Court File No. T-1465-19

FEDERAL COURT

B E T W E E N:

INNOVATIVE MEDICINES CANADA, ABB VIE 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

- and -

CANADIAN ORGANIZATION FOR RARE DISORDERS and CENTRE FOR FREE EXPRESSION & THE THERAPEUTICS INITIATIVE

Interveners

MEMORANDUM OF FACT AND LAW OF CENTRE FOR FREE EXPRESSION AND THERAPEUTICS INITIATIVE

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OVERVIEW

1. The Amendments to the *Patented Medicines Regulations* at issue on this application close the information gap between the Patented Medicine Prices Review Board ("PMPRB") and pharmaceutical patentees, enabling the PMPRB to better fulfill its mandate of protecting Canadian consumers from excessive prices of patented medicines. The central issue on this application is whether the Amendments are *ultra vires* the Governor in Council.

2. Currently, there is a patchwork of public and private payers of patented medicines. The patchwork nature of this system operates to benefit of pharmaceutical patentees, who are able to exploit information gaps between various players in relation to factors that affect the price of patented medicines. The within application is targeted at maintaining the status quo by preventing the implementation of the Amendments. This status quo has led to Canadian consumers paying some of the highest prices for patented medicines in the world.

3. The joint submissions of the interveners the Centre for Free Expression and the Therapeutics Initiative focus on two aspects of the disputed Amendments, both of which close part of the information gap between the PMPRB and pharmaceutical patentees.

4. First, the Amendments enable the PMPRB to consider a patented medicine's pharmacoeconomic value. Pharmacoeconomic value and its calculation provide the PMPRB with a relevant and effective tool in assessing the ratio of price to therapeutic value. Both of those factors – price and therapeutic value – are already considered in determining whether the price of a patented medicine is excessive. Enabling the PMPRB to consider the relationship between those two factors as well as each independently does not alter the PMPRB's role. Instead, it simply furnishes the PMPRB with an additional informational tool to fulfill its mandate effectively.

5. Second, the Amendments enable the PMPRB to consider price and revenue adjustments beyond the prices set at the factory-gate level. While the PMPRB's jurisdiction is limited to the regulation of the factory-gate prices, information about price and revenue adjustments – including confidential discounts – can be highly relevant to the determination whether the

factory gate price is excessive. Again, the effect of the amendment is to close the information gap and provide the PMPRB with an additional tool to better carry out its existing mandate.

6. Thus, while the Amendments may have the effect of lowering patented medicine prices in Canada, the Amendments do not change the PMPRB's statutory mandate of protecting Canadian consumers from excessive prices for patented medicines. The Amendments merely level the informational playing field and assist the PMPRB in determining whether the prices of patented medicines are excessive.

PART I – STATEMENT OF FACTS

A. The Centre for Free Expression

6. The Centre for Free Expression ("CFE") is a non-partisan research, public education, and advocacy centre based in the Faculty of Communication and Design at Ryerson University. The objects of the CFE include serving as a hub for public education, research and advocacy on free expression and the public's right to know. It works collaboratively with other academic and national and provincial organizations to promote better understanding of the importance of freedom of expression in democratic society, to ensure openness and transparency in public matters, and to advance expressive freedom rights in Canada and internationally. Among other things, the CFE works to ensure that regulatory bodies that act on behalf of the public to protect the public interest have access to the necessary information to fulfill their statutory mandates as fully and responsibly as possible.

B. The Therapeutics Initiative

7. The Therapeutics Initiative ("TI") was established in 1994 by the Department of Pharmacology and Therapeutics in cooperation with the Department of Family Practice at the University of British Columbia ("UBC") with its mission to provide physicians and pharmacists with up-to-date, evidence-based, practical information on prescription drug therapy. Currently, the TI is part of Department of Anesthesiology, Pharmacology and Therapeutics in the Faculty of Medicine at UBC. The TI currently employs approximately 30 faculty, contract and university employees in two locations, both at UBC's main campus in Vancouver and its satellite office in downtown Victoria.

8. There are five working groups in the TI, each carrying out a unique part of the TI's mandate. The Drug Assessment Working Group (DAWG) analyzes scientific evidence on the effectiveness and safety of drug therapies used in Canada. The DAWG systematically reviews and critically appraises research relevant to patented and non-patented medicines. The DAWG produces reports that inform the understanding of the benefits and harms of medicines and this information informs drug coverage decisions made by BC's provincial drug coverage agency, BC Pharmacare. The DAWG has played a central role in drug decision making in BC over the last 25 years and has produced hundreds of systematic reviews, and critical analyses of pharmaceuticals.

C. The Patented Medicines Regime and the Amendments

9. The Applicants have sought judicial review in respect of the Governor in Council's decision 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, amending the *Patented Medicines Regulations*, SOR/94-688 (*Regulations*) under the *Patent Act*, RSC 1985, c. P-4 (the *Act*). The Applicants submit that these Amendments are inconsistent with the purpose and object of the *Act.*

10. The PMPRB's mandate is to protect Canadian consumers from the mischief of pharmaceutical patentees charging excessive prices during the exclusivity period. Without this protection, the patented medicine prices could well rise to unacceptable levels.[1] Canadians are entitled to obtain patented medicines at reasonable prices.[2]

11. The PMPRB carries out its statutory mandate by setting a ceiling price above which, in the PMPRB's opinion, the price of a patented medicine is excessive.[3]

1 *Celgene Corp. v Canada (AG)*, 2011 SCC 1 [*Celgene*] at para. 28 (Applicants' Book of Authorities [ABOA], Tab 16).

2 *Celgene*, *supra* at para. 27 (ABOA, Tab 16).

3 *Patent Act*, R.S.C. 1985, c. P-4 (as am), s 83 (ABOA, Tab 1).

12. "Excessive price" is not expressly defined by the *Act*.[4] In determining excessive price, the PMPRB is required to consider several factors if available, none of which is determinative, including[5]:

a. The prices of other medicines (whether patented medicines or not) in the same therapeutic class in the relevant market; and
b. Factors specified in the Regulations.

13. Currently, Canadian patented medicine prices are among the highest in the world. Of the OECD countries, only the United States and Switzerland had higher patented medicines prices than Canada.[6]

14. The current (that is, pre-Amendments) statutory and regulatory factors have proven insufficient in preventing excessive prices of patented medicines in Canada for several reasons including that:

a. Pharmaceutical patentees around the world are increasingly relying on confidential pricing that is not accurately reflected in public list pricing, which drives up reference pricing[7];
b. There has been a sudden influx of very high-cost medicines with few therapeutic alternatives[8];
c. Pharmaceutical market dynamics have evolved[9];
d. In Canada there is a patchwork of public and private players that lack the national buying power to counter the monopoly positions of pharmaceutical patentees[10];
e. Patentees only report information on price adjustments for the first point of sale ("ex-factory" or "factory gate"). Factory gate prices do not include the significant

4 Affidavit of Wayne Critchley [Critchley Affidavit] at para. 51 (Applicants' Record [AR], Vol. 2, Tab 18 p. 694).

5 *Patent Act*, s. 85.

6 Regulatory Impact Analysis Statement re the Amendments, *Canada Gazette*, Part II, Vol. 153, No. 17 (August 21, 2019) [RIAS], Exhibit "D" to the Affidavit of Dr. Pierre-Gerlier Forest (AR, Vol 4, Tab 32, p. 1288).

7 RIAS (AR, Vol 4, Tab 32, p. 1288-1289).

8 RIAS (AR, Vol 4, Tab 32, p. 1288, 1291).

9 RIAS (AR, Vol 4, Tab 32, p. 1289).

10 RIAS (AR, Vol 4, Tab 32, p. 1291).

> confidential rebates and discounts provided to third parties such as public or private drug plans.[11]

15. The Amendments more fully enable the PMPRB to meet its statutory mandate by specifying additional factors to be considered in determining whether the price of a patented medicine is excessive.

16. Specifically, section 4.4(a) of the Amendments requires the PMPRB to take into consideration the medicine's pharmacoeconomic value for the purposes of section 85(1)(e) of the *Act*.

17. Additionally, section 3(4) of the Amendments requires the PMPRB, in calculating the average price per package of a medicine or the net revenue from sales for the purposes of section 4(4)(a) and (b) [of the Act], to consider price adjustments made by the patentee or other parties who directly or indirectly purchase the medicine.

PART II - ISSUES

18. The central issue on this application is whether the Amendments are ultra vires the Governor in Council.

19. The interveners CFE and the TI take no position on that issue or the applicable standard of review. Rather, the interveners' submissions focus on the nature of the information required to be provided pursuant to the Amendments, and the relevance of that information to the PMPRB's mandate. Specifically, the interveners make submissions with respect to the relevance of pharmacoeconomic value and price and revenue adjustments beyond the prices set at the factory-gate to the PMPRB's mandate.

11 RIAS (AR, Vol 4, Tab 32, p. 1297).

PART III - SUBMISSIONS

A. Pharmacoeoconomic value is an appropriate consideration in determining excessive price

20. The Applicants argue that considerations of pharmacoeconomic value are *ultra vires* because (a) there are other public and private bodies that consider pharmacoeconomic value[12]; (b) pharmacoeconomic is used to measure the *relative* value of therapeutic treatments[13]; and (c) the underlying purpose is not to identify instances of excessive pricing, as is the PMPRB's mandate, but to address Canada's lack of national pharmacare.[14]

21. The CTE and TI make the following submissions in relation to those points.

a. Pharmacoeconomic value is relevant to the PMPRB's mandate

22. First, the fact that pharmacoeconomic value is considered by other bodies does not mean that the information contained in a pharmacoeconomics study is not also relevant to the PMPRB's consideration of excessive pricing. Information concerning pharmacoeconomic value and its calculation close part of the information gap between the patentee and the PMPRB regarding the costs of a patented medicine and its therapeutic improvements.

b. Consideration of relative measures is consistent with the PMPRB's mandate

23. Second, while pharmacoeconomic value is a relative measure, the current procedure implemented by the PMPRB already relies on a number of comparative measures similar to the determination of pharmacoeconomic value. For example, the PMPRB considers therapeutic improvement as a relative measure of how a patented medicine compares to other drug products in the same therapeutic class (whether patented or not). Based on the therapeutic improvement offered by the patented medicine, it then compares the price for the patented medicine with the prices of other drugs in the therapeutic class.[15]

12 Applicants' Memorandum of Fact and Law at paras. 129-131.

13 Applicants' Memorandum of Fact and Law at para. 140.

14 Applicants' Memorandum of Fact and Law at paras. 135-138.

15 Critchley Affidavit at paras. 60-61 (AR, Vol. 2, Tab 18, p. 696).

24. Currently, when the PMPRB evaluates a new patented medicine, it begins by categorizing it based on the level of therapeutic improvement it provides relative to other drug products sold in Canada. Therapeutic classes include: (a) breakthrough, (b) substantial improvement, (c) moderate improvement, or (iv) slight or no improvement.[16]

25. Pursuant to PMPRB guidelines, the PMPRB not only considers evidence from the pharmaceutical patentee but may also undertake its own research or consider research from advisory panels constituted pursuant to the guidelines.[17]

26. This exercise is undertaken pursuant to section 85(1)(b) of the *Act*, which requires the PMPRB to consider "the prices at which other medicines in the same therapeutic class have been sold in the relevant market".

27. Once the therapeutic class of the new patented medicine is identified, ceiling prices can be determined based on referencing medicines in the same class[18]:

a. the price of a new breakthrough or substantial improvement medicine should not exceed the higher of the median international price for that drug or the highest priced drug in the therapeutic class;

b. the price of a new drug that provides moderate improvement over an existing drug should not exceed the higher of the highest priced drug in the therapeutic class or the mid-point of the highest priced drug and the median international price of the new drug;

c. the price of a new drug that offers slight or no improvement over an existing drug should not exceed the highest priced drug in the therapeutic class;

d. the price of a new strength of an existing medicine should not exceed a price based on a reasonable relationship to the existing strengths; and

e. the price of all new and existing patented medicines should never exceed the highest of the prices in the other benchmark countries.

16 Critchley Affidavit at paras. 60-61 (AR, Vol. 2, Tab 18, p. 696).

17 Exhibit H to Critchley Affidavit (AR, Vol. 3, Tab 26, p. 922).

18 Critchley Affidavit at paras. 60-61 (AR, Vol. 2, Tab 18, p. 696).

28. Section 4.4(a) of the Amendments would require the PMPRB to, take into consideration the medicine's pharmacoeconomic value, in addition to the factors set out above, for the purposes of section 85(1)(e) of the *Act*.

29. Pharmacoeconomic value is how much a medicine costs for the therapeutic improvement it provides. Pharmacoeconomic value is expressed in a standard unit of measurement.[19] Commonly, this is expressed as cost per quality adjusted life year ("QALY").[20]

30. QALY is another form of measuring therapeutic improvement, which is already done pursuant to section 85(1)(b) of the *Act*.

31. Pharmacoeconomic value, when expressed as cost per QALY considers the overall cost of a drug therapy measured against its health outcome. Additionally, as it is measured in a standardized value it makes is possible to directly compare medicines with similar therapeutic improvements.[21]

32. Similarly, QALY is a standardized measure of therapeutic value where a QALY is the equivalent of one year of life in perfect health. QALY values therefore can be used to determine therapeutic improvements by comparing medicines or treatments. The Applicant's Evidence provides the following example[22]:

> Jane suffers from arthritis. If given Treatment A, Jane will live for 10 years in perfect health. Perfect health is assigned a utility value of 1. Therefore, Treatment A will be said to provide Jane with 10 QALYs: (10 years of life) x (utility value of 1) = 10 QALYs. If, on the other hand, Jane chooses not to treat her arthritis, she will live for 10 years in a lesser state of health. This lesser state of health is represented by say a utility value of 0.7. Therefore, if left untreated, Jane will have only 7 QALYs: (10 years of life) x (utility value of 0.7) = 7 QALYs. In this simplistic example, the health benefit of Treatment A is 3 additional QALYs.

19 Affidavit of Dr. Jean Lachaine [Lachaine Affidavit] atpara. 36 (AR, Vol. 5, Tab 52, p. 1909).

20 RIAS (AR, Vol 4, Tab 32,p. 1290-1291).

21 Lachaine Affidavit at para. 43 (AR, Vol. 5, Tab 52, p. 1910).

22 Lachaine Affidavit at para. 52 (AR, Vol. 5, Tab 52, p. 1911).

33. Using QALY provides decision makers, such as the PMPRB, an objective measure by which to compare the therapeutic improvements of the patented medicine with other drug products in the same therapeutic class.

34. Cost per QALY then factors in incremental cost. For example[23]:

> Treatment B and Treatment C both treat pancreatic cancer. Treatment B costs $100,000 and produces 7 QALYs whereas Treatment C costs $30,000 and produces 5 QALYs. We know that Treatment B is more beneficial as it provides two additional QALYs, but at what cost? The incremental cost per QALY is calculated by dividing the difference in cost between Treatment B and Treatment C by the difference in number of QALYs produced by each treatment:
>
> $$\frac{\$100{,}000 - \$30{,}000}{7 - 5} = \$35{,}000$$
>
> … the incremental cost per QALY associated with Treatment B is $35,000 per QALY. This means that each of the 2 additional QALYs produced by Treatment B cost $35,000.

35. While cost per QALY provides a relative value directly comparable to other medicines in the same therapeutic class (as opposed to a comparison with only the highest priced drug in the therapeutic class), the data contained in pharmacoeconomic value and its calculation are relevant information that can be used to determine if the price (i.e. the cost) of a patented medicine is excessive in relation to the therapeutic improvement (if any) it offers.

36. Simply put, pharmacoeconomic value is a relevant and valuable tool in assessing price to therapeutic value.[24] Both price and therapeutic value are clearly relevant to a determination of whether patented medicines prices are excessive. However, pharmacoeconomic value is not dispositive of price. Like all the factors listed in section 85 of the *Act*, the PMPRB is only required to take into consideration the factors where they are available to the PMPRB.

c. Consideration of pharmacoeconomic value does not alter the PMPRB's mandate

37. Lastly, consideration of pharmacoecomic value, is consistent with the PMPRB's statutory mandate of determining whether patented medicine prices are excessive. This point is dealt with in further detail in section C below.

23 Lachaine Affidavit at para. 57 (AR, Vol. 5, Tab 52, p. 1912).

24 RIAS (AR, Vol 4, Tab 32 p. 1321).

B. Considering price adjustments beyond factory gate prices assists in the determination of whether patented medicine prices are excessive

38. Canada is the only country with a publicly funded health care system that does not include universal pharmaceutical coverage.[25] Instead, medicines are commonly paid on behalf of the Canadian consumer through provincial public drug plans[26] and/or private drug plans.[27] This creates a patchwork of public and private payers that lack the buying power to counter the monopoly position of patentees.[28]

39. Each separate provincial public drug plan maintains a formulary listing of the prescription drug that the province will reimburse.[29] Pharmaceutical patentees negotiate product listing agreements with each public drug plan to list its product on the provincial formulary.

40. While there is a public listing price, generally pharmaceutical patentees provide different confidential discounts off the list price based on the buying power of the respective provincial public drug plan.[30]

41. Given that the private payers, including private insurers and those consumers who pay out of pocket, are unaware of the confidential discounts and are not in a buying power position to counter the pharmaceutical patentees' monopoly position they consistently pay prices that are not a true reflection of prices paid for existing therapies in the Canadian market.[31]

42. As such, section 3(4) of the Amendments requires the PMPRB, in calculating the average price per package of a medicine or the net revenue from sales to consider price adjustments made by the patentee or other parties who directly or indirectly purchase the medicine.

25 RIAS (AR, Vol 4, Tab 32, p. 1291).

26 Note: while there is a federal drug plan, it represents only a small portion of public prescription spending (see Forest Affidavit at para. 57 (AR, Vol. 4, Tab 32, p. 1013)).

27 Forest Affidavit at paras. 55-58 (AR, Vol. 4, Tab 32, p. 1013).

28 RIAS (AR, Vol. 4, Tab 32, p. 1291).

29 Forest Affidavit at para. 60 (AR, Vol. 4, Tab 32, p. 1013-1014).

30 PMPRB, *Strategic Plan, 2015-2018* [Strategic Plan], Exhibit "F" to the Affidavit of Karen Reynolds (AR, Vol. 8, Tab 105, p. 3063).

31 Strategic Plan (AR, Vol 8, Tab 105, p. 3063).

43. This requires pharmaceutical patentees to disclose price and revenue adjustments, including discounts, rebates and free goods and services provided to third parties such as the public or private drug plans, distributors, pharmacies etc.[32]

44. With these price and revenue adjustments, the PMPRB will gain relevant – and indeed, in the interveners' submission important – information concerning the actual prices paid for patented medicines by Canadian consumers. Furthermore, the heavy reliance by pharmaceutical patentees on confidential pricing (i.e. information gaps) drives up reference pricing.[33] Where patented medicines are consistently deeply discounted beyond the factory gate price, this may be an indicator that the price reported to PMPRB is excessive.[34]

45. There are two potential concerns that should be put to rest here. First, providing the PMPRB with information regarding price and revenue adjustments beyond the factory gate does not mean that PMPRB is *regulating* the price of patented medicines beyond the factory gate. Instead, this information enables the PMPRB to better determine the actual prices for patented medicines paid by Canadian consumers. Again, as stated above, where there is a deep discounted price for a first party (for example a provincial formulary with strong buying power) over the price for a second party (for example a Canadian consumer paying out of pocket), this suggests that perhaps the second party is paying an excessive price. Given that the PMPRB is mandated to set ceiling prices, no party in Canada should be paying an excessive price.

46. Second, while the price and revenue adjustments are commercially sensitive information, they remain privileged as per section 87 of the *Act*.[35] The Amendments only require pharmaceutical patentees to report prices and revenue net of all adjustments and not specific adjustments to specific third parties. As such, it will not be apparent to the PMPRB the size or terms and conditions of any specific third party rebate.[36] This information is only required to close the relevant information gap between the pharmaceutical patentees and the PMPRB.

32 RIAS (AR, Vol. 4, Tab 32, p. 1297-1298).

33 RIAS (AR, Vol. 4, Tab 32, p. 1288-1289).

34 RIAS (AR, Vol. 4, Tab 32, p. 1297).

35 RIAS (AR, Vol. 4, Tab 32, p. 1298).

36 RIAS (AR, Vol. 4, Tab 32, p. 1324).

Enabling the PMPRB, a regulatory body tasked with protecting the Canadian consumer, to consider this information fosters and protects the public's right to know.

C. The Amendments do not change the PMPRB's mandate in regulating excessive prices

47. The Applicants argue that the Amendments are a paradigm shift in how the PMPRB regulates patented medicine prices.[37] Specifically, the Applicants state that the net effect of the Amendments in lowering patented medicine prices is unrelated to the PMPRB's statutory mandate in preventing excessive prices of patented medicines.

48. While the Interveners support the lowering of patented medicine prices in Canada, they submit that the lowering of patented medicine prices and prevention of excessive prices are not mutually exclusive. In fact, it can be argued that the PMPRB has failed to meet is statutory mandate of regulating excessive patented medicine prices given that Canadian patented medicine prices are among the highest in the world.

49. The Applicants provided opinion evidence claiming that the PMPRB has been historically successful in carrying out its mandate because there is a high level of voluntary compliance with the PMPRB's guidelines by pharmaceutical patentees and that findings of "excessive" prices have been relatively infrequent.[38]

50. While PMPRB findings of excessive price may have been relatively infrequent to date, the PMPRB's determinations have been based on limited information from the pharmaceutical patentees, which is precisely the issue that the Amendments seek to address. If the PMPRB is equipped with the additional information that flows from the Amendments, they will be in a better position to carry out their mandate in regulating excessive price.

51. In conclusion, the Amendments do not change the PMPRB's mandate in regulating excessive prices. The Amendments assist the PMPRB in fulfilling its statutory mandate by[39]:

37 Applicants' Memorandum of Fact and Law at para. 106.

38 Critchley Affidavit at para. 20 (AR, Vol. 2, Tab 18, pp. 687-688).

39 RIAS (AR, Vol. 4, Tab 32, p. 1290).

a. Equipping the PMPRB with the tools to identify a ceiling price above which it would be unreasonable for any consumer in Canada to pay. Put another way, prices in the PMPRB's opinion are excessive where it is unreasonable for any consumer to pay said price;

b. More closely aligning the ceiling price of patented medicines that is reflective of their value to Canadian consumers. Put another way, prices in the PMPRB's opinion are excessive where patented medicines are no longer offered at a valuable price to Canadian consumers; and

c. Enabling a ceiling price that is informed by the affordability constraints of the Canadian Economy. Put another way, prices in the PMPRB's opinion are excessive where they are no longer affordable in the Canadian economy.

PART IV - COSTS

52. The interveners are public interest organizations represented on this intervention by *pro bono* counsel. They do not seek their costs and ask that no costs be ordered against them.

ALL OF WHICH IS RESPECTFULLY SUBMITTED.

Dated at Toronto, Ontario, this 19th day of May, 2020.

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LIST OF AUTHORITIES

Jurisprudence

1. *Celgene Corp. v Canada (AG)*, 2011 SCC 1

Legislation

2. *Patent Act*, R.S.C. 1985, c. P-4 (as am.)
3. *Patented Medicines Regulations*, SOR/88-474
4. *Patented Medicines Regulations*, SOR/94-688 (as am.)