PUBLIC

CT-2024-006

THE COMPETITION TRIBUNAL

IN THE MATTER OF the *Competition Act*, R.S.C. 1985, c. C-34, as amended;

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

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

BETWEEN

JAMP PHARMA CORPORATION

Applicant

- and -

JANSSEN INC.

Respondent

MEMORANDUM OF FACT AND LAW OF JANSSEN INC.
(Response to Application for Leave Pursuant to Section 103.1 of the* Competition Act*)

BLAKE, CASSELS & GRAYDON LLP
199 Bay Street
Suite 4000, Commerce Court West
Toronto, ON M5L 1A9

Robert E. Kwinter
Phone: (416) 863-3283
Fax: (416) 863-2653
Email: rob.kwinter@blakes.com

Nicole Henderson
Phone: (416) 863-2399
Email: nicole.henderson@blakes.com

Jonathan Bitran
Phone: (416) 863-3289
Email: jonathan.bitran@blakes.com

Joe McGrade
Phone: (416) 863-4182
Email: joe.mcgrade@blakes.com

Brian Facey
Phone: (416) 863-4262
Email: brian.facey@blakes.com

Counsel for the respondent
Janssen Inc.

TABLE OF CONTENTS

Page

PART I: OVERVIEW

1. JAMP Pharma Corporation ("**JAMP**"), seeks leave to bring an abuse of dominance application unsupported by credible or reliable evidence. JAMP is a pharmaceutical manufacturer that has recently introduced to the Canadian market a biologic drug, Jamteki, that is a biosimilar to STELARA® (ustekinumab), an innovative biologic medicine that the respondent, Janssen Inc. ("**Janssen**"), has marketed in Canada since 2009.

2. At its core, JAMP's application for leave is a yarn spun out of its failure to meet its own optimistic sales projections for Jamteki since it launched in March 2024. Its allegations of anticompetitive conduct by Janssen are based on speculation, unreasonable inferences drawn from limited documentary evidence, and inaccurate hearsay. With leave of the Competition Tribunal (the "**Tribunal**"), Janssen has adduced responding evidence directly refuting these allegations. JAMP's key allegation—that Janssen is promoting FINLIUS as a biosimilar—is patently false.

3. JAMP's allegations that Janssen has somehow "gamed" the Canadian patent system similarly hold no water. There is nothing illegitimate in Janssen's efforts to protect its patent rights, including through litigation where necessary. [redacted] belies any suggestion that Janssen's assertion of patent rights was a "sham". [redacted] As a result, even if there was anything to JAMP's claims relating to Janssen's ustekinumab patent litigation, JAMP is barred from asserting any such claim in this proceeding. [redacted]

4. There are myriad explanations for JAMP's failure to meet its sales goals for Jamteki that are unrelated to any conduct by Janssen. Notably, Jamteki is not indicated for treatment of Crohn's disease or ulcerative colitis, conditions that represent over [redacted] of the current patient population for STELARA. JAMP also ignores the fact that within a matter of months, Janssen will no longer

be competing at all for publicly-insured patients, which represent roughly [redacted] of ustekinumab sales in Canada.

5. JAMP has failed to meet its burden on its leave application to adduce sufficient credible evidence to give rise to a bona fide belief that it may have been directly and substantially affected in its business by a reviewable practice, and that the alleged practice could be subject to an order under the *Competition Act* (the "**Act**"). It has not presented a plausible case of abuse of dominance that merits the expenditure of the Tribunal's time and resources (let alone Janssen's). This application should be dismissed.

PART II: STATEMENT OF FACTS

The Parties

Janssen Inc.

6. Janssen is a Canadian subsidiary of Johnson & Johnson, ("**J&J**") a pharmaceutical, biotechnology and medical technologies corporation publicly traded on the New York Stock Exchange and headquartered in New Brunswick, New Jersey. Janssen is part of the J&J Innovative Medicine sector, which develops and markets innovative medicines across multiple therapeutic areas, including oncology, immunology, neuroscience, and pulmonary hypertension.[1]

7. Among other things, Janssen supplies biologic drugs in Canada, including STELARA® and FINLIUS®, which are ustekinumab biologic drugs. STELARA and FINLIUS were developed by J&J Innovative Medicine (then known as the Janssen Pharmaceutical Companies of Johnson & Johnson) to treat complex immunological conditions, as described below.[2]

JAMP Pharma Corporation

8. JAMP is incorporated under the laws of Canada and headquartered in Montreal. In partnership with a third-party biosimilar drug developer, JAMP supplies Jamteki in Canada. JAMP has several business divisions:

---

[1] Affidavit of Andy Williams, sworn September 6, 2024 ("**Williams Affidavit**"), para 2.
[2] Williams Affidavit, para 4.

a. **JAMP Pharma**, a supplier of generic pharmaceutical products;

b. **JAMP Pharma Manufacturing**, a generic drug manufacturing business based in JAMP's 100,000 square foot facility located in Lévis, Quebec.

c. **BioJAMP**, a supplier of biosimilar drug products (including Jamteki) and a related PSP called JAMP Care;

d. **Orimed Pharma**, a supplier of bone health and primary care products;

e. **Wampole**, a supplier of a range of vitamin and nutritional supplements;

f. **Laboratoire Suisse**, a supplier of natural health products (such as probiotics);

g. **Cosmetic Import**, a distributor of personal beauty products (such as soaps, deodorants and bath salts); and

h. **JAMP Acute Care & Injectables**, a supplier of therapeutic injectable and oncology products and a provider of a related out-patient PSP.[3]

STELARA and FINLIUS

Overview

9. Janssen's STELARA and FINLIUS products are biologic drugs, which are derived from living organisms or from their cells. Biologic drugs are often developed and manufactured using biotechnology to treat several diseases and medical conditions. Biologic drugs are generally comprised of more complex molecules than traditional "small molecule" pharmaceutical drugs created through chemical synthesis.[4]

10. In or around 2007, an affiliate of Janssen developed STELARA (ustekinumab), a biologic drug that is effective at treating plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis in adult patients (Crohn's disease and ulcerative colitis are both forms of inflammatory

[3] Affidavit of S. Juneja, sworn July 25, 2024 ("**Juneja Affidavit**"), para 6.
[4] Williams Affidavit, at para 4.

bowel disease ("**IBD**")).[5] (For pediatric patients aged 6 to 17, STELARA is indicated for plaque psoriasis.) Janssen began marketing STELARA in Canada in 2009 for psoriasis. Since STELARA received IBD indications in 2016 and 2020, the majority of STELARA sales in Canada have been for patients with IBD. As of June 21, 2024, [redacted] active STELARA patients [redacted] were for IBD indications.[6]

11. FINLIUS is an authorized alternate brand of Stelara, produced identically to STELARA, but with different branding and packaging. Health Canada approved FINLIUS on April 18, 2023 (by cross-referencing the STELARA new drug submission) and Janssen began to market it in Canada on July 2, 2024.[7] FINLIUS is not a biosimilar drug and Janssen never marketed FINLIUS as a biosimilar.[8] To the contrary, Jannsen's marketing strategy for FINLIUS emphasizes that it is produced identically to STELARA.

BioAdvance

12. Janssen also provides a Patient Support Program ("**PSP**") called BioAdvance, which provides one-on-one support to patients in Canada who are prescribed certain Janssen medications, including STELARA and FINLIUS, and will shortly provide support to certain patients prescribed a biosimilar ustekinumab option, Steqeyma, manufactured by Celltrion Healthcare Canada ("**Celltrion**"), when supply becomes available in Canada.[9]

13. BioAdvance is staffed by "coordinators" (BioAdvance coordinators, or "**BACs**") who serve as a single point of contact for patients and prescribers.[10] Among other things, BACs assist patients in getting timely access to medication – often in advance of determining their insurance coverage, assist in identifying and applying for insurance coverage for biologic medications, assist in facilitating administration of biologic products (including providing training for administering injectable products and arranging clinic visits with BioAdvance's network of third-party clinic service providers), liaise with patients' healthcare providers, provide product information and

[5] *Ibid*.
[6] Williams Affidavit, at para 8.
[7] *Ibid*, at para 12.
[8] *Ibid*.
[9] *Ibid* at paras 27, 40.
[10] *Ibid*, at para 27.

information about BioAdvance services, report adverse events experienced by the patient, and ensure a smooth patient experience overall.[11] BACs are not acting as healthcare professionals and do not prescribe medication to patients; treatment decisions are made by patients in consultation with their treating physicians.[12]

Approvals Process

14. Janssen was required to obtain Notices of Compliance ("**NOCs**") for STELARA and FINLIUS from Health Canada under the *Food and Drugs Regulations* to market these products in Canada. The authorization for STELARA involved Janssen delivering a New Drug Submission ("**NDS**") and subsequent supplemental New Drug Submissions ("**SNDS**"), which includes providing scientific evidence of the product's safety, efficacy, and quality for Health Canada's review. The authorization for FINLIUS as an additional product name was through an administrative labeling-only NDS through cross-referencing the information in the approved STELARA submissions.[13]

Biosimilar Approvals in Canada

15. Innovator drug manufacturers undertake a "significant investment in time and research" to develop new medicines and bring them to market.[14] The *Patent Act* incentivizes investment in these programs by providing a 20-year period of exclusivity for patented inventions starting from the filing date of a patent.[15] This exclusivity period allows innovators to try to recoup a portion of their substantial costs of research and development.

16. In the early 1990s, Parliament sought to facilitate the entry of competing generic drug products *immediately* upon the loss of patent exclusivity to innovator drugs by introducing the "early working exception" into the *Patent Act*.[16] This new exception to what would otherwise be

---

[11] *Ibid.*
[12] *Ibid*.
[13] *Ibid* at para 4.
[14] *Abbott Laboratories v. Canada (Minister of Health)*, 2006 FC 120, [2006] 4 FCR 41 at para 6, rev'd 2007 FCA 73 but not on this point; *Novo Nordisk Canada Inc. v. Canada (Health)*, 2019 FC 822 at para 13.
[15] *Patent Act*, R.S.C., 1985, c. P-4, s. 44 ("***Patent Act"***).
[16] *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, [2005] 1 SCR 533, at para. 11; *Patent Act*, s. 55.2(1).

patent infringement permits biosimilar and generic drug manufacturers to "early work" patented inventions for drugs and to file for regulatory approval for their biosimilar products even before the relevant patent has expired. Because of this exemption, biosimilar drug manufacturers are able to launch their products promptly upon patent expiry.

17. To balance the rights of innovator drug companies and prevent abuse of this early-working exception, the *Patented Medicines (Notice of Compliance) Regulations* (the "***PM(NOC) Regulations***") were enacted to operate as a linkage between the *Food and Drugs Act* and the *Patent Act*. Under the *Food and Drug Regulations*, manufacturers looking to sell a drug in Canada must submit to the Minister of Health ("**Minister**") either an NDS (filed by a "first person" innovative drug manufacturer or a "second person" biosimilar) or an Abbreviated New Drug Submission ("**ANDS**", filed by a "second person" generic manufacturer). In filing an NDS or ANDS, a second person biosimilar or generic manufacturer "may rely on much of the technical, health and safety information originally filed as part of the NDS by the first person."[17] Once the Minister has approved a drug for market, they will issue an NOC in respect of the submission. To receive an NOC for a biosimilar, the biosimilar manufacturer must demonstrate that its drug is similar in terms of safety and efficacy to the reference biologic drug for which the innovator has already received approval.

18. Under the *PM(NOC) Regulations*, an innovator who has received an NOC may submit, for inclusion on the Minister's "patent register". A "patent list" includes patents the innovator believes meet the criteria for inclusion on the Minister's patent register for the particular drug. The Minister then determines if the patent(s) on the patent list(s) meet the required criteria and, if so, the Minister includes the patents on the patent register. The effect of listing a patent on the patent register in respect of a drug is that a biosimilar or generic manufacturer cannot obtain an NOC in respect of that drug until the patents on the patent register are "addressed" by the biosimilar or generic manufacturer.[18] If the Minister declines to list a patent on the patent register, this does not mean

[17] *Novartis Pharmaceuticals Canada Inc. v. Apotex Inc*., 2013 FC 142 at para. 10.
[18] *Eli Lilly Canada Inc. v. Canada (Minister of Health)*, 2003 FCA 24, [2003] 3 FC 140, at para. 8.

that the patent is invalid, it means only that the patent cannot be used in proceedings under the *PM(NOC) Regulations*; the patent holder otherwise maintains the right to sue for infringement.

19. Biosimilar drugs are different than "generic" chemically-produced small molecule drugs. Generic drugs are chemically identical to their reference drug and, by definition, cover the same indications and have indistinguishable efficacy levels. By comparison, biosimilar drugs are often distinctive from their reference biologic drugs (which are naturally variable).[19] As a result, patients are required to obtain a separate prescription from their health care providers when switching between a biologic drug and its derivative biosimilar drug; conversely, there is automatic switching to the generic small molecule drug when the brand name version is prescribed.[20]

JAMP's ustekinumab biosimilar: Jamteki

20. JAMP's Jamteki was the result of a partnership with Alvotech hf. ("**Alvotech**"), an Icelandic business that develops and supplies biosimilar drugs. Alvotech commenced Phase III clinical studies for its ustekinumab biosimilar on June 3, 2021.[21] These clinical trials lasted one and a half years and were completed in October 2022.[22]

21. In the meantime, JAMP launched its BioJAMP biosimilar division in February 2022.[23] After launching its first biosimilar, SIMLANDI® (an adalimumab biosimilar to AbbVie's HUMIRA®), in April 2022, JAMP looked for other biosimilar products to launch in Canada, and targeted Alvotech's ustekinumab biosimilar.[24]

22. Shortly after Alvotech's Phase III clinical trials were complete, JAMP filed an NDS for Jamteki on November 24, 2022. The Minister granted JAMP an NOC on November 9, 2023. That NOC authorized JAMP to market Jamteki as indicated for plaque psoriasis and psoriatic arthritis,

[19] Williams Affidavit at para 4.
[20] *Ibid*.
[21] *Ibid* at para 45.
[22] *Ibid*.
[23] Juneja Affidavit, Exhibit J32 at page 1753.
[24] Juneja Affidavit, para 49.

but not for IBD indications (i.e., Crohn's disease or ulcerative colitis). The Minister did not authorize any indication for the pediatric use of Jamteki.[25]

[redacted]

[25] Williams Affidavit, para 5, and Exhibits 3 and 4.
[26] *Ibid* at para 46.
[27] *Ibid*, at para 47.
[28] [redacted]

[redacted]

27. To date, JAMP has not received approval for or marketed Jamteki for all ustekinumab indications (i.e., it has not obtained "full label" approval) from Health Canada, [redacted] Health Canada rejected JAMP's application to have Jamteki indicated for ulcerative colitis, Crohn's disease, and pediatric indications, as JAMP did not include vial presentations with its submission. [31]

Insurance available for STELARA and FINLIUS

28. Nearly all Canadians purchase medications with the benefit of private and/or public drug insurance, which pays for those medications in whole or in part.[32] Private insurance includes employer-sponsored drug benefit plans and individual personal health insurance sold by insurance companies. Further, each provincial and territorial government offers a publicly-funded drug benefit plan for eligible groups (e.g., seniors, recipients of social assistance, and individuals with diseases or conditions that are associated with high drug costs). [33]

29. Both private and public insurers negotiate with drug manufacturers (including Janssen) the prices they will reimburse for specific medications and will often demand significant discounts or rebates on the list price of medications as a condition of listing the medication on the insurer's approved list or formulary.[34] If private or public insurers do not provide coverage for a medication, particularly for a high-cost product, patients will most often seek an available alternative therapy

[29] Willilams Affidavit, para 49 and Exhibit 62.
[30] *Ibid* at para 51.
[31] Williams Affidavit, para 5.
[32] Williams Affidavit, para 11.
[33] *Ibid*.
[34] Williams Affidavit, para 17.

that is covered by their insurance plan(s). Reaching agreements with private and public insurers to provide coverage for a medication is therefore crucial to the success of a drug.[35]

Public insurers prioritize biosimilar drugs

30. Publicly-funded drug benefit plans are responsible for a significant proportion of the reimbursement of medications in Canada, including biologic drugs.[36] During the period that an innovative medicine is "on patent", public insurers must include the patented medication on their formularies if they are going to cover the drug at all. Once a patent is de-listed from a public formulary, however, generic products (in the case of small-molecule drugs) or biosimilars (in the case of biologic drugs) typically become available for listing on public formularies.[37]

31. In practice, once biosimilar options are available, public insurers begin shifting coverage to those alternatives and stop covering the original innovative biologic medication.[38] The public insurers require all patients currently prescribed the innovative biologic to switch to a listed biosimilar to maintain coverage, regardless of the treatment preferences of patients and their physicians (the industry term for this mandatory requirement is "non-medical switch"). [39]

32. At a high level, non-medical switch is done in three stages:

a. first, the insurer lists the biosimilar product on its formulary as eligible for coverage;
b. second (and sometimes simultaneously with the first step), the insurer de-lists the innovative medication from the formulary, meaning that any new patient is only eligible for coverage for the biosimilar (while existing patients continue to be covered for the innovative medication); and
c. third and finally, the insurer implements a "non-medical switch" policy, requiring that all patients taking the innovative medication (including those originally

[35] *Ibid*.
[36] Williams Affidavit, para 19.
[37] *Ibid*.
[38] Williams Affidavit, para 11.
[39] *Ibid*.

prescribed the innovative medication) switch to the biosimilar product, or else lose coverage altogether.[40]

Once this process is complete, the innovative medication is essentially completely excluded from the public formulary.[41]

33. Following the introduction of biosimilar products, private insurers may choose to cover both the innovative and biosimilar products, or may choose to cover only the biosimilar.[42] Innovative manufacturers therefore continue to compete for privately insured patients even after public insurers have completed the transition away from an innovative drug.

34. In the wake of the approvals of biosimilar ustekinumab products (i.e., Wezlana, Jamteki and, more recently, Steqeyma and Pyzchiva), public insurers have begun the process of de-listing STELARA.[43] For example, Quebec announced that ustekinumab biosimilar products would be listed on its formularies as of April 14, 2024, STELARA would no longer be reimbursed for patients commencing treatment after May 23, 2024, and mandated that non-medical switch away from STELARA must be completed for all patients by November 6, 2024.[44]

35. In Ontario, Wezlana and Jamteki were added to the province's public drug benefit formulary on April 30, 2024.[45] STELARA is no longer reimbursed for patients commencing treatment on or after April 30, 2024 and its existing users will have until January 31, 2025 to transition to a biosimilar drug to maintain coverage. Once each province and territory completes this process, STELARA will no longer be covered by any public insurer (outside of very narrow circumstances for which exceptions may be granted).[46] Once STELARA's delisting and non-

[40] *See e.g.*, the announced policies of many governments in Canada for STELARA: Williams Affidavit, para 21.
[41] Williams Affidavit, para 21.
[42] Affidavit of Genia Radeva, Sworn July 25, 2024 ("**Radeva Affidavit**"), para 12.
[43] Williams Affidavit, para 22.
[44] *Ibid*.
[45] *Ibid*.
[46] Other Canadian public drug insurance programs have announced similar STELARA delisting periods, including in New Brunswick (non-medical switch to take place the earlier of November 30, 2024 and the patient's special authorization expiration date), Nova Scotia (non-medical switch to be completed by December 1, 2024), Newfoundland and Labrador (no new STELARA authorizations as of April 5, 2024), Alberta (non-medical switch to

medical switching is completed, Janssen will not be competing for publicly-insured ustekinumab patients.

36. FINLIUS is not listed on any public formularies in Canada and Janssen has not sought any such listing.[47] In any event, public insurers have a practice of covering only biosimilar products once they become available.[48] As a result, FINLIUS, like STELARA after delisting and non-medical switching is complete, will not compete with Jamteki or other ustekinumab products for publicly-insured patients.

Private insurers prioritize greater patient choice

37. Janssen offers insurers [redacted] as part of its overall drug pricing strategy for a wide range of product offerings in Canada, including for drugs that are still patent-protected.[49] This is commercially necessary to enable insurers to list Janssen products on their formularies and to compete with other manufacturers' drugs that treat the same conditions. Even before the compound patent for STELARA expired, Janssen [redacted]. As a result, [redacted].[50]

38. In the months leading up to the expiration of Janssen's ustekinumab compound patent in Canada, Janssen anticipated that it would [redacted][51] In some cases, this could be accomplished by Janssen [redacted] However, some private insurers prefer "transparent pricing" through a product with a lower list price, due to a preference of some of their

be completed by November 1, 2024), British Columbia (non-medical switch to take place the earlier of December 2, 2024 and the patient's special authorization expiration date), and the federal First Nations and Inuit Non-Insured Health Benefits program (no new STELARA authorizations as of April 25, 2024), Willliams Affidavit, para. 22.

[47] *Ibid* at para 25.

[48] *Ibid*.

[49] Williams Affidavit, para 9.

[50] *Ibid*.

[51] *Ibid* at para 10.

customers not to enter into rebate agreements and the challenges communicating about rebates to their customers (i.e., employers/plan sponsors).[52]

39. Moreover, biosimilar products (with a lower list price) are becoming increasingly accepted by patients and the medical community as viable alternatives to biologic drug products. As a result, private insurers, as stewards of their customers' investments, are often not willing to pay a materially higher price for an innovator's biologic drug if a less expensive biosimilar is available.[53]

40. As a result, Janssen sought regulatory approval for FINLIUS, an alternate brand of STELARA produced identically to STELARA, but with different branding and packaging. FINLIUS is not a biosimilar of STELARA.[54] The purpose of FINLIUS is to sell it [redacted] through those private insurers and insurance plans that prefer "transparent pricing" [redacted]. As a result, numerous private insurers, who might have otherwise declined to cover STELARA in preference to biosimilars [redacted], now offer coverage for FINLIUS. Janssen intends to offer FINLIUS indefinitely in Canada.[55]

41. As negotiated prices are generally treated as confidential in the pharmaceutical industry, Janssen does not know precisely what prices biosimilar manufacturers are offering to private insurers.[56] [redacted] As a result, Janssen has contracted with numerous private insurers to offer STELARA and FINLIUS [redacted] In the case of STELARA, this is accomplished by [redacted] in the

[52] *Ibid*.
[53] *Ibid*.
[54] *Ibid* at para 12.
[55] *Ibid* at para 13.
[56] *Ibid* at para 18.
[57] *Ibid*.
[58] *Ibid*.

case of FINLIUS, the list price is similar to [redacted] In any event, STELARA and FINLIUS are both priced above Janssen's cost.[59]

Celltrion introduces Steqeyma

42. On July 30, 2024, Celltrion received an NOC for its ustekinumab biosimilar, Steqeyma. Janssen had entered into a legally-binding term sheet with Celltrion as of [redacted] to provide BioAdvance services to STELARA or FINLIUS patients who do not have public or private insurance coverage and are then prescribed Steqeyma.[60] This will allow ustekinumab patients who require a biosimilar alternative to STELARA or FINLIUS to access Steqeyma and remain in Janssen's BioAdvance PSP. [redacted] Steqeyma is expected to be commercially available in certain provinces in Canada as early as [redacted]

PART III: POINTS IN ISSUE

43. The only issue before the Tribunal is whether JAMP has met the standard for leave set out in s. 103.1 of the Act, that is whether JAMP has provided sufficient credible evidence to give rise to a *bona fide* belief that:

a) JAMP's business is directly and substantially affected by a reviewable practice; and

b) The alleged practice could be subject to an order under s. 79 of the Act.

PART IV: LAW AND SUBMISSIONS

Test for Leave under Section 103.1 of the Act

44. The Tribunal may grant a private party leave to make an application under s. 79 of the Act only if the application is supported by sufficient credible evidence to give rise to a *bona fide* belief that: (i) the applicant's business is directly and substantially affected by the alleged reviewable

[59] *Ibid* at para 15.
[60] *Ibid* at para 40.
[61] *Ibid*.
[62] *Ibid*.

practice; and (ii) such practice could be subject to an order under s. 79.[63] For either of these conditions to be met, there must necessarily be sufficient credible evidence that the respondent has engaged in a reviewable practice within the meaning of s 79 of the Act.

45. For clarity, Janssen denies (i) that it completely controls any class or species of business; (ii) that it has engaged in any anticompetitive practice; or (iii) conduct that has, or is likely to, prevent or lessen competition substantially with respect to STELARA, FINLIUS, ustekinumab products more broadly, or medications that treat plaque psoriasis, psoriatic arthritis, Crohn's disease, or ulcerative colitis.

Applicant's business must be directly and substantially affected

46. The Tribunal has consistently held that a "substantial effect" on a business must be measured in the context of the entire business, not simply the product line affected by the alleged practice,[64] and that the effect to be considered must be attributable to the alleged practice.[65] It has refused to accept that a substantial impact on subsets of an applicant's business is sufficient, including sales of certain brands of prescription drugs of a pharmacy (*Broadview Pharmacy (Wyeth)*[66], *Broadview Pharmacy (Pfizer)*[67], and *Paradise Pharmacy*[68]), car parts for a specific brand for an auto parts exporter (*Chrysler*)[69], the transportation of a brand of automobiles for a dealer/broker of transportation products (*Construx Engineering*)[70], a perfumes product line for a department store operator (*Sears*)[71], and one line of loss valuation services in a broader data and software solutions business (*Audatex).*

---

[63] *Competition Act*, section 103.1(7), *Audatex Canada ULC v. CarProof Corporation*, 2015 CACT 28 at para 41 ("*Audatex"*), *Symbol Technologies ULC v. Barcode Systems Inc.*, 2004 FCA 339 at para 16 ("*Barcode FCA*").
[64] *Sears*, paras 16, 21.
[65] *Audatex*, paras 53-54.
[66] *Broadview Pharmacy v. Wyeth Canada Inc.*, 2004 Comp. Trib. 22.
[67] *Broadview Pharmacy v. Pfizer Canada Inc.*, 2004 Comp. Trib. 23.
[68] *Paradise Pharmacy Inc. and Rymal Pharmacy Inc. v. Novartis Pharmaceuticals*, 2004 Comp. Trib. 21.
[69] *Canada (Director of Investigation and Research) v Chrysler Canada Ltd*, 1989 CarswellNat 720 (Comp. Trib.) (WL), 27 CPR (3d) 1, aff'd 1991 CarswellNat 1118 (FCA) (WL), 38 CPR (3d) 25.
[70] *Construx Engineering Corporation v. General Motors of Canada*, 2005 Comp. Trib. 21.
[71] *Sears Canada Inc. v. Parfums Christian Dior Canada Inc. and Parfums Givenchy Canada Ltd.*, 2007 Comp. Trib. 6.

47. JAMP attempts to create confusion by stating that the current version of ss. 103.1(1) and 103.1(7) have never been judicially interpreted or applied, and claiming that the Tribunal must interpret these provisions anew with respect to s. 79.[72] While ss. 103.1(1) and 103.1(7) were amended to permit private access to s. 79, the language "directly and substantially affected in the applicant's business" was unchanged. These words have been extensively and consistently interpreted and applied by the Tribunal, Federal Court, and Federal Court of Appeal. There is no reason to interpret the same words of s. 103.7(1) differently in an application for leave to bring an application under s. 79 as opposed to ss. 75, 76, and 77 of the *Act*.

48. This is underscored by the fact that in the recent amendments to the Act, Parliament specifically chose not to broaden s. 103.1 to provide access to the Tribunal for businesses that have only been affected "in part" until June 20, 2025. On that date, the leave standard will be amended to lower the threshold for access, permitting applications by those whose business has been "directly or substantially affected in whole or **in part**" (emphasis added).[73] Parliament specifically chose not to expand the leave test to businesses affected "in part" until June 2025.[74]

JAMP is not Substantially and Directly Affected

49. JAMP has led no evidence to demonstrate that any alleged effect on its business is or would be substantial. Instead, it attempts, as many applicants have attempted and failed to do in prior cases, to show an effect only on a single product line or division of its much larger business.

50. For the purpose of the "substantial effect" test, whether JAMP has correctly defined the relevant markets for the products in question is largely irrelevant. Even if JAMP is correct that "ustekinumab" is a relevant market (which Janssen denies), its own evidence makes clear that the conduct it alleges cannot possibly substantially affect its business as a whole.

51. JAMP is a major generic pharmaceutical producer. On its own evidence, it is a leader in generic product launches, receiving 40 different product approvals from Health Canada in the past

---

[72] Memorandum of Fact and Law of the Applicant ("*Applicant MOFL*") at para 52.
[73] 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, 2023 at section 254(4).
[74] *Ibid* at section 272.

year.[75] Jamteki represents only one product that, according to JAMP, has generated less than [redacted] in revenue. JAMP advertises in its public materials that it is one of the "top five generic companies based on the size of its portfolio", which includes more than 240 prescription and over-the-counter molecules, and has the largest generic sales force in Canada.[76] This includes, notably, at least one other biosimilar (Simlandi) indicated for plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis—the same indications as STELARA and FINLIUS.[77] Moreover, JAMP has multiple divisions that provide products or services unrelated to generic pharmaceuticals.

52. The Act makes clear (including in ss. 75 and 103.1) that the effect of impugned conduct on "a business" (which the Tribunal has confirmed means the "entire business")[78] is the relevant consideration in the circumstances specified in the Act. JAMP has not referenced any provisions of the Act or Tribunal authority supporting that "the business" for the purposes of these provisions is co-extensive with or in any way limited by the relevant product (or geographic) market that may otherwise be in issue.

53. The Tribunal has consistently denied leave under s. 103.1 where the applicant failed to lead evidence regarding the magnitude of the impact of the alleged conduct on its total business. In *Audatex Canada ULC v. CarProof Corporation*, the Tribunal held that "sufficient and credible information on the applicant's own business and on the proportion represented by the suppliers refusing to supply are fundamental and basic elements needed by the Tribunal to give rise to a *bona fide* belief of a direct and substantial effect pursuant to subsection 103.1(7) of the Act."[79]

54. In *Audatex*, the applicant alleged that a refusal to supply Canadian automobile listings data threatened its loss valuation services, which represented approximately one-quarter of the revenues of its "primary business". The Tribunal considered the impact of the refusal to supply on Audatex's

---

[75] Affidavit of S. Juneja, para 5.
[76] Williams Affidavit at para 37.
[77] Radeva Affidavit, Exhibit R5, page 83.
[78] *Sears*, para 16.
[79] *Audatex*, para 68. Further, in other cases such as *Nadeau Poultry Farm Limited v. Groupe Westco Inc et al*., 2008 Comp. Trib. 6, aff'd 2011 FCA 188, the Tribunal found that evidence showing the relative proportion of the affected supply to the applicant's overall business (48% of the overall chicken processing business of the applicant in that case) was sufficient.

overall business, and found that Audatex had failed to provide "clear evidence on the total business of Audatex or on the relative place of its 'primary business' in Audatex's supply of data and software solutions".[80] Similarly, in *Construx Engineering*, the Tribunal denied leave, finding that Construx did not provide sufficient evidence about its business and the impact of the alleged conduct on its business, such that the Tribunal could not assess the significance of sales of the product purchased from the respondent. [81]

55. The applicant's burden can only be discharged by evidence that is non-speculative. In *Broadview (Wyeth)*, *Broadview (Pfizer)*, and *Paradise Pharmacy*, the Tribunal denied leave on the basis that there was no direct and non-speculative evidence about the impact of the refusal on the applicant's business, where the applicant alleged that they feared a loss of customers.

56. JAMP has provided no evidence whatsoever as to the size of its business from which the Tribunal can accurately assess the substantiality of any alleged impact. It has provided no sales information for its full business or other divisions besides BioJAMP, or for any of the dozens of other drugs which it markets. JAMP's assessment of the impact of the alleged practices is speculative and is based only on a failure by JAMP to achieve its own internal sales projections for Jamteki in the five months following its launch. That omission is sufficient in itself for the Tribunal to find that JAMP has failed to provide sufficient credible evidence that it will be directly and substantially affected by the alleged practices.

57. The impact to be assessed under the leave test must also be directly caused by the conduct at issue. Once again, JAMP has led no evidence on causation, effectively asking the Tribunal to draw a dramatic inference based only on JAMP's own failure to meet its internal sales projections. JAMP's attempts to lay the blame of its failure to meet its own lofty and misplaced goals at Janssen's feet is unfounded and ignores a great deal of context about the competitive environment. There are a number of more likely explanations for JAMP's failure to reach its targets. Notably:

a) Jamteki, unlike both STELARA/FINLIUS and Wezlana, is not indicated for treatment of Crohn's disease or ulcerative colitis, or for any pediatric use. This fact alone, and

[80] *Audatex*, paras 64-65.
[81] *Construx Engineering*, para 8.

not any alleged conduct of Janssen, excludes JAMP from over [redacted] of patients who are prescribed ustekinumab products. Further, Crohn's and ulcerative colitis patients receive more frequent doses, making their share of total ustekinumab doses even higher.[82]

b) JAMP has not yet fully benefitted from the implementation of delisting and non-medical switch policies by the publicly-funded provincial drug benefit plans, the timing of which is beyond JAMP's (and Janssen's) control. Non-medical switch windows opened only in May (in Quebec), and many patients will not be switched until closer to the closing of these windows (November 6, 2024 for Quebec).[83]

c) JAMP's forecast assumed that Jamteki will be sold at a discount of [redacted] to STELARA. This assumption proved to be incorrect, as Janssen has competed on price. Janssen is [redacted], and listing FINLIUS [redacted][84] Competition from Janssen and others (e.g., Amgen), not anticompetitive acts, likely impacted JAMP's forecast sales, and JAMP fails to make any attempt to account for such impact.

d) JAMP's projections for sales of Jamteki were based on biosimilar penetration rates for Simlandi, its adalimumab product (a biosimilar for AbbVie's Humira).[85] Humira is a different drug, with its own competitive environment. JAMP has not provided any evidence to explain why the launches of adalimumab and ustekinumab are appropriate comparators from an economic perspective.

e) Finally, JAMPs own representation of its sales are misleading. While JAMP claims to have received only [redacted] in sales for Jamteki, Exhibit 22 of the Faubert Affidavit shows [redacted] in revenue received in March 2024 and [redacted] of revenue received in June 2024 that JAMP did not include in its submissions.[86]

---

[82] Williams Affidavit, para 8.
[83] Williams Affidavit, para 24.
[84] Williams Affidavit, para 16, Exhibit 12.
[85] Faubert Affidavit, para 21.
[86] Exhibit 22, Faubert Affidavit, "JAMTEKI" tab, cell B9.

JAMP Failed to Establish That An Order Could be Issued Under Section 79

JAMP is barred from bringing claims related to the 837 Patent

[redacted] As a threshold issue, none of JAMP's claims relating to alleged conduct prior [redacted] can be subject to an order under s.79, as [redacted]

59. There can be no dispute that the allegations in JAMP's application under s.103.1 and proposed application under s.79 arise out of or relate to Jamteki or STELARA. [redacted] Moreover, the listing litigation did not prevent or delay JAMP from getting its NOC in due course from Health Canada, which it received on November 9, 2023.[88]

60. The Applicant's argument that the Tribunal does not have the jurisdiction to consider whether JAMP's claims regarding the 837 Patent listing litigation are barred is without merit. The Tribunal has broad discretion under s.8 of the *Competition Act* to "hear and dispose of all applications made under Part VII.1 or VIII of the Competition Act and any related matters"[89] (Emphasis added). The test for leave requires the Tribunal to determine whether it could make an order under s. 79. In order to do so, the Tribunal must consider whether the claim is barred. Further, the Tribunal has "with respect to the attendance, swearing and examination of witnesses, the production and inspection of documents, the enforcement of its orders and other matters necessary or proper for the due exercise of its jurisdiction, all such powers, rights and privileged

[87] Williams Affidavit, para 49, Exhibit 62.
[88] Williams Affidavit, Exhibit 4.
[89] *Competition Tribunal Act*, RCS 1985, c 19 (2nd Supp) s.8(1), see also *Chrysler Canada Ltd. v. Canada (Competition Tribunal)*, [1992] 2 SCR 394.

as are vested in a superior court of record" (emphasis added).[90] The Tribunal has ample authority to determine whether it is barred from hearing portions of JAMP's claims, and preventing an abuse of its process or unnecessary expenditure of its resources.

61. JAMP's claims regarding the 837 Patent listing litigation are barred and should be dismissed.

Applicant requires cogent non-speculative evidence that each element of s.79 can be met

62. The Tribunal must be satisfied that each of the elements of s. 79 could be met if the application is heard on the merits.[91] If there is insufficient evidence dealing with one of the elements of s. 79, leave cannot be granted – "bald statements of belief" without supporting evidence are insufficient.[92] Evidence must be cogent, and non-speculative.[93]

63. While the test is a lower standard of proof than on a balance of probabilities, the applicant must still adduce evidence going to each element of the test for leave, including each element of s. 79. As the Federal Court of Appeal emphasized in *Symbol Technologies*, "it is important not to conflate the lower standard of proof on a leave application with what evidence must be before the Tribunal, and what the Tribunal must consider on that application."[94]

64. JAMP has failed to lead sufficient credible evidence to give rise to a *bona fide* belief that Janssen's alleged conduct could be subject to an order under s. 79 of the *Act* if its application were heard on the merits. To satisfy this element of the leave test, JAMP must lead evidence that Janssen: (i) substantially or completely controls a class or species of business throughout Canada; and engaged in, or is engaging in (ii) a practice of anticompetitive acts; and/or (iii) conduct that had, is having, or is likely to have the effect of preventing or lessening competition in a market in which Janssen has a plausible competitive interest that is not the result of superior competitive

---

[90] *Competition Tribunal Act*, s. 8(2).
[91] *B-Flier Inc v. The Bank of Nova Scotia*, 2005 Comp. Trib. 38.
[92] *Brandon Gray Internet Services Inc v Canadian Internet Registration Authority*, 2011 Comp. Trib 17 ("*Gray*"), see also *Audatex* at para 49.
[93] *Audatex*, para 55.
[94] *Barcode FCA*, at para 18, cited in *Audatex*, para 44.

performance. JAMP's case on all counts is assertive and relies only on unfounded speculation and inaccurate hearsay evidence, where there is any evidence at all.

Janssen is not dominant

65. JAMP incorrectly asserts, without any supporting evidence, that ustekinumab constitutes its own product market, and that Janssen is a dominant supplier therein. JAMP provides no supporting evidence to substantiate its claim that there are no other drugs or treatments that compete with ustekinumab, such that ustekinumab should properly be considered a standalone market, notwithstanding the fact that JAMP itself supplies another biologic (Simlandi), which is indicated for treatment of the same conditions as STELARA and FINLIUS.[95]

66. Further, even if Janssen were dominant (which is denied), it will shortly no longer be so as STELARA has been, or will very shortly be, removed from all public insurer formularies in Canada (and FINLIUS has never been listed by these formularies).[96] No new patients with public coverage will be prescribed STELARA or FINLIUS, but will instead receive a biosimilar option, and virtually all existing STELARA patients with public insurance will be required in due course to switch to a biosimilar. Further, several private insurers have delisted STELARA, chosen not to list FINLIUS, and have begun switching patients to biosimilar options, or have listed biosimilars alongside STELARA and FINLIUS.[97]

No anti-competitive acts

67. JAMP alleges several anti-competitive acts by Janssen, all of which Janssen denies, and are unsupported by credible evidence – each is addressed in turn below.

68. **FINLIUS is not a fighting brand:** JAMP alleges that Janssen introduced FINLIUS as a "fighting brand". These claims are not supported by any credible evidence. Stated simply, FINLIUS is not a "fighting brand" at all: this product was not "introduced on a temporary basis to

[95] Radeva Affidavit, Exhibit R5, page 83.
[96] Williams Affidavit, para. 19 and Exhibit 23. STELARA and FINLIUS are not listed for almost all provinces/indications.
[97] *Ibid* at para. 20.

discipline or eliminate a competitor."[98] FINLIUS was introduced by Janssen in response to requests from private insurers for an ustekinumab product [redacted], as opposed to [redacted] STELARA (which can be less desirable for certain insurers).[99]

69. Further, "fighting brands" are typically offered at a substantial discount to an existing "main" brand. By contrast, FINLIUS and STELARA are provided [redacted] Janssen's internal pricing approval documents could not be clearer on this point, citing that [redacted]

70. JAMP alleges that Janssen created uncertainty by representing that FINLIUS would be "the biosimilar" made available to BioAdvance patients qualifying for public funding who are forced to switch from STELARA to a biosimilar.[101] This is factually inaccurate: Janssen agreed to a binding term sheet with Celltrion to provide BioAdvance PSP services to certain patients prescribed Steqeyma. The biosimilar for which BioAdvance will provide services is Celltrion's Steqeyma, not FINLIUS.[102]

71. Further, FINLIUS is only being marketed to private insurers, to whom Janssen is stressing that FINLIUS is produced identically to STELARA, [redacted].[103] Janssen has not sought listing of FINLIUS on any public insurer's formulary.[104] Public health insurers have chosen, as a matter of practice, to support the generic and biosimilar industry by de-listing branded innovator drugs and implementing non-medical switches once biosimilar options are available.[105] Any effort to obtain listing for FINLIUS would likely be futile, given the choice of provincial insurers to use their buying power to support the biosimilar industry over innovator

[98] *Competition Act*, s. 78(1)(d).
[99] Wiliams Affidavit, para 10.
[100] Williams Affidavit, para 16.
[101] JAMP MOFL, para 40.
[102] Williams Affidavit, para 40.
[103] Williams Affidavit, para 14.
[104] Williams Affidavit, para 25.
[105] Williams Affidavit, para 22.

manufacturers.[106] Regardless of how FINLIUS is priced, it would not be listed on any public formulary because Janssen is still an innovator manufacturer.

72. **Janssen has not engaged in predatory pricing:** Competing on price is not predatory pricing, and JAMP has provided no evidence of Janssen pricing STELARA or FINLIUS below cost, or even below the price of Jamteki. Predatory pricing involves a dominant firm reducing its price to loss-making levels to create a monopoly, at which point the dominant firm can recoup its losses by raising prices again.[107] Absent any evidence that Janssen is pricing STELARA or FINLIUS at a loss, JAMP's predatory pricing allegations cannot possibly succeed. Janssen is competing with biosimilars on price, by [redacted], and listing FINLIUS [redacted][108] STELARA and FINLIUS are priced competitively, [redacted][109] Even if Janssen were pricing below cost, which it is not, it could not drive out its rivals because it will be almost completely excluded from supplying ustekinumab to patients with public coverage.

73. **No evidence of Janssen misleading physicians via BioAdvance:** JAMP baldly asserts that Janssen misled physicians regarding BioAdvance by publishing "vague written communications to prescribers advising that a biosimilar would be made available through BioAdvance", and that Janssen representatives then placed phone calls to prescribers, advising them verbally that the biosimilar would be FINLIUS.[110] These allegations are false, and JAMP has provided no credible evidence to support them.

74. The only evidence proffered is hearsay from a JAMP employee who was supposedly advised by unnamed prescribers that they received such calls. The evidence provides no particulars about the prescribers to which this information was supposedly relayed, how many, or any further

---

[106] *Ibid.*
[107] ***Competition Act,*** section 78(i), see also Competition Bureau Abuse of Dominance Enforcement Guidelines, March 7, 2019, at para 59.
[108] Williams Affidavit, para 16.
[109] Williams Affidavit, para 16, Exhibit 12.
[110] JAMP MOFL, para 40.

details of their discussions.[111] This evidence is not credible and should be given no weight by the Tribunal.

75. Janssen, through BioAdvance or otherwise, has never described FINLIUS as a biosimilar to physicians – it is not. Notably, the NOC for FINLIUS' from Health Canada was issued under the submission class "Labelling Only" and the "Reason for Submission" is "Administrative – Additional product name".[112] The absence of any contemporaneous documentary evidence, or direct evidence from a single prescriber or insurer regarding any representation by Janssen that FINLIUS is a biosimilar is telling.

76. JAMP's evidence on this issue falls well short of being sufficient or credible enough to breathe an air of reality into its allegations that Janssen has made misrepresentations about FINLIUS as part of an anticompetitive practice. Without limiting the generality of that submission, the emails to physicians attached to the affidavit of Amélie Faubert are not misleading as JAMP alleges.[113] These emails refer to the future availability of an ustekinumab biosimilar in BioAdvance without referencing a brand name, advising that further information would be forthcoming. Indeed, Steqeyma will be available as a biosimilar option in BioAdvance, but Janssen was unable to disclose that information until Steqeyma received an NOC from the Minister, which it received on July 30, 2024 (after these letters were sent and JAMP's Notice of Application was filed).[114]

77. *Pre-FINLIUS Launch:* In May and June 2024, in response to provincial public insurers introducing non-medical switch policies for STELARA, Janssen provided training to its BACs on how non-medical switch would impact existing and new STELARA patients, and how to communicate this impact to physicians. These training materials were tailored to the specific non-medical switch windows, conditions, and exceptions for each province.[115]

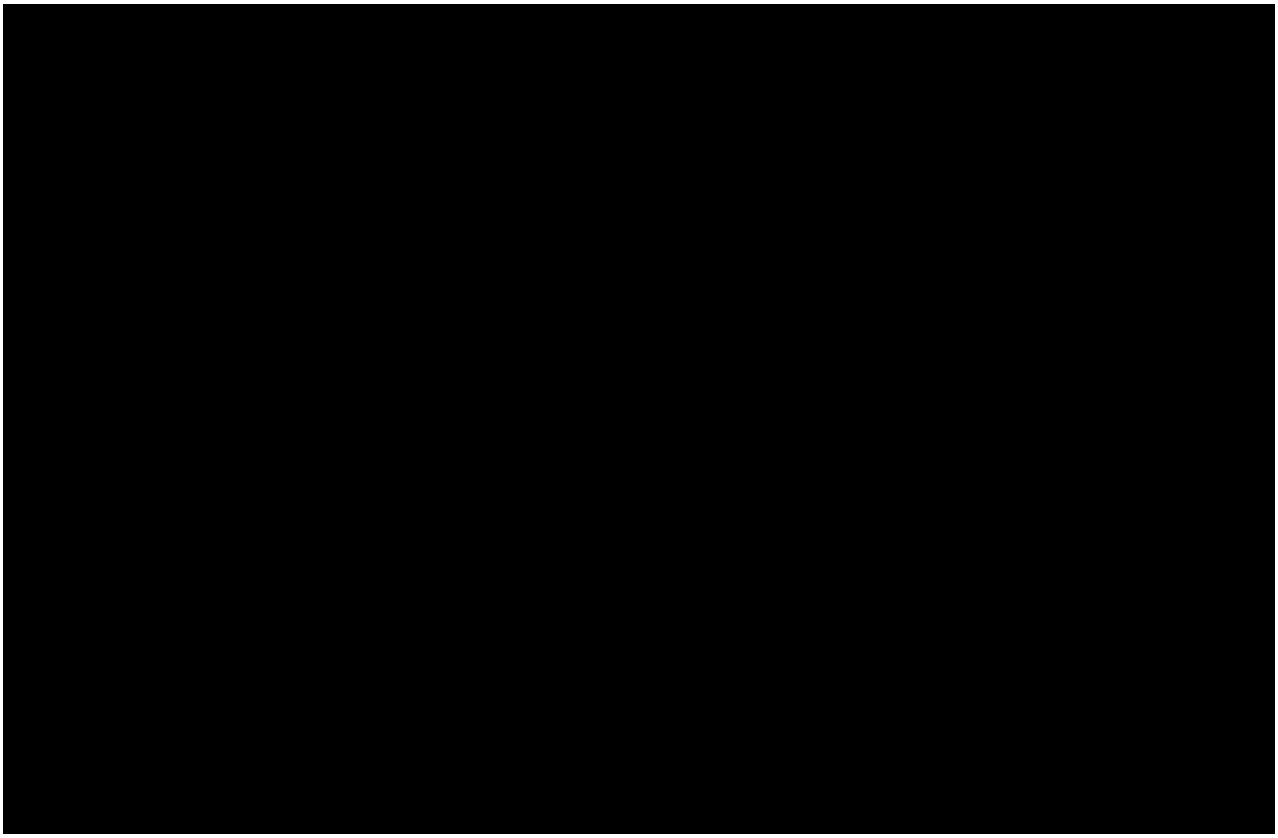
78. The mandated messaging to physicians was to communicate that (i) non-medical switch had been implemented by provincial insurers, (ii) new STELARA patients would no longer receive

[111] Faubert Affidavit, para 29.
[112] Juneja Affidavit, para 35.
[113] JAMP MOFL, para 121, Faubert Affidavit, Exhibit 20.
[114] Williams Affidavit, para 40.
[115] Williams Affidavit, para 34, Exhibits 28-34.

reimbursement for STELARA, (iii) existing publicly insured patients would not need to be switched until the end of the non-medical switch window; (iv) that while privately insured STELARA patients would not be directly affected by the provincial policy, some private insurers might update their plans; and (v) if a physician were to switch a patient to a biosimilar drug early, the patient may be required to leave BioAdvance (which at that time was not providing services in relation to any biosimilar options).[116]

79. JAMP alleges that messaging from Janssen's BACs created confusion as to whether FINLIUS was a biosimilar to STELARA.[117] Janssen's training materials and communication scripts to physicians and patients are clear that FINLIUS is not a biosimilar. BACs were advised to inform physicians that Janssen would be rolling out a solution in the following weeks to allow new STELARA affected by provincial non-medical switch to remain in BioAdvance and receive an ustekinumab biosimilar, and that more information would be provided as it became available. An excerpt of a recommended communication to dermatologists from the Ontario training materials on this point is set out below:

[116] Williams Affidavit, para 31.
[117] JAMP MOFL, para 40.



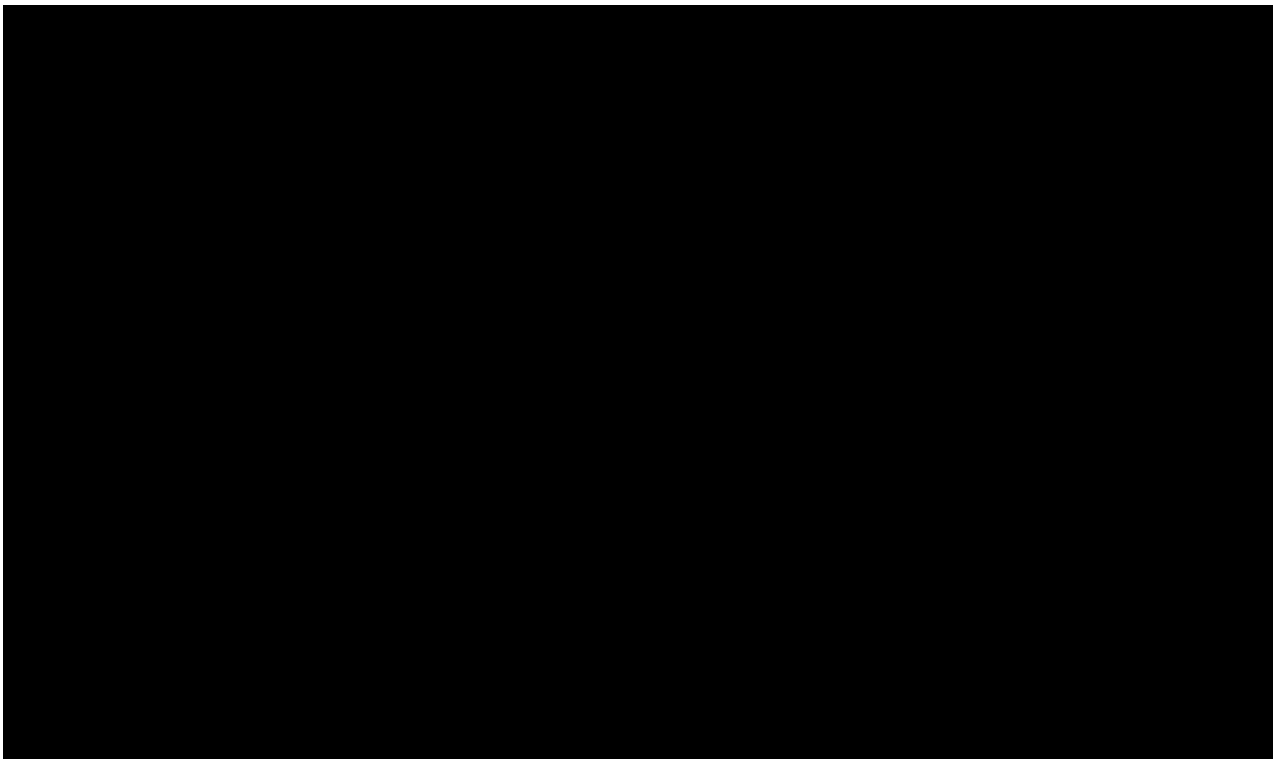
80. The ustekinumab biosimilar referred to in these materials is Celltrion's Steqeyma. Steqeyma was not listed in the training materials as it had not received an NOC at the timing of the training. Nowhere in any of these training materials is FINLIUS listed or described as a biosimilar to STELARA.

81. *Post-FINLIUS Launch:* Once FINLIUS launched in Canada, Janssen again conducted training with coordinators in June and July 2024 regarding the process for patient enrollment and physician marketing for FINLIUS. This training emphasized that: (i) FINLIUS is not a biosimilar to STELARA, but an identical product with different branding; and (ii) FINLIUS would not be available through publicly-funded insurers. A slide from Janssen's BAC training deck on this point is reproduced below:

118

82. BACs were also provided recommended responses for anticipated questions from physicians, which also emphasized that: (i) FINLIUS is not a biosimilar; (ii) FINLIUS would only be available for privately-insured patients; and (iii) Janssen was working to include a separate contracted biosimilar option in BioAdvance (i.e., not FINLIUS) and that further details about this would be provided in due course. [119] Excerpts from the relevant training materials are below:

[118] Williams Affidavit, exhibit 27.
[119] *Ibid*, slide 17.



120

[120] *Ibid*, slide 16.

[121]

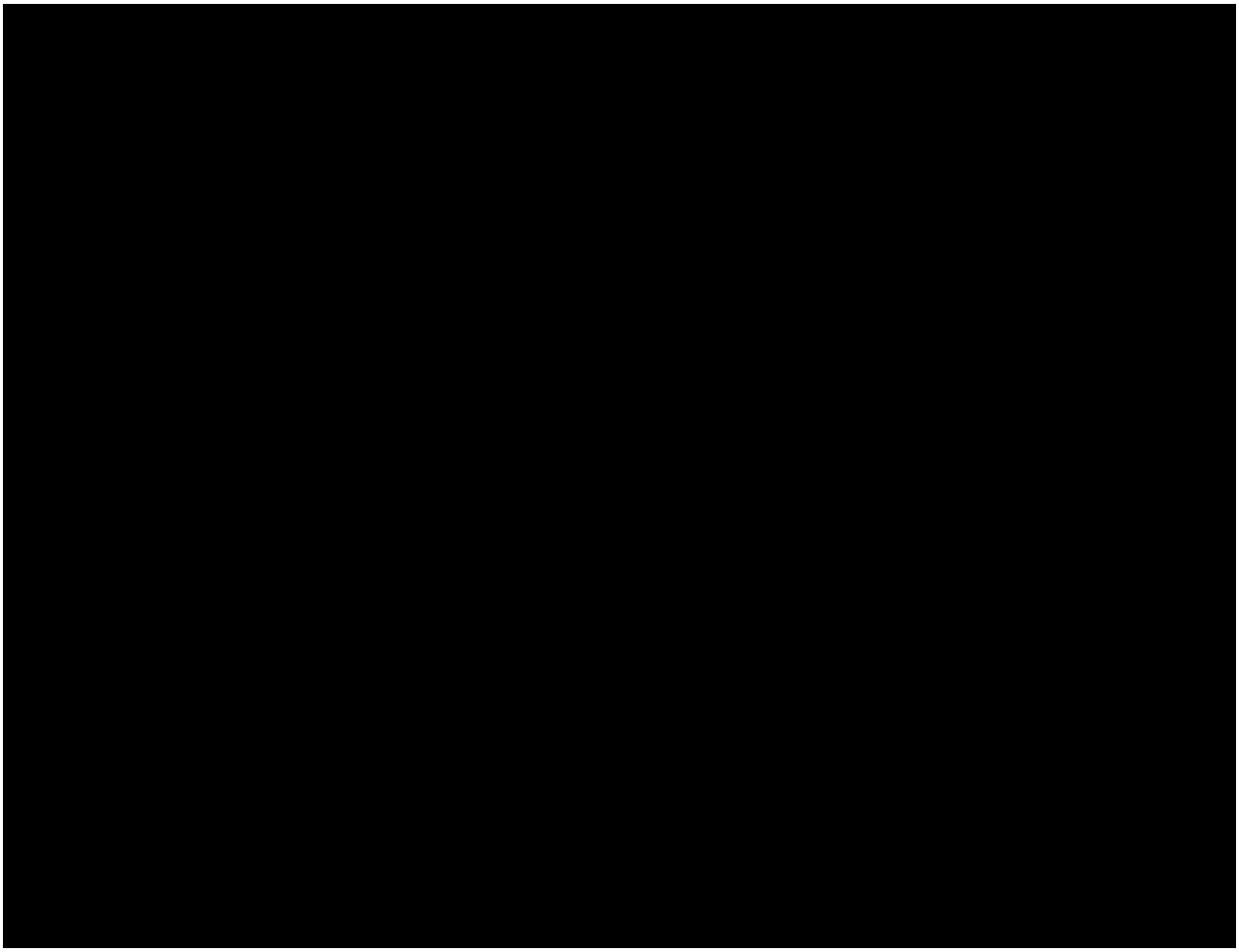
83. **Janssen did not mislead patients.** JAMP also alleges that Janssen representatives contacted patients directly and misled them regarding biosimilars. This is untrue and unsubstantiated by the evidence. The only evidence proffered in support of this allegation is a single email to a Quebec patient from a BAC.[122] JAMP mischaracterizes this email, quotes only one (translated) sentence from the email in its Memorandum of Fact and Law,[123] and does not provide the full context contained in the document.

84. The coordinator who sent the email is responsible for assisting patients in their use of STELARA. The email explains that, while RAMQ (Quebec's public health insurance program) had announced plans to introduce a non-medical switch for STELARA patients to biosimilars, the patient qualified for an exception, as they had had unsuccessful results with two previous treatment options. As a result, this specific patient was not required to switch from STELARA (or BioAdvance). On its face, this communication was tailored to an individual patient and was

[121] *Ibid*, slide 27.
[122] Faubert Affidavit, para 34.
[123] JAMP MOFL, para 121, Faubert Affidavit, Exhibit F20.

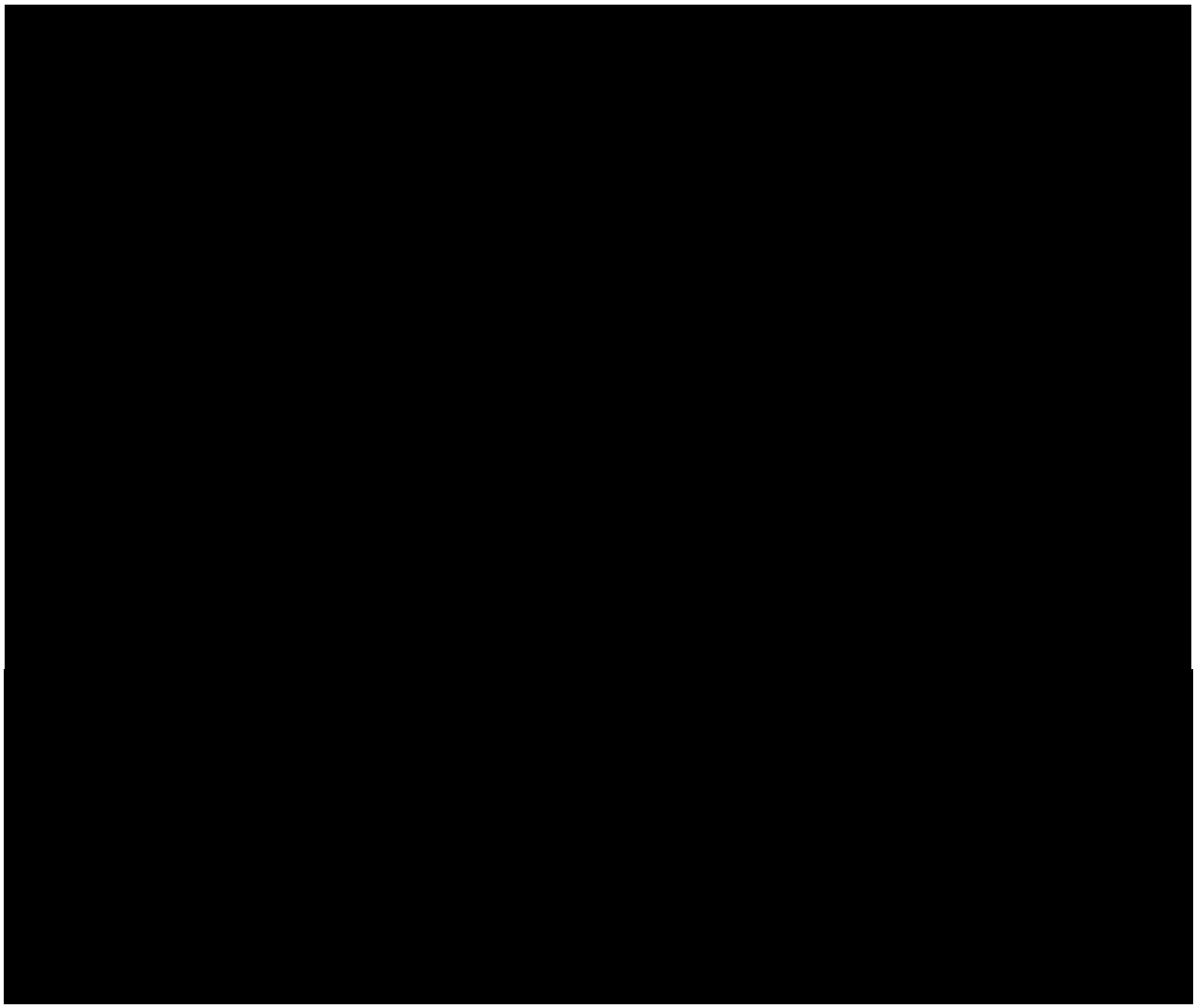
intended to remove uncertainty regarding a newly announced policy that would ostensibly require them to switch their medication and PSP. There was nothing misleading about the BAC's advice to this specific patient.

85. To the contrary, Janssen provided BACs with FAQs and talking points for engaging with patients which were clear and accurate. Excerpts of the Quebec patient FAQs pre-FINLIUS are reproduced below:



86. Post-FINLIUS launch, BACs were provided with updated talking points for patients customized to the non-medical switch policies of each province. This messaging was clear that privately insured patients may have coverage for STELARA or FINLIUS, and guidance for possible combinations of patient insurance status. These talking points again emphasized that

FINLIUS is not a biosimilar but rather an "alternate brand of Janssen ustekinumab."[124] An excerpt of the talking points (for Quebec prescribers and patients) is set out below:



[125]

87. **No evidence of Janssen intimidating prescribers.** JAMP's allegations that Janssen has "intimidated" prescribers to prevent them from meeting with JAMP representatives is beyond the pale.[126] JAMP has led no evidence that Janssen has any non-disclosure agreements that would

[124] Williams Affidavit, Exhibit 31 at page 4.
[125] *Ibid*, page 3.
[126] JAMP MOFL, para 123.

prohibit prescribers from meeting with JAMP staff or otherwise engaging with marketing efforts for Jamteki, let alone a scintilla of evidence of any related "threats" by Janssen.

88. JAMP's only evidence in support of these serious allegations is three emails in which prescribers declined an invitation to discuss Jamteki over lunch. The suggestion that the only reason physicians would cancel lunches with JAMP sales representatives is because of surreptitious anticompetitive conduct by Janssen is risible. It is not unusual or uncommon for prescribers to decline invitations to meet with representatives of drug manufacturers.[127]

89. Janssen has produced its standard-form services agreement ("**Services Agreement**") used for physicians participating in advisory boards, as well as an example of an executed Services Agreement for a medical advisory board for IBD dated April 24, 2024.[128] The confidentiality provisions in the Services Agreement apply only to confidential Janssen information disclosed through the advisory board process. Nowhere in these agreements is there any restriction on a physician's ability to discuss other drugs or treatment options with Janssen's competitors (or anyone else, for that matter). There are no other agreements relating to advisory boards, or otherwise, between Janssen or any of its affiliates and physicians which would prohibit them from discussing Jamteki (or any other medication) with JAMP, or anyone else.[129]

90. **Janssen did not mislead insurers:** JAMP speculates that Janssen misled insurers by advertising FINLIUS as a biosimilar.[130] There is no credible evidence to support this claim. JAMP proffers an Alberta Blue Cross publication that (incorrectly) describes FINLIUS as a biosimilar.[131] There is no evidence whatsoever about why Alberta Blue Cross made this error. Once again, JAMP invites the Tribunal to take a flying leap from a single third-party document to make an inference of unlawful conduct. The fact that an insurance provider may have erred in its description of FINLIUS is far from sufficient credible evidence that Janssen engaged in a misleading advertising campaign targeted at insurers.

---

[127] Williams Affidavit, para 42.
[128] Williams Affidavit, Exhibits 58 and 59.
[129] Williams Affidavit, paras 42-43.
[130] JAMP MOFL, para 130.
[131] JAMP MOFL, para 131.

91. To the contrary, it is abundantly clear from FINLIUS' Health Canada approvals and documentation that it is not a biosimilar to STELARA, but the same product with a different name and branding. The most logical inference to be drawn from this single piece of evidence is that the Alberta Blue Cross made an innocent mistake. In addition, the fact that Canada Life lists FINLIUS in its forms is not evidence of any misleading conduct,[132] as private insurers can and do elect to list STELARA and/or FINLIUS on their formularies, and can do so without any agreement or interaction with Janssen at all.[133]

92. **Competing on price is not a discriminatory response:** Finally, JAMP alleges that Janssen's decision to launch FINLIUS at a competitive price upon the entry of biosimilars is an anticompetitive act.[134] Competing to provide products at lower prices for consumers is not anticompetitive, rather, it is the very essence of competition. It is unreasonable for JAMP to expect Janssen not to compete against it on price. More importantly, such competition is to the benefit of consumers who can receive STELARA or FINLIUS at an equivalent price as biosimilar options.

93. **Janssen did not "game" the regulatory system or engage in sham litigation regarding STELARA or FINLIUS:** As noted above, JAMP's claims relating to the 837 Patent litigation are barred [redacted] In the alternative, for the reasons set out below, Janssen's listing litigation activities could not form the basis for an order under section 79 because the alleged conduct had no impact at all on the timing of approval or market entry of JAMP's Jamteki.

Timeline demonstrates that JAMP was not affected by the 837 Patent listing litigation

94. The timing of the Jamteki Phase III studies and regulatory approval process shows that JAMP's launch was not affected by Janssen at all. More specifically and as explained below, JAMP and Alvotech had full control and were solely responsible for the timing of the NOC for Jamteki. Janssen's conduct had no effect on the timing of Alvotech's Phase III studies; no effect on the timing of JAMP's regulatory submission; no effect on Health Canada's approval process

[132] JAMP MOFL, para 131.
[133] Williams Affidavit, paras 13, 18, 26 31.
[134] JAMP MOFL, para 134.

[redacted]

JAMP's alleged fear of launching "at risk" is not anticompetitive conduct

[redacted]

[135] Williams Affidavit, para 45, Exhibit 61.
[136] Juneja Affidavit, para. 49.
[137] Williams Affidavit, Exhibit 9.
[138] Juneja Affidavit, Exhibit J31.
[139] Williams Affidavit, Exhibit 3.

97. Parliament has clearly provided that the mere exercise of patent rights is not anti-competitive for purposes of section 79:

> **Exception**
>
> **79(5)** For the purpose of this section, an act engaged in pursuant only to the exercise of any right or enjoyment of any interest derived under the *Copyright Act*, *Industrial Design Act*, *Integrated Circuit Topography Act*, *Patent Act*, *Trademarks Act* or any other Act of Parliament pertaining to intellectual or industrial property is not an anti-competitive act.

98. The policy rationale behind s.79(5) is obvious: there is a major difference between a monopoly, in the anti-competitive sense, and an intellectual property right, such as a patent.[140] As the Tribunal has previously noted, "[t]he right granted by Parliament to exclude others is fundamental to intellectual property rights and cannot be considered to be anti-competitive."[141] The Court of Appeal for Ontario has also confirmed that "the normal exercise of an intellectual property right is not an 'abuse of dominance' under [s. 79 of the Act]."[142] Thus, Janssen's legitimate exercise of its 837 Patent rights by attempting to list the 837 Patent pursuant to the *PM(NOC) Regulations* cannot be the subject of an order under s. 79, and JAMP's application for leave on this issue should be dismissed.

99. Further, the fallacy of JAMP's arguments is highlighted in paragraph 31 of its Memorandum of Fact and Law. JAMP's main position there is in relation to alleged "sham" litigation by Janssen. JAMP states that it never believed Janssen's attempts to list the 837 Patent would be successful; yet the purported fears that JAMP relies on in argument depend on the *success* of Janssen's litigation. Paragraph 31(a) of JAMP's argument relies on successful listing of the 837 Patent on the patent register. Likewise, paragraph 31(b) relies on successful patent infringement litigation against JAMP. JAMP's alleged fears of successful listing are simply inconsistent with its allegation of sham litigation. JAMP only faced the risks it describes because the litigation had merit.

---

[140] *Harris v. Glaxosmithkline Inc.*, 2010 ONCA 872 at para. 19 ["***Glaxosmithkline***"].
[141] *Canada (Competition Act, Director of Investigation and Research) v. Warner Music Canada Ltd.*, 1997 CanLII 3725 (CT), 78 C.P.R. (3d) 321 (Comp. Trib.) at p. 15.
[142] *Glaxosmithkline* at para. 20.

[redacted]

No substantial prevention or lessening of competition

101. JAMP has not provided sufficient credible evidence that any of Janssen's alleged conduct resulted in a substantial prevention or lessening of competition. Notably, as described above, STELARA is or will shortly be delisted from all public formularies (and FINLIUS has never been listed). There can be no impact on competition for publicly-insured patients, who comprise a substantial percentage of ustekinumab patients. This alone militates against any *bona fide* belief that there could be a substantial prevention or lessening of competition.

102. Moreover, beyond its claims about the impact on Jamteki, JAMP has not led any evidence about competition in any relevant market more broadly to show that there has been any anticompetitive effects. On the contrary, several ustekinumab biosimilar treatment options have been recently approved (such as Celltrion's Steqeyma), and more are seeking approval.[144]

103. For privately insured patients, STELARA and FINLIUS continue to compete, [redacted] as well as other branded and generic drugs for plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis. Following the approval of ustekinumab biosimilars, STELARA has been removed from certain private formularies (FINLIUS having never been listed on certain private formularies), or is covered alongside

[143] Williams Affidavit, Exhibit 62.
[144] *Ibid* at Exhibit 5.

biosimilars including Jamteki. JAMP is not prevented from competing for private payor patients in any way.

104. JAMP's allegations that the listing litigation regarding the 837 Patent created uncertainty for biosimilar firms and delayed entry hold no water, as described above. It is not credible for JAMP to argue that the potential success of a proceeding that it had internally deemed to be without merit was the sole reason that it delayed the development and marketing of what it views as a highly lucrative product.

105. For these and all the reasons discussed above, JAMP has failed to show that any alleged conduct by Janssen has had any direct and substantial effect on competition.

PART V: ORDER SOUGHT

106. JAMP has not led sufficient credible evidence to satisfy the requirements to obtain leave under s. 103.1 of the *Act* to bring its proposed s. 79 application. Janssen respectfully requests the Tribunal dismiss JAMP's application for leave, with costs.

ALL OF WHICH IS RESPECTFULLY SUBMITTED this 6th day of September, 2024.

BLAKE, CASSELS & GRAYDON LLP
199 Bay Street
Suite 4000, Commerce Court West
Toronto, ON M5L 1A9

Robert E. Kwinter
Phone: (416) 863-3283
Fax: (416) 863-2653
Email: rob.kwinter@blakes.com

Nicole Henderson
Phone: (416) 863-2399
Email: nicole.henderson@blakes.com

Jonathan Bitran
Phone: (416) 863-3289
Email: jonathan.bitran@blakes.com

Joe McGrade
Phone: (416) 863-4182
Email: joe.mcgrade@blakes.com

Brian Facey
Phone: (416) 863-4262
Email: brian.facey@blakes.com

Counsel for the respondent
Janssen Inc.

SCHEDULE A – JURISPRUDENCE

1. *Abbott Laboratories v. Canada (Minister of Health)*, 2006 FC 120, [2006] 4 FCR 41, rev'd 2007 FCA 73.
2. *Audatex Canada ULC v. CarProof Corporation*, 2015 Comp. Trib. 28.
3. *B-Flier Inc v. The Bank of Nova Scotia*, 2005 Comp. Trib. 38.
4. *Brandon Gray Internet Services Inc v Canadian Internet Registration Authority*, 2011 Comp. Trib 1.
5. *Bristol-Myers Squibb Co. v. Canada (Attorney General)*, 2005 SCC 26, [2005] 1 SCR 533.
6. *Broadview Pharmacy v. Pfizer Canada Inc.*, 2004 Comp. Trib. 23.
7. *Broadview Pharmacy v. Wyeth Canada Inc.*, 2004 Comp. Trib. 22.
8. *Canada (Competition Act, Director of Investigation and Research) v. Warner Music Canada Ltd.*, 1997 CanLII 3725 (CT), 78 C.P.R. (3d) 321 (Comp. Trib.).
9. *Canada (Director of Investigation and Research) v Chrysler Canada Ltd*, 1989 CarswellNat 720 (Comp. Trib.) (WL), 27 CPR (3d) 1, aff'd 1991 CarswellNat 1118 (FCA) (WL), 38 CPR (3d) 25.
10. *Chrysler Canada Ltd. v. Canada (Competition Tribunal*), 1992 CanLII 68 (SCC), [1992] 2 SCR 394.
11. *Construx Engineering Corporation v. General Motors of Canada*, 2005 Comp. Trib. 21.
12. *Eli Lilly Canada Inc. v. Canada (Minister of Health)*, 2003 FCA 24, [2003] 3 FC 140.
13. *Harris v. Glaxosmithkline Inc.*, 2010 ONCA 872.
14. *Nadeau Poultry Farm Limited v. Groupe Westco Inc et al*., 2008 Comp. Trib. 6, aff'd 2011 FCA 188.
15. *Novartis Pharmaceuticals Canada Inc. v. Apotex Inc*., 2013 FC 142.
16. *Novo Nordisk Canada Inc. v. Canada (Health)*, 2019 FC 822.
17. *Paradise Pharmacy Inc. and Rymal Pharmacy Inc. v. Novartis Pharmaceuticals*, 2004 Comp. Trib. 21.
18. *Sears Canada Inc. v. Parfums Christian Dior Canada Inc. and Parfums Givenchy Canada Ltd.*, 2007 Comp. Trib. 6.
19. *Symbol Technologies ULC v. Barcode Systems Inc.*, 2004 FCA 339.

SCHEDULE B: DOMESTIC AND FOREIGN LEGISLATION

20. 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 (assented to June 20, 2024).
21. *Competition Act*, RSC 1985, c C-34.
22. *Competition Tribunal Act*, RCS 1985, c 19 (2nd Supp).
23. *Patent Act*, R.S.C., 1985, c. P-4.

SCHEDULE C: SECONDARY SOURCES

1. Competition Bureau Canada, "Abuse of Dominance Enforcement Guidelines" (7 March 2019), online: https://competition-bureau.canada.ca/how-we-foster-competition/education-and-outreach/abuse-dominance-enforcement-guidelines.