July 2, 2024

Canada Gazette I Consultation: *Regulations Amending the Patent Rules and Certain Regulations Made Under the Patent Act*

INTRODUCTION

On behalf of Innovative Medicines Canada (IMC) and its membership, I am writing with respect to the proposed *Regulations Amending the Patent Rules and Certain Regulations Made Under the Patent Act* ("the Proposed Regulations") which were published for consultation in *Canada Gazette Part I (CGI)* on May 18, 2024.[1] IMC reiterates its concerns with the Proposed Regulations, which we have raised in previous consultations on the subject. Particularly, IMC is concerned that Canada's implementation of a patent term adjustment (PTA) system is not compliant with its trade obligations, as it does not provide a meaningful remedy to patentees who are impacted by unreasonable patent office delays.

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-quality, well-paying jobs, invests over $2.4 billion in R&D annually, and our activities contribute $15.9 billion per year 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.[2] PTA has a remedial policy objective - it is intended to compensate patentees for patent term that is lost due to unreasonable delays in

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[1] *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].
[2] Canada-United States-Mexico Agreement *November 30, 2018 Can TS 2020 No 5, at Art. 20.44 [CUSMA].*

prosecuting a patent application. In contrast, the Proposed Regulations would make extensive deductions from the PTA calculation, including for delays that are arguably within the direction or control of the Canadian Intellectual Property Office (CIPO), and would otherwise impose significant barriers that prevent patentees from receiving any PTA. This approach does not align with Canada's 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.[3] By CIPO's own estimates, there will be approximately 140 PTA applications filed each year until 2034. This represents under 1% of the patents granted in Canada each year.[4]

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

1. The PTA application process creates significant uncertainty for patentees.
2. The definition of the "applicable day" prejudices PTA term for Patent Cooperation Treaty (PCT) applications.
3. Deducting delays which are not attributable to, and in many cases cannot be avoided by the applicant, undermines the obligation to compensate for unreasonable delays.
4. Permitting third party observations at the initial PTA determination stage transforms what should be a remedial administrative application into an adversarial process.

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[3] *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.* 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.

[4] *Proposed Regulations,* Regulatory Impact Analysis Statement (**RIAS**) at p. 1256 (the estimate in the RIAS covers approximately eight years of potential PTA applications, as the date the first eligible patents may receive an additional term is December 2, 2025); See also: *CIPO, Patent Statistics: 2022 to 2023* (Last Modified: May 1, 2024). In 2022-2023, 22,305 patents were granted in Canada.

5. High fees will deter patentees from seeking PTA and are contrary to PTA's remedial purpose.

1. The PTA application process creates significant uncertainty for patentees.

While the Proposed Regulations set out some timelines for the PTA determination process, there are no deadlines for critical milestones. For example, there are no prescribed timeframes for making a preliminary eligibility assessment, PTA determinations and certificate issuance,[5] or reconsiderations.[6] The service standard timelines that are described in the RIAS are lengthy (i.e. one-year to make a preliminary determination, or a preliminary reconsideration[7]) and are inconsistent with comparable service standards, such as for the Certificate of Supplementary Protection (CSP) system.[8]

The potentially long process to obtain PTA is contrary to the purpose of the system. It also reflects the stark contrast between Canada and the United States with respect to valuing innovation. The United States Patent and Trademark Office (USPTO) automatically calculates PTA, without separate cost, and makes the determination available to applicants approximately three weeks prior to patent issuance. Once notice is provided, the patentee (not third parties) has two months to seek reconsideration.[9] The USPTO procedure clearly takes ownership over any unjust delays it causes to patentees, and remedies the negative impact through clear, consistent mechanisms that do not create further burden.

In Canada, the drawn-out process, coupled with the lack of prescribed deadlines creates significant uncertainty for both patentees and third parties, since the PTA procedure could last for years, including until after patent expiry. This would create challenges for all parties in the context of commercial transactions and litigation. Instead, the Proposed Regulations should

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[5] *Proposed Regulations* at s. 13, introducing s. 117.01(8).
[6] *Proposed Regulations* at s. 13, introducing s. 117.11(8).
[7] *Proposed Regulations,* RIAS at "Service standards", p. 1263.
[8] In the context of CSPs, first eligibility decisions are provided within 60 calendar days in relation to calculating delays by Health Canada in the regulatory review process: *Health Canada, Guidance Document: Certificates of Supplementary Protection, p. 16.*
[9] *USPTO,* Explanation of Patent Term Adjustment Calculation*, online:* https://www.uspto.gov/patents/apply/checking-application-status/pair-announcements/explanation-patent-term.

ensure that the process is completed in a short and definite time period, by prescribing specific dates and shorter service standards.

2. The definition of the "applicable day" prejudices PTA term for PCT applications.

The Proposed Regulations prescribes that the "applicable day" for a patent issued on the basis of a PCT national phase application is the national phase entry date.[10] While the Proposed Regulations explicitly provide that the subtracted periods are "deemed not to include any day prior to the applicable day", the choice of applicable day does still prejudice PCT national phase applications in terms of the calculation of the PTA threshold date and period (i.e., the base period of PTA determined under s. 46.1 of the *Patent Act* before the subtraction of days). This may have significant impact on foreign applicants who would expect equivalent treatment of applications filed via the PCT system and directly in Canada.

Further, CIPO benefits from the search and examination of applications that are performed during the international stage. PCT applications that enter the national phase in Canada within the standard prescribed period of 30 months from the priority date should be treated like any other applications and given the benefit of the PCT filing date as the "applicable day".

3. Deducting from the PTA calculation delays which are not attributable to, and in many circumstances cannot be avoided by the applicant, undermines the obligation to compensate for unreasonable delays.

In the Proposed Regulations, there are a significant number of days that can be subtracted from the PTA calculation.[11] 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.

i. The Proposed Regulations 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 as the deduction of

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[10] *Proposed Regulations* at s. 13, introducing S. 117.02(2).
[11] *Proposed Regulations* at s. 13, introducing S 117.03(1).

days will begin immediately once a notice requiring applicant action is issued.[12] This means that days will be deducted during a period when even a diligent applicant could not respond (i.e., before the notice is received or the applicant is able to formulate a reply). 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. It should also be noted that this period of time is only deducted in the U.S. PTA system if the applicant takes more than three months to respond to USPTO notices.[13]

Furthermore, the Proposed Regulations contemplate that even the short three-week window provided to make voluntary amendments after an Examiner interview will be deducted.[14] Failing to provide applicants with any reasonable period to respond to CIPO actions will effectively negate periods of actual CIPO delay.

ii. The Proposed Regulations 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. The Proposed Regulations would deduct all days through all levels of appeal,[15] or judicial review applications.[16] This approach conflicts with the purpose of the PTA system and departs from the approach taken by the USPTO, who does not penalize applicants who successfully appeal an adverse determination of patentability. Specifically, the USPTO does not subtract delays associated with "successful appellate review where the patent was issued under a decision in the review reversing an adverse determination of patentability" and time consumed in a successful appeal is itself a basis for PTA ("Type C" delay).[17]

If a patent is granted following a successful appeal to the courts after a patent application was refused, then the Commissioner was mistaken (at least in part) in refusing the patent

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[12] *Proposed Regulations at* s. 13*, introducing* paragraph 117.03(1)(l).
[13] United States Code of Federal Regulations, Title 37 – Patents, Trademarks and Copyrights at § 1.704(b).
[14] *Proposed Regulations* at s. 13, introducing paragraph 117.03(1)(p).
[15] *Proposed Regulations* at s. 13, introducing paragraph 117.03(1)(w).
[16] *Proposed Regulations* at s. 13, introducing paragraph 117.03(1)(z.1).
[17] United States Code, Title 35 – Patents at § 154(b)(1)(C) [35 U.S.C.].

application. Such a delay is not due to the patent applicant and is properly attributed as a delay caused by the Commissioner. There is a public interest in having the Courts consider issues of patentability and successful applicants should not be penalized under PTA for pursuing an appeal.

Similarly, judicial review decisions taken by the Commissioner will often involve the continued prosecution of an application (i.e. an appeal of a finding that a patent application has been allowed to go abandoned without possibility for reinstatement). Again, if the patent has proceeded to grant in such circumstances, the Commissioner will have been incorrect in refusing reinstatement of the application and the delay is attributable to the Commissioner and not the applicant.

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

With respect to Requests for Continued Examination (RCE), CIPO is again proposing significant differences from its U.S. counterparts. Applicants are required by the *Patent Rules* to file an RCE for a response to a third examination report to be considered. Applicants cannot choose to initiate an appeal instead of filing an RCE. Because of this, applicants may be trapped in patent pendency in a state where patent term is being adjusted downwards, even if an applicant would like to conclude examination. Deducting all days after filing an RCE[18] until payment of the final fee is unfair, since applicants can only respond to third examination reports by filing an RCE, but this examination will not necessarily be a Final Action.

While the U.S. PTA system deducts 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. Filing an RCE in the U.S. does not mean that applicants cannot accrue further PTA, it only impacts the type of PTA that can be accrued.

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

[18] *Proposed Regulations* at s.13, introducing paragraph 117.03(1)(o).

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

It is unclear what meaningful input third-parties could provide that would assist the Commissioner in determining the amount of additional term owed due to its own delays. CIPO would already have its own extensive records of the patent prosecution process that would enable it to make a determination. Furthermore, the majority of the actions and periods of time that may be subtracted from additional term pertain only to patentees, their agents or CIPO.[19] Third-parties are largely not privy to the activities contemplated in the examples, and therefore would not be able to provide any insights on such matters.

Additionally, third-parties already have multiple avenues to challenge the PTA term. *The Patent Act* provides that any person may apply to the Commissioner,[20] or bring an action to Federal Court to shorten the PTA duration.[21]

Third-parties can not participate in the USPTO process to determine PTA.[22] Permitting third-parties to participate in Canada's PTA determination process would only increase the time and cost required to administer the system, create further uncertainty, and detract from the remedial purpose of PTA.

5. High fees will deter patentees from seeking PTA and are contrary to PTA's remedial purpose.

The Proposed Regulations impose significant PTA related fees that are inconsistent with other comparable CIPO fees. Such fees are particularly troubling given the remedial nature of the PTA system. Requiring substantial PTA application fees in order to obtain PTA to compensate patentees for CIPO's own delays is an inappropriate requirement. CIPO has an obligation to provide PTA to patentees following its unreasonable delays that impact patentees' rights. To administer PTA, CIPO must only review its internal administrative process to determine whether the time it took to prosecute a patent application was unreasonable, and if so, how

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[19] *Proposed Regulations* at s. 13, introducing paragraph 117.03(1).
[20] *Supra note 4*, ss 46.3(1).
[21] *Supra note 4*, ss 46.4(1).
[22] *35 U.S.C. 154(b)(4)(B).*

much time is owed to patentees. Yet, CIPO has proposed a fee which is similar to, or even greater than, fees for procedures that involve a substantive reconsideration of granted patent scope.[23] The extent of the application fee would disproportionately impact small Canadian inventors.

If PTA is granted, maintenances fees ($1,000 (standard) or $400 (small entity)) will also be due on the 20th anniversary of the patent's filling date, and each subsequent anniversary until the PTA expires. Notably, and especially in light of the proposed calculation framework, the PTA may be considerably less than a year, but the amount of the maintenance fee will remain the same regardless, even if the PTA entitlement is only an additional few days or weeks. The PTA maintenance fee is also significantly higher than the highest maintenance fee amount, currently set at $624, which is due on each of the 15th through 19th anniversaries of the filing date.

Charging a higher fee for PTA than the fee due upon the later years of a patent's initial term is unjustifiable. The administrative burden is similar if not the same. The high fees related to PTA will serve as an unnecessary deterrent to patentees from seeking PTA.

Concern with Miscellaneous Changes contained in the Proposed Regulations

The Proposed Regulations would amend subsection 84(2) of the *Patent Rules* to provide that if an applicant has made an RCE and paid the prescribed fee, the Commissioner must not advance the examination of the application out of its routine order or return it to its routine order if examination is advanced. In Canada, RCE is mandatory to continue examination after receipt of a third "office action". CIPO's practice is to rarely issue Final Actions. Accordingly, an applicant may be forced to make a RCE on an application under advanced examination (i.e. a high priority application), even though the applicant is seeking to conclude examination as soon as possible without delay. All days after making an RCE until payment of the final fee will also be subtracted from the PTA calculation.

There is no rationale provided to support this new RCE procedure. Furthermore, it would prejudice patentees, particularly pharmaceutical patentees, who seek allowance faster in order to align with regulatory approval and other considerations. Given the prejudicial impact, IMC

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[23] 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: March 28, 2024).

requests that the provision be removed. Alternatively, it should be limited to situations where RCE is used by an applicant to re-open examination after allowance.

CONCLUSION

IMC again wishes to reiterate its disappointment with Canada's approach to implementing a PTA system, which it is obliged to do under CUSMA. A clear, reliable system that reflects the principles of PTA has already been functioning well in the United States. It is unclear why Canada would prefer to take such a starkly different approach that involves a lengthy, costly, multi-step, multi-party process. This approach can only further draw out the time and expense associated with Canada's patent prosecution process which will likely deter patentees from seeking PTA. Of greater concern, it reinforces the perception that Canada does not truly value innovation, which sends the wrong signal to both domestic and international life sciences investors.

In addition to the message it sends to the private sector, Canada's approach may also trigger concern with its trading partners – that Canada does not implement its trade obligations reasonably and in good faith. IMC urges CIPO to consult with its counterparts in the other CUSMA nations to better understand how it can implement a straight-forward, efficient PTA system that achieves its intended remedial objectives.

Sincerely,

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