OTTAWA, ONT. | # 13



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

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# MEMORANDUM OF FACT AND LAW OF THE APPLICANT
**(Pursuant to section 103.1 of the *Competition Act*)**

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## I. EXECUTIVE SUMMARY

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.

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. In addition, 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 its 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 have and continue to directly and substantially affect JAMP's ustekinumab and biosimilar business. 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.

9. Only urgent action by the Tribunal can stop the significant harm that is accruing to competition as each day passes. For all of these reasons, JAMP respectfully requests that the Tribunal grant it leave to bring an abuse of dominance application against J&J, so that the Tribunal and the Canadian public can assess J&J's anti-competitive conduct for themselves.

## II. FACTS

### A. The Parties

10. 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 product that is biosimilar to Stelara.

11. 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 product.

## B. Biologic and Biosimilar Drugs

12. 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.

13. 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

14. Biologic and biosimilar drugs are regulated under the *Food and Drug Regulations*.[1] 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.[2] If the dosage form, strength and route of administration of the proposed biosimilar drug is the same as the original biologic drug, Health Canada 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.

15. 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

16. 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

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1 *Food and Drug Regulations* CRC, c. 870.

2 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).

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 increase the drug's volume of sales.

17. 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.

18. 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

19. 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.

20. 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.

21. 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

22. In 2022, biologic drugs accounted for approximately 46% of the value of patented medicine sales in Canada.[3] Moreover, biosimilar uptake in Canada is low compared to other international markets.[4] JAMP perceived an opportunity to develop a biosimilar business in

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3 The Affidavit of Emily Seaby, sworn July 26, 2024 [**Seaby Affidavit**], Exhibit S8 at page 41.

4 Seaby Affidavit, Exhibit S8 at pages 42 and 43.

Canada that would provide savings to payers while improving healthcare outcomes for patients.

23. 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.

24. In February 2022, JAMP announced the creation of a new division, BioJAMP. BioJAMP would not sell any products other than biosimilars, and no other division of JAMP would sell biosimilars. BioJAMP has extensive dedicated resources, including its own personnel and oversight of JAMP Care for the administration of BioJAMP's drugs. BioJAMP operates independently and separately of JAMP's other divisions.

25. BioJAMP takes a decision to launch and market a new biosimilar on a drug-by-drug basis. When a potential new drug is identified, BioJAMP prepares a "bottom-up" demand forecast to estimate the potential biosimilar drug's revenues, and a profit and loss statement to estimate the potential biosimilar drug's profitability. JAMP has extensive experience preparing these types of detailed forecasts.

26. 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.

27. 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

28. 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.

29. 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**")[5] 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.[6] 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.[7]

30. By further example, in parallel to its litigation regarding the 837 Patent and Stelara, J&J submitted a NDS for a "new" ustekinumab drug product, 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."

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5 *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133.

6 *Janssen Inc. v. Canada (Health)*, 2023 FC 870.

7 *Janssen Inc. v. Canada (Health)*, 2023 FCA 229.

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.

31. 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)).

32. These anti-competitive acts are described in more detail in paragraphs 104 to 113, below.

33. 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] Jamteki was launched on March 1, 2024.

**H. BioJAMP's Financial Planning and Marketing Efforts for the Launch of Jamteki**

34. BioJAMP engaged in extensive financial planning and marketing efforts for the launch of Jamteki.

35. Notably, BioJAMP prepared a demand forecast and a profit and loss statement for Jamteki. The demand forecast was objective and conservative. For example, the forecast assumed biosimilar penetration (that is, the rate at which all biosimilars can be expected to capture share from the originator firm) based on the actual penetration rate in a very similar biologic drug, adalimumab (brand name Humira). BioJAMP believed that basing its forecast on biosimilar penetration for adalimumab made sense, given the similarities between the drugs. J&J held the same perspective. In December 2023, Johnson & Johnson's CFO told its investors that, "When modeling the impact [of biosimilar penetration for Stelara], we see the Humira erosion curve as a relatively good proxy…".

36. By further example, the forecast assumed that BioJAMP would need to sell Jamteki at a significant discount to Stelara to generate a profit. [redacted]

37. These estimates of demand were inputted into the profit and loss statement for Jamteki. BioJAMP forecast that Jamteki would generate approximately [redacted] in commercial sales in the first quarter following launch, [redacted]. BioJAMP forecast that Jamteki would generate sales of approximately [redacted] per quarter in the second year of sales, with a modest profit.

38. In addition, BioJAMP prepared to engage in extensive marketing efforts in support of Jamteki. For example, BioJAMP commissioned an independent consultancy to study the financial impact for public drug plans and private insurers of treating different types of patients with Jamteki rather than Stelara. The consultant concluded that substituting Jamteki for Stelara would save the Ontario Drug Benefit Formulary more than $100 million over three years, and a private insurer in Ontario more than $25 million over three years.

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

39. 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).

40. 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.

41. 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.

42. 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.

43. These anti-competitive acts are described in more detail in paragraphs 116 to 133, below.

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

44. 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.

45. At the end of the first quarter after the launch of Jamteki, BioJAMP's commercial sales of Jamteki are less than [redacted] (which is [redacted] less than forecasted). Once Jamteki had penetrated the market for ustekinumab, BioJAMP had anticipated that it would represent [redacted] of its total revenues. JAMP understands that sales of Amgen's Wezlana

are similarly weak. J&J's share of ustekinumab sales in Canada remains above 99.8% of units sold. By contrast, in the first quarter after the launch of biosimilars to Humira, biosimilar drugs had captured a share of approximately 8.7% of units.

46. Later in 2024, JAMP forecasts that two additional biosimilar firms will receive NOCs for new biosimilars to Stelara and enter the market for ustekinumab drugs in Canada. If BioJAMP fails to have converted a significant percentage of Stelara patients to Jamteki by that time, BioJAMP's ability to win patients that switch from Stelara to a biosimilar will be directly and significantly impacted (because BioJAMP will face additional competitors selling a product that is substitutable for Jamteki). In other words, BioJAMP's "first mover advantage" will be permanently lost.

## III. ISSUES

47. The sole issue on this application is whether JAMP should be granted leave under section 103.1 of the Act to make an application under section 79 of the Act against J&J.

## IV. SUBMISSIONS

### A. Test for Leave Under Section 103.1 of the *Competition Act*

48. Subsection 103.1(1) of the Act ("**Current 103.1(1)**") grants private persons the right to apply to the Competition Tribunal (the "**Tribunal**") for leave to make an application under section 79:

> **103.1 (1)** Any person may apply to the Tribunal for leave to make an application under section 75, 76, 77 or 79. The application for leave must

> be accompanied by an affidavit setting out the facts in support of the person's application under that section.[8]

49. Subsection 103.1(7) of the Act ("**Current 103.1(7)**") sets out the test for the Tribunal to grant leave for a private person to commence an application under section 79:

> **103.1 (7)** The Tribunal may grant leave to make an application under section 75, 77 or 79 if it has reason to believe that the applicant is directly and substantially affected in the applicant's business by any practice referred to in one of those sections that could be subject to an order under that section.[9]

50. Parliament amended ss. 103.1(1) and 103.1(7) (collectively, "**Old 103.1**") in 2022 to permit private persons to apply for leave to make an application under section 79.[10]

51. Parliament again amended ss. 103.1(1) and 103.1(7) in 2024 (collectively, "**New 103.1**"). Although the bill in which New 103.1 is contained has received Royal Assent, New 103.1 will not come into force until June 20, 2025.[11]

52. Current 103.1(1) and Current 103.1(7) (collectively, "**Current 103.1**") have never been judicially interpreted or applied, and an application for leave to make an application under section 79 has never been considered by the Tribunal. The Tribunal must determine how Current 103.1 should be interpreted and applied in conjunction with section 79.

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8 *Competition Act,* R.S.C., 1985, c. C-34, ss. 103.1(1) [***The Act***].

9 *The Act,* ss. 103.1(7).

10 Bill C-19, *An Act to implement certain provisions of the budget tabled in Parliament on April 7, 2022 and other measures*, 1st Sess, 44th Parl, 2022, c 10, ss. 266(1) and (4) (assented to June 23, 2022); *The Act,* ss. 103.1(1) & (7) (2009 – 2022).

11 Bill C-59, *An Act to implement certain provisions of the fall economic statement tabled in Parliament on November 21, 2023 and certain provisions of the budget tabled in Parliament on March 28, 2023*, 1st Sess, 44th Parl, 2024, c. 15, ss. 254(1) and s. 272 (assented to June 20, 2024).

*(i) A Proper Interpretation of the Section 103.1 Leave Test for Abuse of Dominance*

53. The Supreme Court has held that the words of a statute must be read and interpreted "in their entire context in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act and the intention of Parliament."[12]

(a) Case Law Under Old 103.1

54. The Tribunal and the Federal Court of Appeal have held, in granting leave under Old 103.1, that the Tribunal's task is to examine whether there is sufficient credible evidence to give rise to a *bona fide* belief that: (1) the applicant may have been directly and substantially affected in the applicant's business by the alleged practice, and (2) the practice in question could be subject to an order.[13]

(a) With respect to the "direct" component, the Tribunal held in respect of Old 103.1 that "its ordinary meaning calls for a close nexus between the [alleged reviewable trade practice] and the impact on the applicant's business."[14]

(b) With respect to the "substantially" component, the Tribunal held in respect of Old 103.1 that "terms such as 'important' are acceptable synonyms to considering

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12 *Re Rizzo & Rizzo Shoes Ltd. (Re)*, [1998] 1 SCR 27 at para 21 [***Rizzo***].

13 *National Capital News Canada v. Canada (Speaker of the House of Commons)* (2002), 2002 Comp. Trib. 41 (CanLII) at para 14, endorsed in *Symbol Technologies Canada ULC v. Barcode Systems Inc*, 2004 FCA 339 at paras 16-17.

14 *Audatex Canada, ULC v. CarProof Corporation*, 2015 Comp. Trib. 28 at para 45 [***Audatex***]. In this memorandum, underlying text indicates that emphasis has been added (the emphasis does not appear in the original).

whether there has been a 'substantial' impact, which is ultimately assessed by reviewing the circumstances at issue."[15]

(c) With respect to the "in the applicant's business" component, the Tribunal held in respect of Old 103.1 that, "It is well-established that the business to be considered on a leave application pursuant to section 75 of the Act is the entire business of the applicant, not simply the product line affected by the refusal to supply."[16]

55. There is no basis in Current 103.1 or section 79 to depart from the past interpretations of the "direct" and "substantially" component. However, given the interpretation under Old 103.1 for the "applicant's business" component was developed specifically for applications under section 75, further consideration is required of the appropriate interpretation for an application under section 79.

(b) A Harmonious Interpretation of the Phrase "In the Applicant's Business"

56. Section 79 refers to a respondent having market power in "a class or species of business".[17]

57. When the Tribunal first analyzed that phrase, a litigant urged the Tribunal to adopt an interpretation that a court had adopted under the predecessor *Combines Investigation Act* (namely, a "commercial" understanding of the phrase). The Tribunal observed that case law under an old statute was not determinative of how it should interpret a new statutory provision. Instead, the Tribunal interpreted the phrase by reference to the legislative

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[15] *Audatex* at para 45.

[16] *Audatex* at para 54 and *CarGurus, Inc v. Trader Corporation*, 2016 Comp. Trib. 15 [***CarGurus***] at para 65.

[17] *The Act,* ss. 79(1).

scheme of the new *Competition Act*, and the logic of how that phrase was to operate in combination with other elements within section 79. The Tribunal ultimately decided that the phrase "is synonymous with the relevant product market."[18] Since that time, the Tribunal and the Federal Court of Appeal have consistently applied the reference to a "class or species of business" to refer to an individual market.[19]

58. In an application under Current 103.1 for leave under section 79, the words "in the applicant's business" should be interpreted in a manner that is harmonious with the words in, and structure of, section 79. Accordingly, the analysis under Current 103.1 should focus on the effect of the impugned practice on the applicant's business in the product market at issue. In other words, the "applicant's business" in an application under Current 103.1 under section 79 is synonymous with the applicant's participation in the product market at issue in the section 79 application (and no broader). This approach would result in a meaningful inquiry related to competition – for example, it could produce insight for the Tribunal into the risk that the applicant will be foreclosed from the product market at issue (and the corresponding risk that there would be one fewer competitor in that market).

59. The desire for a harmonious approach between different sections of the Act may be the best explanation for why the Tribunal originally decided that the words "in the applicant's

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[18] *Director of Investigation and Research v. The NutraSweet Company*, CT-1989-002 – Doct #176a at pages 53 to 56 [***Nutrasweet***].

[19] For example, *Commissioner of Competition v. The Toronto Real Estate Board*, 2016 Comp. Trib. 7 [***TREB***] at para 164; *Canada (Commissioner of Competition) v. Canada Pipe Co*, 2006 FCA 236 at paras 9-16.

business" in an application under Old 103.1 for leave under section 75 should refer to the applicant's entire business.

60. The first Old 103.1 case in which the Tribunal gave careful attention to how the phrase "in the applicant's business" should be interpreted is *Sears Canada*.[20] To interpret the phrase, the Tribunal adopted the outcome (but not the analysis) in an earlier case decided under section 75 – *Chrysler*.[21]

61. *Sears Canada*'s application of the outcome in *Chrysler* to Old 103.1 is surprising for a handful of reasons. First, *Chrysler* was issued thirteen years prior to the enactment of Old 103.1, and so there can be no suggestion that the Tribunal in *Chrysler* expected its factual conclusion to govern the interpretation of other sections of the Act that had not yet been created. Second, the words in section 75(1)(a) are different than the words of Old 103.1 – the former refers to "a person [who] is substantially affected in his business or is precluded from carrying on business..." while the latter refers merely to "a person [who] is substantially affected in his business." Third, the policy objectives of section 75(1)(a) (especially as that provision stood in 1989) and Old 103.1 were different. The best policy explanation for section 75(1)(a) is that it is designed to ensure section 75 protects

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[20] *Sears Canada Inc. v. Parfums Christian Dior Canada Inc. and Parfums Givenchy Canada Ltd.*, 2007 Comp. Trib. 6 [***Sears Canada***]. Earlier cases under section 103.1 contain only brief discussion of this phrase (but focus instead on the word "substantial"), and subsequent cases have typically cited *Sears Canada* rather than the earlier cases. The earlier cases are *177057 Ontario Inc. (c.o.b. as Broadview Pharmacy) v. Wyeth Canada Inc.*, 2004 Comp. Trib. 22, *Paradise Pharmacy Inc. v. Novartis Pharmaceuticals Canada Inc.*, 2004 Comp. Trib. 21, *Broadview Pharmacy v. Pfizer Canada Inc.*, 2004 Comp. Trib. 23 and *Construx Engineering Corporation v. General Motors of Canada*, 2005 Comp. Trib. 21.

[21] *Canada (Director of Investigation and Research) v. Chrysler Canada Ltd.*, CT-1988-004 [***Chrysler***].

competition itself, not competitors.[22] By contrast, Old 103.1 is a test for leave and when it was debated, Members of Parliament described its purpose as "discourage[ing] frivolous litigation" by enabling "[c]ases obviously devoid of merit [to] be 'stopped at the gate' by the Tribunals' right to deny leave".[23] Despite those temporal, linguistic and policy differences, the Tribunal in *Sears Canada* adopted the outcome in *Chrysler* that "substantial effect on a business is measured in the context of the entire business" of the applicant.[24]

62. While the outcome of *Chrysler* was adopted in *Sears Canada*, the analysis was not. In *Chrysler*, the Tribunal carefully examined the facts to identify the business at issue. It concluded in that case that "the effect on the entire activity of which the refused supplies are a part should" be examined. The Tribunal took this approach because it sought "a proper understanding of the effects of the refusal to supply" in that case, not because it was making a legal determination as to how the word "business" should be interpreted in subsequent cases (whether under section 75 or another section). It explained that "a fair analysis of the situation in the present case" required an examination of the complainant's "overall business," but that was because that specific business was "very small, he has few customers and it is possible to inquire meaningfully whether there is a relationship

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[22] *Chrysler* was decided prior to the introduction of subsection 75(1)(e). Thus, the applicant in that case was not required to show any effect on competition. At the time that *Chrysler* was decided, subsection 75(1)(a) – which requires an inquiry into the likelihood of a firm will be excluded – was the only aspect of the section that ensured that section 75 was used for the protection of competition (rather than the resolution of disputes among competitors).

[23] House of Commons Standing Committee On Industry, Science And Technology, "A Plan to Modernize Canada's Competition Regime" (April 2002) at 51. We have not identified any Parliamentary debates that signal an intention to bar persons with multiple businesses from commencing litigation.

[24] *Sears Canada* para. 21.

between" a refusal to supply and the effect on the business. However, the Tribunal also contemplated "a more disaggregated analysis" of the effects of a refusal to supply if the evidence permitted it or if it were meaningful to the effects-based inquiry. The Tribunal also found that certain "gross sales and profits earned from the sale of other products" were "totally unrelated" to the effects based analysis it was conducting, in part because demand for those other products was separate from demand for the products at issue in the case.[25] The Tribunal warned of the "danger of relying on aggregate data when more specific and relevant information is available."[26] As one leading legal commentator explained, "This decision… appeared to leave open the possibility of the Tribunal treating different operating divisions within a single corporate entity as separate businesses for the purposes of Section 75."[27]

63. Because the outcome but not the analysis in *Chrysler* was adopted in *Sears Canada*, the best explanation for the Tribunal's holding in *Sears Canada* may be that it desired a harmonious approach between Old 103.1 and subsection 75(1)(a). Since that time, Parliament amended Old 103.1 to provide for private access for conduct reviewable under section 79; it follows that Parliament intended for Current 103.1 in an application for leave under section 79 to be interpreted harmoniously with section 79.

64. Just as the Tribunal was not required in *Nutrasweet* to adopt an interpretation of "class or species of business" under section 79 that was harmonious with the former *Combines*

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[25] Separate demand is a strong indicator of separate product markets.

[26] *Chrysler*, pages 30-33.

[27] John Bodrug, et al, *Competition Law of Canada*, Juris Publishing, Inc., release 22 2009, at section 5.02[2](c).

*Investigation Act*, there is no obligation on this Tribunal to adopt an interpretation of "the applicant's business" in Current 103.1 that arises from cases decided under Old 103.1 (and which are based on even older case law under section 75). This is particularly so since those cases expressly state that the "entire business" interpretation is for a leave application under section 75.[28]

*(ii) An Alternative Interpretation of the Section 103.1 Leave Test*

65. In the alternative, if the submissions in paragraph 58 are not accepted, then the Tribunal should find that the identification of the "applicant's business" is: (i) a question of fact that must be determined from the evidence; and (ii) not determined merely by reference to the holdings of the corporate entity making the application.

66. Specifically, to make a determination in fact as to the scope of a business, the Tribunal should inquire as to the applicant's actual business activities and, if applicable, any connections (or absence thereof) between the applicant's alleged business and its other businesses. An inquiry into the scope of the applicant's business will give the Tribunal insight into an applicant's ability to continue competing in the market that will be defined under section 79 (even if the applicant's actual business is wider than the product market), and, as a result, a sense of whether the failure to grant leave might result in the loss of a competitor. Such an inquiry is meaningful for the later inquiry under section 79.

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[28] *Audatex* at para 54 and *CarGurus,* at para 65.

67. Conversely, there are a number of reasons why the "applicant's business" is not determined merely by reference to the holdings of the corporate entity making the application.

68. First, such an interpretation would be in conflict with the definitions contained in the Act itself, which apply to section 103.1. Section 2 defines "business" as, among other things, the producing, supplying and dealing in "articles". Nothing about this definition indicates that a "business" is to be defined by reference to a corporate entity's holdings. Instead, the definition is active – that is, it refers to different forms of economic activity.

69. Second, the Tribunal has never expressly held that a corporate applicant's "business" for the purposes of Old 103.1 is determined by reference to the holdings of the corporate entity making the application. There is no jurisprudential support for such an express proposition.

70. Third, by contrast, the Tribunal has frequently conducted a factual inquiry about the business at issue for the purposes of determining the effects under section 75 and Old 103.1, and in doing so has disregarded the applicant's other businesses that are not relevant to its inquiry. As noted in paragraph 62, in *Chrysler* the Tribunal carefully examined the scope of the applicant's business and disregarded certain sales that were "totally unrelated" to the Tribunal's effects-based inquiry. In *Sears Canada* and *Audatex*, the Tribunal disregarded

that the applicants both had a larger American parent.[29] In *CarGurus*, the Tribunal disregarded the fact that the applicant itself operated a far larger American business.[30]

71. Fourth, the Tribunal has conducted a factual inquiry about the business at issue under other sections of the Act, and in so doing has recognized that a litigant can have multiple businesses. For example, in *Tervita*, the Tribunal held that the acquired firm operated multiple businesses – that is, the distinct and separate business that was subject to the Commissioner's application under section 92 (the "development of the Babkirk Site as a hazardous waste facility") and "the other businesses owned by Complete and acquired in the Merger [that] are not relevant for the purposes of this Application because the Commissioner does not allege that they caused or contributed to a substantial prevention of competition."[31]

72. Fifth, finding that a corporate "applicant's business" is determined by reference to the holdings of the corporation making the application would lead to absurd results.[32] For example, in the present case, JAMP could form a new subsidiary without any business activity and transfer all of its ustekinumab rights and activities to that subsidiary. The new

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[29] In *Sears Canada*, the fact that the applicant was a subsidiary of an American retailer (Sears, Roebuck & Co.) was not discussed. In *Audatex*, the applicant's US affiliate is referenced at paras 8, 14 and 26, but the size of that business relative to the Canadian business is not discussed. A similar result occurred in *Nadeau Poultry Farm Limited v. Groupe Westco Inc et al*, 2008 Comp. Trib. 7 at para 24. In that case, an applicant owned a chicken processing facility in New Brunswick, and its corporate affiliate owned another chicken processing facility in Ontario. The respondent asserted that the affected business for the purposes of the application was both the New Brunswick and the Ontario facilities, however the Tribunal disregarded the existence of the Ontario facility.

[30] *CarGurus* at para 8 (describing its original business and website in the United States).

[31] *Commissioner of Competition v. CCS Corporation et al.*, 2012 Comp. Trib. 14 at paras 19 and 48.

[32] *Rizzo* at para 27 ("[A]n interpretation can be considered absurd if it leads to ridiculous or frivolous consequences, if it is extremely unreasonable or inequitable, if it is illogical or incoherent, or if it is incompatible with other provisions or with the object of the legislative enactment.").

subsidiary would then bring this application. It would be absurd for that new subsidiary to be granted leave because its business was substantially affected, but for leave to be denied to JAMP because it operates other businesses. The Act's objective is the maintenance of competition, and, for that reason, the Act is generally not concerned with the ownership structure in which a business is held.[33] The same policy considerations should apply to the interpretation of Current 103.1, and absurd results are to be avoided.

73. Sixth, it avoids establishing a *de facto* rule that only single-line firms are capable of obtaining leave under Current 103.1 (and that multi-line firms are barred). Leading legal commentators have reviewed the case law under Old 103.1 and expressed concern about the existence of such a *de facto* rule. [34] As described in paragraph 60, above, there is no evidence that Parliament ever intended such an outcome.

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[33] There are numerous examples where the Act "looks through" the corporate structure of an entity, for the purposes of identifying the actual scope of economic activity undertaken by a single group of entities under common control. See, for example, sections 11(2) (orders for production from affiliated entities), 45(6)(a) and 47(3)(a) (exempting conspiracies among affiliated entities from the offences), 76(4)(b) and (c) (exempting conduct among affiliates entities), 77(4) (exempting conduct among affiliated entities), 90.1(7) (exempting conduct among affiliated entities), sections 109 and 110 (requiring that the assets and revenues of affiliates be counted for the purposes of applying the merger notification thresholds), 113(a) (exempting transactions among affiliated entities from the merger notification obligations), and 117 (treating "wholly-owned" affiliates as subject to additional disclosure requirements in a merger notification). The policy rationale for the Act's treatment of affiliated entities is that they are not in fact separate – they are under common control – and so there is only one economic actor.

[34] Paul-Erik Veel, *Private Party Access to the Competition Tribunal: A Critical Evaluation of the Section 103.1 Experiment*, 2009 18 Dalhousie Journal of Legal Studies 1 at 22. Veel described the test for leave as "overly onerous," explaining that "the particularly problematic aspect of this requirement from a policy perspective is the notion that what is 'substantial' is to be assessed in the context of the entire business. There are two problems with this. First, as noted above, in terms of the rationale for having a standing requirement in order to simply give standing to applicants who will take proper steps to effectively litigate the application, there seems to be no justification for denying standing to applicants whose companies have only had one product line of their business impacted; this is particularly the case if the degree to which the firm has been affected is still relatively substantial in absolute terms, even if it is not substantial in proportion to the total size of the business. Second, and more importantly, it should be remembered that the purpose of competition law is to protection competition rather than competitors. From the perspective of protection competition, the assessment for impact should be with respect to the product in question rather than the firm… If the purpose of competition is to protect competition rather than competitors, then it seems arbitrary that the small retailer should be given standing but Sears should not." See also, Scott McGrath and Erin Keogh in Niki Iatrou, ed., *Litigating Competition Law in Canada*, 2nd edition,

*(iii) Final Considerations*

74. The Supreme Court of Canada has issued a series of decisions under section 36 (which, like section 103.1, governs the circumstances under which private rights can be asserted under the Act). Those decisions evidence a consistent concern that persons who are harmed by anti-competitive conduct have access to the courts, and parties that engage in anti-competitive conduct not escape from legal sanction due to technicalities that are unrelated to competition law policy. In *Pro-Sys* and other 2013 decisions, the Supreme Court confirmed that "indirect purchasers" had standing to bring claims under section 36, and that the "passing on" defence did not apply.[35] In *Godfrey* in 2019, the Supreme Court confirmed that "umbrella purchasers" also had standing to bring claims under section 36, that the statute of limitations in section 36 did not operate in a way to time bar claims in an absurd manner, and that the Act was not a "complete code" that barred other claims in tort.[36] In all of these cases, faced with the choice to either allow private actions or permit wrong-doers to escape sanction due to technicalities, the Supreme Court interpreted section 36 in a liberal manner guided by the Act's objectives and permitted private actions to continue.

75. Each of the interpretations proposed in paragraphs 58 and 65-66, if adopted, would be consistent with the outcome in the Supreme Court of Canada's decisions regarding section

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LexisNexis Canada: Toronto, 2023 at page 232. McGrath and Keogh explain that "A consequence of this definition of 'substantial' effect may be that large, multi-line companies, such as department stores, could never avail themselves of sections 103.1 because the loss of the supply of any one product would never rise to the level of 'substantial' to its bottom line. One can question the wisdom of this approach."

35 *Pro-Sys Consultants Ltd v Microsoft Corporation*, 2013 SCC 57.

36 *Pioneer Corp v Godfrey*, 2019 SCC 42.

36. In particular, such interpretations would ensure that persons who are harmed by anti-competitive conduct have access meaningful to the Tribunal, and parties that engage in anti-competitive conduct cannot escape from legal scrutiny and sanction due to technicalities that are unrelated to competition law policy.

## B. JAMP's Ustekinumab Business (or its Biosimilars Business, BioJAMP) Has Been Directly and Substantially Affected by J&J's Anti-Competitive Acts

76. This subsection describes: (i) the scope of the business affected by J&J's conduct; (ii) the direct manner in which J&J's conduct has affected JAMP's business; and (iii) the substantial effect that J&J's conduct has had and continues to have on JAMP's business.

### *(i) The Business Affected by the Alleged Practice*

77. If the Tribunal adopts the interpretation of the "applicant's business" that is proposed in paragraph 58, then the business for the purposes of this application is JAMP's ustekinumab business.

78. If the Tribunal adopts the interpretation of the "applicant's business" that is proposed in paragraphs 65 and 66, and the Tribunal intends to conduct a factual inquiry, then the Applicant makes the following submissions:

79. JAMP makes decisions whether to launch and market a new prescription drug on a drug-by-drug basis. For each drug it evaluates and then ultimately launches, JAMP prepares and maintains a separate demand forecast and profit and loss statement. Each profit and loss statement records the revenue generated from sales of the drug; costs that are incurred directly from the sale of the drug (e.g., costs of goods sold); selling, general and

administrative expenses (or "**SG&A**" costs, which are a portion of common overhead costs that are allocated to the drug); and different measures of profit (e.g., EBITDA).

80. Similarly, Health Canada's regulatory approval process is conducted on a drug-by-drug basis. JAMP must obtain regulatory approval from Health Canada for each individual drug product it seeks to market.

81. When it evaluated whether or not to launch an ustekinumab product, JAMP prepared a demand forecast and a profit and loss statement for Jamteki, and determined that doing so would ultimately be profitable [redacted]. Once JAMP resolved to launch an ustekinumab product, JAMP submitted a New Drug Submission that was specific to Jamteki. After Jamteki was approved by Health Canada, and JAMP launched Jamteki, JAMP conducted extensive marketing efforts that were specific to Jamteki. JAMP continues to utilize its profit and loss statement to evaluate the success of Jamteki and make decisions regarding Jamteki. For these reasons, the business affected by J&J's conduct is JAMP's Jamteki business.

82. *In the alternative*, if the Tribunal does not accept that JAMP's Jamteki business is the affected business for the purposes of this application, then the affected business is JAMP's BioJAMP division. JAMP offers a diverse portfolio of products. To organize its affairs efficiently, like many large companies (including Johnson & Johnson, which has created its Innovative Medicines Division that is operated by the Respondent in Canada), JAMP has divided its operations into different operating divisions.

83. Since February 2022, prior to the launch of any biosimilar products, BioJAMP has operated as an independent and separate division of JAMP. There are numerous points of difference between the BioJAMP division and JAMP's other divisions, including the following:

(a) Dedication to Selling Biosimilars. BioJAMP offers biosimilar products, and nothing else. None of JAMP's other divisions sell biosimilars. Indeed, JAMP's other divisions sell products that have no material commercial relationship to biosimilars, such as Cosmetic Import (which sells cosmetic products) and Wampole (which sells over-the-counter nutritional supplements).

(b) Unique Strategic Relationship to Alvotech. BioJAMP is largely able to operate as a result of JAMP having entered into a series of exclusive agreements with Alvotech, a manufacturer of biosimilars. No other division of JAMP has any contractual relationship with Alvotech.

(c) Dedicated Personnel. BioJAMP has a team of employees whose responsibilities are dedicated exclusively to BioJAMP and its products. These dedicated personnel includes a sales director, 10 other sales staff located across Canada and two brand managers, among others. These personnel have no responsibilities at all related to JAMP's other divisions.

(d) Unique Branding, Trademark and Website. BioJAMP operates under the BioJAMP brand. JAMP has registered a trademark for BioJAMP. BioJAMP has a dedicated website, www.biojamp.com, and domain name for email addresses, @biojamppharma.com. None of JAMP's other divisions utilize the BioJAMP

brand, the BioJAMP trademark, the BioJAMP website or the BioJAMP domain name.

(e) JAMP Care. To support the administration of BioJAMP's biosimilars, JAMP established a patient support program called JAMP Care. JAMP Care's services are offered to patients who are prescribed BioJAMP biosimilars as well as a handful of JAMP Pharma specialty products whose administration benefits from support. JAMP Care's costs related to Simlandi and Jamteki (which represent the large majority of JAMP Care's costs) are allocated to BioJAMP, and JAMP Care is overseen by the head of the BioJAMP division.

(f) Segregated Cost Centre. As described above, every JAMP drug's profit and loss statement accounts for SG&A costs, which are a portion of common overhead costs that are allocated to the drug. BioJAMP calculates its own SG&A costs (including the costs of dedicated personnel and JAMP Care), separate from the SG&A costs of other JAMP divisions. BioJAMP's calculated SG&A costs are allocated exclusively to its biosimilars (and not to any other products of other JAMP divisions).[37]

84. It would be inappropriate to identify all of JAMP's divisions as the affected business for the purposes of this application. Like in *Sears Canada*, *Nadeau Poultry Farm*, *CarGurus* and even *Chrysler* when the Tribunal disregarded unrelated businesses of the applicant or

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[37] BioJAMP does not prepare its own profit and loss statements; as described above, JAMP maintains profit and loss statements at the level of individual drugs.

the applicant's affiliates, there would be no competition law policy reason for the Tribunal to examine the effect of J&J's conduct in ustekinumab on JAMP's cosmetics, natural supplements or other unrelated and separate businesses.

*(ii) The Direct Effect of J&J's Anti-Competitive Acts*

85. There is a close nexus between J&J's anti-competitive acts and JAMP's Jamteki business (or, *in the alternative*, its BioJAMP business).

86. As described starting at paragraph 104, J&J's past anti-competitive acts disincentivized JAMP from launching Jamteki until March 1, 2024, more than two and a half years after the last patent listed on Stelara expired. As described starting at paragraph 116, J&J's ongoing anti-competitive acts also directly affect JAMP's sales of Jamteki, as they discourage switching to biosimilars by prescribers, insurers and patients in different ways. J&J's conduct has directly affected JAMP's ability to capture share of ustekinumab sales, including delaying sales to patients who have been mandated to switch to Jamteki (or to a ustekinumab biosimilar more generally) by public insurance plans, and sales to patients who are insured by private insurance plans.

87. In addition, JAMP expects that additional competitors will begin selling ustekinumab biosimilars in the near future (including two additional competitors before the end of 2024). If JAMP is not successful very soon at winning share, then JAMP's ability to win share of ustekinumab sales in Canada will be significantly degraded and the "first mover

advantage" that JAMP earned by launching Jamteki on March 1, 2024 will be permanently lost.[38]

88. BioJAMP itself is also directly affected by J&J's conduct. BioJAMP anticipated that once Jamteki penetrated the market for ustekinumab, Jamteki would generate [redacted] of BioJAMP's revenues.

*(iii) The Substantial Effect of J&J's Anti-Competitive Acts*

89. J&J's practices have had a substantial effect on JAMP's Jamteki ustekinumab business, as well as the BioJAMP business. In the first quarter of commercial sales after launch of Jamteki, BioJAMP forecast it would generate sales of approximately [redacted], and its per quarter sales would grow quickly thereafter. In the second year following launch, BioJAMP forecast it would generate sales of approximately [redacted] per quarter. These forecasts depended, in significant part, on BioJAMP capitalizing on its "first mover advantage."

90. BioJAMP's sales forecasts were objective and conservative in a number of ways. However, BioJAMP's actual sales in the first quarter following Jamteki's launch have been far lower than it forecast, generating revenues of less than [redacted]. This represents an underperformance by over [redacted].[39]

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[38] The Competition Bureau has studied substitution patterns in drug markets in the past and concluded that "timing is of the essence" for entrants after "a brand-name product loses patent protection"; the Bureau's study supported that conclusion with quantitative evidence. See Competition Bureau report, *Generic Drug Sector Study*, October 29, 2007, at section 2.4 and Table 2.

[39] [redacted]

91. BioJAMP also anticipated that once Jamteki penetrated the market for ustekinumab, Jamteki would generate [redacted] of BioJAMP's revenues.[40] As explained in paragraph 87, above, if Janssen's conduct continues BioJAMP may never be able to recover the losses it has suffered as a result of J&J's anti-competitive acts, as its "first mover advantage" will be lost. The loss of this advantage alone illustrates the substantiality of the effect of J&J's anti-competitive practices.

## C. J&J's Anti-Competitive Acts Could be Subject to an Order Pursuant to Section 79 of the Act

92. In assessing this branch of the test, the Tribunal must address each element of the practice. However, it is understood that, at the leave stage, the question of whether the reviewable conduct "could" be subject to an order is being considered in an application which is not supported by a full evidentiary record.[41] In keeping with the expeditious nature of the leave proceeding, the Tribunal may address each element summarily.[42] In considering this part of the test, "hard and fast evidence" is not required on every point, reasonable inferences may be drawn where the supporting grounds are given and circumstantial evidence may be considered.[43] The Tribunal can grant leave under section 103.1 where the evidence

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40 *Audatex*, at para. 80 (describing cases where an approximately 50% impact on the applicant's business was held to be "substantial").

41 *CarGurus,* at para 62.

42 *Audatex* at para 46.

43 *Audatex* at para 47, citing *The Used Car Dealers Association of Ontario v Insurance Bureau of Canada*, 2011 Comp. Trib. 10 at para 34.

presented is "less than a balance of probabilities" so long as it is more than a "mere possibility."[44]

93. Subsection 79(1) of the Act sets out the requirements for the reviewable practice of abuse of dominance:

> **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
>
> **(a)** a practice of anti-competitive acts; or
>
> **(b)** conduct
>
> **(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
>
> **(ii)** the effect is not a result of superior competitive performance.

94. Section 79 was recently amended by Parliament. The effect of the amendments is to change the elements of the reviewable trade practice. At the outset, an applicant must establish that the respondent possesses a dominant position. Thereafter, the applicant need only establish that a respondent's conduct *either* (a) is a practice of anti-competitive acts or (b) has had, is having or is likely to have the effect of preventing or lessening competition substantially. Each of these elements is described below.

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[44] *Barcode Systems Inc. v. Symbol Technologies Canada ULC*, 2004 Comp. Trib. 1 at paras 12-13.

*(i) J&J Has a Dominant Position in Ustekinumab Biologic Drugs in Canada*

95. The product market that is relevant to this application is no wider than ustekinumab drugs. Once a patient begins taking an ustekinumab drug, the drug proves effective and is well tolerated, a prescriber is not likely to switch the patient to another drug (including in response to a small but significant price increase).

96. That ustekinumab drugs are in their own product market is evident from Stelara's history. From Stelara's launch in 2008 until 2023, Health Canada approved a large number of other drugs, but J&J's pricing for Stelara did not change – in general, Stelara was sold for more than $4,000 per dose. Moreover, in that period J&J's revenues from sale of Stelara ballooned from approximately $5.3 million in 2009 to more than $900 million in 2023. Prescribers and patients did not switch to alternative drugs. All of this is strong evidence that a hypothetical monopolist for the sale of ustekinumab drugs would be able to profitably impose a small but significant non-transitory increase in price.[45]

97. Defining the market at issue in this case by reference to a drug's pharmaceutical ingredient is also consistent with the practice of the Competition Bureau in inquiries involving the pharmaceutical industry.[46]

98. The geographic market at issue in this case is no wider than Canada. The sale of all drugs in Canada is regulated under the federal *Food and Drug Regulations*. A hypothetical

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[45] *TREB* at paragraph 123-125, endorsing the use of the hypothetical monopolist test in applications under section 79 of the *Act*.

[46] Competition Bureau Position Statement, *Teva's acquisition of Allergan's generic pharmaceuticals business*, April 18, 2016 ("Consistent with recent pharmaceutical reviews involving generic drugs, the Bureau found that the parties' products should generally be considered within the same relevant product market where they contain the same molecule or active ingredient and are supplied in the same format.").

monopolist for the sale of drugs in Canada would be able to profitably impose a small but significant non-transitory increase in price.

99. There are numerous identifiable segments of customers for ustekinumab in Canada. These segments arise as a result of, among other things, the different formats in which ustekinumab is sold and the differing rules of public and private insurance plans. Deploying different anti-competitive practices vis-à-vis different customer segments is an important part of J&J's effort to maintain its dominant position in the sale of ustekinumab. However, the segments themselves may not be properly defined individual markets. Even if they were, the competitive conditions within those segments are extremely similar (i.e., as described below, J&J is dominant under all plausible market definitions), and for the purposes of the analysis it is appropriate to analyze all the segments together.[47]

100. There are numerous indicators that J&J substantially and completely controls the market for ustekinumab drugs in Canada. These include:

(a) ***Considerable Latitude to Set Prices.*** Since the time of its launch, J&J's pricing for Stelara has not changed – in general, Stelara was sold for more than $4,000 per dose. Moreover, Stelara's growing revenues over a long period of time when large numbers of other drugs were launched demonstrates J&J's considerable latitude to determine pricing, which is an indicator of market power.[48]

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[47] Competition Bureau, *Abuse of Dominance Enforcement Guidelines*, March 7, 2019, at paragraph 14, endorsing the analysis of different product markets together where competitive conditions are sufficiently similar.

[48] *TREB* at para 174.

(b) ***100% Share Between 2008 and 2023.*** Stelara was launched in 2008. From that time until early 2024, Stelara was the only ustekinumab drug marketed in Canada and J&J enjoyed a share of sales of 100%.

(c) ***No Material Changes Following the Launch of Biosimilars.*** In March 2024, two biosimilars to Stelara were launched by JAMP and Amgen. JAMP's product is offered at a discount of approximately [redacted] compared to Stelara (and Amgen's product is likely similarly priced). Because of the anti-competitive practices it has engaged in, J&J has not felt forced to lower its pricing for Stelara, and J&J's share of ustekinumab drugs in Canada remains above 99.8% as of May 2024 (as measured by units sold and revenues generated).

(d) ***High Barriers to Entry.*** There are numerous and extensive barriers to entry for ustekinumab drugs. Among other things: (i) the launch of a new ustekinumab drug requires the regulatory approval of Health Canada; (ii) the development of a New Drug Submission for a new ustekinumab drug is expensive and time-consuming, requiring (among other things) the conduct of a Phase III clinical trial; (iii) the manufacture of biosimilars is complex (i.e., more complex than manufacturing small molecule drugs that are chemically synthesized); (iv) the marketing of biosimilars is complex, as physicians must be convinced to write a new prescription for the biosimilar (i.e., there are no "automatic substitution" rules); and (v) the distribution of biosimilars is complex and requires that biosimilar manufacturers establish competitive "patient support programs" to facilitate the administration of their drugs.

101. The Tribunal has held that, "A large market share can support an initial determination that a firm likely has market power, absent other extenuating circumstances, in general, ease of entry".[49] In the present case, J&J has enjoyed a share in ustekinumab drugs in Canada of 100% for over 15 years, and, in response to entry, J&J has been able to maintain its high pricing and a share of more than 99.8% of sales. Barriers to entry in the sale of ustekinumab products in Canada are very high. There is therefore sufficient evidence to conclude J&J substantially or completely controls the market at issue in this case.

102. For all of these reasons, the preliminary requirement of section 79(1) is satisfied.

*(ii) J&J Has Engaged in a Practice of Anti-Competitive Acts*

103. J&J has engaged or is engaging in a series of anti-competitive acts. The acts listed below can be characterized as anti-competitive because their subjective and objective purpose is the same[50] – to negatively affect and exclude JAMP and other suppliers of biosimilars to Stelara. The acts listed below can also be characterized as anti-competitive because their subjective and objective purpose is to have an adverse effect on competition, in particular by permitting J&J to maintain its high pricing for Stelara and maintain its high share of the market.

104. J&J's past anti-competitive acts include the following.

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[49] *Canada (Director of Investigation and Research) v Tele-Direct (Publications) Inc.* (1997), 73 CPR (3d) 1 (Comp. Trib.), at page 118.

[50] *Canada (Commissioner of Competition) v. Canada Pipe Co*, 2006 FCA 233 [***Canada Pipe***] at para 66.

105. ***Gaming of the Regulatory System and Sham Litigation Regarding <u>Stelara</u> to Exclude Rivals.*** Stelara's "market exclusivity" under the data protection regime expired in 2016 and the last patent registered against Stelara on the patent register under the PM(NOC) Regulations expired in 2021. However, J&J knew that, if it could be seen to be attempting to list an additional patent on the patent register against Stelara, a biosimilar manufacturer would exercise great caution before launching a new drug. This is because, if J&J's patent were listed, then the biosimilar manufacturer's drug would risk being delayed by the automatic 24-month preclusion of the issuance of a NOC under the PM(NOC) Regulations. Alternatively, if the biosimilar manufacturer's launch were not delayed, the manufacturer would have to launch "at risk" and could be exposed to subsequent patent infringement proceedings. Given Stelara's extraordinary revenues, this could expose the biosimilar manufacturer to a potentially catastrophic damages award (especially since patent litigation takes years to result in a trial judgment).

106. Knowing the effect of being seen to attempt to register another patent on the patent register for Stelara, J&J decided in 2022 to submit Canadian Letters Patent No. 3,113,837 (the "**837 Patent**") for listing on the patent register against Stelara. J&J knew that the Minister of Health was very unlikely to accept the 837 Patent for listing, as J&J's submission was clearly out of time. Similarly, J&J knew that its application for judicial review to the Federal Court of the Minister of Health's rejection, and its subsequent appeal to the Federal

Court of Appeal, were also very unlikely to succeed. Indeed, J&J's litigation efforts resulted in predictable and total failure.[51]

107. However, J&J did succeed in its actual competitive objective – that is, signalling to biosimilar manufacturers that they faced a new and significant risk if they launched a new product, such that none were willing to attempt entry during the pendency of the litigation. J&J's efforts amounted to nothing more than a gaming of the regulatory system and subsequent sham litigation, all of which were intended to delay entry of a biosimilar to Stelara. Gaming pharmaceutical regulatory systems to delay entry by rivals has been recognized as an anti-competitive strategy in other jurisdictions, including in markets for biologic drugs.[52] In addition, the United States Federal Trade Commission has expressly concluded that if an originator firm improperly lists ineligible patents on a pharmaceutical patent register, such action can constitute illegal monopolization and harm competition.[53]

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[51] See *Janssen Inc. v. Canada (Health)*, 2023 FC 870 and *Janssen Inc. v. Canada (Health)*, 2023 FCA 229.

[52] See, for example, Joint Statement of the Food & Drug Administration and the Federal Trade Commission Regarding a Collaboration to Advance Competition in the Biologic Marketplace, February 3, 2020, page 3 ("One key goal… is to support market competition by reducing 'gaming' and other attempts to unfairly delay competition… Such behavior might include … abusive repetitive regulatory filings..."). Similarly, the European Commission has issued a Statement of Objections to Teva in respect of alleged anti-competitive practices related to Copaxone, a biologic drug. The European Commission's objections include Teva's alleged "misuse of the patent system to shield itself from competition" that "artificially prolongs legal uncertainty to the benefit of the patent holder, and can effectively block or delay entry of generic or generic-like medicines." See European Commission press release, Commission sends Statement of Objections to Teva over misuse of the patent system and disparagement of rival multiple sclerosis medicine, October 10, 2022.

[53] See Federal Trade Commission's Brief as Amicus Curaie in *Teva v. Amneal*, Civil Action No. 2:23-cv-20964-JXN-MAH. Regarding illegal monopolization, the FTC's position is that "the FTC and courts have long recognized that improper submission of patents for listing in the Orange Book may constitute illegal monopolization – as well as an illegal course of monopolistic conduct – under section 2 of the Sherman Act." Regarding harm to competition, the FTC's position is that "Improper Orange Book listings harm competition by deterring and delaying entry of lower-cost generics… Purchasers, like patients, hospitals, and health plans, are harmed each day that competition is delayed beyond the point the FDA would have otherwise approved a generic challenger's ANDA product. These potential harms—both in terms of higher drug prices and patient health—are serious… [I]mproper Orange Book listings create barriers to entry that may deter generic competitors from entering the market in the first place. Faced with the prospect of a 30-month delay of FDA-approval, a generic

Finally, in the past, the Tribunal has not hesitated to conclude that spurious litigation practices can form part of an anti-competitive scheme.[54]

108. ***Developing a Fighting Brand, Finlius, to Create Uncertainty that Excludes Rivals.*** J&J is experienced in the sale of biologics. When J&J's other biologic drug, Remicade, lost exclusivity and faced competition from biosimilars, J&J developed and obtained approval from the Minister of Health for a new product – Omvyence – that was simply Remicade under another name. In other words, it was a "relabelled biologic". J&J did not ultimately market Omvyence, potentially due to the fact that the Competition Bureau was investigating and ultimately expressed concerns about the exclusionary effects of relabelled biologics.[55]

109. Even though Omvyence was never launched, the mere fact that approval was issued for the drug was effective in creating uncertainty in the market and slowing the diversion of share from J&J's Remicade to lower cost biosimilars. From 2019 to 2020, prior to the approval of Omvyence, J&J's share of infliximab (the drug upon which Remicade is based) unit sales in Canada fell by 9.2%, from 90.4% to 81.2%. Omvyence was approved on December

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competitor may forgo entry altogether, harming competition. The revenue generated by brand drug companies from delays in competition caused by improper Orange Book listings and other practices can be significant."

[54] *Director of Investigation and Research v. Laidlaw Waste Systems Ltd.* (1992), 40 C.P.R. (3d) 289 [***Laidlaw***] at pages 93-94 ("No one can read the evidence concerning the use Laidlaw made of litigation and the threat of litigation in this case without a sense of outrage… It commenced spurious litigation and threatened litigation against its competitors to drive or attempt to drive them out of business by raising their costs of doing business. This is certainly predatory behavior. It is useful to quote from R. H. Bork: 'As a technique for predation, sham litigation is theoretically one of the most promising…'").

[55] See Competition Bureau position statement, *Completion of Preliminary Investigation into Relabelled Biologic drugs*, June 27, 2022 ("While relabelled biologics have yet to be marketed in Canada, the Bureau is of the view that manufacturers engaging in the type of conduct described in this statement has the potential to contravene the abuse of dominance provisions of the Act – particularly if accompanied by other potentially anti-competitive conduct.").

29, 2020. From 2020 to 2021, J&J's share of infliximab unit sales in Canada fell by only 5.7%, from 81.2% to 75.5%; in other words, the rate of diversion to biosimilars slowed after Omvyence was approved (rather than accelerating). The following year, when it became clear that Omvyence was unlikely to actually be launched (including because the Competition Bureau concluded its investigation and issued a public statement), J&J's share fell by 16.5%, from 75.5% to 59.0%; in other words, the rate of diversion accelerated by a factor of 2.9 compared to the year prior. Sales of infliximab in Canada were valued at approximately $1.313 billion in 2021. Actions that ensured J&J's share fell in 2021 by only 5.7%, as opposed to 16.5% (which might be expected if the 2022 rate of diversion were to have occurred earlier) represented an incremental benefit to J&J of approximately $141.8 million (i.e., 10.8% of $1.313 billion).

110. The lesson that J&J learned from Remicade and Omvyence was not that it is contrary to the *Competition Act* to launch a fighting brand. Instead, J&J learned that simply obtaining approval for a fighting brand could create significant uncertainty in the market for a biologic drug that would slow penetration of biosimilars (and create more than $100 million of benefit for J&J in a single year), and that it was not ultimately necessary to launch the fighting brand to derive that benefit.

111. This is precisely the strategy J&J has deployed (again) with Stelara. Recognizing that Stelara would soon face competition, in 2023 J&J sought and obtained approval for Finlius, which was simply a relabelled version of Stelara. J&J then communicated with market participants about Finlius (in ways that are described in more detail below), so that confusion about whether and when Finlius would be available would proliferate. Finlius

was not developed in 2011 or 2014 or any other year when Stelara enjoyed a monopoly. Finlius was only developed on the eve of the launch of biosimilars.[56]

112. Section 78(1)(d) provides that an anti-competitive act includes "use of fighting brands introduced selectively on a temporary basis to discipline or eliminate a competitor."

113. ***Gaming of the Regulatory System and Sham Litigation Regarding Finlius to Exclude Rivals.*** As described above in paragraph 105, J&J's efforts to register the 837 Patent on the patent register for Stelara ended in predictable and total failure. But Health Canada's approval for Finlius created a new opportunity to generate additional uncertainty for biosimilar firms (and extend the time period over which the uncertainty operated). While J&J's hopeless litigation regarding Stelara was proceeding, J&J also attempted to register the 837 Patent on the patent register for Finlius. As J&J must have predicted, the Minister of Health rejected its attempt to conduct an end-run around the requirements of the PM(NOC) Regulations. As it did for Stelara, J&J then applied for judicial review of the Minister of Health's decision. The mere filing of the application accomplished J&J's objectives – it publicly signalled once again to biosimilar firms that the 837 Patent could delay their entry, or else result in infringement proceedings with a potentially catastrophic damages award.

114. Given the weakness of its legal position, J&J made no effort to prosecute its application for judicial review. Instead, it sought a stay pending the outcome of its Stelara litigation. However, when the Stelara litigation failed, J&J took no action to discontinue its Finlius

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[56] J&J recently commenced marketing of Finlius. That conduct is discussed in paragraph 133, below.

litigation. J&J only discontinued the Finlius litigation on February 28, 2024, which was almost three months after the dismissal of its appeal regarding the 837 Patent and Stelara, and only after a request for a status update from the Federal Court. Again, the stay sought by J&J was strategic – it avoided a loss in court, while preserving the uncertainty for biosimilar firms.

115. J&J's efforts to conduct an end-run around the PM(NOC) Regulations by attempting to register the 837 Patent for Finlius amount to another gaming of the regulatory system, and its application for judicial review in Finlius is sham litigation, all of which was intended to delay entry of a biosimilar to Stelara. All of this constituted an anti-competitive act.[57]

116. J&J's ongoing anti-competitive acts include the following.

117. ***Misusing J&J's Patient Support Program to Mislead Physicians Regarding the Availability of a Biosimilar through BioAdvance and Delay Growth of Biosimilars.*** Patient support programs are intended to help patients in different ways, for example, by ensuring a patient is administered drugs according to a schedule prescribed by their physician and ensuring a patient's drug costs are reimbursed by their insurer in an efficient manner. In the period when its biologic drug is protected from competition, an originator firm will obtain information about every prescriber and patient of the drug in Canada through its patient support program.

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[57] See *Laidlaw*.

118. J&J's patient support program is BioAdvance. Rather than support Canadian patients, J&J has elected to misuse BioAdvance for exclusionary purposes. In particular, very shortly after the Ontario Ministry of Health issued a notice requiring that certain patients be prescribed a ustekinumab biosimilar other than Stelara, J&J issued a series of vague written communications to prescribers advising that a biosimilar would be made available through BioAdvance. J&J's representatives then placed phone calls to prescribers, advising verbally that the biosimilar would be Finlius. J&J's representations were untrue – J&J knows that Finlius is not a biosimilar, and is not eligible for reimbursement as a biosimilar.

119. However, the effect of the representation was to create uncertainty for prescribers about the need to begin enrolling patients in the patient support program of a biosimilar firm, and thereby delay the time in which J&J's share of ustekinumab sales in Canada will be diverted. All of this constitutes an anti-competitive act.

120. In the past, the Tribunal has recognized that creating uncertainty to delay competition can be part of an anti-competitive scheme.[58]

121. ***Misusing J&J's Patient Support Program to Mislead Patients and Delay Growth of Biosimilars.*** As noted above in paragraph 117, J&J possesses information about every prescriber and patient of ustekinumab in Canada through its patient support program, and J&J has elected to misuse BioAdvance for exclusionary purposes. By further example, very shortly after the Quebec health insurance board (the Régie de l'assurance maladie du

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[58] *Laidlaw* at page 22 ("The uncertainties created by Laidlaw's legal action against the Kupiak brothers and West Coast, however, delayed the signing of the contract with the Regional District for over a year.").

Québec) added Jamteki to its formulary, J&J's BioAdvance representatives contacted certain patients in Quebec directly and advised them that those patients "must continue your Stelara as prescribed by [your physician]." J&J did not carbon copy the patient's physician.

122. The effect of the representation is to create uncertainty for patients (and, potentially, prescribers) about the need to utilize a lower cost biosimilar, and thereby delay the time in which J&J's share of ustekinumab sales in Canada will be diverted. All of this constitutes an anti-competitive act.

123. ***Misusing its Marketing Tools to Intimidate Prescribers and Delay Growth of Biosimilars.*** J&J engages in extensive marketing efforts for Stelara directed at prescribers, including creating professional opportunities for them. Examples of these professional opportunities include sponsoring academic research papers, maintaining an advisory board on which physicians serve, and paying honoraria to prescribers who speak at conferences J&J organizes or sponsors. J&J frequently requires that prescribers that participate in its marketing efforts enter into non-disclosure agreements.

124. J&J has elected to misuse its marketing efforts, including through threats to enforce its non-disclosure agreements, to intimidate prescribers. The result of these efforts is that prescribers decline to meet with JAMP's sales staff, and otherwise decline to engage with JAMP's marketing efforts for Jamteki.

125. The effect of this intimidation is to delay the time in which J&J's share of ustekinumab sales in Canada will be diverted. All of this constitutes an anti-competitive act.

126. ***Predatory Pricing for Stelara.*** J&J is experienced in the sale of biologics. When J&J's infliximab biologic drug, Remicade, lost exclusivity and faced competition from biosimilars, J&J responded, in part, by offering Remicade below cost for the purposes of excluding rivals. J&J's below cost pricing was publicly reported by the Competition Bureau at the conclusion of an inquiry into J&J's conduct.[59] Despite biosimilars being priced at a significant discount to Remicade's wholesale price, the share of infliximab units that biosimilars represented in Canada grew slowly, from less than 1% in 2016, to 2.7% in 2017, to 6.5% in 2018 to 9.6% in 2019.

127. The lesson that J&J learned from Remicade was not that it was contrary to the *Competition Act* to predate, but that predatory pricing could delay penetration by a biosimilar if conducted selectively (i.e., to specific customers).

128. It is for this reason that, when J&J faced competitors in ustekinumab, J&J contacted prescribers, "telling the physicians NOT to switch their ustekinumab patients and that worst case they'll provide free goods until they find a solution." J&J may be engaged in other examples of predatory pricing, the details of which are not known to JAMP.

129. Section 78(1)(i) provides that an anti-competitive act includes "selling articles at a price lower than the acquisition cost for the purpose of disciplining or eliminating a competitor."

130. ***Misleading Private Insurers About Finlius to Exclude and Delay Biosimilars.*** J&J only advised Health Canada that it had commenced marketing of Finlius on July 2, 2024.

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[59] Competition Bureau position statement, *Inquiry into alleged anti-competitive conduct by Janssen*, February 20, 2019 ("In this case, the Bureau's review confirmed that Janssen was offering Remicade at a price below cost to certain hospitals and patients").

However, it is clear that J&J had been marketing Finlius for some time to private insurers. Moreover, those marketing efforts were misleading, and were intended to result in private insurers believing that Finlius was a biosimilar.

131. J&J's marketing efforts for Finlius are apparent from the publications of private insurers that predate July 2, which contain false information that J&J has made no effort to correct. For example, Canada Life has issued prior-authorization forms for use by prescribers that list Finlius as an available ustekinumab product, even though it was not marketed at the time. Similarly, a March 2024 report by Alberta Blue Cross described Finlius as a biosimilar, which it is not.

132. J&J's purpose for marketing Finlius to private insurers as a biosimilar is multifold:

(a) First, the marketing creates confusion about the availability of Finlius, which delays the willingness of private insurers to enter into discussions with suppliers of biosimilars.

(b) Second, the potential supply of Finlius to private insurers (at a low price) permits J&J to continue charging public drug plans high prices for Stelara. In other words, J&J can offer a low price for an ustekinumab product to private insurers, but not risk the triggering of most-favoured-nation pricing terms in its agreements regarding Stelara with public plans (even though Stelara and Finlius are the same drug).

(c) Third, the potential supply of Finlius to private insurers shrinks the size of the contestable market available to suppliers of biosimilars to Stelara. As described

above, the profit margins of biosimilar suppliers are modest, and a reduction in the size of the contestable market significantly diminishes the incentive to continue selling biosimilars to Stelara.

133. All of this constitutes an anti-competitive act.

134. ***Supplying Finlius, a Fighting Brand, Including at a Selective and Discriminatory Price.*** The caution that J&J exhibited for Omvyence – that is, declining to launch the fighting brand during and following the Bureau's inquiry into relabelled biologics – appears to have abated. J&J is now marketing and supplying Finlius to wholesalers, which are offering Finlius for sale at approximately the same wholesale price as Jamteki. Legal commentators have explained the exclusionary effect on generic drug firms when originator firms launch relabelled drug products: "a brand manufacturer can leverage its patent-induced monopoly over a brand drug to deter generic competitors by introducing a nominally differentiated product, in the form of an authorized generic, into the market for generic drugs."[60] The exclusionary effect is increased if the "nominally differentiated product" is priced at a level that is predatory and / or designed to prevent the biosimilar firm from recouping its costs. The Competition Bureau has also expressed concerns about the effect of relabelled drugs on the incentives of generic firms to launch competing products.[61] As described in paragraph 111, above, Finlius could have been developed in 2011 or 2014 or any other year

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60 Natalie Peelish, *Antitrust and Authorized Generics: A New Predation Analysis*, 72 Note, Stan. L. Rev. 791 (2020).

61 Competition Bureau report, *supra* at footnote 38, at section 2.4 ("An issue about introducing an AG is that it may affect the incentive for a generic manufacturer to develop an IG. This is unlikely to be an issue for drugs having high sales relative to entry costs. However, it has the potential to affect the entry of IGs for drugs having relatively smaller valued sales. This may be particularly significant when the AG is able to obtain a first mover advantage.").

when Stelara enjoyed a monopoly, and priced at a level below Stelara in any of the same years; instead, Finlius was not authorized until the months preceding when the first ustekinumab biosimilars were authorized, and was not launched and priced at a discount to Stelara until shortly after ustekinumab biosimilars were marketed in Canada. J&J's conduct is selective and discriminatory – that is, the timing of its product launch and pricing level is in response to Jamteki's (and Wezlana's) entry and pricing, for the purpose of impeding Jamteki's (and Wezlana's) expansion and eliminating it from the market. Section 78(1)(j) provides that an anti-competitive act includes conduct that represents "a selective or discriminatory response to an actual or potential competitor for the purpose of impeding or preventing the competitor's entry into, or expansion in, a market or eliminating the competitor from a market."

135. J&J may be engaged in additional anti-competitive acts that are not presently known to JAMP, by reason of the fact that J&J makes significant effort to conceal its anti-competitive acts and the effects of those acts.

136. There is no efficiency or pro-competitive rationale for any of the acts listed above.[62] None of the acts listed above make J&J a more efficient competitor, for example, by lowering its production costs. If anything, certain of the acts (such as obtaining approval for Finlius) imposed costs on J&J. None of the acts listed above are pro-competitive, in the sense that they are likely to result in lower prices for patients and payers or expand the set of product

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[62] *Canada Pipe* para 73.

choices available to prescribers and patients.[63] In fact, the acts listed above will result in prices for ustekinumab drugs staying high, and reduce the incentives for biosimilar manufacturers to launch drugs to compete with Stelara or in other biologic drug markets where J&J competes.

137. For all of these reasons, the requirement of section 79(1)(a) is satisfied.

*(iii) J&J's Anti-Competitive Acts Have Prevented Competition Substantially and Continue to Lessen Competition Substantially*

138. J&J's final patent listed on the patent register for Stelara expired on August 9, 2021, but no manufacturer was willing to launch a biosimilar to Stelara until March 1, 2024. J&J's past anti-competitive conduct, as outlined in paragraphs 104 to 113, created significant uncertainty for biosimilar firms and was the direct and proximate cause of this delay. From September 2021 through February 2024, inclusive, J&J generated revenues of $2.138 billion from sales of Stelara in Canada. 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). This substantial portion of sales that would have been lost is an approximate quantification of the amount by which competition was prevented between August 9, 2021 and March 1, 2024. There is no question that that prevention was very substantial.[64]

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[63] The launch of Finlius does not expand the set of product choices available; Finlius is simply Stelara under another name. It is not a new product.

[64] Every month of incremental delay in this period represented, on average, more than $71 million of sales to J&J. The harm to competition that occurs from even minor delay is substantial in its own right. All of this creates powerful incentives for J&J to delay competition by even small periods of additional time.

139. J&J's ongoing anti-competitive conduct, as outlined in paragraphs 116 to 133, above, is also lessening competition substantially. JAMP's demand forecast for Jamteki was based on biosimilar penetration rates in adalimumab, which even Johnson & Johnson believes is the best proxy for the expected biosimilar penetration rate for Stelara. As described in paragraph 90, above, JAMP's actual revenues from the sale of Jamteki are far lower than forecast, and JAMP believes that Amgen's sales are similarly depressed. These drastically lower revenues have occurred in spite of the fact that Jamteki and Wezlana are priced at a very significant discount to Stelara.

140. J&J's conduct is the direct and proximate cause of these depressed revenues. 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). This substantial portion of sales that would have been lost is an approximate quantification of the amount by which competition has been lessened between March 1, 2024 and the present, and will continue to be lost until such time as an order is made prohibiting J&J's anti-competitive practices. This amount is also very substantial.

141. For all of these reasons, the requirement of section 79(1)(b) is satisfied.

## V. ORDER SOUGHT

142. JAMP seeks an order:

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

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

July 26, 2024

**ALL OF WHICH IS RESPECTFULLY SUBMITTED**

David Rosner

**GOODMANS LLP**
Lawyers for the Applicant,
JAMP Pharma Corporation

## VI. LIST OF AUTHORITIES

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| 1. | *Audatex Canada, ULC v. CarProof Corporation*, 2015 Comp. Trib. 28 |
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| 29. | Natalie Peelish, *Antitrust and Authorized Generics: A New Predation Analysis*, 72 Note, Stan. L. Rev. 791 (2020) |
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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

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**MEMORANDUM OF FACT AND LAW OF THE APPLICANT**
**(Pursuant to s. 103.1 of the *Competition Act*)**

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