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Via email: ic.cipoconsultations-opicconsultations.ic@canada.ca
cipoconsultations-opicconsultations@ised-isde.gc.ca

Canadian Intellectual Property Office (CIPO) and the Strategy and Innovation Policy Sector (SIPS) Consultation on Additional Term and Amendments to the Patent Rules

INTRODUCTION

On behalf of Innovative Medicines Canada (IMC) and its membership, I am writing with respect to the Consultation: "Additional Term and Miscellaneous Amendments to the Patent Rules", which was released for comment on August 7, 2023.[1] Specifically, IMC has significant concerns with respect to the proposed regulations related to patent term adjustment (PTA),[2] ("the Proposed PTA Rules") as outlined further below.

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 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.

EXECUTIVE SUMMARY

Canada is required under the Canada-United States-Mexico Agreement (CUSMA) to adopt a system of general PTA by January 1, 2025.[3] PTA has a remedial policy objective - it is intended to compensate patentees for patent term that is unjustifiably lost due to unreasonable delays

[1] "Consultation Scene Setter – Additional Term and Miscellaneous Amendments to the Patent Rules", *Canadian Intellectual Property Office,* August 7, 2023.
[2] *Ibid* at Section 1: Regulations related to Additional Term.
[3] Canada-United States-Mexico Agreement, *30 November 2018, Can TS 2020 No 5, art 20.44, 20.89(4)(b) [CUSMA].*

in prosecuting a patent application. Currently, Canada's PTA framework is not aligned with its trade partners, and does not comply with its international obligations, since it imposes significant and inequitable barriers that prevent patentees from receiving the intended meaningful remedy.[4]

The Proposed PTA Rules only exacerbate such inequities because they render PTA unattainable for most patents because of the extensive time periods proposed to be deducted when determining any additional term. Particularly in the case of challenging applications that are pursued through to successful review by the Patent Appeal Board or an appeal to the Federal Court, the significant associated delay would not be recognized through the granting of additional term. This is inequitable and contrary to the intent of CUSMA.

In particular, IMC has the following concerns with the Proposed PTA Rules, which are discussed in detail below.

1. Deducting from the PTA calculation delays which are not attributable to, and in many circumstances cannot be avoided by, the applicant – undermines Canada's CUSMA obligations to compensate for "unreasonable delay" in patent issuance.

2. Providing residual discretion to the Commissioner to subtract additional unspecified days from the PTA calculation introduces unacceptable uncertainty to the term calculation.

3. Permitting third party observations at the initial PTA determination stage is unnecessary and transforms what should be a remedial administrative application into an adversarial process.

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[4] *Bill C-47,* An Act to implement certain provisions of the budget tabled in Parliament on March 28, 2023, *1st Sess, 44th Parl, 2023;* Patent Act, *RSC 1985, c P-4, division 26 [Bill C-47]* (assented to June 22, 2023)
Of greatest concern, PTA and certificate of supplementary protection terms should run consecutively to align with international trade partners. Additionally, many elements of Canada's PTA system, such as the application and redetermination procedures and fees, are contrary to its remedial purpose. In addition, the requirement to affirmatively request PTA adds administrative burden and costs to patentees, hurts smaller inventors, and adds uncertainty.

1. **Deducting from the PTA calculation delays which are not attributable to, and in many circumstances cannot be avoided by, the applicant.**

The Proposed PTA Rules set out a number of "example" actions and periods of time that may lead to days being subtracted in the determination of additional term.[5] Many of the proposed deductions are unreasonable, do not align with the U.S. PTA system, and may be so extensive as to render the PTA system unavailable to most patentees[6].

i. The Proposed PTA Rules do not provide a reasonable period of time for an applicant to respond to CIPO communications and requisitions.

Applicants must have adequate time to respond to notices without penalty. However, as currently written, applicants would not have any reasonable time period since the deduction of days will begin immediately once a notice requiring applicant action is issued.[7] Deducting this time period may particularly prejudice foreign or larger applicants where CIPO notices must be relayed through multiple parties, such as global head offices, and local or international counsel. This period of time is only deducted in the U.S. PTA system if the applicant takes more than 3 months to respond to USPTO notices.[8] The patentee needs a minimum amount of time to consider and respond to any objections made and should not be penalised for taking this time. Therefore, the patentee should only be penalised for any time more than 4 months from receipt of an examination report that it takes to file a response.

In addition, there appears to be no acknowledgement of the substantive search and examination work accomplished during the international phase of a PCT application, which reduces the examination burden of CIPO during the PCT national phase. Under the PTA system, eligible patentees can be compensated for patent office delays calculated between an

[5] Supra note 5.
[6] By way of background, PTA arose in the US when the US patent term changed from 17-years from grant to 20-years from filing. The goal of PTA was to ensure that US patentees were not penalized by reduced patent protection because of that change. If the patent is issued within 3 years of filing, patentees are not penalized. This 3-year to patent grant target timeframe always contemplated regular back-and-forth between applicant and examiner without penalty for delay. The parallels in Canadian patent history and current prosecution rules are fundamentally the same. Canada provided a patent term of 17-years and changed to 20-years from filing. It is therefore reasonable to expect CIPO to adopt the same target timeframe to grant 3-years after request for examination.
[7] Supra note 1, Annex, 1.a.
[8] 37 CFR § 1.704(b).

"applicable day" and the date of patent grant (which must be later than the fifth anniversary of the "applicable day". The "applicable day" is the filing date in the case of a directly filed Canadian patent application. However, according to the Proposed PTA Rules, in the case of an application filed via the PCT (as the vast majority of pharmaceutical patent applications are) the "applicable day" is the national phase entry date into Canada. In this scenario, the application has already been pending for 1.5 years as a PCT application and during this time it has been searched and published and an opinion on its patentability has been published. This would mean, that CIPO should not need the full 5 years from national phase entry since some of the work has already been done at this point and the "applicable day" for PCT applications should also be the filing date.

ii. The Proposed PTA Rules contemplate that days may be deducted in relation to delays caused by error on the part of the Commissioner, including in relation to appeals to the courts after refusal of a patent application and judicial review of a decision taken by the Commissioner.

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. If a patent is granted following an appeal,[9] or prosecution continues following a judicial review,[10] then the Commissioner will have been incorrect in making its initial determination, and the delay should be attributable to the Commissioner, not the applicant. The U.S. PTA calculation explicitly includes delays associated with "successful appellate review where the patent was issued under a decision in the review reversing an adverse determination of patentability."[11]

iii. The Proposed PTA Rules contemplate that all days following a request for continued examination will be deducted from the PTA calculation.

Canadian patent applicants are required by the *Patent Rules* to file a Request for Continued Examination (RCE) for a response to a third examination report to be considered. While the U.S. PTA system may exclude time consumed by continued examination of the application requested by the applicant, in the U.S. system Final Actions are routinely issued as second or third examination reports, following which applicants can choose to initiate an appeal or continue examination. In other words, an appeal in the U.S. can be precipitated by the

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[9] *Supra note 1,* Annex, 5.c.
[10] *Supra note 1,* Annex, 5.d.
[11] *Title 35,* supra *note 12, § 154(b)(1)(C).*

applicant. This opportunity generally arises consistently after a limited number of substantive actions by the USPTO and, as mentioned above, time related to successful appellate review may be considered under the US PTA calculation. Under the Canadian system, deducting all days after filing an RCE[12] is unfair, since applicants can only respond to third examination reports by filing an RCE, with no option to initiate an appeal and conclude examination. This effectively traps the applicant in a state of patent pendency where patent term is being adjusted downwards. In the U.S., this situation does not arise because the applicant can trigger an appeal and move the matter forward unilaterally. In Canada, the applicant cannot take unilateral action to move to appeal and needs to wait for the examiner to refer the case to the appeal board.

iv. The Proposed PTA Rules contemplate deducting time based on the filing of documents that may be in error and, possibly, not even submitted by the applicant or their agent.

Applicants should not lose PTA term for the time taken to respond (or not) to communications from CIPO precipitated by communications from unauthorized persons.[13] Deducting this period is unfair and contrary to the principle of compensating patentees for unreasonable delays.

2. **Providing residual discretion to the Commissioner to subtract additional unspecified days from the PTA calculation introduces unacceptable uncertainty to the term calculation.**

The Proposed PTA Rules provide that "the Commissioner may be authorized to consider periods of time not explicitly recited in the Patent Rules and may make determinations on the percentage of days in a particular period that are to be subtracted".[14] Enabling the Commissioner to consider ambiguous unknown factors would make it extremely challenging for patentees to determine whether it is feasible to obtain additional term, and therefore assess whether its worth the administrative burden required to apply and pay the prescribed fee.[15]

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[12] Supra note 1, Annex, 4.h.
[13] Supra note 1, Annex, 2.a.
[14] Supra note 1, "The Determination of Additional Term".
[15] Patent Act, ss 46.1(1)(c), as amended by Bill C-47, supra note 4.

Such discretion would also make it difficult for patentees to provide detailed reasons or calculations to support their application for additional term, as contemplated by the Proposed PTA Rules, because they will not know the case to be met.[16] Finally, this discretion could make it more difficult for a patentee to challenge the Commissioner's determination by judicial review, which is the only remedy available to patentees.

The Proposed PTA Rules underscore that an automatic initial determination of PTA upon grant of patent would be fairer for applicants and also align with US practices.

3. **Permitting third party observations at the initial PTA determination stage is unnecessary and transforms what should be a remedial administrative application into an adversarial process.**

The Proposed PTA Rules contemplate third-parties submitting "observations on the initial determination".[17] Permitting third-party observations is unnecessary, marks a departure from domestic and international practices, and renders the procedure adversarial.

It is unclear what meaningful input third-parties could provide that would assist the Commissioner in determining the amount of additional term. As currently set out, the majority of the actions and periods of time that may be subtracted from additional term pertain only to patentees, their agents or CIPO.[18] Third-parties are largely not privy to the activities contemplated in the examples beyond what is available on the public record, and would therefore not be able to provide any insights on such matters.

Additionally, third-parties already have avenues to challenge the PTA term. *The Patent Act* provides that any person may apply to the Commissioner,[19] or bring an action to Federal Court to shorten the PTA duration.[20]

Third-parties cannot participate in the United States Patent and Trademark Office (USPTO) process to determine PTA.[21] Permitting third-parties to participate in Canada's PTA process

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[16] *Supra note 1,* "Applying for Additional Term".
[17] *Ibid,* "Processing of Applications for Additional Term".
[18] *Supra note 5.*
[19] *Patent Act,* ss 46.3(1), as amended by Bill C-47, *supra* note 4.
[20] *Patent Act,* ss 46.4(1), as amended by Bill C-47, *supra* note 4.
[21] *35 U.S.C. 154(b)(4)(B).*

would only increase the time and cost required to administer the system, create further uncertainty, and detract from the intended purpose of PTA.

CONCLUSION

In addition to the substantive issues noted above, IMC would also highlight the significant deficiencies in CIPO's consultation process. It is very difficult for stakeholders to meaningfully respond within a 30-day consultation period, especially during the summer months where statutory and personal holidays are common. Given the nature of the subject matter currently under consultation, collaboration from a number of different parties and comparison to international practices is also required. In addition, the deadline to implement a PTA framework (January 1, 2025) is not imminent and it is unclear why CIPO approached this consultation with such urgency. The combination of a limited time period, the time of initiation, and the unclear need for an expedited process all raise questions regarding the relevance of the consultation.

Moving forward, IMC requests an opportunity to meet with CIPO before proposed rules are published for consultation. IMC remains very concerned that Canada's current approach to implementing a PTA framework does not comply with its trade obligations, as it does not provide a meaningful remedy to patentees who are impacted by unreasonable patent office delays. IMC would be pleased to meet with CIPO to further elaborate upon our concerns upon request.

Sincerely,

Declan Hamill
Vice President Policy, Regulatory and Legal Affairs

cc: Virginie Ethier, Director General and Assistant Commissioner of Patents
Elias Collette, Director General, Corporate Strategies and Services Branch
Samir Chhabra, Director General, Strategy and Innovation Policy Sector