Court File No. A-2 15-20

FEDERAL COURT OF APPEAL

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.

Appellants

— and —

THE ATTORNEY GENERAL OF CANADA

Respondent

1041

FEDERAL COURT OF APPEAL
COUR D'APPEL FÉDÉRALE
FILED / DÉPOSÉ
SEP 10 2020
John Gornick
TORONTO, ON

NOTICE OF APPEAL

TO THE RESPONDENT:

A LEGAL PROCEEDING HAS BEEN COMMENCED AGAINST YOU by the appellants. The relief claimed by the appellants appears on the following pages.

THIS APPEAL will be heard by the Court at a time and place to be fixed by the Judicial Administrator. Unless the Court directs otherwise, the place of hearing will be as requested by the appellants. The appellants request that this appeal be heard at Toronto where the Federal Court of Appeal ordinarily sits.

IF YOU WISH TO OPPOSE THIS APPEAL, to receive notice of any step in the appeal or to be served with any documents in the appeal, you or a solicitor acting for you must prepare a notice of appearance in Form 341 prescribed by the *Federal Courts Rules* and serve it on the appellants' solicitor, or where the appellants are self-represented, on the appellants, WITHIN 10 DAYS of being served with this notice of appeal.

IF YOU INTEND TO SEEK A DIFFERENT DISPOSITION of the order appealed from, you must serve and file a notice of cross-appeal in Form 341 prescribed by the *Federal Courts Rules* instead of serving and filing a notice of appearance.

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 APPEAL, JUDGMENT MAY BE GIVEN IN YOUR ABSENCE AND WITHOUT FURTHER NOTICE TO YOU.

JOHN GORNICK
REGISTRY OFFICER
AGENT DU GREFFE

September 10, 2020 Issued by: _____

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APPEAL

THE APPELLANTS APPEAL to the Federal Court of Appeal from the judgment and declaration of the Honourable Mr. Justice Manson dated June 29, 2020 (the **Judgment**) in Federal Court File No. T-1465-19. The Judgment dismissed in part the Appellants' application for judicial review (the **Application**) 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***) amending the *Patented Medicines Regulations*, SOR/94-688 (the ***Regulations***).

THE APPELLANTS ASK that this Court:

(a) allow the appeal;

(b) set aside paragraph 2 of the Judgment;

(c) declare that the following 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 (***Patent Act*** or ***Act***):

(i) section 4 of the *Amendments*, which introduces new sections 4.1 to 4.4 of the *Regulations* requiring the Patented Medicine Prices Review Board (**PMPRB** or **Board**) to consider three new mandatory factors when determining whether a patented medicine's price is "excessive" under paragraph 85(1)(e) of the *Patent Act* and requiring patentees to report related information to the PMPRB

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

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

(d) order that sections 4 and 6 and the Schedule of the *Amendments* be quashed for being *ultra vires* the *Patent Act*;

(e) award the Appellants their costs of this appeal; and

(f) grant such further and other relief as counsel may advise and this Honourable Court may deem just.

THE GROUNDS OF APPEAL are as follows:

I. Overview

1. This appeal addresses the purpose and scope of the Governor in Council's regulation-making authority under the *Patent Act*.

2. The PMPRB was established under the *Patent Act* to ensure that patentees do not abuse their statutory monopoly by selling patented medicines at prices that are "excessive". The PMPRB's jurisdiction is rooted in the *Patent Act* and in protecting the public from instances of patent abuse.

3. Consistent with its statutory jurisdiction, the PMPRB's role under the *Act* is restricted to reviewing the price at which a patentee sells a patented medicine to its customer at its first point of sale (*i.e.*, the factory-gate transaction).

4. By virtue of the statutory scheme and in accordance with the division of powers, the PMPRB does not have jurisdiction over the pricing of patented medicines generally or transactions beyond the factory gate.

5. The Impugned Amendments are entirely unrelated to regulating patent abuse in the form of "excessive" prices at the factory gate. Instead, the Impugned Amendments are aimed at lowering drug prices generally in order to alleviate pressures faced by provincial health care budgets and to introduce National Pharmacare.

6. In upholding the Impugned Amendments, the Application Judge erred by expanding the Board's mandate beyond its proper statutory purview of patent abuse

and granting the PMPRB a broad mandate to address the overall affordability of patented medicines.

7. The Application Judge failed to apply the relevant constraints on the Governor in Council's regulation-making authority and, in particular, failed to take into account the purpose and scope of the *Patent Act* and the limits of the federal government's patent power under subsection 91(22) of the *Constitution Act, 1867*.

8. The Judgment upholds an "excessive" price jurisdiction for the Board that is untethered from the federal government's patent jurisdiction. The appeal should be allowed and the Impugned Amendments declared *ultra vires* the *Patent Act*.

II. Background

A. The PMPRB and the Patented Medicines Regime

9. The PMPRB was established in 1987 through reforms to the *Patent Act* to ensure that patentees of medicines do not abuse their patent rights by selling patented medicines at prices that are "excessive".

10. The courts have repeatedly recognized that the PMPRB's mandate is constitutionally limited to addressing patent abuse in the form of "excessive pricing".

11. By virtue of the division of powers and its statutory mandate under the *Act*, the PMPRB does not have jurisdiction over the pricing of patented medicines generally. Nor does the Board have the statutory jurisdiction to make health policy decisions on behalf of the public.

12. The statutory framework governing the PMPRB is found in sections 79–103 of the *Patent Act* (the **Patented Medicines Regime**).

13. The Patented Medicines Regime sets out how the PMPRB is to determine whether a patentee is abusing its patent monopoly by charging an "excessive" price.

14. Subsection 85(1) of the *Patent Act* requires the Board to determine whether a price is "excessive" by comparing the patentee's factory-gate price against certain benchmark prices in Canada and internationally. This comparison is known as "reference pricing" and is used to understand how the patentee's price relates to prices charged by patentees elsewhere.

15. If the PMPRB is unable to determine whether a price is "excessive" using the reference pricing scheme under subsection 85(1), subsection 85(2) of the *Act* enables the PMPRB to consider the patentee's costs of making and marketing the medicine.

16. Paragraph 101(1)(d) of the *Patent Act* provides that the Governor in Council may make regulations to introduce additional factors for the purposes of subsections 85(1) and 85(2).

B. The *Amendments*

17. By Order in Council dated August 7, 2019, PC 2019-1197, the Governor in Council introduced the *Amendments* under the *Patent Act*.

18. The *Amendments* were introduced for the express purpose of lowering the prices of patented medicines in Canada. The genesis of the *Amendments* was a January 2016 meeting of the federal, provincial, and territorial Ministers of Health in which they agreed to consider a range of measures to reduce drug expenditures. As a part of that process, the federal government decided to use the PMPRB to "lower the cost of drugs" which, in turn, would "lay the foundation for National Pharmacare".

19. In order to "lower the cost of drugs", the *Amendments* fundamentally alter the role of the PMPRB. The *Amendments* include three significant changes, which:

(a) require the PMPRB to assess pharmacoeconomic value, market size, and gross domestic product (**GDP**) and GDP per capita (the **New Mandatory Factors**);

(b) change the basket of countries used by the PMPRB as foreign price comparators by removing countries with higher average drug prices

(Switzerland and the United States) and by adding six countries with lower average drug prices (Australia, Belgium, Japan, the Netherlands, Norway, Spain) (the **PMPRB11**); and

(c) require patentees to report payments made to third parties in the calculation of price submitted to the PMPRB (the **New Price Calculation**).

20. The *Amendments* have been described by the PMPRB as a "paradigm shift" and by the Minister of Health at the time as the "biggest step to lower drug prices in a generation".

21. The federal government estimates that the *Amendments* will reduce patented medicine prices and, correspondingly, drug expenditures, by $8.8 billion (net present value) over the next ten years. The federal government also estimates that the *Amendments* could cost the industry up to $24.9 billion (net present value) depending on how they are implemented.

III. The Application for Judicial Review

22. The Appellants are 16 of Canada's leading researched-based pharmaceutical companies and Innovative Medicines Canada, a national association of research-based pharmaceutical companies.

23. On the Application below, the Appellants sought an order quashing the New Mandatory Factors, the PMPRB11, and the New Price Calculation as *ultra vires* the *Patent Act*.

24. The basis of the Application was that the *Amendments* are inconsistent with the purpose of the *Patent Act* and exceed the Governor in Council's regulation-making authority. In particular:

(a) the *Amendments* as a whole are unrelated to and inconsistent with the purpose and object of the *Patent Act*;

(b) the New Mandatory Factors are (i) inconsistent with the purpose of the *Patent Act* and (ii) beyond the Governor in Council's statutory authority under sections 85 and 101 of the *Patent Act*;

(c) the PMPRB11 was selected for a purpose and using criteria that are unrelated to and inconsistent with the purpose of the *Patent Act*; and

(d) the New Price Calculation is beyond the Governor in Council's statutory authority under sections 80 and 101 of the *Patent Act*.

IV. The Judgment Under Review

25. On June 29, 2020, the Federal Court granted the Application in part.

26. The Application Judge held the New Price Calculation is "not limited to sales transactions made by the patentee at the factory-gate" and declared it invalid, void, and of no force and effect. The Application Judge concluded that payments made by patentees to third party insurers are unrelated to the "price" at which patented medicines are "sold" within the meaning of paragraph 80(1)(b) of the *Patent Act*.

27. The Application Judge dismissed the remainder of the Application, finding that the decision to promulgate the *Amendments* was otherwise reasonable, and concluded that:

(a) the role of the Board within the Patented Medicines Regime is to ensure that consumers are "protected from the abuse of excessively priced patented medicines, such that prices remain reasonable and affordable to Canadians";

(b) the purpose of the *Amendments* is two-fold: (i) "to modernize the Board with new regulatory tools and information reporting authority" and (ii) "to lower patented medicines prices to protect Canadian consumers from the abuse of excessively [*sic*] pricing";

(c) the purpose of the *Amendments* is "sufficiently connected to and consistent with" the affordability purpose of the Patented Medicines Regime;

(d) the New Mandatory Factors are sufficiently connected to the Board's mandate and are within the scope of the Governor in Council's regulation-making authority; and

(e) the selection of the PMPRB11 is sufficiently connected to the purpose of the Patented Medicines Regime.

V. The Errors Giving Rise to Appeal

28. The Application Judge erred in determining that the Governor in Council acted reasonably in promulgating the New Mandatory Factors and PMPRB11.

29. The Application Judge made three overarching errors:

(a) While the Application Judge appropriately identified reasonableness as the standard of review, he failed to correctly apply the reasonableness framework set out by the Supreme Court of Canada in *Canada (Minister of Citizenship and Immigration) v. Vavilov*, 2019 SCC 65, by disregarding the constraints on the Governor in Council's regulation-making authority.

(b) The Application Judge failed to recognize that as a creature of the *Patent Act*, the PMPRB's jurisdiction over "excessive" pricing is limited to patent abuse and the factory-gate transaction. Questions of willingness to pay or overall "affordability" based on provincial budgetary pressures are unconnected to the PMPRB's jurisdiction.

(c) The Application Judge erred in concluding that the purpose of the Patented Medicines Regime extends broadly to ensuring "affordable" patented medicine prices.

30. In addition, the Application Judge failed to properly take into account the following factors when determining the purpose of the Patented Medicines Regime under the *Patent Act*:

(a) the *Constitution Act, 1867*, which limits Parliament's authority over patented medicine prices to patent abuse;

(b) the purpose of the *Patent Act* as a whole;

(c) the Board's factory-gate jurisdiction;

(d) the legislative history of the Patented Medicines Regime;

(e) the text and context of the Patented Medicines Regime;

(f) the reference pricing scheme established under the Patented Medicines Regime;

(g) relevant international treaties to which Canada has agreed to abide; and

(h) well-established principles of statutory interpretation.

31. The Application Judge erred in concluding that the *Amendments* were promulgated for a valid *Patent Act* purpose, including by:

(a) concluding that "modernization" of the Patented Medicines Regime was a valid purpose that is distinct from the purpose of lowering patented medicine prices;

(b) concluding that where a regulation is promulgated for an inconsistent purpose, it can be saved by the existence of other consistent purposes;

(c) failing to address key evidence that the *Amendments* are unrelated to patent abuse in the form of excessive prices; and

(d) concluding that the purpose of lowering drug prices is an issue of "economic policy and politics" beyond the scope of judicial review.

32. The Application Judge also erred in finding that the New Mandatory Factors are "sufficiently connected" to the Board's mandate and are a valid exercise of the Governor in Council's authority under the *Act*. In particular, the Application Judge:

(a) erred in finding that assessing pharmacoeconomic value is "an objective exercise", despite uncontroverted expert evidence to the contrary;

(b) erred in concluding that the pharmacoeconomic value factor was introduced to address circumstances where the Board has limited reference pricing information, despite the absence of any evidence to support this conclusion;

(c) erred in dismissing the expert evidence on the market size and GDP factors; and

(d) failed to apply the established principles of statutory interpretation, including by failing to consider the text, context and purpose of the relevant provisions in the *Patent Act.*

33. The Application Judge erred in concluding that the criteria used to select the PMPRB11 are consistent with Parliament's jurisdiction, the purpose of the *Patent Act*, and the purpose of the Patented Medicines Regime.

34. The Application Judge erred in failing to conclude that the selection of the PMPRB11 was a form of price control that is inconsistent with the purpose of the Patented Medicines Regime.

THE APPELLANTS RELY UPON:

(a) the Application Record below;

(b) the *Patent Act*, including but not limited to sections 79 to 103;

(c) the *Regulations* and the *Amendments*;

(d) the *Federal Courts Act*, RSC 1985, c F-7, including but not limited to sections 18, 18.1, 27 and 52;

(e) the *Federal Courts Rules*, SOR/98-106;

(f) the *Constitution Act, 1867*;

(g) the *Agreement on Trade-Related Aspects of Intellectual Property Rights*;

(h) the *North American Free Trade Agreement* and/or the *Canada-United States-Mexico Agreement*; and

(i) such further and other grounds as counsel may advise and this Honourable Court may permit.

September 10, 2020

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Court File No. A- -20

FEDERAL COURT OF APPEAL

**INNOVATIVE MEDICINES CANADA,
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— and —

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Respondent

NOTICE OF APPEAL
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