Court File No. T- 1419-20

FEDERAL COURT

BETWEEN:

INNOVATIVE MEDICINES CANADA, ABBVIE CORPORATION, AMGEN CANADA INC., ASTELLAS PHARMA CANADA, INC., ASTRAZENECA CANADA INC., BRISTOL-MYERS SQUIBB CANADA CO., ELI LILLY CANADA INC., GILEAD SCIENCES CANADA, INC., HOFFMANN-LA ROCHE LIMITED, IPSEN BIOPHARMACEUTICALS CANADA, INC., LUNDBECK CANADA INC., MERCK CANADA INC., NOVARTIS PHARMACEUTICALS CANADA INC., NOVO NORDISK CANADA INC., OTSUKA CANADA PHARMACEUTICAL INC., PFIZER CANADA ULC, PURDUE PHARMA, SANOFI-AVENTIS CANADA INC., SUNOVION PHARMACEUTICALS CANADA INC. and TAKEDA CANADA INC.

Applicants

seal

— and —

THE ATTORNEY GENERAL OF CANADA

FEDERAL COURT
COUR FÉDÉRALE
FILED / DÉPOSÉ
NOV 23 2020
Taina Wong
TORONTO, ON

Respondent

NOTICE OF APPLICATION

TO THE RESPONDENT:

A PROCEEDING HAS BEEN COMMENCED by the Applicants. The relief claimed by the Applicants appears on the following pages.

THIS APPLICATION will be heard by the Court at a time and place to be fixed by the Judicial Administrator. Unless the Court orders otherwise, the place of hearing will be as requested by the Applicants. The Applicants request that this application be heard at Toronto.

IF YOU WISH TO OPPOSE THIS APPLICATION, to receive notice of any step in the application or to be served with any documents in the application, you or a solicitor

acting for you must file a notice of appearance in Form 305 prescribed by the *Federal Courts Rules* and serve it on the applicants' solicitor or, if the applicants are self-represented, on the applicants, WITHIN 10 DAYS after being served with this notice of application.

Copies of the *Federal Courts Rules* information concerning the local offices of the Court and other necessary information may be obtained on request to the Administrator of this Court at Ottawa (telephone 613-992-4238) or at any local office.

IF YOU FAIL TO OPPOSE THIS APPLICATION, JUDGMENT MAY BE GIVEN IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

November 23, 2020 Issued by:

_____

(*Registry Officer*)

Address of local office: 180 Queen Street West, Suite 200
Toronto, ON M5V 3L6

TO: **The Administrator**
Federal Court

AND TO: **The Attorney General of Canada**
Office of the Deputy Attorney General of Canada
284 Wellington Street
Ottawa, Ontario K1A 0H8

(service to be effected by filing duplicate copies in the Registry pursuant to section 133 of the *Federal Courts Rules* and section 48 of the *Federal Courts Act*)

APPLICATION

THIS IS AN APPLICATION FOR JUDICIAL REVIEW IN RESPECT OF the decision of the Patented Medicine Prices Review Board (the **PMPRB** or the **Board**) made and communicated to the Applicants on October 23, 2020, to issue Guidelines that will come into force on January 1, 2021 (***Guidelines***).

THE APPLICANTS MAKE APPLICATION FOR:

(a) a declaration that the Guidelines are *ultra vires* the *Patent Act*, R.S.C. 1985, c. P-4 (the ***Patent Act*** or the ***Act***) and invalid, void, and of no force and effect, in whole or in part;

(b) an order quashing and setting aside the decision of the PMPRB to issue the *Guidelines*, in whole or in part;

(c) the costs of the within Application; and

(d) such further and other relief as counsel may advise and this Honourable Court may deem appropriate.

THE GROUNDS FOR THE APPLICATION ARE:

I. OVERVIEW

1. On October 23, 2020, the PMPRB issued new *Guidelines* setting out its price review process.

2. The PMPRB's jurisdiction to establish guidelines is governed by the *Patent Act*. Subsection 96(4) of the *Patent Act* authorizes the PMPRB to make non-binding guidelines that relate to matters within its jurisdiction.

3. The *Guidelines* exceed the Board's jurisdiction under the *Patent Act*, are *ultra vires* and should be set aside:

   (a) The *Guidelines* set a new price review process for patented medicines that includes consideration of certain "rebates", a matter that this Court has already determined falls outside the jurisdiction of the PMPRB.

(b) The *Guidelines* purport to be non-binding on their face but, in fact and in practice, they effectively prescribe the ceiling prices for patented medicines in Canada.

(c) The *Guidelines* also exceed the PMPRB's statutory price-review mandate, which is limited to regulating prices that are excessive.

II. THE PARTIES

A. The Applicants

4. The Applicants, AbbVie Corporation, Amgen Canada Inc., Astellas Pharma Canada, Inc., AstraZeneca Canada Inc., Bristol-Myers Squibb Canada Co., Eli Lilly Canada Inc., Gilead Sciences Canada, Inc., Hoffmann-La Roche Limited, Ipsen Biopharmaceuticals Canada, Inc., Lundbeck Canada Inc., Merck Canada Inc., Novartis Pharmaceuticals Canada Inc., Novo Nordisk Canada Inc., Otsuka Canada Pharmaceutical Inc., Pfizer Canada ULC, Purdue Pharma, sanofi-aventis Canada Inc., Sunovion Pharmaceuticals Canada Inc., and Takeda Canada Inc. (collectively, the **Industry Applicants**), are leading Canadian research-based pharmaceutical companies.

5. Each of the Industry Applicants is:

(a) a patentee subject to the *Guidelines*; and

(b) directly and immediately affected by the *Guidelines*.

6. The Applicant, Innovative Medicines Canada (**IMC**), is a national association representing 43 research-based pharmaceutical companies focused on the discovery and development of new medicines and vaccines. Its members, which include the Industry Applicants, represent the majority of patentees subject to the *Guidelines*.

7. IMC routinely works with its members and liaises with the PMPRB on the regulation of patented medicines, including the *Guidelines*, and has been a party to litigation before the Federal Court involving the jurisdiction of the PMPRB. IMC participated in consultations with the PMPRB regarding the *Guidelines*. Through its work, IMC has developed expertise in the issues raised by this

Application and possesses a unique industry-wide perspective on how the *Guidelines* will affect Canada's research-based pharmaceutical companies.

8. IMC has a genuine interest in the outcome of the Application and has joined with the Industry Applicants in bringing this Application to ensure the most efficient use of judicial resources.

9. Each of the Applicants has standing to bring this Application.

B. The Respondent and the PMPRB

10. The Attorney General of Canada represents the PMPRB. The PMPRB issued the *Guidelines*.

11. The PMPRB is an independent and quasi-judicial tribunal that is required to carry out its functions at arm's length from the government in accordance with the *Patent Act* and the *Patented Medicines Regulations*, SOR/94-688 (the ***Regulations***) made thereunder.

III. OVERVIEW: THE PATENTED MEDICINES REGIME AND THE BOARD'S EXCESSIVE PRICE JURISDICTION

A. The Patented Medicines Regime

12. The Patented Medicines Regime is set out in sections 79 – 101 of the *Patent Act*. These provisions create the PMPRB and establish its powers.

13. The PMPRB's statutory mandate is to prevent pharmaceutical patentees from charging excessive prices to their customers during the statutory monopoly period.

14. The work of the PMPRB is divided between Board staff (**Staff**) and Board members appointed by the Governor in Council. Staff carry out the day-to-day work of the PMPRB, including pricing investigations and administration of the *Regulations* and *Guidelines*. Board members sit as an adjudicative tribunal in the event of a dispute between Staff and a patentee over the price of a patented medicine.

B. The PMPRB's excessive price jurisdiction

15. Section 83 of the *Patent Act* establishes the PMPRB's jurisdiction over patented medicine prices. It authorizes the PMPRB to intervene where the Board finds that a patentee of an invention pertaining to a medicine is selling the medicine in Canada at a price that is excessive.

16. Subsection 85(1) of the *Patent Act* sets out the factors that the Board must consider to determine if a patentee is charging an excessive price:

    (a) Paragraphs 85(1)(a) – (d) list certain price benchmarks that the Board must consider; and

    (b) Paragraph 85(1)(e) provides that the Board must also consider other factors specified by regulation.

17. Pursuant to amendments to the *Regulations* promulgated by the Governor in Council on August 7, 2019 (the **Amendments**), the Board is required to consider three additional factors under subsection 85(1) of the *Patent Act*: (a) pharmacoeconomic value, (b) market size, and (c) Canada's gross domestic product and gross domestic product per capita.

C. Limits on the PMPRB's excessive price jurisdiction

18. At the time that they were introduced, the Amendments also purported to require patentees to include certain confidential and commercially sensitive third-party payments as part of the net sale price reported to the PMPRB. The government described these third-party payments as "rebates" and sought to have patentees report net price taking into account these so-called "rebates" (the **Rebated Price**).

19. On June 29, 2020, the Federal Court set aside those parts of the Amendments that pertained to the Rebated Price as *ultra vires* the *Patent Act* (the **Judicial Review Decision**). This Court concluded that, in determining excessive pricing, the PMPRB does not have jurisdiction to require patentees to report third-party transactions or the Rebated Price.

20. The Judicial Review Decision is currently under appeal in the Federal Court of Appeal (A-215-20).

D. Authority to issue guidelines

21. Section 96 of the *Patent Act* provides the PMPRB with certain powers, including the authority to make rules, by-laws and guidelines. Subsection 96(4) authorizes the Board to issue non-binding guidelines with respect to any matter within its jurisdiction:

> Subject to subsection (5), the Board may issue guidelines with respect to any matter within its jurisdiction but such guidelines are not binding on the Board or any patentee.

22. In addition, it is well-established that guidelines may not:

(a) conflict with legislation; or

(b) impose mandatory requirements enforceable by sanction.

IV. THE *GUIDELINES* ARE INVALID

23. The *Guidelines* are *ultra vires* the *Patent Act* because they:

(a) empower Board Staff to consider the Maximum Rebated Price, a matter outside the PMPRB's jurisdiction, in defiance of the Judicial Review Decision;

(b) serve to set price ceilings for patented medicines in Canada that are binding on patentees and constitute impermissible subordinate legislation; and

(c) apply price tests that have nothing to do with determining "excessive" price.

A. The PMPRB cannot consider Maximum Rebated Price

24. Subsection 96(4) empowers the PMPRB to make guidelines only with respect to matters "within its jurisdiction".

25. By virtue of the Judicial Review Decision, this Court determined that the Rebated Price is not within the jurisdiction of the PMPRB as set out in the Patented Medicines Regime.

26. Nonetheless, the *Guidelines* provide that the PMPRB will continue to calculate a Maximum Rebated Price.

27. The *Guidelines* mention the Maximum Rebated Price more than 70 times and specifically authorize PMPRB Staff to consider the Maximum Rebated Price in certain circumstances.

28. The PMPRB's decision to maintain the Maximum Rebated Price in the *Guidelines* contravenes the Judicial Review Decision. The Board has no jurisdiction to consider the Rebated Price or the Maximum Rebated Price.

29. The PMPRB has deliberately chosen to keep and use the concept of Maximum Rebated Price despite the Judicial Review Decision. As the PMPRB explained in its announcement of the *Guidelines*:

> The effect of this decision on the Guidelines is that, upon coming into force of the amended regulations in January 2021, the new excessive pricing factors will be used by the PMPRB to screen new medicines into either Category I or Category II and, for the those in the former Category, to calculate their applicable Maximum Rebated Price (MRP). However, absent a complaint of excessive pricing being filed, the PMPRB will only open an investigation into the price of a Category I medicine where it appears to be non-compliant with its applicable Maximum List Price (MLP) under the Guidelines. <u>This does not preclude PMPRB Staff from considering the MRP in the context of an investigation once commenced, or the Board in an excessive price hearing. The PMPRB may revisit this approach depending on the outcome of the pending appeal.</u>

30. The inclusion of Maximum Rebated Price in the *Guidelines* contravenes subsection 96(4) of the *Patent Act* and is a jurisdictional error.

B. <u>The *Guidelines* bind patentees</u>

31. Subsection 96(4) of the *Patent Act* requires that any guidelines issued by the PMPRB be non-binding. The *Patent Act* does not grant the PMPRB the power to create subordinate legislation.

32. Nonetheless, the *Guidelines* were designed to be a rulebook that governs patented medicine pricing in Canada by setting out detailed pricing formulas that patentees are expected to use. The vast majority of patented medicines will only ever be regulated by operation of the *Guidelines*.

33. Patentees are expected to comply with the *Guidelines*. If they do, they are assured that the PMPRB will take no action against them. If they do not, they will be investigated, and can be subjected to fines and possible other sanctions and penalties. Such a structure is unlawful: a non-statutory instrument cannot impose mandatory requirements enforceable by sanction.

34. Indicia that the *Guidelines* are, in fact, binding include the following:

(a) the *Guidelines* establish formulas that set what the Board considers to be the non-excessive price for each patented medicine;

(b) the *Guidelines* prescribe deadlines within which patentees must comply with these non-excessive prices;

(c) the *Guidelines* will be applied by Board Staff in all but "exceptional circumstances";

(d) where the price of a patented medicine exceeds the price set by the formulas in the *Guidelines*, Board Staff notify the patentee that its price is "outside the thresholds set out in the Guidelines" and immediately begins to calculate the patentee's "excess revenues", which becomes a liability for the patentee;

(e) Board Staff will commence an investigation where the price of a patented medicine exceeds the maximum non-excessive price determined by the *Guidelines* by 5% or more, or results in annual revenues that are $50,000 higher than allowed by the *Guidelines*;

(f) when such an investigation is commenced, the patentee is publicly designated as "Under Investigation" in the PMPRB's annual report; and

(g) where a patentee fails to price in accordance with the applicable formula set out in the *Guidelines*, the patentee is subject to a process that can result in a penalty payment of up to double the amount of "excess revenue" calculated using the *Guidelines* formula.

35. The *Guidelines* are binding in fact and constitute impermissible subordinate legislation. For each of these reasons, the *Guidelines* are *ultra vires* the *Patent Act*.

C. The new price tests are beyond the Board's jurisdiction

36. The new pricing framework established by the *Guidelines* is not authorized by the *Patent Act*.

37. The *Patent Act* provides the Board with jurisdiction only to address "excessive price". However, all of the new price tests set out in the *Guidelines* for new medicines are based on the "lower", "median" or "lowest" prices among various benchmarks. In particular:

(a) the *Guidelines* require that patentees set their prices below (i) the lower of the initial list price and the median international price of the medicine or (ii) the lower of the list price and the top of a new "domestic therapeutic class";

(b) the new "domestic therapeutic class" consists of the lowest price for each of the medicines identified as comparable to the medicine under review and will also see the PMPRB assess the price of new patented medicines against the median among a range of non-excessive patented medicine prices and against older drugs, including generic drugs; and

(c) in most cases, the *Guidelines* require that the price of a patented medicine remain lower than the median international price of that medicine in the PMPRB11.

38. By definition, an "excessive" price for a patented medicine cannot be the lowest price based on the benchmarks in the *Patent Act*. Nor is it the median price. Nor is it the price of generic drugs. As a result, the *Guidelines* have no

connection with the PMPRB's "excessive" price jurisdiction under the *Patent Act*.

D. The *Guidelines* are *ultra vires*

39. For these reasons, the *Guidelines* are *ultra vires* the *Patent Act* and should be set aside.

THE APPLICANTS RELY UPON:

(a) The *Patent Act*, including but not limited to sections 79 to 103;

(b) The *Regulations* and the Amendments;

(c) The *Federal Courts Act*, including but not limited to sections 18 and 18.1;

(d) The *Federal Court Rules*; and

(e) Such further and other grounds as counsel may advise and this Honourable Court may permit.

THIS APPLICATION WILL BE SUPPORTED BY THE FOLLOWING MATERIAL:

(a) The affidavits of one or more individuals to be filed;

(b) The PMPRB's record of decision, including the materials received pursuant to Rule 317 from the PMPRB; and

(c) Such further and other materials as counsel may advise and this Honourable Court may permit.

Pursuant to Rule 317 of the *Federal Court Rules*, the Applicants request that the PMPRB send certified copies of the following material that is not in the possession of the Applicants but is in the possession of the PMPRB to the Applicants and to the Registry:

(a) Any and all material prepared or reviewed by the PMPRB, including all communications, deliberations, drafts and final documents, regarding:

(i) The decision to adopt the *Guidelines*;

(ii) The inclusion of Maximum Rebated Price in the *Guidelines*;

(iii) The effect of the Judicial Review Decision and any appeal thereof on the *Guidelines*;

(iv) The effect of the *Guidelines* on patented medicine prices in Canada;

(v) The consequences for patentees of non-compliance with the *Guidelines*; and

(vi) The connection between the price tests enumerated in the *Guidelines* and the PMPRB's jurisdiction under the *Patent Act*.

Dated at Toronto this 23rd day of November, 2020.

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Solicitors for the Applicants

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NOTICE OF APPLICATION

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