December 20, 2023

Patented Medicine Prices Review Board
Standard Life Centre, Box L40
333 Laurier Avenue West, Suite 1400
Ottawa, ON K1P 1C1

Subject: Industry Coalition Submissions *re:* PMPRB's Scoping Paper for the Consultations on the Guidelines

The industry coalition composed of Merck, Janssen, Bayer, Boehringer Ingelheim, Servier, Theratechnologies and AVIR Pharma (the "**Constitutional Coalition**") wishes to provide written feedback on the PMPRB's Scoping Paper ("**Scoping Paper**"), released on November 10, 2023 to inform this first phase of consultations on the PMPRB's final guidelines which have yet to be adopted ("**Final Guidelines**").

In addition to providing oral submissions in the context of the roundtable consultations on December 5th and 6th, 2023, the Constitutional Coalition is providing the present written submissions so that the Final Guidelines comply with the Quebec Court of Appeal's decision in *Merck Canada c Canada*, 2022 QCCA 240 ("**QCCA Decision**").

Executive Summary

To begin, it is important to reiterate that the QCCA Decision is binding on the PMPRB.[1] With that in mind, the Constitutional Coalition wishes to remind the PMPRB of certain bright-line principles which were confirmed in the QCCA Decision and must inform the drafting, adoption and application of the Final Guidelines. If the Final Guidelines run afoul of these principles, they are at risk of future court challenges.

- The PMPRB's creation is derived from the *Patent Act*. Its constitutional mandate is therefore limited to the prevention of excessive pricing as a function of patent abuse; it cannot control the price at which a medicine is sold in Canada. This is confirmed in the QCCA Decision: the PMPRB's mandate is to "prevent the monopoly granted by patent from being used to charge "excessive" prices for patented medicines."[2]

- Furthermore, the PMPRB does not exercise a "health" mandate. The Final Guidelines must not have the effect of substituting the PMPRB for the provincial health ministers and agencies.[3]

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[1] *Canada Labour Relations Board v Paul L'Anglais Inc*, [1983] 1 SCR 147 at 161-162; *Strickland v Canada (AG)*, 2015 SCC 37 ¶33.

[2] *Merck Canada c Canada*, 2022 QCCA 240 ¶143.

[3] *Merck Canada c Canada*, 2022 QCCA 240 ¶240.

- The factors enumerated at section 85 of the *Patent Act* must not be used to achieve "optimal" or "reasonable" or "fair" pricing, or be used as a price control tool generally. They cannot be used to drive prices below non-excessive thresholds.

- The QCCA defined an excessive price as: "a price that, ***without justification***, **exceeds** the price of other medicines in the same therapeutic class or that otherwise **exceeds** the price for the same medicine in countries reasonably comparable to Canada".[4] The pricing tests of the Final Guidelines must reflect this definition, which notably emphasizes exceeding the section 85 pricing thresholds.

- An approach which relies on a median price threshold therefore diverges from the clear wording of the QCCA Decision.

- To the extent a single triage measure is to be used in the Final Guidelines, the only such measure that is in keeping with the QCCA Decision is a "higher than HIP" threshold. This test is most consistent with the PMPRB's constitutional mandate and provides for a high level of predictability.

- However, once an investigation is initiated, or at a Board hearing, all section 85 factors must be considered, and they cannot be used to drive prices below non-excessive thresholds.

- A price which is considered non-excessive cannot become excessive overnight. Once a price is reviewed at launch, there should be no re-benching; the price may follow the allowable CPI increase. This is both necessary from a legal and practical perspective to ensure there is predictability over the patent lifecycle.

- Accordingly, existing medicines that are compliant with their NEAP must be grandfathered under the new regime.

The approach proposed below will result in more predictability, lower complexity, less duplication, and increased efficiencies. This level of predictability and clarity in the Final Guidelines is essential, because it has been repeatedly recognized by the courts, including in the QCCA Decision, that the PMPRB's guidelines – although non-binding – are not merely internal administrative rules.[5] They are an integral enforcement mechanism of the PMPRB's regulatory framework and allow the PMPRB to operationalize its regime. As confirmed by the QCCA Decision, the guidelines "are at the heart of the excessive price control regime administered by the Board."[6] The guidelines are the starting point for the PMPRB's pricing analysis, and as such, must provide clear, predictable and constitutionally sound assessment criteria. If the Final Guidelines do not, they are at risk of being declared unconstitutional by the Courts.

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[4] *Merck Canada c Canada*, 2022 QCCA 240 ¶49 (our emphasis, official translation).

[5] *Merck Canada c Canada*, 2022 QCCA 240 ¶166-167, 175; *Alexion v Canada*, 2021 FCA ¶57-63,

[6] *Merck Canada c Canada*, 2022 QCCA 240 ¶167.

Detailed Submissions

i. *Background: The Constitutional Coalition*

In 2019, the Constitutional Coalition filed a constitutional challenge in Québec, challenging the validity of the three amendments to the *Patented Medicines Regulations* introduced by the federal government.

The Québec Superior Court struck down the amendment authorizing the PMPRB to compel disclosure of PLAs and regulate confidential rebated prices, and upheld the rest of the amendments.

On appeal, the Québec Court of Appeal provided important guidance on the scope of the PMPRB's constitutional mandate. The Court confirmed that the PMPRB is not a price regulator. Its mandate is limited to preventing excessive prices flowing from an abuse of the monopoly granted by a patent.[7] The section 85 factors are to be applied solely in pursuit of this objective.[8] The Court of Appeal noted that any attempt to go beyond this mandate in the pursuit of optimal or reasonable pricing would be an unconstitutional exercise of the federal patent power.[9] The QCCA unequivocally stated that:

> […] federal control of the price of patented medicines is constitutionally valid to the extent that its pith and substance is to prevent the adverse effects on prices of the monopoly granted by the patent. Conversely, such control is unconstitutional when it is no longer intended to control the effect on prices of the monopoly granted by patent.[10]

Importantly, the Court of Appeal defined an excessive price as: "a price that, without justification, exceeds the price of other medicines in the same therapeutic class or that otherwise exceeds the price for the same medicine in countries reasonably comparable to Canada".[11]

In application of these principles, the Court of Appeal struck down the pharmacoeconomic factors, including value and market size, finding that these factors were being used purely to create arbitrary price reductions, which the Court confirmed the PMPRB is not permitted to do.[12] In declaring these new factors unconstitutional, the Court confirmed that their purpose was "not to control the effect on prices of the monopoly granted by the patent, but rather to reduce the price of patented medicines so that they are more affordable, nothing more."[13] The Court also confirmed that it is unconstitutional for the federal government to

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[7] *Merck Canada c Canada*, 2022 QCCA 240 ¶143-146, 153, 163, 179.

[8] *Merck Canada c Canada*, 2022 QCCA 240 ¶143-146.

[9] *Merck Canada c Canada*, 2022 QCCA 240 ¶156 (affordability), 204 (consumer products), 228, 235 (price control).

[10] *Merck Canada c Canada*, 2022 QCCA 240 ¶243 (our emphasis).

[11] *Merck Canada c Canada*, 2022 QCCA 240 ¶49 (our emphasis, official translation).

[12] *Merck Canada c Canada*, 2022 QCCA 240 ¶229-231, 237-239, 244

[13] *Merck Canada c Canada*, 2022 QCCA 240 ¶227.

require the disclosure of confidential rebates, and for the PMPRB to attempt to regulate those rebates. Finally, the Court upheld the new basket of comparator countries on the understanding that it would be used only to engage in the regulation of excessive prices and not as a form of price control.

These guiding principles must be reflected in the Final Guidelines.

Theme 1: Efficient Monitoring of Prices without Price Setting

As acknowledged by the PMPRB in the Scoping Paper, its role is not to set or mandate prices, but rather to monitor for potential cases of excessive pricing. As confirmed in the QCCA Decision, "excessive pricing" is understood to refer to pricing where a patentee has abused its monopoly by charging an "objectively excessive" price.[14] Patent abuse and excessive pricing do not command a different threshold. Excessive pricing should only be understood as a form of patent abuse.

The QCCA unequivocally states that an excessive price is "a price that, without justification, exceeds the price of other medicines in the same therapeutic class or that otherwise exceeds the price for the same medicine in countries reasonably comparable to Canada."[15]

The Constitutional Coalition therefore urges the PMPRB to adopt a pricing analysis in the Final Guidelines based on a "higher than highest" approach, whereby a price would be considered excessive only if it exceeds the highest price in a given section 85 comparator category – and without justification for such price. And, if multiple price thresholds are used, no threshold can be used to push prices down below otherwise non-excessive levels.

To the extent any such threshold is based on international or class comparisons, it must be based on the highest list price in the relevant comparator category. Since the PMPRB11 basket is composed entirely of countries that regulate medicine prices, it follows that none of the PMPRB11 prices can plausibly be considered "excessive." The same holds true for comparator prices in any given drug's therapeutic class. Since the PMPRB monitors all patented drugs, if a therapeutic comparator is not deemed excessive, then a comparable treatment could likewise not be excessive.

The QCCA Decision clearly states that once the price of a patented medicine reaches a non-excessive threshold, the PMPRB cannot use its powers to push that price further below an already non-excessive level.[16] This would be an unconstitutional exercise of the PMPRB's power. As such, if a price does not exceed the HIP and the therapeutic comparators, it cannot be considered excessive.

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[14] See *Merck Canada c Canada*, 2022 QCCA 240 ¶154, 216.

[15] *Merck Canada c Canada*, 2022 QCCA 240 ¶49 (our emphasis).

[16] *Merck Canada c Canada*, 2022 QCCA 240 ¶154, 161-162, 227, 244

Finally, the PMPRB must consider that a drug price may be higher than the established thresholds if there is a justification for such price.

- **Question 1.1:** What elements of the 2010 Guidelines should be retained? Which ones and why?

No elements of the 2010 Guidelines should be retained, since the 2010 guidelines were developed based on an entirely different group of comparator countries. Now that the basket of comparator countries consists entirely of countries which regulate the price of medicines, the 2010 Guidelines, and notably a pricing threshold based on an MIP, are no longer relevant.

- **Question 1.2:** Should new Guidelines continue to categorize medicines by therapeutic class comparator characteristics such as the Level of Therapeutic Improvement ("LTI")?

The Level of Therapeutic Improvement is not a factor listed in section 85 of the *Patent Act* nor the *Patented Medicines Regulations*. It is not a relevant factor when assessing prices for excessiveness. The therapeutic value of a medicine is relevant instead for CADTH and INESSS health technology assessments, pCPA price negotiations, as well as public and private insurers who are determining whether a drug should be reimbursed – not for PMPRB excessive pricing reviews. As confirmed by the QCCA Decision, any attempt by the PMPRB to substitute itself to the provincial health ministers or regulatory bodies, such as CADTH and INESSS, would be an unconstitutional exercise of its power under the *Patent Act*.

Indeed, the QCCA declared the pharmacoeconomic factors invalid on this basis: "[…] by introducing new factors that have little or nothing to do with the monopoly granted by patents […] it is clear that the federal government is trying to give the Board a new role so as to substitute it for the provincial bodies, such as the INESSS, and for the provincial health ministers."[17] Considering the clinical value of a medicine when determining whether its price is excessive is an analogous price control mechanism as the pharmacoeconomic factors.

Moreover, the PMPRB has historically constructed therapeutic classes to include generic drugs and off-label comparators, among others, which have the intent of lowering prices. These comparators, including LTI, have been used by the PMPRB to push for lower prices. As confirmed by the QCCA Decision, comparators (including therapeutic class) cannot be used by the PMPRB to achieve optimal pricing or otherwise drive prices below an already non-excessive threshold.[18] Historically, divergent perspectives on LTI have been one of the main reasons for prolonged investigations, VCU negotiations, and hearings. Consequently, avoiding levels of therapeutic improvement in the Final Guidelines will provide greater predictability for patentees.

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[17] *Merck Canada c Canada*, 2022 QCCA 240 ¶239-240.

[18] *Merck Canada c Canada*, 2022 QCCA 240 ¶154, 161-162, 227, 244 .

- **Question 1.3:** Should the Board accord more weight to one or more of the factors set out in s. 85 of the Act in designing the Guidelines?

It has repeatedly been confirmed by the courts that in the course of an investigation, the PMPRB must consider all section 85 factors. No single factor should dominate the others, and in all cases, the PMPRB may not use any of the section 85 factors to drive prices below a threshold that would otherwise be considered non-excessive.

However, to the extent the Final Guidelines are designed as a triage or threshold for investigation, the Constitutional Coalition understands that a single factor may be used to assess prices for the purpose of triggering an investigation.

In this respect, should a single section 85 factor be relied upon as an initial triage measure, the only such threshold that would be constitutionally appropriate and provide sufficient predictability is the HIP. This is because all reference countries in the PMPRB11 have price control measures. As such, prices in all PMPRB11 countries are necessarily non-excessive. Any triage measure based on a threshold lower than the HIP would be unconstitutional. In particular, applying a median price threshold as a triage measure runs afoul of the QCCA's guidance. As confirmed by the QCCA, an excessive price is one that "exceeds the price for the same medicine in countries reasonably comparable to Canada."[19]

- **Question 1.4:** If international prices are used as the initial triage measure for commencing investigations, what price levels within the PMPRB11 should be used as the triage measure? (e.g. HIP or MIP?)

The QCCA Decision held that the PMPRB cannot use its powers to push prices below an already non-excessive level in pursuit of optimal or reasonable pricing. This would be an unconstitutional exercise of its power under the *Patent Act*.

However, in the event the Final Guidelines rely on PMPRB11 comparator prices as an initial triage measure for the purpose of triggering an investigation, the QCCA Decision prevents the PMPRB from applying anything below than the HIP, notably a pricing approach based on the MIP. For the reasons described above, only a HIP pricing threshold would be constitutionally acceptable.

Furthermore, the MIP is inappropriate because it may vary over time as a drug is launched in different countries, or if there is a reduction in price or a drug becomes generic in different countries. A non-excessive price in Canada cannot become excessive (in the sense of patent abuse) simply because the drug is launched in one or more other countries. This would result in an arbitrary variation in the maximum non-excessive price over time. As stated by the QCCA, arbitrary pricing thresholds are not constitutionally justified.[20]

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[19] *Merck Canada c Canada*, 2022 QCCA 240 ¶49.

[20] *Merck Canada c Canada*, 2022 QCCA 240 ¶244.

In sum, a pricing analysis based on the MIP will have the result of lowering an otherwise non-excessive price, i.e., the price in a PMPRB11 country which regulates the price of drugs. The MIP is thus a means of exerting direct price controls, which the QCCA Decision unequivocally confirms falls outside the scope of the PMPRB's constitutional limits.[21] The QCCA Decision aligns with the Federal Court of Appeal's ruling in *Alexion*, which confirmed that the PMPRB cannot use the basket of comparator countries to regulate prices, but only to monitor for excessive prices.[22]

Once an investigation is launched, and at any Board hearing, the PMPRB must consider the other section 85 factors, as well as any other justification for a drug price that would be higher than the benchmark.

- **Question 1.5:** How should the PMPRB conduct an initial review and monitor the prices of patented medicines that have few or no international prices?

If a drug has few or no international prices at launch, the initial review could take place at the earliest of (i) once five countries in the PMPRB11 have a publicly available price or (ii) once three years have passed since launch. In any event, if the introductory price is deemed excessive in Canada post-launch (i.e. once comparator pricing data is available), the excessive revenues can be reimbursed retroactively. Indeed, companies will have no incentive to launch in Canada at a price that exceeds the HIP.

- **Question 1.6:** Would an expedited price review (e.g., within 90 days after initial Form 2 submission) of a new medicine based solely on international prices being below the MIP accelerate introduction of innovative medicines?
    i. How soon after an expedited review should a full price review take place?

The Constitutional Coalition believes it is premature to comment on this question without further details of the proposed measure.

<u>Theme 2: Transition to PMPRB11 – New versus Existing Medicines</u>

Existing medicines should be grandfathered.

It is important to reiterate that a price cannot become excessive overnight when that price has not changed. Existing medicines should therefore be grandfathered in. Indeed, re-assessing the price of existing medicines – already considered non-excessive, will arbitrarily drive existing prices below previous non-excessive thresholds. This is akin to price control, which the QCCA Decision determined would be an unconstitutional exercise of the PMPRB's excessive pricing mandate.

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[21] See for ex: *Merck Canada c Canada*, 2022 QCCA 240 ¶154, 161-162, 227, 244.

[22] *Alexion v Canada*, 2021 FCA 157 ¶55-60.

Notwithstanding this, if existing medicines are subject to new price thresholds, then they must be assessed according to the same threshold as new medicines, i.e., "higher than the highest."

- **Question 2.1:** Should the Guidelines distinguish between medicines that existed as of July 2022 (existing medicines) and medicines introduced afterwards (new medicines)?

As discussed above, existing medicines should be grandfathered in and reviewed only in the event the price exceeds the allowable CPI increase, since a price cannot become excessive overnight when that price has not changed.

The initial NEAP, plus the allowable CPI increase, should be considered the maximum non-excessive price for existing medicines, irrespective of new pricing data in the PMPRB11. The PMPRB11 cannot be used to lower the price of existing medicines. Any other distinction between "existing" and "new medicines" reflects a pursuit of "optimal" or "reasonable" prices, which is a form of price control.

Indeed, to the extent existing medicines are grandfathered in, any distinction between existing and new medicines becomes a moot issue, since existing medicines will not be subject to pricing re-assessments or re-benching.

In all cases, the Final Guidelines must not introduce different (i.e. lower) thresholds for certain medicines based solely on launch date. Any attempt to distinguish between "new" and "existing" medicines is arbitrary, since neither the *Patent Act* nor the *Patented Medicines Regulations* draw any distinctions between new and existing medicines. A price reduction imposed only on new medicines is thus necessarily arbitrary and contrary to the QCCA Decision.

- **Question 2.2:** What approach should the Board take with respect to existing medicines with prices above the HIP of the PMPRB11? Should the Board review these prices, and if so, how soon?

The PMPRB should only review the price of an existing medicine if its maximum non-excessive price exceeds the allowable CPI increase. As stated, a non-excessive price cannot later become excessive simply by the application of a new threshold, i.e. a new basket of comparator countries.

Theme 3: Price Reviews during Product Life Cycle

Once a price is deemed non-excessive, it cannot subsequently become excessive unless the price is raised beyond the allowable CPI increase. Indeed, the PMPRB's role in the product's life cycle is limited to monitoring for an excessive price – at launch and then subsequently against CPI. The QCCA Decision clearly states that this is the extent of the PMPRB's mandate in the lifecycle of a drug:

> "[The PMPRB's] objective price comparison exercise allows the Board to determine an introductory price in Canada that is not excessive, and which may subsequently evolve in accordance with the CPI without triggering a more thorough inquiry by the Board."[23]

The PMPRB's role is not to ensure optimal or fair pricing, whether this be at launch or any other time in the patent's life cycle. If the PMPRB were to engage in reassessing or re-benching medicines after the initial price review, this would be akin to price control.

- **Question 3.1:** How often should price reviews be conducted?

As stated above, the price of a medicine should be assessed only once at launch (or first sale) and then only subsequently monitored against the allowable CPI increase. This is the only assessment frequency and timing that would comply with the clear wording of the QCCA Decision. Indeed, the QCCA Decision explicitly provides for the possibility of a drug price increasing over time in accordance with the CPI "without triggering a more thorough inquiry by the Board."[24] The Final Guidelines must comply with this guiding principle as confirmed by the QCCA.

A non-excessive price cannot later become excessive simply by the application of a new threshold or a variation thereof, for example if the prices of medicines in certain PMPRB11 countries decrease over time. In particular, if there are changes internationally to pricing or fluctuations in the exchange rate, this should not impact the Canadian list price provided it has not increased beyond CPI. Predictability over the product life cycle is required.

- **Question 3.2:** What criteria besides time should be used to trigger a price review?
  - i. Approval of a significant new indication?
  - ii. Significant change to the therapeutic class comparators? Availability of new/stronger evidence related to benefit vis-à-vis therapeutic class comparators?
  - iii. Departure from identified pricing thresholds?

No criteria, including time, should be relied upon to re-assess or re-bench medicines for which the price was already reviewed at launch. As stated above, there should only be an

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[23] *Merck Canada c Canada*, 2022 QCCA 240 ¶146.

[24] *Merck Canada c Canada*, 2022 QCCA 240 ¶146 (our emphasis).

initial price review at launch (or first sale), following which the PMPRB may only monitor against the allowable CPI increase. A fluctuation in exchange rates or a decrease in price in a comparator country cannot result in creating an excessive price in Canada where the Canadian price did not change.

In particular, none of the above-listed circumstances should have a bearing on whether a price that was initially deemed non-excessive might later be considered excessive. We note in particular that availability of evidence related to benefit vis-à-vis therapeutic class comparators is not relevant as the PMPRB cannot consider the value of a medicine.

- **Question 3.3:** Should the relative weighting given to different section 85 (*Patent Act*) factors change over the lifecycle of a medicine?

In light of the above comments, i.e., a medicine's price should only be reviewed once at launch (or first sale) and subsequently only monitored against the allowable CPI increase, it is not relevant to consider different weighting of the section 85 factors over the lifecycle of a medicine.

- **Question 3.4:** How should the PMPRB treat the allowable Consumer Price Index increase in the context where international list prices are decreasing?

Forcing a reduction in a medicine's price in Canada, which was previously considered non-excessive, simply because of a decrease in price in a PMPRB11 country would be akin to price control. The PMPRB11 comparator countries all regulate the price of drugs and, as the buyers of drugs, have in place price control mechanisms which may require lowering the list price over time. Contrary to these regulatory bodies, the PMPRB's constitutional mandate is limited to preventing excessive prices as a function of patent abuse, nothing more. It does not exercise a health mandate or a price control mandate; that role is occupied by the provinces.

In sum, once a price has been reviewed at launch, the PMPRB may only monitor prices against the allowable CPI increase. In any event, given that CPI is one of the factors provided for at section 85, patentees must always be permitted to take CPI increases. This was expressly confirmed in the QCCA Decision: "[…] an introductory price in Canada that is not excessive […] may subsequently evolve in accordance with the CPI without triggering a more thorough inquiry by the Board."[25]

[25] *Merck Canada c Canada*, 2022 QCCA 240 ¶146.

Theme 4: Investigations and Referral to Hearing

The Constitutional Coalition maintains that investigations and hearings (and related compliance mechanisms, such as VCUs) must respect the QCCA Decision and the legal principles provided for therein.

Theme 5: Relation to pan-Canadian Health Partners, Insurers (Private and Public); and Alignment with Broader Government Initiatives

The PMPRB does not exercise a "health" mandate. It derives its power exclusively from the *Patent Act*, that is to ensure drug prices are not sold at "objectively excessive" levels as a function of patent abuse. As such, it is not relevant to consider if and how the PMPRB should "align with and complement the priorities and objectives of other health partners in the Canadian pharmaceutical landscape." Any measures that aim to align, complement, integrate or coordinate with these bodies would be well outside the scope of the PMPRB's constitutional limits. This was confirmed in the QCCA Decision: the PMPRB must not "substitute it for the provincial bodies, such as the INESSS, and for the provincial health ministers."[26]

Conclusion

The Final Guidelines must be drafted with the QCCA Decision in mind, and the legal principles contained therein. If the Final Guidelines depart from the QCCA Decision, they are at risk of being challenged before the courts. As confirmed by the QCCA Decision, the PMPRB guidelines cannot escape judicial scrutiny on the pretext that they are non-binding: "it would be unacceptable for a regulatory regime to escape constitutional review on the ground that a court could not consider guidelines, whose adoption is prescribed by the Act, and which are indeed determinative in the application of the regime as a whole."[27]

The Constitutional Coalition thanks the PMPRB for this opportunity to provide feedback on this first phase of consultations for the Final Guidelines. The Constitutional Coalition is committed to working cooperatively with the PMPRB to implement its constitutional mandate in a manner that is consistent with the QCCA Decision. We welcome the opportunity to sit down with the Board members to discuss the important guidance provided by the QCCA Decision in greater depth.

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[26] *Merck Canada c Canada*, 2022 QCCA 240 ¶240.

[27] *Merck Canada c Canada*, 2022 QCCA 240 ¶174.