Strong Patent Protection Drives Innovation

Written submission to the Standing Committee on International Trade

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INNOVATIVE MEDICINES CANADA

INTRODUCTION

Innovative Medicines Canada (IMC) is pleased to provide comments in writing as part of the Standing Committee on International Trade's study on Non-Tariff Barriers in Canada's Existing and Potential International Trade Agreements.

IMC's immediate concern is the impact of Bill C-47, *An Act to implement certain provisions of the budget tabled in Parliament on March 28, 2023*, on Canada's obligations with regard to patent term adjustments (PTA) as a signatory of the Canada-United States-Mexico Agreement (CUSMA).

Patents are critical to protecting the work of innovators, who invest time, effort, and money in developing cutting-edge, life-saving drugs and therapies. The value of timely access to this innovation is clear: a 2022 analysis by the C.D. Howe Institute concludes that vaccines were highly effective at reducing COVID-19 cases, hospitalizations, and deaths between January 2021 to May 2022.[1] Specifically:

- 21 percent (1.19 million) fewer cases
- 37 percent (68,000) fewer hospitalizations
- 34,900 fewer deaths

Vaccination also prevented about 54,500 cases of long COVID in the working population, which represents an impact of $331 million in what would have been lost wages due to extended time off and reduced working hours.

We hope Members of the Committee will recommend the government amend Bill C-47 to ensure the Canadian PTA system supports innovation and complies with its international commitments, as proposed in Appendix A.

RECOMMENDATIONS

1) **Patent Term Adjustment and Certificate of Supplementary Protection terms should run consecutively to align with international trade partners.**
    - Ensure that PTA terms run independently of CSP terms; and
    - Align with the practices of Canada's international trading partners.
2) **Redetermination should be equitable and unbiased.**
    - Empower the Commissioner to also provide additional PTA if justified upon redetermination;
    - Empower the Court to also order additional PTA upon application of another person; and
    - Provide patentees with an opportunity to appeal the Commissioner's decision to another decision-maker.

[1] 'Damage Averted: Estimating the Effects of Covid-19 Vaccines on Hospitalizations, Mortality and Costs in Canada', R. WYONCH, T. ZHANG, *C.D. Howe Institute* (website), December 15, 2022, https://www.cdhowe.org/public-policy-research/damage-averted-estimating-effects-covid-19-vaccines-hospitalizations

3) **The Patent Term Adjustment system and fees should be consistent with PTA's remedial objective.**

- Set the deadline to file a PTA application as 4-months from the date of patent issuance;
- Prescribe a time limit in which challenges to PTA decisions can be initiated; and
- Limit PTA application and maintenance fees.

ABOUT INNOVATIVE MEDICINES CANADA

Innovative Medicines Canada (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. The association represents 49 companies in the research and development (R&D) pharmaceutical sector. Collectively, our sector supports more than 107,000 high-value jobs, invests over $2.4 billion in R&D annually, and contributes nearly $16 billion to Canada's knowledge-based economy.

According to Statistics Canada's analysis of the Canadian Research and Development Pharmaceutical Sector, total R&D expenditures by the R&D pharmaceutical sector for 2020, against total sales per the PMPRB's 2020 annual report, placed the industry's R&D-to-Sales ratio between 7.7 and 10.0%.[2] [3] In 2020, the sector increased its in-house R&D expenditures by 11.9% from the previous year, over half of which ($692 million) funded research activities, and the remaining spent on experimental development ($582 million).

[2] 'The Canadian Research and Development Pharmaceutical Sector, 2020', *Statistics Canada (website)*, January 30, 2023, https://www150.statcan.gc.ca/n1/pub/11-621-m/11-621-m2023001-eng.htm

[3] 'Annual Report 2020', *Patented Medicines Prices Review Board*, March 30, 2022, https://www.canada.ca/content/dam/pmprb-cepmb/documents/reports-and-studies/annual-report/2020/pmprb-ar-2020-en.pdf

PATENTS PROTECT CANADIAN INNOVATION

Since patent terms begin on the day on which a patent application was filed, the time that it takes to process patent applications has significant impacts on the rights of patentees. The signatories of the Canada-United States-Mexico Agreement (CUSMA) rightfully recognized that patent granting authorities have an obligation to process applications in an efficient and timely manner, with a view to avoiding unreasonable and unnecessary delays that negatively impact the rights of innovators.

When unreasonable delays do occur, the CUSMA signatories are obliged to provide patent term adjustment (PTA), which is intended to compensate patentees for the time lost on their patent rights due to delays in processing their applications. CUSMA also sets out minimum standards in fulfilling this obligation.

While it is encouraging that Canada is taking steps to implement a PTA system, IMC has significant concerns with the proposed implementation framework, which is inconsistent with Canada's international treaty obligations under CUSMA in addition to its obligations under the Comprehensive Economic and Trade Agreement (CETA) with the European Union.

If implemented without amendments, Canada's proposed PTA system will not comply with its international commitments, since it imposes significant and inequitable barriers that prevent patentees from receiving the intended meaningful remedy for patent office delays.

RECOMMENDATION 1: *Patent Term Adjustment and Certificate of Supplementary Protection terms should run consecutively to align with international trade partners.*

- Ensure that PTA terms run independently of Certificates of Supplementary Protection (CSP) terms; and
- Align with the practices of Canada's international trading partners.

Bill C-47, *An Act to implement certain provisions of the budget tabled in Parliament on March 28, 2023*, proposes that any PTA granted to patentees will run concurrently with a Certificate of Supplementary Protection (CSP) term.[4] This approach is highly concerning as the PTA and CSP regimes 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. Due to the eligibility requirements, the proposed approach would only prejudice pharmaceutical patentees since they are the only type of innovator who experiences multiple unjustifiable delays that impact their patent protection.

[4] *Supra note 1*, at Section 498(2).

CUSMA recognizes PTA and CSP as two independent obligations related to compensation for unreasonable delays or curtailment of patent term. First, PTA extends the length of the patent term and applies to patent applications related to any type of invention that experiences unreasonable delays due to the granting authority, which, in our domestic context, is the Canadian Intellectual Property Office (CIPO).[5] CUSMA sets out certain limited circumstances in which delays may be subtracted in calculating the amount of PTA owed. Notably, all of the categories of delay that may be subtracted are related to activities before CIPO and do not include time spent pursuing marketing approval for a pharmaceutical product.

The second independent obligation in CUSMA relates to CSPs, which provide patent-like protection only to certain pharmaceutical products following the end of the patent term. CSPs are intended to compensate pharmaceutical innovators for time lost on their patent during the regulatory approval process.[6] Unlike PTA, the scope of CSP protection (which was originally implemented by Canada under CETA in 2017) is limited and does not provide the same rights as the patent. However, CUSMA stipulates that any "limitations" on CSP protection must not interfere with the patent owner's right to compensation for "unreasonable curtailment of the effective patent term as a result of the marketing approval process".[7] This provision, along with the fact that the obligation is set forth in a separate article and subsection of the agreement that is specific to marketing approval for pharmaceutical products, underscores that compensation for CSP term is a separate obligation that must be distinctly upheld from the PTA term obligation in order to be effective and therefore comply with CUSMA.

As proposed, Canada's approach, in which CSP and PTA terms run concurrently, would be contrary to both of these two independent obligations under CUSMA because the term of one is likely to vitiate the term of the other whenever the two terms do not run consecutively. The following example presents a simple scenario where a patent is granted six years after its filing date, and a pharmaceutical product covered by the patent receives marketing approval 10 years after the patent filing date.

If the CSP and PTA terms are concurrent, the patentee will, in effect, not be compensated for the 1 year of unreasonable delay by CIPO in issuing the patent because it is subsumed by the maximum CSP term of two years to compensate for the time the patent owner had an enforceable patent but had not yet received marketing approval. Given the distinct types of compensation to be provided by PTA and CSP, these terms must be applied to a patent term consecutively in order for Canada to comply with its independent obligations under CUSMA:

[5] *CUSMA, Article 20.44, under Subsection A: General Patents*
[6] *CUSMA, Article 20.46, under Subsection C: Measures Relating to Pharmaceutical Products.*
[7] *CUSMA, Article 20.46, paragraph 2, under Subsection C: Measures Relating to Pharmaceutical Products.*

Filing Date	Patent Grant	Marketing Approval	CSP[8] Grant	PTA[9] Grant	Patent Term[10] (CSP & PTA Terms Concurrent)	Patent Term (CSP & PTA Terms Consecutive)
Jan. 1, 2023	Jan. 1, 2029	Jan. 1, 2033	2 years (maximum)	1 year	Jan. 1, 2045	Jan. 1, 2046

Further, under the proposal to have PTA and CSP terms run concurrently, patents that qualify for CSP, namely certain pharmaceutical patents, will not receive the full benefit of the PTA and CSP grants to which they are entitled. In particular, if the PTA term is shorter than the CSP term, then the PTA term essentially has no effect on the overall term of the patent. In this situation, a patent owner is in practice only being compensated for time lost during Health Canada's marketing approval process, and not for CIPO delays in issuing the patent. This would mean that pharmaceutical patents are treated differently than other types of patents when it comes to PTA. Similarly, whenever the PTA term is longer than the CSP term, the CSP grant will essentially have no effect on the overall term of the patent. In that situation, a patent owner is in practice only being compensated for CIPO delays, and not for delays in the marketing approval process.

The United States, Canada's largest trading partner, acknowledges the different purposes of the equivalent compensatory patent term mechanisms. The US has explicitly legislated that the term of a patent includes any patent term adjustment, and any patent extension provided for delays in regulatory approval shall be applied only after the adjusted expiry date takes place.[11]

Canada also has an obligation to provide CSP under the CETA treaty with its second largest trading partner, the European Union. Under CETA, CSP protection "shall take effect at the end of the lawful term of [the] patent" (Article 20.27(4)). If granted, patentees must continue to pay related maintenance fees during the PTA period. Accordingly, the PTA period essentially extends the lawful term of the patent, such that the simultaneous operation of a CSP term

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[8] *CSP is determined as the time between [the filing date of the patent application] and [the date of marketing authorization for the medicine], then subtract [five years], with a maximum CSP term of two years.* See *Patent Act, Subsection 116(3).*

[9] *PTA is proposed to be determined as the number of days between the patent issue date and the later of: (i) the fifth anniversary of the patent filing date (assuming that the "applicable day" is the filing date of the patent application), and (ii) the third anniversary of the first day on which a request for examination has been made. Additional days can be subtracted owing to delays attributed to the patent applicant.* See *Bill C-47, Subsection 493, s. 46.1(1)-(4).*

[10] *The duration of a Canadian patent is 20 years from the filing date.* See *Canada Patent Act,* Section 44.

[11] 35 U.S.C. *§ 156(a).*

would be contrary to Canada's CETA obligation.

RECOMMENDATION 2: *Redetermination should be equitable and unbiased.*

- **Empower the Commissioner to also provide additional PTA if justified upon redetermination;**
- **Empower the Court to also order additional PTA upon application of another person; and**
- **Provide patentees with an opportunity to appeal the Commissioner's decision to another decision-maker.**

As proposed, the Commissioner's redetermination powers would be highly inequitable. Currently, the Commissioner may reconsider the length of the PTA term at any time on their own initiative or upon application of another person.[12] However, upon reconsideration, it appears that the Commissioner can only shorten the duration of the PTA provided or dismiss the application for redetermination.[13] PTA can also be shortened by the Federal Court upon application of another person.[14]

There is no opportunity for patentees or another person (e.g., a licensee) to seek redetermination if they believe additional PTA is owed, unless they initiate costly judicial review litigation. Since calculation issues may occur resulting in either more or less PTA being granted initially, the implementation legislation should empower the Commissioner to also grant more PTA upon redetermination, as opposed to only being able to reduce the term.

Additionally, it is concerning that the same decision-maker who made the initial calculation is also responsible for conducting redeterminations. Applicants should have an opportunity to have another decision-maker reconsider the PTA granted by the Commissioner.

RECOMMENDATION 3: *PTA system and fees should be consistent with PTA's remedial objective.*

- **Set the deadline to file a PTA application as 4-months from the date of patent issuance;**
- **Prescribe a time limit in which challenges to PTA decisions can be initiated; and**
- **Limit PTA application and maintenance fees.**

[12] *Bill C-47* at Section 46.3(1).
[13] *Bill C-47* at Section 46.3(4).
[14] *Bill C-47* at Section 46.4(1).

As proposed, Canada's PTA system is both uncertain and inequitable. Patentees are required to pay an application fee without assurance that any PTA will be granted. It is unclear what, if any, opportunity a patentee has to make submissions in the PTA determination process, and as noted above, the opportunities to review any PTA granted are completely ineffective for patentees. To fulfill the remedial objectives that PTA system seeks to achieve, greater clarity must be built into the process so that PTA application, calculation and challenge processes are clear and predictable and are not punitive towards patentees.

For example, a PTA application should be due at least four months (as opposed to the proposed three months)[15] after patent issuance. This four-month period aligns with the period afforded to file a CSP application and would provide the time that is necessary to verify term computations and obtain instructions.

Certainty should also be built into dispute procedures. The Commissioner should be required under the *Patent Act* to provide reasons for refusal. Additionally, a limitation period in which redetermination requests can be made should be set. As written, the unlimited challenge period creates ambiguity around a PTA grant's true length, which harms both innovators as well as third-party challengers. Limiting challenges to a reasonable time period after PTA is granted would provide patentees with greater assurance that, following the end of the set timeframe, the PTA decision is final and will not be subject to any subsequent challenge or potential reduction.

Finally, the PTA regime is intended to compensate a patentee for unreasonable delays beyond the patentee's control. Elevated fees, including unrecoverable application fees, would be inequitable since they would undermine the regime's remedial objective by unreasonably penalizing patentees. For example, no fees are charged by the US in association with PTA. Additionally, the imposition of significant PTA fees would disproportionately impact smaller biotechnology companies and start-ups. Application fees should be nominal since the existing maintenance fees would extend into the longer PTA period and are sufficient to ensure the cost recovery of the program.

CONCLUSION

Canada has a genuine opportunity to bolster innovation domestically and ensure Canadians have timely access to the latest medicines and therapies they need. To take advantage of this opportunity, the federal government must ensure that its initiatives, such as the Biomanufacturing and Life Sciences Strategy, are supported by legislation and policies that demonstrate Canada is a predictable market for investment, including strong protections for patents that comply with our international trade treaty obligations.

[15] *Bill C-47* at Section 46.1(1)(c).

APPENDIX A

CURRENT	PROPOSED
498 (1) Subsection 116(2) of the Act is replaced by the following: **Taking effect** **(2)** A certificate of supplementary protection takes effect on the expiry of the term referred to in section 44, without taking into account section 46, of the patent set out in the certificate, but the certificate takes effect only if the patent remains valid until, and is not void before, the expiry of that term.	**498 (1) Subsection 116(2) of the Act is replaced by the following:** **Taking effect** **(2)** A certificate of supplementary protection takes effect on the expiry of the term referred to in section 44, ~~without taking into account section 46,~~ which shall include any additional term granted under section 46.1, of the patent set out in the certificate, but the certificate takes effect only if the patent remains valid until, and is not void before, the expiry of that term.
498 (2) Section 116 of the Act is amended by adding the following after subsection (5): **For greater certainty** **(6)** For greater certainty, the certificate's term runs concurrently with any additional term granted under section 46.1.	**498 (2) Section 116 of the Act is amended by adding the following after subsection (5):** **For greater certainty** **(6)** For greater certainty, the certificate's term runs ~~concurrently~~ consecutively with any additional term granted under section 46.1.