1465

Court File No. T- -19

**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.,
HOFFMANN-LA ROCHE LIMITED,
IPSEN BIOPHARMACEUTICALS CANADA, INC.,
LEO PHARMA CANADA INC., LUNDBECK CANADA INC.,
NOVARTIS PHARMACEUTICALS CANADA INC.,
NOVO NORDISK CANADA INC.,
OTSUKA CANADA PHARMACEUTICAL INC., PFIZER CANADA ULC,
SANOFI-AVENTIS CANADA INC., and TAKEDA CANADA INC.**

Applicants

— and —

**THE ATTORNEY GENERAL OF CANADA**

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.

September 6, 2019. Issued by: JENA RUSSELL
REGISTRY OFFICER
AGENT DU GREFFE
(*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 Her Excellency the Governor General in Council to promulgate the *Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)*, SOR/2019-298 (the ***Amendments***) made by Order in Council dated August 7, 2019, PC 2019-1197, communicated to the Applicants on August 9, 2019, published in *Canada Gazette*, Part II, Vol. 153, No. 17 on August 21, 2019 (**CG2**), and amending the *Patented Medicines Regulations*, SOR/94-688 (***Regulations***).

**THE APPLICANTS MAKE APPLICATION FOR:**

(a) A declaration that certain provisions of the *Amendments* are invalid, void, and of no force and effect because they are *ultra vires* the *Patent Act*, RSC 1985, c P-4 (the ***Patent Act*** or the ***Act***):

(i) section 4 of the *Amendments*, which introduces new section 4.4 of the *Regulations*, requiring the Patented Medicine Prices Review Board (**PMPRB** or the **Board**) to consider three new mandatory economic factors under paragraph 85(1)(*e*) of the *Patent Act*, as well as new sections 4.1, 4.2, and 4.3 of the *Regulations*, requiring patentees to report related information;

(ii) section 6 and the Schedule of the *Amendments*, which replace the price comparator countries listed in the Schedule to the *Regulations*; and

(iii) subsection 3(4) of the *Amendments*, which amends paragraphs 4(4)(*a*) and (*b*) of the *Regulations*, requiring patentees to alter the way that price is calculated,

(collectively, the **Impugned Amendments**);

(b) An order quashing subsection 3(4), sections 4 and 6, and the Schedule of the *Amendments* for being *ultra vires* the *Patent Act*;

(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. The purpose of the *Patent Act* is to foster innovation by granting patentees a statutory monopoly in exchange for the disclosure of new and useful inventions.

2. Under the *Patent Act*, the PMPRB's mandate is to ensure that patentees of medicines do not abuse these exclusive rights by selling patented medicines at prices that are "excessive".

3. The PMPRB's jurisdiction under the *Patent Act* is limited to the price at which the patented medicine is sold by the patentee — the PMPRB's statutory authority is often described as a "factory-gate" jurisdiction.

4. On August 7, 2019, the Government of Canada (the **Government**) amended the *Regulations* under the *Patent Act* for the express purpose of lowering the prices of patented medicines in Canada. The Government expects the *Amendments* to save the Canadian health system $8.8 billion (net present value) over the next 10 years and, depending on how they are implemented by the PMPRB, may cost industry up to $24.9 billion (net present value).

5. In order to achieve this end, the *Amendments* transform the role of the PMPRB. As the PMPRB itself has noted, the Impugned Amendments introduce a "paradigm shift" in how the PMPRB operates. In particular, the *Amendments*:

   (a) require the PMPRB to consider pharmacoeconomic value, market size, and gross domestic product (**GDP**) and GDP per capita when determining whether the price of a patented medicine is excessive (the **New Mandatory Factors**);

   (b) change the basket of countries used by the PMPRB as a benchmark by removing countries with higher drug costs from the basket (Switzerland and the

United States) and by adding six countries with low drug costs (Australia, Belgium, Japan, the Netherlands, Norway, Spain) (the **PMPRB11**); and

(c) require patentees to alter the manner in which the sale price of patented medicines is calculated and reported to the Board (the **New Price Calculation**).

6. In an attempt to justify the Impugned Amendments, the Government seeks to rely on the PMPRB's consumer protection mandate to address "affordability challenges for consumers that, if left unaddressed, pose a very real threat to the sustainability of the pharmaceutical system in Canada".

7. The PMPRB's consumer protection mandate is limited to protecting consumers from a patentee abusing its statutory monopoly by selling a patented medicine at an "excessive" price. The Impugned Amendments impermissibly expand the role of the PMPRB beyond its statutory mandate and beyond its factory-gate jurisdiction.

8. The Governor in Council does not have the authority to fundamentally alter the statutory role of the PMPRB by way of regulation. Only Parliament may alter the patented medicines regime by amendment to the *Patent Act*.

9. The Impugned Amendments are inconsistent with the objectives of the *Patent Act*, exceed the scope of the regulation-making authority conferred by the statute, and should be declared invalid and quashed.

## II. THE PARTIES

### A. The Applicants

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

11. Each of the Industry Applicants is:

(a) a patentee subject to the requirements of the *Regulations*; and

(b) directly and materially affected by the Impugned Amendments.

12. The Applicant, Innovative Medicines Canada (**IMC**), is a national association representing 41 research-based pharmaceutical companies focussed on the discovery and development of new medicines and vaccines. The majority of its members, which include the Industry Applicants, are patentees subject to the requirements of the *Regulations*.

13. IMC routinely works with its members and liaises with Health Canada and the PMPRB on the requirements of Canada's patented medicines regime, including the *Regulations*, and has been a party to past litigation before the Federal Court involving the jurisdiction of the PMPRB. IMC represented the pharmaceutical industry in Government consultations regarding the *Amendments* and has participated in consultations led by the PMPRB. Through its work, IMC has developed expertise in the issues raised by this Application and possesses a unique and systemic perspective on how the *Amendments* will affect Canada's innovative pharmaceutical industry.

14. 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.

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

### B. The Respondent and the PMPRB

16. The Attorney General of Canada represents the Governor in Council, who made the *Amendments* on the recommendation of the Minister of Health.

17. 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 *Regulations*. The PMPRB does not have the jurisdiction to make regulations and is not a party to this Application.

## III. OVERVIEW: THE *PATENT ACT* AND THE PATENTED MEDICINES REGIME

### A. The *Patent Act* and the patent bargain

18. The main purpose of the *Patent Act* is to foster innovation by granting patentees, including patentees of patented medicines, the exclusive right to make, use, and sell an invention in exchange for the disclosure of that invention to the public.

19. This *quid pro quo*, often called the "patent bargain", is the organizing principle of the *Patent Act*.

20. The *Patent Act* confers a statutory monopoly that allows a patentee to monetize its invention free from direct competition for the term of the patent. This economic benefit is aimed at incentivizing innovation and allowing patentees to recover the costs of research and development.

21. The right to patent exclusivity, and the accompanying economic benefits that flow from that right, are at the heart of the patent bargain. Absent these statutory rights and benefits, the purpose of the *Patent Act* is undermined.

### B. The patented medicines regime

22. By way of amendments to the *Patent Act* in 1987 and 1993, Parliament ended Canada's compulsory licence regime for patented medicines and provided these patentees with the same patent rights as other patentees.

23. These legislative changes were made to ensure that the rights provided to patentees of patented medicines under the *Patent Act* conformed with Canada's treaty obligations under the World Trade Organization's *Agreement on Trade-Related Aspects of Intellectual Property Rights* and the *North American Free Trade Agreement*. Canada's treaty obligations require it to accord patented medicines the same patent rights as other patented inventions and to refrain from interfering with the normal exploitation of the patent by a patentee.

24. As part of this statutory reform, Parliament set out the patented medicines regime in sections 79–103 of the *Patent Act* (the **Patented Medicines Regime**) and provided for the establishment of the PMPRB.

25. The PMPRB's jurisdiction is legislated by the *Patent Act*. Parliament created the PMPRB for the specific purpose of ensuring that patentees selling patented medicines in Canada do not abuse their statutory monopolies by charging "excessive" prices.

26. The PMPRB's statutory mandate is to monitor the price at which a patentee sells its patented medicine to its customer at the first point of sale — in common parlance, the PMPRB regulates the factory-gate sale.

27. The Board's role is to protect the Canadian public from specific instances of "excessive" pricing by a patentee. This oversight role has been described by the courts as a form of "consumer protection" — protecting Canadians from patentees potentially abusing their patent rights.

28. Under the *Patent Act*, the PMPRB does not have jurisdiction over prices charged by wholesalers, supply chain markups, dispensing or handling fees, the provision of public or private health insurance, listing arrangements with public or private insurers, or the ultimate retail price of drugs.

29. In short, the PMPRB does not have jurisdiction over the pricing of patented medicines generally nor over any of the commercial dealings that take place beyond the factory gate.

### C. "Excessive" price

30. Section 83 of the *Patent Act* establishes the PMPRB's jurisdiction over patented medicine prices. Pursuant to section 83, if the PMPRB finds that a patented medicine has been sold by a patentee at a price that is "excessive", it may direct the patentee to reduce the maximum price of the medicine or take other steps to offset the amount of the excessive revenue derived by the patentee.

31. Section 83 is part of the broader scheme of the *Patent Act*. Section 83 does not authorize the PMPRB to interfere with the ordinary enjoyment of patent rights, nor to lower the prices of patented medicines generally. Rather, section 83 preserves the freedom of pharmaceutical patentees to price their patented inventions in a manner consistent with the rights enjoyed by all patentees —

subject to oversight by the PMPRB to ensure that patent rights are not abused by patentees charging "excessive" prices.

32. Although the *Patent Act* does not define the meaning of "excessive" price, section 85 of the *Patent Act* sets out the factors that the PMPRB must consider in determining whether the price of a patented medicine is "excessive".

**(i) Reference pricing**

33. The *Patent Act* requires that the PMPRB use comparative pricing to ensure that a patentee is not abusing its patent monopoly by charging an "excessive" price for a patented medicine.

34. Subsection 85(1) of the *Patent Act* sets out four mandatory factors that the Board must take into account in determining whether the price of a patented medicine is "excessive":

(a) the prices at which the medicine has been sold in Canada;

(b) the prices at which other medicines in the same therapeutic class have been sold in Canada;

(c) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada; and

(d) changes in the Consumer Price Index.

35. In accordance with subsection 85(1), the Board must determine whether a patented medicine is being sold at an "excessive" price by examining certain other benchmark prices in Canada and internationally. This comparison is known as "reference pricing": How does the price charged compare to the price of similar medicines in Canada? How does the price charged compare to the price of the same medicine and medicines in the same therapeutic class internationally?

36. The Schedule to the *Regulations* sets out the jurisdictions for which prices must be reported to the PMPRB, which are used by the PMPRB for international reference pricing.

37. In the usual course, the Board has assigned a maximum or "ceiling" price for the medicine upon its introduction in Canada based on a reference pricing analysis using the Schedule.

**(ii) Secondary factors**

38. If and only if the PMPRB is unable to determine whether a price is "excessive" using the mandatory factors in subsection 85(1), subsection 85(2) of the *Act* provides that the PMPRB may consider the costs of making and marketing the medicine.

**(iii) Additional factors**

39. The *Patent Act* provides that the Governor in Council may make regulations to introduce additional factors for the limited purpose of determining whether a patentee has acted abusively by charging an "excessive" price:

(a) paragraph 85(1)(*e*) contemplates the possible addition of other mandatory factors within the scope of subsection 85(1); and

(b) paragraph 85(2)(*b*) provides that additional secondary factors within the scope of subsection 85(2) may be introduced either by way of regulation or in the discretion of the PMPRB.

## D. Reporting of price information

40. Section 80 of the *Patent Act* requires patentees to provide the PMPRB with certain information to facilitate the Board's determination of whether the price of a patented medicine is "excessive". In particular:

(a) paragraph 80(1)(*b*) provides for regulations that require patentees to report information relating to the price at which the patentee sells the medicine to be used for the mandatory analysis under subsection 85(1); and

(b) paragraph 80(1)(*c*) provides for regulations that require patentees to report information on the costs of making and marketing the medicine to be used for the secondary analysis under subsection 85(2).

41. The *Patent Act* provides that the precise information to be reported by patentees is to be specified in regulations. The *Regulations* specify the price information to be reported by patentees. However, no regulations have been made concerning the reporting of cost information.

## IV. THE IMPUGNED AMENDMENTS ARE *ULTRA VIRES*

42. The Impugned Amendments are *ultra vires* in at least four respects:

(a) the purpose of the Impugned Amendments is inconsistent with the purpose of the *Patent Act*;

(b) the New Mandatory Factors exceed the regulation-making authority conferred by the *Patent Act* and are inconsistent with the *Patent Act*, including section 85 in particular;

(c) the PMPRB11 exceeds the regulation-making authority conferred by the *Patent Act* and is inconsistent with the *Patent Act,* including sections 83 and 85 in particular; and

(d) the New Price Calculation exceeds the regulation-making authority conferred by the *Patent Act* and is inconsistent with the *Patent Act*, including section 80 in particular.

### A. Inconsistent purpose

#### (i) The purpose of the *Patent Act*

43. The purpose of the *Patent Act* is to foster innovative solutions to practical problems and to provide for their public disclosure through the promise of a time-limited statutory monopoly.

44. This statutory monopoly provides a patentee with the right to exclude others from using or selling the patented invention and, more practically, to set the price at which the patented product is sold to its customers.

45. The *Patent Act* contains provisions to protect against the abuse of patent monopoly rights. The Patented Medicines Regime addresses a particular

instance of patent abuse: where a patentee sells a patented medicine at an "excessive" price.

### (ii) The purpose of the Impugned Amendments

46. The Impugned Amendments were not made for the purpose of addressing occurrences of either patent abuse generally or "excessive" pricing in particular.

47. Instead, the Governor in Council has improperly used the limited regulation-making authority conferred by Parliament in the Patented Medicines Regime to require the PMPRB to address the overall fiscal constraints of federal and provincial governments and to lay the groundwork for national pharmacare.

48. The genesis of the *Amendments* was a joint federal-provincial-territorial initiative to address the affordability of medicines generally. As Health Canada explained in a document titled "Protecting Canadians from Excessive Drug Prices: Consulting on Proposed Amendments to the Patented Medicines Regulations" published on May 16, 2017:

> In January 2016, federal, provincial and territorial Ministers agreed to work together to improve the affordability, accessibility and appropriate use of prescription drugs to better meet health care system needs. The Government of Canada is firmly committed to this work and is taking action to significantly lower the cost of prescription drugs ....
>
> This important work includes reducing the cost of patented drugs through the modernization of the pricing framework under the Patent Medicine Prices Review Board (PMPRB). [emphasis added]

49. The Regulatory Impact Analysis Statement (**RIAS**) for the *Amendments* states that the Impugned Amendments are expected to lower patented medicine prices for the purpose of facilitating objectives unrelated to the *Patent Act*:

> The Amendments are expected to result in 10-year total savings to public, private and out of pocket-payers of $8.8 billion present value (PV) as a result of lower patented medicine costs. Lower prices will alleviate financial pressures on public and private insurers and

> improve affordable access for Canadians paying out-of-pocket.

50. Health Canada published a news release announcing the *Amendments*. The Minister of Health specifically acknowledged that the purpose of the *Amendments* was to lay the groundwork for national and universal prescription drug coverage:

> Government of Canada Announces Changes to Lower Drug Prices and Lay the Foundation for National Pharmacare
>
> "Today, we take the biggest step to lower drug prices in a generation. Building on the progress we've already made towards lower drug prices, these bold reforms will both make prescription drugs more affordable and accessible for all Canadians — saving them an estimated $13 billion dollars in the next decade — and lay the foundation for National Pharmacare".
>
> *The Honourable Ginette Petitpas Taylor*
> *Minister of Health*

51. This Application does not challenge the merits of the Government's policy choices. Rather, this Application is brought because the *Amendments* are *ultra vires*, as they were introduced for purposes unrelated to the *Patent Act*.

### (iii) The purpose of the Impugned Amendments is inconsistent with the purpose of the *Patent Act*

52. The Impugned Amendments are *ultra vires* the *Patent Act* because:

(a) considerations of "affordability" and "value" have been introduced to free up resources for other areas of the health system or lay the groundwork for national pharmacare — considerations wholly unrelated to patent abuse and fundamentally inconsistent with the rights granted to patentees, including under the patent bargain; and

(b) the PMPRB's jurisdiction has been impermissibly expanded beyond its limited statutory role of monitoring pricing at the factory gate and transformed into a broad mandate to regulate affordability and value at the drug store counter.

53. The Governor in Council does not have the authority to alter the patent grant by way of regulation under the *Patent Act* for purposes wholly unrelated to the *Patent Act*.

54. Moreover, the Government's actions ignore Canada's treaty commitments to refrain from discriminating against patentees of patented medicines and from imposing unreasonable limitations on the normal exploitation of the patent.

### B. The New Mandatory Factors

55. The Impugned Amendments require the PMPRB to consider three New Mandatory Factors in determining whether the price of a patented medicine is "excessive":

(a) the pharmacoeconomic value of the medicine;

(b) the size of the market for the medicine in Canada; and

(c) the gross domestic product in Canada and gross domestic product per capita in Canada.

56. The New Mandatory Factors are accompanied by new reporting obligations in sections 4.1 to 4.3, which require patentees to provide the PMPRB with information relevant to these New Mandatory Factors (the **New Reporting Obligations**).

57. The New Mandatory Factors are inconsistent with the *Patent Act* and the PMPRB's statutory jurisdiction.

58. The Board's mandate is to determine whether a patentee has abused its patent monopoly by charging an "excessive" price at the factory gate. To perform this function, paragraphs 85(1)(*a*)–(*d*) of the *Act* require the PMPRB to consider price information.

59. Under paragraphs 85(1)(*e*) and 101(1)(d) of the *Patent Act*, the Governor in Council is permitted to make regulations introducing new mandatory factors for the PMPRB to consider, but only "for the purposes of subsection 85(1)". The New Mandatory Factors are, however, of an entirely different character

from the existing mandatory factors in subsection 85(1). They require the PMPRB to, *inter alia*, take into account consumer demand considerations: "affordability" and "value".

60. The Governor in Council cannot use her limited regulation-making authority under paragraphs 85(1)(*e*) and 101(1)(*d*) to radically alter the PMPRB regime that was put in place by Parliament under the *Patent Act*.

61. The New Mandatory Factors are outside the purview of the PMPRB. The PMPRB's statutory role is focused on the price charged by patentees at the factory gate, to determine whether the statutory monopoly has been abused. The PMPRB has no mandate to consider governmental budget constraints, whether monies are being effectively allocated within Canada's health care system, or how to facilitate national pharmacare.

62. The Government has suggested that the New Mandatory Factors are intended to ensure that the PMPRB has the benefit of economic factors reflecting demand (*i.e.*, the consumer perspective on value and affordability) to complement the fact that issues of supply are already found within the scheme (*i.e.*, the patentee perspective on the costs of making and marketing the medicine, *per* subsection 85(2) of the *Patent Act*).

63. However, the affordability-driven demand-side considerations in the New Mandatory Factors have been structured to take precedence over the existing supply-side factor (*i.e.*, the costs of making and marketing the medicine), which may only be considered as a last resort under subsection 85(2). The scheme of the *Patent Act* properly requires that if demand-side factors are to be considered at all, they must be treated consistently with supply-side factors under subsection 85(2).

64. In any event, the New Mandatory Factors are already taken into account in Canada, including by (1) existing health technology assessment bodies conducting cost-utility analyses, such as the Canadian Agency for Drugs and Technologies in Health and the Institut national d'excellence en santé et services sociaux, (2) the pan-Canadian Pharmaceutical Alliance, a negotiating

consortium of the federal, provincial and territorial public insurers, and (3) public and private insurers.

65. Given that the New Mandatory Factors are *ultra vires* the *Patent Act*, it follows that the related New Reporting Obligations are also invalid. In the absence of section 4.4, new sections 4.1, 4.2, and 4.3 lack any statutory purpose.

### C. The PMPRB11

66. The *Patent Act* authorizes the PMPRB to determine whether a patentee has abused its patent rights by selling a patented medicine in Canada at an "excessive" price.

67. Subsection 85(1) requires the PMPRB to consider the prices of medicines in countries other than Canada to make this determination. To fulfill this requirement, the PMPRB compares the price of a patented medicine in Canada to a benchmark derived from factory-gate prices in other countries.

68. The Impugned Amendments replace the previous benchmark of seven comparable countries with the PMPRB11.

69. The Schedule containing the PMPRB11 is *ultra vires* the *Patent Act*.

70. The Schedule has been selected for the purpose of lowering drug prices. The PMPRB11:

(a) removes higher-priced countries: the United States and Switzerland; and

(b) adds lower-priced countries: Australia, Belgium, Japan, the Netherlands, Norway, and Spain.

71. Moreover, the RIAS for the *Amendments* states that the PMPRB 11 was tailored to exclude countries in which there is "free market" pricing of patented medicines:

> Three criteria were used to select the countries which makeup the new schedule. First, countries needed to have

policy measures in place to constrain free market pricing for medicines.

72. As a result, the criteria used to select the PMRPB11 conflict with the purpose of section 85 of the *Patent Act*. The free market price of a patented medicine is directly relevant to the question of whether a patentee is abusing its statutory monopoly.

### D. The New Price Calculation

73. To facilitate the PMPRB's determination of whether a patentee has abused its patent monopoly by selling a patented medicine at an "excessive" price, paragraphs 80(1)(*b*) and 101(1)(*a*) of the *Patent Act* authorize regulations specifying the information and documents patentees must provide to the Board regarding the price at which the medicine is or has been sold.

74. In turn, subsection 4(1) of the *Regulations* specifies the precise information that patentees must provide "for the purposes of paragraph 80(1)(*b*)". The key reporting requirement is found in subparagraph 4(1)(*f*)(i), which requires patentees to report the average price per package or the net revenue from sales of a patented medicine (together, the **Price**).

75. Subsection 4(4) then sets out how patentees are to calculate Price.

76. The Impugned Amendments change how Price is calculated under subsection 4(4) and expand the definition of Price to include transactions with third parties that take place separate and apart from sales by patentees of medicine products to customers.

77. The New Price Calculation requires patentees to calculate Price by including as "adjustments" the economics of certain transactions between the patentee and third parties — who by definition are not party to the factory-gate sale.

78. Subsection 4(4) exceeds the regulation-making authority conferred by paragraphs 80(1)(*b*) and 101(1)(*a*) of the *Act*.

79. The scope of paragraph 80(1)(*b*) is confined to the factory-gate sale. Paragraph 80(1)(*b*) only requires patentees to report the "price at which the medicine is

being or has been sold" to the patentee's customer. This limit has been acknowledged by the PMPRB, the Government, and the courts.

80. The New Price Calculation is *ultra vires* since it requires medicine manufacturers, in their capacity as patentees, to report information on their business dealings with third parties beyond the limits of paragraph 80(1)(*b*).

81. Moreover, the New Price Calculation is inconsistent with the statutory requirements of subsections 85(1) and (2) of the *Act*.

82. In considering whether the price of a patented medicine is "excessive", the PMPRB is required to consider the price factors in subsection 85(1). The PMPRB is only permitted to consider the cost factors in subsection 85(2) if it is unable to make a determination based on the price factors in subsection 85(1).

83. Consistent with this scheme, the reporting requirements under the *Patent Act* distinguish between the reporting of:

(a) price information under paragraph 80(1)(*b*) for the purposes of subsection 85(1); and

(b) cost information under paragraph 80(1)(*c*) for the purposes of subsection 85(2).

84. The New Price Calculation requires patentees to report market-access payments made to third parties as part of the "price at which the medicine is being or has been sold" even though such transactions are part of the "costs of making and marketing the medicine".

85. As a result, the New Price Calculation impermissibly introduces cost considerations into the calculation of price and conflates "price" and "cost", contrary to the explicit statutory direction that the PMPRB must consider the former and may not consider the latter except in specifically limited circumstances.

**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 Courts Rules*;

(e) The *Agreement on Trade-Related Aspects of Intellectual Property Rights*;

(f) The *North American Free Trade Agreement* and/or the *Canada–United States–Mexico Agreement*; and

(g) 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 Government's record of decision, including the materials received pursuant to Rule 317 from the Governor in Council; and

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

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

(a) Any and all materials prepared or reviewed by the Governor in Council, including all communications, deliberations, drafts and final documents, regarding:

(i) The purpose of the *Amendments*;

(ii) The purpose of and statutory authorization to promulgate the New Mandatory Factors;

(iii) The purpose and selection of the PMPRB11, including the reasons for excluding each of the United States of America and Switzerland from the Schedule, retaining each of France, Germany, Italy, Sweden, and the United Kingdom, and adding each of Australia, Belgium, Japan, the Netherlands, Norway, and Spain; and

(iv) The purpose of and statutory authorization to promulgate the New Price Calculation.

Dated at Toronto this 6th day of September, 2019.

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**Solicitors for the Applicants**

Court File No. T- -19

**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., HOFFMANN-LA ROCHE LIMITED, IPSEN BIOPHARMACEUTICALS CANADA, INC., LEO PHARMA CANADA INC., LUNDBECK CANADA INC., NOVARTIS PHARMACEUTICALS CANADA INC., NOVO NORDISK CANADA INC., OTSUKA CANADA PHARMACEUTICAL INC., PFIZER CANADA ULC, SANOFI-AVENTIS CANADA INC., and TAKEDA CANADA INC.**

Applicants

— and —

**THE ATTORNEY GENERAL OF CANADA**

Respondent

**NOTICE OF APPLICATION**

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I HEREBY CERTIFY that the above document is a true copy of the original issued out of / filed in the Court on the 6 day of Sept A.D. 2019

Dated this 6 day of Sept 2019