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Canada Gazette 1 Consultation: Global Affairs Canada *Consulting Canadians on the Canada-United States-Mexico Agreement (CUSMA)*

INTRODUCTION

On behalf of Innovative Medicines Canada (IMC) and its membership, this submission is in response to the government notice *Consulting Canadians on the Canada-United States-Mexico Agreement (CUSMA)* which was published in *Canada Gazette Part I (CGI)* on August 17, 2024.[1]

In IMC's view, Canada is currently not in compliance with its CUSMA obligations. Specifically, the CUSMA chapter on Intellectual Property includes a requirement to provide patent term adjustment (PTA) to compensate patentees for unreasonable delays by the patent office in the processing of patent applications. In the domestic context, this refers to delays by the Canadian Intellectual Property Office (CIPO).

The government has been working to implement this obligation since 2023. At every opportunity, IMC has provided feedback with respect to how Canada can introduce this trade obligation in a meaningful way and in alignment with its trade partners. Throughout the development process, IMC repeatedly raised concerns with the approach Canada has taken with respect to its proposed PTA framework, which is set to take effect next year. Given that Canada's current approach is not compliant with its trade obligations, remedial measures should be taken in advance of the 2026 joint review.

[1] "Consulting Canadians on the Canada-United States-Mexico Agreement", *Canada Gazette*, Part 1, Volume 158, Number 33 (August 17, 2024).

ABOUT IMC

IMC is the national association representing the voice of Canada's innovative pharmaceutical industry. The association advocates for policies that enable the discovery, development, and delivery of innovative medicines and vaccines to improve the lives of all Canadians and supports the members' commitment to being a valued partner in the Canadian healthcare system. Collectively, our sector supports more than 103,000 high-quality, well-paying jobs, invests over $3 billion in R&D annually, and our activities contribute $16billion per year to Canada's knowledge-based economy.

EXECUTIVE SUMMARY

PTA has a remedial policy objective – it is intended to compensate patentees for patent term that is lost due to unreasonable delays in prosecuting a patent application. However, Canada has created a PTA framework which includes inequitable barriers that constructively undermine the treaty provision, and which will prevent patentees from obtaining compensation for unreasonable delays. IMC has the following specific concerns with Canada's PTA framework:

- The process to apply for PTA is burdensome, costly, and will create significant market uncertainty:
    - The process to obtain any PTA may be lengthy;
    - Third party observations are permitted throughout every step of the PTA determination process without a clear rationale, and will create an adversarial process; and
    - Significant application and maintenance fees will deter patentees from applying for the remedy.
- Despite incurring unreasonable delays, patentees are unlikely to obtain a PTA term that reflects the duration of the delay, if at all:
    - Significant periods of time may be deducted from the PTA term, including delays that are beyond the patentee's control;
    - The Commissioner of Patents (the Commissioner) has residual discretion to subtract additional unspecified days that will be impossible to predict;
    - PTA terms run concurrently with any Certificate of Supplementary Protection (CSP) term, effectively cancelling out the remedy; and
    - The redetermination process is inequitable and biased against patentees.

Our concerns are further elaborated in our previous submissions,[2] and are also summarized below.

THE PROCESS WILL DETER PATENTEES FROM APPLYING FOR PTA

There are a number of barriers throughout the PTA application process which will create significant uncertainty for patentees, and will ultimately discourage them from seeking the remedy.

Drawn-out processes create significant uncertainty for patentees and third parties

It is unclear how long it will take the patent office to determine whether PTA is owed to patentees. From the limited timelines that have been provided (i.e. one year to make a preliminary determination, or a preliminary reconsideration)[3], it is expected that the process of obtaining a final determination will be lengthy. A lengthy PTA determination process contradicts the purpose of the system, causing further delay to calculate the compensation owed for previous delays that patentees have already experienced. It also represents a marked departure from U.S. practices, where PTA is automatically calculated and communicated to patentees before patent issuance. The drawn-out process will create challenges for all parties in the context of commercial transactions and litigation.

Third parties make the process of obtaining PTA longer and more adversarial

Third parties are given significant opportunity to participate in the PTA determination process, but are largely not privy to the patent prosecution process. It is unclear what meaningful input third parties could provide that would assist the Commissioner in determining if PTA is owed and if so, how much. Allowing third party observations at each stage of the determination

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[2] For more information see:
"Strong Patent Protection Drive Innovation: Written submission to the Standing Committee on International Trade", Innovative Medicines Canada, May 2023 [IMC May 2023 Submission];
"Canadian Intellectual Property Office (CIPO) and the Strategy and Innovation Policy Sector (SIPS) Consultation on Additional Term and Amendments to the Patent Rules", Innovative Medicines Canada, September 8, 2023 [IMC September 2023 Submission];
"Canada Gazette I Consultation: *Regulations Amending the Patent Rules and Certain Regulations Made Under the Patent Act*", Innovative Medicines Canada, July 2, 2024 [IMC July 2024 Submission].

[3] *Regulations Amending the Patent Rules and Certain Regulations Made Under the Patent Act*, *Canada Gazette,* Part 1, Volume 158, Number 20 (May 18, 2024) [the Proposed Regulations], RIAS at "Service standards", p. 1263.

process only complicates the process by adding time, expense and potential disputes into what should be a simple and predictable administrative process.

The PTA costs are out of line with existing standards

The application and maintenance fees associated with PTA are inconsistent with the remedial purpose. The current application fee is higher than fees for comparable procedures.[4] Additionally, if PTA is granted, the annual maintenance fee will not be pro rated if the PTA duration is a few days or weeks, and the amount due will be higher than the amount due during the later years of a patent's initial term. No justification has been provided for these costs, which will act as a deterrent for all patentees, but are particularly onerous for small and medium sized entities.

PTA TERMS WILL NOT REFLECT THE DURATION OF UNREASONABLE DELAYS

If a patentee decides to apply for PTA despite the barriers set out above, it is unlikely that they will obtain adequate compensation for unreasonable delays, given that Canada's current approach is designed to reduce the PTA term through a variety of inequitable deductions.

Significant time may be subtracted from the PTA calculation

In calculating the PTA term, a significant number of days can be subtracted for various types of actions, including actions that are outside of the control of, or cannot be avoided by, the patentee.[5] These deductions may be so extensive that they offset the duration of the wrongful delay, and the net result will be that PTA is unavailable to patentees.

IMC has previously identified a number of deductions that are unreasonable and undermine the obligation to compensate for unreasonable CIPO delays.[6] For example, delays related to litigation to correct errors by the Commissioner will be deducted in the PTA calculation.[7] Applicants who successfully appeal a patent refusal, or challenge another determination of the Commissioner should not be penalized for exercising their right to appellate review. Notably, time taken to successfully appeal a decision is itself a basis for PTA in the U.S.[8] Another

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[4] For comparison, other standard (i.e. non-small entity) fees applicable to granted patents are the fee for reissue ($2,220) and the fee for re-examination ($2,775). See also: CIPO, Fees in respect of patents (Last Modified: July 31, 2024).
[5] *Proposed Regulations* at s. 13, introducing s 117.03(1).
[6] See *IMC September 2023 Submission* and *IMC July 2024 Submission*.
[7] *Proposed Regulations* at s. 13, introducing paragraph 117.03(1)(w) and introducing paragraph 117.03(1)(z.1).
[8] *United States Code,* Title 35 – Patents at § 154(b)(1)(C) [35 U.S.C.].

example of an unreasonable deduction relates to the time taken to respond to CIPO communications and requisitions.[9] Currently, days will be deducted once a notice requiring applicant action is issued. This immediate deduction process is unreasonable, since applicants must have a reasonable amount of time to respond to notices without penalty.

Notwithstanding the enumerated deduction periods, the Commissioner also has residual discretion to subtract additional unspecified days from the PTA calculation. This power makes it challenging for patentees to estimate whether they are likely to obtain any PTA, and evaluate whether it is worth the administrative resources to apply.

PTA terms can be reduced or vitiated by CSP terms

Presently, PTA and Certificate of Supplementary Protection (CSP) terms will run concurrently,[10] which may result in the term of one vitiating the term of the other. Patents that qualify for both remedies will not receive the full benefit to which they are entitled, despite being intended to address unrelated delays. Separate and apart from delays at the patent office, pharmaceutical patentees may be eligible for CSPs if they lose patent protection due to delays by Health Canada in the regulatory approval process. CUSMA recognizes PTA and CSP as two independent obligations[11] related to compensation for unreasonable delays or curtailment of patent term. However, Canada's approach effectively treats the two as interchangeable since the term of one is likely to vitiate the term of the other.

CSPs and PTA fulfill separate trade obligations, serve different purposes, and are intended to compensate for different delays experienced by innovators at different points of a product's life cycle as a result of distinct governmental functions. Applying the terms of each at the same time is unreasonable, inequitable and contrary to Canada's CUSMA obligations.

The redetermination process can only result in a shorter PTA term

Currently, the Commissioner can reconsider and reduce the amount of PTA term granted at any time, either on their own initiative or at the request of a third party.[12] However, there is no

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[9] *Proposed Regulations* at s. 13, introducing paragraph 117.03(1)(l).
[10] *Bill C-47, An Act to implement certain provisions of the budget tabled in Parliament on March 28, 2023*, 1st Sess, 44th Parl, 2023 [Bill C-47] at Division 26, Patent Act, RSC 1985, c P-4, [*PTA Legislative Amendments*] at s. 493 introducing paragraph 46.1(3).
[11] For PTA, see: *CUSMA, Article 20.44, under Subsection A: General Patents*
For CSPs, see: *CUSMA, Article 20.46, under Subsection C: Measures Relating to Pharmaceutical Products.*
[12] *PTA Legislative Amendments,* at s. 493 introducing paragraph 46.3(1).

opportunity for a patentee to seek a redetermination if they believe additional PTA is owed, unless they initiate costly judicial review litigation. Calculation issues may occur, especially in light of the subjective nature of many of the deduction periods. Similar to other features of the PTA system, this approach to reconsideration seems intended to reduce or vitiate potential PTA awards.

CONCLUSION

There are significant deficiencies in Canada's PTA system. Considered holistically, these deficiencies will make PTA unavailable to patentees in all but the most exceptional circumstances. The time, cost and uncertainty to determine whether any PTA is owed, coupled with the multiple and significant reductions in time through a variety of measures, will deter patentees from seeking a remedy that Canada committed to providing under CUSMA. Canada's approach to PTA is a stark contrast to the U.S. system that is already functional, efficient and serves the remedial purpose as intended. Canada must adjust its framework to ensure it is compliant with CUSMA prior to the 2026 review process. IMC thanks Global Affairs Canada (GAC) for the opportunity to comment on this issue, and requests an opportunity to meet with GAC as it prepares for the upcoming review to further discuss its concerns.