File No. CT-2024-006

COMPETITION TRIBUNAL

IN THE MATTER OF the Competition Act, R.S.C. 1985, c. C-34 (the "**Act**");

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

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

BETWEEN:

JAMP PHARMA CORPORATION

Applicant

– and –

JANSSEN INC.

Respondent

REPLY OF THE APPLICANT, JAMP PHARMA CORPORATION
(Pursuant to section 103.1 of the *Competition Act*)

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I. EXECUTIVE SUMMARY

> "Hubris is interesting, because you get people who are often very clever, very powerful, have achieved great things, and then something goes wrong – they just don't know when to stop."
>
> - Margaret MacMillan

1. J&J's response is very critical of the evidence tendered by JAMP in support of its application for leave to bring an application pursuant to section 79. J&J goes so far as to call it not "credible", not "reliable", and "based on speculation, unreasonable inferences drawn from limited documentary evidence, and inaccurate hearsay."[1]

2. In contrast, J&J's response is very self-congratulatory regarding its own evidence, describing it as "directly refuting" JAMP's allegations of anti-competitive conduct.[2]

3. Whether through negligence, inadvertence or hubris (or some combination thereof), J&J appears to have overlooked that the very evidence it fought hard to tender, and in which it takes great pride, evidences its market power and a scheme of deliberate and glaring anti-competitive conduct that maps directly onto JAMP's allegations. If anything, J&J's internal documentary evidence, which amounts to a self-inflicted wound, demonstrates a more organized and singular scheme of anti-competitive conduct that goes beyond what JAMP conceived of based on the competitive intelligence and public information it had gathered.

4. J&J's response to JAMP's application for leave under s. 103.1 of the *Competition Act* has two main components, each of which suffers from superficiality:

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[1] Memorandum of Fact and Law of Janssen Inc., dated September 6, 2024 ["**J&J's Response**"], ¶1-2.

[2] J&J's Response, ¶2.

(a) First, J&J asserts that JAMP is barred from asserting an unspecified portion of its allegations [redacted].

(b) Second, J&J asserts that its evidence demonstrates that an order could not be made under s. 79.

5. Regarding the first issue, at its highest, J&J's position would appear to be that a subset of litigation related to J&J's futile attempts to list the 837 Patent against Stelara is not permitted to form part of the subject matter of JAMP's proposed application pursuant to section 79. Even if this were true, which it is not, it is difficult to imagine that the Tribunal's decision regarding whether to grant JAMP leave would turn on this relatively small component of its proposed application.

6. [redacted] The Tribunal should not permit respondents to use non-competition law maneuvers to shield their anti-competitive conduct from scrutiny under s. 79 of the *Competition Act*.

7. Regarding the second issue, as alluded to above, the inculpatory documentary evidence voluntarily tendered by J&J satisfies every element of section 79.

8. First, J&J's documents explain its understanding that it controls the market for ustekinumab today, and will continue to control that market into the future. That market power is so entrenched that J&J felt confident it could unilaterally and profitably [redacted] the list price of Finlius by [redacted] even in the face of competition from biosimilars.[3]

9. Second, J&J's documents explain its anti-competitive intent. One document that outlines its strategy for defending Stelara brags in bold font that [redacted].[4] This is direct proof of the allegation in paragraph 47 of the Proposed Notice of Application that J&J's anti-competitive practices in ustekinumab are from a playbook J&J developed to maintain its dominant position in Remicade.

10. Third, J&J's documents and submissions detail its anti-competitive practices. For example, the documents explain [redacted] – that is, J&J's frequent use of predatory pricing.[5] By further example, in a surprising admission against interest, J&J admits that Finlius' offered pricing is [redacted] than Stelara's offered pricing, and that such differences are "typical" of a "fighting

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[3] Affidavit of Andy Williams, sworn September 6, 2024 ["**Williams Affidavit**"], Exhibit 12 at page 534.

[4] Williams Affidavit, Exhibit 10 at page 520.

[5] Williams Affidavit, Exhibit 8 at page 439; Williams Affidavit, Exhibit 28 at page 715.

brand."[6] By further example, the documents explain that (i) J&J's goal is that J&J perform the function of selecting a patient's ustekinumab drug through BioAdvance, and (ii) J&J always self-preferences the drug that generates the most profit for itself and excludes rival biosimilars.[7]

11. Fourth, J&J's documents detail the magnitude of the harm to competition caused by the maintenance of its market power. As noted above, after ensuring it had sufficient market power, J&J used that power to profitability [redacted] the list price of Finlius by [redacted]

12. The evidence now before the Tribunal, including the inculpatory documents voluntarily tendered by J&J, is more than sufficient to permit the Tribunal to form a *bona fide* belief that JAMP's business has been directly and substantially affected, and that the Tribunal could make an order under section 79.

13. Accordingly, JAMP respectfully requests that the Tribunal grant leave to JAMP to bring its application under section 79, with costs awarded to JAMP.

II. PRELIMINARY PROCEDURAL MATTERS

14. While J&J brought a motion seeking an extension of time to serve and file its response by September 20, 2024, the Tribunal ordered that J&J deliver its materials by September 6, 2024.[8]

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[6] J&J's Response, ¶68-69.

[7] See ¶66, below.

[8] *JAMP Pharma Corporation v. Janssen Inc.*, 2024 Comp Trib 4, ¶55 and 59.

15. Despite this clear order, and the requirement that all documents must be filed with the Tribunal by 5:00 PM (Ottawa time).[9] J&J did not deliver its response to JAMP until September 6, 2024 at 7:03 PM, and does not appear to have filed its response until September 9, 2024.

16. Given the late delivery of materials (after business hours on a Friday), JAMP advised J&J that it would accept service as of Monday, September 9, 2024. However, JAMP put J&J on notice that JAMP's acceptance of service did not relieve J&J from its obligation to seek relief from the Tribunal for being out of time to serve and file its response. JAMP further expressed its trust that J&J would take the appropriate steps to seek relief from the Tribunal.

17. As far as JAMP is aware, J&J has not sought any form of relief from the Tribunal regarding its late service and filing of its response. Further, to date, J&J has offered JAMP no explanation for its tardiness and has not even requested JAMP's consent to an indulgence.

18. Nevertheless, on the assumption that the Tribunal may accept and consider J&J's Response despite its late service and filing, and to preserve the original schedule contemplated by the Tribunal's prior order, JAMP has prepared, served and filed this Reply by September 13, 2024.

III. [redacted]

19. [redacted]

[9] Rule 18(3) of the *Competition Tribunal Rules*, SOR/2008-141.

[redacted]

A. [redacted]

20. [redacted][12]

21. [redacted]

B. [redacted]

22. [redacted].

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[10] J&J's Response, ¶3 and 23-26.

[11] J&J's Response, ¶58-60.

[12] Memorandum of Fact and Law of the Applicant, dated July 26, 2024 ["**JAMP's Memorandum**"], ¶28-33; JAMP's Proposed Notice of Application Pursuant to Section 79 of the *Competition Act*, dated July 26, 2024, ¶41.

[13] J&J's Response, ¶3, 26 and 58.

23. [redacted].[14]

24. [redacted]:[15]

[redacted]

25. [redacted]

[14] *Sattva Capital Corp. v. Creston Moly Corp.*, 2014 SCC 53, ¶47, 57 and 64.

[15] [redacted] Agreement, s. 5.5, Williams Affidavit, Exhibit 62, page 1001.

[redacted][16]

26. [redacted].[17]

27. [redacted].

28. [redacted]

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[16] Written Representations of the Commissioner of Competition, dated September 6, 2024, ¶10.

[17] *Competition Act*, s. 79(1), 79(2) and 79(3.1).

[18] [redacted] Agreement, Recitals, Williams Affidavit, Exhibit 62, page 996.

[redacted].

29. [redacted].

30. [redacted].

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[19] J&J's Response, ¶59.

[20] For example, the listing litigation for Stelara continued until the Federal Court of Appeal's dismissal on November 21, 2023, and the listing litigation for Finlius continued until its discontinuance on February 28, 2024; See: Affidavit of Sukhad Juneja, sworn July 25, 2024 ["***Juneja Affidavit***"], ¶34 and 40.

[21] Juneja Affidavit, ¶35.

C. J&J Confuses [redacted] and Litigation for the Listing of a Patent

31. J&J also advances a curious argument that, somehow, [redacted] rehabilitates J&J's conduct in pursuing sham litigation related to the listing of the 837 Patent.[22] J&J's argument evinces either a fundamental misunderstanding of governing "listing" law or a desire to confuse the Tribunal (or both).

32. The power of listing a patent on the Patent Register and the body of law governing the propriety of listing a particular patent against a particular drug at a particular time have nothing to do with [redacted]. Rather:

(a) The power of listing a patent on the Patent Register is the fact that it effectively provides a 24-month interlocutory injunction from making, using and selling the (generic or biosimilar) drug in circumstances where such an interlocutory injunction would almost certainly be unavailable in the absence of listing;[23] and

(b) The propriety of listing a patent on the Patent Register is governed by timing requirements and eligibility requirements unrelated to [redacted]

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[22] J&J's Response, ¶3, 24 and 96.

[23] Outside the confines of the *Patented Medicines (Notice of Compliance) Regulations* ("***PM(NOC) Regulations***"), which permit the listing of patents on the Patent Register (where timing and eligibility requirements are met), it is challenging (if not impossible) for pharmaceutical patentees to obtain interlocutory injunctions precluding the marketing of generic versions of their patented drugs pending trial. The most common reason for this is an inability to demonstrate "irreparable harm" given that, after a successful patent infringement action, a pharmaceutical patentee can recover compensatory damages to be made whole for any harm suffered; See: *AstraZeneca v. Apotex*, 2011 FCA 211 ¶6, affirming 2011 FC 505.

[redacted].[24]

33. Hence, the issue on the proposed application pursuant to section 79 will not be [redacted]. Instead, the issue will be whether J&J's litigation relating to listing the 837 Patent against Stelara and Finlius was a practice of anti-competitive acts (designed to disincentivize and delay potential biosimilar entrants for ustekinumab due to the threat of litigation and delayed market entry). JAMP intends to argue that the litigation was so devoid of any substantive merit that it must have constituted sham litigation designed to create the spectre of risk of delayed market entry for biosimilars (and confusion regarding J&J's intentions related to marketing Finlius).[25]

D. [redacted]

34. [redacted].

35. [redacted]

[24] *PM(NOC) Regulations*, ss. 4(2), 4(5) and 4(6). See also: *Merck Canada Inc. v. Canada (Health)*, 2021 FC 345, ¶7-9; *Janssen Inc. v. Canada (Health)*, 2023 FC 870, ¶7-18.

[25] See also the discussion at ¶74, below.

[redacted].[26]

[redacted]

36. [redacted].

37. [redacted]

[26] [redacted] Agreement, s. 9.2, Williams Affidavit, Exhibit 62, 1005.

[redacted][27]

38. [redacted][28].

E. Limits of the Tribunal's Jurisdiction

39. Separate from the foregoing arguments, which JAMP submits are dispositive, the Tribunal should decline to entertain J&J's vague arguments because of the limits of its jurisdiction.

40. The Tribunal is a statutory court established by s. 3 of the *Competition Tribunal Act*, which also prescribes its jurisdiction. Subsection 8(1) provides that, "The Tribunal has jurisdiction to hear and dispose of all applications made under Part VII.1 or VIII of the

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[27] *Douez v. Facebook, Inc.*, [2017] 1 SCR 751, ¶1 and 29-31.

[28] J&J's Response, ¶60.

Competition Act and any related matters…".[29] [redacted]

[redacted].[30]

41. However, J&J has not identified any instance where the Tribunal determined it had jurisdiction to enforce a private agreement. Indeed, J&J omits reference to the two Tribunal cases where the Tribunal considered if it had jurisdiction over private agreements.[31] In each case, the Tribunal was asked to enforce the terms of a private agreement that: (i) was negotiated and entered into by the Commissioner of Competition in resolution of an ongoing matter related to the enforcement of the *Competition Act*; (ii) was capable of being the subject of an order under the *Competition Act*; and (iii) memorialized the respondents' consent to the registration of the agreement as an order of the Tribunal. Despite the close nexus among those agreements, the enforcement of the *Competition Act* and permissible proceedings before the Tribunal, the Tribunal interpreted s. 8 of the *Competition Tribunal Act* narrowly and declined jurisdiction in both instances.

42. [redacted]:

(a) [redacted]

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[29] *Competition Tribunal Act*, R.S.C., 1985, c. 19 (2nd Supp.), ss. 8(1).

[30] J&J's Response, ¶60.

[31] *Director of Investigation and Research v. Imperial Oil Limited* (1994), CT-1989/003, [1994] CCTD No 23 (in declining to exercise jurisdiction over a private agreement, the Tribunal held, "The *Competition Act* does not confer open-ended jurisdiction on the Tribunal to deal with any and all competition issues. It is given specific powers which are set out in the *Competition Act* and in the *Competition Tribunal Act*. It may only act where it has been given the power to do so."); *Commissioner of Competition v. Abitibi-Consolidated Inc.*, 2002 Comp Trib 3.

[redacted];

(b) [redacted]

(c) [redacted].

43. [redacted] J&J has not articulated any such basis. Instead, J&J has merely referenced certain administrative and procedural powers listed in subsection 8(2) of the *Competition Tribunal Act*,[32] and suggested that same confer wide subject-matter jurisdiction to the Tribunal despite the fact that the Tribunal has previously expressly declined to interpret those provisions as conferring such wide jurisdiction.

F. Other Considerations

44. In a number of prior cases, respondents have made efforts to shield their anti-competitive conduct from scrutiny under Part VIII of the *Competition Act* by relying on non-competition law maneuvers. While those prior cases are not closely analogous to the present case, it is notable that, in each instance, the efforts failed.[33] The Tribunal has never

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[32] J&J's Response, ¶60.

[33] In *Director of Investigation and Research v. Tele-Direct (Publications) Inc., et al*, CT-1994/003, the respondent unsuccessfully asserted that its conduct was shielded from scrutiny under s. 79 because the Director was estopped from bringing his application. In *B-Filer Inc. v. The Bank of Nova Scotia*, 2005 Comp. Trib. 31, the respondent

permitted a respondent to shield its conduct from scrutiny under Part VIII of the *Competition Act*, and there is no reason to permit such shielding in the present case.

IV. J&J HAS NO PRINCIPLED RESPONSE REGARDING THE MEANING OF "DIRECTLY AND SUBSTANTIALLY AFFECTED IN THE APPLICANT'S BUSINESS"

45. JAMP advanced a clear and principled argument regarding why, when Current 103.1 is interpreted and applied in conjunction with section 79, the analysis should focus on the effect of the impugned practice on the applicant's business in the product market at issue (rather than the applicant's "entire" business, as is done pursuant to paragraph 75(1)(a)).[34] The Commissioner of Competition independently advanced a similar, principled interpretation of "directly and substantially affected in the applicant's business".[35]

46. In two superficial paragraphs,[36] J&J has offered no substantive response to the principled arguments advanced by JAMP and the Commissioner of Competition. That, with the passage of 38 days from the service of JAMP's Memorandum, J&J was unable to divine a single, principled argument – whether rooted in law or competition law policy considerations – as to why the phrase "directly and substantially affected in the applicant's business" should be interpreted in the same manner in proposed applications pursuant to

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unsuccessfully asserted that its conduct was shielded from scrutiny in an application for leave under s. 103.1 by *res judicata*, see: ¶60. In *Commissioner of Competition v. Vancouver Airport Authority*, 2019 Comp Trib 6, the respondent unsuccessfully asserted that its conduct was shielded from scrutiny under s. 79 by operation of the regulated conduct defence.

[34] JAMP's Memorandum, ¶55-75. JAMP's Memorandum also advanced a principled alternative argument regarding the factual inquiry necessary to identify the business at issue in a section 103.1 application, and the many reasons why the business at issue is not synonymous with all of the activities of a corporate applicant as a matter of law.

[35] Written Representations of the Commissioner of Competition, footnote 16, ¶12-17.

[36] J&J's Response, ¶46-47.

section 75 and section 79 speaks volumes.

47. Instead, J&J asks this Tribunal to do what is legally impermissible: to rely on New 103.1, which does not come into force until June 2025, to interpret Current 103.1.[37]

48. This argument is not open to J&J (or any litigant) because subsection 45(3) of the *Interpretation Act* expressly provides 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."[38] The Supreme Court and the Federal Court of Appeal have consistently interpreted this provision to mean that subsequent legislative history casts no light on the intention of the legislature regarding prior versions of the same legislation.[39]

V. THERE IS SUFFICIENT EVIDENCE THAT JAMP'S BUSINESS IS DIRECTLY AND SUBSTANTIALLY AFFECTED

49. The evidence before the Tribunal is more than sufficient to permit it to form a *bona fide* belief that JAMP's ustekinumab business (or, in the alternative, its BioJAMP business) has been directly and substantially affected by J&J's anti-competitive practices.

50. In disputing the substantiality of the effect of its practices on JAMP, J&J argues that JAMP's Jamteki sales projections have not been met because they fail to account for "a great deal of context about the competitive environment."[40] J&J then offers five "likely

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[37] J&J's Response, ¶48.

[38] *Interpretation Act*, R.S.C., 1985, c. I-21, s. 45(3).

[39] *R v. Breault*, 2023 SCC 9, ¶42; *R v. D.A.I.*, 2012 SCC 5, ¶46; *United States v. Dynar*, 1997 CarswellOnt 1981, ¶45-46 (SCC); *Canada v. Microbjo Properties Inc.*, 2023 FCA 157, ¶62; *Canada v. Oxford Properties Group Inc.*, 2018 FCA 30, ¶46 and 86.

[40] J&J's Response, ¶57, including sub-paragraphs (a) to (e), which are mirrored in paragraphs 52 to 56, below.

explanations" for why JAMP's Jamteki sales projections have not been met.

51. A careful (rather than superficial) examination of the evidence demonstrates that all of the missing "context" that J&J alludes to, and each of J&J's "explanations", were already conservatively accounted for in JAMP's Jamteki sales projections.

52. First, J&J asserts that, because Jamteki is not indicated for Crohn's disease or ulcerative colitis, JAMP over-estimated its potential future sales. [41] This is plainly incorrect. JAMP's Jamteki sales projections *excluded* demand from patients with Crohn's disease or ulcerative colitis for at least [redacted] following Jamteki's launch (*i.e.*, until [redacted], by which time Jamteki will likely possess these additional indications).[42]

53. Second, J&J asserts that JAMP over-estimated its sales because non-medical switch windows have only recently opened.[43] This too is plainly incorrect. JAMP's Jamteki sales projections conservatively accounts for the non-medical switching windows of public payers.[44]

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[41] J&J's Response, ¶57(a).

[42] Affidavit of Amélie Faubert, sworn July 25, 2024 ["***Faubert Affidavit***"], Exhibit F6 at tab "Forecast Usteki Year 1", rows 34-45 (i.e., zero sales of Jamteki indicated for "GI" (which refers to ulcerative colitis and Crohn's disease) for the first [redacted] post-launch). Further, the sales forecast excludes GI patients by assuming that [redacted] of any ustekinumab drug are indicated for use only for treatment of Crohn's disease or ulcerative colitis (see Faubert Affidavit Exhibit F6 at tab "Forecast Usteki Year 1", cell B19). J&J's evidence validates the accuracy of this assumption – [redacted] (Williams Affidavit, Exhibit 8, calculated as those patients not receiving [redacted]). Note that JAMP's sales projections also exclude "free goods" as sales (the data for the analog (adalimumab), on which Exhibit F6 relies, do not include "compassionate use" drugs, as explained in the Faubert Affidavit at Exhibit F6 at tab "Demand Forecast" at cell AD15).

[43] J&J's Response, ¶57(b)

[44] Faubert Affidavit, Exhibit F6 at tab "Forecast Usteki Year 1", rows 21-32. These cells show sales growth by individual province occurring gradually, which is based on estimates of the rate of switching through windows of time.

54. Third, J&J asserts that JAMP's Jamteki sales projections are inaccurate because JAMP mistakenly believed that Jamteki would be sold at a [redacted]% discount to Stelara, and that J&J would not compete on the basis of price.[45] This criticism is superficial and irrelevant. The sales projections' estimates of Jamteki's sales volumes are driven by a number of variables, but the list and net price of Stelara (or Finlius), or the difference between the pricing of Jamteki and Stelara (or Finlius), is not one of them.[46]

55. Fourth, J&J asserts that JAMP's Jamteki sales projections are not reliable because they are based on adalimumab, and complains that JAMP has not provided "any evidence to explain why the launches of adalimumab and ustekinumab are appropriate comparators from an economic perspective."[47] This too is plainly incorrect. As JAMP's Memorandum explained, it was J&J's Chief Financial Officer who advised J&J's own shareholders that adalimumab and ustekinumab are appropriate comparators, and an affidavit from a JAMP business person lists the numerous points of similarity between the two drugs.[48]

56. Fifth, J&J asserts that JAMP misled the Tribunal by providing inconsistent evidence regarding its sales of Jamteki.[49] This too is plainly incorrect. J&J's assertion is based on wholesale sales (not prescriptions to actual patients) that are recorded in JAMP's normal

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[45] J&J's Response, ¶57(c).

[46] Faubert Affidavit, Exhibit F6. The sales forecast does capture J&J's anticipated competitive response, by assuming the response will be as aggressive as AbbVie's competitive response when adalimumab biosimilars to Humira were launched. This sales forecast – a 23-tab Excel spreadsheet, with its formulae and coding visible – was provided in native format to the Tribunal and J&J's counsel, marked "Confidential Level A". Exhibit F6 is explained in detail in the Faubert Affidavit, from pages 17-20. J&J's Response makes no reference to it.

[47] J&J's Response, ¶57(d).

[48] JAMP's Memorandum, para. 35; Faubert Affidavit, ¶21(b); Faubert Affidavit, Exhibit F7 and F8.

[49] J&J's Response ¶57(e).

course business documents, but the Faubert Affidavit at paragraph 36 clearly explained the differences between wholesale volumes and prescription volumes, and how wholesale sales should be interpreted when compared to the Jamteki sales projections (which is based on anticipated demand from actual prescriptions, [redacted]).

57. It is remarkable that each of J&J's arguments as to why JAMP is not substantially affected crumbles under even the slightest scrutiny. The only available explanations for J&J's spurious arguments are that J&J did not actually read the evidence already on the record or, more troublingly, J&J is attempting to mislead the Tribunal.

58. The reality is that JAMP has presented detailed and reliable evidence of its conservative sales forecasts for Jamteki, and that JAMP has missed those sales forecasts by a very wide margin (despite the accuracy and reliability of similar forecasts in comparator drugs). At the same time, J&J has engaged and continues to engage in a plethora of anti-competitive practices, a number of which the Competition Bureau has expressed significant concerns about in other contexts.[50] All of this evidence is more than sufficient to permit the Tribunal to form a *bona fide* belief that JAMP has been directly and substantially affected in its business by J&J's conduct.

[50] Written Representations of the Commissioner of Competition, dated September 6, 2024, footnote 16, ¶23-28.

VI. THERE IS SUFFICIENT EVIDENCE THAT EACH ELEMENT OF SECTION 79 IS SATISFIED

59. The evidence before the Tribunal is more than sufficient to permit it to form a *bona fide* belief that each element of section 79 could be satisfied, and therefore an order could be made under section 79 in respect of J&J's anti-competitive practices. Indeed, on this issue the inculpatory evidence voluntarily provided by J&J tips the scales decisively in JAMP's favour. This section describes the elements of s. 79 and J&J's documentary evidence in detail.

A. Market Definition and Dominance

60. J&J asserts that JAMP has offered no evidence for its asserted market definition.[51] That is plainly incorrect.

61. JAMP's Memorandum explained that J&J's ustekinumab product, Stelara, has been sold for more than $4,000 per dose for approximately 15 years. At the same time, Health Canada approved a large number of other drugs (many of which were sold at lower prices). Prescribers and patients of Stelara did not switch to those other drugs; instead, Stelara's sales grew throughout the period. JAMP's Memorandum then set out a hypothetical monopolist test, and explained how pharmaceutical product markets are frequently defined.[52] J&J failed to engage with this evidence or to proffer any alternative market definition.

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[51] J&J's Response, ¶22.

[52] JAMP's Memorandum, ¶95-99. See also Faubert Affidavit, ¶10.

62. J&J also denies that it is dominant for ustekinumab, but offers no arguments or evidence supporting that denial. Surprisingly, J&J instead tendered many internal documents that confirm its dominance both before the entry of biosimilars and after. For example:

(a) Stelara has been sold for more than $4,000 per dose for approximately 15 years.[53] J&J asserts that [redacted],[54] but provides no evidence of this assertion. Instead, J&J's own documents explain it only began offering rebates for Stelara [redacted].[55] J&J had no reason to lower Stelara's price prior to [redacted], because J&J faced no competition and had a dominant position.

(b) J&J expects it will be able to control pricing after the entry of biosimilars to Stelara. J&J's documents indicate that its pricing teams had decided upon a list price for Finlius in [redacted]. In [redacted] – presumably after analyzing [redacted] performance by new entrant biosimilars – J&J's documents show that its pricing team was sufficiently confident about the extent of its market power that it could unilaterally and profitably [redacted] Finlius' list price by [redacted]. J&J's documents explained that

[53] Faubert Affidavit, ¶10.

[54] J&J's Response, ¶37; Williams Affidavit, ¶9.

[55] Williams Affidavit, Exhibit 12, page 533 ([redacted]").

the [redacted] would result [redacted]

[redacted]"[56]

(c) J&J expects to maintain a dominant market share even after the entry of biosimilars. In slides explaining its strategy for Stelara, J&J brags in bold font that [redacted].[57]

63. Finally, J&J appears to argue that its dominance is not durable, because public insurance programs are in the process of switching to biosimilars and as a result very soon J&J will be "excluded" and "will not be competing for publicly-listed ustekinumab patients."[58] However, those assertions are contradicted by J&J's documents. The documents show that J&J is laser focused on using exclusionary strategies to keep publicly-insured patients (in spite of provincial insurance policies), and that J&J brags that [redacted].[59] These documents make it obvious that J&J has a competitive interest in all ustekinumab patients.

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[56] Williams Affidavit, Exhibit 12, page 534 ("NTS" refers to "net total sales" and "LRFP" refers to "long range financial plan") and also Williams Affidavit, Exhibit 13, page 541 and 543. [redacted].

[57] Williams Affidavit, Exhibit 10, page 520 and Exhibit 25, page 649.

[58] Williams Affidavit, ¶21 and J&J's Response, ¶35, 66, 72 and 101 ("there can be no impact on competition for publicly-insured patients, who comprise a substantial percentage of ustekinumab products").

[59] See footnote 57, above, the flow charts described in ¶66 and footnote 61, below, and ¶69, below. For an example of a flow chart involving public insurance, see Williams Affidavit, Exhibit 28, page 715 (despite the BC government's policies, J&J [redacted]

B. Anti-Competitive Intent

64. Without access to J&J's internal documents, in its application, JAMP did not present evidence that the subjective intent of J&J's anti-competitive practices was to exclude rivals and adversely effect competition. Helpfully for the Tribunal, however, J&J voluntarily provided internal documents that are replete with such evidence.

65. First, as noted above, J&J brags in bold font that [redacted]. The strategy, which was code-named [redacted], is to counsel physicians to prescribe [redacted][60] See Figure 1, below.

66. This strategy gives J&J the opportunity to conduct what it euphemistically calls [redacted][61] [redacted]

[redacted]). J&J predates in order to keep publicly-insured patients, despite its affiant claiming that J&J does not compete for these patients.

[60] [redacted] See, for example, Williams Affidavit, Exhibit 35, page 838 ([redacted]" and the corresponding answer). See also Williams Affidavit, Exhibit 25 at page 649, explaining that for infliximab, "[redacted]"

[61] See the numerous flow charts included in the Williams Affidavit, including the following examples: Williams Affidavit, Exhibit 27, page 672 (resulting in "[redacted]")), page 674, and page 679 ([redacted]

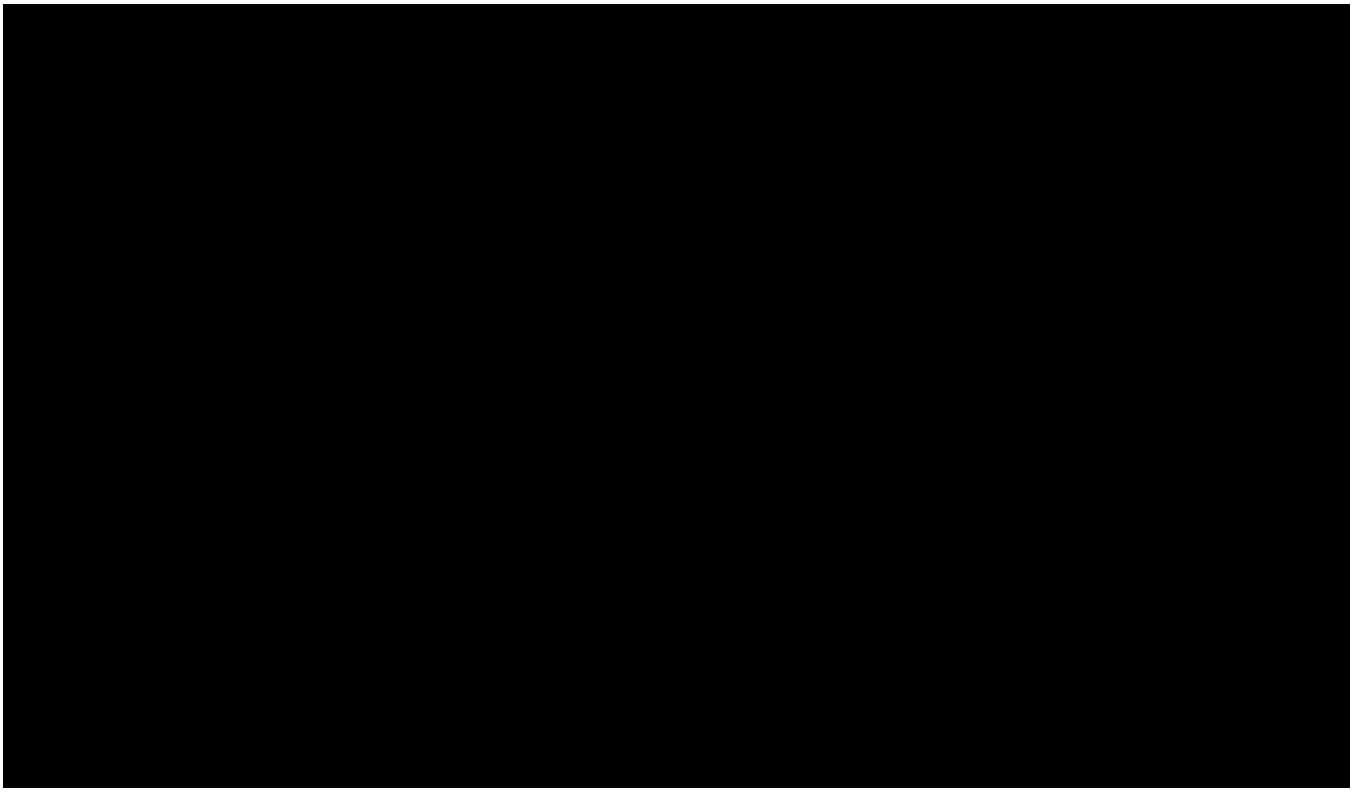
[redacted].[63]

[redacted]); Williams Affidavit, Exhibit 28, page 712 ([redacted]" even though the BC government's policy is that patients receiving Stelara must switch to a biosimilar); and Williams Affidavit, Exhibit 29, page 731 [redacted]", even though the Alberta government's policy is that patients receiving Stelara should switch must switch to a biosimilar).

[62] [redacted]. See Williams Affidavit, Exhibit 27, page 667 ([redacted] (see Williams Affidavit, Exhibit 57, page 941).

[63] See Williams Affidavit, Exhibit 27, pages 703-706, [redacted]

Figure 1 – J&J's Internal Documents – Evidence of Intention to Develop a Strategy that Will Maintain Market Power for Stelara [64]



67. Figure 1 is direct proof of the allegation in paragraph 47 of the Proposed Notice of Application that J&J's anti-competitive practices in ustekinumab are from a playbook J&J developed to maintain its dominant position in Remicade. The Competition Bureau has explained its conclusion that J&J "had engaged in, and continued to engage in conduct that could raise concerns under the Act" with respect to Remicade.[65]

[64] Williams Affidavit, Exhibit 25, page 649 (see also Exhibit 10, page 520).

[65] See the Written Representations of the Commissioner of Competition, footnote 16, ¶24- 26 and the authorities cited therein.

Figure 2 – J&J's Internal Documents – [redacted] Permits J&J to Self-Preference its Own Products (including [redacted]), Even Where Insurers Prefer a Third Party Biosimilar[66]

68. J&J argues, and the Williams Affidavit asserts, that J&J staff "are not acting as healthcare professionals and … treatment decisions are made by patients in consultation with their treating physicians,"[67] but J&J's flow charts show that that is not true. Instead, the documents explain that (i) J&J's goal is that J&J perform the function of selecting a patient's ustekinumab drug through BioAdvance, and (ii) J&J always self-preferences the drug that generates the most profit for itself and excludes rival biosimilars.[68] In other

[66] Williams Affidavit, Exhibit 25, page 649 (see also Exhibit 10, page 520).

[67] J&J's Response, ¶13 and Williams Affidavit, ¶27.

[68] See Williams Affidavit, Exhibit 25 at page 649, explaining that for infliximab, [redacted] It is the job of physicians to worry about such matters, not J&J's. A real-life example of J&J providing advice about which drug to take to a patient, without involving the patient's physician, is included in the Faubert Affidavit, ¶34 and Exhibit F20.

words, J&J does not "discover" the drug that is best for a patient – J&J selects the drug that is best for J&J.

69. Second, J&J explains "out loud" its goal of monopolizing relationships with prescribers and patients, so that it can execute upon its exclusionary strategies. BioAdvance's slogan is "ONE Point of Contact".[69] J&J's internal documents summarize the goal of its exclusionary strategies for Stelara (and other drugs) thus: "[redacted]"[70]

70. Third, the timing for the creation of J&J's [redacted] leaves little question about J&J's anti-competitive intent. J&J [redacted].[71] That is <u>precisely the same day</u> that J&J [redacted].[72] J&J's only reason to commence discussions with Celltrion, and then permit Celltrion to participate in BioAdvance as [redacted][73] was that J&J was now certain of [redacted] and J&J needed to ensure it would have access to the portfolio of drugs it needed to continue monopolizing its relationship with patients (which

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[69] Williams Affidavit, Exhibit 27, starting at page 655 (in the lower left corner).

[70] Williams Affidavit, Exhibit 27, page 672.

[71] [redacted] Agreement, Williams Affidavit, Exhibit 62.

[72] Williams Affidavit, Exhibit 57, page 934 [redacted].

[73] The hierarchy is even reflected in the [redacted] at Williams Affidavit, Exhibit 57 at pages 939 and 940).

J&J established when Stelara was subject to patent protection and faced no competition).[74]

C. Anti-Competitive Practices

71. J&J argues that JAMP's allegations of anti-competitive practices are "unsupported by credible evidence."[75] An examination of JAMP's allegations, in the order that they are listed in the Proposed Notice of Application at paragraph 41, and J&J's responses to each allegation (including its documents), reveals the opposite.

72. **JAMP's first three allegations** – that J&J gamed the regulatory system with different strategies to disincentivize and delay the entry of biosimilars – are supported by the record. J&J was unsuccessful in its efforts to list the 837 Patent on the Patent Register for either Stelara or Finlius, J&J was unsuccessful in or abandoned its various litigation efforts regarding listing, and J&J obtained regulatory approval for Finlius (a product that J&J admits is identical to Stelara) but did not launch the product for a long period of time.[76]

73. J&J's response is to mischaracterize these allegations as merely "related to the 837 patent,"[77] and then to attempt to shelter under subsection 79(5) of the *Competition Act* regarding the exercise of intellectual property rights. As described above, the ability to list patents on the Patent Register turns on timing and eligibility requirements set out in the *Patented Medicines (Notice of Compliance) Regulations* that are independent of the actual

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[74] For a discussion of the unique advantage created by patient support programs for originator biologic manufacturers over biosimilar manufacturers, see JAMP's Memorandum, ¶40.

[75] J&J's Response, ¶67.

[76] See JAMP's Memorandum, ¶105-115. See also Juneja Affidavit, ¶30-40.

[77] J&J's Response, ¶58 and 93. See Williams Affidavit, ¶12 for J&J's admission that Finlius is the same product as Stelara, and that J&J obtained approval for Finlius in April 2023 but did not launch the product until July 2024.

validity of those patents (and the actual exercise of intellectual property rights).

74. J&J omits that it had no listing rights under the *Patented Medicines (Notice of Compliance) Regulations*, which are the rights at issue in JAMP's allegations (a) and (c).[78] J&J's attempts to obtain such listing rights were rejected by Health Canada (twice), by the Federal Court and the Federal Court of Appeal (and then abandoned by J&J itself). J&J's knowingly futile attempts to obtain such listing rights were clearly "something more than the mere exercise of patent rights" that could affect competition in the relevant market,[79] and therefore are not protected by subsection 79(5).

75. Separately, J&J offers no explanation for the long delay between the NOC and the launch of Finlius, despite J&J's claims that Finlius was demanded by certain of its customers;[80] J&J's documents in fact explain that the delay in launching Finlius was [redacted].[81]

76. **JAMP's fourth and fifth allegations** are that J&J misused BioAdvance and provided misleading information to prescribers and patients. J&J argues that BioAdvance is for the benefit of patients,[82] but J&J's own documents (and BioAdvance's corporate slogan) show that BioAdvance's real purpose is to monopolize the relationship with prescribers and

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[78] See the discussion at ¶31-33, above.

[79] *Eli Lilly and Co. v. Apotex*, 2005 FCA 361, ¶16-18. See also the discussion at ¶31-33, above.

[80] J&J's Response, ¶38 and 40.

[81] Williams Affidavit, Exhibit 12, page 534 ([redacted]) and Exhibit 13, page 538 (regarding Finlius, "[redacted]").

[82] J&J's Response, ¶12 and 13. See also the description of patient-centric services listed in the Williams Affidavit, ¶27.

patients and to serve J&J's commercial objectives, so that J&J can self-preference itself in different ways – see paragraphs 65 to 70, above.[83]

77. In addition, J&J's internal documents clearly demonstrate that J&J provided misleading information to prescribers and patients through BioAdvance. Here are four examples:

(a) J&J claims that it is always explicit in its communications that Finlius is not a biosimilar, and the Williams Affidavit attests that "all of Janssen's physician marketing materials clearly state that FINLIUS… is not a biosimilar."[84] The Williams Affidavit appends six Finlius-related physician marketing materials that allegedly contain such statements, but, on closer inspection, four of them do not.[85] That such disclosure is absent is precisely the point of Finlius – to create confusion and uncertainty in the market, and delay switching to biosimilars.

(b) It is contrary to the *Food and Drug Regulations* to "sell or advertise a new drug unless," among other things, a NOC has been issued for the drug.[86] Finlius received its NOC on April 18, 2023, and Celltrion's Steqeyma received its NOC on July 30, 2024.[87] Surprisingly, J&J's Response admits that it engaged in marketing prior to July 30, 2024 for the benefit of Steqeyma, even though the product "had not

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[83] See Williams Affidavit, Exhibit 10, page 519, [redacted]. See also Williams Affidavit, Exhibit 11, page 527.

[84] J&J's Response, ¶79-82 and Williams Affidavit, ¶39.

[85] See Williams Affidavit, ¶38 and 39, as well as Exhibits 51 to 56. Exhibits 51 to 54 make no reference to whether Finlius is a biosimilar or not.

[86] *Food and Drug Regulations*, C.R.C. 870, s. C.08.002(1).

[87] Williams Affidavit, ¶12 and 40.

received an NOC…"[88] [redacted].[89] The two potential explanations for J&J's (often vague) statements are that J&J was: (i) advertising Finlius (which was misleading because Finlius is not a biosimilar); or (ii) advertising Steqeyma without a NOC having been issued (in contravention of the prohibition in the *Food and Drug Regulations*). In either circumstance, J&J's representations created confusion and uncertainty in the market, and delayed switching to biosimilars.

(c) J&J's documents demonstrate how it markets to physicians using half-truths and misleading omissions. For example, a J&J marketing document contains [redacted]

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[88] J&J's Response, ¶76 and 80.

[89] See, for example, Williams Affidavit, Exhibit 47 (email from Andy Williams dated May 7, 2024 advising that "[redacted]"); as well as Exhibits 48 to 50. For earlier messaging, see Williams Affidavit, Exhibit 10, page 521 (approved messaging that "[redacted]") and page 523 ([redacted]); Williams Affidavit, Exhibit 25, page 644-645 (March 2024, explaining that [redacted]); Williams Affidavit, Exhibit 25, page 651; Williams Affidavit, Exhibit 27, page 667 ([redacted], and at page 697 [redacted] page 680, page 686, page 703 (describing how "[redacted]"); Williams Affidavit, Exhibit 28, page 715 ([redacted]), pages 718-721 (each time referencing "[redacted]"). There are numerous other examples in Exhibits 29 to 45, all of which [redacted]

[redacted]

[redacted]

[redacted]

[redacted]". [90] The real answer, as the Williams Affidavit explains, is that Finlius is not a biosimilar and provincial insurers have made a "policy choice… to support the biosimilar industry", and so Finlius cannot "be listed on any public formulary because Janssen is still an innovator manufacturer". [91] J&J's documents contain numerous other examples of such half-truths. [92] The most competitively dangerous of these half-truths is J&J's frequent messaging to physicians that, despite the creation and implementation of policies by public insurers to switch patients to biosimilars, [redacted] (that is, prescribers should not take action to switch their patients to a biosimilar). [93] J&J knows that patients are required to switch to another drug in the near-term (*e.g.*, six months or less) to maintain insurance coverage, but its messaging avoids such disclosure and instead seeks to create delay [redacted]

[redacted]

[redacted]

[redacted]. This delay imposes higher costs on public insurance plans and

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[90] Williams Affidavit, Exhibit 27, page 669. [redacted]

[91] Williams Affidavit, ¶22.

[92] See, for example, Williams Affidavit, Exhibit 11, page 528 ([redacted]" even though Wezlana (marketed by Amgen Canada Inc.) does offer these indications).

[93] Williams Affidavit, Exhibit 10, page 521 and 528; Exhibit 25, page 644 and 645; Exhibit 30, page 754, 755 and 760. This expression, or variations of it, appear numerous times in the exhibits to the Williams Affidavit.

other payors (because patients stay on high-priced Stelara longer) and excludes biosimilar manufacturers.

(d) As alleged in JAMP's Memorandum, Janssen deliberately markets its products verbally to avoid creating a written record (or to minimize that record).[94] J&J says that that allegation is false.[95] However, J&J's documents show how it [redacted].[96] Courts assessing anti-competitive conduct have been very critical of respondents with market power that engage in practices that appear intended to avoid the creation of a written record.[97]

78. **JAMP's sixth allegation** is that J&J has misused its marketing tools to intimidate prescribers. J&J denies only a portion of the allegation, arguing that its non-disclosure agreements with physicians do not prevent physicians from meeting with JAMP.[98]

79. J&J does not attest that it has not threatened to enforce those agreements, or that it has not otherwise taken steps to prevent or discourage physicians from accepting marketing from

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[94] JAMP's Memorandum, ¶40 and 118.

[95] J&J's Response, ¶83.

[96] See, for example, Williams Affidavit, Exhibit 27, pages 669, 703-707; and Exhibit 28, page 715 and 718-723. Exhibits 29 to 45 contain numerous [redacted]

[97] See, for example, *United States of America v. Google LLC*, Case 1:20-cv-03010-APM, August 5, 2024, at page 275 ("the court is taken aback by the lengths to which Google goes to avoid creating a paper trail for regulators and litigants. It is no wonder then that this case has lacked the kind of nakedly anticompetitive communications seen in Microsoft and other Section 2 cases. *[internal citations omitted]* Google clearly took to heart the lessons from these cases. It trained its employees, rather effectively, not to create "bad" evidence. Ultimately, it does not matter. Section 2 liability does not rise or fall on whether there is "smoking gun" proof of anticompetitive intent.").

[98] J&J Response, ¶87-89 and Williams Affidavit, ¶42.

biosimilar manufacturers. Instead, J&J's documentary evidence indicates that BioAdvance [redacted] including their [redacted].[99] J&J's agreements with physicians that participate in its advisory boards – [redacted][100] – among other levers, give J&J numerous means to discourage physicians from engaging with biosimilar manufacturers.

80. **JAMP's seventh allegation** is that J&J has engaged in predatory pricing. J&J denies the allegation, arguing that "JAMP has provided no evidence of Janssen pricing STELARA or FINLIUS below cost, or even below the price of Jamteki." J&J has also submitted affidavit evidence, avowing that it only sells its product above cost.[101] Despite seeking and obtaining permission from the Tribunal to submit evidence on this topic, J&J offers no quantifiable information about its pricing.[102]

81. However, J&J's own internal documents explain that more than [redacted]% of all Stelara patients receive their drugs [redacted][103] Moreover, the documents show that [redacted][104] The documents show that

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[99] See Williams Affidavit, Exhibit 27, pages 704 and 705 (referencing the [redacted]

[100] Williams Affidavit, Exhibit 59, page 963 ([redacted] and page 973 ([redacted]

[101] J&J's Response, ¶72 and Williams Affidavit, ¶15 ("In any event, STELARA and FINLIUS have, in all instances, been sold above cost.").

[102] See footnote 8, above, at ¶30 and 35.

[103] Williams Affidavit, Exhibit 8, page 440.

[104] See the J&J documents referenced in footnotes 61 and 62, above, and Figure 2.

[redacted][105]

82. **JAMP's eighth allegation** is that J&J has misled private insurers. J&J denies the allegation, arguing that the evidence that a private insurer's March 2024 publication described Finlius as a biosimilar is an "error" of the private insurer alone.[106]

83. J&J offers no explanation for why it never corrected the insurer about its "innocent mistake",[107] which is surprising given the significant efforts drug companies make to ensure their products adhere to the prescriptive rules for the marketing of drugs in Canada. Moreover, J&J's documents reveal that it was engaged in [redacted].[108] The Tribunal has previously recognized that conduct intended to prevent a new entrant from becoming an effective competitor is anti-competitive.[109]

84. **JAMP's ninth allegation** is that Finlius is a fighting brand and is supplied at a selective

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[105] Williams Affidavit, Exhibit 28, page 712.

[106] J&J's Response, ¶90.

[107] J&J's Response, ¶91.

[108] Williams Affidavit, Exhibit 13, at page 539 and 540 (see the relationship on page 540 between biosimilar pricing initiatives and J&J responses, and J&J's efforts to [redacted]").

[109] *Director of Investigation and Research v. Laidlaw Waste Systems Inc.*, CT-1991-002 – Doc #72, pages 50-51 and 98-100 (in each instance, describing conduct that prevented a rival from achieving minimum viable scale).

and discriminatory price. J&J denies the allegation. First, J&J makes submissions and provides affidavit evidence about the alleged preferences of private insurers for identical products with different pricing attributes.[110] According to J&J, "some private insurers prefer "transparent pricing" through a product with a lower list price, due to a preference of some of their customers not to enter into rebate agreements…".[111] Despite seeking and obtaining permission from the Tribunal to submit evidence on this topic,[112] J&J offers no documentary evidence whatsoever to support its assertion about the preferences of insurers.[113] Second, [redacted] and therefore argues that Finlius cannot be a fighting brand.[114]

85. Contrary to its submissions and the evidence of its affiant, Mr. Williams, J&J has tendered internal documents that clearly demonstrate that [redacted].[115] These facts are in direct conflict with the asserted desires of private insurers that J&J claims to have served by launching Finlius.

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[110] J&J's Response, ¶38 and 68; see also Williams Affidavit, ¶10.

[111] J&J's Response, ¶37 and 38; Williams Affidavit, ¶10.

[112] See footnote 8, above, at ¶29 and 34.

[113] For example, J&J does not offer a pre-existing email or letter from an insurer making a request to J&J for a product like Finlius.

[114] J&J's Response, ¶69.

[115] Williams Affidavit, Exhibit 12, page 534 (referencing how a pricing team "[redacted]") and Williams Affidavit, Exhibit 13, page 542 ([redacted]). The native version of Exhibit 13 (which is electronically accessible through a link in Exhibit 12) contains PowerPoint "Speaking Notes" that are not visible in the Williams Affidavit. On slide 6 (the equivalent of page 542), the speaking notes explain, [redacted]"

86. J&J's argument about the pricing of Stelara and Finlius is also contradicted by J&J's own evidence. Without referencing any academic or economic sources, J&J argues that fighting brands "are typically offered at a substantial discount to an existing "main" brand."[116] In the next sentence, J&J then [redacted] J&J's documents show that the offered prices of Stelara and Finlius [redacted].[117] All of this appears to be a surprising admission against interest – supported by J&J's own documents – that Finlius has characteristics that are "typically" found in a fighting brand.

87. In the absence of evidence that might "negate" or "refute" JAMP's allegations, the undisputed facts are as follows:

(a) Stelara obtained its NOC in 2008;

(b) Biosimilars to Stelara were first marketed in March 2024;

(c) Finlius is identical to Stelara (that is, it is a relabelled biologic);

(d) J&J waited 15 years to apply for and obtain a NOC for Finlius in April 2023, and first marketed Finlius in July 2024 (although it could have done so at any time since 2008);

(e) Finlius is offered at a substantially lower price than Stelara; and

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[116] J&J's Response, ¶69.

[117] Williams Affidavit, Exhibit 12, page 534 (comparing the [redacted])

(f) J&J's explanations for why it launched Finlius are contradicted by the internal documents that it has tendered.

88. The foregoing is more than credible evidence to form a *bona fide* belief that the "overall character" of Finlius is to operate as a fighting brand, as defined in section 78 of the *Competition Act*.

D. Substantial Effect on Competition

89. J&J argues that JAMP has not provided sufficient credible evidence that any of J&J's alleged conduct resulted in a substantial prevention or lessening of competition.[118] However, there is ample evidence of the effects on competition caused by J&J's conduct.

90. First, despite no patents being listed on the Patent Register against Stelara since 2021, no biosimilar to Stelara entered the Canadian market until March 2024. During this period, sales of Stelara grew and J&J faced no competitive pressure to discount its prices. Instead, J&J generated additional sales in excess of $2.138 billion.[119]

91. Second, the harm from J&J's continuing conduct is observable in market shares. Despite the entry of lower cost biosimilars and policies of insurers to encourage substitution for lower cost biosimilars, J&J's share of ustekinumab products remains in excess of 99%.[120]

92. Third, J&J has demonstrated the effect of how it exercises market power. In particular,

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[118] J&J's Response, ¶101.

[119] JAMP's Memorandum, ¶44.

[120] JAMP's Memorandum, ¶45. This figure remains true as of the date of this Reply.

J&J's documents project that its market power (derived, in part, from its continuing conduct) will permit it to profitably [redacted] the list price of Finlius by [redacted]%.[121]

93. Fourth, J&J has launched Finlius, a relabelled biologic. The Competition Bureau has warned that an originator company that obtains approval for and markets a relabelled biologic drug "could harm competition by making it less likely that patients will switch away from an originator biologic drug to biosimilars, reducing incentives for pharmaceutical companies to develop and market biosimilars."[122]

94. The foregoing is credible evidence to form a *bona fide* belief that J&J's conduct has and is likely to continue to prevent and lessen competition substantially.

VII. CONCLUDING MATTERS AND COSTS

95. Given the harm to competition, and to JAMP's business, that arises from J&J's continuing conduct, JAMP's interest is in an expedited resolution of this application. Accordingly, JAMP does not request an oral hearing, but is available to support the Tribunal with any questions that may arise (including via teleconference).

96. JAMP ought to be awarded its costs in this application for leave. Among other reasons (apart from the result of this application), JAMP notes the following:

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[121] See ¶62(b), above, and footnote 56, above.

[122] See the Written Representations of the Commissioner of Competition, footnote 16, ¶27-28 and the authorities cited therein.

(a) J&J delayed in bringing a motion for leave to tender responding evidence and then refused to agree to a motion schedule that would permit the Tribunal time to issue a decision prior to the end of the period for submitting J&J's response;

(b) J&J sought to introduce wide-ranging evidence but failed to deliver a draft affidavit to the Tribunal, contrary to the Tribunal's guidance;[123]

(c) J&J delivered its response after the extended deadline set by the Tribunal, has made no effort to seek relief from the Tribunal, and has offered no explanation for its tardiness;

(d) Despite its motion, J&J failed to provide any evidence in a number of categories that the Tribunal permitted as an exception to the rule against responding evidence;[124] and

(e) J&J's arguments about its conduct are directly contradicted by its own internal documents, which indicates a lack of respect for these proceedings and the Tribunal.[125]

97. Given the foregoing, JAMP reiterates its request for an Order:

(a) granting it leave to commence an Application against J&J pursuant to section 79, in the form contained within the Proposed Notice of Application; and

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[123] See footnote 8, at ¶25.

[124] See for example ¶81 and 84, above.

[125] See for example ¶63, 77(a), 77(d), 81, 85 and 86 above.

(b) awarding JAMP its costs of this Application for leave.

September 13, 2024 **ALL OF WHICH IS RESPECTFULLY SUBMITTED**

David Rosner

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Lawyers for the Applicant,
JAMP Pharma Corporation

VIII. LIST OF AUTHORITIES

TAB	DESCRIPTION
Case Law	
1.	*AstraZeneca v. Apotex*, 2011 FCA 211, affirming 2011 FC 505
2.	*B-Filer Inc. v. The Bank of Nova Scotia*, 2005 Comp. Trib. 31
3.	*Canada v. Microbjo Properties Inc.*, 2023 FCA 157
4.	*Canada v. Oxford Properties Group Inc.*, 2018 FCA 30
5.	*Commissioner of Competition v. Abitibi-Consolidated Inc.*, 2022 Comp Trib 3
6.	*Commissioner of Competition v. Vancouver Airport Authority*, 2019 Comp Trib 6
7.	*Director of Investigation and Research v. Imperial Oil Limited* (1994), CT-1989/003, [1994] CCTD No 23
8.	*Director of Investigation and Research v. Laidlaw Waste Systems Inc.*, CT-1991-002 – Doc #72
9.	*Director of Investigation and Research v. Tele-Direct (Publications) Inc., et al*, CT-1994/003
10.	*Douez v. Facebook, Inc.*, [2017] 1 SCR 751
11.	*Eli Lilly and Co. v. Apotex*, 2005 FCA 361
12.	*JAMP Pharma Corporation v. Janssen Inc.*, 2024 Comp Trib 4
13.	*Janssen Inc. v. Canada (Health)*, 2023 FC 870
14.	*Merck Canada Inc. v. Canada (Health)*, 2021 FC 345
15.	*R v. Breault*, 2023 SCC 9
16.	*R v. D.A.I.*, 2012 SCC 5
17.	*Sattva Capital Corp. v. Creston Moly Corp.*, 2014 SCC 53
18.	*United States of America v. Google LLC*, Case 1:20-cv-03010-APM
19.	*United States v. Dynar*, 1997 CarswellOnt 1981

TAB	DESCRIPTION
Legislation & Rules	
20.	*Competition Act,* 1985 RSC c C-34
21.	*Competition Tribunal Act,* 1985 RSC c 19
22.	*Competition Tribunal Rules,* SOR 2008-141
23.	*Food and Drug Regulations*, C.R.C. 870
24.	*Interpretation Act,* 1985 RSC c. I-21
25.	*Patented Medicines (Notice of Compliance) Regulations,* SOR 93-133

File No. CT-2024-006

COMPETITION TRIBUNAL

IN THE MATTER OF the Competition Act, R.S.C. 1985, c. C-34 (the"**Act**");

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

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

BETWEEN:

JAMP PHARMA CORPORATION

Applicant

– and –

JANSSEN INC.

Respondent

REPLY OF THE APPLICANT, JAMP PHARMA CORPORATION
(Pursuant to s. 103.1 of the *Competition Act*)

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