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

Subject: Constitutional Coalition Submissions *re:* Draft Guidelines for PMPRB Staff

The industry coalition that brought the constitutional challenge before the Quebec Superior Court and Court of Appeal, composed of Merck, Janssen, Boehringer Ingelheim, Bayer, and Servier (the "**Constitutional Coalition**"), takes this opportunity to provide written feedback on the PMPRB's Draft Guidelines for PMPRB Staff (the "**Draft Guidelines**"), published in December 2024, in view of the publication and adoption of the final guidelines (the "**Final Guidelines**").

Executive Summary

The Constitutional Coalition provides these written submissions to ensure that the Final Guidelines comply with the constitutional jurisdiction of the PMPRB as defined in the Quebec Court of Appeal's decision in *Merck Canada c Canada*, 2022 QCCA 240 (the "**QCCA Decision**") and the legal principles established therein. These submissions address the elements proposed in the Draft Guidelines that relate to the scope of the PMPRB's constitutional mandate, as established in the QCCA Decision:

(a) **Re-benching during Annual Reviews and for Existing Medicines**:
   i. Whether it is constitutionally appropriate to conduct Annual Reviews using criteria other than consumer price index (CPI);
   ii. Whether it is constitutionally appropriate to review Existing Medicines against criteria other than CPI;

(b) **In-Depth Reviews**: The constitutionally appropriate pricing considerations and use of s. 85 factors at the In-Depth Review stage;

(c) **Compliance timelines for new medicines**: Constitutionally appropriate timing of the Initial Review for New Medicines;

(d) **The constitutional scope of the Board's mandate**:
   i. Articulation of the Guidelines as "for staff";
   ii. Patent dedication and patents pertaining to a medicine;
   iii. Galderma decision;
   iv. The use of complaints, including by private payors; and
   v. The use of deferral letters.

These submissions are in keeping with the Constitutional Coalition's previous submissions of December 2023 and September 2024 submitted in the context of the prior phases of consultations.

Legal Context & Background

It is important to reiterate that the QCCA Decision is binding on the PMPRB, and the PMPRB's mandate and powers are subject to the principles established in the QCCA Decision. The QCCA Decision 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.[1] The section 85 factors and any resulting Guidelines are to be drafted and applied solely in pursuit of this objective.[2] 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.[3]

The QCCA Decision also established that the PMPRB's Guidelines are not exempt from "constitutional review".[4] They must be conceived, adopted and applied within the constitutional framework set out in the relevant case law, including notably the QCCA Decision.[5] The QCCA Decision must therefore inform the drafting, adoption, and application of the Final Guidelines. If the Final Guidelines are not elaborated within these clear parameters, they are at high risk of being judicially reviewed.

In this respect, the Coalition notes that the Guidelines are aimed at the Board Staff to guide the staff in its pricing assessment and do not set any "price ceilings." Only the Board, after a hearing may determine whether a price is excessive in Canada, after careful analysis of all the relevant factors. However, the Guidelines are also intended to provide transparency to rights holders.[6] A price threshold set out in the Guidelines will therefore guide patentee pricing decisions.

Despite language pointing to the "non-binding" nature of the Guidelines, the Guidelines are the very anchor and starting point for all PMPRB pricing assessments[7]. All pricing thresholds and assessment criteria set out therein must therefore uphold the constitutional limits of the Board's jurisdiction, as confirmed by the QCCA Decision and other relevant case law.[8] This is necessary to ensure that their application by the Board Staff will also be constitutionally valid.

If any aspect of the Final Guidelines runs afoul of these principles, for example by establishing arbitrary pricing thresholds which reflect a pricing regulation objective (as opposed to patent abuse

[1] *Merck Canada c Canada*, 2022 QCCA 240 ¶143-146, 153, 163, 179. See also *Galderma v. Canada (AG)*, 2024 FCA 208 ¶12-19.

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

[3] See *Merck Canada c Canada*, 2022 QCCA 240 ¶156, 204, 228, 235.

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

[5] *Merck Canada c Canada*, 2022 QCCA 240 ¶166-167, 174-175. See also *Alexion v Canada*, 2021 FCA 157 ¶57-63.

[6] See sections 4 and 24 and Appendices of Draft Guidelines.

[7] *Merck Canada c Canada*, 2022 QCCA 240 ¶165-176.

[8] See e.g. *Galderma v. Canada (AG)*, 2024 FCA 208.

regulation), any Staff or Board action flowing from the Guidelines will inevitably be based on unconstitutional criteria. In this way, the PMPRB must ensure that the Final Guidelines do not use the section 85 factors to drive prices below constitutionally acceptable non-excessive thresholds. Otherwise, the Final Guidelines are at high risk of future court challenges.

As the Coalition understands that this is the last opportunity for stakeholders to make submissions to the PMPRB before new guidelines are adopted, the Coalition members urge the Board to ensure that the Final Guidelines fully respect the constitutional parameters as set out by the relevant jurisprudence.

Detailed Submissions

The Constitutional Coalition acknowledges that several aspects of the Draft Guidelines respect the constitutional parameters set out in the QCCA Decision.

With respect to the PMPRB's proposal to adopt the highest international price (HIP) as the initial triage measure for the purpose of triggering an In-Depth Review, the Constitutional Coalition highlights that HIP is the only international price comparison (IPC) threshold that is aligned with the PMPRB's constitutional mandate, as defined in the QCCA Decision.[9] Indeed, the QCCA Decision clearly states that an excessive price is one that "exceeds the price for the same medicine in countries reasonably comparable to Canada,"[10] without justification.

The Constitutional Coalition therefore is of the view that anything less than HIP would not respect the constitutional division of powers. This should continue to be reflected in the Final Guidelines.

In spite of the above, there remain certain aspects which run afoul of the QCCA Decision and the constitutional mandate of the PMPRB. Below, we highlight those aspects.

a) Re-Benching

This section deals with "re-benching" of medicines (i) at the annual review stage and (ii) with respect to Existing Medicines. At all stages of its life cycle, the price of a medicine must be assessed against constitutionally valid thresholds. To the extent the price of a medicine is re-assessed (i.e. re-benched) according to criteria that do not respect the constitutional parameters of the PMPRB's mandate, this would be an unconstitutional exercise of the PMPRB's powers.

i. Annual Reviews

The Draft Guidelines provide that Board Staff shall conduct an initial price review upon introduction (i.e., the "Initial Review") and subsequently on an annual basis (i.e. the "Annual

[9] *Merck c Canada*, 2022 QCCA 240 ¶49, 143-146. See also *Alexion v Canada*, 2021 FCA 157 ¶55-60.

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

Review"), wherein drug prices would be compared against not only changes in CPI, but also the HIP.

The Constitutional Coalition submits that the price of a medicine should be assessed against HIP during an Initial Review and then only subsequently monitored against the allowable CPI increase. This is the only method that complies with the clear wording of the QCCA Decision.

The QCCA clearly established that a price that is under the acceptable thresholds at launch can validly evolve over the course of its life cycle in accordance with the allowable CPI increase. As the QCCA stated:

> The purpose [of the pricing assessment] is to ensure that the price charged for the patented medicine in Canada compares favourably to the price charged for the same medicine and medicines in the same therapeutic class in Canada and in other countries. The non-excessive price thus determined may then evolve in accordance with the Consumer Price Index ("CPI"), which is the other factor to consider. […]
>
> This 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.[11] [Emphasis added]

The PMPRB cannot re-assess the price of a medicine (or "re-bench") at the Annual Review against any criteria other than the allowable CPI increase, i.e. it cannot reintroduce the HIP at this stage. Doing so would run afoul of the QCCA Decision's guidance and does not reflect the constitutional mandate of the PMPRB of preventing excessive prices flowing from an abuse of the monopoly granted by a patent.

This is because an evolving HIP reflects changing market and/or regulatory conditions in other jurisdictions and over which a Canadian patentee has no control. Such a factor cannot be considered to determine excessive pricing in Canada ***as a function of patent abuse***. Whatever market or regulatory changes occur internationally – be they fluctuations in the exchange rate, regulatory amendments or otherwise – cannot possibly suggest that a patentee is suddenly abusing its patent.[12] Indeed, the PMPRB must keep in mind that prices may indeed decrease over time in other PMPRB11 countries due to all sorts of considerations in those countries, including their respective price control measures. Therefore, following those international price changes could allow the PMPRB to import a price control mandate where it is not constitutionally acceptable to do so.

At the Initial Review, if the price of the medicine in Canada is in line with the applicable thresholds because it respects HIP, other factors that are external both to patents and to Canada cannot be used to subsequently drive price thresholds down. Re-benching due to changes in foreign market

[11] *Merck Canada c Canada*, 2022 QCCA 240 ¶144, 146.

[12] See *Alexion v Canada*, 2021 FCA 157, ¶55-68.

or regulatory conditions that occur after the Initial Review is an attempt to arbitrarily drive prices down beyond acceptable (non-excessive) thresholds and to regulate the market itself. This is pricing regulation, not patent abuse regulation.

On this, the QCCA notes:

> […] by imposing arbitrary price reductions […] on prices already deemed not to be excessive, the federal government is no longer acting within its jurisdiction over patents of invention and discovery because it does not want to regulate the effects on prices of the monopoly granted by the patent, but rather the market itself.[13]

Furthermore, re-benching at the Annual Review stage could result in pharmaceutical companies having to renegotiate their product listing agreements ("PLAs") with the provinces, since a change in list price could impact the confidential pricing agreements negotiated with the provinces. This is further demonstration that Annual Reviews against anything other than CPI are an unconstitutional process that would disrupt the constitutional balance of powers. PLAs are an essential part of the price control measures undertaken by the provinces in the exercise of their power over health and property and civil rights.[14]

By conducting Annual Reviews against criteria other than CPI (namely HIP), a patentee might need to reduce its price annually to avoid a hearing (and by extension, necessarily amend its PLAs annually). The PMPRB would therefore take on a "role in the optimization of provincial resources and provincial health budgets [and be] directly intruding into provincial heads of power," which the QCCA confirmed would be an unconstitutional exercise of its mandate.[15]

If the PMPRB engages in re-benching medicines after the Initial Review (beyond the allowable CPI increase), this would be akin to price control and unconstitutional. The Final Guidelines must reflect the constitutional limits of the PMPRB's mandate and remove the HIP criteria from the Annual Review.

ii. Existing Medicines

Likewise, Existing Medicines should be "legacied,"[16] meaning they should not be subject to any additional price review under the Final Guidelines (except for the allowable CPI increase). Existing Medicines sold at prices that were considered non-excessive based on the PMPRB's own criteria prior to the implementation of the Final Guidelines (i.e. the guidelines previously in effect) should continue to be considered non-excessive under the Final Guidelines, with the addition of

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

[14] *Merck Canada c Canada*, 2022 QCCA 240 ¶79-84.

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

[16] We use the term "legacied" instead of "grandfathered", which is more inclusive.

allowable CPI. These Existing Medicines were launched with the understanding and expectation that they would be assessed based on the rules that were in effect at the time they were launched.

Indeed, a price cannot become excessive overnight when that price has not changed (except for the allowable CPI increase). Re-assessing the price of Existing Medicines – already considered non-excessive by the PMPRB's own standards – will arbitrarily drive existing prices below 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.[17]

By the time the Final Guidelines come into effect for Existing Medicines, they will have been on the market for many years. It is not constitutionally appropriate to re-assess the price of a medicine so far into its life cycle against any criteria other than CPI.

Indeed, at that point in a product's life cycle, it has likely lost market exclusivity, whether by generic versions of the same medicine or competition within the class (wherein some class competitors may have generic equivalents). In either case, the medicine does not have a true monopoly which could be abused.

Put differently, where there is competition (especially generic competition), patent abuse is effectively implausible. It bears repeating here: the PMPRB's mandate is limited to monitoring for excessive prices that result from an abuse of the monopoly granted by a patent. The QCCA was unequivocal on this point:

> Thus, the federal jurisdiction over the price of patented medicines concerns the effects of the monopoly granted by the patent, not the effects on the market as a whole. It therefore concerns the control of excessive prices resulting from the monopoly.[18]

Consequently, where there are generic versions of an Existing Medicine on the market or class competitors, the Board carries a heavier burden to demonstrate that any price alleged to be excessive is due to a monopoly that could be abused.

Furthermore, not only does giving legacy status to Existing Medicines ensure predictability to patentees over the life cycle of a medicine, but not doing so for Existing Medicines may require patentees to revise their PLAs with the provinces, as is the case with re-benching at the Annual Review stage (as above).

As with Annual Review re-benching, we reiterate what the QCCA said on this point: "This objective price comparison exercise allows the Board to determine an introductory price in Canada

[17] See e.g., *Merck Canada c Canada*, 2022 QCCA 240 ¶197, 244.

[18] *Merck Canada c Canada*, 2022 QCCA 240 ¶216.

that is not excessive, and which may subsequently evolve in accordance with the CPI without triggering a more thorough inquiry by the Board."[19]

In sum, the price of an existing medicine, plus the allowable CPI increase, should be considered the maximum non-excessive price for Existing Medicines, irrespective of the introduction of the PMPRB11. The PMPRB11 cannot be used to arbitrarily lower the price of Existing Medicines already deemed non-excessive by the PMPRB's own standards.

b) In-Depth Reviews

At the In-Depth Review stage, the Board Staff must continue to apply constitutionally-appropriate standards when assessing prices.

The Coalition acknowledges that the Board Staff can and should consider all s. 85 factors in its assessment at this stage, but cautions that the PMPRB may not rely on the section 85 factors to drive prices down below otherwise non-excessive thresholds.

In this context, we note that the HIP is one such threshold. As previously discussed, and more fully detailed in our December 2024 submission, the PMPRB11 basket is composed entirely of countries considered to be comparable to Canada and that regulate the price of medicines. Indeed, the highest price among a select group of countries with robust regulatory mechanisms for drug pricing provides a ceiling that has been recognized as acceptable – thus non excessive – within similar healthcare economies.

It follows that none of the PMPRB11 prices (including the HIP) can plausibly be considered "excessive." The prices in each of these countries have been effectively vetted and considered reasonable by experienced regulatory entities, making the characterization of a price at or below HIP as "excessive" implausible.

This is true at the Initial Review stage, and it remains true at the In-Depth Review as well.

As a result, a price at or below the HIP should never be considered excessive and should therefore not be recommended for a hearing, regardless of where that price sits in relation to the other s. 85 factors (in particular the TCC).

Similarly, the highest price of innovative therapeutic comparators that are for a materially similar approved indication or use is also a non-excessive threshold. Consequently, a price that is at or below the TCC threshold should likewise never be considered excessive and should not be recommended for a hearing, regardless of where that price sits in relation to the other s. 85 factors (in particular the HIP).

In other words, the PMPRB cannot rely on the section 85 factors to drive prices down below these otherwise non-excessive thresholds. As the QCCA explained:

[19] *Merck Canada c Canada*, 2022 QCCA 240 ¶144, 146 (our emphasis).

> The *Patent Act* does not define an excessive price, but it can be understood from the factors set out in the Act that it 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.[20]

Consequently, to be the subject of a hearing and ultimately considered excessive, a price needs to be higher than the HIP and higher than the TCC *without justification*.[21] The Final Guidelines should reflect this so that the Board Staff applies a constitutionally-appropriate standard when assessing prices at the In-Depth Review stage.

The Coalition therefore urges the PMPRB to provide greater clarity on how the s. 85 factors will be used during In-Depth Reviews and how they will guide the Staff's decisions on whether a hearing should be recommended.

In particular, while suggested in the appendices, the Coalition urges the PMPRB to clearly implement the following assessment criteria during In-Depth Reviews for the purposes of whether to recommend a hearing:

- When determining whether to recommend a hearing, the only IPC threshold the Board Staff may consider is the HIP. The Final Guidelines must consistently use this term (i.e. "HIP") rather than generally refer to "IPC" to avoid confusion as to which IPC threshold will be applied (see for example the Appendices, where the term "IPC" is used rather than "HIP").
- The therapeutic class comparison (TCC) cannot be used to drive prices down below otherwise non-excessive thresholds; TCC may only be used to justify a price higher than the HIP.
- A "highest of the high" standard, whereby a medicine would be recommended for a hearing only if its price exceeds both the HIP and the TCC – and without justification for such price.
- Even with a "highest of the high" approach, the Final Guidelines should retain the "significant" differential threshold in determining whether to recommend a hearing.

In keeping with the QCCA Decision, if the Final Guidelines are drafted in a way that suggests that the Staff could recommend a hearing if a price is below the HIP, or is not higher than both the HIP and TCC respectively, or is not "significantly above" any of the factor thresholds, they would be constitutionally suspect. It bears repeating here: the PMPRB has a patent abuse mandate, not a price control mandate. As such, all aspects of the Final Guidelines, including how the s. 85 factors will be weighted at the In-Depth Review stage, must be drafted and implemented from a patent abuse standpoint.

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[20] *Merck Canada c Canada*, 2022 QCCA 240 ¶49 (see also ¶154, 161-162, 227, 244).

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

c) ***Compliance Timelines***

The Coalition urges the Board to revise the timelines to come into compliance in a way that is constitutionally appropriate, i.e. (i) there must not be a retroactive application of the Final Guidelines; and (ii) the Final Guidelines should provide a transition period that more adequately reflects the constitutional framework.

i. No Retroactive Application

Section 55 of the Draft Guidelines provides that New Medicines will be "reviewed" immediately after the Guidelines come into effect. The Coalition urges the PMPRB to clarify the meaning of the word "reviewed" to ensure the Guidelines are not applied retroactively. While the prices of New Medicines must comply with the Guidelines as of their coming into force (assuming January 1, 2026), the PMPRB may only begin assessing prices following the January – June 2026 reporting period. In other words, the PMPRB cannot assess pricing data from the July 2025 – December 2025 reporting period against the price thresholds in the new Guidelines prior to their coming into force. This would result in a retroactive application of the Guidelines and effectively extend their application an additional six months prior to their coming into force, thus requiring compliance as of July 2025. This would be an illegal application of the Guidelines and would raise serious concerns of fundamental justice.[22]

Moreover, the Coalition reminds the PMPRB that New Medicines include those which were first sold on or after July 1, 2022. This means that as of the date of this submission, some of these medicines will have already been on the market for 2.5 years. By the time Final Guidelines are adopted, some will have been on the market for 3 years or longer. The prices of these New Medicines were established during a period of uncertainty when there was no predictability about final pricing guidelines. Still, in order to ensure that Canadians had access to the newest innovations, patentees launched their products and entered into confidential listing agreements with public and private insurers.

In addition, the Coalition is aware that patentees are receiving PMPRB status reports for the 2024 reporting period for their medicines currently on the market (i.e., Existing and New medicines), which indicate that "Once the new guidelines are in place, the Interim Guidance will cease to apply and the relevant provisions of the new Guidelines will apply to the prices of sales made during the Interim Period." This is concerning. As above, any form of retroactive application of the Final Guidelines raises serious questions of fundamental justice and procedural fairness, since there was no way for patentees to comply prior to the publication of the Final Guidelines.

ii. Transition Period

A transition period for New Medicines is needed to provide Rights Holders adequate time for price adjustments, including potential renegotiation with public and private insurers. The Constitutional

[22] See *Canada (AG) v. Whaling*, 2014 SCC 20 ¶55. The same would be true for Existing Medicines: compliance would effectively be required as of July 2026 if they are "reviewed" in January 2027.

Coalition submits that Staff should therefore wait until a minimum of two reporting periods have passed, starting on the period during which the Final Guidelines come into effect, to perform an Initial Review. In particular, the Coalition proposes that Staff should conduct the Initial Review at the earlier of either: (i) three years from the date of the introduction of the patented medicine in Canada; or (ii) the date when the patentee has filed international price information for at least five of the PMPRB11 countries.

With respect to Existing Medicines, the Coalition's position is, as stated above, that they should be legacied; the issue of a compliance timeline would therefore be moot. However, if the Final Guidelines do not give legacy status to Existing Medicines, the Coalition urges the PMPRB to adopt the proposed one-year transition period as a minimum.

The Coalition submits this would be a constitutionally appropriate assessment timeline. The more international pricing data is available, the more accurate the pricing analysis will be. This will ensure the IPC factor is used in a constitutionally relevant way, since a more fulsome picture will be available to the Board Staff to conduct its pricing assessment in Canada.

Finally, since pharmaceutical companies are generally precluded from increasing the list price of a medication that is subject to a provincial PLA (which often takes 2 to 3 years to conclude), but may otherwise safely launch at the HIP (pursuant to the PMPRB framework to avoid recommendation for a hearing), this proposed timeline would ensure that both the provincial and federal regimes are aligned and not conflicting with one another. In other words, the proposed timeline would ensure that medications are launched in Canada at a price that conforms to the constitutional division of powers.

d) The constitutional scope of the Board's mandate

As a final matter, the Coalition wishes to remind the Board of certain aspects of the Draft Guidelines pertaining to the scope of its constitutional mandate as a patent abuse regulator, not a pricing regulator. This has to be reflected in all aspects of the Final Guidelines, as further outlined below.

i. The use of complaints, including by private payors

There is no legal basis for complaints in the *Patent Act* and no constitutional justification for them either. The Constitutional Coalition therefore submits that there should be no complaints mechanism at all.

Indeed, if a price is considered compliant per the PMPRB's own criteria (for example, following an Initial Review and during Annual Reviews), that price cannot (and should not) be considered non-compliant and subjected to an In-Depth Review simply as a result of a third-party complaint.

The opinion of a third-party should have no bearing on the PMPRB's determination of whether a price is compliant. The PMPRB has spent months (if not years) consulting on the constitutionally

appropriate thresholds to apply. If a price is in line with these thresholds, then it is not excessive and should not be subject to further review.

What's more, a third-party may have different motives for submitting a complaint to the PMPRB. We note for example that there is a clear conflict of interest for private payers to be able to file complaints given they represent private, for-profit interests. Indeed, private payers are in some instances legally required to provide equivalent coverage to public plans. In these cases, amongst others, they could be incentivized to use the complaint process to lower the list price of a drug for their own commercial benefit or as a delay tactic during the negotiation of rebates. Since In-Depth Reviews put a higher burden on rights holders in terms of time, costs, and uncertainty, the PMPRB must ensure that this process cannot be abused in this way.

Consequently, the Coalition urges the Board to remove the ability for third parties (and especially private payors) to submit complaints. Failing that, the Board should at least implement a clear threshold pursuant to which a complaint would actually lead to an In-Depth Review, for example above the HIP. In sum, there should be no mechanism for complaints to go straight to an In Depth Review. Otherwise, the complaint mechanism could be misused, and in the case of private payors, for private commercial gain.

ii. Patent Dedication

The Coalition submits that the Final Guidelines must accurately reflect that the PMPRB ceases to have jurisdiction in the event of patent dedication. At section 32, the Draft Guidelines continue to inaccurately assert that the PMPRB has jurisdiction over medicines whose patents have been dedicated to the public.

In support of this position at footnote 8, the PMPRB incorrectly relies on its decision of 1992, *Genentech Canada Inc. (Re)*.[23] However, this decision was clearly superseded by the more recent Federal Court of Appeal ("FCA") decision, *Parke Davis Division v. Canada (Minister of Health)*,[24] wherein the FCA held that *Genentech* does not establish a general rule that patent dedication is impossible or not recognized by the *Patent Act*.

Instead, the FCA confined *Genentech* to its very specific facts (namely an attempt to use a backdated dedication to retroactively evade the PMPRB's jurisdiction), writing that *Genentech* "does not establish that it is impossible as a matter of law to surrender patent rights by means of a dedication to public use,"[25] and "the *Genentech* case is not on point" because none of the dedications at issue in *Parke Davis* were backdated.[26] Reliance on *Genentech* as creating a general rule that it is impossible to dedicate a patent is inconsistent with this FCA ruling.

[23] [1992] 44 CPR (3d) 316.

[24] 2002 FCA 454.

[25] *Parke Davis Division v. Canada (Minister of Health)*, 2002 FCA 454 ¶79.

[26] *Parke Davis Division v. Canada (Minister of Health)*, 2002 FCA 454 ¶83.

Similarly, the Draft Guidelines suggest that because patent dedication "is not expressly recognized in the Act," it is impossible. Once again, the FCA rejected this position in *Parke Davis*, writing that the *Patent Act*'s "silence on this matter […] is not determinative."[27] Indeed, the validity of patent dedication has been recognized in multiple subsequent cases: *Sandoz Canada v. Abbott Laboratories*,[28] *G.D. Searle v. Merck*,[29] and *Merck v. Canada (Health)*.[30] These decisions are clear that dedication is a recognized and effective means of terminating patent rights, and they are all binding on the Board.

If a patentee relinquishes its patent rights on a medicine via dedication, then that medicine is no longer protected by a patent. Excessive pricing as a result of patent abuse is thus impossible, and the PMPRB no longer has jurisdiction over that medicine. The Coalition therefore urges the Board to reconsider its position regarding patent dedication and follow the clear position of the Federal Court of Appeal in *Parke Davis* and subsequent cases.

iii. Galderma Decision

At section 31 of the Draft Guidelines in its description of the scope of its jurisdiction, the PMPRB relies on the 2017 and 2019 *Galderma* decisions[31] as to whether an invention pertains to a medicine. However, as the PMPRB is surely aware, the Federal Court of Appeal ("FCA") recently revised the conclusions of these decisions in *Galderma Canada v Canada (AG)*, 2024 FCA 208. In this decision, the FCA unequivocally confirms that the Board's jurisdiction extends only to patented medicines. As the FCA stated: "Quite simply, under the *Constitution*, the *Patent Act* and the jurisprudence under each, the Board does not have the power to regulate the prices of unpatented medicines during the period they are unpatented."[32]

The Final Guidelines must therefore reflect the current state of the law and be drafted in line with *Galderma 2024* (notably at footnotes 6 and 7). Similarly, the review of any associated DINs at the In-Depth Review stage (as contemplated at sections 47 and 52 of the Draft Guidelines) must be justified, i.e. all DINS under review must relate to patented medicines.

iv. The Use of Deferral Letters

Finally, the Coalition wishes to raise a concern with respect to the use of deferral letters. The Coalition urges the Board to provide greater clarity on how and when deferral letters will be issued. Per section 5 of the Draft Guidelines, the Guidelines "are designed to ensure procedural fairness and consistency in that all similarly placed Rights Holders are subject to the same process and process timelines."

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[27] *Parke Davis Division v. Canada (Minister of Health)*, 2002 FCA 454 ¶81.

[28] 2010 FCA 168 ¶30-40.

[29] 2002 FCT 540 ¶96.

[30] 2010 FC 1043 ¶30.

[31] *Galderma Canada v. Canada (AG)*, 2017 FC 1023 and *Canada (AG) v Galderma Canada*, 2019 FCA 196.

[32] *Galderma Canada v Canada (AG)*, 2024 FCA 208 ¶8.

The language used in the Guidelines (namely at sections 5 and 24) creates a legitimate expectation for rightsholders that their medications will be reviewed in a transparent and procedurally fair manner. Rights holders may therefore expect the Board to assess medications in a timely manner. Notably, rights holders are entitled to a certain amount of predictability with respect to how far back excess revenues may be claimed.

Likewise, sections 5 and 24 of the Guidelines create a legitimate expectation that all rights holders will be subject to the same assessment timelines. Rights holders may therefore also expect the Board to assess medications in an equally timely manner.

The use of deferral letters will therefore run afoul of the Board's own stipulations and, what's more, basic principles of administrative law. Not only will their use by the Board Staff place rights holders in a procedurally unfair state of uncertainty, but it will also create discrepancy between how rights holders are treated by the PMPRB.

Conclusion

The Final Guidelines must be drafted and implemented in keeping with the QCCA Decision and the legal principles contained therein. If the Final Guidelines depart from the QCCA Decision, they are at high 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."[33]

As a final matter for the Board's consideration, it is important to note that in the current political and economic context, where there is much uncertainty owing to cross-border tariffs, the Coalition urges the Board to adopt a flexible approach when examining prices that may be subject to tariffs. Indeed, if tariffs apply to some pharmaceutical products, this must be amply considered by the PMPRB at all stages.

The Constitutional Coalition thanks the PMPRB for this opportunity to provide feedback on this final 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.

Sincerely,

Fasken Martineau DuMoulin LLP

Fasken on behalf of the Constitutional Coalition (Merck, Janssen, Bayer, Boehringer Ingelheim, Servier)

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