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

PROPOSED NOTICE OF APPLICATION

(Pursuant to section 79 of the *Competition Act*)

TAKE NOTICE THAT:

1. The Applicant will make an application to the Competition Tribunal ("**Tribunal**") pursuant to section 103.1 of the *Competition Act* (the "**Act**") for:

    a. an Order pursuant to subsection 79(1) of the Act prohibiting the Respondent:

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

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

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

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

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

        vi. for a period of 5 years from enforcing or threatening to enforce non-disclosure agreements against health care professionals, or withholding any thing of value or threatening to withhold any thing of value from health care professionals, due in whole or in part to any health care professional's

decision to prescribe, administer or deal in any drug, accept or consider marketing of any drug by a third party, or make decisions in accordance with the health care professional's exercise of their knowledge, skill and judgment relating to any patient or other matter; and

vii. for a period of 5 years from communicating with any patient enrolled in BioAdvance about (a) the availability of any biosimilar drug, interchangeable drug or bioequivalent drug and (b) the requirements, rules or procedures of any insurance plan or reimbursement scheme as it pertains to any biosimilar drug, interchangeable drug or bioequivalent drug, unless prior approval is obtained from the monitor described in paragraph 1.b.ii.

b. an Order pursuant to subsection 79(2) of the Act:

i. requiring the Respondent to communicate with all health care professionals whose patients were enrolled in BioAdvance for Stelara between January 1, 2021 and the date of the Order that (i) Finlius is not a biosimilar product, (ii) Finlius will not be marketed for 10 years, (iii) no drug that is biosimilar to Stelara will be offered through or in connection with BioAdvance for 5 years, (iv) the Respondent is prohibited from taking the actions described in paragraph 1.a.vi, (v) the Respondent's marketing and sale of biologic drugs is overseen by a monitor as described in paragraph 1.b.ii, and (vi) the email address and phone number of that monitor, on terms that the Applicant will advise or that the Tribunal deems just; and

ii. appointing a monitor, responsible for monitoring compliance by the Respondent with the Order and compliance with section 79 of the *Competition Act* as it pertains to the Respondent's marketing and sale of biologic drugs in Canada for a period of 5 years, on terms that the Applicant will advise or that the Tribunal deems just.

c. an Order pursuant to subsection 79(3.1) of the Act requiring the Respondent to pay, in any manner that the Tribunal specifies, an administrative monetary penalty in an amount of three times the value of the benefit derived from the Respondent's anti-

competitive practices, which is at least $1,000,000,000, or such other amount as the Applicant may request and the Tribunal deems just;

d. an Order expediting the hearing of the within Application;

e. an Order for costs, if the within Application is opposed; and

f. such further and other interim orders as the Applicant may request and the Tribunal deems just.

AND TAKE NOTICE THAT:

2. The person against whom the order is sought is the Respondent: Janssen Inc. Respondent's address is set out below.

3. The Applicant will rely on the Statement of Grounds and Material Facts attached as Schedule A hereto; the Affidavit of Sukhad Juneja, sworn July 25, 2024; the Affidavit of Amélie Faubert, sworn July 25, 2024; the Affidavit of Genia Radeva, sworn July 25, 2024; the Affidavit of Emily Seaby, sworn July 26, 2024; the Memorandum of Fact and Law accompanying this Application; and such further or other material as counsel may advise and the Tribunal may permit.

4. A concise statement of the economic theory of the case is contained in Schedule B hereto.

5. The Applicant requests that this Application be heard in the English language.

6. The Applicant requests that the documents for this Application be filed in electronic form.

Dated at Toronto this 26th day of July, 2024.

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SCHEDULE A
STATEMENT OF GROUNDS AND MATERIAL FACTS

1. Canada's laws protect an originator firm's drugs from competition for a limited period of time, but once that period is up, the Competition Act (the "Act") requires that all firms compete. This policy extends to all types of drugs, including biologics, a new and complex category of drugs that make up a rapidly growing share of Canadian drug expenditures. The Respondent, Janssen Inc. ("**J&J**"), has abused its dominant position in a valuable biologic drug, excluding competitors, preventing and lessening competition substantially, and maintaining its monopoly.

I. EXECUTIVE SUMMARY

2. An affiliate of the Respondent, Janssen Inc. ("**J&J**"), developed ustekinumab, a biologic medicine. In 2008, Health Canada approved the sale of Stelara, which is J&J's drug product that contains ustekinumab as an active ingredient. Stelara proved to be an effective long-term treatment for many patients suffering from certain chronic diseases, such as psoriasis.

3. J&J's monopoly over the Canadian market for ustekinumab spanned many years. Canada's data protection regime ensured that Stelara could face no competition until December 2016. Canada's patent regime, coupled with the *Patented Medicines (Notice of Compliance) Regulations*, ensured that Stelara could face no competition until August 2021, when the last of J&J's patents for Stelara listed on the patent register expired.

4. J&J sells Stelara for more than $4,000 per dose. As a result of the time-limited monopolies granted by Canada's data protection and patent regimes, J&J's revenues from Stelara in Canada ballooned, growing every year and totalling more than $690 million on a wholesale

basis in 2021. Between launch in 2008 and August 2021, J&J earned revenues of $2.249 billion from sales of Stelara in Canada.

5. At that point, apparently unsatisfied with its thirteen years of monopolistic profits, and rather than accepting that its time-limited monopoly was at an end and engaging in competition for ustekinumab, J&J gamed the pharmaceutical regulatory system and used sham litigation to disincentivize rivals from launching their own ustekinumab drugs. This resulted in J&J being the only supplier of ustekinumab drugs in Canada between August 2021 and March 1, 2024. In that period alone, because it still did not face any competition, J&J almost doubled its total revenue from the first 13 years of selling Stelara in Canada, generating an additional $2.138 billion of revenues.

6. The inevitable eventually happened and two of J&J's rivals (including the Applicant, JAMP Pharma Corporation ("**JAMP**")) launched competing new ustekinumab drugs called biosimilars in March 2024. Now that J&J faces actual rivals, it has again declined to compete as Parliament intended – for example, by lowering Stelara's price or innovating. Instead, J&J again seeks to defend and maintain its monopoly. To do so, J&J has conceived of and implemented a series of inter-connected anti-competitive acts, including:

   (a) the development of a fighting brand;

   (b) the misuse of a patient support program;

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

   (d) predatory pricing; and

(e) selective and discriminatory responses to a competitor for the purpose of impeding its expansion and eliminating it from a market.

7. Some of these anti-competitive acts come from a playbook that J&J developed when defending and maintaining its monopoly in another biologic drug. But Parliament recently updated the *Competition Act* and so yesterday's abusive practices are no longer shielded from legal scrutiny today.

8. All of these anti-competitive acts are intended to have an exclusionary negative effect on competitors and an adverse effect on competition. These anti-competitive acts are intended to maintain J&J's monopoly for ustekinumab drugs in Canada and preserve Stelara's high prices. The anti-competitive acts deprive Canadian patients of the ability to access new competitive options for ustekinumab drugs, and result in Canadian patients and payers (including provincial drug plans and private insurers) paying far more than they otherwise would for this vital medicine.

II. FACTS

A. The Parties

9. The Applicant, JAMP Pharma Corporation ("**JAMP**"), is a company incorporated under the laws of Canada and headquartered in Montreal. JAMP operates a diverse portfolio of businesses across seven divisions. One of those divisions is BioJAMP, which sells biosimilar products, including Jamteki, an ustekinumab drug that is biosimilar to Stelara.

10. The Respondent, Janssen Inc. ("**J&J**") is a Canadian pharmaceutical company that is a subsidiary of Johnson & Johnson, the New Jersey-based multinational pharmaceutical, biotechnology and medical technologies corporation. Janssen Inc. operates Johnson &

Johnson's Innovative Medicine Division in Canada. J&J sells biologic drugs, including Stelara, an ustekinumab drug.

B. Biologic and Biosimilar Drugs

11. Biologic drugs are a new and complex category of drugs that are extracted from living cells, such as animal cells, bacteria or yeast. Biologics can be contrasted with older generation small molecule drugs that are chemically synthesized. Biologic drugs feature complex (and larger) molecules, and their manufacture is comparatively complex.

12. Because biologic drugs are extracted from living cells in which there is inherent variability, it is not possible to produce a chemically identical "generic" version of a biologic drug. However, it is possible to produce a highly similar drug – that is, a new biologic drug that has no expected clinically meaningful differences in efficacy and safety compared to the originator biologic drug. Such drugs are referred to as "biosimilars."

C. Regulation of Biosimilar Drugs

13. Biologic and biosimilar drugs are regulated under the *Food and Drug Regulations*. An originator firm seeking approval for an innovative biologic drug must submit a New Drug Submission ("**NDS**") to Health Canada, seeking a Notice of Compliance ("**NOC**"). Similarly, a biosimilar firm seeking approval for a biosimilar drug must submit a NDS to Health Canada, seeking a NOC.[1] If the dosage form, strength and route of administration of the proposed biosimilar drug is the same as the original biologic drug, Health Canada

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[1] Because the biosimilar drug and the original biologic drug are not identical, the biosimilar firm is not permitted to submit an Abbreviated New Drug Submission (which is a simpler process that is available for generic versions of small molecule drugs).

will issue a NOC for the biosimilar drug based on fewer phase III clinical trials than are required for an originator firm seeking approval for an innovative biologic drug.

14. Because the original biologic drug and the biosimilar drug are not identical, the biologic drug and the biosimilar drug are not subject to the "automatic substitution" rules that are maintained by provincial drug plans and other payers, which mandate the substitution of lower cost generic drugs for higher priced brand name drugs (when they are dispensed at pharmacies). Instead, for a biosimilar drug to be dispensed to a patient, the patient's physician must write a new prescription for the specific biosimilar drug.

D. Patient Support Programs

15. The administration of biologic drugs can be complex. For example, many biologic drugs must be administered by an infusion or injection. In addition, biologic drugs tend to have high prices. To support the adoption of drugs with complex administration, drug firms have established patient support programs ("**PSPs**"). At the time a prescription for a biologic drug is written, a physician will enroll a patient in the PSP of the drug's manufacturer. A representative of the PSP will typically contact the patient to establish a schedule for the administration of the drug, and take steps to facilitate the reimbursement of the drug's cost for the patient (e.g., by contacting the patient's insurer and handling paperwork). These efforts ensure the patient is administered the drug in the prescribed manner, which improves health care outcomes. These efforts also reduce the likelihood of the patient avoiding the drug for administrative or financial reasons and also increase the drug's volume of sales.

16. Enrolling a patient in a PSP gives a drug firm extensive information about the identity and practices of the physicians who prescribe the drug and the patients who use them. A firm that originates an innovative biologic drug (and is protected from competition for a period) will obtain information on every prescriber and patient for the drug in Canada, as well as a means to establish and maintain communication with them. During that same period where the drug is protected from competition, prescribers and patients will become habituated to the originator firm's PSP. At the time it launches a biosimilar drug, a biosimilar firm will not possess such information about physicians and patients (but faces a rival that does), and may face resistance to switching from physicians and patients who have become familiar with the originator firm's PSP.

17. Each of J&J and JAMP operate a patient support program. J&J's patient support program is called BioAdvance. JAMP's patient support program is called JAMP Care.

E. Ustekinumab, Stelara and Stelara's Loss of Exclusivity

18. Ustekinumab is a biologic drug that was developed by an affiliate of J&J. Ustekinumab is effective at treating several life-threatening autoimmune diseases, including psoriasis, Crohn's disease and ulcerative colitis.

19. In 2008, Health Canada issued a NOC for Stelara, which is J&J's drug product that contains ustekinumab. Stelara proved to be an effective long-term treatment for some patients suffering from certain autoimmune diseases. J&J sold Stelara for more than $4,000 per dose. As a result, J&J's revenues from Stelara in Canada ballooned, growing from approximately $5.3 million in 2009 to more than $900 million in 2023.

20. Stelara's eight-year exclusivity period under the data protection regime expired on December 12, 2016. In addition, the final patent listed on the patent register against Stelara expired on August 9, 2021. Following that date, Stelara no longer benefited from any barrier to competitive entry of biosimilars under Canadian law.

F. JAMP's Biosimilar Business and the Identification of a Biosimilar to Stelara

21. In 2022, biologic drugs accounted for approximately 46% of the value of patented medicine sales in Canada, and the uptake of biosimilars in Canada is low compared to other international markets. JAMP perceived an opportunity to develop a biosimilar business in Canada that would provide savings to payers while improving healthcare outcomes for patients.

22. JAMP entered into a strategic partnership with Alvotech hf, an Icelandic firm that specializes in the development and manufacture of biosimilars, for the supply and sale of biosimilar drugs in Canada.

23. In February 2022, JAMP announced the creation of a new division, BioJAMP to sell biosimilars.

24. In April 2022, JAMP announced the launch of BioJAMP's first biosimilar drug, Simlandi, an adalimumab biosimilar to Humira, which is marketed by AbbVie. The launch of Simlandi was a success.

25. Following the success of Simlandi, BioJAMP planned to launch additional biosimilars. As Stelara no longer benefited from any barrier to competitive entry under Canadian law,

BioJAMP identified ustekinumab as an attractive potential market. JAMP submitted a NDS for Jamteki, a biosimilar to Stelara, on November 24, 2022.

G. J&J Creates Legal Uncertainty for Potential Entrants for Biosimilars to Stelara, Including JAMP

26. J&J was not content with the monopoly and extraordinary revenues it enjoyed over the sale of ustekinumab drugs in Canada from 2008 to 2021. Instead of competing on the merits, J&J devised a number of new strategies to maintain its privileged position by disincentivizing biosimilar firms from launching biosimilars to Stelara.

27. For example, on July 25, 2022, J&J attempted to list Canadian Letters Patent No. 3,113,837 (the "**837 Patent**") on the patent register against Stelara. It was apparent that J&J was out of time under the *Patented Medicines (Notice of Compliance) Regulations* ("**PM(NOC) Regulations**") to have the patent listed, and Health Canada declined the attempt to list the 837 Patent. Undeterred, J&J filed an application for judicial review in the Federal Court. When that did not succeed, J&J appealed to the Federal Court of Appeal. J&J's appeal was dismissed from the bench on November 21, 2023.

28. By further example, in parallel to its litigation regarding the 837 Patent and Stelara, J&J submitted a NDS for a "new" ustekinumab drug, Finlius. Health Canada issued approval for Finlius on April 18, 2023. As J&J has admitted in its own court filings, "Finlius is merely another name for Stelara but is otherwise an identical product." Nevertheless, J&J attempted to list the 837 Patent on the patent register against Finlius. Health Canada once again declined the attempt, which was nothing more than an end-run around the requirements of the PM(NOC) Regulations. Once again, J&J filed an application for judicial review with the Federal Court. Knowing that its end-run was doomed to fail, J&J

stayed its application for judicial review pending the outcome of its litigation with the 837 Patent and Stelara. J&J only discontinued its application on February 28, 2024, which was almost three months after the dismissal of J&J's appeal regarding the 837 Patent and Stelara, and only after a request for a status update from the Federal Court.

29. All of these strategies were a predictable failure in court, but succeeded in the market. The strategies created two alternative risks for any firm contemplating the launch of a biosimilar to Stelara:

(a) If J&J succeeded at having the 837 Patent listed on the patent register for either Stelara or Finlius, the biosimilar firm would be met with an automatic 24-month preclusion of the issuance of a NOC under the PM(NOC) Regulations.

(b) Alternatively, if J&J was not successful, then the biosimilar firm would be forced to launch "at risk", as J&J could commence patent infringement proceedings against the biosimilar firm that, if successful, could expose the biosimilar firm to a potentially catastrophic damages award (since J&J generated more than $900 million in sales from Stelara in 2023, and patent litigation takes years to result in a trial judgment (with potential liability accruing throughout)).

30. J&J anticipated rivals' desire for entry and acted promptly to discourage them by relying on Stelara's success. J&J used the threat of patent litigation's potentially ruinous damages awards or automatic 24-month stays to lower potential entrants' incentives to offer an ustekinumab biosimilar.

31. Given the significant degree of risk it faced from the launch of Jamteki, its biosimilar to Stelara, BioJAMP chose to refrain from launching the drug. [redacted]

[redacted] Jamteki was launched on March 1, 2024.

H. J&J's Anti-Competitive Acts to Delay Growth of Biosimilars

32. In response to the launch of Jamteki on March 1, 2024, J&J responded with a series of strategies, the common purpose of which was to prevent or delay switching from Stelara to biosimilars such as Jamteki (or Amgen's Wezlana).

33. For example, J&J misused its patient support program – which benefits from having information about every prescribing physician and patient for ustekinumab drugs in Canada – by contacting physicians and patients to advantage its own business. J&J issued vague communications to physicians, promising that a biosimilar drug would become available through BioAdvance, and then called physicians to verbally advise that the biosimilar would be Finlius. Those representations were not true – Finlius is not a biosimilar, and at the time it was not marketed in Canada – but the representations had the desired effect of delaying efforts by JAMP to facilitate switching of patients by prescribing physicians to a biosimilar. J&J also contacted patients, advising them to continue taking Stelara despite a provincial drug plan's directive regarding switching to Jamteki. These communications had the same effect of delaying efforts by BioJAMP to facilitate a switch to Jamteki.

34. By further example, J&J has taken advantage of the non-disclosure agreements and other means of control it has over prescribing physicians to intimidate those physicians not to meet with BioJAMP's sales representatives to discuss Jamteki, and has indicated its

intention to engage in predatory pricing against Jamteki for the purposes of delaying a switch from Stelara to an ustekinumab biosimilar.

35. By further example, J&J is now actively marketing and supplying its fighting brand, Finlius, in a selective and discriminatory manner for the purpose of impeding biosimilar expansion and eliminating biosimilars from the market.

I. Effects of J&J's Anti-Competitive Acts

36. As a result of J&J's acts between August 2021 and March 2024, no biosimilar firm was willing to launch a biosimilar to Stelara. In this period, J&J's revenues from sales in Stelara in Canada were $2.138 billion. But for J&J's anti-competitive conduct, rival manufacturers would have launched biosimilars to Stelara earlier than March 2024, and a substantial portion of J&J's sales would have been lost (either in revenue diverted to biosimilar manufacturers, or as a result of price competition, or both).

37. As a result of J&J's acts between March 1, 2024 and the present, the rate of penetration of lower cost biosimilar drugs is far lower than it would otherwise be. J&J's share of ustekinumab sales in Canada remains above 99.8% of units sold. By contrast, the rate of penetration of other lower cost biosimilar drugs is far higher. But for J&J's anti-competitive conduct, JAMP and Amgen would have generated substantially greater sales than they have realized between March 1, 2024 and the present, and a substantial portion of J&J's sales in that period of time would have been lost (either in revenue diverted to JAMP or Amgen, or as a result of price competition, or both).

III. GROUNDS FOR THE SECTION 79 APPLICATION

38. J&J has repeatedly and continues to breach subsection 79(1) of the Act. Such breaches have prevented and lessened competition substantially in the relevant market. J&J has derived an enormous benefit from these breaches such that an order prohibiting the impugned conduct will not restore competition. Instead, orders under subsections 79(2) and 79(3.1) are necessary to overcome the effects of the breaches in the relevant market and to promote practices that are in conformity with the purposes of section 79.

39. Subsection 79(1) of the Act provides as follows:

> **Prohibition if abuse of dominant position**
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> **79 (1)** On application by the Commissioner or a person granted leave under section 103.1, if the Tribunal finds that one or more persons substantially or completely control a class or species of business throughout Canada or any area of Canada, it may make an order prohibiting the person or persons from engaging in a practice or conduct if it finds that the person or persons have engaged in or are engaging in
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> **(a)** a practice of anti-competitive acts; or
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> **(b)** conduct
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> **(i)** that had, is having or is likely to have the effect of preventing or lessening competition substantially in a market in which the person or persons have a plausible competitive interest, and
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> **(ii)** the effect is not a result of superior competitive performance.

40. The product market that is relevant to this application is no wider than ustekinumab drugs in Canada. J&J substantially and completely controls the relevant market. J&J has market power, and is a monopolist, for ustekinumab drugs in Canada.

41. J&J has conceived of, and has and is continuing to engage in, a series of anti-competitive practices contrary to section 79. Those past practices include, among other things: (a)

gaming of the regulatory system and sham litigation regarding Stelara to exclude rivals; (b) developing a fighting brand, Finlius, to create uncertainty that excludes rivals; and (c) gaming of the regulatory system and sham litigation regarding Finlius to exclude rivals. Those ongoing practices include, among other things: (d) misusing J&J's patient support program to mislead health care professionals regarding the availability of a biosimilar through BioAdvance and delay biosimilar uptake; (e) misusing J&J's patient support program to mislead patients and delay biosimilar uptake; (f) misusing J&J's marketing tools to intimidate prescribers and delay biosimilar uptake; (g) engaging in predatory pricing for Stelara; (h) misleading private insurers about Finlius to exclude biosimilars and delay biosimilar uptake; and (i) supplying Finlius, a fighting brand, including at a selective and discriminatory price. The subjective and objective purpose of these anti-competitive practices is to negatively affect and exclude competitors, and to have an adverse effect on competition by permitting J&J to maintain its high pricing for Stelara and maintain its dominant share of the market.

42. J&J's conduct has prevented and lessened competition substantially. Between August 2021 and March 2024, J&J's revenues from sales in Stelara in Canada were $2.138 billion. But for J&J's conduct, rival manufacturers would have launched at least one lower cost biosimilar to Stelara prior to March 1, 2024, and prevailing prices for Stelara would have been lower. From March 1, 2024 to the present, J&J has maintained a share of units of ustekinumab drugs in Canada above 99.8%. But for J&J's conduct, the penetration rate of ustekinumab biosimilars would have been significantly greater, and prevailing prices for Stelara would have been lower.

43. Subsection 79(2) of the Act provides as follows:

Additional or alternative order

(2) If, on an application under subsection (1), the Tribunal finds that a practice of anti-competitive acts amounts to conduct that has had or is having the effect of preventing or lessening competition substantially in a market in which the person or persons have a plausible competitive interest and that an order under subsection (1) is not likely to restore competition in that market, the Tribunal may, in addition to or in lieu of making an order under subsection (1), make an order directing any or all persons against whom an order is sought to take actions, including the divestiture of assets or shares, that are reasonable and necessary to overcome the effects of the practice in that market.

44. JAMP pleads the contents of paragraph 42, above. J&J sells Stelara, a biologic drug based on ustekinumab. J&J's Stelara represents more than 99.8% of units sold of ustekinumab drugs in Canada. J&J has a competitive interest in the sale of ustekinumab drugs in Canada.

45. A prohibition order under subsection 79(1) is not likely to restore competition in the market for the sale of ustekinumab drugs.

46. J&J's anti-competitive practices include the communication of misleading information to health care professionals, private insurers and patients, the effect of which is to delay the switch to biosimilars to Stelara. An order is therefore required that J&J take certain steps to correct that misleading information, to restore competition and overcome the effects of J&J's anti-competitive practices.

47. J&J's anti-competitive practices in ustekinumab drugs are from a playbook J&J developed in support and protection of the dominant position of another biologic drug, Remicade (infliximab). An order is also required for the appointment of a monitor, who will be responsible for overseeing J&J's compliance with an order of the Tribunal and compliance with section 79 of the Act as it pertains to J&J's marketing and sale of biologic drugs in Canada, to restore competition and overcome the effects of J&J's anti-competitive practices.

48. Subsections 79(3.1) to (3.3) of the Act provide as follows:

> **Administrative monetary penalty**
>
> **(3.1)** If the Tribunal finds that a person has engaged in or is engaging in a practice of anti-competitive acts that amounts to conduct that has had or is having the effect of preventing or lessening competition substantially in a market in which the person has a plausible competitive interest and it makes an order against the person under subsection (1) or (2), it may also order them to pay, in any manner that it specifies, an administrative monetary penalty in an amount not exceeding the greater of
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> > **(a)** $25,000,000 and, for each subsequent order under either of those subsections, an amount not exceeding $35,000,000, and
> >
> > **(b)** three times the value of the benefit derived from the anti-competitive practice, or, if that amount cannot be reasonably determined, 3% of the person's annual worldwide gross revenues.
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> **Aggravating or mitigating factors**
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> **(3.2)** In determining the amount of an administrative monetary penalty, the Tribunal shall take into account any evidence of the following:
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> > **(a)** the effect on competition in the relevant market;
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> > **(b)** the gross revenue from sales affected by the practice;
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> > **(c)** any actual or anticipated profits affected by the practice;
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> > **(d)** the financial position of the person against whom the order is made;
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> > **(e)** the history of compliance with this Act by the person against whom the order is made; and
> >
> > **(f)** any other relevant factor.
>
> **Purpose of order**
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> **(3.3)** The purpose of an order made against a person under subsection (3.1) is to promote practices by that person that are in conformity with the purposes of this section and not to punish that person.

49. JAMP pleads the contents of paragraphs 42 and 44, above. The Tribunal should order that J&J pay an administrative monetary penalty in the amount of three times the value of the

benefit derived from its anti-competitive practices. In making this order, the Tribunal should take into account the following:

(a) J&J's anti-competitive practices have had a very substantial effect on competition, and on Canadians more broadly. J&J has disincentivized rival manufacturers from developing biosimilars, including ustekinumab drugs. But for J&J's anti-competitive practices, a significant percentage of the billions of dollars of revenue J&J earned from the sale of Stelara in Canada after August 2021 would have been retained by Canadian payors (including provincial drug plans) on account of lower market wide prices. J&J's gaming of the regulatory system and sham litigation also wasted government and judicial resources, which are funded by tax payers.

(b) J&J's sales from its anti-competitive practices are extraordinary. From September 2021 through February 2024, inclusive, J&J generated revenues of $2.138 billion from sales of Stelara in Canada. Since March 1, 2024, J&J has continued to earn extraordinary revenues from sales of Stelara in Canada as a result of its share of units sold in ustekinumab drugs remaining in excess of 99.8%.

(c) J&J's profits from its anti-competitive practices are likely also extraordinary. Although JAMP has no information about J&J's precise profit levels from the sale of Stelara, J&J's parent, Johnson & Johnson, reported global sales of US $85.159 billion and net earnings of US $35.153 billion, implying group wide net profit margins of 41.3%. J&J's margins on the sale of Stelara in Canada (adjusted, to account for margins earned by J&J's affiliates that manufacture Stelara) may be even higher.

(d) J&J is a subsidiary of Johnson & Johnson, which is one of the fifty largest publicly traded companies by revenue in the United States. Johnson & Johnson currently has a market capitalization in excess of US $380 billion.

(e) J&J's anti-competitive practices appear to be from a playbook it developed from the sale of another high-price, high-revenue biologic drug in Canada.

50. Without ordering an administrative penalty that approximates the magnitude of the benefit that J&J derived from its anti-competitive practices, J&J will be incentivized to return to the same playbook for the next biologic drug it sells that loses exclusivity under Canada's laws, and exclude competitors once again.

IV. RELIEF SOUGHT

51. JAMP seeks:

(a) an Order pursuant to subsection 79(1) of the Act prohibiting J&J:

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

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

(iii) for a period of 5 years from offering a drug that is biosimilar to Stelara through or in connection with the BioAdvance patient services program;

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

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

(vi) for a period of 5 years from enforcing or threatening to enforce non-disclosure agreements against health care professionals, or withholding any thing of value or threatening to withhold any thing of value from health care professionals, due in whole or in part to any health care professional's decision to prescribe, administer or deal in any drug, accept or consider marketing of any drug by a third party, or make decisions in accordance with the health care professional's exercise of their knowledge, skill and judgment relating to any patient or other matter; and

(vii) for a period of 5 years from communicating with any patient enrolled in BioAdvance about (a) the availability of any biosimilar drug, interchangeable drug or bioequivalent drug and (b) the requirements, rules

or procedures of any insurance plan or reimbursement scheme as it pertains to any biosimilar drug, interchangeable drug or bioequivalent drug, unless prior approval is obtained from the monitor described in paragraph IV.49(b)(ii).

(b) an Order pursuant to subsection 79(2) of the Act:

(i) requiring J&J to communicate with all health care professionals whose patients were enrolled in BioAdvance for Stelara between January 1, 2021 and the date of the Order that (i) Finlius is not a biosimilar product, (ii) Finlius will not be marketed for 10 years, (iii) no drug that is biosimilar to Stelara will be offered through or in connection with BioAdvance for 5 years, (iv) J&J is prohibited from taking the actions described in paragraph IV.49(a)(vi), (v) J&J's marketing and sale of biologic drugs is overseen by a monitor as described in paragraph IV.49(b)(ii), and (vi) the email address and phone number of that monitor, on terms that JAMP will advise or that the Tribunal deems just; and

(ii) appointing a monitor, responsible for monitoring compliance by J&J with the Order and compliance with section 79 of the Act as it pertains to J&J's marketing and sale of biologic drugs in Canada for a period of 5 years, on terms that JAMP will advise or that the Tribunal deems just.

(c) an Order pursuant to subsection 79(3.1) of the Act requiring J&J to pay, in any manner that the Tribunal specifies, an administrative monetary penalty in an amount of three times the value of the benefit derived from J&J's anti-competitive

practice, which is at least $1,000,000,000, or such other amount as JAMP may request and the Tribunal deems just; and

(d) an Order requiring J&J to pay the costs of this proceeding;

(e) an Order granting all other orders or remedies that may be required to give effective to the orders in paragraph IV.49(a) to restore competition in the market for ustekinumab drugs; and

(f) such further orders and relief as JAMP may request and the Tribunal deems just.

SCHEDULE B
CONCISE STATEMENT OF THE ECONOMIC THEORY OF THE CASE

1. This schedule provides a concise statement of economic theory that supports the Application requesting that the Tribunal issue orders under subsection 79(1), 79(2) and 79(3.1) of the Act.

The Relevant Market and J&J's Market Power

2. The relevant product market is no wider than ustekinumab drug products sold in Canada. A hypothetical monopolist for the sale of ustekinumab drugs in Canada would be able to profitably impose a small but significant non-transitory increase in price.

3. In 2008, Health Canada approved the sale of Stelara, J&J's biologic drug based on ustekinumab. Stelara was protected from competition until August 2021. In March 2024, JAMP launched Jamteki and Amgen Canada Inc. launched Wezlana; both of those drugs are biosimilars of Stelara. In July 2024, J&J launched Finlius, a relabelled version of Stelara (i.e., Finlius and Stelara are the same thing, except for their name).

4. Until March 2024, J&J's share of sales of ustekinumab drugs in Canada was 100%, and since that time J&J's share has remained above 99.8%. During that period, Health Canada approved the sale of a large number of drugs, but J&J has always sold Stelara for more than $4,000 per dose. There are high barriers to entry for the sale of ustekinumab drugs. For all of these reasons, J&J has market power for the sale of ustekinumab drugs in Canada.

J&J's Practice of Anti-Competitive Acts

5. J&J's past practices of anti-competitive acts include: (a) gaming of the regulatory system and sham litigation regarding Stelara to exclude rivals; (b) developing a fighting brand,

Finlius, to create uncertainty that excludes rivals; and (c) gaming of the regulatory system and sham litigation regarding Finlius to exclude rivals. J&J's ongoing practices of anti-competitive acts include: (d) misusing J&J's patient support program to mislead health care professionals regarding the availability of a biosimilar through BioAdvance and delay growth of biosimilars; (e) misusing J&J's patient support program to mislead patients and delay growth of biosimilars; (f) misusing J&J's marketing tools to intimidate prescribers and delay growth of biosimilars; (g) engaging in predatory pricing for Stelara; (h) misleading private insurers about Finlius to exclude and delay biosimilars; and (i) supplying Finlius, a fighting brand, including at a selective and discriminatory price.

6. The subjective and objective purpose of these anti-competitive practices is to negatively affect and exclude competitors, and to have an adverse effect on competition by permitting J&J to maintain its high pricing for Stelara and maintain its dominant share of the market.

J&J's Conduct Prevents and Lessens Competition Substantially

7. J&J's conduct has prevented and lessened competition substantially. Between August 2021 and March 2024, J&J's revenues from sales in Stelara in Canada were $2.138 billion. But for J&J's conduct, rival manufacturers would have launched at least one lower cost biosimilar to Stelara prior to March 1, 2024, and prevailing prices for Stelara would have been substantially lower. From March 1, 2024 to the present, J&J has maintained a share of units of ustekinumab drugs in Canada above 99.8%. But for J&J's conduct, the penetration rate of biosimilars to Stelara would have been significantly greater, and prevailing prices for Stelara would have been substantially lower.

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 sections 79 of the Act;

BETWEEN:

JAMP PHARMA CORPORATION

Applicant

– and –

JANSSEN INC.

Respondent

PROPOSED NOTICE OF APPLICATION
(Pursuant to s. 79 of the *Competition Act*)

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