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

AMENDED PROPOSED NOTICE OF APPLICATION

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

TAKE NOTICE THAT:

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

    a. an Order pursuant to section 79(1) of the Act prohibiting Respondents for a period of 10 years from engaging in (i) practices that hinder or delay the supply to the Applicant of ICLUSIG® (ponatinib) ("**ICLUSIG**") or any other drug supplied by Respondents for which Respondents have received a Notice of Compliance under the *Food and Drug Regulations* and (ii) other practices that form the basis for the within Application;

    b. an Order pursuant to section 79(2) of the Act requiring Respondents, jointly and severally, to supply 360 tablets of 15 mg ICLUSIG to the Applicant, or such other volumes of ICLUSIG as the Applicant may reasonably request, within five business days of the Tribunal's Order, at the same price applicable to other sales of ICLUSIG in Canada;

    c. an Order pursuant to section 79(3.1) of the Act requiring Takeda Canada Inc. and Takeda Pharmaceuticals U.S.A. Inc. ~~Respondents~~, jointly and severally, to pay an administrative monetary penalty represented by the amount of revenue earned by Paladin Labs Inc. from the sale of ICLUSIG in Canada between September 22, 2023 and the date of the Order, multiplied by three, or such other amount as the Applicant may request and the Tribunal deems just;

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

    e. an Order for costs of the within Application; and

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

2. The persons against whom the orders are sought are the Respondents: Paladin Labs Inc., Endo Pharmaceuticals Inc., Takeda Canada Inc. and Takeda Pharmaceuticals U.S.A. Inc. Respondents' addresses are set out below.

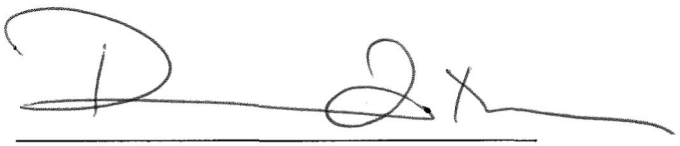
3. The Applicant will rely on the Statement of Grounds and Material Facts attached as Schedule "A" hereto; the Affidavit of Nick Boorman, sworn September 29, 2023; the Memorandum of Fact and Law accompanying this Application; and such further or other material as counsel may advise and the Tribunal may permit.

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

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

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

Dated at Toronto this 29th day of September, 2023.



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SCHEDULE "A" – STATEMENT OF GROUNDS AND MATERIAL FACTS

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' conduct stymies Parliament's regulatory scheme. Respondents' effort to rag the puck deprives patients of a competitive option, and results in patients and payors (including provincial governments) paying more.

I. EXECUTIVE SUMMARY

2. 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 first 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 is a pharmaceutical company that produces innovative (or "branded") drugs. Takeda 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 has appointed 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 and Paladin 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, Takeda and Paladin substantially and completely control the supply of ponatinib in Canada, and are monopolists. The subjective intent and

objectively foreseeable result of Takeda and Paladin's practices is to exclude, prevent, and delay the entry of a potential competitor. The effect of Takeda and Paladin's practices is to prevent or delay competition substantially, and thereby preserve their market power for ponatinib products. Takeda and Paladin' practices contravene section 79 of the *Competition Act*, deprive Canadian patients and payors (including provincial governments) of a new competitive option, and increase the costs for treatment for vulnerable patients.

8. Since Takeda and Paladin are unwilling to supply Apotex, Apotex asks this Tribunal to order them to do so and impose an administrative monetary penalty on Takeda that deprives them of the revenues generated in connection with their abusive conduct, among other things.

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, and are affiliates for the purposes of section 2(2) of the *Competition Act* ("**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, and are affiliates for the purposes of section 2(2) 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.

12. Takeda US, Takeda Canada, Endo and Paladin are the Respondents.

B. Key Aspects of the Regulation of Drugs in Canada and the Provinces

13. 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* and its regulations (including the *Food and Drug Regulations* ("**FDR**")), which regulate the sale of pharmaceutical products throughout Canada. Neither Health Canada nor the Minister of Health is a party to these proceedings.

14. 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 person in respect of the new drug.

15. 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 ways to a drug for which a NOC has already been issued (a "**Reference Product**"). In particular, under Section C.08.002.1(1) a manufacturer may file an Abbreviated New Drug Submission ("**ANDS**") where it 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 administration of the new drug is the same as the Reference Product; and (d) the conditions of use of the new drug fall within the conditions of use of 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."

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

17. 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."

18. 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)

19. 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**"). Ponatinib is from a class of drugs called "tyrosine kinase inhibitors" ("**TKI**"). Patients with CML and Ph+ ALL experience uncontrollable growth of certain blood cells. TKIs slow or stop this uncontrolled growth, significantly improving outcomes for patients with these types of leukemia.

20. A ponatinib-based product was developed by ARIAD Pharmaceuticals, Inc. ("**ARIAD**") under the brand name ICLUSIG. Health Canada issued a Notice of Compliance 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 the importer and distributor of ICLUSIG for Canada. In Canada, ICLUSIG is exclusively marketed in 15 mg tablets.

21. 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. 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.

22. Health Canada requested a Risk Management Program for ICLUSIG. Paladin satisfied this request by establishing a "Controlled Distribution Program" ("**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.

23. ICLUSIG is a valuable and expensive product. At a global level, TPCL reported 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). In Canada, according to information published by health data company IQVIA, sales of ICLUSIG in 2022 were valued at CAD $8,210,594. According to IQVIA, these revenues were generated from the sale of approximately 51,900 doses of ICLUSIG. This implies an average sale price per dose of CAD $158.20.

24. Every month in which Takeda US and Paladin are the monopolist 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 monopolist for as long as possible. Takeda Canada and Endo, their affiliates, have the same incentives.

25. 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. Apotex's Business Plan for a Ponatinib Product

26. Apotex intends to launch a ponatinib based product to compete against ICLUSIG. At present, Apotex's ponatinib business has no share of sales, and generates $0 in revenue. Upon the launch of its product, Apotex expects that its ponatinib business' lower priced generic product will quickly capture a significant share of the market for ponatinib and generate significant revenues and profits.

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

27. To obtain a NOC for its ponatinib product, Apotex requires a small supply of ICLUSIG with which to conduct a bioequivalence study.

28. Apotex attempted to obtain a small supply of ICLUSIG from numerous intermediaries in the pharmaceutical industry in Canada and outside Canada. In each instance, the intermediary was unwilling or unable to supply ICLUSIG to Apotex.

29. 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 to conduct a bioequivalence study. Apotex did not receive any reply.

30. 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 requested that the supply be delivered within 20 business days (i.e., September 22, 2023).

31. 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.

32. 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 or cannot be supplied expeditiously, and requested that Apotex participate in a series of tasks that are not commercially reasonable.

33. Paladin's delays, excuses and other communications are contrary to the notice published by Health Canada.

III. GROUNDS FOR THE SECTION 79 APPLICATION

34. Respondents' conduct is contrary to section 79 of the Act.

35. Apotex's ponatinib business has been substantially and directly affected by Respondents' conduct. By refusing to supply ICLUSIG to Apotex's ponatinib business, Respondents are preventing Apotex from conducting a bioequivalence study, which is a prerequisite to ultimately launching a generic ponatinib product that would rapidly capture share from Paladin and lower the price paid per dose for all patients.

36. Subsections 79(1) and (2) of the Act provide as follows:

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

37. Respondents individually and jointly substantially and completely control, in all of Canada, the supply and sale of ICLUSIG. Respondents individually and jointly have market power, and are monopolists, for ponatinib-based products throughout Canada.

38. Respondents, by refusing to supply (and delaying the supply of) ICLUSIG to Apotex's ponatinib business are engaged in an anti-competitive practice. The subjective intent, predominant purpose, and reasonably foreseeable result of the refusal to supply is to prevent Apotex from conducting a bioequivalence study between its generic product and ICLUSIG, or to delay such a study. Absent that study, Respondents know (and intend) that Apotex cannot submit an ANDS, cannot obtain a NOC, and cannot launch a competing generic product. Respondents' purpose is to exclude and delay Apotex from entering the market for ponatinib.

39. Respondents' refusal to supply ICLUSIG to Apotex's ponatinib business as a Reference Product is contrary to the guidance issued by Health Canada, is intended to frustrate the scheme for the launch of generic products in Canada established by Parliament in the FDR, and is likely to prevent competition substantially by preventing or delaying the time when a generic and lower-priced ponatinib product is made available to Canadian patients and payors. There is no pro-competitive rationale for Respondents' abuse of dominance, and Respondents' anti-competitive practices are not engaged in pursuant to any intellectual property right.

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

Administrative monetary penalty

> **(3.1)** If the Tribunal makes an order against a person under subsection (1) or (2), it may also order them to pay, in any manner that the Tribunal specifies, an administrative monetary penalty in an amount not exceeding the greater of
>
> > **(a)** $10,000,000 and, for each subsequent order under either of those subsections, an amount not exceeding $15,000,000, and
> >
> > **(b)** three times the value of the benefit derived from the anti-competitive practice, or, if that amount cannot be reasonably determined, 3% of the person's annual worldwide gross revenues.
>
> ***Aggravating or mitigating factors***
>
> **(3.2)** In determining the amount of an administrative monetary penalty, the Tribunal shall take into account any evidence of the following:
>
> > **(a)** the effect on competition in the relevant market;
> >
> > **(b)** the gross revenue from sales affected by the practice;
> >
> > **(c)** any actual or anticipated profits affected by the practice;
> >
> > **(d)** the financial position of the person against whom the order is made;
> >
> > **(e)** the history of compliance with this Act by the person against whom the order is made; and
> >
> > **(f)** any other relevant factor.
>
> ***Purpose of order***
>
> **(3.3)** The purpose of an order made against a person under subsection (3.1) is to promote practices by that person that are in conformity with the purposes of this section and not to punish that person.

41. Takeda US and Paladin's practices erect and maintain an absolute barrier to Apotex's entry. Every day that Apotex is delayed in launching its generic ponatinib product, Takeda US and Paladin earn additional revenues from the sale of ICLUSIG at a price they have set that can exceed CAD $150 per dose. Endo and Takeda Canada also benefit from such delay. In

determining the amount of the administrative monetary penalty on Takeda US and Takeda Canada, the Tribunal should take into account the following aggravating factors:

a. Parliament designed a regulatory scheme to facilitate the launch of new generic drugs, including through the promulgation of the FDR. This scheme lowers the barriers to entry for generic drug makers. Respondents are aware, or should be aware, of the FDR. Respondents' practices are intended to defeat or hinder the operation of that scheme, and to raise barriers to entry. Respondents' practices demonstrate contempt for Parliament's scheme.

b. Health Canada has issued a public notice that RMPs are not to hinder or delay the supply of a Reference Product. Respondents are aware, or should be aware, of Health Canada's notice. Respondents' delays, including its attempts to have Apotex comply with aspects of its CDP, demonstrate Respondents' contempt for Health Canada's notice.

c. Respondents' pricing for ICLUSIG generates substantial revenues every day. These revenues are generated from patients suffering from advanced forms of leukemia and other payors (such as provincial governments who pass along additional costs to taxpayers). Respondents benefit incrementally from their anti-competitive practices every single day those practices continue.

d. Respondents' anti-competitive practices extend the time frame of their monopoly over ponatinib, and cannot self-correct. It is contrary to public policy for branded drug companies to profit from such practices.

e. Any other relevant factor.

IV. RELIEF SOUGHT

42. Apotex seeks an Order from the Tribunal pursuant to subsections 79(1), 79(2) and 79(3.1) of the Act:

a. prohibiting Respondents for a period of 10 years from engaging in (i) practices that hinder or delay the supply to the Apotex of ICLUSIG or any other drug supplied by Respondents for which Respondents have received a Notice of Compliance under the Food and Drug Regulations and (ii) other practices that form the basis for the within Application;

b. requiring Respondents, jointly and severally, to supply 360 tablets of 15 mg ICLUSIG to Apotex, or such other volumes of ICLUSIG as Apotex may reasonably request, within five business days of the Tribunal's Order, at the same price applicable to other sales of ICLUSIG in Canada;

c. requiring Takeda Canada Inc. and Takeda Pharmaceuticals U.S.A. Inc. ~~Respondents~~, jointly and severally, to pay an administrative monetary penalty represented by the amount of revenue earned by Paladin from the sale of ICLUSIG in Canada between September 22, 2023 and the date of the Tribunal's order, multiplied by three, or such other amount as the Applicant may request and the Tribunal deems just;

d. requiring Respondents to pay the costs of this proceeding;

e. granting all other orders or remedies that may be required to give effect to the foregoing prohibitions, to restore competition in the market for ponatinib-based products; and

f. granting such further and other relief as the Tribunal deems just.

SCHEDULE "B" – CONCISE STATEMENT OF THE ECONOMIC THEORY OF THE CASE

1. This schedule provides a concise statement of the economic theory that supports the Application requesting that the Tribunal issue orders under subsection 79(1), 79(2) and 79(3.1) of the Act. This schedule explains why refusals by branded drug companies to supply samples of their products to generic drug companies extends their market power and harms competition.

2. Respondents have refused to supply a small volume of ICLUSIG, a ponatinib-based drug used for the treatment of different types of leukemia, to Apotex. Respondents' refusal is not a garden variety refusal to deal. Instead, it occurs in a specific regulatory context, which has been created by Parliament to facilitate the development and launch of generic drugs in Canada. Respondents' refusal is an exclusionary plan to prevent and delay Apotex from being able to develop and launch a competing generic ponatinib-based product. Respondents' conduct stymies Parliament's regulatory scheme.

3. Upon the launch of Apotex's generic product, Apotex's lower priced product is likely to capture a significant share of the market. Respondents' exclusionary conduct prevents and delays competition substantially.

Market Power in the Relevant Market

4. The relevant product market is ponatinib-based products. In other words, competition is harmed in the sale of ponatinib-based products, which are used for the treatment of different types of leukemia. The only ponatinib-based product is ICLUSIG. ICLUSIG is indicated for treatment of individuals for whom other related therapies are not appropriate.

There is therefore no substitute for ICLUSIG. That ICLUSIG has no substitute is demonstrated by its extraordinary price, which is estimated to be approximately CAD $158.20 per dose.

5. The relevant geographic market is Canada, given, among other things, the federal statutory framework that applies to the approval for new drugs.

6. Respondents are the only supplier of a ponatinib-based product in Canada. Respondents substantially and completely control the market for ponatinib-based products in Canada. Respondents individually and jointly possess market power, and are monopolists for, the sale of ponatinib-based products in Canada.

Practice of Anti-Competitive Acts

7. Apotex wishes to launch a generic ponatinib product that will be sold in competition with ICLUSIG. Under Canadian law, to obtain regulatory approval for its generic product, Apotex must obtain a small sample of ICLUSIG and conduct a study to demonstrate that its own generic product is bioequivalent to ICLUSIG. Health Canada has issued a public notice that the supply of products to generic drug manufacturers, such as Apotex, for the conduct for the conduct of bioequivalent studies is not to be hindered or delayed.

8. Apotex cannot obtain ICLUSIG from any third party. Apotex requested a supply of a small volume of ICLUSIG from Respondents, to be delivered promptly. Respondents have refused to supply ICLUSIG to Apotex. Instead, Respondents have offered a series of implausible excuses for why ICLUSIG cannot be supplied or supplied expeditiously, and requested that Apotex participate in a series of tasks that are not commercially reasonable.

All of these excuses and requests are intended to delay the moment in time at which Respondents are forced to supply ICLUSIG to Apotex (which in turn delays when Apotex can conduct a bioequivalence study and, in due course, launch a competing generic drug). There is no pro-competitive rationale for Respondents' abuse of dominance, and Respondents' anti-competitive practices are not engaged in pursuant to any intellectual property right.

Substantial Prevention of Competition

9. The price set by Respondents for ICLUSIG is extraordinary. Based on publicly available data, Respondents' average price per dose is estimated to be CAD $158.20.

10. A generic drug is typically sold at a price that is significantly lower than the branded drug against which it is compared. 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.

11. By refusing to supply ICLUSIG to Apotex, whether at all or a timely manner, Respondents extend the time during which they possess market power, and a monopoly, for ponatinib-based products. In the absence of such anti-competitive acts, Apotex would conduct a bioequivalence study and launch its lower-priced generic ponatinib product earlier. In the absence of such anti-competitive acts, the market-wide prices at which ponatinib-based

products are sold in Canada would fall by a substantial amount earlier. In the interim, Respondents' practices deprive patients of a competitive option, and result in patients and payors (including provincial governments) paying more.

File No. CT-2023-007

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Respondents

AMENDED NOTICE OF APPLICATION FOR LEAVE
(Pursuant to s. 103.1 of the *Competition Act*)

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