Federal Court  Cour fédérale

Date: 20200629

Docket: T-1465-19

Citation: 2020 FC 725

Ottawa, Ontario, June 29, 2020

PRESENT: The Honourable Mr. Justice Manson

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

and

CANADIAN ORGANZATION FOR RARE DISORDERS

Intervener

JUDGMENT AND REASONS

I. Introduction

[1] This is an application for judicial review of recent amendments to the *Patented Medicines Regulations*, SOR/94-688 [the *Regulations*], under the *Patent Act*, RSC 1985, c P-4. The Applicants seek a declaration that certain provisions of the *Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)*, SOR/2019-298 [the *Amendments*] are invalid because they are *ultra vires* the *Patent Act*.

[2] The Applicants essentially challenge the federal government's use of the Patented Medicine Prices Review Board [the Board] as a mechanism to reduce patented medicines prices in Canada. The Applicants take issue with three aspects of the *Amendments*. First, the *Amendments* specify additional factors that the Board must consider when determining whether the price of a patented medicine is excessive. Second, the *Amendments* change the "basket" of comparator countries for the purpose of reference pricing. Third, the *Amendments* require patentees to take into account discounts and rebates provided to third parties when reporting medicine prices to the Board [collectively, the Impugned Amendments].

[3] The *Amendments* were scheduled to come into force on July 1, 2020. At the outset of the hearing, the Respondent informed the Court that by Order in Council PC 2020-413, dated May 30, 2020, the coming into force of the *Amendments* has been deferred until January 1, 2021.

II. Background

A. *The Parties*

[4] The Applicants are Innovative Medicines Canada [IMC], a national association of research-based pharmaceutical companies, and several Canadian innovative pharmaceutical companies. Each pharmaceutical company Applicant is a member of IMC and a patentee subject to the requirements of the *Regulations,* and will be directly affected by the Impugned Amendments.

[5] The intervener, the Canadian Organization for Rare Disorders [CORD], is a national network of patient organizations representing Canadians with rare disorders. By definition, rare disorders affect 1 in 2000 people, and ultra-rare disorders affect fewer than 20 people per million. Patients with rare diseases rely on innovative medicines for treatment.

[6] CORD was granted leave to intervene to speak to the unique perspective of patients with rare disorders. CORD takes similar positions to the Applicants, albeit from a different perspective.

B. *History of the Patented Medicine Prices Review Board*

[7] Created by Parliament in 1987, the Board is a quasi-judicial body that regulates the prices that patentees can charge for patented medicines during the statutory monopoly period. The Board's mandate includes a type of consumer protection: ensuring that patentees do not abuse their patent rights by charging "excessive" prices for patented medicines. The Board's mandate

is not to set prices for patented medicines, but to ensure patentees do not sell patented medicines at excessive prices (*Pfizer Canada Inc v Canada (Attorney General)*, 2009 FC 719 at para 11 [*Pfizer*]; *Sanofi Pasteur Limited v Canada (Attorney General)*, 2011 FC 859 at para 17 [*Sanofi*]).

[8] The Board was created to balance expanded patent rights extended to patentees of medicines pursuant to the 1987 amendments to the *Patent Act* with the need to prevent excessive pricing of those medicines by patentees. The 1987 amendments significantly curtailed the compulsory licensing regime, opened up patent protection to pharmaceutical products, and extended the patent term to 20 years from the date of filing of a patent application. Parliament sought to ensure that patented medicines prices would not become excessive because of these changes.

[9] During the legislative process leading up to the 1987 amendments, the Honourable Harvie Andre, then Minister of Consumer and Corporate Affairs, stated that the purpose of the Board is to "ensure that prices of drugs not yet discovered…will be reasonable" and that the proposed amendments included "enormous checks and balances" to meet this objective (*House of Commons Debates*, 33-2, Vol 1 (October 7 and November 20, 1986) at 152 and 1373 (Hon Harvie Andre)).

[10] In 1993, Parliament further amended the patented medicines regime, abolishing the compulsory licensing regime altogether in order to better align Canada's patent system with international treaty obligations. Amongst other changes, the 1993 *Patent Act* amendments enhanced the Board's powers to address excessive pricing of patented medicines sold in Canada. The Board was given the power to address introductory prices of patented medicines, and

expanded powers to make new types of orders including orders to offset past excess revenues, and orders imposing fines or imprisonment on patentees.

[11] The 1993 amendments defined the Minister of Health and Welfare (now the Minister of Health) as the Minister responsible for sections 79 to 103 of the *Patent Act* [the Patented Medicines Regime]. Prior to 1993, this regime fell under the purview of the Minister of Consumer and Corporate Affairs.

[12] Further, these amendments updated the factors that the Board considers when determining whether a medicine has been sold at an excessive price in Canada, and provided the Governor in Council with an express regulation-making authority to specify additional factors for the Board to consider. Prior to the regulations at issue in this application, the Governor in Council had never exercised this authority.

[13] In the legislative debates surrounding the 1993 amendments, the Government again highlighted the Board's role in protecting Canadian consumers from excessive patented medicines prices. The Honourable Pierre Blais, then Minister of Consumer and Corporate Affairs, stated that the amendments to the Patented Medicines Regime were a "guarantee that Canadians can continue to buy patented drugs at a price that is and will remain reasonable" (*House of Commons Debates*, 34-3, Vol 10 (September 17, 1992) at 13258 (Hon Pierre Blais)).

C. *Operation of the Governing Statutory Scheme*

[14] As noted above, the Patented Medicines Regime is set out in sections 79 to 103 of the *Patent Act*.

[15] Section 83 of the *Patent Act* empowers the Board to issue certain orders to patentees who are selling or have sold medicines in any market in Canada at a price that, in the Board's opinion, is excessive. Upon such a finding, the Board may, amongst other things, order the patentee to reduce the price to a non-excessive level, and order the patentee to pay a specified amount to Her Majesty in right of Canada.

[16] Section 83 also provides patentees with a right to a hearing prior to the Board making any order.

[17] In practice, price reductions and repayment of excess revenues by patentees occur pursuant to a Voluntary Compliance Undertaking [VCU], or a Board order made following a public hearing and Board determination that the medicine has been sold at an excessive price.

[18] A VCU is a written undertaking by a patentee to adjust its price to conform to the Board's guidelines. Following a finding that the price of a patented medicine appears to have been sold at an excessive price, the Board, pursuant to its guidelines, offers patentees the opportunity to submit a VCU.

[19] Section 85 of the *Patent Act* prescribes factors for the Board to consider when determining whether the price of a patented medicine is excessive under section 83. Subsection 85(1) defines mandatory factors that the Board *must* consider, and subsection 85(2) sets out additional factors the Board *may* consider where it is unable to determine whether a patented medicine has been sold at an excessive price based only on the mandatory factors.

[20] The mandatory factors defined in subsection 85(1) require the Board to consider the price of the medicine at issue as compared to the prices of other medicines in the same therapeutic class, and the prices of the same and similar medicines in other countries. This comparison is referred to as “reference pricing”. The schedule to the *Regulations* sets out a list of comparator countries to be used as international reference pricing benchmarks. From 1988 to 2019, the comparator countries were France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States [the PMPRB7].

[21] Subsection 85(1) also requires that the Board consider changes in the Consumer Price Index and “such other factors as may be specified in any regulations made for the purposes of this subsection.” Prior to 2019, no regulations had been enacted for the purposes of applying subsection 85(1).

[22] Section 80 of the *Patent Act* governs information that patentees must provide to the Board to enable it to conduct excessive price reviews. Patentees with inventions pertaining to medicines must provide the Board with information and documents as prescribed by regulation with respect to:

> (a) the identity of medicine;
>
> (b) the price at which the medicine is being sold in Canada and elsewhere;
>
> (c) the costs of making and marketing the medicine;
>
> (d) the factors referred to in section 85; and
>
> (e) any other related matters.

[23] Subsection 101(1) provides the Governor in Council with broad regulation-making authority. Relevant to this proceeding, the Governor in Council may make regulations "specifying the information and documents that shall be provided to the Board under subsection 80(1) or (2)" (paragraph 101(1)(a)) and "specifying factors for the purposes of subsection 85(1) or (2)" (paragraph 101(1)(d)).

[24] Subsection 101(2) states that no regulations may be made under paragraphs 101(1)(d), (f), (h), and (i) except on the recommendation of the Minister of Health, made after the Minister has consulted with the provincial health ministers, and consumer groups and pharmaceutical industry representatives that the Minister deems appropriate.

[25] It bears emphasizing that the Board, the Minister of Health, and the Governor in Council are separate entities, each with different mandates, powers, and responsibilities under the Patented Medicines Regime.

D. *Events Leading to the Amendments*

[26] The parties frame the consultation and amendment process differently. The Applicants assert that following a January 2016 meeting between the federal, provincial, and territorial Ministers of Health to discuss health care funding, the federal government formed a plan to use the Board to lower prices of patented medicines.

[27] In particular, in a May 2017 letter to the Ontario Minister of Health and Long-Term Care, the federal Minister of Health referenced the governments' commitment to improve the affordability, accessibility, and appropriate use of prescription drugs. She noted that within

federal jurisdiction, this includes lowering high drug prices through modernization of the regulatory framework that guides the work of the Board.

[28] The Respondent notes that in light of relatively high patented drug prices and record low pharmaceutical research and development in Canada, the Board itself had identified the need for modernization as early as 2014. The Minister of Health's recognition of this need at the outset of the consultation process signified the government taking up the Board's call for modernization.

[29] The Regulatory Impact Analysis Statement [the RIAS] that accompanied the *Amendments* describes how the pharmaceutical industry has changed significantly since the Board was created, making it more difficult for the Board to fulfill its statutory mandate of identifying and preventing excessive patented medicine prices (*Canada Gazette Part II,* Vol 153, No 17 at 5946-5996).

[30] Specifically, the RIAS notes that patentees are increasingly focusing on high cost patented medicines with few, if any, direct comparators. These types of medicines pose the potential for an increased risk of excessive prices. Further, the PMPRB7 comparator countries were selected on the understanding that price and patent protection were key determinants of the location of worldwide pharmaceutical research and development. The RIAS states that this understanding has not been borne out in reality, and is no longer considered an appropriate basis for selecting comparator countries. Finally, over time the discrepancy between the net prices reported by patentees to the Board and the actual prices and revenues realized by drug companies has increased. The RIAS states that this increase is attributable to the practice of manufacturers

negotiating confidential rebates and discounts with third parties in exchange for having their products listed on public and private formularies.

[31] The Board identified each of these trends prior to the Minister of Health commencing the pre-amendment consultation process. The Board conducted consultation on updating its guidelines to combat these trends, completing the first phase of consultation in October 2016. As explained in the RIAS, simply changing the Board's guidelines could not address underlying limitations in the *Regulations*, and the Board opted not to adopt the proposed guideline changes.

[32] Pursuant to subsection 101(2) of the *Patent Act*, the Minister of Health started a pre-consultation process in May 2017, consulting with her provincial and territorial counterparts and engaging numerous other stakeholders, including innovative and generic pharmaceutical companies, insurers, academics, and patient organizations.

[33] Consultation and refinement of the proposed amendments took place between May 2017 and August 2019. In December 2017, proposed amendments and an accompanying RIAS were published in the *Canada Gazette Part I*, followed by a 75-day consultation period. Roundtable consultation meetings between pharmaceutical industry representatives and Health Canada were held in April 2018, October 2018, and May 2019.

III. Decision Under Review

[34] The decision under review is the Governor in Council's decision to promulgate the Impugned Amendments.

[35] On the recommendation of the Minister of Health, the Governor in Council made the *Amendments* by Order in Council PC 2019-1197, dated August 7, 2019, published in the *Canada Gazette Part II*, on August 21, 2019. By Order in Council PC 2020-413 dated May 30, 2020, the *Amendments* will come into force on January 1, 2021.

[36] The Impugned Amendments at issue are:

i. Section 4 of the *Amendments*, which introduces new section 4.4 of the *Regulations*, requiring the Board to consider three new mandatory economic factors under paragraph 85(l)(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 [the New Mandatory Factors];

ii. Section 6 and the schedule to 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 [the New Price Calculation].

[37] The full text of the Impugned Amendments is included in the Appendix.

[38] The Applicants made a Rule 317 request for the record of the Governor in Council's decision. They were provided with the Order in Council, but other material before the Governor in Council concerning the *Amendments* was withheld as a confidence of the Queen's Privy Council for Canada. That said, the RIAS sets out the rationale for the decision.

[39] The RIAS identifies the issues that led to the *Amendments*: (1) the Board's regulatory framework had not been substantively updated since its inception in 1987; (2) since that time, market changes had eroded the Board's ability to fulfill its mandate, as it was relying on outdated regulatory tools and information that pricing authorities in other countries had long-since updated; (3) because of this outdated regulatory framework, Canada's patented medicines prices were among the highest in the world; and (4) the Board was in need of modernization.

[40] Accordingly, the *Amendments* update the Board's regulatory framework to include new price regulatory factors and patentee information reporting requirements in order to protect Canadian consumers from excessive prices.

[41] Section 4 of the *Amendments* adds three new mandatory factors that the Board must consider in determining whether the price of a patented medicines is "excessive" for the purposes of subsection 85(1) of the *Patent Act*:

> i. The pharmacoeconomic value of the medicine;
>
> ii. The size of the market for the medicine in Canada;
>
> iii. The Gross Domestic Product [GDP] in Canada and GDP per capita in Canada.

[42] Pharmacoeconomic value is a measure of how much a medicine costs for the health benefit it provides. The pharmacoeconomic value for a given medicine can be compared to other medicines or treatments, such as surgery, by using a standard measure of benefit. This factor was selected to allow the Board to take into account the concept of opportunity cost in determining whether a patented medicine price is excessive (RIAS, above at 5954-5955).

[43] The RIAS expressly states that the policy intent behind adding pharmacoeconomic value as a mandatory factory is to require the Board to adopt the perspective of the public health care system (RIAS at 5955):

> Given that the private market for pharmaceuticals in Canada is an offshoot of the public system and cannot function without it, the policy intent is for the PMPRB to adopt the perspective of the public health care system and favour a supply-side cost-effectiveness threshold in estimating opportunity cost.

[44] The RIAS further states that in Canada, consumer protection from excessively priced patented medicines includes the protection of both individual and institutional purchasers.

[45] Patentees will be required to provide the Board with cost-utility analyses prepared by a publicly funded Canadian organization such as the Canadian Agency for Drugs and Technologies in Health [CADTH] or the Institut national d'excellence en santé et services sociaux [INESSS]. CADTH and INESSS specialize in clinical and economic evaluation of medicines and their cost-utility analyses help inform coverage and reimbursement decisions made by public drug plans. Both organizations communicate their reports to patentees. This reporting requirement only applies to medicines whose annual cost exceeds 50% of Canada's GDP per capita, and patentees are not required to prepare a cost-utility analysis if one does not already exist (RIAS at 5959-5960).

[46] Market size was added to ensure that the Board considers the economic impact of paying for the medicine for everyone who needs it, and to allow the Board to reassess prices of patented medicines as market size changes over time (RIAS at 5956).

[47] Patentees must provide the Board with the estimated maximum use of the patented medicine in Canada as measured by the quantity of the medicine that is estimated to be sold in final dosage form (RIAS at 5961).

[48] GDP is considered an indicator of overall societal wealth, and GDP per capita can be viewed as an indicator of individual wealth within that society. GDP and GDP per capita were added as mandatory factors under subsection 85(1) to serve as a rough proxy for what the entire Canadian population and individual consumers, respectively, can afford to pay for new patented medicines that come to market (RIAS at 5956).

[49] Overall, the New Mandatory Factors and the corresponding reporting requirements are intended to enable the Board to assess the economic impact of a patented medicine's price on both insurers and individual consumers. With this information in hand, the Board will be empowered to develop screening criteria and market size tests for medicines that are likely to pose affordability challenges to the health care system as a whole (RIAS at 5957).

[50] Section 6 of the *Amendments* updates the schedule of countries for which patentees must report publicly available ex-factory prices to the Board. Switzerland and the United States were removed from the previous list, and Australia, Belgium, Japan, the Netherlands, Norway, and Spain were added. France, Germany, Italy, Sweden, and the United Kingdom remain on the list. The new list of countries is referred to as the PMPRB11.

[51] The schedule of countries was updated to better align with the Board's consumer protection mandate and the federal government's commitment to improve affordability of

prescription drugs in Canada. Three criteria were used to select the new basket of countries: policy measures constraining free market pricing, similar economic standing to Canada, and similar market characteristics to Canada, such as population, consumption, and access to medicines containing new active ingredients (RIAS at 5957).

[52] Subsection 3(4) of the *Amendments* changes how patentees report prices and revenues to the Board. Patentees will be required to report the actual price obtained for the medicine, taking into account any adjustments made by the patentee or any party that directly or indirectly purchases the medicine or reimburses for the purchase of the medicine. The actual price obtained must also take into account any reduction given to any party in the form of free goods, free services, gifts or any other similar benefit.

[53] The current reporting requirements only require patentees to report information on price adjustments for the first point of sale, referred to as the “ex-factory” or “factory-gate” price. Patentees are not required to report rebates and discounts they may provide to third party insurers, such as public drug plans, that reimburse consumers for the cost of a medicine. According to the RIAS and the Respondent, the new reporting requirement to deduct adjustments such as indirect rebates will allow the Board to better understand the actual prices patentees charge for medicines.

[54] The *Amendments* also reduce reporting requirements for patented veterinary, non-prescription, and “generic” drugs. The Applicants do not challenge this aspect of the *Amendments*.

IV. Evidence

[55] The Applicants submitted affidavits from four expert witnesses and three fact witnesses. The Respondent submitted affidavits from two fact witnesses. None of the witnesses were cross-examined, so all of the evidence is uncontroverted.

[56] The Respondent's fact evidence predominantly details the legislative history of the Patented Medicines Regime and the consultation process that took place in the lead up to promulgation of the *Amendments*. The Applicants' fact evidence describes some of the same history, but also details how medicines are sold and reimbursed in Canada, and how the *Amendments* will affect pharmaceutical patentees.

[57] The Applicants filed affidavits from the following expert witnesses:

- **Wayne Critchley, Executive Director of the Board from 1990–2005**. Mr. Critchley gave evidence on the origins of the Board and its regulatory mandate and operation;
- **Dr. Pierre-Gerlier Forest, Director of the School of Public Policy at the University of Calgary**. Dr. Forest gave evidence on the Canadian health care system, the genesis of the *Amendments*, and the impact of the Impugned Amendments on the role of the Board;
- **Dr. Jean Lachaine, professor of Pharmacy at the University of Montreal.** Dr. Lachaine gave evidence describing pharmacoeconomics, and how it is already used in the Canadian health care system;
- **Dr. Ian Cockburn, business school professor at Boston University.** Dr. Cockburn opined on the economic benefits of the patent monopoly, the role of reference pricing, and the consequences of the Impugned Amendments.

[58] The Respondent alleges the Applicants' expert opinion evidence is largely irrelevant as it is directed towards the purported *effect* of the *Amendments* and the wisdom of the policy choices upon which they are based, rather than whether the Impugned Amendments are consistent with the purposes of the enabling legislation.

[59] In general, I agree with the Respondent. Some of the expert evidence assists in understanding the complex patented medicine market in Canada, but much of the relevant context is also included in the Applicants' fact evidence. To the extent the expert evidence canvasses policy considerations and potential effects of the *Amendments* on the pharmaceutical industry in Canada, it is beyond the scope of this application. As will be discussed further below, a *vires* challenge inquiry does not involve assessing the policy merits of the regulations at issue.

V. Issue

[60] The issue is whether the Impugned Amendments are *ultra vires* the *Patent Act*.

VI. Standard of Review

[61] In *Canada (Minister of Citizenship and Immigration) v Vavilov*, a majority of the Supreme Court of Canada [Supreme Court] held that it would "cease to recognize jurisdictional questions as a distinct category attracting correctness review" (2019 SCC 65 at para 65 [*Vavilov*]). Prior to *Vavilov*, the issue of whether a regulation had been enacted within the jurisdiction of its enabling statute was treated as a legal question attracting the correctness standard (*Portnov v Canada (Foreign Affairs)*, 2018 FC 1248 at paras 25-26, citing *Canadian Council for Refugees v Canada*, 2008 FCA 229 at para 57).

[62] Pursuant to *Vavilov*, determination of the standard of review begins with a presumption that reasonableness is the applicable standard in all cases. None of the exceptions to this presumption apply here, and therefore the standard of review when considering the exercise of the Governor in Council's regulation-making authority is reasonableness (*Vavilov*, above at paras 23, 66-68).

[63] For the reasons that follow, I find that:

A. The Impugned Amendments in sections 4 and 6, and the schedule to the *Amendments* are *intra vires* the *Patent Act*.

B. The Impugned Amendment in subsection 3(4) of the *Amendments* is *ultra vires* the *Patent Act*.

VII. Analysis

[64] Reasonableness review is not merely a "rubber-stamping" process. It remains a robust form of review, responsive to context (*Vavilov* at paras 13, 67). Reasonableness review does not give administrative decision makers license to enlarge their powers beyond what the legislature intended. When applying the reasonableness standard to a decision maker's interpretation of its authority, precise or narrow statutory language will necessarily limit the number of reasonable interpretations open to the decision maker (*Vavilov* at para 68).

[65] In cases such as this where no formal reasons are given, the Court must look to the record as a whole to understand the decision (*Vavilov* at para 137). The assessment of reasonableness in the present case must focus on the relevant factual and legal constraints around the Governor in Council's exercise of her delegated powers (*Vavilov* at para 105). In a challenge to the *vires* of

regulations, the governing statutory scheme, principles of statutory interpretation, and other statutory and common law are particularly relevant (see *Vavilov* at para 106 for a non-exhaustive list of elements that are generally relevant in conducting reasonableness review).

[66] While *Vavilov* establishes a general framework for substantive review of administrative decisions that applies to a wide variety of decision makers, in the context of a *vires* challenge, other Supreme Court precedents where statutory grants of authority were at issue remain relevant (*Katz Group Canada Inc v Ontario (Health and Long-Term Care)*, 2013 SCC 64 at para 24 [*Katz*]; *Catalyst Paper Corp v North Cowichan (District)*, 2012 SCC 2; *Green v Law Society of Manitoba*, 2017 SCC 20; *West Fraser Mills Ltd v British Columbia (Workers' Compensation Appeal Tribunal)*, 2018 SCC 22 [*West Fraser Mills*]).

[67] In *Katz*, the Supreme Court concisely detailed the appropriate approach to considering a challenge to the *vires* of regulations.

[68] As a starting point, regulations benefit from a presumption of validity. This presumption places the burden on challengers to demonstrate the invalidity of regulations. This is consistent with the teaching in *Vavilov* that the burden lies on the Applicants to show the decision to promulgate the regulations was unreasonable (*Vavilov* at para 100). Further, the presumption of validity favours an interpretive approach that reconciles the impugned regulation with its enabling statute (*Katz*, above, at para 25).

[69] A successful challenge to the *vires* of regulations requires the challenging party to show that the regulations are inconsistent with the objective of the enabling statute or the scope of the

statutory mandate. The test for conformity with the enabling statute is not necessarily satisfied by merely showing that the decision maker stayed within the literal terms of the power-conferring provision. The power-conferring language is qualified by the overriding requirement that the regulations accord with the purposes and objects of the enabling statute read as a whole (*Katz* at para 24).

[70] The Court must take a broad and purposive approach to interpreting the challenged regulation and the enabling statute, consistent with the Supreme Court's guidance on statutory interpretation generally (*Katz* at para 26).

[71] A *vires* challenge does not involve assessing the policy merits of the regulations. The motives for promulgation of the regulations are irrelevant, and the Court is not inquiring into the underlying political, economic, social, or partisan considerations (*Katz* at paras 27-28).

[72] Regardless of whether the Court believes the regulations will actually succeed in achieving the statutory objectives, the challenging party must establish that the regulations are "irrelevant", "extraneous", or "completely unrelated" to the statutory purpose to be *ultra vires* on the basis of inconsistency with statutory purpose (*Katz* at para 28).

[73] In light of the relevant constraints on the Governor in Council's regulation-making authority, the Applicants made arguments directed at both the scope of the Governor in Council's mandate, and the purpose of the *Patent Act*. I find it helpful to characterize each argument as a "scope" argument or a "purpose" argument in order to focus on the essential nature of the attacks on each Impugned Amendment.

[74] The Applicants make four principal arguments:

i. The Impugned Amendments as a whole are unrelated to the purpose of the *Patent Act* [a purpose argument];

ii. The New Mandatory Factors are both inconsistent with the purpose of the *Patent Act*, and were promulgated by the Governor in Council exceeding the scope of her mandate under sections 85 and 101 of the *Patent Act* [purpose and scope arguments];

iii. The purpose of selecting the PMPRB11 was to import price controls into the *Patent Act*, and this purpose is inconsistent with the purpose of the *Patent Act* [a purpose argument];

iv. The Governor in Council exceeded the scope of her regulation-making authority by enacting the New Price Calculation. This Court, in *Pfizer*, has already determined the issue of whether the Board has jurisdiction over third party payment information, and the analysis in that case is applicable to the facts in this case [a scope argument].

[75] As discussed below, I find that the "improper purpose" arguments must fail, and the scope argument related to the New Mandatory Factors must also fail. However, the Applicants have satisfied me that the New Price Calculation exceeds the scope of the Governor in Council's regulation-making authority in the context of the scheme of the *Patent Act*, the Patented Medicines Regime within that *Act*, and the legislative intent that bears on the purposive approach to the impugned amendment.

A. *The Purpose of the Enabling Statute*

[76] The policy rationale underlying the *Patent Act* is the patent bargain, or *quid pro quo*. The patent bargain encourages innovation by offering an inventor exclusive rights in a new and useful invention for a limited period in exchange for disclosure of the invention so that society

can benefit from this knowledge (*Teva Canada Ltd v Pfizer Canada Inc*, 2012 SCC 60 at para 32). Two central objectives of the *Patent Act* as a whole are to "advance research and development and to encourage broader economic activity" (*Free World Trust v Électro Santé Inc*, 2000 SCC 66 at para 42; *Harvard College v Canada (Commissioner of Patents)*, 2002 SCC 76 at para 185 [*Harvard College*]).

[77] As acknowledged by both the Applicants and the Respondent, patent monopoly rights are not unlimited, and Parliament has at times balanced promotion of ingenuity against other considerations (*Harvard College*, above, at para 185). Parliament implemented the Patented Medicines Regime to ensure that patentees of medicines do not abuse their statutory monopoly by charging excessive prices for those medicines (*Canada (Attorney General) v Galderma Canada Inc*, 2019 FCA 196 at para 10 [*Galderma*]).

[78] While the Respondent takes issue with characterizing "excessive pricing" as abuse, arguing that patent abuse is a separate concept dealt with in section 65 of the *Patent Act*, the Board and Health Canada have used this exact language to describe the Board's mandate (*Genentech Canada Inc, Re* (1992), 44 CPR (3d) 316 at 328–329; *Canada Gazette Part I*, Vol 151, No 48 at 4500). Moreover, the Courts have endorsed this framing of the Board's mandate (*Manitoba Society of Seniors Inc v Canada (Attorney-General)*, 1991 CanLII 8289 (MB QB), aff'd 1992 CanLII 8541 (MB CA); *Galderma*, above, at para 10).

[79] The Supreme Court has referred to the Board's purpose as one of consumer protection, noting that Parliament's intent in creating the Board was "to address the 'mischief' that the patentee's monopoly over pharmaceuticals during the exclusivity period might cause prices to

rise to unacceptable levels" (*Celgene Corp v Canada (Attorney General)*, 2011 SCC 1 at para 28 [*Celgene*], quoting with approval from *ICN Pharmaceuticals Inc v Patented Medicine Prices Review Board*, 1996 CanLII 11903 (FC), aff'd 1996 CanLII 4089 (FCA)).

[80] The Supreme Court endorsed an approach to the Board's mandate that takes into account its "responsibility for ensuring that the monopoly that accompanies the granting of a patent is not abused to the financial detriment of Canadian patients and their insurers" (*Celgene*, above, at para 29).

[81] That said, I agree with the Respondent that the jurisprudence does not suggest that Courts have equated the "abuse" of excessive pricing with "patent abuse" under section 65 of the *Patent Act*. Instances of "patent abuse" and the powers of the Commissioner of Patents in such cases are detailed in sections 65 and 66 of the *Patent Act*. The Board's mandate is limited to the specific and separate "abuse" of excessive pricing, and the powers conferred on the Board are limited to those found in sections 79 to 103 of the *Patent Act*.

[82] This Court has considered the statutory purpose of a distinct division of a statute when determining *vires* (*Syncrude Canada Ltd v Canada (Attorney General)*, 2014 FC 776 at paras 131-135, aff'd 2016 FCA 160). While the *Patent Act* is not divided into Parts and Divisions in the same way as the enabling statute at issue in *Syncrude*, the Patented Medicines Regime is, effectively, a distinct division of the *Patent Act* with its own definitions, applicable only to patented medicines. Further, the Minister responsible for the Patented Medicines Regime is the Minister of Health, whereas the Minister of Industry is generally responsible for other aspects of the *Patent Act*.

[83] The focus should be on the purpose of the Patented Medicines Regime within the context of the purpose of the *Patent Act* as a whole.

[84] The legislative history establishes that the Patented Medicines Regime was intended to strike a balance between competing policy objectives in the *Patent Act*. Increased patent protection extended to patentees of medicines in 1987 and 1993 were balanced with increased consumer protection, intended to ensure that Canadian consumers are protected from the abuse of excessively priced patented medicines, such that prices remain reasonable and affordable to Canadians.

[85] However, in striking that balance, Parliament never intended for the Board to set prices (*Pfizer*, above, at para 11; *Sanofi*, above, at para 17). The Board is not empowered to control or lower prices absent a finding of excessive pricing, based on the factors set out in the *Patent Act*. To this point, the Honourable Harvie Andre made the following statements during 1986 Legislative Committee meetings leading up to the Board's creation:

> We do not constitutionally have the ability in Canada of setting prices at the federal level. But again, it is worth repeating that it is not right to say there are not strong price control mechanisms in Canada; there are. They are at the provincial level. Through the fact that they purchase 60% of the drugs, have formularies in some provinces, and can have laws that direct that pharmacists must provide the lowest cost equivalent, and through the bulk purchasing and so on, the net result is that we do have in fact a price control system in Canada.
>
> [Emphasis added]
>
> (*House of Commons Minutes of Proceedings and Evidence of the Legislative Committee on Bill C-22*, 33-2, No 1 (December 11 and 16, 1986) at 41 (Hon Harvie Andre))

[86] Minister Andre further commented on how the Board's role is limited to exercising powers in relation to patentees:

> We have legal opinion that indeed it is constitutionally valid based on the following reasons. The federal government has, under subsection 91.22 of the Constitution Act, jurisdiction over patents. In conformity with this jurisdiction, the board exercises powers in relation to patentees and its sanction is revoking patent exclusivity. This is what the board is doing.
>
> The board is not setting prices; it is exercising the authority of the federal government in terms of exclusivity.
>
> [Emphasis added]
>
> (*House of Commons*, Legislative Committee on Bill C-22, *Minutes of Proceedings and Evidence*, 33-2, No 16 (February 18 and 19, 1987) at 68 (Hon Harvie Andre))

[87] In Senate Committee proceedings on the bill creating the Board, Mr. George Redling, Chief of Legal Analysis-Intellectual Property in the Department of Consumer and Corporate Affairs stated that the Board does not purport to fix or set prices:

> The board does not purport to fix prices or control prices by setting a price at which a medicine may be sold. The board attempts to deal with abuse. It is the abuse of the monopoly granted to the patentee, not price-fixing, in which the board is involved.
>
> (*Senate*, Special Committee on Bill C-22, *Proceedings*, 33-2, No 19 (July 7, 1987) at 20 (George Redling))

[88] This commentary from government actors leading up to the Board's creation indicates that Parliament did not intend for the Board to engage in setting prices for patented medicines, but rather, that the Board would address the abuse of excessive pricing of patented medicines.

[89] The jurisprudence aligns with the legislative history. Decisions of the Supreme Court and Federal Court of Appeal have been consistent: the purpose of the Patented Medicines Regime is

to ensure that patentees of medicines do not abuse their patent monopolies by charging consumers excessive prices. The Board, created by Parliament as part of this regime, operates to balance the promotion of innovation with measures to protect institutional and individual consumers from excessive patented medicines prices.

B. *The Purpose of the Amendments*

[90] While the Applicants challenge three specific aspects of the *Amendments*, the Court must consider the purpose of the *Amendments* as a whole. A purposive interpretation of the Impugned Amendments necessitates reading them in the context of the entirety of the *Patent Act*, to provide a proper framework for determining their *vires* within the scheme of the *Patent Act*.

[91] Determining whether the regulations at issue represent a reasonable exercise of delegated power is, at its core, an exercise in statutory interpretation, considering the text, context, and purpose of the laws (*West Fraser Mills*, above, at para 12). The Court must take a broad and purposive approach to interpreting the challenged regulation and the enabling statute, consistent with the Supreme Court's guidance on statutory interpretation generally (*Katz* at para 26).

[92] The Court can consider the RIAS accompanying regulations in determining the purpose of the regulations and their intended application (*Bristol-Myers Squibb Co v Canada (Attorney General)*, 2005 SCC 26 at para 157). The RIAS sets out the purpose of the *Amendments* as follows (RIAS at 5954):

> The purpose of these Amendments is to equip the PMPRB with the regulatory tools and information reporting authorities it needs to effectively protect Canadian consumers from excessively priced patented medicines in today's regulatory environment.

[93] The Applicants submit that the Impugned Amendments have no connection to patent abuse—the term is not even mentioned in the RIAS—and the animating purpose of the *Amendments* is to deliver health care savings and pave the way for national pharmacare. As discussed above, the purpose of the Patented Medicines Regime of the *Patent Act* is not to prevent patent abuse in general, but to prevent the specific abuse of excessive pricing of patented medicines. The purpose of the *Amendments* as stated in the RIAS is consistent with the Board's consumer protection mandate to prevent excessive pricing. However, other telling statements made by the federal Minister of Health and Health Canada paint a different purpose beyond controlling excessive pricing.

[94] In a May 2017 letter to the Ontario Minister of Health and Long-Term Care, the federal Minister of Health noted the federal government's commitment to using the regulatory framework that guides the Board's work to lower high drug prices:

> At our January 2016 Health Ministers' Meeting, we committed to taking concrete action to advance our shared interest in improving the affordability, accessibility and appropriate use of prescription drugs. Within federal jurisdiction, this includes lowering high drug prices through modernization of the regulatory framework that guides the work of the Patented Medicine Prices Review Board (PMPRB).
>
> [Emphasis added]
>
> (Exhibit K to the January 9, 2020 Affidavit of Karen Reynolds)

[95] Similar language is found in a May 2017 Health Canada Consultation Document:

> 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;

> […]
>
> [T]he PMPRB's current regulatory framework does not provide it with adequate tools to effectively protect Canadians from excessive prices, or for optimal price setting in today's pharmaceutical environment. That is why Health Canada is advancing the proposed amendments for consultation.
>
> [Emphasis added]
>
> (Exhibit E to the October 3, 2019 Affidavit of Dr. Forest)

[96] The Applicants particularly take issue with Health Canada's framing of the Board as a regulatory tool for "optimal price setting". That said, the final articulation of the government's intention in the RIAS suggests that the Board is to use the tools at its disposal to set a non-excessive price ceiling applicable to all Canadian consumers, as opposed to setting "ideal" prices for different types of consumers (RIAS at 5954):

> Given the PMPRB's mandate and status as a federal regulator, the intention is for the Board to use these tools in order to identify a national ceiling price above which it would be unreasonable for any consumer in Canada to pay, as opposed to an ideal price for different types of consumers having regard to their individual ability and willingness to pay.
>
> [Emphasis added]

[97] The Applicants further refer to the following statement made by the federal Minister of Health during Commons Debates in June 2019 as evidence of the government's true intentions:

> We are in the process of modernizing the Patented Medicine Prices Review Board in order to once again make sure we lower the cost of drugs and are able to move forward with this program.
>
> (*House of Commons Debates*, 42-1, Vol 148, No 433 (June 13, 2019) at 29103 (Hon Ginette Petitpas Taylor))

[98] On this point, the Respondent submits that motives of the Minister of Health should not be imputed to the Governor in Council, relying on *Canadian Union of Public Employees v Canada (Attorney General)*, 2018 FC 518 at paragraph 146 – a case about legitimate expectations. Based on the record before the Court, the only material definitively before the Governor in Council when she promulgated the *Amendments* was the regulatory package, consisting of the *Amendments* themselves and the RIAS. Conversely, the Applicants submit that the Court may consider the Minister's comments, so long as these comments have "an institutional quality" (*Airport Taxicab (Pearson Airport) Association v Toronto (City)*, 2009 CanLII 25973 (ON SC)).

[99] As previously noted, the Minister and the Governor in Council are separate entities, and the decision under review is that of the Governor in Council. That said, the Minister's comments describing modernizing the Board to "lower the cost of drugs" are consistent with the explanation for the *Amendments* found in the RIAS, which states that the *Amendments* "contribute to the Government's commitment [to improve the accessibility, affordability, and appropriate use of medicines] by lowering the prices of patented medicines in Canada" (RIAS at 5949). Therefore, these comments are not merely reflective of the Minister of Health's individual concerns or motivations, but reflect the broader institutional intent of the Governor in Council.

[100] The comments made by the Minister of Health and in the RIAS with respect to lowering the prices of patented medicines in Canada must be read in the context of the rest of the RIAS. As quoted above, the stated purpose of the *Amendments* is to modernize the Board with the necessary regulatory tools to effectively protect Canadian consumers from excessive patented medicines prices (RIAS at 5954).

[101] The purpose statements in the RIAS recognize the Board's mandate to lower prices only where it finds a patentee has abused its monopoly by charging excessive prices for a patented medicine. The Minister's comments and statements in the RIAS related to lowering drug prices must be read in this context. Lower drug prices may have been a motivating factor leading to the *Amendments*, but this is an issue of "economic policy and politics", beyond the scope of this application (*Thorne's Hardware Ltd v The Queen*, [1983] 1 SCR 106 at 115 [*Thorne's Hardware*]; *Katz* at paras 27-28).

[102] The parties blurred the lines between the "purpose" of the *Amendments* and the "motives" that led to their promulgation. While the motives for promulgating the *Amendments* are irrelevant to this judicial review, a given factor could be both a motive and a purpose. Fully disentangling motive from purpose may not always be possible. It is the purpose of the *Amendments* and scope of the Governor in Council's regulation making authority that are key in determining whether any of the proposed *Amendments* may be *ultra vires*.

[103] The purposes for promulgating a regulation may be multifaceted (*Thorne's Hardware*, above at 117). In the present case, much like in *Thorne's Hardware*, the lowering of patented medicines prices is clearly one factor that prompted the *Amendments*. That said, even if this were considered a "purpose" of the *Amendments* for the purposes of the *vires* analysis, lowering prices was not the sole reason for the *Amendments*. The *Amendments* update the Board's arsenal of regulatory tools and information reporting authority in order to effectively protect Canadian consumers from excessively priced patented medicines. In the words of the Respondent, "recognition that the Amendments may result in cost savings does not mean it must be their purpose".

[104] Having considered the *Amendments*, the RIAS, and the extrinsic evidence from the Minister of Health and Health Canada, the purpose of the *Amendments* is to modernize the Board with new regulatory tools and information reporting authority, and to lower patented medicines prices to protect Canadian consumers from the abuse of excessively pricing.

[105] The Applicants also submit that the *Patent Act* should be read to conform to Canada's international treaty obligations, and the *Amendments* are inconsistent with these obligations. Specifically, the Governor in Council's regulation-making authority is constrained by the prohibition on discrimination based on field of technology contained in the *Agreement on Trade-Related Aspects of Intellectual Property Rights* [TRIPS] and the *North American Free Trade Agreement* [NAFTA]. The Respondent submits that these international agreements provide minimum standards of protection, and Canada's patent regime is fully compliant.

[106] International treaties, even those not implemented domestically by statute, can help inform whether an administrative decision was reasonable (*Vavilov* at para 114). Article 27 of TRIPS states that "patents shall be available and patent rights enjoyable without discrimination as to […] the field of technology". Pursuant to Article 28, the minimum rights conferred on a patent owner are the exclusive rights of making, using, offering for sale, selling, or importing the patented invention. These rights are enshrined in Canadian law in section 42 of the *Patent Act*.

[107] Notably, section 42 of the *Patent Act* and Article 28 of TRIPS do not guarantee patentees the right to charge whatever price they would like for their patented inventions. I agree with the Applicants that one benefit generally conferred by a patent is the ability to charger a higher "monopoly" price, but this benefit is not an unrestricted right.

[108] Therefore, the Board's jurisdiction to prevent excessive pricing of patented medicines does not offend Article 27 of TRIPS, as the alleged discrimination does not target a right to which patentees of medicines are entitled. NAFTA Article 1709 includes nearly identical language to TRIPS Articles 27 and 28.

[109] The Applicants do not appear to suggest that the Board's powers to regulate excessive pricing of patented medicines as exercised up until 2019 breached Canada's international obligations. This alleged "discrimination" against patented medicines as compared to other fields of technology has clearly been present since the Board's inception. I am satisfied that the *Amendments* comply with Canada's international obligations under TRIPS and NAFTA.

[110] The Applicants make further arguments about the factory-gate limits of the Board's jurisdiction, and I will address these below in connection with the New Price Calculation.

[111] I find the purpose of the *Amendments* related to the New Mandatory Factors under section 4 of the *Amendments*, and the PMPRB11 under section 6 and the schedule to the *Amendments* is sufficiently connected to and consistent with the purpose of the Patented Medicines Regime in the context of the *Patent Act*: protecting consumers from the abuse of excessive pricing. Each Impugned Amendment is discussed further below.

C. *The Impugned Amendments*

(1) Section 4 of the *Amendments*: the New Mandatory Factors

[112] Section 4 of the *Amendments* adds New Mandatory Factors that the Board must consider in determining whether the price of a patented medicines is "excessive" for the purposes of subsection 85(1) of the *Patent Act*:

i. The pharmacoeconomic value of the medicine;

ii. The size of the market for the medicine in Canada;

iii. The GDP in Canada and GDP per capita in Canada.

[113] The Applicants submit that the New Mandatory Factors constitute an unreasonable exercise of the Governor in Council's regulation-making authority under paragraphs 85(1)(e) and 101(1)(d) of the *Patent Act*. Their two primary submissions are that the New Mandatory Factors undermine the objects of the *Patent Act* and the Board's jurisdictional limits, and are inconsistent with the governing statutory scheme, particularly section 85 of the *Patent Act*.

(a) *Pharmacoeconomic Value – consistency with the object of the Patent Act*

[114] As previously discussed, pharmacoeconomic value is a measure of how much a medicine costs for the health benefit it provides, and this measure for a given medicine can be compared to other medicines or treatments. Pharmacoeconomic value provides information on the *relative* value of a drug as compared to other treatment options. A commonly used standardized unit of pharmacoeconomic value is the "quality-adjusted life year" or "QALY". As explained by Dr. Lachaine, "cost-per-QALY", which is the cost to deliver one additional year of life in perfect

health, can be used to estimate the cost effectiveness of a drug. Public and private insurers will often use a cost-per-QALY threshold to set a limit on drug coverage, refusing to cover drugs that exceed the threshold. Dr. Lachaine's evidence is that if the Board is to use pharmacoeconomic value to drive pricing decisions, it must use a cost-per-QALY threshold.

[115] The Applicants submit that the new mandatory pharmacoeconomic value factor requires the Board to make systemic judgments on value for all Canadians; a role entirely unrelated to its statutory mandate to regulate patent abuse through excessive pricing of patented medicines. In the Applicants' view, inputs related to pharmacoeconomic value relate to policy decisions that have nothing to do with the patent grant or any action by the patentee that could be considered abusive, and this factor is therefore irrelevant to the statutory role of the Board. I again note that the Applicants repeatedly refer to patent abuse in general, which obscures the Board's actual mandate of preventing and regulating the specific abuse of excessive pricing.

[116] CORD makes a similar submission on this point, arguing that the intention of adding economic-based factors is to cause significant price reductions for patented medicines, unrelated to whether prices were excessive. CORD suggests that this approach will reduce the incentive offered by the patent bargain in the name of generally lowering patented medicines prices.

[117] The Applicants suggest the RIAS supports their position that the pharmacoeconomic value factor was chosen to "bring national pharmacare to Canada" (RIAS at 5955):

> It is often noted that Canada is the only country with a publicly funded health care system that does not include universal pharmaceutical coverage. The result is a patchwork of public and private payers who lack the national buying power to counter the monopoly position of patentees. That monopoly position is bolstered by an increasing proportion of public and private

> spending that is taken up by high-cost medicines with few or no therapeutic alternatives. Requiring the PMPRB to consider the pharmacoeconomic value of these medicines will ensure that the concept of opportunity cost is taken into account in determining whether their price is excessive.

[118] In my view, the Applicants misinterpret this passage from the RIAS, and misconstrue the relevance of pharmacoeconomic value to a determination of excessive pricing. As argued by the Respondent, assessing pharmacoeconomic value is an objective exercise using a standardized measure of benefit. Such an exercise could justify higher prices for patented medicines that offer pharmacoeconomic value. As noted in the RIAS, this factor becomes more relevant for high-cost medicines with few or no therapeutic alternatives. Where the Board has limited reference pricing information available, it is limited in how it can conduct its excessive pricing determination. Recognizing this limitation, the Governor in Council introduced this new factor and corresponding reporting requirement.

[119] Further, the Applicants and CORD both focus on pharmacoeconomic value as if it will be used as a standalone factor. CORD submits that the Board will overtake the role of CADTH and INESSS by using fixed cost-per-QALY thresholds, ultimately picking “winners and losers” unrelated to whether a medicine has been priced excessively. This position overlooks the fact that the Board must consider pharmacoeconomic value alongside all the other mandatory factors – none of the factors are looked at in isolation. Otherwise, any decision of the Board could be reviewed on the basis of being unreasonable for failing to consider all mandatory factors.

[120] The Board must consider each subsection 85(1) factor, and cannot ignore any one factor, or allow any one factor to dominate such that other factors are rendered irrelevant (*Teva*

Neuroscience GP-SENC v Canada (Attorney General), 2009 FC 1155 at para 47). The three New Mandatory Factors complement the four pre-existing factors in subsection 85(1). The weight given to any given factor by the Board will depend on the facts of each case.

[121] The remainder of CORD's submissions are ultimately connected to the pharmacoeconomic value factor. CORD suggests that by implementing this factor, the Board will make policy decisions applying value-based price ceilings to patented medicines, and these decisions will have a disproportionately negative impact on patients with rare disorders due to the difficulty in determining the cost-effectiveness of treatments for rare disorders.

[122] Dr. Lachaine opines that some medicines may only treat a small patient pool and may provide only limited health improvements, but are nevertheless considered highly valuable in that particular disease space. CORD's concern is that for small patient population sizes—inherent to rare diseases—price ceilings will be based on inaccurate estimates of value due to scarce data, and patentees may be unwilling to market medicines for these disorders in Canada due to the prohibitively low price ceilings.

[123] Further, CORD submits that the *Amendments* will inevitably result in reduced access to medicines for the treatment of rare disorders and fewer clinical trials being conducted in Canada; results that are inconsistent with the purpose of the *Patent Act* and the *Amendments*.

[124] I agree with the Respondent that each of these submissions is speculative, and outside the scope of a *vires* challenge. The Court's view of whether the *Amendments* will succeed in achieving the statutory objectives is irrelevant (*Katz* at para 28). Much of CORD's submissions

mirror the position it took during stakeholder consultation with the Minister of Health, and the RIAS explains that the international evidence does not support the suggestion that patentees will delay market entry in Canada due to the *Amendments*. A *vires* challenge is not an opportunity to litigate policy issues explored with stakeholders in the consultation process.

(b) *Market Size and GDP – consistency with the object of the Patent Act*

[125] With respect to market size and GDP, the Applicants submit that these factors address affordability, requiring the Board to consider the impact of the cost of the drug across all patients and the average Canadian's ability to pay. These matters, the Applicants say, are unrelated to the reference pricing scheme in the *Patent Act* and inconsistent with the patent bargain. To this point, Dr. Cockburn—a business professor—opines that the patent monopoly allows the patentee to make its own pricing decisions, and these decisions may affect the ability of some to purchase the product.

[126] I find the Applicants' arguments unpersuasive, and Dr. Cockburn's opinion misses the mark.

[127] While the patent monopoly allows patentees to price their products in a competition-free environment, patentees of medicines do not have unfettered pricing discretion. They must comply with Parliament's excessive pricing scheme as contained in the Patented Medicines Regime and implemented by the Board. The prevention of excessive patented medicines prices comes within Parliament's jurisdiction over patents under subsection 91(22) of the *Constitution Act 1867* (*Canada (Attorney General) v Sandoz Canada Inc*, 2015 FCA 249 at para 116

[*Sandoz*]; *Alexion Pharmaceuticals Inc v Canada (Attorney General)*, 2017 FCA 241 at para 61 [*Alexion FCA*]).

[128] In *Katz*, the Supreme Court found it is "somewhat ethereal to speak of a commercial 'right' to trade in a market as highly regulated as is the pharmaceutical market in Ontario", noting that the relevant legislation expressly authorised interference with a manufacturer's ability to enter and remain in the market (*Katz* at para 44). Similarly, patentees of medicines do not have a general "right" to make their own pricing decisions in Canada. The Patented Medicines Regime, validly enacted pursuant to Parliament's constitutional jurisdiction over patents, expressly authorises the Board to monitor, and when necessary challenge, a patentee's ability to set prices based on what the Board determines to be excessive, and expressly authorises the Governor in Council to make regulations that the Board must consider in making its determination.

[129] The Board's consumer protection mandate is intended to ensure patent monopolies are not abused to the financial detriment of Canadians (*Celgene* at paras 28-29). This mandate places the focus on the consumer, and is directly connected to affordability. This point was recognized by the Honourable Harvie Andre in the House of Commons debates leading up to the Board's creation:

> There is the question of consumer protection. What good would come of it if we had all kinds of new drugs and no one could afford them? If the sick and elderly could not get access to the drugs, what good would come of it?
>
> […]
>
> I humbly submit that anybody who takes an objective view of what we are proposing will see that we have in place enormous checks

> and balances to ensure that consumer prices of drugs remain reasonable…
>
> (*House of Commons Debates*, 33-2, Vol 1 (November 20, 1986) at 1371 and 1373 (Hon Harvie Andre))

[130] Moreover, the Applicants' position centres on the reference pricing factors specified in paragraphs 85(1)(a) through (d). As part of the 1993 *Patent Act* amendments, Parliament contemplated that further factors may be required over time to enable the Board to fulfill its mandate, and thus empowered the Governor in Council to make new regulations specifying factors for the purposes of subsection 85(1) on the recommendation of the Minister of Health. Pursuant to paragraph 85(1)(e), any such factors must be considered by the Board in determining whether a patentee sold a medicine at an excessive price. In this way, gaps in the Board's ability to fulfill its mandate can be addressed efficiently by way of regulations (*West Fraser Mills* at para 20).

(c) *Inconsistency of the New Mandatory Factors with the statutory scheme*

[131] Finally, the Applicants submit that the text and structure of the *Patent Act* support a finding that the Governor in Council exceeded the scope of her regulation-making authority by promulgating the New Mandatory Factors. In support of this position, they say that section 85 of the *Patent Act* was drafted with the clear intent that the Board is to make assessments based on factors related to price, and price only. The Applicants invoke principles of statutory interpretation, specifically the *ejusdem generis* rule, to argue that Parliament intended to limit the scope of the Governor in Council's authority to make regulations specifying factors for the purposes of subsection 85. Specifically, the Applicants argue that any new subsection 85(1) factor must be rationally connected to the reference pricing scheme set out in subsection 85(1).

[132] For the following reasons, I disagree.

[133] The governing statutory scheme is likely “the most salient aspect of the legal context” relevant to the administrative decision (*Vavilov* at para 108). Whether an administrative decision maker’s interpretation of its statutory grant of authority is justified will depend on the context, including the language chosen by the legislature in defining the scope of the decision maker’s authority (*Vavilov* at para 110).

[134] At issue is the scope of the Governor in Council’s regulation-making authority, as found in section 101 of the *Patent Act*. The decision under review is that of the Governor in Council, not the Board. As previously noted, these are different entities with separate roles and powers within the Patented Medicines Regime.

[135] While *Vavilov* directs reviewing courts to consider whether the decision maker has properly justified its interpretation of its statutory grant of authority in light of the surrounding context, in cases such as this, there are no reasons for the Court to review. The most this Court can deduce from the Order in Council is that the Governor in Council quite clearly believed she had the authority to make the *Amendments* pursuant to subsection 101(1) of the *Patent Act*. The Court must therefore determine whether this interpretation was reasonable, having regard to the text, context, and purpose of the provision at issue.

[136] The regulation-making authority conferred on the Governor in Council by subsection

101(1) of the *Patent Act* is broad. Relevant to the New Mandatory Factors is the text of paragraph 101(1)(d):

101 (1) Subject to subsection (2), the Governor in Council may make regulations	**101 (1)** Sous réserve du paragraphe (2), le gouverneur en conseil peut, par règlement :
[…]	[…]
(d) specifying factors for the purposes of subsection 85(1) or (2), including factors relating to the introductory price of any medicine to which a patented invention pertains;	**d)** définir les facteurs d'application des paragraphes 85(1) ou (2), y compris les facteurs relatifs au prix de lancement d'un médicament;

[137] Subsection 101(2) includes a condition precedent that applies to paragraph 101(1)(d), requiring a recommendation from the Minister of Health made after the Minister has consulted with the necessary stakeholders. The Minister of Health consulted with the relevant parties on all aspects of the Impugned Amendments before recommending that the Governor in Council make the *Amendments.* The condition precedent was therefore satisfied, and the Applicants do not argue otherwise.

[138] On its face, the language of paragraph 101(1)(d) does not limit the type of factors the Governor in Council may specify by way of regulation, so long as such factors are "for the purposes of subsection 85(1) or (2)".

[139] Subsection 85(1) of the *Patent Act*, described above in the Background section, reads as follows:

85 (1) In determining under section 83 whether a medicine is being or has been sold at an excessive price in any market in Canada, the Board shall take	**85 (1)** Pour décider si le prix d'un médicament vendu sur un marché canadien est excessif, le Conseil tient compte des facteurs suivants, dans la

into consideration the following factors, to the extent that information on the factors is available to the Board:	mesure où des renseignements sur ces facteurs lui sont disponibles :
(a) the prices at which the medicine has been sold in the relevant market;	**a)** le prix de vente du médicament sur un tel marché;
(b) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;	**b)** le prix de vente de médicaments de la même catégorie thérapeutique sur un tel marché;
(c) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;	**c)** le prix de vente du médicament et d'autres médicaments de la même catégorie thérapeutique à l'étranger;
(d) changes in the Consumer Price Index; and	**d)** les variations de l'indice des prix à la consommation;
(e) such other factors as may be specified in any regulations made for the purposes of this subsection.	**e)** tous les autres facteurs précisés par les règlements d'application du présent paragraphe.

[140] The Applicants begin their contextual argument by submitting that "in paragraph 85(1)(e), Parliament provides the Governor in Council with a limited jurisdiction to add new mandatory factors." Their principal contextual argument is this: paragraphs 85(1)(a)-(d) all list *price* factors that the Board must consider, so the common feature in the list is "price" at which a medicine has been "sold". Applying the *ejusdem generis* rule, paragraph 85(1)(e) therefore only authorizes the Governor in Council to add new mandatory factors related to the "price" at which the medicine is "sold". In the words of paragraph 85(1)(e), the factors must be "for the purposes of this subsection".

[141] The *ejusdem generis*, or "limited class" rule is "a working rule of construction which, properly applied, is of assistance in elucidating the intention of the legislature" (*Johnston v Canadian Credit Men's Trust Assn*, [1932] SCR 219 at 220). When interpreting a clause in a

statute that sets out a list of specific words followed by a general term, the rule dictates that the general term is limited to "the genus of the narrow enumeration that precedes it" (*National Bank of Greece (Canada) v Katsikonouris*, [1990] 2 SCR 1029 at 1040).

[142] The difficulty with the Applicants' submission is that paragraph 85(1)(e) is not the power-conferring provision at issue. The Applicants have misconstrued the statutory scheme in an attempt to use the *ejusdem generis* rule to limit the addition of new factors to those related to the original factors set out by Parliament at the time of drafting.

[143] Subsection 85(1) prescribes factors that the Board must consider when determining whether the price of a patented medicine is excessive under section 83. This provision is directed towards the Board, guiding it in its mandate to prevent excessive pricing. Paragraph 85(1)(e) requires the Board to consider factors made by regulation "for the purposes of this subsection".

[144] The Governor in Council's regulation-making authority to specify factors for the purposes of subsection 85(1) is found in paragraph 101(1)(d) of the *Patent Act*, and is not limited by the existing subsection 85(1) factors. In my view, "for the purposes of subsection 85(1) or (2)" as used in paragraph 101(1)(d) means for the purpose of specifying additional mandatory and optional factors for the Board to consider in determining whether a patented medicine has been sold at an excessive price.

[145] To this point, the Respondent submits that to apply the *ejusdem generis* rule as the Applicants urge would lead to an insensible result where new factors could only be factors that the legislators thought to enact at the time of drafting. Such a limitation would constitute a

profound and unfounded limitation on Parliament's ability to delegate regulation-making authority, defeating the stated purpose of paragraph 101(1)(d).

[146] The cases relied on by the Applicants involve scenarios where the power-conferring provision included a list of specific words or phrases followed by a general term (*Newfoundland (Minister of Forest Resources and Agrifoods) v AL Stuckless and Sons Ltd*, 2005 NLCA 11 at paras 22, 83-34; *Rascal Trucking Nanaimo (City) v Rascal Trucking Ltd*, 2000 SCC 13 at paras 9, 21-22). The Courts in these cases found that the broad, general power-conferring provision was limited by the more specific words preceding it, applying the *ejusdem generis* rule to the power-conferring provision.

[147] None of the cases relied upon provide support for the Applicants' position that the broad regulation-making authority granted to the Governor in Council in paragraph 101(1)(d) of the *Patent Act* is somehow limited by existing mandatory factors that the Board must consider in subsection 85(1). The Applicants improperly ask the Court to read the existing factors into the power-conferring provision.

[148] The Applicants' final contextual interpretation argument is that the narrow jurisdiction afforded to the Governor in Council under paragraph 85(1)(e) is reinforced by the broader language of paragraph 85(2)(b). This provision allows the Board to take into consideration such factors "as are, in the opinion of the Board, relevant in the circumstances" where the Board is unable to reach a determination based on the factors in subsection 85(1). The Applicants say that Parliament's choice of broad language in this paragraph signals its intention that the ambit of paragraph 85(1)(e) is solely related to the items already set out in that subsection.

[149] Again, paragraph 85(1)(e) is not the power-conferring provision at issue. Section 85 is directed towards the Board, with subsection 85(1) dictating mandatory factors the Board must consider, and subsection 85(2) defining optional factors the Board may consider in certain circumstances. The "textual confines" of this provision do not serve to limit the regulation-making authority granted to the Governor in Council in paragraph 101(1)(d).

(d) *Conclusion on section 4 of the Amendments*

[150] To conclude, I agree with the Respondent that the New Mandatory Factors and corresponding reporting requirements set out in section 4 of the *Amendments* fall within the Governor in Council's regulation-making authority pursuant to paragraph 101(1)(d) of the *Patent Act*. Further, the Applicants have not established that section 4 of the *Amendments* is "irrelevant", "extraneous", or "completely unrelated" to the statutory purpose of the Patented Medicines Regime in the context of the *Patent Act* as a whole.

[151] I find that the Applicants' position is unsupported by the text of section 101 and the scheme of the *Patent Act*, and would unreasonably narrow the authority conferred on the Governor in Council in paragraph 101(1)(d).

[152] The New Mandatory Factors included in section 4 of the Amendments are within the scope of the Governor in Council's regulation-making authority to "specify factors for the purpose of subsection 85(1)" found in paragraph 101(1)(d).

[153] The Governor in Council's decision to promulgate this regulation is therefore reasonable.

(2) Section 6 and the schedule to the *Amendments*: the PMPRB11

[154] The Applicants acknowledge that the Governor in Council has discretion to select the basket of comparator countries, but submit that the basis upon which the Governor in Council selected the PMPRB11 conflicts with the purpose of subsection 85(1), and the *Patent Act* in general, and is therefore unreasonable. Even where, as here, an administrative decision maker has considerable discretion in making a particular decision, that decision must comply with the rationale and purview of the governing statutory scheme (*Vavilov* at para 108; *Katz* at para 24).

[155] As part of its excessive pricing determinations, paragraph 85(1)(c) requires the Board to consider prices of medicines in countries other than Canada. The list of comparator countries is set out in the schedule to the *Regulations*, and may be changed by the Governor in Council using her regulatory making authority to specify information patentees must report to the Board. Section 6 of the *Amendments* changes the existing list of countries—the PMPRB7—to the list of countries in the schedule to the *Amendments*: the PMPRB11. The decision to modernize the schedule was made in part because the original criteria used to select comparator countries were found to provide an incomplete and flawed basis of comparison (RIAS at 5953).

[156] The PMPRB11 countries were selected based on three requirements: measures that constrain free market pricing; similar economic standing to Canada; and similar market characteristics to Canada.

[157] The Applicants make two primary submissions on the PMPRB11. First, excluding countries that have free market pricing directly conflicts with the patent bargain, as the patent

monopoly provides the patentee with discretion over its prices. Second, the Governor in Council has improperly used the selection of the PMPRB11 as a form of price control. To this point, Dr. Cockburn opines that the manner in which the new basket of comparator countries was selected moves Canada away from a system of detecting patent abuse, and effectively imports a price control scheme reflective of federal government efforts to lower drug prices.

[158] In the Applicants' submission, the purpose for selecting the PMPRB11 is inconsistent with the purpose of the *Patent Act*. I disagree.

[159] As previously noted, patentees of medicines do not have unfettered discretion to make their own pricing decisions in Canada. Patented medicines prices are regulated in the context of the Patented Medicines Regime.

[160] Moreover, the PMPRB11 does not, in and of itself, constitute a form of price control. The schedule merely requires patentees to file pricing information from the eleven countries listed, if available. The updated list of countries do not amount to price control any more than the previous list of countries. Board staff use this pricing information to identify prices that appear to be excessive based on its guidelines, and the Board can only order price reductions if, following a hearing, it determines that the price of a patented medicine is excessive based on all of the subsection 85(1) factors. Simply performing a price comparison does not dictate that a specific conclusion must follow (*Alexion Pharmaceuticals Inc v Canada (Attorney General)*, 2019 FC 734 at para 59 [*Alexion 2019*], quoting with approval from *Leo Pharma Inc v Canada (Attorney General)*, 2007 FC 306 at para 18).

[161] I also note that the Federal Court of Appeal has held that the Patented Medicines Regime—sections 79 to 103 of the *Patent Act*—make up a constitutionally valid price control scheme enacted by Parliament to prevent the abuse of excessive pricing (*Alexion FCA*, above, at paras 60-63; *Sandoz*, above, at para 116). The Patented Medicines Regime empowers the Board to make determinations of excessive pricing, having considered particular factors.

[162] The Applicants have not established that the selection of the PMPRB11 is inconsistent with or irrelevant to the purpose of the Patented Medicines Regime in the context of the *Patent Act*. The Governor in Council's decision to amend the basket of comparator countries is therefore reasonable.

(3) Subsection 3(4) of the *Amendments*: the New Price Calculation

[163] The New Price Calculation expands the information that patentees must take into consideration when reporting "the price at which the medicine is being or has been sold in any market in Canada and elsewhere" under paragraph 80(1)(b). Pursuant to subsection 3(4) of the *Amendments*, the calculation of "price" for the purposes of this paragraph now includes financial dealings with third parties. Patentees must account for "any adjustments that are made by the patentee or any party that directly or indirectly purchases the medicine or reimburses for the purchase of the medicine and any reduction given to any party in the form of free goods, free services, gifts or any other benefit of a like nature" (*Amendments*, s 3(4)).

[164] The *Regulations* currently require patentees to report price adjustments at the first point of sale only (referred to generally as "ex-factory" or "factory-gate sales"). As stated in the RIAS, the New Price Calculation is intended to capture formulary listing payments that drug

manufacturers often pay to insurers, including public drug plans, to have their products listed on the insurer's formulary (RIAS at 5961).

[165] Formulary listing payments commonly arise in the context of negotiations to have drug products listed on formularies. Public drug plans and private insurers will demand financial or other concessions from drug manufacturers in exchange for agreeing to list a drug on their formularies.

[166] The supply chain for the sale and reimbursement of medicines can generally be described as follows:

i. The vast majority of a patentee's factory-gate sales are made to drug wholesalers. The patentee receives payment directly from the wholesaler, and title to the medicine passes to the wholesaler;
ii. Wholesalers then distribute medicines to retail pharmacies and hospitals;
iii. Retail pharmacies and hospitals stock and dispense medicines to patients;
iv. Patients may recover some or all of their costs through public drug plans funded by the federal, provincial, and territorial governments, or private insurance coverage. Public and private insurers will generally only reimburse patients for drug products listed by their program.

[167] Drug manufacturers also make some other ex-factory sales, for example to certain hospitals and government programs. Notably, patentees generally do not sell medicines to public drug plans or private insurers, and these entities do not purchase or take title of medicines from patentees.

[168] Before a drug product is listed for reimbursement on a formulary, organizations such as CADTH and INESSS conduct thorough evaluations to establish the value for money of the drug. Manufacturers will then negotiate with a centralized body, the pan-Canadian Pharmaceutical Alliance. Successful negotiations lead to confidential contractual agreements between the drug manufacturer and the public drug plan or private insurer known as product listing agreements [PLAs].

[169] Public drug plans represent approximately 40% of total drug spending, and drug manufacturers are therefore motivated to enter into PLAs in order to access these drug markets, which would otherwise be unavailable to them.

[170] Terms of PLAs vary, and can include monetary terms, non-monetary terms such as patient support programs or free goods, and payments made to third parties other than the listing insurer. Depending on the structure of the agreement, listing payments pursuant to a PLA may arise years after the drug manufacturer makes its initial sale to wholesalers.

[171] The purpose of the New Price Calculation, as stated in the RIAS, is to require patentees to report price information net of discounts and rebates offered to parties further down the supply chain, such as insurers, allowing the Board to factor third party rebates into its calculation of average transaction prices to inform existing factors (RIAS at 5961). Further, the New Price Calculation will facilitate compliance with anticipated lower price ceilings that will arise from the Board's application of the new subsection 85(1) factors. This information will be considered privileged pursuant to section 87 of the *Patent Act* (RIAS at 5961-5962).

[172] Patentees will not be required to report specific information on the size or existence of third party rebates. Rather, they will need to report the total net revenues for the medicine, the number of units sold for the medicine, and the average transaction price for any market in Canada, net of all price adjustments, whether to third parties or not (RIAS at 5988).

[173] The Applicants submit that in promulgating New Price Calculation, the Governor in Council exceeded the scope of her regulation-making authority, and this regulation is therefore *ultra vires.*

[174] The Applicants make two primary submissions on this amendment. First, the New Price Calculation exceeds the Board's factory-gate jurisdiction under the *Patent Act*. In *Pfizer*, this Court held that the Board's jurisdiction is limited to the "sale" of the medicine by the patentee, and this decision has been cited in subsequent decisions, including a decision of this Court from last year (*Alexion 2019*, above at para 94). Second, the scheme of the excessive pricing factors in section 85 distinguishes between the price of a medicine and its manufacturing and marketing costs. The Applicants argue that listing payments are a cost of market access, and should not be considered part of the "price" at which a medicine was sold under subsection 85(1) and paragraph 80(1)(b).

[175] At issue in *Pfizer* was a stakeholder communiqué released by the Board itself. Madam Justice Anne Mactavish held that the communiqué was not consistent with the *Regulations* (*Pfizer* at para 90). The stakeholder communiqué required patentees to include payments made to third parties, including the provinces, in the calculation of the average price for sales of patented medicines. The *Patent Act* and *Regulations* contemplate a "sale" to a "customer", and the

Regulations require patentees to report price reductions in the form of rebates and discounts. Justice Mactavish found that the provinces were not "customers" of the patentees, and the requirement to report such price reductions could not be extended to strangers to the initial sale transaction (*Pfizer* at paras 80, 87-89).

[176] Justice Mactavish went on to observe that her interpretation of the *Patent Act* and *Regulations* was consistent with the Board's constitutional limitations:

> I would also observe that my interpretation of the *Patent Act* and the *Patented Medicines Regulations* is consistent with the constitutional limitation on the Board's ability to look beyond the factory-gate price of patented medicines, to consider contractual arrangements involving patentees and entities further down the distribution chain.
>
> (*Pfizer* at para 83)

[177] The Applicants submit that Justice Mactavish's reasoning is sound and the facts have not changed: patentees still do not sell medicines to insurers. Therefore, discounts and rebates to insurers cannot be included in the price calculation, as these transactions are beyond the Board's factory-gate jurisdiction. Because Justice Mactavish's decision is grounded in the *Patent Act* and the Board's constitutional limitations, the reasoning in *Pfizer* is equally applicable in the present application, even considering the amendments to the *Regulations*.

[178] Conversely, the Respondent submits that the decision in *Pfizer* is limited to the stakeholder communiqué and the *Regulations* as they then read. Justice Mactavish did not address the Governor in Council's authority to amend the reporting requirements.

[179] While *Pfizer* focused on the Board's stakeholder communiqué, I agree with the Applicants that much of Justice Mactavish's analysis of the statutory scheme remains relevant to the interpretation of the regulation-making authority at issue in the present case.

[180] As previously mentioned, the Court must take a broad and purposive approach to interpreting the challenged regulation and the enabling statute, consistent with the Supreme Court's guidance on statutory interpretation generally (*Katz* at para 26). The words of the *Patent Act* "are to be read in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament" (*Canada Trustco Mortgage Co v Canada*, 2005 SCC 54 at para 10).

[181] Furthermore, every enactment is deemed remedial, and shall be given such fair, large and liberal construction and interpretation as best ensures the attainment of its objects (*Interpretation Act*, RSC, 1985 c I-21, s 12).

[182] The text of subsection 101(1) gives the Governor in Council the authority to make regulations specifying information patentees must provide to the Board under subsection 80(1):

101 (1) Subject to subsection (2), the Governor in Council may make regulations	**101 (1)** Sous réserve du paragraphe (2), le gouverneur en conseil peut, par règlement :
(a) specifying the information and documents that shall be provided to the Board under subsection 80(1) or (2) or 88(1);	**a)** préciser les renseignements et les documents à fournir au Conseil en application des paragraphes 80(1) ou (2) ou 88(1);

[183] The objects of the Patented Medicines Regime in the context of the *Patent Act* as a whole have been previously discussed and need not be repeated here. The regulation-making authority

conferred on the Governor in Council by paragraph 101(1)(a) must be read in its entire context, harmoniously with the scheme and objects of the *Patent Act*.

[184] Paragraph 80(1)(b) requires patentees to provide the Board with such information respecting "the price at which the medicine is being or has been sold in any market in Canada and elsewhere" as the regulations may specify.

[185] Subsection 4(1) of the *Regulations* links directly to paragraph 80(1)(b) of the *Patent Act*, and details the information identifying the medicine and concerning the price of the medicine that patentees must report to the Board. Pursuant to subparagraph 4(1)(f)(i) of the *Regulations*, patentees must provide the Board with price information indicating "either the average *price* per package or the *net revenue from sales* in respect of each dosage form, strength and package size in which the medicine was *sold by the patentee … to each class of customer* in each province and territory" (emphasis added).

[186] As defined in the Oxford English Dictionary, "price" is "the amount of money (or a material equivalent) expected, required, or given in payment for a commodity or service". Similarly, "sale" is defined as "the exchange of a commodity for money or other valuable consideration" (*HW Liebig Co v Leading Investments Ltd*, [1986] 1 SCR 70 at para 24). Paragraph 80(1)(b) of the *Patent Act* and the related *Regulations* require patentees to provide the Board with information respecting the amount of money received in exchange for a patented medicine.

[187] The statutory scheme remains the same as it was when Justice Mactavish rendered her decision in *Pfizer*. Then, as now, "what is clearly contemplated by the Act and the Regulations is a *sale* by a patentee to a *customer*" (*Pfizer* at para 67, emphasis in original). Any regulations made by the Governor in Council specifying information or documents that patentees must provide to the Board under paragraph 80(1)(b) must relate to sale of medicines by patentees to customers.

[188] What will change when the *Amendments* come into force is the way in which patentees are required to calculate "price" and "revenue", pursuant to paragraphs 4(4)(a) and (b) of the *Regulations*. Subsection 4(4) begins with the words "for the purposes of subparagraph 1(f)(i)", directly linking subsection 4(4) to subsection 4(1) of the *Regulations*, which in turn is linked to paragraph 80(1)(b) of the *Patent Act*. The way price is calculated, therefore, is connected to and must flow from the requirement in paragraph 80(1)(b) for patentees to provide the Board with information on the *price* at which a medicine has been *sold*.

[189] A blackline comparison of the current language of paragraph 4(4)(a) of the *Regulations* and the amended language included in subsection 3(4) of the *Amendments* highlights the differences between the regulations as they now read, and the New Price Calculation:

Current text of paragraph 4(4)(a)

in calculating the average price per package of medicine, the actual price ~~after~~ any reduction given ~~as a promotion or~~ in the form of ~~rebates, discounts, refunds~~, free goods, free services, gifts or any other benefit of a like nature ~~and after the deduction of the federal sales tax shall be used~~;	le prix ~~après déduction des réductions accordées à titre de promotion~~ ou sous forme de ~~rabais, escomptes, remboursements~~, biens ou services gratuits, cadeaux ou autres avantages semblables ~~et après déduction de la taxe de vente fédérale~~ doit être utilisé pour le calcul du prix moyen ~~par emballage dans lequel le médicament était~~

~~vendu~~;

Paragraph 4(4)(a), as amended by subsection 3(4) of the *Amendments*

in calculating the average price per package of a medicine, the actual price obtained by the patentee shall be used, taking into account any adjustments that are made by the patentee or any party that directly or indirectly purchases the medicine or reimburses for the purchase of the medicine and any reduction given to any party in the form of free goods, free services, gifts or any other benefit of a like nature;	le prix obtenu par le breveté, compte tenu des ajustements apportés par le breveté ou toute partie qui, directement ou indirectement, achète le médicament ou en rembourse l'achat et de toute déduction accordée à toute partie sous forme de biens ou services gratuits, cadeaux ou autres avantages semblables, doit être utilisé pour le calcul du prix moyen du médicament par emballage;

[190] As emphasized in the underlined text above, in calculating price, patentees will be required to factor in any adjustments made by "any party that directly or indirectly purchases the medicine or reimburses for the purchase of the medicine and any reduction give to any party". This expansive language is not limited to adjustments made by the patentee or the customer, but extends to any adjustments made by any party. The New Price Calculation is therefore not limited to sales transactions made by the patentee at the factory-gate.

[191] The Respondent acknowledges that the New Price Calculation will allow the Board to factor in transactions that take place beyond the patentee's factory-gate, but submits that the hook that ties this information in to the statutory scheme is that these transactions are to be used to calculate the price that the patentee actually obtains for a medicine. The New Price Calculation will allow the Board to look further downstream in the chain of transactions, however, there must always be a connection to the patentee, and therefore this regulation falls within the federal government's purview. In other words, the Governor in Council has used her

regulation-making authority to mandate a broad, holistic interpretation of the "price" at which the patented medicine in question is "sold" by the patentee.

[192] The Respondent also submits that the Board's consumer protection mandate favours a broad interpretation of the "price" at which a patentee "sells" a medicine. The Supreme Court took such an approach in rejecting a narrow interpretation of the term "sold in any market in Canada" which would have excluded medicines sold from the United States to Canadian consumers from the Board's purview (*Celgene* at paras 22 and 25). Further, in *Sandoz,* the Federal Court of Appeal focused on whether the transaction at issue involved a patentee, rather than whether the sale took place at the manufacturer's factory-gate (*Sandoz* at paras 73-76). In the Respondent's view, these decisions supplant this Court's decision in *Pfizer*.

[193] As acknowledged above, *Pfizer* did not address the specific issue of the Governor in Council's authority to amend the reporting requirements. However, *Celgene* and *Sandoz* are of limited value in interpreting the specific provisions of the *Patent Act* at issue.

[194] In *Celgene,* the Supreme Court rejected a strict commercial law interpretation of the word "sold" in paragraph 80(1)(b) which would have prevented the Board from regulating sales made from other countries in to Canada, but paradoxically would have given the Board authority over medicine sales made in Canada destined for other countries. This result would have been inconsistent with the legislative purpose of protecting Canadian consumers. While the Supreme Court endorsed a broad interpretation of the word "sold" in these circumstances, it did not address the Governor in Council's regulation-making authority, and did not address patentees reporting price net of transactions made with third parties.

[195] In *Sandoz*, the Federal Court of Appeal found that parties further down the supply chain from the patentee manufacturer may fall within the broad definition of "patentee" in section 79 by way of implied license. The primary issue was the definition of "patentee" under the Patented Medicines Regime, and the Court did not consider the calculation of "price" within the regime.

[196] I cannot accept the Respondent's submission that *Celgene* and *Sandoz* generally instruct this Court to adopt a broad interpretation of the price at which a medicine is sold. Contrary to the Respondent's suggestion that the Federal Court of Appeal in *Sandoz* focused on the price *obtained* by the patentee, the analysis in fact focused on the definition of "patentee" and the "price *charged* by the patentee" (*Sandoz* at para 76, emphasis added). In both *Celgene* and *Sandoz*, the Courts recognized that the Board's jurisdiction is over sales made by patentees to customers.

[197] Because the New Price Calculation directly links to paragraph 80(1)(b) of the *Patent Act*, the Governor in Council's regulation-making authority is limited to specifying information respecting the price at which the patentee sells the medicine. I adopt the words of Justice Mactavish that to interpret the term "sale" (or "sold") in such a way as to encompass the relationship between patentees and third parties who do not purchase or take title of medicines from patentees would "do violence to the ordinary meaning of the term" (*Pfizer* at para 78).

[198] Furthermore, the New Price Calculation is inconsistent with subparagraph 4(1)(f)(i) of the *Regulations*, which requires patentees to indicate the price at which a medicine was "sold by the patentee … to each class of customer". Requiring patentees to take into account financial transactions with third parties who are not customers—and are strangers to the original sale

transaction—exceeds the scope of the Governor in Council's statutory mandate by untethering the price calculation from the sale of the patented medicine.

[199] It bears repeating that the Board's mandate under the *Patent Act* is not to set prices for patented medicines, and the Board does not regulate profits made by patentees. The Board's mandate to control prices is only engaged where it finds a patentee has abused its monopoly by charging excessive prices. The Board's role is "to monitor the *prices charged by patentees* for patented medicines, so as to ensure that these prices are not excessive" (*Pfizer* at para 70, emphasis added). This interpretation of the Board's role accords with the extrinsic evidence of legislative intent quoted above at paragraphs 85-87.

[200] The Respondent submits that the Applicants have attempted to make a constitutional argument "in stealth" without directly raising a constitutional division of powers issue. Although the Applicants deny any such constitutional argument, the Respondent says the Applicants effectively ask the Court to find that this regulation crosses the line of constitutional permissibility.

[201] Counsel for the Applicants made clear in oral argument that the Applicants do not challenge the constitutionality of the *Amendments*. The Applicants did not file a Notice of Constitutional Question in the present proceeding. Further, a separate proceeding challenging the constitutionality of the *Amendments* is ongoing in the Superior Court of Québec. The Applicants maintain, however, that constitutional limitations constrain the Governor in Council's regulation-making authority in the context of statutory *vires*.

[202] Constitutional validity is not at issue in the present proceeding. Moreover, I accept the Respondent's position that reasonableness review does not invite the Court to consider whether the administrative decision maker's interpretation *might* be unconstitutional, and the Court is not to prioritize all possible answers to a question and identify the best among them (*Sandoz* at paras 68-70).

[203] That said, the question the Court must answer is whether the Governor in Council's decision meets the threshold of acceptability and defensibility characteristic of a reasonable decision in light of the relevant constraints. Having considered the governing statutory scheme and the relevant jurisprudence, I find that it does not.

[204] I need not consider constitutional division of powers limitations as the New Price Calculation is inconsistent with the governing statutory scheme. The Court does not accept that the Applicants have dressed up constitutional arguments in the cloak of a statutory *vires* challenge. This judicial review is about statutory *vires* alone, and whether the Governor in Council's mandate under the *Patent Act* is sufficiently broad to allow for the promulgation of the New Price Calculation regulation. Again, I find that it is not.

[205] The evidence before the Court in this application is that a vast majority of patentees' sales are made to drug wholesalers. Patentees generally do not sell medicines to public drug plans or private insurers, and these entities do not purchase or take title of medicines from patentees. Rebates and discounts provided 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*.

[206] In reaching this conclusion, I recognize that the *Amendments* benefit from a presumption of validity favouring an interpretive approach that reconciles the New Price Calculation with the *Patent Act* (*Katz* at para 25). Applying a broad, purposive approach to subsection 3(4) of the *Amendments* and sections 80 and 101 of the *Patent Act*, the New Price Calculation is irreconcilable with the enabling statute.

[207] The Respondent further submits that the question the Court must answer is whether the purpose of the Patented Medicines Regime—protecting consumers from excessive patented medicines prices—aligns with the intended application of the New Price Calculation regulation. In the Respondent's view, the answer is yes, as the intended application is no different from that of the pre-amendment price calculation.

[208] While the New Price Calculation is ostensibly intended to protect consumers from excessive pricing of patented medicines, the Governor in Council cannot exceed the scope of her regulation-making authority within the scheme of the *Patent Act* in attempting to advance this objective. The New Price Calculation does just that, and is therefore *ultra vires* the *Patent Act.* An interpretation that may accord with an objective of the Patented Medicines Regime, but is inconsistent with the Board's mandate within the scheme of the *Patent Act* and flies in the face of the ordinary meaning of the "price" at which a medicine is "sold" is not reasonable.

[209] Finally, the Respondent submits there is no support in the *Patent Act* for the factory-gate limitation on the Governor in Council's regulation-making authority, and to find otherwise would undermine the purpose of the Patented Medicines Regime by allowing patentees to utilize

creative indirect pricing mechanisms; the precise issue the Governor in Council sought to address.

[210] This argument overstates the freedom patentees have to devise their own pricing mechanisms. As recognized by Justice Mactavish in *Pfizer*, in some circumstances, patentees are actually prohibited by law from selling patented medicines to provinces (*Pfizer* at para 73; *Food and Drug Regulations*, CRC, c 870, C.01.043(1)). The substance of this provision remains the same today, and patentees still do not sell prescription medicines to provinces.

[211] At least with respect to prescription medicines, patentees sell to wholesalers in the context of a government mandated regulatory framework, and negotiate PLAs outside of this sales framework. Contrary to the Respondent's assertion that finding the New Price Calculation *ultra vires* will allow patentees to use creative indirect pricing mechanisms to undermine the purpose of the Patented Medicines Regime, patentees will continue to operate within this complementary regulatory framework established by the federal government. As submitted by the Applicants, patentees are motivated to enter into PLAs in order to access insurer formularies.

[212] The Applicants' second main argument on the New Price Calculation relates to the scheme of sections 80 and 85 of the *Patent Act*. The Applicants submit that section 85 distinguishes between price factors, which must be considered under subsection 85(1), and cost factors, which may be considered under subsection 85(2) only where the mandatory factors are not determinative. Similarly, paragraphs 80(1)(b) and (c) distinguish between price and cost information that patentees must report to the Board.

[213] The Applicants argue that listing payments are a “cost” of market access based on the evidence describing the price negotiation and PLA process between drug manufacturers and insurers, as described above. In the Applicants’ submission, the New Price Calculation requires patentees to report listing costs as part of the price at which the medicine has been sold, impermissibly introducing cost considerations into the calculation of price.

[214] This argument is a corollary to the Applicants’ first argument, and having found the New Price Calculation to be an unreasonable exercise of the Governor in Council’s regulation-making authority in light of the relevant constraints, I need not address this argument in detail. As previously stated, payments made to third parties, which may be conceptualized as costs to a patentee, do not form part of the price at which a patentee sells a medicine.

[215] To conclude, the requirement for patentees to report price information net of transactions involving third parties unrelated to the factory-gate sale of the a patented medicines is inconsistent with subparagraph 4(1)(f)(i) of the *Regulations* and paragraph 80(1)(b) of the *Patent Act*. By amending subsection 4(4) of the *Regulations* in this way, the Governor in Council exceeded the scope of her regulation-making mandate found in paragraph 101(1)(a) of the *Patent Act*.

[216] To be clear, this should not be interpreted as a strict finding that the Board’s mandate is limited to a reference pricing scheme only, or that the Governor in Council is confined within this scheme. As held above, the Governor in Council has the broad authority under paragraph 101(1)(d) to specify additional factors that the Board must take into consideration under subsection 85(1). The Governor in Council also has a broad authority under paragraph 101(1)(a)

to specify information and documents that patentees must provide to the Board under subsection 80(1).

[217] However, amending subsection 4(4) of the *Regulations*—which is linked to paragraph 80(1)(b) of the *Patent Act* in particular—in such a way to include payments or adjustments made to third parties in the calculation of the price at which a medicine has been sold, is unreasonable. Having implemented the New Price Calculation by amending subsection 4(4) of the *Regulations*, the Governor in Council was constrained by the text, context, and purpose of the related passages of the *Patent Act* and *Regulations*.

[218] Having considered the relevant constraints on the Governor in Council, particularly the scheme of the *Patent Act* and the relevant jurisprudence, the Applicants have established that the New Price Calculation is *ultra vires*.

VIII. Conclusion

[219] In conclusion, the Impugned Amendments in sections 4 and 6, and the schedule to the *Amendments* are *intra vires* the *Patent Act*. The Impugned Amendment in subsection 3(4) of the *Amendments* is *ultra vires* the *Patent Act*.

[220] The Applicants are entitled to a declaration that subsection 3(4) of the *Amendments* is invalid, void, and of no force and effect, as it is *ultra vires* the *Patent Act*. In light of this finding, subsection 4(4) of the *Regulations* will continue to operate as it currently reads.

IX. Costs

[221] The Applicants and Respondent agreed not to seek costs of this application, regardless of the outcome. By Order of this Court dated March 30, 2020, no costs shall be awarded against or in favour of CORD in respect of its intervention.

[222] Accordingly, no costs are awarded to any party.

JUDGMENT IN T-1465-19

THIS COURT'S JUDGMENT AND DECLARATION is that:

1. Subsection 3(4) of the *Amendments* is invalid, void, and of no force and effect as it is *ultra vires* the *Patent Act*;

2. The *Amendments* made by the Governor in Council are otherwise valid;

3. No costs are awarded to any party.

"Michael D. Manson"
Judge

Appendix

Relevant Provisions of the *Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)*, SOR/2019-298

3 (4) Paragraphs 4(4)(a) and (b) of the Regulations are replaced by the following:

(a) in calculating the average price per package of a medicine, the actual price obtained by the patentee shall be used, taking into account any adjustments that are made by the patentee or any party that directly or indirectly purchases the medicine or reimburses for the purchase of the medicine and any reduction given to any party in the form of free goods, free services, gifts or any other benefit of a like nature; and

(b) in calculating the net revenue from sales in respect of each dosage form, strength and package size in which the medicine was sold in final dosage form, the actual revenue obtained by the patentee shall be used, taking into account any adjustments that are made by the patentee or any party that directly or indirectly purchases the medicine or reimburses for the purchase of the medicine and any reduction given to any party in the form of free goods, free services, gifts or any other benefit of a like nature.

3 (4) Les alinéas 4(4)a) et b) du même règlement sont remplacés par ce qui suit :

a) le prix obtenu par le breveté, compte tenu des ajustements apportés par le breveté ou toute partie qui, directement ou indirectement, achète le médicament ou en rembourse l'achat et de toute déduction accordée à toute partie sous forme de biens ou services gratuits, cadeaux ou autres avantages semblables, doit être utilisé pour le calcul du prix moyen du médicament par emballage;

b) le montant des recettes obtenues par le breveté, compte tenu des ajustements apportés par le breveté ou toute partie qui, directement ou indirectement, achète le médicament ou en rembourse l'achat et de toute déduction accordée à toute partie sous forme de biens ou services gratuits, cadeaux ou autres avantages semblables, doit être utilisé pour le calcul des recettes nettes pour chaque forme posologique, chaque concentration et chaque format d'emballage dans lesquels le médicament a été vendu sous sa forme posologique finale.

4 The Regulations are amended by adding the following after section 4:

4.1 (1) For the purposes of paragraphs 80(1)(d) and 2(d) of the Act, in respect of the factor referred to in paragraph 4.4(a), the patentee shall provide to the Board every cost-utility analysis prepared by a publicly funded Canadian organization, if published and communicated to the patentee, for which the outcomes are

4 Le même règlement est modifié par adjonction, après l'article 4, de ce qui suit :

4.1 (1) Pour l'application des alinéas 80(1)d) et (2)d) de la Loi, le breveté fourni au Conseil, à l'égard du facteur prévu à l'alinéa 4.4a), toute analyse coût-utilité préparée par un organisme canadien financé par l'État qui a été publiée et qui lui a été communiquée et dont les résultats sont exprimés en fonction

expressed as the cost per quality-adjusted life year for each indication that is the subject of the analysis.

(2) The patentee shall provide to the Board any information about the medicine that was redacted from a published analysis.

(3) An analysis shall be provided

(a) if the analysis is published before the day on which the medicine is first offered for sale in Canada, within 30 days after that day; or

(b) if the analysis is not published before the day on which the medicine is first offered for sale in Canada, within 30 days after the day on which it is published.

(4) Despite subsection (3), in the case of a medicine that is offered for sale in Canada before July 1, 2020, an analysis shall be provided

(a) if the analysis is published before July 1, 2020, by July 30, 2020; or

(b) if the analysis is not published before July 1, 2020, within 30 days after the day on which it is published.

(5) An analysis shall be provided to the Board only if any cost for the medicine as identified in the analysis is or would be, when that cost is pro-rated to account for that medicine's use over a 12-month period, greater than or equal to 50 per cent of the gross domestic product per capita in Canada at the time of publication of the analysis.

4.2 (1) For the purposes of paragraphs 80(1)(d) and (2)(d) of the Act, in respect of the factor referred to in paragraph 4.4(b), the patentee shall provide to the Board the estimated maximum use of the

du coût par année de vie pondéré par la qualité, pour chaque indication faisant l'objet de l'analyse.

(2) Le breveté fourni au Conseil tout renseignement visant le médicament qui a été caviardé dans l'analyse publiée.

(3) L'analyse doit être fournie :

a) si elle est publiée avant le jour où le médicament est offert en vente au Canada pour la première fois, dans les trente jours suivant ce jour;

b) sinon, dans les trente jours suivant sa publication.

(4) Malgré le paragraphe (3), s'agissant d'un médicament offert en vente au Canada avant le 1er juillet 2020, l'analyse doit être fournie :

a) si elle est publiée avant le 1er juillet 2020, au plus tard le 30 juillet 2020;

b) sinon, dans les trente jours suivant sa publication.

(5) L'analyse est fournie au Conseil uniquement si un coût établi dans celle-ci pour le médicament est ou serait, lorsqu'il est calculé sur la base d'une utilisation du médicament répartie sur une période de douze mois, égal ou supérieur à 50 pour cent du produit intérieur brut par habitant au Canada au moment de la publication de l'analyse.

4.2 (1) Pour l'application des alinéas 80(1)d) et (2)d) de la Loi, le breveté fourni au Conseil, à l'égard du facteur prévu à l'alinéa 4.4b), l'utilisation maximale estimative du médicament au Canada, en fonction de la quantité totale des prévisions de ventes du médicament sous sa forme posologique finale.

medicine in Canada, as measured by the total quantity of the medicine in final dosage form expected to be sold.

(2) The patentee shall provide to the Board the period of time used for the estimate of the maximum use of the medicine.

(3) The patentee shall provide to the Board the estimated maximum use of the medicine within 30 days after the day on which the medicine is first offered for sale in Canada.

(4) Despite subsection (3), in the case of a medicine that is offered for sale in Canada before July 1, 2020, the most recent version of the estimated maximum use of the medicine shall be provided

(a) if the medicine is first offered for sale in Canada during the period beginning on July 1, 2017 and ending on June 30, 2020, by July 30, 2020; or

(b) if the medicine is first offered for sale in Canada before July 1, 2017, but the Minister of Health assigns a drug identification number under the *Food and Drug Regulations*

(i) during the period beginning on the day on which the *Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements)* are published in the Canada Gazette, Part II and ending on June 30, 2020, by July 30, 2020, or

(ii) after June 30, 2020, within 30 days after the day on which the drug identification number is assigned.

(5) The patentee shall update the estimated maximum use of the medicine within 30 days after the day on which the Minister of Health issues a notice of

(2) Le breveté fourni au Conseil la période sur laquelle est fondée l'estimation de l'utilisation maximale du médicament.

(3) Le breveté fourni au Conseil l'utilisation maximale estimative du médicament dans les trente jours suivant la date où le médicament est offert en vente au Canada pour la première fois.

(4) Malgré le paragraphe (3), s'agissant d'un médicament offert en vente au Canada avant le 1er juillet 2020, la version la plus récente de l'utilisation maximale estimative du médicament doit être fournie :

a) si le médicament est offert en vente au Canada pour la première fois pendant la période commençant le 1er juillet 2017 et se terminant le 30 juin 2020, au plus tard le 30 juillet 2020;

b) si le médicament est offert en vente au Canada pour la première fois avant le 1er juillet 2017, mais que le ministre de la Santé lui attribue une identification numérique conformément au *Règlement sur les aliments et drogues* :

(i) pendant la période commençant le jour où le *Règlement modifiant le Règlement sur les médicaments brevetés (facteurs additionnels et exigences supplémentaires relatives à la fourniture de renseignements)* est publié dans la partie II de la Gazette du Canada et se terminant le 30 juin 2020, au plus tard le 30 juillet 2020,

(ii) après le 30 juin 2020, dans les trente jours suivant la date d'attribution de l'identification numérique.

(5) Le breveté met à jour l'utilisation maximale estimative du médicament dans les trente jours suivant la date de la délivrance par le ministre de la Santé de tout avis de conformité approuvant une utilisation

compliance approving a new or modified therapeutic use of the medicine.

4.3 (1) Despite subsections 4.1(3) and (4) and 4.2(3) and (4), in each of the following cases, the information referred to in subsections 4.1(1) and (2) and 4.2(1) and (2) shall be provided within 30 days after the day on which the Board sends a request for the patentee to provide that information:

(a) the medicine is not a prescription drug as defined in section A.01.010 of the *Food and Drug Regulations* and is not a drug described in Schedule D to the *Food and Drugs Act*;

(b) the medicine contains *a controlled substance* as defined in subsection 2(1) of the *Controlled Drugs and Substances Act*, the sale or provision of which does not require a prescription under that Act;

(c) a notice of compliance has been issued in respect of the medicine on the basis of information and material contained in a submission filed under section C.08.002.1 of the *Food and Drug Regulations*;

(d) the medicine is for veterinary use.

(2) The requirements of subsection 4.2(5) apply in respect of the information provided under subsection (1).

4.4 For the purposes of paragraph 85(1)(e) of the Act, the other factors that the Board shall take into consideration to determine whether a medicine that is sold in any market in Canada after June 30, 2020 is being or has been sold at an excessive price are the following:

(a) the medicine's pharmacoeconomic value in Canada;

(b) the size of the market for the medicine

thérapeutique nouvelle ou modifiée du médicament.

4.3 (1) Malgré les paragraphes 4.1(3) et (4) et 4.2(3) et (4), s'agissant des médicaments ci-après, les renseignements visés aux paragraphes 4.1(1) et (2) et 4.2(1) et (2) doivent être fournis au Conseil dans les trente jours suivant l'envoi, par ce dernier, d'une demande au breveté visant à ce que celui-ci fournisse ces renseignements :

a) le médicament qui n'est pas une *drogue sur ordonnance*, au sens de l'article A.01.010 du *Règlement sur les aliments et drogues*, ni une drogue mentionnée à l'annexe D de la *Loi sur les aliments et drogues*;

b) le médicament qui contient une *substance désignée*, au sens du paragraphe 2(1) de la *Loi réglementant certaines drogues et autres substances*, dont la vente ou la fourniture ne nécessite pas d'ordonnance aux termes de cette loi;

c) le médicament à l'égard duquel un avis de conformité a été délivré d'après les renseignements et le matériel contenus dans la présentation déposée en vertu de l'article C.08.002.1 du *Règlement sur les aliments et drogues*;

d) le médicament qui est destiné à l'usage vétérinaire.

(2) Les exigences du paragraphe 4.2(5) s'appliquent à l'égard des renseignements fournis en application du paragraphe (1).

4.4 Pour l'application de l'alinéa 85(1)e) de la Loi, les autres facteurs dont le Conseil doit tenir compte pour décider si le prix d'un médicament vendu après le 30 juin 2020 sur un marché canadien est excessif sont les suivants :

a) la valeur pharmacoéconomique du

in Canada; and

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

médicament au Canada;

b) la taille du marché de ce médicament au Canada;

c) le produit intérieur brut du Canada et le produit intérieur brut par habitant au Canada.

6 The schedule to the Regulations is replaced by the schedule set out in the schedule to these Regulations.

6 L'annexe du même règlement est remplacée par l'annexe figurant à l'annexe du présent règlement.

SCHEDULE

(Section 6)

ANNEXE

(article 6)

SCHEDULE

(Subparagraph 4(1)(f)(iii))

Australia

Australie

Belgium

Belgique

France

France

Germany

Allemagne

Italy

Italie

Japan

Japon

Netherlands

Pays-Bas

ANNEXE

(sous-alinéa 4(1)f)(iii))

Allemagne

Germany

Australie

Australia

Belgique

Belgium

Espagne

Spain

France

France

Italie

Italy

Japon

Japan

Norway	Norvège
Norvège	*Norway*
Spain	Pays-Bas
Espagne	*Netherlands*
Sweden	Royaume-Uni
Suède	*United Kingdom*
United Kingdom	Suède
Royaume-Uni	*Sweden*

FEDERAL COURT

SOLICITORS OF RECORD

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