UNIVERSITY OF ALBERTA

SCHOOL OF PUBLIC HEALTH

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

Dr Mike Paulden
Associate Professor
School of Public Health
University of Alberta

3-300 Edmonton Clinic Health Academy
11405 87 Ave NW
Edmonton, AB, T6G 1C9
CANADA

paulden@ualberta.ca

To whom it may concern,

RE: Consultation on 2022 Proposed Updates to the PMPRB Guidelines

We are academic health economists, with expertise in pharmacoeconomics, health economic evaluation, and health technology assessment.

In a personal capacity, we wish to make some observations about the proposed updates to the Patented Medicine Prices Review Board (PMPRB) Guidelines, and to offer some proposals for how the federal government can address their limitations.

Disclaimer: MP, SP and LC have no relationships with, or financial interests in, any payers, insurance companies, patient groups, or pharmaceutical companies. CM, DC and PP have historical relationships with parties that would be affected by the proposed regulations. Our comments reflect our personal views only. None of our comments constitute legal advice. We have translated some quotes from French to English using Google Translate; in such cases, the French original takes precedence.

1. The Canadian federal government has the constitutional authority to regulate patented medicine prices so that they align with those that would arise in a competitive market

In *Merck Canada Inc. et al. v. Canada (Attorney General), 2022 QCCA 240A*, the *Quebec Court of Appeal* clarified the extent of the federal government's jurisdiction over the price effects of the monopoly conferred by patented medicines.[1] The court concurred with an earlier ruling that:

> *"... if the federal government can confer a monopoly on a drug by means of a patent, it certainly has jurisdiction to counter the effects of this monopoly through measures that promote competitive prices for these drugs"* [translated; para. 214].

The court held that the federal government's jurisdiction to regulate patented medicine prices is limited to this narrow purpose. Specifically, it found that:

> *"... federal price control of patented medicines is constitutionally valid to the extent that its pith and substance is to avoid the adverse price effects of the monopoly conferred by the patent"* [translated; para. 243].

In other words, the federal government has the constitutional authority to regulate the price of a patented medicine down to the price at which the medicine would otherwise have been sold in a competitive market (i.e. in the absence of the monopoly protection afforded by the *Patent Act*), but no further than this.

2. There are compelling moral and economic reasons for the federal government to regulate medicine prices to the full extent permitted under its jurisdiction

In the case cited above, the *Quebec Court of Appeal* recognized the *moral* basis for regulating the prices of medicines so that they align with the competitive market price. The court found that, while increases in prices due to patent monopolies *"may be socially acceptable for most patented products and processes, this is not always the case for patented medicines, since it is human health that is at stake"* [translated; para. 208]. Patents on medicines therefore *"raise questions of public interest that distinguish them from patents for other types of products or processes"* [translated; para. 209].

Over recent years, health economists have made remarkable progress in developing and applying methods to empirically estimate the adverse impacts on the health of patients that arise from the incremental costs of spending on patented medicines and other health technologies within public or private health care systems.[2,3] As a result of these advances, the health losses incurred by patients due to excessive patented medicine prices are no longer abstract; they can be estimated and taken into account by policymakers. These health losses occur because limited resources spent on patented medicines cannot otherwise be used to expand access to other health care of value to patients, including routine and high value therapies that are currently subject to waiting lists across Canada.

The COVID-19 pandemic has exacerbated these resource constraints, resulting in a growing backlog of surgeries that has put unprecedented pressure upon Canada's public health care systems.[4] The Ontario Medical Association has proposed a 'five-point plan' for recovering from the pandemic, including additional investments to reduce wait times and strengthen mental health supports and pandemic preparedness; excessive patented medicine prices consume valuable resources that could be used to support these and other proposals.[5]

In this context, we believe that the federal government has a moral responsibility to ensure that federal patent law and price regulation does not harm Canadians by placing further pressure on Canada's public health care systems. To the extent that the federal *Patent Act* may result in higher prices for medicines, the federal government must ensure that the PMPRB has the tools and supports necessary to regulate prices so that they align with what prices would otherwise be in the absence of a patent monopoly. The *Quebec Court of Appeal* has confirmed that the federal government has the constitutional authority to do this.

There is also an *economic* case for regulating the prices of patented medicines so that they align with those that would arise in the absence of a patent monopoly. The *Quebec Court of Appeal* noted that:

> *"While the monopoly conferred by the patent allows innovative pharmaceutical companies to generate significant revenues in order to promote pharmaceutical research and development – a social objective of great importance – it can also have the effect of increasing the price of a patented medicine compared to what the pharmaceutical company might otherwise charge for that medicine in a competitive market free of monopoly."* [translated; para. 209]

In other words, the court recognized that a patent monopoly can increase revenues for the patent holder in two distinct ways:

1. By allowing the patent holder to retain the entire producer surplus that would otherwise arise in a competitive market (with no need to share this with other firms, as would be the case under competition);

2. By enabling the patent holder to raise the price, relative to that in a competitive market, so as to increase the producer surplus.

The second of these is rightly recognized as problematic, since it results in a greater loss of consumer surplus than the resulting gain in producer surplus, such that total welfare is reduced; this loss in total welfare is commonly referred to as the 'deadweight loss', and is a widely understood problem associated with unregulated monopolies. Regulating prices to those that would arise in a competitive market is a rational means for mitigating this deadweight loss.[6]

It should be emphasized that regulating prices to the competitive level still permits the patent holder to retain the entire producer surplus that would arise in a competitive market (the first point above), providing additional revenues to support research and development (R&D) and preventing other firms from being able to free-ride on the patent holder's investments in R&D. But there is no good reason for the federal government to permit prices above this competitive level; if society desires that even greater resources be provided to support medicine R&D, it would be more efficient to provide these as lump sum transfers (e.g. federal grants for scientific research) than by permitting inefficiently high prices that result in a deadweight loss to society.

3. The proposed PMPRB Guidelines do not support effective price regulation to the full extent permitted under the federal government's jurisdiction

Despite the compelling moral and economic basis for regulating patented medicine prices so that they align with the competitive market price, as permitted under the federal government's jurisdiction, the proposed PMPRB Guidelines do little to support the Board in achieving this.

This is because the proposed Guidelines are necessarily focused upon the factors listed in section 85(1) of the *Patent Act*, yet none of these factors meaningfully assists in estimating the price that a medicine would be expected to be sold at in Canada in the absence of a patent monopoly.[7] Some reasons for this are as follows:

a) The first factor in section 85(1) is *"the prices at which the medicine has been sold in the relevant market"*. Since Canada has had patent protection for medicines since 1987, none of the prices at which currently patented medicines have been sold in Canada reflect the prices that these medicines would otherwise have been sold at in the absence of a patent monopoly.

b) The second factor is *"the prices at which other medicines in the same therapeutic class have been sold in the relevant market"*. If there were no *Patent Act*, the Canadian prices of *other* medicines in the same therapeutic class would also likely be lower, since patent monopolies affect more than just the price of the medicine under consideration. It follows that this factor tells us little about what the prices of these other medicines would be - and even less about what the price of the medicine in question would be - in the absence of a patent monopoly.

c) The third factor is *"the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada"*. Critically, every other PMPRB11 country has its *own* patent laws that may increase domestic list prices above those that would arise in a competitive market. There is no rational basis for why the prices for a medicine observed *in other countries* in the *presence* of a patent monopoly would reflect the price that would otherwise arise *in Canada* in the *absence* of a patent monopoly.

d) The fourth factor is *"changes in the Consumer Price Index"*. While this is a useful factor when considering potential changes in medicine prices over time, it does not assist in estimating the price that would have arisen in the absence of a patent monopoly.

e) The final element of section 85(1) allows the federal government to propose *"other factors as may be specified in any regulations made for the purposes of this subsection"*. The 'economic factors' previously proposed by the federal government were examples of such 'other factors'; however, following their repeal earlier this year, there are no such 'other factors' currently specified in any regulations.

In short, the factors listed in section 85(1) of the *Patent Act* are insufficient to support estimation of the prices of medicines that would arise in the absence of a patent monopoly. Yet the *Quebec Court of Appeal* has confirmed that the federal government has the jurisdiction to regulate to this extent, and there is a compelling moral and economic basis for doing so. It follows that there is an inconsistency between the extent of the federal government's jurisdiction to regulate patented medicine prices, and the factors currently specified in section 85(1) of the *Patent Act*.

Since the proposed Guidelines are necessarily focused upon these section 85(1) factors, their application would result in inadequate price regulation of patented medicines. Patent holders would be permitted to price medicines above the competitive market price, resulting in a loss of economic welfare and adverse impacts on the health of Canadian patients.

4. Additional factors that could be specified under section 85(1)(e) of the Patent Act

Given the inadequacies of the section 85(1) factors in the *Patent Act*, the federal government should specify additional factors under section 85(1)(e) to be used by the PMPRB to estimate the price that would arise in the absence of a patent monopoly. The PMPRB Guidelines should then be updated to allow for consideration of these additional factors.

It should be noted that the federal government's previous attempt to propose additional factors was declared *ultra vires* by the *Quebec Court of Appeal* because their pith and substance were not focused upon addressing the adverse price effects associated with the patent monopoly. Yet it would clearly be possible to specify additional factors under section 85(1)(e) - including 'economic' factors - provided that these are considered only to the extent that they support the PMPRB in estimating the price that would be expected to arise in the absence of a patent monopoly. The fact that a previous attempt to introduce additional factors was struck down for having an inappropriate pith and substance is a poor reason for avoiding further efforts that strike the right constitutional balance, particularly in light of the inadequacy of the current factors listed in section 85(1) of the *Patent Act* and the adverse implications for the health of Canadians that arise from weak federal price regulation of patented medicines.

Additional factors that could be considered under section 85(1)(e) include, but are not limited to:

I. The patent holder's marginal costs of supplying the medicine, and the marginal costs that would be faced by other firms when supplying the medicine in a competitive market. Understanding these marginal costs would allow for consideration of the lowest price at which the medicine could be supplied in a competitive market.

II. The medicine's market size. This is important for considering the extent of competition that a medicine would face in the absence of a patent monopoly. For example, a medicine with larger market size might be expected to face greater competition in a competitive market, resulting in a lower price.

III. Aspects of the medicine's pharmacoeconomic value that impact upon the competitive market price. For example, a more effective medicine would likely command a higher price in a competitive market. The competitive market price would also reflect the willingness-to-pay of purchasers (public payers, private payers, and individuals).

IV. The extent to which the prices of other medicines have been observed to fall following patent expiry and generic entry. This might provide a useful baseline to consider the expected gap between the price of a new medicine in a competitive market and its price when protected by a patent monopoly. However, a new medicine might be expected to attract greater interest from generic competitors than an older medicine at the end of its patent life, resulting in greater competition and a correspondingly lower price; a greater reduction than this baseline might therefore be warranted.

V. The implications of international reference pricing for the lowest price at which a patent holder and other firms would be willing to supply in a competitive market.

5. A potential stopgap: section 85(2) of the Patent Act

Section 85(2) of the *Patent Act* allows the following 'additional factors' to be taken into account in cases where *"the Board is unable to determine whether the medicine is being or has been sold in any market in Canada at an excessive price"* based on the factors in section 85(1):

a) *"the costs of making and marketing the medicine"*; and

b) *"such other factors as may be specified in any regulations made for the purposes of this subsection or as are, in the opinion of the Board, relevant in the circumstances"*.

Factor (a) is very relevant for determining the price that a medicine would be sold for in a competitive market, provided it allows for consideration of the medicine's marginal costs of production (an important determinant of the competitive market price).

The scope for considering 'other factors' under (b) would allow the PMPRB to take into account one or more of the additional factors proposed above, provided that these are considered by the Board to be *"relevant in the circumstances"*. In determining their relevance, we would encourage the Board to consider the recent decision of the *Quebec Court of Appeal*, and define an 'excessive' price for a patented medicine as one that exceeds the price that would be expected to arise in the absence of a patent monopoly. This would allow for more appropriate federal price regulation than is possible when considering the factors currently listed in section 85(1).

Nevertheless, the use of section 85(2)(b) for this purpose should be considered a stopgap measure until more relevant factors can be specified in regulations under section 85(1)(e) and incorporated into future PMPRB Guidelines.

6. Summary

There are compelling moral and economic reasons for the federal government to regulate patented medicine prices to the full extent permitted by the constitution. According to the *Quebec Court of Appeal* decision in *Merck Canada Inc. et al. v. Canada (Attorney General), 2022 QCCA 240A*, this means aligning prices to those that would arise in the absence of a patent monopoly.

A decision by the federal government not to regulate to the full extent of its jurisdiction imposes a burden on provincial and territorial health care systems, with adverse implications for patients, since the consequence of excessive patented medicine prices for Canada's public health care systems is forgone spending on other effective health care for patients in need.

If such regulation is not currently possible due to the inadequacy of the factors specified in section 85(1) of the *Patent Act*, then the federal government has both the means and the responsibility to address this by specifying additional factors under section 85(1)(e).

In the meantime, the proposed PMPRB Guidelines do not support the Board in regulating patented medicine prices to the full extent permitted under the federal government's jurisdiction, with adverse implications for Canadian patients.

Regards,

Dr Mike Paulden
Associate Professor
School of Public Health
University of Alberta

Dr Stuart Peacock
Professor
Faculty of Health Sciences
Simon Fraser University

Dr Christopher McCabe
Professor
Centre for Public Health and Queen's Management School
Queen's University Belfast

Dr Lauren Cipriano
Associate Professor
Ivey Business School and Schulich School of Medicine & Dentistry
Western University

Dr Doug Coyle
Professor
School of Epidemiology and Public Health
University of Ottawa

Dr Petros Pechlivanoglou
Associate Professor
Child Health Evaluative Sciences
The Hospital for Sick Children

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