File No. CT-2023-007

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 Apotex Inc. 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 Apotex Inc. for an order pursuant to section 79 of the Act;

BETWEEN:

APOTEX INC.

Applicant

– and –

PALADIN LABS INC., ENDO PHARMACEUTICALS INC., TAKEDA CANADA INC., and TAKEDA PHARMACEUTICALS U.S.A. INC.

Respondents

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

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1. Respondents are the only suppliers of ponatinib, a leukemia treatment with a sale price of more than CAD $150 per dose. Apotex wishes to launch a generic version of this drug and compete. The launch of a generic version of ponatinib will drive down the price of this drug significantly. To obtain regulatory approval for its generic drug, Apotex needs a small sample of ponatinib from Respondents. Health Canada's policy is that Respondents should supply Apotex with a sample without delay. Respondents are abusing their monopoly by refusing to supply (and delaying the supply of) ponatinib. This is not a garden variety refusal to deal. The subjective intent and objectively foreseeable result of Respondents' practices is to exclude, prevent and delay Apotex from launching a competing generic drug. Respondents' effort to rag the puck deprives patients of a competitive option, and results in patients and payors (including provincial governments) paying more. Respondents' conduct stymies Parliament's regulatory scheme. Apotex's ponatinib business is directly and substantially affected by Respondents' abuse of dominance. Apotex seeks leave to bring an application for abuse of dominance against Respondents.

I. EXECUTIVE SUMMARY

2. Apotex Inc. ("**Apotex**") is a Canadian-based pharmaceutical company that produces high-quality, affordable medicines (both generic and branded drugs).

3. To launch a new generic drug, a company must file an "Abbreviated New Drug Submission" ("**ANDS**") with Health Canada, requesting the issuance of a "Notice of Compliance" ("**NOC**") for its product. The ANDS must include a study demonstrating that the filer's generic drug is "bioequivalent" to another drug for which Health Canada has

already issued a NOC (i.e., the "**Reference Product**"). To conduct a bioequivalence study, the company must obtain a small sample of the Reference Product.

4. A generic drug is typically sold at a price that is significantly lower than a Reference Product. Canadian governments maintain rules that, with some exceptions, require a pharmacist to dispense a generic drug when the pharmacist is presented with a prescription for a branded drug (a practice commonly referred to as "automatic substitution"). Due to the lower prices of generic drugs and the automatic substitution rules, the first generic product to enter a market typically captures a significant share of the market quickly upon its launch.

5. Takeda Pharmaceuticals U.S.A. Inc. ("**Takeda US**") is a pharmaceutical company that produces innovative (or "branded") drugs. Takeda US produces ICLUSIG® ("**ICLUSIG**"), a drug with a NOC that is indicated for the treatment of different types of leukemia. ICLUSIG's active ingredient is ponatinib hydrochloride ("**ponatinib**"). Takeda US has appointed Paladin Labs Inc. ("**Paladin**") as the importer and distributor of ICLUSIG in Canada. The current price of ICLUSIG, which is set by Takeda and Paladin, can exceed CAD $150 per dose.

6. Apotex wishes to develop and launch a generic ponatinib product. Apotex requires a sample of ICLUSIG to conduct a bioequivalence study for inclusion in its ANDS. Takeda US and Paladin (together with their respective affiliates, Takeda Canada Inc. ("**Takeda Canada**") and Endo Pharmaceuticals Inc. ("**Endo**", collectively with Takeda US, Paladin and Takeda Canada, "**Respondents**") carefully control the supply and distribution of ICLUSIG, and as a result ICLUSIG cannot be obtained from any person other than Takeda

and Paladin. Takeda and Paladin have refused to supply (and delayed the supply of) a sample of ICLUSIG to Apotex. Apotex's launch of a generic ponatinib product will be prevented or delayed as a result.

7. As the sole suppliers of ICLUSIG, Respondents substantially and completely control the supply of ponatinib in Canada, and are monopolists. The subjective intent and objectively foreseeable result of Respondents' practices is to exclude, prevent and delay the entry of a potential competitor. The effect of Respondents' practices is to prevent or delay competition substantially, and thereby preserve their market power for ponatinib products. Respondents' practices deprive Canadian patients and payors (including provincial governments) of a new competitive option, and increase the costs for treatment of vulnerable patients.

8. Respondents' practices contravene section 79 of the Competition Act ("**Act**"),[1] and Apotex has been directly and substantially affected by those practices. Apotex's proposed application meets the low threshold required on a leave application. Accordingly, Apotex seeks leave to commence an application under section 79 of the Act against Respondents pursuant to section 103.1 of the Act. Apotex's application for leave should be granted.

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[1] RSC 1985, c C-34.

II. FACTS

A. The Parties

9. The Applicant, Apotex Inc. ("**Apotex**"), is a company incorporated under the laws of Ontario. Apotex produces high-quality, affordable medicines (both generic and branded drugs).

10. Takeda Pharmaceutical Company Limited ("**TPCL**") is a Japanese-based pharmaceutical company. Takeda Pharmaceuticals U.S.A. Inc. ("**Takeda US**") and Takeda Canada Inc. ("**Takeda Canada**") are each wholly-owned subsidiaries of TPCL,[2] and are therefore affiliates of each other for the purposes of paragraph 2(2)(a) of the Act. Takeda US and Takeda Canada produce innovative (or branded) drugs.

11. Endo International plc is an Irish-domiciled pharmaceutical company. Endo Pharmaceuticals Inc. ("**Endo**") and Paladin Labs Inc. ("**Paladin**") are each subsidiaries of Endo International plc,[3] and are therefore affiliates of each other for the purposes of paragraph 2(2)(a) of the Act. Endo produces generic and branded drugs. Paladin is Canadian-based pharmaceutical company that, among other things, imports and distributes drugs on behalf of third parties.

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2 TPCL, *Form 20-F, FY2022* (28 June 2023) at F-74.

3 Endo International plc, *Form 10-K for the fiscal year ended December 31, 2022* (6 March 2023) at exhibit 21.1.

B. Why It is Critical that Branded Drug Companies Supply Generic Drug Companies

12. Health Canada is a department of the Government of Canada. Health Canada's responsibilities include assisting the Minister of Health with the administration of the *Food and Drugs Act*[4] and its regulations (including the *Food and Drug Regulations*[5] ("**FDR**")), which regulate the sale of pharmaceutical products throughout Canada. Neither Health Canada nor the Minister of Health is a party to these proceedings.

13. Section C.08.002(1) of the FDR prohibits any person from selling or advertising a new drug unless, among other things, the Minister of Health has issued a Notice of Compliance ("**NOC**") to the manufacturer in respect of the new drug.

14. Applying to obtain a NOC for a new drug is a complex process. However, the FDR provides for a simpler application process where a manufacturer can establish that its drug is equivalent in certain specific ways to a drug for which a NOC has already been issued (a "**Reference Product**"). In particular, Section C.08.002.1(1) permits a manufacturer to file an Abbreviated New Drug Submission ("**ANDS**") where, in comparison with a Reference Product, the manufacturer can demonstrate (a) the new drug is the pharmaceutical equivalent of the Reference Product (i.e., it has the same "active ingredient"); (b) the new drug is bioequivalent to the Reference Product, based on the pharmaceutical characteristics (i.e., the "bioavailability" of the generic drug after administration to a patient is the same as the Reference Product); (c) the route of

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4 RSC 1985, c F-27.

5 CRC, c 870.

administration of the new drug is the same as that of the Reference Product; and (d) the conditions of use of the new drug fall within the conditions of use for the Reference Product. Drugs that obtain a NOC via an ANDS are typically referred to as "generic drugs" or "generics". Drugs that obtain a NOC without an ANDS (i.e., through a more complex New Drug Submission) are typically referred to as "branded".

15. As an additional element of its authority, Health Canada may request that a manufacturer establish a Risk Management Plan ("**RMP**") for a drug, including for a drug with a new active ingredient. While each RMP is different, an RMP will typically restrict the distribution of and access to a drug, to prevent adverse effects or other drug-related problems.

16. In August 2020, Health Canada issued a public notice to "clarify to drug manufacturers and sponsors that elements of [RMPs] required by Health Canada … are not intended to restrict access to [Reference Products] for generic drug manufacturers for the purposes of conducting comparative testing. Any RMP elements should not delay or hinder comparative testing with generic products or hinder their ability to enter the market…. [Health Canada] reminds sponsors that RMP elements should not be seen as a reason to delay or stop comparative testing with generic products, or to prevent them from entering the market."[6]

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[6] Health Canada, *Notice of clarification to drug manufacturers and sponsors – Risk Management Plans – Update*, August 13, 2020.

17. Branded drugs are typically expensive. By contrast, generic drugs are typically sold at a price that is significantly lower than a branded drug. To lower the costs of drugs for patients and payors (including provincial governments), Canadian governments maintain rules that, with some exceptions, require a pharmacist to dispense a generic drug when the pharmacist is presented with a prescription for a branded drug (a practice commonly referred to as "automatic substitution"). Due to the lower prices of generic drugs and the automatic substitution rules, the first generic product to enter a market typically captures a significant share of the market quickly upon its launch.

C. ICLUSIG (ponatinib)

18. Ponatinib is an anticancer drug that is indicated for the treatment of two types of leukemia: chronic myeloid leukemia ("**CML**") and Philadelphia chromosome positive acute lymphoblastic leukemia ("**Ph+ ALL**").[7] Ponatinib is from a class of drugs called "tyrosine kinase inhibitors" ("**TKI**"). Patients with CML and Ph+ ALL experience uncontrolled growth of certain blood cells. TKIs slow or stop this uncontrolled growth, significantly improving outcomes for patients with these types of leukemia.

19. A ponatinib-based product was developed by ARIAD Pharmaceuticals, Inc. ("**ARIAD**") under the brand name ICLUSIG. Health Canada issued a NOC to ARIAD for ICLUSIG that permitted it to be marketed as of August 21, 2015. TPCL acquired ARIAD in 2017, and the right to market ICLUSIG in Canada is now registered to Takeda US. Takeda US has entered into an agreement with Paladin, whereby Paladin is appointed the importer and

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[7] Takeda US, ICLUSIG Product Monograph (Revised 3 October 2022) at 1.

distributor of ICLUSIG for Canada. In Canada, ICLUSIG is exclusively marketed in 15 mg tablets.

20. ICLUSIG is specifically indicated for patients for whom other TKI therapy is not appropriate, including patients with prior TKI resistance or intolerance and patients with a specific chromosomal abnormality known as the T315I mutation.[8] There are no substitutes for ICLUSIG. Takeda US and Paladin substantially and completely control, have market power for, and are monopolists for, the sale of ponatinib-based products throughout all of Canada.

21. Health Canada requested an RMP for ICLUSIG. Paladin satisfied this request by establishing a "Controlled Distribution Program" (the "**CDP**"). The CDP restricts supply of ICLUSIG in a number of different ways. Notably, Paladin certifies which prescribers (i.e., physicians) may prescribe ICLUSIG, and maintains a list of those prescribers. In addition, Paladin will only supply ICLUSIG to pharmacies that agree to follow certain requirements for the dispensing of ICLUSIG, including an obligation to verify that a prescription for ICLUSIG was written by a prescriber on the list maintained by Paladin. The effect of the CDP is that Paladin controls every dose of ICLUSIG in Canada at every level of distribution. Under the terms of the CDP, no pharmacist or physician will supply any amount of ICLUSIG to a company like Apotex. Apotex can only obtain ICLUSIG from Paladin or Takeda US.

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[8] Takeda US, ICLUSIG Product Monograph (Revised 3 October 2022) at 4.

22. ICLUSIG is a valuable and expensive product. At a global level, TPCL reports revenues of ¥47.2 billion from the sale of ICLUSIG for the fiscal year ended March 31, 2023 (equivalent to approximately CAD $480,496,000).[9] In Canada, according to information published by health data company IQVIA, sales of ICLUSIG in Canada in 2022 were valued at CAD $8,210,594. According to IQVIA, these sales were generated from the sales of approximately 51,900 doses of ICLUSIG. This implies an average sale price per dose of CAD $158.20.

23. Every month in which Takeda US and Paladin are the exclusive supplier of a ponatinib product in Canada presents an opportunity to earn significant additional revenue and profits. Takeda US and Paladin have very strong incentives to maintain their status as the exclusive supplier of a ponatinib product in Canada for as long as possible. Takeda Canada and Endo, their affiliates, have the same incentives.

24. Health Canada requires that manufacturers report actual and anticipated shortages of drugs. No actual or anticipated shortage of ICLUSIG has ever been reported to Health Canada.

D. Respondents' Exclusionary Practices Stymied and Delayed Apotex's Attempts to Enter Ponatinib Market

25. Apotex intends to launch a ponatinib based product to compete against ICLUSIG. Upon the launch of its product, Apotex expects to quickly capture a significant share of the market for ponatinib. In the normal course of business, Apotex uses a forecast model to estimate its anticipated sales of a new drug, based on its extensive experience bringing new

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[9] TPCL, *Form 20-F, FY2022* (28 June 2023) at 63.

generic drugs to market. Apotex's model forecasts, based on a set of conservative assumptions, that within a year of launching a generic ponatinib product, Apotex's ponatinib business would grow from $0 in revenue to capture more than [redacted] of sales across Canada and generate more than CAD [redacted] million in revenue and CAD [redacted] million in gross margin. Apotex's model forecasts that in order to capture such a share and generate such revenues, Apotex would sell its ponatinib product at a price of [redacted] per dose (which is a discount of more than [redacted] compared to the prevailing price for which Paladin is believed to sell ICLUSIG).

26. Apotex has taken a number of business steps associated with the development of its ponatinib product. One of Apotex's upcoming steps is to obtain a NOC. To prepare its ANDS, Apotex first requires a small supply of ICLUSIG with which to conduct a bioequivalence study.

27. Apotex has made diligent efforts to attempt to acquire a supply of ICLUSIG. In 2023, Apotex attempted to obtain a small supply of ICLUSIG from numerous different intermediaries in the pharmaceutical industry in Canada and outside Canada. In each instance, the intermediary was unwilling or unable to supply the requested ICLUSIG to Apotex.

28. On June 12, 2023, Apotex wrote to Takeda US and Paladin, requesting the supply of ICLUSIG. Apotex requested a supply of 360 tablets of ICLUSIG. Apotex's letter expressly advised that the purpose of the request was to use the supply as a Reference Product and to conduct a bioequivalence study. Apotex did not receive any reply.

29. On August 24, 2023, Apotex wrote to Takeda Canada, Endo and Paladin, repeating its request for the supply of a small volume of ICLUSIG, and indicated its desire that the supply be delivered within 20 business days (i.e., September 22, 2023).

30. On September 8, 2023, Endo wrote to Apotex via email. That email (i) confirmed that Endo and Paladin are affiliated; (ii) confirmed that Paladin distributes ICLUSIG in Canada; (iii) advised that Endo and Paladin had conferred with Takeda US and Takeda Canada about Apotex's request; and (iv) directed Apotex to contact Paladin's customer service department to establish an account and place an order for ICLUSIG.

31. On September 8, 2023, Apotex wrote to Paladin's customer service department to establish an account and place an order for ICLUSIG. Paladin did not respond, and so Apotex repeated its request on September 15, 2023. Paladin did not respond until September 17, 2023. Since that time, Paladin has offered implausible excuses for why ICLUSIG cannot be supplied expeditiously, and requested that Apotex participate in a series of tasks that are not commercially reasonable. For example:

    (a) Paladin has adopted the position that it does not have sufficient stock to supply Apotex. As noted, the volume that Apotex has requested is small (sufficient for only four patients over a single month who are prescribed three doses per day) and there is no actual or anticipated shortage of ICLUSIG in Canada. Apotex has asked whether Paladin would order additional supply from Takeda US, and asked Takeda US whether it would ship additional supply to Paladin; neither company has responded to Apotex's requests.

(b) Paladin has requested that Apotex apply for a line of credit before completing the transaction. Apotex did not request a line of credit, and is willing to pay for the order on Paladin's publicly listed terms and conditions (or other terms that are commercially reasonable).

(c) Paladin has requested that Apotex personnel undergo certain training and become certified under Paladin's CDP before completing the transaction; Apotex is neither a pharmacist nor prescriber, and is not subject to the requirements of the CDP.

32. Apotex's ponatinib business cannot proceed with the launch of its product without obtaining a NOC, a prerequisite of which is to conduct a bioequivalence study between Apotex's generic ponatinib product and a small sample of ICLUSIG.

33. Branded pharmaceutical companies are aware that generic drugs, upon entry, are sold at a price that is a significant discount to the brand's price, and capture a significant share of total sales. To prevent and delay Apotex's entry in the market for ponatinib, Respondents have chosen to rag the puck on the supply of ICLUSIG. Respondents have made this decision despite Health Canada's overt guidance to the industry.

III. ISSUES

34. The sole issue on this application is whether Apotex should be granted leave under section 103.1 of the Act to make an application under section 79 of the Act against Respondents.

IV. SUBMISSIONS

A. The Applicable Legal Test

35. Section 103.1 of the Act grants private parties the right to commence an application pursuant to sections 75, 76, 77 or 79 of the Act, with the leave of the Competition Tribunal (the "**Tribunal**"):

> **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.

36. Subsection 103.1(7) sets out the test for the Tribunal to grant leave for a person (other than the Commissioner of Competition) to obtain leave to commence an application under section 79:

> **Granting Leave**
>
> (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.

37. Parliament amended the Act in 2022 (the "**2022 Amendments**"), including section 103.1.[10] The substantive change to section 103.1 is that, previously, section 103.1 did not permit the Tribunal to grant leave to a person to make an application under section 79 ("**Old 103.1**").

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[10] 2022, c 10, s 266.

38. The current iteration of section 103.1 has never been judicially considered. Under Old 103.1, the relevant test is that Tribunal must be satisfied that there is sufficient credible evidence to give rise to a *bona fide* belief (1) that the applicant may have been directly and substantially affected in his business by the alleged practice, and (2) that the practice in question could be subject to an order.[11]

39. The threshold for an applicant obtaining leave is not a difficult one to meet.[12] It is sufficient for an applicant to provide credible evidence of what is alleged to give rise to a *bona fide* belief by the Tribunal, a standard that is lower than the standard of proof on balance of probabilities.[13]

B. Apotex's Ponatinib Business Has Been Directly and Substantially Affected by the Respondents' Conduct

40. This is the first case in which the Tribunal will have the opportunity to apply section 103.1 to an application for leave to bring an application under section 79.

41. The Supreme Court has held that the words of a statute must be read "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."[14] In interpreting Old 103.1, the Tribunal

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[11] *Luigi Coretti v Bureau de la Sécurité privée and Garda World Security Corporation et al*, 2019 Comp Trib 4 at para 9; *Symbol Technologies Canada ULC v Barcode Systems Inc*, 2004 FCA 339 at para 16 [***Symbol***].

[12] *Symbol* at para 17.

[13] *Ibid*.

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

has held that the terms "directly" and "substantially" should be given their ordinary meaning.[15]

(i) Apotex's Ponatinib Business is Directly Affected

42. 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."[16] Apotex's ponatinib business currently generates $0 in revenues in Canada. Without access to a sample of ICLUSIG for use as a Reference Product, Apotex's ponatinib business is foreclosed from obtaining a NOC for its generic product, and will never capture any share or earn any revenue. With delayed access to a Reference Product, the time period when Apotex's ponatinib business can expect to begin capturing share and earning revenues of more than CAD [redacted] million and gross margin of more than CAD [redacted] million is delayed by a corresponding amount of time. There is no question that Respondents' refusal to supply (and delay in supply) of a Reference Product to Apotex is directly affecting Apotex's ponatinib business.

(ii) Apotex's Ponatinib Business is Substantially Affected

43. With respect to the "substantial" component, the Tribunal held in respect of Old 103.1 that, "terms such as 'important" are acceptable synonyms to considering whether there has been a 'substantial' impact, which is ultimately assessed by reviewing the circumstances at issue."[17] As noted, Apotex's ponatinib business expects to capture a significant share of

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15 *Audatex Canada, ULC v CarProof Corporation*, 2015 CACT 28 at para 45 [***Audatex***].

16 *Ibid*.

17 *Ibid.*

the market, generate revenues of more than CAD [redacted] million per year and gross margin of more than CAD [redacted] million per year. Respondents refusal to supply (and delay in supply) of a reference Product to Apotex prevents and delays Apotex's ponatinib business from earning such revenues and margins. Those effects are substantial in their own right, and extremely substantial when compared to the current revenues and margins of Apotex's ponatinib business, which are $0.

44. Apotex's proposed approach to measuring the substantiality of the effect on its business for the purposes of section 103.1 (when applying for leave for an application under section 79) is consistent with the guidance of the Supreme Court that the words of the statute be read harmoniously. Each of section 103.1 and section 79 utilize the word "business". Section 79(1)(a) refer to a respondent having market power in "a class or species of business." In the specific context of section 79, the Tribunal and the Federal Court of Appeal have consistently interpreted the reference to a business to refer to an individual product and geographic market.[18] In an application under section 103.1 for leave to bring an application under section 79, the words "substantially affected in the applicant's business" should be interpreted in a way that is harmonious with the interpretation of the word "business" that applies under section 79, and the analysis should focus on the effect of the practice on the applicant's business in the product market at issue.

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[18] *Commissioner of Competition v The Toronto Real Estate Board*, 2016 CACT 7 at para 164; *Canada (Commissioner of Competition) v Canada Pipe Co*, 2006 FCA 236 at paras 9-16; *Director of Investigation and Research v Tele-Direct Inc*, CT - 1994 / 003 – Doc # 204a at 42.

45. Apotex's proposed approach to measuring the substantiality of the effect on its business for the purposes of section 103.1 (when applying for leave for an application under section 79) is also consistent with guidance of the Supreme Court to examine a statute's scheme. Part VIII of the Act, where both section 103.1 and section 79 are located, examines whether different types of practices have an effect on competition within an individual product and geographic market.[19] It would be inconsistent with the scheme of Part VIII of the Act to apply section 103.1(7) in a manner that denies standing to bring an application under section 79 where there is *bona fide* evidence of an anti-competitive effect in a market, simply because of the relative size of the applicant's multiple lines of business compared to the single line of business at issue in the application.

46. Apotex's proposed approach to measuring the substantiality of the effect on its business for the purposes of section 103.1 (when applying for leave for an application under section 79) is also consistent with guidance of the Supreme Court to examine the object of the statute and the intention of Parliament. The object of the Act is defined in section 1.1 to include, among other things, the "maintain[ing] and encourage[ing] of competition in Canada in order to… provide consumers with competitive prices and product choices." The Supreme Court has recognized that another object of the Act is deterrence, and that private enforcement of the Act has a role to play in deterring anti-competitive conduct.[20] It is

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[19] To make an order under sections 79(1) or (2), among other things, the Tribunal must find there has been an impact on competition "in a market." The same reference to "in a market" is utilized throughout Part VIII, including in sections 75(1), 76(1), 77(2), and 81(1). Section 92(1), for its part, lists a broad range of synonyms for a product and geographic market, and includes the catch all provision in section 92(1)(d).

[20] *Pro-Sys Consultants Ltd v Microsoft Corporation*, 2013 SCC 57 at paras 46-48; See *Infineon Technologies AG v Option consommateurs*, 2013 SCC 59 at para 111 (specifically discussing the Act's objectives); See *Pioneer Corp v Godfrey*, 2019 SCC 42 at para 66.

inconsistent with the object of Part VIII to apply section 103.1(7) to deny standing to bring an application under section 79 where there is *bona fide* evidence that the practices result in higher prices and less product choice, or to ignore the deterrence objective of the Act and permit anti-competitive conduct to continue, simply because of the relative size of the applicant's multiple lines of business compared to the single line of business at issue in the application.

47. Apotex is aware that the Tribunal has previously held, when considering applications under Old 103.1 for leave to bring an application under other sections of Part VIII, 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… The substantiality of the effect must therefore be measured against the business as a whole."[21] Apotex respectfully submits that these prior holdings of the Tribunal under Old 103.1 do not apply to applications under section 103.1 for leave to bring an application under section 79, which has never before been considered by the Tribunal.

48. The Tribunal's decisions under Old 103.1 were developed in the specific context of section 75. It is notable that early decisions of the Tribunal under Old 103.1 contain no discussion about standing being unavailable to applicants unless the substantial effect of the refusal to deal impacted its <u>entire</u> business (as opposed to a single line of business).[22] However, subsequent decisions of the Tribunal referred back to a 1989 case adjudicated under section 75 that was initiated by the Director of Investigation and Research (i.e., the Commissioner

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21 *Audatex* at para 54.

22 See e.g., *Barcode Systems Inc v Symbol Technologies Canada ULC*, 2004 Comp Trib 1 [***Barcode***].

of Competition), which was thirteen years before Parliament created Old 103.1.[23] Similar to the language of section 103.1, section 75(1)(a) requires the Tribunal test whether a person is "substantially affected in his business."[24] Because that 1989 case under section 75 accepted that the impacts of a refusal to deal needed to be substantial compared to the size of the "small business" at issue in that case, the Tribunal imported the requirement that an applicant under Old 103.1 demonstrate that any refusal to deal substantially affect the applicant's entire business.[25] However, it is notable that even in the 1989 case, the Tribunal expressly recognized that other approaches to determining whether a person was substantially affected might be appropriate in different circumstances. Critically, the Tribunal in the 1989 case explained that testing for a substantial affect in a different manner might be appropriate where a "disaggregated analysis" was possible (but such an approach was "not necessary" in the circumstances in that case).[26] Unlike section 75, there is no language in section 79 that is similar to the "substantially affected" language. Therefore the earlier Tribunal case law decided in the context of section 75 and then imported into decisions deciding leave applications under Old 103.1 does not bind the Tribunal when adjudicating a new application under section 103.1 for leave to bring an application under section 79. Moreover, where a "disaggregated analysis" is possible (and especially where

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[23] *Broadview Pharmacy v Wyeth Canada Inc*, 2004 Comp Trib 22 at para 20, quoting *Canada (Director of Investigation and Research) v Chrysler Canada Ltd* (1989), 27 CPR (3d) 1 [***Chrysler***].

[24] See *Symbol* (and discussion of "use of essentially the same words in subsection 103.1(7) and paragraph 75(1)(a)").

[25] See e.g., *Sears Canada Inc v Parfums Christian Dior Canada Inc and Parfums Givenchy Canada Ltd*, 2007 Comp Trib 6 at para 21.

[26] *Chrysler* at 31 ("Reliance on an examination of the overall business result may be appropriate where it is difficult to do a more disaggregated analysis. This is not necessary in the case of Brunet's business; it is very small, he has few customers and it is possible to inquire meaningfully whether there is a relationship between transactions.")

such an analysis is consistent with the scheme and object of the Act, as previously described), the Tribunal should conduct such an analysis.

49. An alternative interpretation, which would prevent multi-product firms from winning standing when they are substantially affected in a single line of business, would have undesirable consequences, and be inconsistent with Supreme Court jurisprudence and Parliament's intention.

50. Such an alternative interpretation would produce "absurd consequences" of the type against which the Supreme Court has counselled.[27] For example, in the present case Apotex could establish a new subsidiary without any business activity other than an intention to launch a ponatinib product, and that new subsidiary (because it has no other source of revenues) would therefore succeed at demonstrating it is "substantially affected" by the Respondents' conduct. Such a result would be absurd and cannot have been Parliament's intention.

51. The Supreme Court's series of decisions under section 36 of the Act (which, like section 103.1, governs the circumstances under which private rights can be asserted) evidence a consistent concern that persons who are harmed by anti-competitive conduct have access to the courts, and wrong-doers not escape from legal sanction due to technicalities. Thus, for example, in *Pro-Sys* and other decisions in 2013, the Supreme Court confirmed that "indirect purchasers" had standing to bring claims under section 36, and that the "passing on" defence did not apply. By further example, in *Godfrey* in 2019, the Supreme Court

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[27] *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.").

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. In all of these cases, faced with the choice to allow or deny private actions, or to 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.

52. When the Old 103.1 was debated, Members of Parliament described its standing requirements as "designed to discourage frivolous litigation" by enabling "[c]ases obviously devoid of merit [to] be 'stopped at the gate' by the Tribunals' right to deny leave to commence the application."[28] Legislators made no mention of a desire to exclude applications based on the number of lines of business operated by an applicant. The alternative interpretation would be inconsistent with the requirements of the *Interpretation Act*[29] to give every statute a "large and liberal" interpretation that Parliament clearly intended for section 103.1.

C. The Respondents' Conduct Could be Subject to an Order Pursuant to Section 79 of the Act

53. 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

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[28] House of Commons Standing Committee On Industry, Science And Technology, "A Plan to Modernize Canada's Competition Regime" (April 2002) at 51.

[29] RSC 1985, c I-21.

supported by a full evidentiary record.[30] In keeping with the expeditious nature of the leave proceeding, the Tribunal may address each element summarily.[31] 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.[32] The Tribunal can make an order under section 103.1 where the evidence presented is "less than a balance of probabilities" so long as it is more than a "mere possibility."[33]

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

> **Prohibition if abuse of dominant position**
>
> **79 (1)** If, on application by the Commissioner or a person granted leave under section 103.1, the Tribunal finds that
>
> **(a)** one or more persons substantially or completely control, throughout Canada or any area thereof, a class or species of business,
>
> **(b)** that person or those persons have engaged in or are engaging in a practice of anti-competitive acts, and
>
> **(c)** the practice has had, is having or is likely to have the effect of preventing or lessening competition substantially in a market,
>
> the Tribunal may make an order prohibiting all or any of those persons from engaging in that practice.

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30 *CarGurus, Inc v Trader Corporation*, 2016 CACT 15 at para 62.

31 *Audatex* at para 46.

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

33 *Barcode* at paras 12-13.

55. Individually and jointly Respondents substantially and completely control the sale of, and are monopolists for, ICLUSIG, the sole ponatinib product available in Canada that has a NOC. There are no substitutes for ICLUSIG. One piece of evidence demonstrating that ICLUSIG has no substitutes and that Respondents are monopolists is its extraordinary price that Respondents charge. Paragraph 79(1)(a) is satisfied.

56. Respondents have engaged or are engaging in anti-competitive acts by refusing to supply (or delaying the supply of) ICLUSIG. Respondents' practices have the direct consequence of preventing Apotex from conducting a bioequivalence study for its ponatinib product, thereby preventing Apotex from obtaining a NOC and launching a new ponatinib product. Respondents earn substantial revenues from the sale of ICLUSIG, and Respondents' reasonable expectation is that Apotex will offer its product at a significant discount that will capture a significant share of sales. Respondents' practices are intended to exclude (or delay) Apotex from participating in the ponatinib market, capturing market share and driving down the price of ponatinib. Alternatively, these consequences are objectively foreseeable. Health Canada's has advised that RMPs should not hinder or delay the conduct of bioequivalence studies, but Respondents engage in their practices regardless. Similarly, the Competition Bureau has expressed repeated concern that "policies and practices alleged to restrict Generics from accessing samples of brand name drugs… could raise serious issues under the abuse of dominance provisions of the Act…", but Respondents' engage in

their practices regardless.[34] Paragraph 79(1)(b) is satisfied. Respondents show contempt for regulators, and their practices stymie Parliament's regulatory scheme.

57. The Respondents' practice has had, is having or is likely to have the effect of substantially preventing or lessening competition for the sale of ponatinib in Canada. Respondents' refusal to supply (and delay of supply) of ICLUSIG has the effect of preventing Apotex from launching a competing ponatinib product, or delaying the launch of that product. Respondents' conduct will prevent patients (and payors, such as provincial governments) from having access to an additional ponatinib product choice. Respondents' conduct will prevent or delay a collapse in the price at which ICLUSIG is offered for sale, which is likely to occur as Apotex will offer its product at a significant discount and will capture a significant share of the market. Paragraph 79(1)(c) is satisfied.

V. ORDER SOUGHT

58. Apotex seeks an order:

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

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

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[34] Competition Bureau Position Statement, *Competition Bureau statement regarding its inquiry into alleged anti-competitive conduct by Otsuka*, April 2, 2020.

September 29, 2023

ALL OF WHICH IS RESPECTFULLY SUBMITTED

David Rosner
Per: DR

GOODMANS LLP
Lawyers for the Applicant, Apotex Inc.

VI. LIST OF AUTHORITIES

TAB	DESCRIPTION
Case Law/Literature	
1.	*Animalerie Le Toucan*, CT-2021-001 (discontinued)
2.	*Audatex Canada, ULC v. CarProof Corporation*, 2015 CACT 28
3.	*Barcode Systems Inc. v. Symbol Technologies Canada ULC*, 2004 Comp. Trib. 1
4.	*Broadview Pharmacy v. Wyeth Canada Inc.*, 2004 Comp. Trib. 22
5.	*Canada (Commissioner of Competition) v. Canada Pipe Co.*, 2006 FCA 236
6.	*Canada (Director of Investigation and Research) v. Chrysler Canada Ltd.*, CT-1988-004
7.	*CarGurus, Inc v. Trader Corporation*, 2016 CACT 15
8.	*Commissioner of Competition v. The Toronto Real Estate Board*, 2016 CACT 7
9.	Competition Bureau Position Statement, *Competition Bureau statement regarding its inquiry into alleged anti-competitive conduct by Otsuka*, April 2, 2020
10.	*Director of Investigation and Research v. Tele-Direct Inc*, CT - 1994 / 003 – Doc # 204a
11.	Future of Canada's Competition Policy Consultation – What We Heard Report, September 23, 2023
12.	Health Canada, *Notice of clarification to drug manufacturers and sponsors – Risk Management Plans – Update*, August 13, 2020.
13.	House of Commons Standing Committee On Industry, Science And Technology, "A Plan to Modernize Canada's Competition Regime" (April 2002) at 51
14.	*Infineon Technologies AG v. Option consommateurs*, 2013 SCC 59
15.	*Luigi Coretti v. Bureau de la Sécurité privée and Garda World Security Corporation et al*, 2019 Comp. Trib. 4
16.	*Pioneer Corp. v. Godfrey*, 2019 SCC 42

TAB	DESCRIPTION
17.	*Pro-Sys Consultants Ltd. v. Microsoft Corporation*, 2013 SCC 57
18.	*Re Rizzo & Rizzo Shoes Ltd.*, [1998] 1 SCR 27
19.	*Sears Canada Inc. v. Parfums Christian Dior Canada Inc. and Parfums Givenchy Canada Ltd.*, 2007 Comp. Trib. 6
20.	*Symbol Technologies Canada ULC v. Barcode Systems Inc*, 2004 FCA 339
21.	*The Used Car Dealers Association of Ontario v. Insurance Bureau of Canada*, 2011 Comp. Trib. 10
Legislation	
22.	*Competition Act* (Amendment) 2022, c. 10, s. 266
23.	*Competition Act,* RSC 1985, c. C-34 (2023)
24.	*Competition Act,* RSC 1985, c. C-34 (2002-2009)
25.	*Competition Act,* RSC 1985, c. C-34 (2009-2022)
26.	*Food and Drug Regulations* CRC, c. 870
27.	*Interpretation Act*, RSC 1985, c. I-21

File No. CT-2023-007

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 Apotex Inc. 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 Apotex Inc. for an order pursuant to sections 79 of the Act;

BETWEEN:

APOTEX INC.

Applicant

– and –

PALADIN LABS INC.
ENDO PHARMACEUTICALS INC.
TAKEDA CANADA INC.
TAKEDA PHARMACEUTICALS U.S.A. INC.

Respondents

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

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