitive conduct which were rebutted by Janssen's evidence, to new unsubstantiated allegations that were not previously pleaded.[1] JAMP has not, however, pivoted away from its strategy of speculation, misconstruing evidence, and inviting the Tribunal to draw unwarranted inferences based on cherry-picked aspects of the documents before it.

2. Contrary to JAMP's bluster, Janssen included substantial contemporaneous documentary evidence in its response to this leave application, not as a show of hubris, but to bring to light the facts, which rebut the rampant speculation in JAMP's materials. Janssen's strategic plans to ensure that its ustekinumab products and BioAdvance program continue to remain available to those patients who want them (and physicians who want to prescribe them) are entirely lawful competitive responses to the entry of ustekinumab biosimilars.

3. JAMP's new allegations constitute improper reply, and in any event are unavailing, for the reasons described below. While Janssen vigorously disagrees with the remainder of JAMP's reply submissions, this sur-reply is limited to these new matters.

PART II: NEW ALLEGATIONS ARE WITHOUT MERIT AND MISLEADING

Claims regarding FINLIUS pricing are misleading

4. JAMP refers to one sentence of an email, taken out of context, to argue that Janssen "expects it will be able to control pricing after the entry of biosimilars to Stelara", specifically that it will be able to [redacted] Finlius' list price by [redacted].[2] This submission is misleading on even a cursory reading of the document. The preceding sentences of that email (omitted by JAMP) unequivocally state that FINLIUS will be sold at "[redacted] The [redacted] figure cited by JAMP refers to total anticipated sales of FINLIUS over the term of [redacted]

[1] All capitalized terms in this sur-reply have the same meaning as in Janssen's responding memorandum of fact and law dated September 6, 2024.
[2] JAMP Reply, para 62(b).

[redacted] The [redacted]e did not and will not result in any increased revenue to Janssen, [redacted]d.[3] Moreover, this document is dated May 9, 2024, well before the launch of FINLIUS in July 2024, and, as such, refers to planning discussions regarding potential future prices, not a change to any existing pricing.[4]

New allegations regarding BioAdvance are meritless and misleading.

5. JAMP originally alleged that Janssen misused BioAdvance by issuing vague communications to physicians and patients suggesting that FINLIUS was a biosimilar to STELARA, in order to create confusion and hinder the entry of biosimilars.[5] Those allegations were disproven by Janssen's evidence that BACs were instructed to convey exactly the opposite.

6. Now, in reply, JAMP advances three new allegations with respect to BioAdvance, namely that Janssen: (i) "self-preferences" its own drugs via BioAdvance's insurance discovery process, and that BACs perform the function of selecting a patient's ustekinumab drug, instead of a patient's physician;[6] (ii) attempts to "monopolize" relationships with prescribers and patients;[7] and (iii) has misled physicians regarding the requirements of provincial non-medical switch policies.[8] Each of these allegations is easily disproven on the evidentiary record.

Patients and physicians decide on the best treatment option

7. All patient treatment decisions are made by patients in consultation with their physicians. BACs cannot write prescriptions for patients or choose which medication a physician prescribes – they are not physicians (nor are they sales representatives).[9] It is clear, even in the flow-charts excerpted out of context in JAMP's reply, that the first step to enroll a patient in BioAdvance is a

[3] Williams Affidavit, Exhibit 12 (which is misquoted by JAMP at para. 62 of its Reply) and Exhibit 13.
[4] See Williams Affidavit, Exhibit 13, page 538 "[redacted]
[5] Notice of Application, paras 41(d)-(e).
[6] JAMP Reply, paras 66-68 and 76.
[7] JAMP Reply, paras 69 and 76.
[8] JAMP Reply, para 77(c).
[9] Williams Affidavit, para 27.

physician's prescription for STELARA or FINLIUS.[10] A patient does not have any contact with BioAdvance unless and until their physician prescribes FINLIUS or STELARA.

8. Janssen's BAC training materials explain that STELARA is available if it is "prescribed as 1st choice by a patient's [health care practitioner]". FINLIUS is available if it is "prescribed as 2nd choice, if STELARA coverage is not available", and that Janssen has contracted with a biosimilar manufacturer (Celltrion) to allow patients "who are initially prescribed STELARA/FINLIUS and then prescribed the contracted biosimilar as an alternative, to be enrolled in the BioAdvance Patient Support Program".[11]

9. Janssen's approved written and verbal communications to physicians regarding provincial non-medical switch emphasize that the physician determines the best treatment option for patients. BioAdvance's role is to assist in providing them information regarding the patient's insurance coverage for the treatment option selected by the physician. The mandated communications for BACs to physicians for all provinces underscore this, for example:

[redacted][13]

10. Similarly, approved messaging to STELARA patients in British Columbia affected by provincial non-medical switch reads [redacted]

[10] See JAMP Reply, Figure 2. This slide is excerpted from Exhibit 13 of the Williams Affidavit, page 672. The first box of the flow chart reads "[redacted]

[11] Williams Affidavit, Exhibit 27, page 667.
[12] Williams Affidavit, Exhibit 35, page 834.
[13] Williams Affidavit, Exhibit 35, pages 835-836.

[redacted] (emphasis added).[14] The decision of which drug should be described remains between physician and patient, as it should.

11. There is no foundation for JAMP's new allegation that Janssen somehow controls the prescribing decisions of physicians (who are independent and sophisticated professionals). The role of BioAdvance is to make the patient's treatment experience a smooth one once their physician has already made the decision to prescribe a Janssen ustekinumab drug. This includes helping patients navigate insurance coverage, coordinating clinic visits, and educating patients on the administration of biologic drugs—not making medical treatment decisions for patients.

Janssen does not "monopolize" contact with physicians or patients

12. JAMP's new allegation that Janssen, through BioAdvance, somehow "monopolizes" relationships with patients and prescribers is similarly without foundation. This spurious claim is based on a single phrase, taken out of context, from Janssen's BAC training materials: namely, that BioAdvance seeks to maintain "ONE Point of Contact". This refers to patients only having to deal with a single BAC within the BioAdvance program. It has nothing to with the nature or frequency of communication between biosimilar manufacturers and patients or physicians. A patient's relationship with a BAC is separate from the relationship between the patient and their physician (or between a biosimilar manufacturer and physicians).

13. JAMP also alleges that Janssen's goal is to allow patients affected by government biosimilar policies to stay within the BioAdvance program.[15] Again, this is not anticompetitive behavior, but serves to prevent a disruption in the care provided through BioAdvance if that is what a physician decides is best for their patient. The full quote from the document excerpted by

[14] Williams Affidavit, Exhibit 35, page 835.
[15] JAMP Reply, para 69.

JAMP is [redacted]

New allegations regarding misleading communications about non-medical switch are false

14. JAMP alleges for the first time in reply that Janssen misled physicians regarding provincial non-medical switch windows.[17] To the contrary, Janssen's mandated physician outreach scripts and communications are clear regarding details and timing of the non-medical switch announcements,[18] as are its training materials to BACs.[19] Further, the provincial non-medical switch windows were all publicly announced by provincial insurers (as produced by Janssen in its response),[20] and would have been known to physicians. Janssen correctly communicated to physicians that, for patients who otherwise would lose access to BioAdvance, it was pursuing a contract with a biosimilar manufacturer such that patients could continue receiving ustekinumab drugs while maintaining continuity of care in BioAdvance.

15. Further, Janssen did not "predate[redacted].[21] Compassionate use programs are not themselves anticompetitive; indeed they are pro-social. There is also no evidence in the record as to how many STELARA patients [redacted]s. JAMP's allegations that [redacted] was an effort to thwart biosimilar entry is speculative and based on point-in-time statistics from which it is asking the Tribunal to draw wide-ranging conclusions.

16. Finally, JAMP's entirely new allegation that Janssen marketed Steqeyma prior to it receiving an NOC on July 31, 2024 is baseless and, in any event, irrelevant to this application for leave. Janssen's communications regarding ustekinumab products, including Steqeyma, have at all times been lawful.

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[16] Williams Affidavit, Exhibit 13, page 521. Note that the citation at footnote 70 of the JAMP Reply is incorrect.
[17] JAMP Reply, para 77(c).
[18] Williams Affidavit, Exhibits 47-50.
[19] Williams Affidavit, Exhibits 28-46.
[20] Williams Affidavit, Exhibits 14-22.
[21] JAMP Reply, para 66.

JAMP bears the burden of proof

17. Throughout its reply, JAMP argues that Janssen "failed" to proffer evidence on several topics. Among other instances, JAMP criticizes Janssen for not affirmatively giving wide-ranging evidence that Janssen has not taken steps to discourage physicians from meeting with biosimilar sales representatives.[22] This is a curious submission considering JAMP's strident opposition to Janssen's motion for leave to adduce responding evidence. Moreover, the Tribunal's August 22, 2024 Order specifically limited Janssen's evidence on this topic to the issue of its advisory board agreements.[23]

18. More fundamentally, these arguments are an attempt to shift the burden of proof on this leave application onto Janssen. It is JAMP's burden to adduce sufficient credible evidence to discharge its onus. Where its evidence fails to meet that threshold, it is no answer to suggest that Janssen should have led evidence that it did not have leave to adduce.

JAMP`s arguments regarding the [redacted] *are wrong in law*

19. JAMP now alleges in reply that the [redacted][24] That is of no moment. [redacted]. JAMP's leave application is entirely related to the effect of the alleged conduct on Jamteki and is therefore barred to the extent its claims [redacted]. Contrary to JAMP's reply submissions, Janssen is not asking the Tribunal to [redacted]t. Rather, it asks that the leave application be dismissed as an abuse of the Tribunal's process.[25] [redacted] the jurisdiction of the Tribunal to prevent an abuse of its own process, and the Tribunal unquestionably has jurisdiction to do so. [26]

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[22] JAMP Reply, para 79, see also paras 61-62 with respect to market definition and dominance, paras 75 and 87 with respect to the launch timing of FINLIUs, paras 80 and 87 with respect to pricing (notwithstanding that Janssen did introduce evidence rebutting JAMP's claims regarding predatory pricing, see Janssen's Memorandum of Fact and Law at para 41, Williams Affidavit at para 18), paras 84-86 with respect to the preference of insurers (which is addressed in the Williams Affidavit, at para 17).
[23] 2024 CACT 4 at para 41.
[24] JAMP Reply at para. 30.
[25] Shannex Inc. v Dora Construction Ltd., 2016 NSCA 89 at para 55.
[26] Rona - Reasons of Order and Order (public version) (Professional English translation not revised), 2005 CanLII 94055 (CT), at para 28.

PART III: CONCLUSION AND COSTS

20. Considering the above and Janssen's prior submissions dated September 6, 2024, this application for leave to bring an application under s. 79 of the *Act* should be dismissed with costs. Janssen rejects JAMP's claims that its conduct has in any way obstructed the timely hearing of this leave application or that an adverse costs award is warranted. Janssen successfully obtained leave to produce evidence, and did so in a timely fashion as directed by the Tribunal.

ALL OF WHICH IS RESPECTFULLY SUBMITTED this 20th day of September, 2024.

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